

Senate Hearings

Before the Committee on Appropriations

Departments of Labor,
Health and Human Services,
Education, and Related
Agencies Appropriations

Fiscal Year 2007

109th CONGRESS, SECOND SESSION

H.R. 5647/S. 3807

PART 6

DEPARTMENT OF EDUCATION
DEPARTMENT OF HEALTH AND HUMAN SERVICES
NONDEPARTMENTAL WITNESSES

Labor-HHS-Education Appropriations, 2007 (H.R. 5647/S. 3807)—Part 6

**DEPARTMENTS OF LABOR, HEALTH AND HUMAN
SERVICES, EDUCATION, AND RELATED AGEN-
CIES APPROPRIATIONS FOR FISCAL YEAR 2007**

HEARINGS

BEFORE A

SUBCOMMITTEE OF THE
COMMITTEE ON APPROPRIATIONS
UNITED STATES SENATE
ONE HUNDRED NINTH CONGRESS

SECOND SESSION

ON

H.R. 5647/S. 3807

AN ACT MAKING APPROPRIATIONS FOR THE DEPARTMENTS OF LABOR,
HEALTH AND HUMAN SERVICES, AND EDUCATION, AND RELATED
AGENCIES FOR THE FISCAL YEAR ENDING SEPTEMBER 30, 2007, AND
FOR OTHER PURPOSES

PART 6

**Department of Education
Department of Health and Human Services
Nondepartmental Witnesses**

Printed for the use of the Committee on Appropriations

Available via the World Wide Web: <http://www.gpoaccess.gov/congress/index.html>

U.S. GOVERNMENT PRINTING OFFICE

27-036 PDF

WASHINGTON : 2007

For sale by the Superintendent of Documents, U.S. Government Printing Office
Internet: bookstore.gpo.gov Phone: toll free (866) 512-1800; DC area (202) 512-1800
Fax: (202) 512-2250 Mail: Stop SSOP, Washington, DC 20402-0001

COMMITTEE ON APPROPRIATIONS

THAD COCHRAN, Mississippi, *Chairman*

TED STEVENS, Alaska	ROBERT C. BYRD, West Virginia
ARLEN SPECTER, Pennsylvania	DANIEL K. INOUE, Hawaii
PETE V. DOMENICI, New Mexico	PATRICK J. LEAHY, Vermont
CHRISTOPHER S. BOND, Missouri	TOM HARKIN, Iowa
MITCH McCONNELL, Kentucky	BARBARA A. MIKULSKI, Maryland
CONRAD BURNS, Montana	HARRY REID, Nevada
RICHARD C. SHELBY, Alabama	HERB KOHL, Wisconsin
JUDD GREGG, New Hampshire	PATTY MURRAY, Washington
ROBERT F. BENNETT, Utah	BYRON L. DORGAN, North Dakota
LARRY CRAIG, Idaho	DIANNE FEINSTEIN, California
KAY BAILEY HUTCHISON, Texas	RICHARD J. DURBIN, Illinois
MIKE DEWINE, Ohio	TIM JOHNSON, South Dakota
SAM BROWNBACK, Kansas	MARY L. LANDRIEU, Louisiana
WAYNE ALLARD, Colorado	

J. KEITH KENNEDY, *Staff Director*
TERRENCE E. SAUVAIN, *Minority Staff Director*

SUBCOMMITTEE ON DEPARTMENTS OF LABOR, HEALTH AND HUMAN SERVICES,
EDUCATION, AND RELATED AGENCIES

ARLEN SPECTER, Pennsylvania, *Chairman*

THAD COCHRAN, Mississippi	TOM HARKIN, Iowa
JUDD GREGG, New Hampshire	DANIEL K. INOUE, Hawaii
LARRY CRAIG, Idaho	HARRY REID, Nevada
KAY BAILEY HUTCHISON, Texas	HERB KOHL, Wisconsin
TED STEVENS, Alaska	PATTY MURRAY, Washington
MIKE DEWINE, Ohio	MARY L. LANDRIEU, Louisiana
RICHARD C. SHELBY, Alabama	RICHARD J. DURBIN, Illinois
	ROBERT C. BYRD, West Virginia (<i>Ex officio</i>)

Professional Staff

BETILOU TAYLOR
JIM SOURWINE
MARK LAISCH
SUDIP SHRIKANT PARIKH
CANDICE NGO
LISA BERNHARDT
ELLEN MURRAY (*Minority*)
ERIK FATEMI (*Minority*)
ADRIENNE HALLETT (*Minority*)

CONTENTS

WEDNESDAY, MARCH 1, 2006

	Page
Department of Education: Office of the Secretary	1

WEDNESDAY, MAY 3, 2006

Department of Health and Human Services: Office of the Secretary	61
--	----

FRIDAY, MAY 19, 2006

Department of Health and Human Services: National Institutes of Health	105
--	-----

NONDEPARTMENTAL WITNESSES

Department of Labor	301
Department of Health and Human Services	315
National Institutes of Health	384
Department of Education	538
Related Agencies	575

**DEPARTMENTS OF LABOR, HEALTH AND
HUMAN SERVICES, EDUCATION, AND RE-
LATED AGENCIES APPROPRIATIONS FOR
FISCAL YEAR 2007**

WEDNESDAY, MARCH 1, 2006

U.S. SENATE,
SUBCOMMITTEE OF THE COMMITTEE ON APPROPRIATIONS,
Washington, DC.

The subcommittee met at 10:45 a.m., in room SD-124, Dirksen Senate Office Building, Hon. Arlen Specter (chairman) presiding.

Present: Senators Specter, Craig, Harkin, Kohl, Murray, and Landrieu.

DEPARTMENT OF EDUCATION

OFFICE OF THE SECRETARY

STATEMENT OF HON. MARGARET SPELLINGS, SECRETARY

ACCOMPANIED BY: THOMAS SKELLY, DIRECTOR, BUDGET SERVICE

OPENING STATEMENT OF SENATOR ARLEN SPECTER

Senator SPECTER. Good morning Ladies, and Gentlemen, the subcommittee on Labor, Health and Human Services, and Education will now proceed with our hearing on the budget from the Department of Education. I regret our delayed start, but we just finished a vote on the PATRIOT Act, and Senator Harkin was on the floor and should be here I think, shortly. Scheduling has been complicated because of this vote. As you know we had moved the time from 9:30 to 11:00 and then back to 10:30 and we don't like to keep people waiting, especially the Secretary of Education. But we welcome you here, Madam Secretary.

You were confirmed on January 20, 2005. You have extensive experience working for the President when he had been a Governor; you were Assistant to the Secretary for Domestic Policy. You were Senior Advisor to then Governor Bush with responsibilities for developing and implementing the Governor's education policy. You are a graduate of the University of Houston, with a bachelor's degree in political science and journalism.

PREPARED STATEMENT

Madam Secretary, I shall be relatively brief because of our time here, our late start. Without objection, my written statement will be included in the record. As you and I have talked briefly earlier

this week, I'm concerned about the overall budget. We had a budget for this subcommittee, which has in addition to the Department of Education, Health and Human Services and Labor, which fell about \$8 billion short when you figure the cuts and take into account, inflation. I know that it is difficult as a loyal member of the administration when you have the policies working up through the Office of Management and Budget. But as I said to you in our telephone conversation, and as I've said repeatedly, I think there's a real need for someone in your position to be a tough advocate for your Department. Education is simply under funded. When I took a look at the President's budget, we're always asked for comment and I wanted to be definitive and brief and chose the word scandalous which I think it is. I know the President, the administration have tremendous problems in many, many areas but when you have so much money for the National Institutes for Health, and the Centers for Disease Control and Prevention, and Worker Safety, and Mine Safety, and important education programs, it's simply insufficient to have continual cuts on discretionary programs. We're regrettably moving to a system where there will be no discretionary funding at all. We'll all be out of jobs. The Appropriations Committee, which used to be—was once a powerful committee.

[The statement follows:]

PREPARED STATEMENT OF SENATOR ARLEN SPECTER

This morning, the Subcommittee on Labor, Health and Human Services, and Education will discuss the President's \$54.410 billion 2007 budget request for the Department of Education. We are delighted to have before us the distinguished Secretary of Education, the Honorable Margaret Spellings, our Nation's 8th Secretary of Education.

Madam Secretary, your impressive biography clearly illustrates your abilities and potential for leading this important Department. Being a mother of two school-age daughters gives you important insights into your other job as Secretary of Education.

This subcommittee is pleased to see several shared priorities funded in the fiscal year 2007 budget including the \$200 million request for school improvement grants, \$380 million for the American Competitiveness Initiative, and additional funding for foreign language instruction and the Advanced Placement Program.

However, I am concerned that the budget is \$2.1 billion below the fiscal year 2006 level and that there are 42 program eliminations. For example, \$303 million currently available for Gear-Up, which provides for the transition from seventh grade to college; \$1.2 billion for State grants for vocational and technical education programs; and \$23 million for correctional education programs all are proposed for elimination. The Pell Grant maximum award is frozen at \$4,050 for the fifth year in a row.

I know, Madam Secretary, that you can appreciate the difficult tradeoffs that this subcommittee will need to negotiate in the coming months as we balance the competing pressures of biomedical research, worker protection programs and continued investment in our Nation's youth. Madam Secretary, I look forward to working with you to craft an appropriations bill that maintains our commitment to fiscal restraint while preserving funding for high priority programs.

Senator SPECTER. Senator Landrieu, would you care to be acting ranking and make an opening statement?

STATEMENT OF SENATOR MARY L. LANDRIEU

Senator LANDRIEU. Thank you, Mr. Chairman.

Senator SPECTER. Or not be acting, just make an opening statement.

DEPARTMENT LAUDED FOR HURRICANE RESPONSE

Senator LANDRIEU. It's hard shoes to fill, but I will make an opening statement. Just very briefly because I appreciate that we want to hear our witness. But I wanted, Mr. Chairman, to be here this morning to give compliments to this Department—being mindful of what you said and agreeing with the level of funding which I'll get back to in a minute. Which I fully agree is scandalous. But Madam Secretary, your Department has been really a model of partnership for the State of Louisiana through the most difficult time that our State has experienced. I spoke to the Secretary, Mr. Chairman, privately before to let her know that if every Department of the Federal Government had worked this honestly, this reliably, with us we would not be experiencing the problems that we're experiencing now. In all of the calls, and I had thousands of calls about Katrina and Rita and the devastation that occurred, not one call did my office receive from any school or university in the country or from any parent saying they couldn't find a place for their child, or their young person to go to school. Number one, because the word went out across the country, please take the 330,000 children that showed up for school on Friday; the hurricane hit on Sunday, and they had no school to go to on Monday.

Mr. Chairman, it's a credit to the education establishment in this country that almost to my knowledge, every high school student, every elementary school student, and every college student that wanted to, found a place to continue their education of the last 6 months, and Madam Secretary, I think you deserve a lot of credit for that.

Second, the quickness in which we were able in a bipartisan way, we were able to implement with the chairman's help and assistance the special funding for getting our schools back up and started also is a great model. Having said that, we still have many problems as you know. We're hoping the new school system that emerges in New Orleans can be a model for the Nation as it emerges as a network of public charter schools and we're going to need your ongoing help and commitment to that end.

We do have problems with FEMA in terms of reimbursing and not reimbursing for school construction, we've lost over 100 school buildings, Mr. Chairman, which is a great strain on any system, to have to try to build the physical plants as well as the internal operations. But I did want to start with that and then finally say, having said that, the overall budget for the Nation is just not sufficient to meet the new standards and challenges that we have set for our schools as we struggle to provide excellence, opportunity, no guarantee Madam Secretary, but an opportunity.

TITLE I FUNDING

Title I funding, is the only Title that helps poor and lower middle-income children get the resources they need; to have the kinds of schools they need to be excellent. With that funding decreasing I don't know how our poor counties and middle-income counties that are struggling can meet the targets of No Child Left Behind, which means closing that achievement gap. So that's what I'm

going to focus on in the committee and, Mr. Chairman, I thank you very much.

Senator SPECTER. Well thank you very much, Senator Landrieu. Well welcome again, Madam Secretary, the floor is yours, and we look forward to your testimony.

SUMMARY STATEMENT OF HON. MARGARET SPELLINGS

Secretary SPELLINGS. Thank you very much, Mr. Chairman. It does seem like all roads lead to you today, and so I'm at your service, and thank you for all your work that you're doing, not only in this arena, but in many others.

EDUCATION FUNDS DISBURSED FOR HURRICANE RECOVERY

Senator Landrieu, thank you for your very generous comments. I appreciate the opportunity to be here and your support. Let me begin first, by thanking all of you for your work on behalf of the victims of hurricanes Rita and Katrina. As Senator Landrieu has talked about, we've worked a lot on that. After you passed the Hurricane Education Recovery Act in December, we sent immediately \$250 million to Louisiana, Mississippi, Texas, and Alabama to help re-open schools in the region. That was in addition to \$20 million that we sent to help open, or re-open, charter schools for affected students in Louisiana, and more than \$200 million that we sent to help college students in the region. We'll be sending another \$500 million in aid to these States in the coming days, and we've been consulting with experts at the Federal, State, and local levels, reviewing records from tax data, property loss data, and insurance claims, to make sure that this money is allocated fairly.

We'll also be providing \$645 million to reimburse districts all over the country for the cost of educating displaced students, as they've done so welcomingly, and so well. We've been working with States to help accelerate this process and to identify the number of displaced students so we can begin sending this money to schools.

FISCAL YEAR 2007 EDUCATION BUDGET REQUEST

But today I'm here to talk about the President's budget, and it's more important than ever that we spend taxpayer dollars wisely and well. Since taking office in 2001, the President has worked with you to increase funding for education by about 30 percent. The new budget increases education spending in key areas, but, as you've observed, not across the board. I know together we have a very tough job ahead. The programs you make funding decisions for are discretionary and you don't have much room to maneuver. It's only getting harder to fund priorities and reduce the deficit, because of the rising cost of entitlement spending.

AMERICAN COMPETITIVENESS INITIATIVE

At the same time, as policymakers we must focus on results. We've looked at data to see what policies are working for students, and where we can save taxpayers money or work more efficiently and effectively by eliminating and consolidating less effective programs. Raising student achievement is always our watch word. The

President's new American Competitiveness Initiative would devote \$380 million to strengthen K–12 math and science education. Overall the Department of Education will increase funding for its programs in these critical fields by 51 percent. The President has asked me to form a national math panel of experts to help us bring together the best research on proven strategies for teaching math; just as we've done in reading. His budget includes \$250 million for a new program called Math Now, that will help elementary and middle school students develop the academic foundation to eventually take higher-level classes in high school, such as Advanced Placement courses. The trouble today is that more than a third of our high schools offer no AP classes and that needs to change, especially when we know that students are going to need these skills in a world where 90 percent of the fastest growing jobs require postsecondary education.

The President has also called for \$122 million to prepare an additional 70,000 teachers to lead Advanced Placement and International Baccalaureate classes in math, science, and critical foreign languages. The budget includes \$25 million to help recruit 30,000 math and science professionals to become adjunct high school teachers in these critical areas.

I know there are concerns about resources, but in reality we have resources available around these priorities. Currently 13 different government agencies spend about \$2.8 billion on 207 different programs for math and science. The problem is that these programs are in their own silos with little or no coordination with No Child Left Behind and its goals for raising student achievement. It's a 1,000 flowers blooming and maybe even a few weeds throughout the Government.

We should align these efforts with the principles of No Child Left Behind by continuing to hold schools accountable for getting students to grade-level proficiency by 2014, and by giving local policy-makers and educators resources, authority, and the research base to do what's best.

SCHOOL IMPROVEMENT AND HIGH SCHOOL REFORM

Thanks to No Child Left Behind, we've reached a point where we have the data to see what's working in our schools and what needs to work better. We're proposing a new \$200 million School Improvement program to help States use what we've learned to turn around schools in need of improvement. Now we must build on the foundations of the NCLB law, which is working in grades three through eight, to extend the benefits of assessment and accountability for results into our high schools, with the President's \$1.5 billion high school reform proposal. There's a wide and growing consensus that we have a problem in our high schools and we must work together to address these issues. A high school diploma must be a record of achievement and not just a certificate of attendance. If we raise the bar, our students will rise to the challenge just as they always have, but we must give them the skills to compete.

PREPARED STATEMENT

Thank you. I'd be glad to answer any questions. With me today is Tom Skelly, our Budget Director, who tells me he's been doing this since 1976. So he knows what he's doing by now.

[The statement follows:]

PREPARED STATEMENT OF HON. MARGARET SPELLINGS

Mr. Chairman and Members of the Committee. Thank you for this opportunity to testify on behalf of the President's 2007 budget for education. I know you have received our Congressional justifications and other background materials laying out the details of our request, so I will concentrate on a few key highlights.

President Bush is requesting \$54.4 billion in discretionary appropriations for the Department of Education in fiscal year 2007. We are proposing significant increases in key areas, as well as substantial savings from reductions in lower priorities. The result would be a discretionary total that is up more than \$12 billion, or 29 percent, since fiscal year 2001.

We know the 2007 budget process will involve difficult trade-offs among existing programs, just as was the case with the 2006 appropriations bill. In 2006, we saw that this Subcommittee was willing to balance funding for priority programs with reductions and eliminations in other activities, and we hope you will take the same approach in 2007.

For example, our budget would save \$3.5 billion by eliminating funding for 42 programs. These reductions and terminations reflect the Administration's longstanding goal of providing local control, streamlining government to avoid unnecessary duplication, and targeting taxpayer dollars to those programs with the greatest promise of improving student outcomes. Let me add that we very much appreciate the efforts of this Subcommittee last year in eliminating five Department programs, and making significant reductions in several others, in order to better target existing resources. We look forward to working with you on this goal again this year.

A BROAD EMPHASIS ON COMPETITIVENESS

President Bush has made ensuring American competitiveness in the global economy a strong priority in his overall 2007 budget, primarily through his American Competitiveness Initiative. Several of the increases in the Department's request are part of that Initiative, and I'll say more about them in a minute, but I think most of you would agree that we need to address the competitiveness issue in America's schools now, this year. This is why most of our major increases for 2007—not just those included in the President's Initiative—are aimed at keeping our students, and our workforce, competitive for the 21st century.

In that context, a key proposal for 2007 is a renewed request for High School Reform, a \$1.5 billion initiative to support a wide range of locally determined reforms aimed at ensuring that every student not only graduates from high school, but graduates with the skills to succeed in either college or the workforce. The High School Reform proposal also would require States to assess students, in reading or language arts and math, at two additional grades in high school. NCLB currently requires assessments in these subjects for just one high school grade. We believe the additional assessments are needed to increase accountability and give parents and teachers the information they need to keep all students on track toward graduation. And more generally, these assessments will help researchers and policymakers understand more about what works and what doesn't work in our high schools, a key goal when about 1 million high school students a year drop out, at great cost to our economy and society. Too many students drop out, and too many of them are minorities.

We also are seeking \$100 million for the Striving Readers program, which is applying the lessons of the successful Reading First model, which translates research into practice to improve reading instruction for young children, at the secondary school level. The \$70 million increase for this program would expand support for the development and implementation of research-based methods for improving the skills of teenage students who are reading below grade level, and who otherwise might end up dropping out of school. It's hard to compete with anyone if you don't finish high school.

MATH AND SCIENCE

A critical new focus for 2007 is on improving student achievement in math and science from the early grades through high school, and the President is seeking \$380 million in new funding to support this goal through his American Competitiveness Initiative (ACI). That total includes \$250 million for two proposed programs we call Math Now, one focused on developing and implementing proven instructional practices for students in grades K–6, and one to support research-based interventions for middle school students. Both initiatives would be guided by the recommendations of a National Mathematics Panel that I will appoint soon, and that will be charged with identifying essential math content and sound instructional principles, just as the National Reading Panel did for reading instruction.

Another key ACI request is a \$90 million increase for the Advanced Placement program, to expand incentives for training teachers and encouraging students, particularly in high-poverty schools, to take high-level Advanced Placement and International Baccalaureate courses in math, science, and critical foreign languages. We also are proposing a new requirement for State or private-sector matching funds to expand the reach of the AP program, so that we can train an estimated 70,000 teachers over the next five years. Over the long term, this proposal would increase the number of students taking AP-IB exams in math, science, and critical foreign languages from 380,000 today to 1.5 million in 2012, and triple the number of students passing these tests to 700,000 by 2012.

I believe that increasing the number of American students studying and gaining fluency in critical foreign languages is essential not only for our national security, as suggested by the President's National Security Language Initiative, but also to maintain our economic competitiveness. That's why I'm very pleased that our request includes \$35 million in new funds for a package of proposals that would encourage more students to master a critical foreign language. The largest proposal is \$24 million for Advancing America Through Foreign Language Partnerships, a new program that would link postsecondary institutions with school districts to support language learning from kindergarten through high school, as well as advanced language study at the postsecondary level.

BUILDING STATE CAPACITY FOR SCHOOL IMPROVEMENT

We continue to make good progress in implementing No Child Left Behind, with scores on State assessments up significantly across the country, and the National Assessment of Educational Progress showing real improvements in closing achievement gaps, especially in the early grades addressed by key NCLB programs like Title I and Reading First. Our 2007 request would help maintain that positive momentum, while providing a new push in the area of school improvement. Our budget would provide \$12.7 billion for Title I Grants to Local Educational Agencies, which is the foundation of NCLB, while funding a \$200 million School Improvement Grants program. This initiative would help States to establish and expand the state-wide systems of improvement and support that are essential to the long-term success of NCLB. If we're going to reach the 100-percent proficiency goal by 2013–14, we need to make continuous improvement our watchword, and our request would help States do just that.

Our request also would support additional options for students enrolled in schools that have been identified for restructuring—these are chronically low-performing schools that have not made adequate yearly progress under NCLB for at least 5 years. The \$100 million America's Opportunity Scholarships for Kids program would permit the parents of such students to transfer their children to a private school or to obtain intensive tutoring or other supplemental services, including after-school and summer-school instruction. The President believes that for accountability to be meaningful, there must be real consequences for schools and real options for students and parents.

OTHER PROGRAMS

The 2007 budget would provide a \$100 million increase for the reauthorized Special Education Grants to States program, for a total increase of \$4.3 billion, or 69 percent, over the past five years. We also would maintain a \$4,050 Pell Grant maximum award with a \$12.7 billion request for that program, while continuing to support the new Academic Competitiveness Grants and National SMART Grants program. I want to thank the Members of this Subcommittee, along with your colleagues in the House, for supporting these critical new grant programs. In particular, SMART Grants complement the President's American Competitiveness Initiative by awarding up to \$4,000 annually to third- and fourth-year postsecondary

students majoring in physical, life, or computer sciences, mathematics, technology, engineering, or a critical foreign language.

CONCLUSION

These highlights of our 2007 request show that within the very tight constraints required by the need to reduce the Federal budget deficit in a time of war, we are proposing a strong education budget, one that will maintain and even accelerate progress under No Child Left Behind, while making key new investments in critical areas designed to ensure our future competitiveness in the 21st century global economy.

I will be happy to answer any questions you may have.

FISCAL YEAR 2007 EDUCATION BUDGET PRIORITIES

Senator SPECTER. Thank you very much, Madam Secretary. I begin with the questions which I posed in the letter which I sent to you, last month. I focus at the outset on the proposed budget for the Department of Education, being \$2.1 billion below last year. The Department has highlighted rising test scores, a narrowing of the achievement gaps since the passage of No Child Left Behind, and the increase in Federal funding that has accomplished those results. What are the prospects for continued progress with the budget cuts which are in your proposal?

Secretary SPELLINGS. Well Senator, I think there are a couple of answers to that. One is that the priorities of No Child Left Behind are indeed funded in the President's budget—the emphasis on reading, the emphasis on teacher development, the emphasis on Title I. Then there are the additional resources that we are requesting for school improvement—the \$200 million that we need as the No Child Left Behind law matures—as well as the investment in competitiveness, and in high schools, and in math and science. So I think that where we have resources we've focused them on the goals of No Child Left Behind. Second, I would say that a lot of the infrastructure that was needed to be put in place to do No Child Left Behind, such as assessments, and reading curriculum reform and those sorts of things, has been done, and now we're turning our attention to the maturing of No Child Left Behind and these other priorities.

Senator SPECTER. The difficulty, Madam Secretary, is that there are cuts in a lot of programs which impact the students whom you're trying to deal with in No Child Left Behind. You're robbing Peter to pay Paul, really. When you have a net decrease of \$2.1 billion and you have the inflation factor as well, it just seems to me that it's impossible to make it up with the shuffling that you're suggesting.

PUBLIC SCHOOL CHOICE AND SUPPLEMENTAL SERVICES

What is the situation with the repeated public comments about the difficulty of moving students from one school which is not satisfactory to other schools? We see constant complaints that the recipient school districts are unable to accommodate the students, that that has not really been a practical or realistic program?

Secretary SPELLINGS. Let me make a couple of comments about that, Senator. First, I've observed that also. We have about a 10 percent take-up, if you will: 2 million students are eligible for supplemental services, and about 200,000 students are seeking those options. So we must do a better job of making sure those options

for parents are real. But one of the things I think I've learned, and we're piloting strategies in various places around the country, is, does it make more sense—and we ought to get some data about this—to allow students to get extra intervention and supplemental services before the public school choice options are used. So we're testing that theory in Chicago, Los Angeles, New York, and some districts in Virginia will also test that out. Does it make more sense, before we ship them off to other schools, to get them additional remediation. That's why the President's call for an additional \$100 million for either choice, or ramped up supplemental services, makes a lot of sense.

Senator SPECTER. But you still are letting them choose to go to another district, aren't you?

Secretary SPELLINGS. The public school choice options, yes, are still in place. But what I'm saying is, perhaps parents would be equally satisfied or more satisfied to receive supplemental services first.

Senator SPECTER. Well, are you saying that in all situations where children want to move from an inferior school to a better school that there are remedial programs to discourage their moving?

Secretary SPELLINGS. Well, I'm saying that perhaps in the meantime, as we address these choice issues, that getting remediation in a particular skill or subject, quickly and readily available, convenient—

Senator SPECTER. Well, are you talking about something which is realistic, so that we have inferior schools in those situations, all of those situations, or almost all of those situations, or most of those situations, you have remedial programs to discourage going to another school?

Secretary SPELLINGS. Well, I think it's a range of fallibility if you will. I mean, some of these schools are chronically low performing and that's why we need to spend \$200 million to make sure that real school restructuring takes place.

EFFECTIVENESS OF SUPPLEMENTAL SERVICES

Senator SPECTER. Madam Secretary, my time is almost up and I'm going to observe the time. But the question really is, is that a palliative and a fig leaf, or does it really work?

Secretary SPELLINGS. I think supplemental services can work very well educationally for kids.

Senator SPECTER. Can. But do they, are they? Are there sufficient supplemental services to pick up on this very critical program problem?

Secretary SPELLINGS. In some places there are, and in some places there are not, Senator. Clearly, I agree.

Senator SPECTER. Well, that's not satisfactory. My red light went on, so I'm going to yield at this point to distinguished ranking member Senator Harkin.

Senator HARKIN. Thank you very much Mr. Chairman, I apologize for being late, I'll just forgo my opening statement and ask that it be made a part of the record, if that's okay.

Senator SPECTER. Without objection, it will be made part of the record.

[The statement follows:]

PREPARED STATEMENT OF SENATOR TOM HARKIN

Good morning, Madam Secretary. I don't get to see you that often in person, so I want to take this opportunity to commend you for the steps you've taken to make the No Child Left Behind Act more flexible. There's still room for improvement, but you're responding to the concerns that many people have with this law, and you deserve credit for that.

Today, however, our focus is on the President's proposed budget for education. And I must speak frankly: I don't see how anyone in this administration can defend it.

This budget would cut federal education spending by \$2.1 billion. That's the largest cut, in dollars, in the 26-year history of the Education Department. And it comes on the heels of a \$600 million cut in fiscal year 2006—the first cut in a decade.

It looks to me as if this administration has basically given up on the three programs that matter most to the Nation's students—Title I, IDEA, and Pell.

Title I is the cornerstone program for the No Child Left Behind Act. It's the program that targets aid to the students who are most at risk of failing. That's why NCLB calls for a \$2.2 billion increase for Title I this year. But how much more does the President ask for? Zero. It's flat funded.

This administration has also given up on funding for students with disabilities. In fact, it's moving in the wrong direction. In fiscal year 2005, the federal government provided 19 percent of the average per-pupil expenditure toward the costs of special education. This year, fiscal year 2006, it went down to 18 percent. Next year, under this budget, it would go down again, to 17 percent. As the federal share goes down, states and local districts have to pick up more of the tab. And we all know what that means—higher property taxes.

This administration has also given up on student aid. Under this budget, the maximum Pell Grant award would be frozen at \$4,050, the same level as four years ago. I wonder if there are any colleges in America that charge the same amount for tuition that they did four years ago. I doubt it. It gets tougher and tougher all the time for low- and middle-income families to afford college, but this administration doesn't seem to care.

It's as if the President said, "Well, I spent a little money on education during the first couple years of my administration. So much for that. I'm done."

So if there's nothing in this budget for Title I, Pell, and IDEA, what is there? Unfortunately, a lot of the "same old, same old."

Once again, the President proposes a high school reform initiative. But as far as I'm concerned, it's dead on arrival. The President asked for it last year, Congress rejected it, and the same thing will happen again this year, as long as it's contingent on eliminating the Perkins vocational ed program.

And speaking of eliminations, the budget zeroes out 42 programs in all. Forty-one of them are programs you tried, unsuccessfully, to eliminate in the past. Congress restored the funding for them last year, and I can tell you right now, we'll restore funding for almost all of them again this year.

Like I said, more of the "same old, same old."

There are really only two new initiatives in this budget of any significance: the Math Now programs, which cost a total of \$250 million, and the Title I School Improvement Grants, which are budgeted for \$200 million.

I happen to like both of these ideas. In fact, I was the first Member of Congress to include funding for School Improvement Grants in an appropriations bill. In fiscal year 2003, when I was chairman of this subcommittee, I included \$100 million for this program in the Senate Labor-HHS bill. It didn't end up getting funded, but I'd like to see it happen.

But where will the money come from to fund these new initiatives? I guarantee you: We're going to restore the TRIO programs that this budget would eliminate. There's enormous bipartisan support for TRIO. So that's \$456 million that we've got to find from somewhere. We're going to restore GEAR-UP, at \$303 million. We're going to restore the Robert C. Byrd Scholarships, at \$41 million. We're going to restore the counseling programs, at \$35 million. I created that program, so I can assure you that Congress will save it.

I could go on and on, program after program. But here's the bottom line: Unless the President helps up find more money overall for education, his new initiatives are simply not going to get funded, at least not anywhere close to the levels he wants.

I've served on this subcommittee as ranking member or chairman since 1989, so I know what I'm talking about. If you want us to fund these presidential initiatives,

you're going to have to work with us to get our congressional priorities funded as well.

Again, Madam Secretary, I want to welcome you to the subcommittee. I look forward to hearing your testimony.

NO CHILD LEFT BEHIND FLEXIBILITY PROVISIONS

Senator HARKIN. Madam Secretary, welcome. First a compliment before I get into the other stuff, if you don't mind; I don't see you that often, I just want to take the opportunity to commend you for the steps that you've taken to make the No Child Left Behind Act more flexible. That has always been a sore point, and I appreciate that. There's I think, still some room for improvement. But I think you were responding to the concerns that many people have with this law, and I think you deserve credit for that—to get that flexibility in there. But that's aside from today.

FISCAL YEAR 2007 EDUCATION DEPARTMENT BUDGET REQUEST

We're talking about the budget. I guess my first question was, the budget that you've sent up for our subcommittee on education, would you Madam Secretary, like to see it passed exactly as you sent it up?

Secretary SPELLINGS. Well, Senator, as you know, we propose and you dispose. It's a process between the two of us, we seldom end up—you know, you all seldom enact exactly what the President sends up. I mean obviously——

Senator HARKIN. I'm just asking you. Do you back it? Do you back it as you sent it up?

Secretary SPELLINGS. Certainly. I support the President's budget.

Senator HARKIN. Does your boss the President back it as it was sent up.

Secretary SPELLINGS. Yes, he does.

Senator HARKIN. So he wants it enacted just like that?

Secretary SPELLINGS. Well, I think he believes that this is the smartest, best allocation of resources, given all the various priorities in the Government.

PROPOSED EDUCATION BUDGET CUTS

Senator HARKIN. I just want to get that clear for the record. That this isn't just some little game, that this is a budget that your boss the President of the United States, proposed to us, and this is how he'd like to see it enacted and so would you, Madam Secretary. Here is the biggest cut in Federal education spending, \$2.1 billion in the 26 year history of the Education Department. Do you disagree with that?

Secretary SPELLINGS. Well, Senator——

Senator HARKIN. Is that figure correct, or not?

Secretary SPELLINGS. I can't remember the exact figure, the \$2.1——

Senator HARKIN. That's what I have; I just want to make sure we're on the same page.

Mr. SKELLY. It's the biggest since 1988. So not 26 years.

Senator HARKIN. So what year was the bigger cut?

Mr. SKELLY. 1988.

Senator HARKIN. 1988 was a bigger cut?

Mr. SKELLY. In dollars and in percentage.

Senator HARKIN. In dollars and in percentage, in 1988.

Mr. SKELLY. Yes sir.

Senator HARKIN. Okay, so I was off a few years. Then we had a \$600 million cut in fiscal year 2006. Right?

Mr. SKELLY. That's right, Senator.

[CLERK'S NOTE.—Senator Harkin was correct. The proposed cut of \$2.1 billion would be the largest reduction in the 26-year history of the Education Department. The cut in 1988 was larger as a percentage of the total budget, but not in dollars.]

TITLE I GRANTS TO LEAS

Senator HARKIN. Okay. I just want to make sure we're on the same page. Now let's turn to Title I, cornerstone program of the No Child Left Behind Act. Madam Secretary, I read your testimony, you said it was the cornerstone.

Secretary SPELLINGS. I do.

Senator HARKIN. No Child Left Behind calls for a \$2.2 billion increase for Title I this year, how much did the President ask for? Zero. Flat funded.

Secretary SPELLINGS. As well—

Senator HARKIN. That's quite a cornerstone.

Secretary SPELLINGS. As well as some additional resources that attach to No Child Left Behind, like \$200 million for school improvement.

Senator HARKIN. But Title I is the cornerstone, you say that. When it's flat funded and when No Child Left Behind Act calls for a \$2.21 billion increase for Title I this year, something's wrong with the cornerstone.

SPECIAL EDUCATION

Special education, Republicans and Democrats for years have been saying we've got to get it to the 40 percent level, you know what I'm talking about.

Secretary SPELLINGS. Right, I do.

Senator HARKIN. We've talked about it; we've had votes on it, Senate Resolutions that are 100 to nothing, or 99 to 1 or something like that, about doing this. Well, we've been inching up the last few years, under the leadership of Senator Specter. We've been getting it up; we've gone up to 19 percent. An all time high. Last year we went back to 18, under this budget we go back to 17 percent.

I don't know how you can see this as any kind of progress at all on how the administration can support this.

PELL GRANTS

Student aid Pell Grants are now frozen at \$4,050, the same as 4 years ago. Can you name me one college in the United States where the tuition is the same this year as it was 4 years ago? There isn't such a place. Yet the Pell Grant's frozen at that. These are for the poorest of kids. I mean you know what you have to do to qualify for a Pell Grant?

Secretary SPELLINGS. I do.

Senator HARKIN. You just about have to have nothing to qualify for a Pell Grant. But yet, the President talks about his competitiveness initiative. Sounds great, we all believe in that, but is it just competitiveness just for the kids of wealthy families, or families who can get loans and stuff like that; how about competitiveness for the kids that qualify for Pell Grants. What about them? What about their competitiveness? Where do they fit into this picture? Well—I just don't see how you can support that. I'm not saying it's all bad. There are some things that you got in there that are good. Some of the math and science stuff is okay. That's fine. Little bits and pieces here and there. But in total, I just can't imagine your support for that. I see my time is up now, and I didn't really get a question in, but I wanted to make sure that we were talking about apples and apples, and not oranges and apples and that kind of stuff, and maybe on the second round I can have a question about that. Thank you very much.

Senator SPECTER. Thank you, Senator Harkin. Senator Landrieu.

EDUCATION RESPONSE FOR HURRICANE RECOVERY

Senator LANDRIEU. As the ranking member is here—before you came in Senator, I was complimentary of the Department, of the great work that they have done for the Hurricane Katrina and Rita victims, and said what a reliable partner they've been. I want to thank you also, Senator Harkin, because without you and Senator Specter our education aid bill would not have passed the way it did, and I want to say how much we appreciate that.

FISCAL YEAR 2007 BUDGET REQUEST

Having said that, I want to agree with what both the chairman and ranking member said; not only do I think this budget is scandalous in terms of short changing our goals, Madam Secretary, for No Child Left Behind, but it's disheartening and wholly inadequate. Disheartening for the army of people out there trying to close these achievement gaps, making the changes, pushing themselves to achieve excellence, only to find their budget is being cut. While Title I is flat funded dollar for dollar for last year, because it does not have an inflation factor and it's not taking into consideration the extra efforts being made to move these poor and low-income, and moderate-income children up, it really is short changing their ability.

Last night I got to attend a function in Washington, the Youth National Guard Youth Challenge Program, that tries to focus on reaching the 33 million Americans between the ages of 16 and 24 that do not have a high school diploma—33 million Americans between the ages of 16 and 24. Those numbers don't just pop, they are created by budgets like this that do not provide the support of children in those early grades so that they could get a diploma of achievement—they can read, and calculate at grade level.

I know that as the Department's Secretary you're responsible for carrying out the President's budget. But I want to say as a Senator who is given choices between extending dividend tax cuts, reducing capital gains taxes, this is what is paying for those tax cuts. The short changing in education for children in Louisiana, Mississippi, the Gulf Coast, Arizona, in Pennsylvania, in Wisconsin, and in

places in Iowa, and all places are paying for those tax cuts. I think it's too heavy of a price. I just want to go on record. It's too heavy of a price to pay. We end up paying for it, in you know, criminal justice systems. We end up paying it in mental health services. The taxpayer's don't get a break. The taxpayers just pick it up in a more painful, more expensive way. I don't know when we're going to learn that investment in early childhood education is giving children a fighting chance. There's no guarantee of success, but I want to say for the record and my time, and I'd like to ask you this question because only our Federal portion represents about 8 to 10 percent of the total. The States are picking up about 70 percent, is that correct Madam Secretary of Education, expenses at the State level?

Secretary SPELLINGS. It varies around the country.

EQUITABLE DISTRIBUTION OF EDUCATION RESOURCES

Senator LANDRIEU. What is the Department doing to try to equalize or make more equitable the funding in the country, from our wealthier counties, to our poor counties? If you could just focus a minute of your answer. I know we haven't directed you as such. Title I attempts to try to equal—it's Congress' best attempt to try to give poor and middle income children the same resources available. But is this Department at all focused on that resource gap? There's an achievement gap, but there's a resource gap. Do you know what it is, can you just tell us, and give us a minute of what you're doing to try to close that gap?

DISTRIBUTION OF HIGHLY QUALIFIED PERSONNEL

Secretary SPELLINGS. Well, that's a great question and I think it manifests itself in a lot of ways. Highly qualified teachers: one of the dirty little secrets in education is that our most qualified people are in our least challenging environments and vice versa, and so as we implement No Child Left Behind we ought to look at how States and school districts allocate highly qualified personnel. The President's budget proposal on Advanced Placement (AP)—I talked about the 40 percent of the high schools that offer no AP at all. I use the example in my speeches that in Fairfax County, Virginia, you can find schools with 20 plus AP classes, whereas in the District of Columbia, Ballou High School has just 3 or 4. Those are exactly the kinds of things that we need to address as part of either implementing No Child Left Behind or the resources that the President has asked for.

No Child Left Behind—whether it's for special education students or limited English speakers—has focused educators on bottom line results for all kids and resources. Obviously, our Federal commitment has always been to our Nation's neediest students, and that's why we invest so much money in IDEA and Title I, to help level out those educational opportunities around the country. With respect to Title I, obviously the formula reflects the numbers of poor kids as they migrate around our country.

PER PUPIL EXPENDITURES ACROSS THE NATION

Senator LANDRIEU. Just to conclude though, Mr. Chairman, we focus on the neediest. But I can say from—there are a lot of middle-income families now that would classify themselves as middle-income that are stretched and need help and as we continue to cut these programs back, we're touching the bottom 5 or 7 percent, when we should be trying to help the bottom 40 or 50 percent. Tom, I would like you just to submit for the record, the difference in resources from the poorest counties, to the wealthiest counties to give us an update for the record of this committee. I understand in some places it's like \$3,000 or \$4,000 a child, and then in some counties we're spending \$12,000–\$14,000 a child. I know that we don't direct that funding, but we can you know recognize that while there's an achievement gap, there's a resource gap that this committee has an obligation to fix, or try to fix. Thank you.

[The information follows:]

EDUCATION FUNDING IN HIGH-POVERTY AND LOW-POVERTY DISTRICTS

Average expenditures per student vary across local educational agencies (LEAs) from about \$3,300 to over \$20,000 per student, according to the 2003 Public Elementary-Secondary Education Finance Data compiled by the Census Bureau. Most of the largest and smallest figures are for very small school districts with limited enrollment. For example, of the 10 LEAs with expenditures per student between \$3,000 and \$4,000, only 1 had an enrollment of over 100 students. They are mostly small, rural school districts, including 5 in Nebraska and 3 in Montana. However, even excluding the very small and rural school outliers, there is a significant difference in the per-student averages among the poorest and wealthiest LEAs (with "poor" and "wealthy" defined on the basis of the percentage of school-aged children living in poverty). The 100 LEAs with the lowest poverty rates and enrollment of at least 1,000 had average expenditures of \$9,585 per student, while the 100 LEAs with the highest poverty rates and enrollment of at least 1,000 had average expenditures of \$7,897 per student.

Among the poorest LEAs, defined as those with poverty above 40 percent, there are many sizable school districts with average expenditures well below the national average of about \$8,100. For example, Roosevelt Elementary School District in Arizona, with a poverty rate over 45 percent and enrollment of 11,000, had an average expenditure per student of \$5,900. Laredo Independent School District in Texas (45 percent poverty; enrollment of 24,000) had an average expenditure per student of \$6,900. Greenville Public School District in Mississippi (42 percent poverty; enrollment of 7,400) had an average expenditure per student of \$5,900. But there are also many poor districts with larger than average expenditures per student. These include Muskegon Heights School District in Michigan (44 percent poverty; \$10,300 per student), Todd County, South Dakota (40 percent poverty; \$11,500 per student) and Rochester City School District in New York (40 percent poverty; \$12,711 per student).

The same can be said for the wealthier school districts. There are examples of high per-student expenditures, such as Fairfax County, Virginia (6 percent poverty; \$9,500 per student), Montgomery County, Maryland (7 percent poverty; \$10,580 per student), and Cherry Hill, New Jersey (3 percent poverty; \$11,300 per student) as well as examples of low per-student expenditures, such as Clay County, Florida (9 percent poverty; \$5,600 per student), Scottsdale School District, Arizona (7 percent poverty; \$5,600 per student), and Alpine School District in Utah (9 percent poverty; \$4,400 per student).

While the spread is significant between the poorest and wealthiest districts, there is a more noticeable pattern among States. The 142 LEAs with an average expenditure per-student below \$5,000 are in only 17 States, with the majority in Arizona, Oklahoma, Utah, Montana, and Nebraska. At the other end of the spectrum, half of the 200 LEAs with the highest average expenditure per student are in three States: California, New York, and New Jersey.

VOCATIONAL EDUCATION FUNDS

Senator SPECTER. Thank you, Senator Landrieu. Senator Kohl.

Senator KOHL. Thank you very much Mr. Chairman.

Secretary Spellings; you'll recall that we spoke at last year's hearing about Perkins Vocational Education program. Perkins is very important to every State, but particularly my State. Wisconsin received almost \$25 million in Perkins funds last year, and over 23,000 students benefit in my State from Perkins services. The vast majority of Perkins recipients in Wisconsin have gone on to graduate and obtain high skill, high wage jobs. Last year the President proposed to eliminate Perkins funding but the Congress refused to go along, as you know. The Senate voted to reauthorize Perkins by a vote of 99 to nothing. We also worked to restore most of the funding cut by the President. One would think that these actions would have sent a very strong message to the President, and Senators in both parties feel strongly about Perkins. Yet once again, as you know, the President's proposed elimination of this vital program in 2007. Would you explain how he apparently is so out of touch with we here who live and work with the problem everyday in our States? Not just to reduce Perkins, which is unacceptable, but to eliminate Perkins, which seems to me to be incomprehensible.

INVESTMENT IN SECONDARY EDUCATION

Secretary SPELLINGS. Senator, yes I will. The President believes that we ought to gather up the resources that we spend in vocational education, TRIO, and GEAR UP and a number of our secondary school investments and create a high school reform program; a \$1.5 billion high school initiative for States to use as they see fit, around graduation rates and enhanced achievement for all high school students, including additional accountability and the like. When and where vocational education programs, GEAR UP, TRIO, any of those programs work well, then States can and should—and I'm confident will—continue to invest in those. But I think we also have to look at our results of secondary education, and that is about half of the African American and Hispanic kids who start high school do not complete high school. When these resources and these programs are targeted to them I think we have to ask ourselves, are they working as well as they can be in the aggregate.

Senator KOHL. Well, I don't think you've really answered the question, he still proposes eliminating Perkins and aggregating it all really in the final analysis results in cuts. But it's just done in a way that we don't really see how these cuts occur, but that's I believe pretty clear to most of us who look at this closely that aggregating really involves cutting. Madam Secretary, I supported the No Child Left Behind because it guaranteed flexibility and accountability would come with more Federal funding to make it work. Instead, funding levels have fallen billions of dollars short of what was authorized and these cuts as you know cause real hardships. Schools are being forced to cut staff and important programs like summer school, class size reductions, arts, physical education, and languages. Last year almost 11,000 schools failed to make ade-

quately yearly progress under No Child Left Behind thus facing Federal sanctions. These schools will face even greater challenges as testing and teacher quality requirements go into full effect.

So isn't it time to provide the funding that was promised so that we can give schools and students a real chance to succeed which was the premise behind No Child Left Behind, that there would be funding which is by all accounts not what was promised. Where do we go from here?

ALLOCATION OF BUDGET RESOURCES

Secretary SPELLINGS. I think what you'll find in the President's budget, and it is a tough budget no doubt about it, is that the resources are allocated around the core principles of No Child Left Behind, such as our sustained investments in Title I, in reading, in teacher quality, and the accountability features and achievement. That those are our most—that's our most urgent calling, and our highest priority for resources.

PELL GRANTS

Senator KOHL. Madam Secretary, the President's budget proposal also targets student aid programs for harmful cuts including a \$4.6 billion reduction in funding for Pell Grants. The maximum Pell Grant award is again frozen at \$4,050 for the fifth year in a row, despite rising tuition costs. These may just seem like numbers but they also have a real impact on students who are struggling to go to college. The University of Wisconsin in Madison alone dispersed \$9.2 million in Pell Grants to 3,751 low-income students last year. In 1975 the Pell Grant recovered 80 percent of the costs of a 4-year public education in college and today that number is down to about 40 percent. So my question is, how can this administration claim to want to make higher education a reality for low-income students while at the same time cut the very programs that would help them achieve that goal.

Secretary SPELLINGS. Well, let me respond in a couple of ways. One, while as you said the Pell Grant itself is still \$4,050, the actual grant has not been cut. There will be about 59,000 more students who will be taking advantage of Pell Grants. In addition to that, as part of the reconciliation that you all passed, there are additional resources for students who are studying in the critical areas of science, technology, engineering and math. Starting with about an additional \$750 for year one of their studies, going up to \$4,000 by the fourth year if they pursue those particular fields. As you know, the Congress finally has eliminated the Pell shortfall that has vexed us for so long, which is most of that \$4 billion that you spoke of, but I think what we know is that the community colleges, in particular, continue to be able to offer a full and complete education at the Pell Grant level. So it's a matter of students frequently starting there at community college as opposed to a State university. But the Pell Grant does remain stable at \$4,050.

PREPARED STATEMENT

Senator KOHL. Thank you, and before I turn it back to the chairman, my time has expired. When you keep a program like Pell

Grants at the same level for 5 years, you are reducing its value, obviously. When I pointed out that the Pell Grant covered in 1975, 80 percent of your public education and today it's 40 percent, that describes the erosion of keeping the number at a constant level. Thank you so much, and thank you Mr. Chairman.

[The statement follows:]

PREPARED STATEMENT OF SENATOR HERB KOHL

Thank you, Mr. Chairman. Secretary Spellings, I join my colleagues in welcoming you here today. You face a significant and challenging task in managing the Department of Education and I hope that we can work together to improve access to education for all Americans.

I appreciate the difficult task you face in funding the many education priorities of our country. That job is more challenging, in our view, because this Administration has chosen budget and tax policies that have led to rising deficits and diminishing resources available for essential education programs.

This budget is abysmal for the education community. It proposes the largest cut to federal education funding in the 26-year history of the Department. Students, educators, parents, and administrators all lose out under this budget. Funding for No Child Left Behind and Special Education, the main federal funding streams for our local school districts, are a far cry from their authorized levels. More specifically, funding for No Child Left Behind is \$12.3 billion dollars below the authorization level, and IDEA is \$6.3 billion short in 2007. In addition, over forty programs are slated for elimination, including funding for Career and Technical Education, Safe and Drug Free Schools, and TRIO programs.

The President's budget should reflect our nation's priorities—but these are just a few examples of this budget being out of step with our values. I will continue to work with my colleagues to improve upon this budget. Madame Secretary, I hope that you will work with us to better meet our nation's education needs.

Senator SPECTER. Thank you Senator Kohl, Senator Craig.

AMERICAN COMPETITIVENESS INITIATIVE

Senator CRAIG. Mr. Chairman, thank you very much. Madam Secretary, I'm pleased you're with us this morning. First and foremost, I want to commend you and the President for including the American Competitiveness Initiative in his State of the Union. I thought that was critically important, and I'm looking forward to working with the Department of Education and in this instance the Department of Energy will have a fair chunk of that, and my colleagues in the implementation of many of those proposals. I think it's important. I think we can convince the American people it's important, that we remain competitive and that we design a system that allows us to do that. When we were holding hearings on that recently in the Energy committee I was likening it to our reaction to Sputnik. The Defense Education Act of the 1960s that followed and the tremendous—and the fallout, the positive fallout of that down through the decades, as we trained a generation of mathematicians, and scientists, all because we found ourselves not competitive in the real world in a cold war environment and out of that space initiative and everything else. Of course because the—what I believe is a national crisis we're in today as it relates to energy, we take that a lot easier because the lights are still on, and even though gas is more expensive at the pump, it's still there and we're adjusting accordingly even though it's costing us, you know, lots of jobs out there in the industrial sector today, and all that. The new world that we compete in is going to be ever demanding.

We all know those stories, they are real and I'm glad to see the President out on the edge of that, pushing it. That's extremely im-

portant for us. In the context of doing that although, I think we have to shape budgets that begin to fit that and move us in those directions, and they are bits and pieces of all that we're talking about in order to meet the challenges laid out by the President in the Competitiveness Initiative. I believe that bringing professionals into the classrooms will be tremendous assets to our students. Yet the system is so rigid to allowing that to happen today that it almost, at the very beginning unless we break down some of those barriers towards the very initiative that's underway. What programs have been or are being implemented to ensure that professionals interested in teaching have the training they require, and do you believe the President's budget provides adequate funding to bring these professionals ultimately into the classroom to work alongside the educator in inspiring these young people into these different areas that are within the Competitiveness Initiative?

ADJUNCT TEACHERS PROGRAM

Secretary SPELLINGS. Thank you for that question. The President's budget calls for \$25 million to start to seed some of this kind of activity, which we call Adjunct Teachers. We use this all the time in higher education, especially in community colleges, and it's very effective. Typically, people who are engaged in their own profession teach part time in higher education. Many of these students now, high school students, enjoy dual enrollment programs between community colleges and high schools, and they are already being served by the kind of professionals that you talk about. IBM has committed 1,200 engineers and other highly skilled professionals to make transitions into the teaching profession, so I do think there's an appetite and a willingness out there and a need—a dramatic need—for those sorts of competencies. We have some models to build on through Troops-to-Teachers, Teach for America, and some other programs that have taken mid-career professionals and helped them become effective teachers. But I think the notion is, let's be able to get some of our expertise and resources from the broad community around some of these 185 day, 10-month contract sort of structures, that we're so used to dealing with in education.

INNOVATIVE HIGH SCHOOL RESTRUCTURING IN IDAHO

Senator CRAIG. I had the privilege, Mr. Chairman, of walking through a new high school in Idaho during this last recess. The largest building in our State from the standpoint of an educational institution, 2,200 students. I thought, oh my goodness, how can they possibly handle 2,200; surely they must be lost in the system, because I was thinking of the old models. But I walked into a school with academies, and the allowance to actually begin shaping from your freshman year on, some core competencies that move you then into community colleges, or into University settings. In the junior senior year, that nexus with the community college that you had—I spent a couple of hours there, spoke with the senior class, and walked out with a total different opinion. Or a sense of understanding as to these new structures, and in this particular school district which is the fastest growing in our State, they're building a new high school about every 2 years now, they're moving to this concept. They feel they can go to larger schools but they allow the

student to actually identify with a much smaller unit within the school. It's impressive. It's happening at other places in the county. Idaho is not alone in it certainly, and it makes some very real sense, tied to this competitive initiative, and being able to move young people out earlier. Those who chose to, to get into that higher learning, frankly, can break through the rigidity of the current system that says, no, no this is the way we've always done it, we control it, so this is the way you're going to do it. If it isn't providing us with that level of training and talent, then we've got to break through it, and if you can't live within it, you get outside of it, I guess, and that's starting to happen in parts of Idaho where we have community college settings in which they can cooperate. That's a pretty exciting concept. But in doing so—and then transitioning them forward, there was concern about the Pell Grants and other tools to make sure that those students can carry on, and I'm looking at this budget concerned about obviously areas like the Federal Direct Student Loans and the Federal Family Education Loans, and all of those kind of things. Those tools are going to be in part a necessary component of any kind of competitiveness initiative to move these young people forward.

Secretary SPELLINGS. I agree with that.

Senator CRAIG. Thank you.

Secretary SPELLINGS. Absolutely, Senator. I think I'd love to visit that school, I mean these are places as you said—

Senator CRAIG. You want to visit it?

Secretary SPELLINGS. I would like to.

Senator CRAIG. Fine, you'll get an invitation today.

Secretary SPELLINGS. Good.

Senator CRAIG. We'd love to have you out.

ADJUNCT TEACHERS

Secretary SPELLINGS. Establishing the nexus between higher education and high school, that can be more efficient and more effective as we get these professionals who are working in the field, and who have this expertise, because we're frankly going to be very challenged to do it other ways.

Senator CRAIG. Well, it's an exciting model, and as I say, there are many large schools across the country that are recognizing that high schools of 2,000, if not restructured, lose children.

Secretary SPELLINGS. Exactly.

Senator SPECTER. Thank you very much, Senator Craig. Senator Murray.

SCHOOLS-WITHIN-SCHOOLS

Senator MURRAY. Well, thank you very much Mr. Chairman, and Senator Craig, I'm delighted to hear that you went to that school. The Gates Foundation has been focusing on schools-within-schools, with some real successful programs.

Senator CRAIG. If you'll let me interrupt. I'm not absolutely sure, but it's very possible they're participating in this one. Yes.

ACADEMIC COMPETITIVENESS AND NATIONAL SMART GRANTS

Senator MURRAY. Yeah. I agree with the focus on high schools. I think it's absolutely critical that we as a Nation really find out why we're losing kids at such dramatic rates. Those kinds of programs really make a difference. But let me, Madam Secretary, talk with you a minute about some of the academic competitive grants in the national science and mathematics act says to retain talent, the SMART grants. To receive those American competitive grants, students have to have completed what is called the rigorous secondary school program of study. Now I agree, as I said that we have to do everything we can to prepare students for the global economy they're going to be in. Whether—but I think a student's luck in where they attend high school, whether it's Senator Craig's or another one, shouldn't determine whether or not the Federal Government helps them attend college. CBO estimated that only 9.9 percent of the Pell eligible students are going to be able to take advantage of those academic competitiveness and SMART grants in 2007. Now the maximum Pell Grant has not increased for 4 years despite as we all know tuition rising at our Nation's public colleges by over 7 percent last year. So if the \$850 billion that those grants cost in 2007 were spent on Pell Grants, students would actually receive an additional \$200 in aid that would have made a tremendous difference. I would like to find out from you, how you anticipate judging what constitutes a rigorous secondary school curriculum?

RIGOROUS HIGH SCHOOL CURRICULUM

Secretary SPELLINGS. That's a great question and we're struggling with that at the Department now. About a week ago, we had folks in from the Gates Foundation, from the National Governors Association, and from the Council of Chief State School Officers to look at and talk about what's the most appropriate way to do that while being very respectful of our prohibition at the Department of Education for prescribing curriculum. I certainly don't want to sit up here and look at high school course syllabi and so forth. So we're working on that right now. I mean, I think we know things that are widely accepted, like Advanced Placement, International Baccalaureate, and the State Scholar's program—that 14 States have already bought into place, i.e. their determination of a college-ready curriculum. For State Scholars this is 4 years of English, 3 years of math and science, and 2 years of foreign language. We'll be announcing another 8 to 12 States that will be joining the State Scholars program soon. So States have come to terms largely, or are beginning to, with what they believe to be college-ready, so that, I hope, will be informative as we look at the Academic Competitiveness Grants.

Senator MURRAY. Well, I appreciate the goal, but here we are in 2007 where less than 10 percent of the students are going to be eligible for these grants, and in tight budget times it seems to me that using those dollars to help all kids get \$200 in aid, not just those who are lucky enough to attend a high school that works out to have a "rigorous schedule." I just think it's something we have to manage. So I'm very concerned about a large amount of money

funneling to a few kids who happen to be in the right high school, with the right curriculum, versus us being able to help all students with an additional \$200 with the same pot of money. So it's just a budget issue in my mind. Obviously you've got a program you love, and you want to go down that road. But in tight budget times we have to say, are we going to help all kids out there, or just the ones who are lucky enough to have that somehow undefined yet rigorous curriculum.

Secretary SPELLINGS. Well, it's also obviously our responsibility to make sure that we have a college-ready curriculum, and this is why we need more Advanced Placement in more places, and so forth, making such a curriculum available to all kids everywhere.

Senator MURRAY. Well, I think it's good to provide incentives to high schools to move towards a rigorous curriculum, I'm with you on that. But I don't want to see us use the kids as a tool. Because in the end they are the ones who are not going to be able to go to college based on where they went to school. I think it's so important that we provide that opportunity, but it's a philosophical debate.

HEA TITLE IX

I have limited time. I wanted to ask you about Title IX. On March 17, the Department released a new guidance on the interest prong of the three-part test which schools are using to show their compliance with Title IX. As you are aware, I have some really grave concerns about this new guidance, because I believe it sets a new low bar for compliance with the Federal Civil Rights Law. Schools would now be allowed to use an email survey to show their compliance with Title IX. The school would only have to send that survey to women. So, a lack of response at our universities where kids already have a lot to do, and may just say to heck with that, seems to me a very poor way to be determining compliance with Title IX. Now I know that it's used—surveys are used as part of compliance, but it's the sole means to making sure whether a school complies or not, to me seems really wrong headed.

Now as you know there's a lot of concern over this new guidance, and there's a bipartisan group of Senators on the subcommittee who have asked for a report on the guidance and the use of surveys and I wanted to find out from you this morning what the status is of that?

Secretary SPELLINGS. We'll be completing that next month. I believe you all gave us a deadline for March sort of timeframe there. We will be completing it then. I do want to note that we've not had any complaints about the survey aspect yet, and frankly as you know it is a legitimate prong to ascertain interest. This is prong three.

Senator MURRAY. But the sole prong is a problem.

Secretary SPELLINGS. We have about 116 schools around the country that do that now. But your report is due March 17, and we intend to meet that deadline.

Senator MURRAY. Okay, well there's a lot of confusion on behalf of schools about the guidance. I want to know what your department is doing regarding technical assistance to schools on the guidance of that?

Secretary SPELLINGS. You have recently confirmed Stephanie Monroe as AS for OCR. I've had a vacancy in that job for a long time, and we are providing technical guidance around that issue. I'm a mother of two daughters, I'm very committed to their opportunities as well, and so—

PREPARED STATEMENT

Senator MURRAY. Well, we all are. But if we base compliance on an e-mail survey to women in college expecting that their response back as students is going to decide whether or not a school is compliant, I think that is just not a very smart way to go. I'm going to continue to work with other likeminded Senators to make sure we don't somehow use that information to take away the ability of many young women in this country to be able to access sports in colleges.

[The statement follows:]

PREPARED STATEMENT OF SENATOR PATTY MURRAY

Secretary Spellings, thank you for coming today to talk with us about the President's fiscal year 2007 budget request for the Department of Education. I want to take this opportunity to say that I have always believed that the federal budget is more than just a compilation of numbers. Rather, it is a collective statement of the values and priorities of our nation. Looking at the figures included in the President's fiscal year 2007 budget request for the Department of Education—which is the largest cut in federal education funding in 26 years—I have to say that I question the value that the President is placing on educating our nation's youth this year.

As a country, we are required to articulate and defend our values and priorities, particularly as we undergo the annual budget process. While I share the President's stated commitment to preparing our nation and workforce for the competition of the 21st century, I am disheartened to see that his rhetoric about the importance of leaving no child behind is not matched by the budget numbers this administration put forward in its fiscal year 2007 request.

I want to remind my colleagues that what we do in the next few weeks will affect us—and the American people—for a long time. The budget decisions we make now will either empower us—or tie our hands—when we turn to determining funding levels in this appropriations committee later this year. That is why I must say I strenuously object to the request put forward by the President.

While it's true that the President's budget includes increased dollars for math and science education, these funds come at the expense of cuts or elimination to other important programs. I view new initiatives in math and science as complements to, but in no way substitutions for, the other federal education investments we have made over the past 40 years. While science and math competence are undoubtedly a critical piece of what our students need to compete globally, it cannot come at the expense of helping disadvantaged students succeed academically, investing in our high schools, and ensuring our college students have the financial means to attend postsecondary education.

I am particularly disheartened that the administration continues to fall behind in meeting its commitments under the No Child Left Behind Act. The President's fiscal year 2007 request does not include any increases in NCLB's cornerstone program, Title I. The administration's decision to recommend level funding—at a time when requirements and accountability provisions for our schools continue to grow—essentially asks our schools to do more with less resources. This inconsistent messaging is disingenuous and unfair. What's worse, our students, parents, teachers and schools suffer as a result.

I also want to express my concern about the High School Reform package the President is promoting. As you know, I have been an advocate for focusing federal education resources to our nation's high schools. That is why last year I introduced my Pathways for All Students to Succeed (PASS) Act, to provide targeted resources to our nation's high schools. The PASS Act would help America's teenagers graduate from high school, go on to college, and enter the working world with the skills they need to succeed.

While I appreciate the President's interest in high school reform, the reality is that he elected to pay for these reforms by cutting important programs. The \$1.475 billion he is proposing for his high school package doesn't come close to replacing the money we currently spend on the 42 programs, including vocational and technical education, GEAR UP and TRIO, proposed for elimination. At a time when 3,000 students drop out of high school each and every school day and when half of our nation's African American and Latino students do not complete high school, we need to be doing more, not less, to make our high schools places where all students can learn.

In addition to stemming the tide of high school dropouts, we must assist students in the transition from high school to college by providing financial resources to facilitate access to higher education. Yet recently the federal government cut \$12.7 billion from student loans that help low- and middle-income families pay for college. This decision, during a year in which tuition and fees increased by 7.1 percent for four-year public universities and 5.9 percent for private universities, does not reflect our national priorities. In the same vein, the value the President purports to place on higher education is not reflected in his budget, which level-funds the Pell Grant program for the fourth year in a row.

As we work together in the next few weeks to prepare the budget resolution, I will do my best to ensure that the values and priorities of our nation and my state of Washington are reflected in the numbers to which we will hold ourselves. As a policymaker and parent, I know that American competitiveness demands a more comprehensive approach to education. We must match our rhetoric with the necessary resources to support all of our students, at all grade levels, in all subject areas. Our children—and our country—deserve nothing less.

Thank you.

PROPOSED GEAR UP PROGRAM ELIMINATION

Senator SPECTER. Thank you, Senator Murray. Madam Secretary, what participation did you have in the elimination of the program known as "GEAR UP" that's been in existence for about 7 years? On the ratings by OMB, they say "GEAR UP" is based on successful models for increasing the college enrollment rate of at-risk students. Initial program results suggest that grantees have been more successful in increasing the percentage of students taking a more challenging course load, better preparing these students for future college enrollment.

It was an idea advocated by Congressman Chaka Fattah, who has had a lot of experience in government in Philadelphia, where there are tough schools with a lot of dropouts and a lot of students with problems. It has been a program which has been funded principally out of the Senate that I have spoken about repeatedly. Let me ask you a two-part question. What do you think the chances are that "GEAR UP" is going to be dropped by the Congress? Second, what did you have to do with dropping it, if anything?

Secretary SPELLINGS. Well, Senator, first let me say that you know "GEAR UP" was invented in Houston, Texas, I mean when President Bush was Governor, we were strong supporters of it.

Senator SPECTER. Does President Bush know that?

Secretary SPELLINGS. Yes. President Bush, then Governor Bush.

Senator SPECTER. Does President Bush know it's being dropped?

Secretary SPELLINGS. I presume he does.

Senator SPECTER. I'm going to tell him.

Secretary SPELLINGS. I presume he does.

Senator SPECTER. Have you told him?

Secretary SPELLINGS. Yes, sir. But let me tell you what his—

Senator SPECTER. No, no. Have you—well you can tell me, but first tell me, have you told him?

Secretary SPELLINGS. Have I told him specifically “GEAR UP” is not in the budget?

Senator SPECTER. Yes, ma’am, specifically. Have you told him that “GEAR UP” has been dropped?

Secretary SPELLINGS. I don’t believe that I have told him that specifically.

Senator SPECTER. Do you know if anybody has told him that specifically?

Secretary SPELLINGS. I do not.

Senator SPECTER. Get the President on the phone.

Secretary SPELLINGS. I certainly will tell him.

START OF GEAR UP PROGRAM

Senator SPECTER. He calls me with some frequency when he wants Supreme Court Justices confirmed. Next time he calls, I’m going to parry him with this question about “GEAR UP”; I didn’t know it was started in Houston.

Secretary SPELLINGS. By Jim Ketelsen. The former CEO of Tenneco.

Senator SPECTER. The first question I’m going to ask him is, Mr. President, do you know “GEAR UP” was started in Houston? Second question I’m going to ask him is, do you know that “GEAR UP” has been dropped? The third question is, do you know the Secretary of Education didn’t personally tell you that it was being dropped?

Secretary SPELLINGS. You can tell him that.

Senator SPECTER. Okay. It’s your turn.

HIGH SCHOOL REFORM INITIATIVE

Secretary SPELLINGS. But let me say this, the President’s philosophy here around this high school reform issue is that you need a block grant kind of program. That we ought to gather secondary school resources into a \$1.5 billion title that we’re saying would get results. That we shouldn’t sit up here and say, here’s how you should get results. Now I fully believe that in Houston, Texas, in Philadelphia, and places where these programs are working well, and effectively, they will continue to do those. I can’t say that that’s necessarily true in the aggregate. Where they’re going to be effective they’ll be maintained. I’m confident of that. The President’s philosophy—

Senator SPECTER. How will they be maintained without funding?

Secretary SPELLINGS. They will be paid for then out of the high school initiative.

Senator SPECTER. So you rob Peter to pay Paul, which is what I said on my last round of questions, I’ll probably say it in my fourth round, too.

Secretary SPELLINGS. I mean, I guess you could look at it that way. We’re gathering resources out of silos, out of specific prescribed programs.

Senator SPECTER. So you think really, you ought to keep “GEAR UP” but under another name?

Secretary SPELLINGS. No. I’m saying that States and local school districts ought to have the opportunity to design and choose pro-

grams as they see fit, including GEAR UP, Vocational Education, or others.

Senator SPECTER. But, when it's been a successful Federal program, and has all the backing from the Members of the House and Senate, why submit a budget which cuts it?

Secretary SPELLINGS. Well, I think the President believes that successful programs will be invested in with Federal dollars and maintained and enhanced at the State and local level.

Senator SPECTER. Federal programs will be invested with Federal dollars and maintained, and enhanced at the State and local level?

Secretary SPELLINGS. That where—in Philadelphia where this is working well, they will use their high school resources to invest in “GEAR UP” and they'll probably use State and local—

Senator SPECTER. What resources? They're strapped to the edge now.

Secretary SPELLINGS. Under the high school reform block grant, if you will, the \$1.5 billion in Federal funds that would be invested in high school reform, this program would absolutely be an allowable purpose.

FISCAL YEAR 2006 FUNDING LEVEL OF PROPOSED TERMINATIONS

Senator SPECTER. Well, since that will happen I can rest easy seeing it cut, I guess. Except that I won't. Senator Harkin, why don't you do that on your time. Harkin wisely points out. What was it you wisely pointed out?

Senator HARKIN. That their reform package is \$1.5 billion, but the total amount that gets cut out of all these other programs is \$2.1 billion.

Senator SPECTER. How about that, Madam Secretary?

Secretary SPELLINGS. Well, I think it's more like the \$1.5 billion that we have gathered up. I don't know what all the elements are that are in the \$2 billion estimate that you have, Senator Harkin, but it depends on what's on the list, I guess, is the short answer.

Senator SPECTER. Madam Secretary, you can see the smooth coordination. I frequently use the expression that when we change chairman and ranking member that it's a seamless passage of the gavel, which I now undertake to do, so that he can follow up on his Charlie McCarthy, Edgar Bergen question that I asked on his behalf. Senator Harkin.

Senator HARKIN. Wait a minute. Which one am I?

Senator SPECTER. You're Edgar Bergen, I can tell you that.

Senator HARKIN. Okay, well, to follow up on this.

Senator SPECTER. Secretary Spellings is too young to really know who either is.

Secretary SPELLINGS. I was just going to say you're dating yourselves. But I wasn't going to say anything.

Senator HARKIN. But to follow up on it, Madam Secretary. I understand the High School Initiative program is at \$1.475 billion. But there are 40 some programs that were eliminated. All the TRIO programs, Talent Search, Upward Bound, Smaller Learning Communities, that's \$2.1 billion. So you've taken away \$2.1 billion that goes out to these high schools, and saying now, here's \$1.5 billion.

HIGH SCHOOL REFORM INITIATIVE

Secretary SPELLINGS. Here's the difference. Part of the Perkins Vocational Education Program goes into community colleges and is in the postsecondary education environment, if you will, and so the high school reform proposal at \$1.5 billion reflects the investments that are currently going to K-12 schools. The difference, the additional funds, can be found in community colleges, which is obviously higher education.

Senator HARKIN. Oh, so you're saying that Talent Search, Upward Bound and all those programs are now shifted somehow to community colleges?

Secretary SPELLINGS. No, sir. I'm saying that the Perkins Voc Ed Program, some of those resources end up in community colleges, some end up in high schools. Trio, GEAR UP, those sorts of programs that are high school programs, would, could be funded from the \$1.5 billion high school side of it.

Senator HARKIN. Okay. I understand what you're saying now. Please understand what I'm saying, that you add up all those cuts in those programs, it's \$2.1 billion. You replace that with \$1.475 billion for your high school initiative. So when you say that schools, well, if they want to continue the successful programs, they could. Well, I guess what I would ask you to submit to this committee is which of these, is it 42 programs, 40 some, I forget what it was, that you're asking to be eliminated—I mean, which of those are you saying are not successful?

Secretary SPELLINGS. Well—

Senator HARKIN. Which of them are not successful? Please.

Secretary SPELLINGS. We have a PART process that rates the programs. I certainly could give that PART list for the 42 programs and will. The difference I want to say on the \$2 billion worth is that, in the Perkins Program, part of those resources go to community colleges, so the high school initiative at \$1.5 billion is, it reflects the resources that are spent in K-12 schools.

[The information follows:]

OMB PART RATINGS FOR PROGRAMS PROPOSED FOR TERMINATION IN THE FISCAL
YEAR 2007 BUDGET REQUEST

OMB developed the Program Assessment Rating Tool (PART) in order to assess and improve program performance so that the Federal Government can achieve better results. Ratings are based on questions in four critical areas—purpose and design, strategic planning, management, and results and accountability. The answers to questions in each of the four areas result in numeric scores, which are combined to achieve an overall qualitative rating that ranges from Effective, to Moderately Effective, to Adequate, to Ineffective. Programs for which we have insufficient evidence from either performance data or rigorous program evaluations cannot be assessed and receive a PART rating of Results Not Demonstrated. PART assessments help our Department and OMB improve the performance of Federal programs by identifying flaws in program design, management, or implementation that undermine effectiveness. PART assessments also help inform funding decisions, but a program's PART rating would not dictate budget policy. For example, the Administration might not request funding for a program for which there is not a clear Federal role or which is duplicative of other programs, even if it is rated Effective or Moderately Effective.

The following chart shows whether programs proposed for termination in the fiscal year 2007 budget request have been assessed using the PART, and if assessed, the year of the assessment and the rating the program received.

OMB PART FINDINGS FOR EDUCATION DEPARTMENT DISCRETIONARY PROGRAMS PROPOSED FOR
TERMINATION IN FISCAL YEAR 2007

Program	Year assessed	Rating ¹
TRIO Talent Search	2003/2005	Moderately Effective
Comprehensive School Reform	2002	Adequate
GEAR UP	2003	Adequate
Projects with Industry	2004	Adequate
Even Start	2002	Ineffective
Safe and Drug-Free Schools State Grants	2002	Ineffective
TRIO Upward Bound	2002	Ineffective
Vocational Education State Grants	2002	Ineffective
B.J. Stupak Olympic Scholarships	2004	Results Not Demonstrated
Byrd Honors Scholarships	2004	Results Not Demonstrated
Educational Technology State Grants	2005	Results Not Demonstrated
Leveraging Educational Assistance Partnership	2004	Results Not Demonstrated
National Writing Project	2004	Results Not Demonstrated
Parental Information and Resource Centers	2004	Results Not Demonstrated
Smaller Learning Communities	2005	Results Not Demonstrated
Teacher Quality Enhancement	2003	Results Not Demonstrated
Tech-Prep State Grants	2002	Results Not Demonstrated
Academies for American History and Civics	Not Assessed
Arts in Education	Not Assessed
Civic Education	Not Assessed
Close Up Fellowships	Not Assessed
Demonstration Projects for Students with Disabilities	Not Assessed
Elementary School Counseling	Not Assessed
Excellence in Economic Education	Not Assessed
Exchanges with Historic Whaling and Trading Partners	Not Assessed
Federal Perkins Loans Cancellations	Not Assessed
Foundations for Learning	Not Assessed
Javits Gifted and Talented	Not Assessed
Mental Health Integration in Schools	Not Assessed
Ready to Teach	Not Assessed
Safe Drug-Free Schools Alcohol Abuse Reduction	Not Assessed
School Dropout Prevention	Not Assessed
School Leadership	Not Assessed
Star Schools	Not Assessed
State Grants for Incarcerated Youth Offenders	Not Assessed
Thurgood Marshall Legal Educational Opportunity Program	Not Assessed
Underground Railroad Program	Not Assessed
Vocational Education National Programs	Not Assessed
VR Migrant and Seasonal Farmworkers	Not Assessed
VR Recreational Programs	Not Assessed
VR Supported Employment State Grants	Not Assessed
Women's Educational Equity	Not Assessed

¹ Reflects the most recent rating for programs that were reassessed.

NOTE: A total of 74 ED programs have been assessed since 2002 using the Program Assessment Rating Tool (PART); additional programs will be rated in the future.

Senator HARKIN. So in your opinion the \$2.1 billion and \$1.5 billion that's just money that normally goes to community colleges, is that right?

Secretary SPELLINGS. Yes, sir.

Senator HARKIN. Well, I'll have to take a look at that. I'm not certain about that one but give me some documents on that and I'll—

Secretary SPELLINGS. I'll definitely do that.

Senator HARKIN. Let me ask you, but one thing I did want to cover is this what's happening with special education. I said earlier it goes from 19 percent to 18 percent, now down to 17 percent and, right, but here's the real problem, as bad as that is, there's another hit coming to these schools outside your jurisdiction but you should be cognizant of it, Medicaid pays for the cost of coverage services

for eligible children with disabilities. School districts can be reimbursed by Medicaid for transportation costs they incur in providing services if this works. The administration wants to prohibit schools from getting reimbursed for transportation and in fiscal year 2007 schools are expected to receive \$615 million from Medicaid for that purpose. If this change goes through then they're going to have to pay the \$615 million in transportation costs themselves. So while you might say that there's been a slight increase in IDEA funding from \$10.583 to \$10.683, a \$100 million increase, still not keeping up with inflation or anything, there's going to be another cut from Medicaid reimbursement for these kids. Where are these schools going to get that \$615 million, \$650 million, \$615 million, can't read it, \$615 million for transportation? Did I make myself clear?

Secretary SPELLINGS. You did. Senator, as you know, those are reimbursements through HHS and I'm sure you'll discuss that with Secretary Leavitt. My understanding is, those are places where they found a lot of fraud and abuse with respect to those reimbursements and, you know, with respect to IDEA funding overall we've had a 68.5 percent increase in funding since 2001 and, you know, we continue investments on the education side for special education. With respect to the transportation funding, my understanding is that it's been a place where there's been some fraud and abuse and that that needs to be curtailed.

Senator HARKIN. I'm all for cutting fraud and abuse but when you disallow the whole thing, I mean, you're saying that every dollar's being abused. I mean, you're not saying it—

Secretary SPELLING. I'm just not very familiar with the particulars, since we don't run that program.

Senator HARKIN. You're not saying that but OMB or the administration's saying that and since there's a close correlation here between the two, between you and HHS on this, I mean, somehow we've got to bring that together because if we cut the \$615 million COLA, that's going to be a big hit.

ESEA TITLE I PROPOSED FUNDING DECREASE

Title I, let me just say one thing about Title I. Right now 29 States will get less Title I funds under the budget, than they did last year. My State, Iowa, was one of 15 States that will get less Title I funding than they did 3 years ago in fiscal year 2004. On the district level it's even bleaker. This fiscal year was the third year in a row that most districts got less Title I funding than they did the year before. Fiscal year 2007 will be the fourth straight year. In my State, two-thirds of Iowa districts got less Title I funding this year than they did 3 years ago. So how can you say you're giving schools enough money for No Child Left Behind when our budget once again cuts Title I funds the most to the districts?

Secretary SPELLING. Well, as you know, under Title I the distribution formulas follow the kids and the poorest kids as they move around and as those populations shift. There are also obviously States who are getting additional Title I resources owing to the distributional mechanics of Title I funds following those poorest, neediest kids.

SCHOOLS CATEGORIZED AS NEEDING IMPROVEMENT

Senator HARKIN. I'm told there are about 11,000 schools in this country that have been designated in need of improvement, is that about right?

Secretary SPELLINGS. That's sounds about right—

Senator HARKIN. 11,000.

Secretary SPELLINGS [continuing]. That sometimes gets characterized as failing schools. I think, you know, we all know that there are schools that need improvement when half the minority kids aren't getting out of high school. We have work to do with special ed students and limited English speakers and so on and so forth, so, it doesn't surprise me that 11,000 schools need improvement.

ESEA TITLE I FUNDING

Senator HARKIN. Yeah, but again how are we going to help these schools when we're cutting Title I funding? I mean, you say it follows the kids around and I know poverty's gone up in some areas but I can tell you we still have, I suppose, kids in Iowa and rural areas and places like that that are getting cut out, because it's almost like you're assuming there's a static level of poor kids just goes to this level and they shift around but it always stays static, I mean the total number stays static. That's not true. I don't think there's any figures that show that. The number of poor kids in this country has gone up.

Secretary SPELLINGS. Right. That's why we supported increases in Title I for the poor through the course of the present administration.

Senator HARKIN. Well, we're getting less Title I money.

Secretary SPELLINGS. I'm talking about in the entirety of the President's term, Title I funding is up about 45 percent.

Senator HARKIN. Oh, I see. So it went up a couple of years in a row. Now we can sit back and we don't have to increase it any more.

Secretary SPELLINGS. Well, I'm not suggesting that we can sit back by any stretch but—

Senator HARKIN. We hear that when we double the funding for NIH and we got it up there, now we say, well they did that, now we don't have to worry any more and we just sit back. I think what we were doing in the first couple of years is trying to play catch-up ball in funding these kids in Title I. That doesn't mean it's remained static and I just think the program funds Title I.

Secretary SPELLINGS. Well, we've also called for \$200 million for School Improvement. You talked about the 11,000 schools.

Senator HARKIN. I know about the \$200 million. I just divide that out to 11,000, it's about \$20,000 per district.

Secretary SPELLINGS. Well, I think we can learn from each other. I think States will be doing more systematic and systemic work at a State level that will leverage some of those resources.

Senator HARKIN. Our time is up. Madam Secretary, you said quite frankly in your opening statement that the Federal Government's role is providing help to States for under-privileged, poor kids and kids with disabilities. Well, this is it, right here, and I

think we're shirking our responsibility in that area to provide that kind of help to the States. Thank you.

HIGH SCHOOL DROPOUTS—THE SILENT EPIDEMIC

Senator SPECTER. Thank you, Senator Harkin. One final inquiry and, Madam Secretary, we're having votes about to begin, force back votes on the PATRIOT Act. The publication of *The Silent Epidemic* is out on dropouts—I see you nodding in the affirmative—thanks to the Gates Foundation on funding it, and it shows that about 3.5 million young people between the ages of 16 and 25 have dropped out of high school, were not in school in the year 2003, the most recent year in which such an estimate is available. What in the budget is being directed to that major problem?

ADDRESSING THE HIGH SCHOOL DROPOUT PROBLEM

Secretary SPELLINGS. Well, Senator, a few things. One, as that study observes, and I'm meeting with one of those authors of the report this afternoon, I think, of the things we know is that kids drop out because they don't have the necessary reading and deciphering skills, particularly reading skills, to do high-school-level work. That's why we support the Striving Readers Initiative for a \$100 million, so we can take some of our reading research and extend it in the middle schools and get these kids caught up so that they can do more rigorous work. The other thing, as the report observes, and I think it speaks to boredom and a lack of rigor sometimes in high school, is that many of the students that drop out, you know, are passing. They are kids that are effective in attending school and they're just completely disengaged and tend not to find it very satisfying. So I think if we expand Advanced Placement, if we expand dual enrollment, and provide some of these things that are more engaging and more interesting and more rigorous, and more relevant to kids—I think those are some things we can do to guard against dropouts.

Senator SPECTER. What do you think the prospects are of ameliorating that problem?

Secretary SPELLINGS. Well, I think it's, you know, obviously going to be a journey. I don't think this is something that happens overnight. I think we need to know more. This is why the President has called for enhanced accountability in high schools. We don't know very specifically as policy-makers what is it about high school that's working and not working and for whom. Is it reading? Is it rigor? Is it, you know, disengagement? Is it a lack of vocational—

Senator SPECTER. How do you propose to find out?

Secretary SPELLINGS. Well, what the President has called for is additional accountability, more measurement in high school. We only test in one grade in high school. Typically States have elected to do that in the 10th or the 11th grade. So after 8th grade we lack information about what the state of high schools really is and an ability to parse that down for a policy tool.

Senator SPECTER. Where the President has called for it, what has the response been?

Secretary SPELLINGS. Many States have put high school assessments in place. I would say half or so have a full complement of assessment through high school. That's the Governor's—

DEPARTMENT'S COMMENTS ON THE SILENT EPIDEMIC

Senator SPECTER. Madam Secretary, we're going to have to recess here in a moment but what I would ask you to do is to give us your evaluation, your Department's evaluation of this report on dropouts and what is currently being done and what you think ought to be done. That's a gigantic problem which we really ought to address.

Secretary SPELLINGS. I agree.
[The information follows:]

SCHOOL DROPOUTS

"The Silent Epidemic: Perspectives of High School Dropouts," a March 2006 report by Civic Enterprises in association with Peter D. Hart Research Associates for the Bill and Melinda Gates Foundation, is based on a series of focus group interviews conducted with young people aged 16–25 who identified themselves as high school dropouts from public schools in large cities, suburbs, and small towns. As the report notes, the study's purpose was to approach the dropout problem from the perspectives of the former students themselves, to better understand the lives and circumstances of students who drop out of high school and to help ground the research in the stories and their reflections.

Though the study is primarily anecdotal and was not designed to be nationally representative, its findings are consistent with the Administration's emphasis on the need for high school reform in the 2006 and 2007 President's Budget proposals, as well as the effort to bring more rigor to the high school curriculum through such initiatives as the expansion of support for Advanced Placement courses.

For example, fully one-third of those surveyed said that they dropped out of high school because they were "failing in school," and 45 percent said they lacked academic preparation for the challenges of high school. In response, The Silent Epidemic recommended the development of "early warning systems" to help identify students at risk of failing in school, the provision of intensive assistance to struggling students, and research on what works in high school. The Administration's \$1.5 billion High School Reform initiative, first proposed in the President's 2006 Budget, would address each of these recommendations. Grantees would use test scores of incoming high school students to identify those most at risk of not meeting State standards and potentially dropping out, develop individualized performance plans to meet student needs, and support research on specific interventions and strategies for improving student achievement in high school.

The 2007 request also includes two other proposals specifically targeted to the needs of students like those discussed in The Silent Epidemic. First, a \$70 million increase for the Striving Readers program would significantly expand the development and implementation of research-based interventions to improve the skills of teenage students who are reading significantly below grade level. And a new, \$125 million Math Now for Middle School Students initiative would support research-based math interventions in middle schools.

In addition, the proposed \$90 million increase to expand the availability of Advanced Placement and International Baccalaureate programs in schools with large populations of low-income students would help ensure that such students are able to prepare for and successfully complete challenging, college-level curricula.

Finally, the Department already has played a key leadership role in working with the National Governors Association (NGA) to reach a common definition for calculating high school graduation rates. In particular, the National Governors Association also agreed on the use, while States ramp up their own capacity for a long-term solution, of an Average Freshman Graduation Rate, an interim calculation developed by the Department to provide comparable State-level graduation data.

The Department believes that momentum is building for a serious, nationwide effort to improve the performance of our high schools. President Bush has provided strong leadership in this area for the past two years, and The Silent Epidemic should contribute to that momentum and help persuade Congress that the time for action is now.

STATEMENT OF SENATOR THAD COCHRAN

Senator SPECTER. We have received the prepared statement of Senator Thad Cochran which will be placed in the record.

[The statement follows:]

PREPARED STATEMENT OF SENATOR THAD COCHRAN

Mr. Chairman, I welcome Secretary Spellings to the subcommittee and look forward to her testimony about the fiscal year 2007 Budget proposal for the Department of Education.

I first want to thank the Secretary for her extraordinary efforts and those of her staff following Hurricane Katrina. The first questions our school superintendents in Mississippi had as they began recovering were about being able to comply with the No Child Left Behind standards and regulations. The Secretary showed understanding and compassion for the difficulties faced by these administrators who still are simply trying to get schools back in operation and students back in their classrooms. Her actions to waive and provide flexibility under these trying circumstances are greatly appreciated. Her visits to Southaven, Pass Christian, and Jackson and those of the Assistant Secretary for Elementary and Secondary Education, Henry Johnson to Biloxi and others to my State have been well received and again, appreciated. An especially helpful gesture to my staff was detailing Beverly Ward, a Department employee here in Washington, to my Mississippi Gulf Coast office. She is still there, and has helped to provide coordination, communication, and a sense of comfort to those in both K-12 and higher education. Thank you very much for that assistance, Madam Secretary.

While the overall budget for the Department of Education is \$2.2 billion less than last year, I am happy to see the budget proposal includes continuation and even some increases in important programs such as, Title I grants to schools for disadvantaged students this is especially important in my State; an increase of \$100 million for Special Education grants; continuation of Ready to Learn Television; and a \$2 million increase in the Foreign Language Assistance Program grants to schools.

The budget is challenging again this year, and the President has proposed a number of reductions and eliminations that include programs that have proven to be popular and successful, so we will work to find a consensus agreement on what and at what amounts programs should be funded. I note for example, the National Writing Project, Arts Education, Gifted Education, and Civic Education are among the proposed program eliminations. I'll be working with you, Mr. Chairman, in an effort to ensure those programs are continued.

We will discuss the details of these programs over the next few months. As always, we begin the process of the appropriations cycle with a number of competing interests: those from the administration, members of this Committee, other Senators, and the members of the House. We will work to accommodate as many of those priorities as possible, and come to decisions as a committee that will reflect what we ascertain as the best course of action.

ADDITIONAL COMMITTEE QUESTIONS

Senator SPECTER. There will be some additional questions which will be submitted for your response in the record.

[The following questions were not asked at the hearing, but were submitted to the Department for response subsequent to the hearing:]

QUESTIONS SUBMITTED BY SENATOR ARLEN SPECTER

AMERICAN COMPETITIVENESS INITIATIVE

Question. The budget proposes to strengthen math and science achievement of K-12 students through a new \$380 million American Competitiveness Initiative. I am a co-sponsor of S. 2198, which addresses many of the same issues identified in this Initiative. My concern is that this worthwhile Initiative is funded through reductions in programs that many members of Congress support. Can you explain how this budget will accommodate both this new initiative and the other priority programs of various members of Congress?

Answer. We very much appreciate the strong support that you and other Members of the Senate have shown for our efforts to improve math and science education, as shown by the very similar goals of S. 2198 and the ACI. As for your concerns about funding the ACI proposals, I would point out that at seven-tenths of 1 percent of our discretionary budget, the \$380 million request for the ACI represents a modest, targeted approach to improving math and science education. The Congress should be able to finance this initiative by reducing funding for less needed or less

effective programs. I understand very well that trade-offs will be required by the Congress to fund the ACI, because we made those very same trade-offs in preparing our 2007 request. At the same time, we know that in negotiating the 2006 appropriations bill, your Subcommittee demonstrated a willingness to balance funding for priority programs with reductions and eliminations in other activities. We hope to work with you to achieve that same kind of funding discipline for 2007, and our request includes many examples of programs that could be reduced or eliminated to pay for new initiatives like the ACI.

FEDERAL PERKINS LOANS

Question. Your budget includes \$664 million in spending that is offset by the recall of the Federal contribution to the Perkins Loan program. During last year's session, the House and Senate Authorizing Committees agreed to extend the Perkins Loan program, not phase it out, as your budget assumes. Can you tell me how my subcommittee should make-up for the fact that this \$664 million offset is not a viable mechanism for additional spending proposed in your budget request?

Answer. The administration continues to believe needy students would be better served by redirecting Perkins Loan funds to more broadly available student aid programs, such as the Pell Grant, Federal Family Education Loan (FFEL), and Direct Loan programs. With the number of Perkins Loan institutions declining from 3,338 in academic year 1983–84 to 1,796 in 2003–04 and with only 3 percent of students enrolled in postsecondary education receiving Perkins Loans each year, the Administration believes the Federal share of funds held by this small group of institutions would be more effective if used in a way that serves all eligible students regardless of institution.

USE OF TITLE I SCHOOL IMPROVEMENT FUNDS FOR COMPREHENSIVE SCHOOL REFORM

Question. In the last two Department of Education Appropriations Acts, the conferees have included language in the statement of the managers which encourages the Secretary to notify States of a priority that they should place on the awarding of funds from the 4 percent school improvement. Can you explain what actions your Department has taken to comply with this language?

Answer. On March 9, 2005, the Department sent an e-mail to Title I State directors to notify them of the provision in the fiscal year 2005 appropriations report language and to inform them of the conditions that must be met for a State educational agency to use Title I school improvement funds for comprehensive school reform (CSR) projects. A Department official also discussed the directive at the Title I State directors' meeting last year.

In addition, the Department has hosted three regional meetings of State Title I directors and State CSR directors to talk about capturing the lessons learned from CSR, building bridges between Title I and CSR, and leveraging statewide systems of support to disseminate information learned through CSR.

The Department will hold a meeting this spring focused on building State capacity to improve schools using CSR and Title I to institutionalize what has been learned about working with high-performing, high-poverty schools. At the meeting Department staff will discuss the fiscal year 2006 report language about using Title I school improvement funds to support CSR projects.

COMPREHENSIVE SCHOOL REFORM AS SCHOOL IMPROVEMENT STRATEGY

Question. Given that one rationale for the elimination of the Comprehensive School Reform program was that States could use funds under their 4 percent set asides for the same activities, do you have any evidence that States have made or will make subgrants that support comprehensive school reform activities in school districts, and if not, why not?

Answer. We do not yet have any evidence, either from evaluation data or other reports, that States or school districts are using comprehensive school reform as part of their school improvement strategy. In part, this may reflect the progressive nature of the No Child Left Behind Act's (NCLB) school improvement requirements, which gradually move from school improvement plans in the first 2 years to replacement of curricula or staff under corrective action to alternative governance during restructuring. Comprehensive school reform generally represents the kind of thoroughgoing, fundamental change called for under corrective action and restructuring and, thus, may be adopted more frequently as increasing numbers of schools are subjected to these more stringent improvement measures.

Also, while the school improvement requirements in NCLB are fairly prescriptive, they do not specifically mention comprehensive school reform as an improvement strategy. States and districts naturally look to the statute for guidance as to what

they must do to support schools in the various stages of improvement, and will tend to adopt the specific remedies found there.

Finally, comprehensive school reform is intensive and time-consuming and requires considerable technical assistance from States and school districts that have been focused in recent years on overall implementation of NCLB. As States establish and strengthen their statewide systems of support for LEA and school improvement, they are likely to gain greater capacity to support activities like comprehensive school reform. The President's School Improvement Grants proposal would support this kind of evolution in State-level improvement capabilities.

TITLE I SCHOOL IMPROVEMENT SET-ASIDE

Question. In the fiscal year 2007 budget request, you have proposed overriding a provision in the No Child Left Behind Act to allow States to reduce the grants to local educational agencies below the amount they received in the 2006–2007 school year to generate sufficient funds under the 4 percent school improvement provision of the law. Could a State reduce the Title I grant funds of a school district identified for improvement and subgrant those funds to another district?

Answer. Yes, that would be possible, but any such reduction would be very small. Under the Administration's proposal, all districts would contribute proportionately to the pool of funds available to support State and local school improvement, not just those districts receiving increased allocations under the Title I formulas. States would then subgrant 95 percent of those funds to school districts with schools identified for improvement, with priority on those districts with the greatest need for such funds and the strongest commitment to using them to raise the performance of the lowest-achieving schools. By the way, the hold-harmless also leads States to reduce allocations to districts identified for improvement and redirect funds to other districts; it simply does so by disproportionately taking funds from districts that otherwise qualify for more Title I funds.

LIMITATION ON REDUCTION OF TITLE I GRANTS FOR SCHOOL IMPROVEMENT PURPOSES

Question. Would this proposal establish any limit to the amount by which a State could reduce a school district's Title I grant?

Answer. Yes, unlike current law, our proposal actually would limit any reduction for school improvement purposes to 4 percent. Under current law, districts that receive increased Title I funding often see their allocations reduced by more than 4 percent to make up for those districts protected by the hold-harmless.

Question. If not, why do you believe that is unnecessary?

Answer. As I said, our proposal actually would restore a meaningful limit to the State reservation for school improvement.

TITLE I SCHOOL IMPROVEMENT FUNDING GENERATED BY 4 PERCENT SET-ASIDE

Question. With more than 9,000 schools identified for improvement in the 2004–2005 school year, effective interventions that reduce this number and lead to improved student outcomes would help States and local school districts meet the goals of No Child Left Behind. How much funding has been generated and allocated under the 4 percent set-aside for each of the past 3 fiscal years?

Answer. We do not have actual data on the amounts reserved and allocated by the States during this period. We estimate that States reserved and allocated for school improvement purposes approximately \$484 million in fiscal year 2004 and \$500 million in fiscal year 2005, and will reserve and allocate roughly \$499 million in fiscal year 2006.

Question. Is there any information about the reach of this funding and the number of schools identified for improvement, or on watch lists, that have not been assisted?

Answer. Earlier this year, the Department published a report, "Title I Accountability and School Improvement from 2001 to 2004," which found that about 90 percent of school districts with schools identified for improvement reported that they provided at least some kinds of the assistance required by NCLB. At the same time, more than half of "continuously identified schools" (those identified for improvement throughout the period studied) reported that they did not receive more intensive assistance, such as assistance from a school support team or a school-based staff developer. The Department study also found, however, that State practices for allocating school improvement funds varied widely, partly because the study began prior to the implementation of No Child Left Behind, which brought significant changes to school improvement funding that were not fully implemented when the study was completed.

The recently released report, “National Assessment of Title I: Interim Report,” found that less than three-quarters of districts with identified schools reported having the staff, expertise, time, or money to improve the performance of those schools.

Question. Is there any information on how the 4 percent set-aside for school improvement funds have been used to remove schools from school improvement lists?

Answer. We currently do not have data directly linking school improvement funding with success in exiting improvement status.

TITLE I SCHOOL IMPROVEMENT MONITORING

Question. Has the Department done any monitoring of the types of activities funded with the 4 percent school improvement set-aside established under the No Child Left Behind Act?

Answer. Yes. The monitoring indicators used by ED’s Title I monitoring team include a focus on whether SEAs have (1) reserved and allocated Title I Part A funds for school improvement activities, and (2) created and sustained a statewide system of support that provides technical assistance to schools identified for improvement. The SEA must provide documentation that it has established effective school support teams with members who are knowledgeable about scientifically based research and practices related to school improvement. Likewise, the SEA must provide documentation that the teams provide support to schools on such topics as the design and operation of the instructional program and strategies for improving student performance. Monitors also seek evidence that SEAs are ensuring that LEAs carry out their own school improvement activities.

Another area reviewed is how the SEA distributes the 4 percent school improvement funds. Of the amount it reserves, the SEA must allocate not less than 95 percent directly to LEAs that operate schools identified for improvement to support improvement activities. In most cases, States are using these funds to provide special grants to support improvement in those schools. In a few instances, States, with the approval of the LEAs, directly provide improvement activities or arrange to provide them through regional educational centers.

At the local level, ED’s Title I monitors review how LEAs and schools are using the funds for improvement activities. This information is gleaned through interviews with LEA and school staffs.

Question. In particular, has the Department monitored the use of funds for implementing required 2-year improvement plans incorporating strategies based on scientifically based research and addressing the specific issues that led to schools being identified for improvement?

Answer. Yes. The monitoring indicators used by ED’s Title I monitoring team seek information and evidence that the SEA has assisted LEAs in developing or identifying effective curricula aligned with State academic achievement standards and disseminated the curricula to each LEA and school within the State. Additionally, monitors review and discuss school improvement plans with LEA and school staffs to discern how these plans address the 10 required components under NCLB, including how the improvement plans incorporate strategies that are research based and strategies that address the specific issues that led to the school being identified for improvement.

SCHOOL IMPROVEMENT GRANTS PROGRAM AND EFFECTIVE SCHOOL IMPROVEMENT ACTIVITIES

Question. What are your plans for using any knowledge generated through research on effective school improvement activities; and how will the fiscal year 2007 budget request support this goal?

Answer. The new \$200 million request for School Improvement Grants recognizes the critical need for State leadership and support in LEA and school improvement. While States currently reserve 4 percent of Title I, Part A allocations for school improvement activities—an amount totaling more than \$500 million annually, they must subgrant 95 percent of these funds to LEAs, leaving just \$25 million available for State-level school improvement activities. The request would provide substantial new support for State-led LEA and school improvement efforts and would help build State capacity to carry out statutory improvement responsibilities.

One research based approach that the Department is considering for the proposed School Improvement Grants program is requiring each State to use diagnostic assessments in schools that repeatedly fail to make adequate yearly progress. Such tests would help LEAs and schools clearly identify student strengths and weaknesses in a particular subject and develop appropriate instruction.

SUPPLEMENTAL EDUCATIONAL SERVICES

Question. Budget documents supporting the budget request note that “While many students attending schools identified for restructuring receive SES, the services tend to be of limited duration.” How does the amount of funding generated from the appropriations for Title I Grants to LEAs under the 20 percent SES/choice requirement relate to this finding?

Answer. The statement in the budget request simply reflects the reality that the duration and intensity of current supplemental educational services (SES) are limited by the statutory cap on per-pupil payments, with the current cap averaging about \$1,500 nationally. There are other factors that affect the duration of services, such as the structure of SES programs and the actual costs charged by various providers, but the general point is that the America’s Opportunity Scholarships for Kids proposal would roughly double the funding available for SES, from \$1,500 to \$3,000 and, therefore, greatly increase the intensity and duration of available services.

Question. If limited funding is not the reason for such limited intensity, what are the primary causes of it?

Answer. The premise of our budget request was to enable parents to purchase more extensive services with greater resources, and that students in schools identified for restructuring are likely to be those students who would most benefit from more extensive services than are available under current law.

Question. What is the impact of this finding of limited intensity on the effectiveness of the SES activity?

Answer. The SES program is still in its early years and we do not yet have meaningful impact data.

Question. How is the Department monitoring the requirement in NCLB that requires low-achieving students to receive priority for services under choice and supplemental services options?

Answer. ED’s Title I monitors review documentation to show that the SEA has developed and disseminated guidance to LEAs outlining requirements for implementing public school choice and supplemental education services and that this guidance includes the requirement that low-achieving students receive priority for these services. At the LEA level, ED’s Title I monitors review parent notification letters, guidance documents, LEA contracts with SES providers, and other documentation to determine if the LEA has complied with the required priority for providing the choice and SES options.

SUPPLEMENTAL EDUCATIONAL SERVICES PILOT PROGRAM

Question. You announced a number of pilots last year giving a select number of districts in need of improvement the flexibility to serve as supplemental educational service (SES) providers in exchange for greater student participation and achievement data. All of your other pilots invited interested States to “apply” before being offered this sort of flexibility. Can you explain how you selected the handful of districts that are in the SES pilot and why you circumvented States altogether and negotiated with districts directly?

Answer. For each of the pilots that we started last year (allowing Chicago and Boston to be providers although they are districts in need of improvement and allowing four districts in Virginia to reverse the order of choice and SES), the Department discussed and sought approval from each of the States before the pilots began. In the case of the Virginia pilots, we negotiated directly with the State throughout the entire process. For Chicago and Boston, we sought and received approval from their respective States for participation in the pilot. As for selection of these particular districts for the pilots, in the case of Chicago and Boston we worked with the Council of the Great City Schools to help us identify districts that were willing and able to participate in the pilot. Virginia had been in communication with the Department about ways to strengthen SES in the State, and came to the Department with a formal request to reverse the order of choice and SES. It was the first State to do so, and we granted this flexibility on a trial basis.

SELECTION OF DISTRICTS FOR SES PILOT PROGRAM

Question. Why was Chicago selected as opposed to districts such as Pittsburgh or Philadelphia, for instance?

Answer. As I mentioned, the Department worked with the Council of the Great City Schools to identify districts that had the ability to provide high-quality SES services and would meet the terms of the pilots. Pittsburgh and Philadelphia were not identified at the time as districts meeting these conditions.

STUDENT PARTICIPATION AND ACHIEVEMENT UNDER THE SES PILOT PROGRAM

Question. How many additional students are benefiting from each of the 3 pilots, which waive your regulation around prohibiting districts in need of improvement from serving as an SES provider?

Answer. Chicago and Boston are the two districts participating in this pilot. New York City was invited to participate but declined for this year. In Chicago, approximately 55,000 students are participating in SES through Chicago's program and private providers' programs; this compares to about 40,000 last year. In Boston, about 3,700 are participating, compared to about 2,000 last year.

Question. When will we be able to see the data on the benefits of SES on student achievement from these pilots?

Answer. We anticipate that this summer, after the spring State assessment results are in, we should be able to collect data on student achievement.

Question. How are you assuring high-quality tutoring programs in SES?

Answer. As a condition of participation in these pilots, each district had to meet a set of guiding principles that the Department identified as key elements of high quality SES programs. These included communicating to parents about SES through multiple venues and in languages that parents could understand, holding extended windows for enrollment, and allowing providers to serve students at school facilities for a reasonable fee.

EXPANSION OF THE SES PILOT PROGRAM

Question. Do you plan to expand this pilot to additional districts in the next school year?

Answer. We have monitored each of the pilot districts and collected data on their implementation this year. We are now in the process of reviewing these data and making determinations as to whether the Chicago, Boston, and Virginia pilots will continue, and whether additional sites will be added.

Question. If you do plan to expand the pilot program, what will be the selection process and how many do you anticipate selecting?

Answer. In the near future, we will be making determinations as to whether these pilots continue and the criteria we will use to select sites for participation.

Question. Do you plan to put any additional requirements on school districts serving as SES providers and, if so, what changes might there be next year?

Answer. We are considering whether to add any additional criteria to sites that participate in the pilots next year. We are using the information we have gained from this year's pilot sites to consider ways to strengthen the agreements with districts and help ensure that more students are receiving quality SES services.

AMERICA'S OPPORTUNITY SCHOLARSHIPS FOR KIDS

Question. The Department's budget includes \$100 million for a proposed voucher program that could be used by students in schools identified for restructuring so that they can transfer to a private school or receive intensive tutoring services. Why does the budget request \$100 million for vouchers for an estimated 2 percent of Title I schools and request no increase in the amount of funds available for the Title I grant program, the cornerstone of Federal assistance for helping disadvantaged students?

Answer. Congress has invested nearly \$200 billion in Title I Grants to LEAs over the past 40 years, including \$12.7 billion in the current fiscal year. While we agree that Title I is the cornerstone of our efforts to improve the quality of elementary and secondary education, particularly for low-income and minority students in high-poverty schools, the size of the program limits the impact of additional funding available under current budget constraints. For example, the \$100 million proposed by President Bush for the America's Opportunity Scholarships for Kids program represents less than one-tenth of one percent of the funding provided for Title I Grants to LEAs, and would have little or no impact when spread across 14,000 school districts. However, this amount is sufficient to permit a meaningful demonstration of the potential for expanded choice and tutoring options to improve the achievement of students attending chronically low-performing schools. Moreover, these funds would be targeted to the same students who are the focus of the Title I program and, in the case of students who select the tutoring option, would help improve the performance of Title I schools undergoing restructuring.

Also, the President is requesting first-time funding for School Improvement Grants, which would provide an additional \$200 million for State-led efforts to turn around low-performing school districts and schools. These funds would directly benefit participating Title I districts and schools that have been identified for improve-

ment. For this reason, it is not entirely accurate to say that the President's 2007 budget includes no increase in the amount of funds available for Title I.

MEASURING PERFORMANCE OF THE IMPACT AID PROGRAM

Question. The Administration has been undertaking an examination of how to measure performance under the Impact Aid program and has identified a model for estimating unmet need of eligible school districts. Please provide information on the findings of unmet need for various types of Impact Aid districts.

Answer. In 2005, the Department created a simplified model to analyze the effectiveness of the Impact Aid formulas and, more specifically, address the question of whether or not funds are adequately compensating for a Federal presence and the associated tax burden. The Department sent a review and analysis of the model to the House and Senate Committees on Appropriations in January 2006.

The report applied the simplified model to calculate the gap between available revenues to the LEA and the amount needed to fund schools at the State average per-pupil expenditure for Florida, Alabama, and Wyoming, three States for which adequate data were available. Comparing this gap to the actual payments made to Impact Aid districts revealed that there was very little correlation between the computation of local need from the simplified model and actual payments.

The model incorporates tax data into the analysis and, while it brings us closer to being able to compute valid economic analyses of the program, because of data limitations the model has not yielded the desired results. In order to answer these questions properly, more sophisticated analysis with better data will likely be needed.

IMPROVING TEACHER QUALITY PROGRAMS

Question. In November 2005, the Government Accountability Office released report GAO-06-25, which relates to State implementation of teacher qualification requirements of the No Child Left Behind Act. This report noted that some teachers who provide instruction in more than one core academic subject—such as special education teachers and those in rural schools—and secondary math and science teachers might not meet the teacher qualification requirement by the current deadline. What activities are funded currently and proposed in the fiscal year 2007 budget to help States and districts ensure that all students are taught by a highly qualified teacher?

Answer. In 2007, the administration is requesting funds for several programs that focus on improving teacher quality to help ensure that all teachers are highly qualified. These include: Improving Teacher Quality State Grants (\$2.9 billion), Title I Grants to Local Educational Agencies (\$624 million—the estimated professional development portion), Mathematics and Science Partnerships (\$182.2 million), Transition to Teaching (\$44.5 million), Teaching of American History (\$50 million), Troops-to-Teachers (\$14.6 million), and Advanced Placement (\$122.2 million).

HIGHLY QUALIFIED TEACHERS

Question. What specific steps will be taken to ensure that the disparity between the proportion of highly qualified teachers in lower income school districts and higher income schools is eliminated?

Answer. The Elementary and Secondary Education Act (ESEA), as amended by the No Child Left Behind Act, establishes the important goal that all students be taught by a "highly qualified teacher" (HQT) who holds at least a bachelor's degree, has obtained full State certification, and has demonstrated knowledge in the core academic subjects he or she teaches. Further, the ESEA requires States and LEAs to include, in their annual report cards, information on the percentage of classes not taught by highly qualified teachers, disaggregated by high- and low-poverty schools. In addition, the Individuals with Disabilities Education Improvement Act of 2004 reinforced the NCLB goal by aligning the requirements for special education teachers with the NCLB requirements.

The Department has been requiring States to submit data as part of their Consolidated State Performance Reports on the percentage of core academic classes taught by highly qualified teachers in high- and low-poverty schools, as well as the reasons why, for classes taught by teachers who are not highly qualified, the teacher is not highly qualified. In addition, States must have an equity plan in place to ensure that poor or minority children are not taught by inexperienced, unqualified, or out-of-field teachers at higher rates than are other children. The Department will be looking at States' progress in both of these areas this spring and summer. Although States and school districts are making significant progress in meeting the HQT requirement, there is still a lot of work to do to ensure that each State can

meet the goal that every child is taught by a highly qualified teacher by the end of the 2005–2006 school year.

Meeting the NCLB Highly Qualified Teacher Requirement

In the Department's ongoing visits and communications with State and local officials, we are often asked what will happen if, despite their best efforts, districts cannot hire a highly qualified teacher for every class in a core academic subject by the end of the 2005–2006 school year. Personnel decisions are made at the State and local levels, and the law relies on education leaders in the States to make the best educational decisions for improving student achievement. Last fall, I sent a letter to the chief State school officers to assure them that States that did not quite reach the 100 percent goal by the end of the 2005–2006 school year would not lose Federal funds if they were implementing the law and making a good-faith effort to reach the HQT goal in NCLB as soon as possible.

The letter also stated that the Department will determine whether or not a State is implementing the law and making a good-faith effort to reach the HQT goal by examining four elements of implementation of the HQT requirements: (1) the State's definition of a "highly qualified teacher," (2) how the State reports to parents and the public on classes taught by highly qualified teachers, (3) the completeness and accuracy of HQT data reported to the Department, and (4) the steps the State has taken to ensure that experienced and qualified teachers are equitably distributed among classrooms with poor and minority children and those with their peers. In addition, the Department will look at States' efforts to recruit, retain, and improve the quality of the teaching force. If States meet the law's requirements and the Department's expectations in these areas but fall short of having highly qualified teachers in every classroom, they will have the opportunity to negotiate and implement a revised plan for meeting the HQT goal by the end of the 2006–2007 school year. However, for States that either are not in compliance with the statutory HQT requirements or are not making a good-faith effort to meet the goal of having all teachers highly qualified, the Department reserves the right to take appropriate action, such as the withholding of funds.

Departmental Review of States' Efforts to Meet the NCLB Highly Qualified Teacher Requirements

In March 2006, I sent a follow-up letter to the chief State school officers with timelines and additional information about the Department's review of States' efforts to meet the HQT requirement. By the middle of May, the Department will assess States' Consolidated State Performance Report data for the 2004–2005 school year, HQT data for previous years, and supporting information that we have obtained through State monitoring visits and the review of publicly available records. The Department will then make determinations about whether the State is on track to meet the highly qualified teacher requirement.

Using the protocol "Assessing State Progress in Meeting the Highly Qualified Teacher Goal," the Department will determine whether each State's 2004–2005 data indicate that the State has a reasonable expectation of meeting the 100 percent HQT goal by the end of the 2005–06 school year and is faithfully implementing the law. If this is the case, the State may not be required to submit a revised plan, though it certainly may.

It is likely, however, that the Department will request most States to submit a revised plan detailing the new steps they will take to reach the 100 percent HQT goal by the end of the 2006–2007 school year. As part of the plan, each State will explain how and when the SEA will complete the High Objective Uniform State Standard of Evaluation (HOUSSE) process for those teachers not new to the profession who were hired prior to the end of the 2005–2006 school year, and how the SEA will limit the use of HOUSSE procedures for teachers hired after the end of the 2005–2006 school year to those secondary school teachers teaching multiple subjects in eligible rural schools (who, if highly qualified in at least one subject at the time of hire, may use HOUSSE to demonstrate competence in additional subjects within 3 years), and those special education teachers teaching multiple subjects (who, if they are new to the profession and highly qualified in language arts, mathematics, or science at the time of hire, may use HOUSSE to demonstrate competence in additional subjects within 2 years). Peers and teacher-quality experts will review the State's revised plan and evaluate how effectively the plan addresses the State's challenges in reaching the 100 percent HQT goal.

Corrective Steps for Districts not Meeting Highly Qualified Teacher Requirements

Finally, if the Department determines that a State has not fulfilled its obligations under the statute and is not on track to have all teachers highly qualified by the

end of the 2005–2006 school year, the Department will take corrective actions in addition to requiring the State to submit a revised plan.

By the middle of May, the Department will notify States, in writing, of the results of the assessment of their HQT progress and will request the States, as appropriate, to submit revised plans. States will have until July 7 to submit their revised plans to the Department, and the Department then will determine whether a revised State plan is sufficient to attain the HQT goal in 2006–2007 and beyond. In August, the Department will begin a new cycle of State monitoring visits to ensure that States are implementing their revised plans.

INFORMATION DISSEMINATION ON HIGHLY QUALIFIED TEACHER REQUIREMENTS

Question. The report also identified some information dissemination challenges. What actions has the Department taken or planned for making helpful information available?

Answer. The GAO report recommended that the Department “explore ways to make the Web-based information on teacher qualification requirements more accessible to users of its Web site. Specifically, the Secretary may want to more prominently display the link to state teacher initiatives, as well as consider enhancing the capability of the search function.”

As noted in the GAO report, the Department agrees with the recommendation and has been working to improve the Department’s website so that it is more user friendly for teachers and officials who are trying to find information about the highly qualified teacher requirements. For example, the website now directs students, teachers, parents, and administrators to specific pages for materials of interest to them. The teacher page has a section that describes State and local initiatives to improve teacher quality, and both the teacher and administrator web pages have direct links to information about the highly qualified teacher provisions.

STATES’ REPORTING OF HIGHLY QUALIFIED TEACHER DATA

Question. The Congressional Justification states, “The Department is not entirely confident that all States are reporting accurately on the highly qualified status of their teachers, particularly special education teachers.” This statement is consistent with the Government Accountability Office’s recent report regarding teacher quality issues. What actions are you taking to specifically address this issue and what plans do you have for future actions?

Answer. Under the Improving Teacher Quality State Grants section of the congressional justification, we did report that the Department is not entirely confident that all States are reporting accurately on the highly qualified status of their teachers, particularly special education teachers. To address this concern, the Department has been working closely with States, especially through monitoring visits, to help them improve the quality of the data that they report. As of late March 2006, the Department has monitored all but three States concerning their highly qualified teacher status and will monitor the remaining States this spring.

We will also be looking very carefully at States’ efforts to report accurately HQT data this spring and summer when we review their progress in meeting the requirement that all teachers of core academic subjects be highly qualified by the end of the 2005–2006 school year. After that review, we will likely require many States to submit revised State plans, and we may take corrective actions against any States that are not making a good-faith effort to improve their data collection and reporting. The Department also plans to begin a new round of State monitoring visits late this summer.

Question. How does your budget support your current and planned actions?

Answer. The Department is planning to use Salaries and Expenses funds to review States’ HQT data and their efforts towards meeting the goal of having all teachers of core academic subjects highly qualified.

ENFORCEMENT OF HIGHLY QUALIFIED TEACHERS REQUIREMENT

Question. In your October 21, 2005 policy letter regarding the “highly qualified teacher” issue, you assured States they would not lose Federal funds if they failed to meet the 100 percent requirement and were making a good faith effort to implement the law. One of the ways you will make such a determination is by evaluating whether States take action to ensure that inexperienced, unqualified, or out-of-field teachers do not teach poor or minority children at higher rates than other children. How are highly qualified teachers distributed currently between low-income and high-income school districts?

Answer. States are reporting steady improvement towards meeting the goal of having all teachers of core academic subjects highly qualified by the end of the

2005–2006 school year. Data for the 2005–2006 school year will be reported in 2007. For 2003–2004, the data indicate that 81 percent of core academic classes in high-poverty schools were taught by highly qualified teachers, an increase of 7 percentage points over the baseline of 74 in 2003. 2004 data for the percentage of core academic classes taught by highly qualified teachers in low-poverty, elementary, and secondary schools was 89 percent, 89 percent, and 84 percent, respectively.

ENSURING HIGHLY QUALIFIED TEACHERS FOR STUDENTS OF ALL SOCIOECONOMIC STATUS

Question. What steps is the Department taking to ensure socioeconomic status does not determine whether a student has access to a qualified teacher or not?

Answer. For the Improving Teacher Quality State Grants program, the Department requires States to report on teachers' highly qualified status at the classroom level. For example, in the 2003–2004 school year, 81 percent of core academic classes in high-poverty schools were taught by highly qualified teachers. We believe that, by requiring States to report on all classrooms, we are sending the message that we expect all core academic teachers to be highly qualified, whether they are teaching in a high- or low-poverty school, or whether at the elementary- or secondary-school levels.

As mentioned earlier, the Department will closely evaluate States' progress in meeting the HQT requirement this spring and summer as part of our determination of whether they are making a good-faith effort to meet the 100 percent objective. This will include a review of their Title I equity plans, which are meant to ensure that poor or minority children are not taught by inexperienced, unqualified, or out-of-field teachers at higher rates than are other children.

FEDERAL EFFORTS TO ADDRESS INEQUITABLE DISTRIBUTION OF HIGHLY QUALIFIED AND UNQUALIFIED TEACHERS

Question. How have States used Federal funds to address this issue?

Answer. The Department sponsored a 2-day meeting for State coordinators in March 2006 that focused on the inequitable distribution of teachers who are unqualified, inexperienced, or out-of-field. Working with experts and researchers from the National Comprehensive Center for Teacher Quality (at Learning Point, Inc.), the Educational Testing Service, and the Council of Chief State School Officers, the Department provided the State coordinators with a series of written tools they can use to examine the inequity issue and begin to prepare State plans to address the issue. The Department also provided all of the States with a protocol that will be used to examine whether revised State plans, which must be provided to the Department this summer, will satisfactorily address this issue.

For most States, this is the first time they will be preparing formal, written equity plans. In previous years, States had difficulty determining if there was an equity distribution problem, so they were unsure how to best address concerns about the unequal distribution of highly qualified teachers. The availability of valid data about the distribution of highly qualified teachers is now helping States to think about the problem and develop equity plans.

Although States are just now developing their equity plans, many States already have incentive programs and strategies to encourage teachers to take on more challenging assignments. The Department is highlighting some of these strategies at the following weblink: <http://www.teacherquality.us/Public/PublicHome.asp>.

TEACHER QUALITY ENHANCEMENT PROGRAM AND TEACHER RECRUITMENT AND RETENTION

Question. In recent years, Congress has tried to affect teacher recruitment and retention through a number of legislative efforts, including scholarships for those who commit to teaching in certain geographic or content areas, loan forgiveness programs, and other efforts. In addition, there are new requirements that districts and States are trying ardently to meet as required by No Child Left Behind's "highly qualified teacher" provisions. Why is the Department acknowledging the crucial role teachers play in maintaining the country's competitiveness, while at the same time it is proposing elimination of the Higher Education Act's Teacher Quality Enhancement program? Can you explain these seemingly conflicting efforts?

Answer. We do not believe that there is any conflict in the Department's efforts to improve teacher recruitment and retention and the Department's proposal to terminate duplicative programs, such as the Teacher Quality Enhancement program. The Department continues to recognize that the quality of the teacher is one of the most critical components in how well students achieve and that improving efforts to recruit and retain top quality teachers, especially in geographic and academic

areas of high need, is critical to improving the overall quality of the Nation's teachers. The Department's proposal to terminate the Teacher Quality Enhancement program is based, in part, on the fact that State and local entities may already use funds they receive under a number of other Department programs to carry out the activities supported through the Teacher Quality Enhancement program. Both the Improving Teacher Quality State Grants program and the Transition to Teaching program include provisions designed to improve teacher recruitment and retention, including all of the activities that are allowable under the Teacher Quality Enhancement program. The Department's proposal to eliminate funding for the Teacher Quality Enhancement program would reduce unnecessary duplication, improve programmatic efficiency, and simplify the grant process for potential recipients.

DATA MANAGEMENT INITIATIVE

Question. The Government Accountability Office report (GAO), GAO-06-06, released in October 2005, included an assessment of the Department's efforts to identify performance-related data items that could be collected and reported by States that would promote the evaluation of the effectiveness of Federal programs. This report identified several challenges with respect to the participation of and perceived benefit for States and quality and consistency of data collected through the system. What is the Department's plan for addressing the challenges identified in the GAO report and how much funding is being allocated in fiscal year 2006 and requested in fiscal year 2007 for this initiative?

Answer. The GAO report recommended that the Department develop a strategy to help States improve their ability to provide quality data. As described in the Corrective Action Plan we submitted to the GAO in response to their report, we have taken several steps to improve the quality of the data the Department collects. By the end of this fiscal year, we will have awarded nearly \$50 million in grants to States under the Statewide Data Systems program to develop and implement statewide longitudinal data systems. The President's 2007 budget requests a \$30 million increase for this program.

The National Center for Education Statistics is working with the staff of the Department's central database, the Education Data Exchange Network (EDEN), to provide technical support and oversight for our grantees. The Department provides additional technical assistance to States through the Data Quality and Standards Contract with the Council of Chief State School Officers. The Department is also a contributing partner in the Data Quality Campaign, a partnership of more than 10 national organizations that helps States implement high-quality statewide information management systems. Finally, the Department has established a Partner Support Center that provides expert technical assistance to States on data submission processes and quality issues related to EDEN.

The Department is conducting a rigorous assessment of the quality of our data collection and reporting. As part of this process, the Department recently announced the launch of EDFacts, a new reporting and analysis tool for data collected and compiled through sources such as EDEN. In 2006, \$5.705 million is being allocated for enhancements to the EDFacts and EDEN systems, and \$6.244 million is requested for 2007.

Question. Specifically, how will these funds be utilized?

Answer. These funds will be used to support the operation of the Partner Support Center, development of new enhancements for the EDEN and EDFacts systems (including this year's successful online collection of the Consolidated State Performance Report), maintenance of these systems, and development of new reports and tools that enhance program offices' efficient use of collected K-12 performance data.

FOREIGN LANGUAGE ASSISTANCE PROGRAM

Question. The budget proposes a \$2 million increase for the Foreign Language Assistance program. Budget documents supporting this request state that beginning with the 2006 competition, the Department will focus this program on providing incentives for States and districts to provide instruction in critical needs language, especially those programs using technology. Please explain how the 2006 competition will be structured to address the issues raised in the fiscal year 2006 Senate Committee Report and the Statement of the Managers accompanying the fiscal year 2006 Conference Report. Specifically, what type of priority are you proposing for the 2006 competition, and what is the complete list of foreign languages that will be eligible for such a priority?

Answer. The Department is committed to ensuring that all school districts that demonstrate the capacity to successfully implement a program receive consideration for competitive grant funds. In response to the concerns raised both in the Senate

Committee Report and the Statement of Managers that the poorest districts may be shut out of Foreign Language Assistance grants due to their inability provide the required 50 percent match, the Department has taken active steps to increase awareness of waiver availability for eligible grant applicants. The application package for grants includes detailed information about what resources may contribute to a grantee's matching requirement, and the Department considers waivers for any district that can demonstrate financial hardship. The program office also has expanded its outreach efforts to include details about the waiver process and eligibility on the Department's web page, at professional workshops, and in fact sheets about the program. The combination of improved grant application materials and increased public awareness about waivers will help ensure that disadvantaged districts are not precluded from participating in the program.

Foreign Language Assistance Program—Critical Need Languages Priority

In addition to giving increased attention to grantees that may be eligible for waivers, the Department established a priority relating to critical need languages for the 2006 grant competition. In conjunction with the President's National Security Language Initiative, the Department will give preference to grant applicants that demonstrate the ability to build programs and courses in languages that have significant political or economic importance. The specific languages that have been identified as critical are Arabic, Chinese, Korean, Japanese, Russian, and the languages in the Indic, Iranian, and Turkic language families.

ARTS EDUCATION

Question. The No Child Left Behind Act recognizes the arts as a core academic subject and studies show that the arts are proven to help close the achievement gap and improve essential academic skills. You have stated previously that a "well-rounded curriculum that includes the arts and music contributes to higher academic achievement." If arts have been proven to be essential to the learning process, why has the President proposed the elimination of arts education in the fiscal year 2007 budget?

Answer. Our request to zero-fund Arts in Education reflects the Administration's policy of increasing resources for high-priority programs by eliminating categorical programs that have narrow or limited effect. These categorical programs siphon off Federal resources that could be used by State and local educational agencies to improve the academic performance of all students.

Districts desiring to implement arts education activities may use funds provided under other Federal programs. The Elementary and Secondary Education Act also provides LEAs with flexibility to consolidate certain Federal funds to carry out activities, including arts education programs, that best meet the needs of their district. For example, under the State and Local Transferability Act, most LEAs may transfer up to 50 percent of their formula allocations under various State formula grant programs to their allocations under: (1) any of the other authorized programs; or (2) Part A of Title I. Activities to support arts education are an allowable use of funds under the State Grants for Innovative Programs authority. Therefore, an LEA that wants to implement an arts education program may transfer funds from its allocations received under the authorized programs to its State Grants for Innovative Programs allocation, without having to go through a separate grant application process.

In addition, under the Improving Teacher Quality State Grants program, local educational agencies can use their funds to implement professional development activities that improve the knowledge of teachers and principals in core academic subjects, including the arts. The flexibility that is available under these Federal programs provides additional justification for the Administration's policy of eliminating discrete categorical grant programs such as Arts in Education.

Question. As a "core academic subject," the arts should be included in all research and data collection. The No Child Left Behind Act and current Department of Education policy make it clear that decisions regarding education are made on the basis of research. The FRSS report, "Arts in Education in Public Elementary and Secondary Schools," is the only research report produced by the Department on the status of how arts education is delivered in America's public schools. The last report was for data collected in the 1999–2000 school year and the fiscal year 2006 statement of the managers urges IES to repeat this comprehensive data collection and report. When is the Department planning on another round of data collection for an updated report, which will help study and improve access to the arts as a core academic subject?

Answer. We agree that having periodic information about arts education is important. The next National Assessment of Educational Progress (NAEP) arts assess-

ment is scheduled for 2008. It will be an 8th-grade assessment that will include components for music, theater, and the visual arts, as was the case with the last arts assessment in 1997. Work on the 2008 assessment began last year with item development, and we will conduct a field test this year.

The Department has not budgeted for an arts education survey in the National Center for Education Statistics (NCES) Fast Response Survey program for fiscal year 2007. The expense of replicating a survey involving multiple samples of teachers in the visual arts, music, and dramatic arts is too great, given competing demands for funds and the costs of the ongoing data collection programs of NCES. The National Endowment for the Arts requested the earlier 1999–2000 arts education survey and paid for it in part.

READY TO TEACH PROGRAM AND MATH AND SCIENCE EDUCATION

Question. Madam Secretary, the fiscal year 2007 budget allocates \$380 million for new or increased funding for math and science programs aimed at giving students the skills they need to become competitive workers in the global economy of the 21st century. Specifically, part of this funding is targeted to address the critical shortage of qualified teachers for math and science education, particularly in high-concentration areas for low-income students.

The Ready To Teach program funds the development of digital educational content and online professional development in partnerships with the public television community. Congress has invested in this program over several years to ensure that it is easily accessible, flexible and tailored to local, State, and national standards. The most recent grant competition recognized the continued success of PBS TeacherLine service, and technology-based programs that offer a cost-effective complement to off-campus training. In a difficult budget environment, the Department should work to utilize the assets of programs such as Ready to Teach in its effort to strengthen math and science education, especially in the area of teacher training. How will the Department utilize this investment in advancing math and science education?

Answer. The Department has no plans to utilize the Ready to Teach program to advance math and science education. There is limited information on the effectiveness of professional development activities supported through this small technology program. It's also not at all clear that nonprofit telecommunications entities, like Ready to Teach program grantees, are very well equipped to address the critical training and professional development and training needs of current and future math and science teachers.

In past years, Ready to Teach has played a very limited role in helping schools and districts address professional development needs, and next to no role in actually providing teacher training. In light of recent research findings on the critical influence of highly qualified teachers on student learning, and the seriousness of the ongoing teacher shortage crisis, the Administration believes that funds should not be provided for small categorical programs like this one that have limited impact and that siphon off Federal resources that could be used by States and districts to pursue more important goals.

READY TO LEARN PROGRAM

Question. Madam Secretary, last year the Department restructured the Ready to Learn educational television program to focus solely on programming that teaches literacy, and eliminated much of the widespread community outreach portion of the program. We all agree that literacy proficiency is central to fulfilling the goals of No Child Left Behind, and we applaud the Administration's including funds for Ready to Learn in the Administration's budget request. However, the elimination of the outreach activities concerns many of us here in Congress. How does the Department plan to build upon the successes of the local outreach activities by public television stations across the country?

Answer. Over the current 5-year budget period, the Department intends to dedicate approximately \$20 million to support on-going Ready to Learn (RTL) community outreach activities. While it's true that the Department restructured the Ready to Learn educational television competition, it's not true that "much of the widespread community outreach portion of the program" was eliminated. In fiscal year 2005, the Department made three new awards under the Ready to Learn program, including one 5-year outreach award to the Corporation for Public Broadcasting (CPB). Under this outreach award, CPB will continue to work strategically with public television stations across the country to support a variety of local outreach activities.

WORKSHOP APPROACH TO OUTREACH AND IMPACT ON STUDENT LEARNING OUTCOMES

Question. A recent evaluation of “the workshop approach” to outreach supported by previous RTL grantees (entitled “Using Television as a Teaching Tool: The Impacts of Ready to Learn Workshops on Parents, Educators, and the Children in Their Care”) suggests that RTL has yet to achieve intended results in key areas of outreach implementation. Although a link between RTL workshops and adults’ self-reported behaviors at 3 and 6 months after the workshops was established, the effect sizes were small and the impacts on adult behaviors did not translate into impacts on children. This study concluded that the workshop approach to outreach had no measurable effects on student learning outcomes and only moderate impacts on parent/caregiver behaviors. As the study pointed out, enhancing children’s school readiness to the point of significant, measurable improvement usually requires large investments in child-focused interventions over extended periods of time. Thus, it’s not surprising that the workshops, which necessarily cannot be implemented at the level of intensity usually associated with most interventions that improve student-learning outcomes, showed no measurable effects on student behaviors and learning outcomes. Based on the findings of this rigorous 5-year evaluation, we believe that RTL outreach activities can be targeted far more effectively, to the end of ensuring that all children read on grade level by the third grade.

Because outreach is such a critical component of the RTL program, under the new outreach award CPB plans to use the latest evidence from social marketing research to target their efforts more effectively. CPB will continue to rely heavily on community partnerships, and will strategically partner with public broadcasting stations as local community hubs. However, unlike in past outreach work, CPB will partner with PBS to promote public awareness of RTL at the national and local levels through press and media outlets such as newspapers, television, and radio, emphasizing those most likely to reach the target audience of low-income parents and caregivers.

More specifically, isn’t there a way to combine the educational television programming on PBS funded by Ready to Learn, with local workshops for parents and teachers and other outreach activities by local public stations, such as free book distribution.

Answer. As indicated in our response to the previous question, a recent evaluation of “the workshop approach” to outreach supported by previous RTL grantees (entitled “Using Television as a Teaching Tool: The Impacts of Ready to Learn Workshops on Parents, Educators, and the Children in Their Care”) suggests that RTL has yet to achieve intended results in key areas of outreach implementation. Based on this evaluation, we believe that RTL outreach activities can be targeted far more effectively, to the end of ensuring that all children read on grade level by the third grade.

Under the new outreach award, CPB plans to change its outreach strategy by using the latest evidence from social marketing research to inform its work. CPB will continue to rely heavily on community partnerships, and will strategically partner with public broadcasting stations as local community hubs. However, unlike in past outreach work, CPB will partner with PBS to promote public awareness of RTL at the national and local levels through press and media outlets such as newspapers, television, and radio, emphasizing those most likely to reach the target audience of low-income parents and caregivers.

READY TO LEARN CONTINUATION PROJECTS

Question. Additionally, given the President’s emerging initiative in math and science education, would you support a proposal to expand the focus of Ready to Learn to include, in addition to literacy, math and science education programming?

Answer. All of the Ready To Learn funds requested for fiscal year 2007 are needed to cover the continuation costs of current grantees, which were awarded 5-year grants in 2005. Both programming awards must focus on utilizing the principles of scientifically based reading research to improve literacy outcomes for young children, consistent with the priority established for last year’s competition and the cooperative agreements. By 2010, however, when the awards under this program will be re-competed, it is possible that the research base on how children acquire math and science knowledge will be sufficiently well-developed to support the development of new children’s educational programming in these areas.

MATH AND SCIENCE EDUCATION—MATH NOW PROGRAM AND MATH AND SCIENCE PARTNERSHIPS

Question. The fiscal year 2007 budget proposes to establish Math Now for Elementary and Secondary School programs, which are intended to improve math instruction for elementary and middle school students. What is the potential overlap between the proposed math programs and the existing Math and Science Partnerships program?

Answer. The administration believes that Mathematics and Science Partnerships, a formula-grant program that promotes strong teaching skills for elementary and secondary school teachers, is important for ensuring that all States have high-quality mathematics and science professional development programs that focus on implementing scientifically based research and technology into the curriculum.

The Math Now programs, which will implement proven practices in mathematics instruction, including those recommended by the National Mathematics Panel, will go one step further by helping to ensure that American students are prepared to take and pass algebra courses in middle school, which will encourage them to take and pass higher-level mathematics and science courses in high school. They will focus more precisely than does Mathematics and Science Partnerships on the need to ensure that elementary-school students receive what the best research indicates is the most effective math instruction and for middle-school students who are struggling in math to receive the interventions they need.

MATHEMATICS AND SCIENCE PARTNERSHIPS AND MATH NOW PROGRAM ACTIVITIES

Question. The States have some flexibility on how they target those funds through their sub-granting process. Is there any information about the extent to which States have targeted funding to the same issues proposed to be addressed by these new programs?

Answer. The Department began collecting data from States and partnerships this year that will describe how Mathematics and Science Partnerships (MSP) subgrantees are implementing the program. These data will include information about the kinds of activities MSP subgrantees are conducting with program funds, and the information should be available this summer.

Although we do not have a better sense of the activities MSP grantees are conducting, it is possible that there may be some overlap between the MSP and Math Now programs. However, we expect that it will be minimal. For example, the MSP program focuses on providing professional development for mathematics and science teachers, while the Math Now programs would have several allowable uses of funds, including professional development, but focusing more on improving elementary-school math instruction and helping middle-school students who are significantly below grade level in math. The Math Now grantees would also implement instructional principles and promising practices developed by the National Mathematics Panel, which is not a requirement of MSP subgrantees.

NATIONAL MATHEMATICS PANEL

Question. The fiscal year 2007 President's budget proposes to establish a National Mathematics Panel to identify approaches and interventions that meet either the scientifically based research standard, as defined in the No Child Left Behind Act, or "promising practices." How will the selections for the National Mathematics Panel be made, so that individuals with diverse backgrounds are represented on the panel?

Answer. In order to ensure a diverse pool of expertise, the Secretary will appoint no more than 20 members from the public and private sectors, as well as no more than 10 members from the Department of Education and other Federal agencies to the National Mathematics Panel. Panel members may include researchers who study mathematics, professors of mathematics and mathematics education, professors of psychology and/or cognitive development, practicing teachers, principals, State or local education officials, parents, business leaders, foundation representatives, members of education associations, and other individuals selected on the basis of their expertise and experiences as appropriate.

Question. How will "promising practices" be defined for purposes of identifying approaches and interventions?

Answer. Once it has been convened, members of the National Mathematics Panel will meet and determine the appropriate definitions and methodology for their review and synthesis of the evidence base on mathematics education. One of their charges will be to recommend, based on the best available scientific evidence, instructional practices, programs, and materials that are effective for improving math-

ematics learning. Since the scientific evidence base in mathematics education is inadequate in many areas, we anticipate that the Panel will also provide guidance that will help States and districts determine which approaches and interventions have some evidence—even though it does not yet meet the standards for scientifically based research—that indicate that the interventions will improve student outcomes.

MATHEMATICS AND SCIENCE EDUCATION

Question. The President’s Academic Competitiveness Initiative (ACI) clearly emphasizes the need for improved science, technology, engineering and mathematics (STEM) education. The Department of Education’s 2007 budget request makes substantial improved mathematics education via the Math Now program, but does not make a comparable investment in science education. What is the Department’s plan for investing in science education?

Answer. Both mathematics and science are important subjects for our students to learn well if we are to remain competitive in the global economy. Because we need to set priorities within our budget, we are focusing on mathematics first through the Math Now programs. Mathematics is a “gateway” course for upper-level mathematics and science learning, so we believe that it is crucial for students to first have a firm foundation in mathematics. In addition, because Title I mathematics assessments are already in place (while the science assessments will not come on line until 2007–2008), we have an immediate source of information for measuring the effectiveness of new strategies in teaching mathematics, but not in science.

Science Education Support

Finally, the budget request includes either increases or level funding for a number of programs that focus on science, including Mathematics and Science Partnerships and Graduate Assistance in Areas of National Need. The new Advanced Placement and Adjunct Teacher Corps proposals would target science, in addition to mathematics and critical foreign languages. Other Department programs that allow grantees to focus on science include Transition to Teaching, Troop-to-Teachers, and Improving Teacher Quality State Grants.

INVESTMENTS IN ADVANCED PLACEMENT

Question. The fiscal year 2007 budget proposes to expand the reach of the Advanced Placement program by requiring grantees to offer incentives for teachers to become qualified to teach Advanced Placement and International Baccalaureate Organization classes in mathematics, science, and foreign languages and to teachers whose students pass tests in those subjects. The budget also proposes to require grantees to secure public and private matching funds to leverage the Federal investment. How much money does the Department expect the private sector to contribute toward the matching requirement for the Advanced Placement (AP) program?

Answer. The Department expects the private sector to invest roughly \$114 million in the AP program, which matches the Department’s funding request for AP Incentive Grants. Based on conversations with potential donors, who are very excited about this initiative, we believe this assumption is realistic.

Question. What is the basis for that projection?

Answer. Conversations between Department officials and representatives of private companies indicate that very substantial non-governmental support will be forthcoming. Senior officials are encouraging supporters of the proposal to publicize their commitment, and we hope to provide more information in the coming weeks.

Question. Please provide the same information for State contributions.

Answer. The Department is aware that many States are already committed to investing in the AP program, and believe that States will contribute their support and resources to increasing low-income students’ access to challenging coursework. Our expectation is that State and local funds will amount to approximately \$114 million, resulting in roughly a one-third/one-third/one-third split in Federal, State and local, and private-sector contributions.

Question. Also, does the Department plan to institute a maintenance-of-effort requirement for States; why or why not?

Answer. No, because the statute already includes a “supplement, not supplant” provision, which will prevent the Federal funds from merely supplanting existing State and local efforts.

ADVANCED PLACEMENT INCENTIVE PROGRAM

Question. How will the Department ensure that the proposed incentive for teachers whose students pass AP/IB tests will not lead to the unintended consequence of discouraging students from taking these tests?

Answer. Providing a bonus to teachers for each student who passes an AP test should be an incentive for teachers to get more students to take and pass AP exams. According to “Do What Works: How Proven Practices Can Improve America’s High Schools,” written by Tom Luce, now our Assistant Secretary for Planning, Evaluation, and Policy Development, and Lee Thompson, the AP incentive program increased the number of students taking AP courses and passing AP exams in Texas. The Department’s proposal would extend the opportunities granted to students in Texas to young people across America.

FEDERAL STUDENT AID

Question. Budget documents supporting the recall of the Federal portion of repayments made under the Federal Perkins Loans program indicate that, “the Administration believes the Federal share of funds held by this small group of institutions might more effectively help students if used in a way that serves all eligible students regardless of institution.” In addition to the \$664 million proposed recall of Perkins proceeds, the proposed budget includes a reduction of \$436 million in funding from the Student Financial Assistance account. How does the proposed budget more effectively serve all eligible students by recalling \$664 million from the Perkins loans program and reducing the Student Financial Assistance account by \$436 million?

Answer. It is important to look at the Federal investment in student aid from a broad perspective. Overall, the President’s Budget would build on student benefits included in the Higher Education Reconciliation Act (HERA) to provide a record \$82 billion in new student grant and loan assistance in fiscal year 2007. The HERA created Academic Competitiveness Grants, a new need-based program supported with mandatory funding that will award annual grants of up to \$1,300 to high-achieving first- and second-year students who have completed a rigorous high school curriculum or up to \$4,000 for third- and fourth-year students majoring in mathematics, science, technology, engineering, or critical foreign languages. In 2007, the program would provide \$850 million in grants to 600,000 low-income postsecondary students. Over 2006–2010, grant awards would total more than \$4.5 billion.

In addition, the HERA makes student loans more affordable by phasing out student origination fees and fixing student interest rates at 6.8 percent, reducing the maximum rate from the previous 8.25 percent. (If calculated today, the current variable rate formula—which will continue to apply for loans originated prior to July 1, 2006—would be 7.11 percent; if recent trends continue through June, the actual rate may be even higher.) The HERA also expands loan limits for first- and second-year students and graduate students and permanently expands loan forgiveness from \$5,000 to \$17,500 for math, science and special education teacher serving low-income communities.

Within the Student Financial Assistance account itself, most of the \$436 million reduction you mention reflects the effect of the new scoring rule for the Pell Grant program, which reduces the need for current year budget authority by allowing the use of excess funds from the previous fiscal year. The balance of the reduction reflects revised, lower estimates of fiscal year 2007 Pell Grant program costs and the elimination of two redundant, ineffective, or unnecessary programs: Federal Perkins Loans and Leveraging Education Assistance Partnerships.

COMMISSION ON THE FUTURE OF HIGHER EDUCATION

Question. Specifically, how will low- and middle-income students achieve the same access to postsecondary education as high-income students have, which is an objective of the Department of Education?

Answer. In today’s highly competitive global economy it is vital that no American student be denied access to effective postsecondary education due to high costs. Accordingly, in September 2005 the Secretary’s Commission on the Future of Higher Education was created to examine how we as a Nation can keep higher education affordable and accessible. The Commission, made up of experienced leaders from education, business, and government, is holding a series of meetings around the country and gathering data from respected experts on higher education. A final report with the commission’s findings is expected by August.

FUNDING FOR HIGHER EDUCATION

Question. In “Cracks in the Education Pipeline: A Business Leader’s Guide to Higher Education Reform,” it is stated that low-income families, those with incomes in the bottom 40 percent of the earnings distribution, spend one-third of their income to send a child to community college and 43 percent to enroll in a public 4-year school. Further, the document states that, “Student aid has the greatest impact when targeted on low-income students who otherwise would not enroll in college.” What is proposed in this budget to help such families finance their goals for postsecondary education?

Answer. The President’s 2007 Budget for student aid builds on a number of significant accomplishments in 2006 to provide a record \$82 billion in assistance to more than 10 million students and parents. Adopting a proposal from the 2006 President’s Budget, Congress appropriated \$4.3 billion in mandatory funding in 2006 to eliminate a long-standing funding shortfall in the Pell Grant program, putting this vital program—the foundation of Federal need-based aid—on a firm financial footing after years of growing fiscal instability. Congress also adopted new budget rules proposed by the President to prevent shortfalls from occurring in the future. In addition, the Higher Education Reconciliation Act, signed by the President in February, would further help the neediest students by phasing out origination fees for Stafford Loans and providing over \$4.5 billion over 5 years in new need-based Academic Competitiveness and SMART Grants.

ADVANCING AMERICA THROUGH FOREIGN LANGUAGE PARTNERSHIPS

Question. The fiscal year 2007 budget proposes a new program, through appropriations language, to establish partnerships between institutions of higher education and school districts that support programs of study in grades K–16 in critical need languages. Specifically, how will this proposed program complement existing Department programs, such as those authorized and funded under title VI of the Higher Education Act and the Fulbright-Hays Act?

Answer. The Advancing America Through Foreign Language Partnerships program is intended to complement, not duplicate, existing Department programs that provide support for foreign language and areas studies education. Distinctive elements of the Advancing America Through Foreign Language Partnerships program, compared to the Title VI of the Higher Education Act and those authorized by the Mutual Educational and Cultural Exchange Act (Fulbright-Hays), include partnerships between institutions of higher education and school districts; the degree of focus on “critical need languages” such as Arabic, Chinese, Russian, Hindi, Farsi, and others; and unique language programs of study that enable successful students to advance from early learning in elementary school through advanced proficiency levels in high school to superior levels in college. The Title VI and Fulbright-Hays programs support 14 distinct yet interrelated programs designed to strengthen the capability and performance of American education in foreign languages and in area and international studies in a number of world regions. These programs do not establish articulated programs of study in grades K–16 in critical need foreign languages.

In addition, the objectives of this proposed program that relate to establishing fully articulated K–16 programs that produce college students who achieve a superior level of proficiency cannot be accomplished through grants to local and State educational agencies under the Department’s Foreign Language Assistance program (FLAP). FLAP is focused on improving the quality of foreign language instruction in elementary and secondary schools. Institutions of higher education are not eligible to apply for funding under the FLAP program. Moreover, FLAP is not an appropriate vehicle for establishing the kind of partnerships needed between school districts and institutions of higher education to ensure an articulated curriculum and consistent goals and continual progress toward the required outcomes at all educational levels, including the postsecondary level.

The Advancing America Through Foreign Language Partnerships program fits within the Department’s mission and complements Title VI and other Department activities relating to the teaching and learning of foreign languages.

ADVANCING AMERICA THROUGH FOREIGN LANGUAGE PARTNERSHIPS AND DOD NATIONAL FLAGSHIP LANGUAGE INITIATIVE

Question. How will this new program complement related programs administered by other Federal agencies?

Answer. The Advancing America Through Foreign Language Partnerships program would operate following the model created under the National Flagship Lan-

guage Initiative at the Department of Defense. The Administration seeks to expand on DOD's pilot K-16 Mandarin Chinese program by awarding an additional 24 grants to institutions of higher education for partnerships with school districts for programs of language study in a variety of languages critical to national security such as Arabic, Chinese, Russian, Hindi, Farsi, and others. The Administration is proposing that ED (and not DOD) undertake the expansion of this program because the goals of the program fit within the Department's mission and the program complements other ED activities relating to the teaching and learning of foreign languages.

REQUIREMENTS OF ADVANCING AMERICA THROUGH FOREIGN LANGUAGE PARTNERSHIPS
GRANTEES

Question. Supporting budget documents note that applicants would have to demonstrate the long-term success of their project, as well as commit to a significant amount of cost sharing. Would you please provide more information about each of these proposed requirements?

Answer. To address the need for skilled professionals with superior competency in foreign languages critical to U.S. national security, such as Arabic, Chinese, Russian, Hindi, Farsi, and others, participants in the Advancing America Through Foreign Language Partnerships program would be expected to make significant commitments. We would expect that institutions of higher education applying for grants would be able to identify each local educational agency partner and describe each partner's responsibilities (including how they would be involved in planning and implementing program curriculum, what resources they would provide, and how they would ensure continuity of student progress from elementary school to the postsecondary level). Participating institutions of higher education would be expected to work with partner school districts to develop and implement an articulated curriculum with consistent pedagogical philosophy and goals throughout all educational levels of the program. To ensure long-term success of the project, we would expect applicants to be able to describe in their applications how they would support and continue the program after the grant has expired, including how they would seek support from other sources, such as State and local government, foundations, and the private sector. We would also expect grantees to provide a non-Federal contribution, in cash or in kind, that would help carry out the activities supported by the grant.

STATEWIDE DATA SYSTEMS PROGRAM

Question. The fiscal year 2007 budget requests \$54.6 million for the Statewide Data Systems program, an increase of \$30 million over the fiscal year 2006 amount. Budget documents supporting this request indicate that 14 States are receiving funds from this program, although all States need assistance to develop or refine and fully implement systems that allow them to track the progress of individual students statewide. Budget documents also state that the requested increase for fiscal year 2007 would focus on the issue accelerating the capacity of high schools to report and use accurate high school graduation and dropout data. How are States utilizing funds from fiscal year 2005 and fiscal year 2006?

Answer. The Statewide Longitudinal Data Systems (SLDS) grant program is supporting State educational agencies in designing, developing, implementing, and using longitudinal individual student data and linking the student data to other contextual and management data, such as program, staffing, facilities, financial, early childhood, or post-secondary data. The resulting data systems will allow States to evaluate learning of all students and track the effectiveness of schools, programs, or interventions. Under the grant program, States are required to provide data and meaningful analyses back to local stakeholders, including teachers, principals, and districts. States are also required to develop ongoing evaluation procedures to ensure that the data collected are: (1) of high quality, (2) responsive to local information needs, and (3) useful for improving instruction and student learning.

States receiving SLDS grant money are required to incorporate data from kindergarten to 12th grade in their data systems. Most have also proposed to incorporate preschool and even birth-to-preschool data. Similarly, most grantees propose to incorporate postsecondary data in their systems, spanning prekindergarten-16 and even prekindergarten-20. Some States will also link their data to those from non-education agencies, such health or labor. These longitudinal student data, especially with links to rich contextual data, will for the first time allow States and districts to reliably link student outcomes to different variables, including curricula, educational environment, funding, socioeconomic background, and other factors that affect student learning.

STATEWIDE LONGITUDINAL DATA SYSTEMS

Question. How does this proposed priority fit with the basic needs of States for developing longitudinal data systems?

Answer. Statewide longitudinal data systems (SLDS) grants enable States to have more informative and reliable data on what is happening and what works in high schools, including the ability to evaluate and track how students' pre-high school experience affects how well they do in high school. These funds also enable States to understand how what happens in high school affects students' success in postsecondary education and/or employment. Grant funds support data system development and enhancements that enable States to conduct a wide range of rigorous longitudinal analyses, including computations of a standard four-year adjusted cohort graduation rate, as adopted by the National Governors Association (NGA). Most of the first cohort of grantee States have not collected and compiled these data before. Some States in the first cohort of grants can currently compute the NGA graduation rate, but these States still depend upon their grant funding to ensure the quality of their data collection.

The requested increase in funding for this program will enable more States that do not currently have this capacity to collect data necessary for the computation of accurate high school graduation and dropout rates necessary data on high school. For States that already collect these data, the requested funding will enable them to connect all relevant data in one longitudinal data system with better and more efficient verification of data over time and across different educational and other data systems. In these States, the SLDS grant will result in better data faster.

NATIONAL ASSESSMENT OF EDUCATIONAL PROGRESS

Question. The budget requests an additional \$4 million to allow the Department to begin work on essential activities for implementing in 2009 State-level assessments at the 12th grade level. What activities will be funded by this requested increase?

Answer. The funds requested for fiscal year 2007 would be used to conduct validation studies to ensure that the assessment has predictive validity and is an appropriate measure of readiness for work, postsecondary education, or military service. The funds would also be used for the development and pilot testing of new mathematics and reading frameworks.

12TH GRADE NAEP INITIATIVE—READING AND MATH ASSESSMENTS

Question. What is the total cost of the 12th grade NAEP initiative, and what is the range of options being considered for implementing this new policy?

Answer. Assuming that State participation is mandatory, the estimated total cost of the 12th grade State-level assessments in Reading and Math for 2009 would be \$45 million above the current NAEP appropriation.

The following chart presents estimated costs for an assessment in the 50 States, the District of Columbia, and Puerto Rico; as well as for a non-mandated assessment, with 45 States volunteering to participate; and for a pilot State assessment, with 10 States selected to participate. Once the development and phase-in of the 12th grade State-level assessments are complete, we estimate that the annual cost, beginning in 2010, of conducting State-level assessments in Reading and Mathematics would be \$22.5 million for the mandatory scenario and \$20.5 million for the voluntary scenario.

[Estimated cost, in millions of dollars]

Year	12th Grade State-Level Reading and Math Assessments		
	Mandatory (52 jurisdictions)	Voluntary (45 jurisdictions)	Pilot (10 jurisdictions)
2007	4.0	4.0	4.0
2008	18.5	18.5	4.0
2009	22.5	18.5	3.6
Total	45.0	41.0	11.6

OFFICE OF COMMUNICATIONS AND OUTREACH

Question. Budget documents supporting your fiscal year 2007 budget request indicate that staffing for communications and outreach will change from 14 FTE in 2005 to 140 in fiscal year 2006. Will you explain the need for 140 FTE's in this office,

instead of utilizing these staff in grants monitoring and other program administration capacities?

Answer. Staffing for communications and outreach did not increase from 14 to 140. The reason there appears to be an increase is that we took staff from other areas and consolidated them under a new centralized communications office. In an effort to better coordinate the communication functions of the Department to ensure clear, consistent communications, a new Office of Communications and Outreach (OCO) was created. It now includes the former Office of Public Affairs (OPA), most of the functions of the former Office of Intergovernmental and Interagency Affairs (OIIA) and the function of internal communications. The new Office of Communications and Outreach encompasses speechwriting, public affairs, web site, publications, event services, external affairs and the Secretary's 10 regional offices. The Office of Communications and Outreach is responsible for creating and distributing appropriate education materials to inform the work and decision-making of educators, policymakers, government officials, parents and students.

DEPARTMENT EXPENDITURES FOR PUBLIC RELATIONS AND OUTREACH

Question. How much did your Department spend on public relations and outreach in fiscal year 2005?

Answer. In fiscal year 2005, the Department spent \$1,132,246 on public relations and outreach, in procurement of items and services such as speeches and editing for senior staff, logistical outreach event support, webcasting, and the monthly "Education News Parents Can Use" satellite broadcasts.

Question. How much do you plan to spend in fiscal year 2006 and fiscal year 2007, and what are the primary outcomes intended to be achieved by these expenditures?

Answer. The Department plans on spending \$1,025,000 in fiscal year 2006 and \$1,100,000 in fiscal year 2007 on public relations and outreach events which are designed to inform members of the public about No Child Left Behind and other Department programs, the monthly "Education News Parents Can Use" satellite broadcast, and technical support for webcasting.

Each "Education News Parents Can Use" broadcast explains U.S. Department of Education programs to parents using practical, plain-language discussions of topics such as ensuring safe and drug free schools, teaching reading, serving students with disabilities, and using new education technology. Each broadcast offers this information in a format that features short segments, including one-on-one interviews, "how-to" demonstrations, and brief conversations with parents, educators, education experts, and community, business and religious leaders.

Technical and production support is needed for the creation of high quality, live, or previously videotaped multi-media programs that can be broadcast over the Internet. These productions are for the purpose of raising the general public's awareness of and encouraging participation in programs associated with ED's education reform initiatives.

QUESTIONS SUBMITTED BY SENATOR DANIEL K. INOUE

NATIVE HAWAIIAN EDUCATION

Question. First and foremost, I'd like to express my sincere appreciation for the continued funding of Native Hawaiian Education. This funding facilitated uninterrupted curricula development, teacher training and recruitment programs as well as scholarship offerings. Programs such as these allowed many young Hawaiians' the opportunity to fully realize their dreams. Through continued support of Native Hawaiian Vocational Education, countless individuals can now successfully enter, compete and advance in the ever-changing and competitive technological workplace.

I would also like to extend my personal thanks to your Department administrators who have traveled to Hawaii to meet our local program coordinators and provide technical assistance to our remote communities. No doubt, your staff has seen first hand the tremendous impact and success these funded programs have had on the people of Hawaii.

Madam Secretary, what are the indicators or measures your Department uses to manage existing competitive grantees under the Native Hawaiian Education Act?

Answer. The Department has established three performance measures for the Native Hawaiian Education program authorized under Title VII of the ESEA. The measures are:

—The percentage of teachers involved with professional development activities that address the unique educational needs of program participants.

- The percentage of Native Hawaiian children participating in early education programs who improve on measures of school readiness and literacy.
- The percentage of students participating in the program who meet or exceed proficiency standards in mathematics, science, or reading.

The Department collects data on these measures through the annual performance reports submitted by grantees.

Question. Please also describe the process by which these indicators were selected.

Answer. The development of the performance indicators for the Native Hawaiian Education program was based on an analysis of the program's purpose, priorities and authorized activities, and how those align with the overall priorities and purpose of the No Child Left Behind Act. As the program authorizes a wide number of project activities, we also had to narrow somewhat the areas for performance measurement for the program, in order to minimize the burden of data collection and reporting. Since we were unable to arrive at one performance indicator that would be appropriate for all projects possible or allowed under the program, we conducted an analysis of grantee activities and goals. The analysis showed that most grantees are implementing projects around a small number of areas (early childhood, teacher professional development, and math and science education) and, thus, we developed indicators to track program performance in those areas.

WOMEN IN TECHNOLOGY

Question. The Women in Technology (WIT) program originated in Maui 5 years ago as a workforce development project initially funded through a grant from the U.S. Department of Labor. A core mission component of the program was to partner with educators and industry to create a pipeline from education to employment in science, technology, engineering and math. This concept was first introduced in our local middle and high schools, to increase the confidence and interest of under represented populations in math and science studies and expose them to educational and professional opportunities in high-tech professions. This was accomplished at no cost to the students.

Elementary school is a critical time to begin outreach efforts to attract students into the science, technology, engineering and math pipeline. National research indicates that gender identities and stereotyping about career roles are set by age seven. One of the goals of Women in Technology includes training elementary school teachers in "inquiry-based learning" methods. In this method, teachers learn how to harness the natural inquisitive nature of their students and nurture it into scientific questions/hypothesis and self-directed activities to prove/disprove the students' questions. The inquiry-based activities are integrated into the teaching curriculum and align with grade level and standards. This method of teaching is well suited to children of both genders and stimulates all styles of learning. A pilot program, recently launched in Maui, included a professional development workshop for one dozen elementary teachers.

Madam Secretary, Women In Technology is a critically important program to securing a more prosperous future for many young Hawaiians. So strong is my belief in the value of this program, that in years past, I sought funding for it via my earmarks. As such are no longer available, will the Department of Education provide funds for the expansion of science, technology, engineering and math "inquiry-based learning" curriculum and training to all elementary school teachers throughout the State of Hawaii?

Answer. The agency operating the Women in Technology (WIT) program may pursue discretionary funding opportunities under a number of Department of Education programs that support activities such as the ones you describe. WIT may apply, for example, for funding under the Native Hawaiian Education program, which supports innovative projects to provide supplemental services that address the educational needs of Native Hawaiian children and adults. Authorized activities under that program include development and implementation of professional development programs to prepare teachers to address the unique needs of Native Hawaiian students.

WIT may also be eligible for funding under the Mathematics and Science Partnerships program. Funds for the program are distributed to States based on a formula, and each State then administers a grant competition for the funds. The program supports State and local efforts to improve students' academic achievement in mathematics and science by promoting strong teaching skills for elementary and secondary school teachers, including integrating teaching methods based on scientifically based research and technology into the curriculum. Grantees may also use program funds to develop more rigorous mathematics and science curricula that are aligned with challenging State and local content standards; establish distance learn-

ing programs for mathematics and science teachers; and recruit individuals with mathematics, science, and engineering majors into the teaching profession through the use of signing and performance incentives, stipends, and scholarships. Professional development can include summer workshops, or institutes and programs, that bring mathematics and science teachers into contact with working scientists, mathematicians, and engineers in order to expand teachers' subject-matter knowledge. WIT administrators should contact the Hawaii Department of Education for information on applying for this program.

QUESTIONS SUBMITTED BY SENATOR HERB KOHL

SPECIAL EDUCATION FULL FUNDING

Question. Many of us here have worked hard every year to increase funding for Special Education. Year after year, school districts in Wisconsin tell me that this is one of their top concerns. But this year's budget is especially worrisome. It proposes to cut the Federal share of IDEA costs from 18 percent to 17 percent—that is less than half of the 40 percent “full funding” level that Congress committed to paying when IDEA was first adopted 31 years ago. This deliberate step backward begs the question: does this Administration plan to ever fully fund IDEA?

Answer. Under the President's leadership, funding for the Grants to States program has increased by 67 percent since 2001. The President's 2007 request for the Special Education—Grants to States program of \$10.7 billion, which includes an increase of \$100 million, would provide about 17 percent of the national average per pupil expenditure (APPE) for 6.9 million children with disabilities receiving special education, compared to about 14 percent of the APPE in 2001. No Administration has come close to requesting 40 percent of APPE, but this Administration has proposed record-high increases in funding for the program and has achieved record-high levels of the Federal contribution.

EARLY CHILDHOOD EDUCATION FUNDING

Question. While I support the President's proposals to increase resources to support math and science education at the high school level, I am concerned about the decrease in funding for programs that support early childhood education. Research shows that 80 percent of brain development takes place during the first 3 years of a child's life. In light of this research, please explain the Administration's rationale for funneling resources away from programs that support our youngest learners—like the Foundations for Learning and Even Start programs—and putting those funds into our high school age programs.

Answer. The Department remains dedicated to the goal of promoting cognitive development for all children, and the President's budget request reflects a strong commitment to programs that have a proven record of success in serving our Nation's youngest citizens. Neither Even Start nor Foundations for Learning has a track record of demonstrated effectiveness. While some local Even Start programs are successful at supporting the development of children's early academic skills, the program's overall reliance on the family literacy model has not been shown to be effective. In addition, the Foundations for Learning program is duplicative of other programs that serve very young children and its size precludes any large impact on the populations to which it is targeted. Other programs, such as Early Reading First and the Early Childhood Educator Professional Development program, focus on proven methods of addressing the cognitive development and school readiness needs of young children

PERKINS LOANS AND OTHER STUDENT AID PROGRAMS

Question. Not only does this budget cut Pell Grants, but it also calls for the elimination of the Federal Perkins loan program. This academic year, the University of Madison-Wisconsin served 5,202 students with \$13.2 million in Federal Perkins Loans. These loans helped students cover the gap between other financial aid and the actual cost of attendance. They are also a good option for low-income students because they are not dependent on credit history. Secretary Spellings, if Congress were to agree to the President's recommendation and eliminate Perkins loans, what do you suggest these students do to pay for higher education?

Answer. First, to clarify, the President's Budget does not cut Pell Grants; current estimates indicate every eligible student would receive his or her full award under our proposal. The reduction in budget authority compared with fiscal year 2006 reflects the new scoring rule under which an estimated \$273 million in unused funds

from fiscal year 2006 can be used to reduce the need for new appropriations, as well as a slight reduction in the estimated cost of the Pell Grant program.

More broadly, even with the Perkins Loan proposal, student aid would increase under the President's Budget by more than \$4.6 billion in fiscal year 2007 over the previous year, including \$790 million in new need-based Academic Competitiveness and SMART Grants. In addition, student loans under the Federal Family Education Loan and Direct Loan programs will be a better bargain for borrowers due to lower interest rates and reduced origination fees.

ELEMENTARY AND SECONDARY SCHOOL COUNSELING PROGRAM

Question. School counselors play a vital role in the lives of American youths by providing guidance on issues both academic and personal. During times of war and the ongoing fear of terrorism, the need for effective school counseling is clearer than ever. In addition, counselors continue to guide students in career, academic and social development. That's why I am very concerned that the President's budget again eliminates funding for the School Counseling Program. In Wisconsin, each public school counselor oversees 461 students—a caseload that already leaves many students underserved.

School counselors play an important role in helping students meet the goals of No Child Left Behind. Why would the Administration cut a program that is helping to make its signature education policy work?

Answer. The budget request to eliminate funding for the Elementary and Secondary School Counseling program is part of an overall budget strategy to discontinue programs that duplicate other programs that may be carried out with flexible State formula grant funds, or that involve activities that are better or more appropriately supported through State, local, or private resources. Specifically, the 2007 budget proposes termination of 42 programs in order to free up almost \$3.5 billion (based on 2006 levels) for reallocation to higher-priority activities within the Department. These higher-priority activities include the Administration's \$1.5 billion High School Reform Initiative. Under this Initiative, local educational agencies will be able to include student counseling services as part of the comprehensive strategies they adopt to raise high school achievement and eliminate gaps in achievement among subgroups of students.

In addition, if school districts choose to do so, they may support counseling programs with the funds they receive under the State Grants for Innovative Programs authority, which allows them to implement programs that best meet their needs. Furthermore, the Elementary and Secondary Education Act (ESEA) provides school districts with additional flexibility to meet their own priorities by consolidating a sizable portion of their Federal funds from their allocations under certain State formula grant programs and using those funds under any other of these authorized programs. A school district that seeks to implement a school counseling program in some or all of its schools may use funds from those programs to do so.

QUESTIONS SUBMITTED BY SENATOR PATTY MURRAY

ACADEMIC COMPETITIVENESS/SMART GRANTS

Question. The fiscal year 2006 Budget Reconciliation bill created Academic Competitiveness grants and the National Science and Mathematics Access to Retain Talent (SMART) grants. To receive the Academic Competitiveness grants, students must have completed a rigorous secondary-school program of study. While I agree that we need to be doing all we can prepare students for a job in a global economy, a student's luck in where they attend high school shouldn't determine whether or not the Federal Government helps them attend college. The Congressional Budget Office has estimated that only 9.9 percent of Pell eligible students will be able to take advantage of the Academic Competitiveness and SMART grants in 2007.

The maximum Pell grant has not increased for years despite tuition rising at our Nation's public colleges rising by over 7 percent last year. If the \$850 million that these grants cost in fiscal year 2007 were spent on Pell grants, students would receive an additional \$200 in aid.

How do you anticipate judging what constitutes a rigorous secondary-school curriculum?

Answer. The Department of Education is working with all States to help them identify high school programs of study they can submit to the Secretary of Education for recognition as rigorous secondary programs of study. In addition, there will be alternative eligibility provisions for students from States that have not yet submitted designated programs to the Secretary. These State-identified, eligible rig-

orous secondary school programs or acceptable alternatives will soon be posted on a Department web site.

Question. Particularly in such tight budget times, shouldn't we be spending our resources on helping all students attend college regardless of their circumstance, not benefiting the few who are lucky enough to attend the "right" high school?

Answer. Taken together, the Federal student aid programs under the President's fiscal year 2007 budget request would provide over \$82 billion to students and families, much of it focused on the neediest Americans. Within this larger investment, we believe it is appropriate to target a portion of need-based aid—Academic Competitiveness/SMART Grant recipients must be eligible for a Pell Grant—to encourage the type of rigorous high school study and challenging college coursework that is linked to success both for individuals and, ultimately, for our Nation.

TITLE IX REPORT

Question. On March 17, 2005, the Department of Education released new guidance on the interest prong of the three-part test which schools use to show compliance with Title IX in athletics. As you are aware, I have grave concerns about the new guidance because I believe it sets a new low bar for compliance with a Federal civil rights law. Schools would now be allowed to use an email survey to show compliance with Title IX. Further, the school would only have to send that survey to women and a lack of response could be determined as lack of interest in sports. Surveys have been used in the past to show compliance with Title IX, but not as a sole means and other factors such as emerging sports had to be taken into consideration.

Because of concern over this new guidance, a bipartisan group of Senators on this subcommittee asked for a report on the guidance and use of surveys due March 17. What is the status of the requested report?

Answer. The report in response to guidance and the use of surveys for Title IX was submitted to the Committee on March 17, 2006.

TITLE IX TECHNICAL ASSISTANCE

Question. Clearly, there is a lot of confusion on behalf of schools about this new guidance. What is the Department doing regarding technical assistance on the guidance?

Answer. The Office for Civil Rights (OCR) regularly provides technical assistance on a variety of issues to interested parties, including elementary and secondary schools and colleges and universities. Assistance is an important method to help educational institutions achieve voluntary compliance with the civil rights laws and assist in preventing civil rights violations by educating schools about their responsibilities. OCR provides guidance through a variety of methods, including responses to thousands of requests for individualized technical assistance, via phone, email, or mail, each year from individuals, recipients, and groups representing recipients and beneficiaries. Our technical assistance also includes on-site consultations, conferences, training, community outreach, publishing and disseminating materials, through the Department's website and direct mailings, and issuing guidance.

With respect to Title IX of the Education Amendments of 1972 (Title IX), the Department issued the Additional Clarification of Intercollegiate Athletics Policy (Additional Clarification) to clarify one method schools may choose to use to assess athletic interests and to provide a practical tool they may choose to use to conduct that assessment.

To further assist schools, OCR has been and continues to actively seek out opportunities to provide technical assistance on a continuous basis. In the year since the Additional Clarification was issued, OCR has provided technical assistance on the Additional Clarification to more than a thousand coaches, athletic directors, Title IX coordinators and legal advisors, in addition to regularly providing individualized technical assistance. These presentations have included secondary schools, 2- and 4-year colleges and universities, and conferences sponsored by umbrella organizations responsible for developing and implementing the governing rules and procedures for national and regional athletics at the secondary, junior college, and 4-year college levels. We will continue to proactively seek out opportunities to educate recipients, educational and athletic organizations, administrators, parents and students regarding nondiscriminatory implementation of Title IX and the Additional Clarification.

AMERICA'S OPPORTUNITY SCHOLARSHIPS FOR KIDS

Question. The President's budget again proposes school vouchers through the America's Opportunity Scholarships for Kids program. The President's education budget also eliminates 42 programs. We often hear that the programs are proposed for elimination because they are ineffective. However, there is no evidence that pri-

vate school vouchers do anything to improve achievement for any students. Further, we still have yet to see any real evaluation of achievement under the D.C. voucher program.

In such a tight budget, how does the Administration justify spending \$100 million on a program that has yet to be found effective?

Answer. To offer the opportunity of a high-quality education to more students who attend schools in restructuring around the country, the Department proposes the creation of a national school choice program that gives parents the choice to send their children to any public or private schools that they believe would better serve their student's needs. Though it is too early to know the potential effects on academic achievement of the D.C. School Choice Incentive Program, we do know that the program has generated significant support among parents of students in low-performing schools in Washington, DC. The America's Opportunity Scholarships program would extend that option to parents whose children attend low-performing schools across the Nation. In addition, several research studies, such as "Private School Vouchers and Student Achievement: An Evaluation of the Milwaukee Parental Choice Program" by Cecilia Rouse, and Jay Greene's "The Effect of School Choice: an Evaluation of the Charlotte Children's Scholarship Fund," suggest that participation in the private school choice programs leads to improvements in student achievement.

IMPACT OF MEDICAID CHANGE ON CHILDREN WITH DISABILITIES

Question. The Department of Health and Human Services reflects a change in how Medicaid is dealt with at schools. While I understand this change is proposed in the HHS budget and not the Department of Education, the impact will be felt by students and schools. The HHS budget says that certain costs associated with services provided to special education students who are also on Medicaid will no longer be reimbursed to the schools through Medicaid. The estimated savings to HHS is over \$600 million for fiscal year 2007 and the 10-year savings is over \$9 billion. The President's budget proposes only a \$100 million increase to IDEA. While we will certainly fight for increasing funding for IDEA and other education programs, given these tight budget times, I have a feeling IDEA won't receive \$9 billion in the next 10 years.

I am concerned that students will feel the impact of this change. The Federal Government has yet to live up to the promise of funding 40 percent of the cost of educating a special education student and schools will not be able to absorb the costs associated with this change. Students will be told to get such services outside of school hours.

How do you propose ensuring that students get all the necessary service they receive now if this change happens at HHS?

Answer. The President's 2007 Budget includes a proposal that would prohibit Federal Medicaid reimbursement for Medicaid administrative activities performed in schools. It additionally provides that Federal Medicaid funds will no longer be available to pay for transportation required to be provided to children with disabilities by the Individuals with Disabilities Education Act. HHS has had long-standing concerns about improper billing by school districts for administrative costs and transportation services. Both the HHS Inspector General and the Government Accountability Office have identified these categories of expenses as susceptible to fraud and abuse. Schools would continue to be reimbursed for direct Medicaid services identified in an Individualized Education Program (IEP) or Individualized Family Service Plan (IFSP) and provided to Medicaid-eligible children, such as physical therapy, that are important to meeting the needs of Medicaid-eligible students with disabilities.

A shift in funding responsibility for administrative and transportation costs associated with Medicaid eligible children with disabilities should not affect services for these children. State and local governments are responsible for ensuring that needed services are provided for all children with disabilities, regardless of whether they are Medicaid eligible. The change in policy would treat Medicaid eligible children with disabilities the same as other children with disabilities with regard to administrative and transportation costs. The Department of Education and HHS intend to work together to ensure that implementation of this change in policy is done in an orderly and sensible fashion.

21ST CENTURY COMMUNITY LEARNING CENTERS

Question. The President's budget would freeze funding for the 21st Century Community Learning Centers Program for the fifth year in a row. Furthermore, NCLB's fiscal year 2007 authorization level for the program is \$2.5 billion. This is a program

that enjoys extraordinary public and bipartisan congressional support. All of us hear from constituents who want and need more funding to develop more afterschool programs in their communities. These programs help working families, provide vital additional academic support to students and provide safe, supervised environments for kids afterschool—priorities that appear to match many of the President's major goals.

With such diverse, bipartisan support, why has the Department continued to propose only \$981 million for the program? That gap leaves the States, communities, families and students—as many as 1.4 million children—behind and more than 25 States unable to offer new grant opportunities in fiscal year 2005.

Answer. The program does, indeed, enjoy bipartisan support in Congress, and we do receive many letters from Members asking us to increase funding. However, in a tight budget environment, we need to target the limited available funding on programs that show evidence of success or that have a strong potential to fill major unmet needs. The results of the only national evaluation of 21st Century Community Learning Centers were not very positive and did not present a case for increasing the funding. However, the Department's Institute of Education Sciences has launched a study of specific math and reading interventions that will determine after-school programs' potential impact on academic achievement. We will review the results of that study, and also the program performance results that States submit, in determining whether to request increases in future years.

CIVIC EDUCATION

Question. As you know, we face a crisis today with young people who are disenchanted with politics; they are apathetic and cynical about Government and its institutions. I was disappointed to discover the elimination of the Education for Democracy Act in the President's budget request. This program funds domestic civic and international civic and economic education programs. The Civic Education program is successful in helping American students understand and appreciate fundamental values and principles of our Government.

Can you comment on why a program that is consistent with the Administration's desire for American students to have a basic understanding and appreciation of the workings of our Nation's Government and politics along with its values and principles was eliminated in the President's budget?

Answer. The Administration agrees that there is a critical need for education programs that effectively promote basic understanding and appreciation of the workings of our Nation's Government and politics, along with its values and principles. However, we question the efficacy and wisdom of statutorily mandating that 100 percent of funds available for domestic civic education activities must go to a single organization, particularly when so little is known about the efficacy of civic education interventions developed and supported by this organization. The Administration believes that a more effective approach to addressing the issue is to invest in programs that make competitive awards to local schools districts and other eligible entities to help create safe learning environments where students understand, care about, and act on core ethical and citizenship values, such as Character Education (which would receive \$24.2 million under the President's request) and Safe Schools/Healthy Students (which would receive \$79.2 million under the President's request).

While the Civic Education program, as currently authorized, supports some worthwhile activities, there are no reliable measures of overall effectiveness of interventions supported using program funds. Studies and evaluations conducted by the Center for Civic Education provide limited information on program performance, but none are sufficiently rigorous to yield reliable information on the overall effectiveness or impact(s) of the various interventions supported through this program.

The administration does not believe additional funding is necessary for the implementation of activities currently supported by the Center for Civic Education—an established non-profit organization with a broad network of program participants, alumni, volunteers, and financial supporters at the local, State, and national levels. The Center also has a long history of success raising additional support through such vehicles as selling program-related curricular materials, training and workshops, partnering with non-profit groups on core activities, lobbying, and seeking support from foundations.

SUBCOMMITTEE RECESS

Senator SPECTER. Thank you very much. The subcommittee will stand in recess to reconvene at 10 a.m., Wednesday, May 3, in room SD-226. At that time we will hear testimony from the Honor-

able Michael Leavitt, Secretary, Department of Health and Human Services.

[Whereupon, at 12 noon, Wednesday, March 1, the subcommittee was recessed, to reconvene at 10 a.m., Wednesday, May 3.]

**DEPARTMENTS OF LABOR, HEALTH AND
HUMAN SERVICES, EDUCATION, AND RE-
LATED AGENCIES APPROPRIATIONS FOR
FISCAL YEAR 2007**

WEDNESDAY, MAY 3, 2006

U.S. SENATE,
SUBCOMMITTEE OF THE COMMITTEE ON APPROPRIATIONS,
Washington, DC.

The subcommittee met at 10:15 a.m., in room SD-226, Dirksen Senate Office Building, Hon. Arlen Specter (chairman) presiding.

Present: Senators Specter, Craig, Harkin, Kohl, Murray, and Durbin.

DEPARTMENT OF HEALTH AND HUMAN SERVICES

OFFICE OF THE SECRETARY

STATEMENT OF HON. MICHAEL O. LEAVITT, SECRETARY

OPENING STATEMENT OF SENATOR ARLEN SPECTER

Senator SPECTER. Good morning, ladies and gentlemen. The hearing for the Appropriations Subcommittee on Labor, Health and Human Services, Education, and Related Agencies will now proceed. I regret a little late start here, but we have been conferring with the distinguished Secretary of Health and Human Services, and we wanted to get some background information before coming into the public hearing. This is a very important hearing because it involves the budget for the Department of Health and Human Services, and health is our number one capital asset. Without health, none of us can function.

I could give an extensive testimonial to that over the past year, but I'll save that for another day and instead focus on the proposals for Federal expenditures. I say at the outset, as I have said privately to the Secretary, that I am very disturbed at the reduction in funds for his Department. There is a \$1.6 billion reduction in funding for the Department of Health and Human Services, and that follows a pattern of reductions for—the other departments which are within the purview of this subcommittee. There have been reductions of some \$2.2 billion for the Department of Education, reductions for the Department of Labor so that effectively, from the year—fiscal year 2005 until the present time, we have a reduction of \$15.7 billion, and that means that there are vital programs for health, vital programs for human services which are in-

adequately funded to start with and are now really effectively starved.

The National Institutes of Health (NIH), which is the crown jewel of the Federal Government, is level funded, and that means taking into account inflation, there will be fewer grants made, and there have been enormous advances made by NIH. The leadership's been provided really from this subcommittee long before you became Secretary, Mr. Secretary. When we took the NIH budget from \$12 to \$29 billion, there have been remarkable advances in the research on Alzheimer's and Parkinson's and heart disease and cancer, but not enough.

As we speak, a very distinguished Federal jurist who has been named the 101st Senator as suffering from prostate cancer, and I lost my Chief of Staff, Carey Lackman, a beautiful young woman of 48 recently from breast cancer. In 1970, President Nixon declared war on cancer. If we had devoted the resources to the war on cancer which we devote toward other wars, we would have conquered cancer. In the past year, I have made the Kleenex industry wealthy, Mr. Secretary. This is a lingering aspect of chemotherapy treatment, and that brings me back to personalizing it just for a paragraph or two, but had the war on cancer been fought vigorously, I wouldn't have gotten Hodgkin's, I believe. The chances are good I wouldn't have. Well, that's the backdrop of these hearings and my views.

As I told you privately a few moments ago and I think it's worth repeating publicly, the President called in a number of committee chairmen last week for our views on what ought to be done, and when I had the opportunity to talk to the President, and I have had the opportunity to get to know President Bush rather well, he was in Pennsylvania 44 times in 2004 when he ran for reelection and I was up too, and I was with him on most of those occasions, and I have a very high regard for the President and the job he is doing notwithstanding the poll figures. Up close, he is very much engaged, very much on top of the job. The persona that comes through the news media is very very different. But at any rate, he is prepared to hear candid views even if they don't agree with his, and I told him about the \$15.7 billion reduction in spending and told him what was happening in the National Institutes of Health. I know that you are not the President, and as you reminded me, you are not even the Director of the Office of Management and Budget (OMB), but you are the Secretary of Health and Human Services. What I am calling upon all of the candid officers where I have a chairmanship and can make a constructive suggestion is to carry this fight to the Director of OMB and carry this fight to the President, and no department is more important than yours. To have level funding for NIH and to have cuts in the Centers for Disease Control and Prevention (CDC) with all the work CDC has to undertake is just unacceptable.

Well, I appreciate your being here, Mr. Secretary, and I genuinely appreciate the job you are doing—leaving the Governorship of Utah, coming to Washington, tackling really big issues, and this matter of pandemic flu is of gigantic importance. Senator Harkin has been the leader, and I have worked with him as his partner, and we have moved ahead against some problems to produce \$6.6

billion in funding. The potential for the pandemic flu if it strikes could be calamitous. When it has struck this country and the world in the past, millions of people have died. That's a real danger, and I am pleased to see what you are doing and what you plan to do even with major announcements to come tomorrow. Senator Murray has a time conflict, and I will yield to her at this time.

STATEMENT OF SENATOR PATTY MURRAY

Senator MURRAY. Well, thank you very much, Mr. Chairman. I am managing the floor for the Democrats in the supplemental and need to get back to the floor, and I appreciate the chairman yielding. I would second his statement and thank him for being the champion of NIH research, but also education and healthcare and all of the things that fall under the purview of this budget that you are presenting on behalf of the administration and echo his comments that investments in these diseases, investments in our future are absolutely critical to our Nation and the strength of our Nation in the future. I want to thank the chairman for his tremendous work on behalf of this and echo his sentiments that I am deeply concerned about the cuts that are coming. I can't stay for the questioning. I did want to submit some for the record and tell you personally that I have been out in the state talking to many seniors about the new Medicare Part D prescription drug benefit.

MEDICARE PART D DEADLINE EXTENSION

Although I voted against it, I want it to work. I want our seniors to be able to sign up for this and make it work. I am very concerned about what I am hearing from seniors as this May 15 deadline looms from seniors who can't get access or think they have signed up for something find out several weeks later they haven't. Many seniors are holding back signing up for it because they are worried about whether or not it's going to cover their drugs. I mean, you have heard all of it as well, and I hope that we can be thoughtful in our approach, and I would encourage you to look at extending the deadline—at least for those whose benefits don't begin until January of next year at the very minimum so that we don't cause a lot of seniors harm in the process. What I see is people signing up for these plans out of fear rather than out of knowledge. I think in the long run, we will all be hurt if that occurs, and I wanted to encourage you to work with us and continue to work with us. I know you are hearing some of the same things we are and really would like to see this—and to talk with you about that, but I specifically wanted to ask because we are now seeing seniors who signed up January 1 fall into the donut hole.

There is tremendous concern about those seniors who had pharmacy assistance plans who had drugs before who signed up for a drug are now falling into that donut hole. Are they considered uninsured, or are they considered insured for the purposes of being covered under the pharmacy assistance plans—and would like to get you or your staff to work with us as we try to help those seniors through that challenge right now. But Mr. Chairman, I will submit questions for the record, but I would like you and all of us to seriously look at this May 15 deadline and try and accommodate many of these seniors who are really having challenges who I think

we don't want to lose in this process, and we want to make sure that we have given them a benefit and not given them some dire circumstances. So I appreciate the opportunity to throw that out there and look forward to working with you, Mr. Secretary.

Senator SPECTER. Thank you, Senator Murray. Before yielding to Senator Craig, let me call upon our current distinguished ranking member for an opening statement. Before you walked in, Senator Harkin, I was praising you behind your back for your leadership—the number one leader on the funding for pandemic flu, and I said I was your partner, and the floor is yours.

STATEMENT OF SENATOR TOM HARKIN

Senator HARKIN. Well, that's kind of you, Mr. Chairman, but I just follow your lead—that's all. If some of the reflective glory comes up, I am—that's all right, that's fine with me. Mr. Chairman, first of all, I want to thank you for your great leadership in so many areas—of course in this area of health. There is no stronger champion for the National Institutes of Health than the Senator from Pennsylvania.

I have been by his side in—well, it's now going on about 16 years now. If it weren't for Senator Specter's great leadership, we would never have doubled the funding for NIH that we did in the late 1990s and put it up where it is. Now, of course, we have some problems now in making sure we continue that funding, and of course that's one of the problems that I have with the President's budget, and I am sure the chairman does also.

Welcome the Secretary, and then we'll just get to some questions in at that time.

Senator SPECTER. Okay. Thank you very much, Senator Harkin. Senator Craig?

STATEMENT OF SENATOR LARRY CRAIG

Senator CRAIG. Well, Mr. Chairman, I want to welcome the Secretary, and I must say that these two gentlemen struggle mightily with a very tough budget that Congress and this Senate have always supported, but your environment and our environment is one that we are being increasingly squeezed out of discretionary monies by mandatory spending. Someday, we'll get brave enough to take it on in a responsible way. But until that time, the struggle of the chairman and the ranking member and this member will continue to go on because there has to be a sense of fiscal responsibility. I just came from the floor suggesting that the supplemental that we have got out there deserved to be vetoed by a President who had sent a message because it was about \$10 billion out of line, and that's because we can't quit spending around here without a collective pressure being brought upon us. At the same time, there are priorities of spending that we get squeezed away from. I will say, Mr. Secretary, when I was home in the last recess, the good news—even though the Senator from Washington expresses continued concern about prescription drugs—is that you are having a phenomenal success, and I hope you will speak about it today. To stand up and bring on line a massive new program that this one is and to already be able to register the kinds of successes—some one said to me well, gee, it must have been pushed off the front

page by the price of oil. I said no, it was pushed off the front page because there was less criticism today and more praise as the results come in. I hope you will share those with us. Deadlines are important to cause people to react and to analyze and to decide on decisions that are necessary for them to make in a confused world. I will lastly say a couple of weeks ago, I am walking through the security line at the Boise Airport, and the fellow checking my ID said Senator, there are too many decisions, too many choices in prescription drugs, and I said well, then you would have preferred that we would have mandated a single program for you? Oh no, not at all.

Then I said you need to get with it. He said I am and laughed. I said you saving money? He said, a lot of money, but it was a tough choice. He said I really had to force myself to do a little studying. Thank you. I yield the floor.

Senator SPECTER. Thank you very much, Senator Craig. Senator Durbin, would you care to make an opening statement?

STATEMENT OF SENATOR RICHARD DURBIN

MEDICARE PART D FORMULARY PRICES

Senator DURBIN. Mr. Chairman, thank you very much. I would just say briefly thank you, Mr. Secretary, for being here. I think you have an awesome responsibility and some very important programs that are under your control and leadership. I would say on Medicare Part D that I will not quarrel with the premise that offering senior citizens coverage for prescription drugs is a good thing. It keeps them healthy and independent, strong, and out of hospitals and nursing homes longer. That's what they need. I do believe, though, that in my State there are still over 300,000 people who haven't made that choice. I don't know if that number has come down significantly in the last few days, but they only have 2 weeks left before they face a penalty for not making a choice. It is also a fact that those who have made a choice in terms of their prescription drug plan are going to be somewhat surprised to learn that the prices are not locked in. The prices of the drugs—in fact, the formulary—the available drugs that you can purchase under a plan can change on a daily basis, which leads to some uncertainty about their future. Many of us felt that it would have been a better approach to allow Medicare to offer one universal plan which consumers could choose if they like, allow Medicare to bargain for deep discounts in drugs and to offer them nationwide. Then if private insurers wanted to compete, they would be allowed to. That position did not prevail. So, in Illinois, it meant some 45 different choices for prescription drug plans, and some seniors struggled with them. Many pharmacists continue to struggle with them as of today.

NIH BUDGET CUTS

I would also want to echo what I know was said earlier by Senator Harkin. The pride that we have taken in Congress in the fact that the research money for the National Institutes of Health was doubled over a period of time. A former congressman from my State, John Porter, was the chairman of the Appropriations subcommittee that led that effort. He couldn't have made it without

the cooperation and enthusiastic help from the Senate side, and I think that Senators Specter and Harkin are justifiably proud of that as well. But I am troubled that we have seen that growth in NIH research stall in last year's budget and this year's budget continues. It's hard for me to believe that we are now at full capacity in terms of research for new drugs in America. I do believe that we need to expand the horizons, expand the opportunities to find cures for diseases, and this budget does not reflect that, and I hope that you will address that issue.

MEDICAL PROFESSIONAL AVAILABILITY

One other issue that troubles me is the availability of medical professionals. With an aging American population, with increased demands for medical help for all of us, we want to make certain that when we push the button in our room, a nurse will show up, that a good doctor will be there to tend to our needs, and I am worried that we are not keeping up with that demand for our society. Sadly, one of the ways that we supplement our need for medical professionals is to go overseas, and I have done it myself—to go to other countries that will send us these medical professionals. In most cases, these countries cannot afford to give up their own, but they do because of the lure of living in the United States and the attractive salaries that might be available for these medical professionals. The only morally responsible thing that we can do is to increase the number of medical professionals in America. When it came to the Nurse Reinvestment Act, which Senator Mikulski and others pushed forward, we have not adequately funded it, and I think we are going to pay a price for it in terms of medical professionals and this continuing brain drain on the poorest countries in the world that are sending us their medical professionals they desperately need.

As tough as it may be to practice medicine in the inner city of Chicago, it could not compare to practicing it in the Congo where there is one doctor for every 160,000 people, one surgeon for every 3 million. That is an impossible situation, and we make it worse because we bring those medical professionals to the United States—many times at the expense of these countries. The responsible thing for us to do is to develop our own medical professionals to meet the needs in the future. I hope that you will be able to tell us that your budget addresses that. I look forward to your testimony, and thank you for joining us today.

Senator SPECTER. Well, thank you, Senator Durbin. Well, we welcome you here, Secretary Leavitt, notwithstanding the opening statements of the Senators. You come to this position with a very distinguished record in public service—elected three times as Governor of the State of Utah, having served as Administrator for the Environmental Protection Agency and having taken over this very important job at the very beginning of the President's second term in late January 2005. We give you the floor, Mr. Secretary. Take as long as you like. Do not run the clock on the Secretary.

SUMMARY STATEMENT OF HON. MICHAEL O. LEAVITT

Secretary LEAVITT. Thank you, Senator. I will submit a formal statement for the record.

Senator SPECTER. Your statement will be made a part of the record and any other prepared statement.

FISCAL YEAR 2007 HHS BUDGET

Secretary LEAVITT. You acknowledged in a very kind way my service—previously as Governor. I will tell you that I value every day I had that opportunity. However, I will also confess to you that earlier this week, I spoke with my colleagues at HHS and told them that I am among the few people I suspect in the world who can honestly say I can think of nothing that I would rather do in my life right now than exactly what I am doing. The issues here are demanding, but they are extraordinarily important to the people of this country and, may I say, the world. I say that with a sense of gratitude and humility with being in a position to have some impact on delivering on the most noble of aspirations that our country has—our desire to see cancer cured, to see other diseases cured as well, to find ways in which we can prepare ourselves for a pandemic influenza and to do the other things that are currently my responsibility. I just want you to know that these are difficult issues, but I am grateful for the opportunity to serve the American people. The budget that I'll reflect today is a big budget. It's \$700 billion. \$75.5 billion of that we refer to as discretionary. Senator Craig referenced the fact that that number is being squeezed by the fact that the rest of the budget continues to grow at an alarming rate. I have a new grandson. He is now 8 months old. When he turns 35, Medicare alone—one of the programs that I am responsible to manage—will be 8 percent of our gross domestic product. By the time he retires at age 65, it will be 11 percent. I think everyone in this room knows that any nation that has one program that pays for the healthcare of those who have concluded their careers will likely not be on the economic leader board. I am deeply concerned about that as others are. It is having the impact of constraining our discretionary budgets. The budget I am here today to discuss is a deficit reduction budget. It is \$1.5 billion less than the budget that I was here a year ago to discuss. You mentioned my 11 years as Governor. During that period of time, I was responsible as the chief executive of my State to balance that budget, and I know that any time you are doing a deficit reduction budget, you are dealing with programs that have been on the budget for a very good reason and you are having to basically offset good programs against good programs. There are no easy choices here. There will be disagreement on what the priorities should be. I acknowledge that, and my purpose today is only to tell you the basis on which I made decisions given the need for this deficit reduction budget. You will find new initiatives here, things that I believe are extraordinarily important and that are important to the President, things that you have talked about.

One of the things I am concerned about is our investments. At NIH, for example, we are seeking level funding at NIH, but there are new initiatives at HHS—for example, what we call critical path. Despite the fact that we have doubled the NIH budget, the number of molecules that we are able to actually take into the marketplace has been cut almost in half during that period of time. What that tells me is that we have to change the regulatory proc-

ess and find new tools. So, one of the new initiatives we call critical path is essentially 76 science projects, if you will, to find new ways of measuring the efficacy and the safety of drugs that will allow us to dramatically improve that rather dismal statistic. You will see some Presidential initiatives here that will be familiar to you, such as a continued expansion of the community health centers. You will also see bioterrorism emphasized and pandemic influenza preparedness. I hope we'll have a chance to talk at some length about our preparation. It is a very important matter, and we are giving it the highest level of priority at HHS. I have laid out the discretionary budget and asked those who helped me prepare it to use a set of principles—some things you will see follow through this entire budget. Some of those would be a pause in construction of new buildings, for example. Another thing you will see is that there are programs whose purposes have been addressed in other areas. I have discovered, like in many departments of the Federal Government, there are silos. There are places that deal in one silo with a problem and places that deal with it in another, and I have done my best to try to bring them together, and what that has allowed me to do is to find a way to be more efficient. You will see some programs with carryover funds where I have taken those funds and put them into some other purpose.

PREPARED STATEMENT

Those are the means by which I have done it. I laid out a group of principles. I have tried to target as opposed to looking at general problems. I have tried to work at prevention as opposed to just ongoing funding of dilemmas. I have tried to look for places where there was new innovation. We'll get a chance to talk about all of them. I won't take more time. I am anxious to get directly to your questions, but I do want to tell you how appreciative I am of the chance to serve the American people and to be here today to work with you to accomplish that same purpose.

[The statement follows:]

PREPARED STATEMENT OF HON. MICHAEL O. LEAVITT

Good morning, Mr. Chairman, Senator Harkin, and Members of the Committee. I am honored to be here today to present to you the President's fiscal year 2007 Budget for the Department of Health and Human Services (HHS).

Over the past 5 years, the Department of Health and Human Services has worked to make America healthier and safer. Today, we look forward to building on that record of achievement. For that is what budgets are—investments in the future. The President and I are setting out a hopeful agenda for the upcoming fiscal year, one that strengthens America against potential threats, heeds the call of compassion, follows wise fiscal stewardship and advances our Nation's health.

In his January 31 State of the Union Address, the President stressed that keeping America competitive requires us to be good stewards of tax dollars. I believe that the President's fiscal year 2007 Budget takes important strides forward on national priorities while keeping us on track to cut the deficit in half by 2009. It protects the health of Americans against the threats of both bioterrorism and a possible influenza pandemic; provides care for those most in need; protects life, family and human dignity; enhances the long-term health of our citizens; and improves the human condition around the world. I would like to quickly highlight some key points of this budget.

We are proposing new initiatives, such as expanded Health Information Technology and domestic HIV/AIDS testing and treatment that hold the promise for improving health care for all Americans. We are continuing funding for Presidential initiatives, including Health Centers, Access to Recovery, bioterrorism and pandemic

influenza; and we are also maintaining effective programs such as the Indian Health Service, Head Start, and the National Institutes of Health.

We are a Nation at war. That must not be forgotten. We have seen the harm that can be caused by a single anthrax-laced letter and we must be ready to respond to a similar emergency—or something even worse. To this end, the President's Budget calls for a four percent increase in bioterrorism spending in fiscal year 2007. That will bring the total budget up to \$4.4 billion, an increase of \$178 million over last year's level.

This increase will enable us to accomplish a number of important tasks. We will improve our medical surge capacity; increase the medicines and supplies in the Strategic National Stockpile; support a mass casualty care initiative; and promote the advanced development of biodefense countermeasures to a stage of development so they can be considered for procurement under Project BioShield.

We must also continue to prepare against a possible pandemic influenza outbreak. We appreciate your support of \$2.3 billion for the second year of the President's Pandemic Influenza plan in the fiscal year 2006 Emergency Supplemental Appropriations Act for Defense, the Global War on Terror, and Hurricane Recovery. It is vital that this funding be allocated in the most effective manner possible to achieve our preparedness goals, including providing pandemic influenza vaccine to every man, woman and child within six months of detection of sustained human-to-human transmission of a bird flu virus; ensuring access to enough antiviral treatment courses sufficient for 25 percent of the U.S. population; and enhancing Federal, state and local as well as international public health infrastructure and preparedness. We also want to work with you to ensure that this funding is appropriated prior to October 1, 2006.

The President's fiscal year 2007 budget also provides more than \$350 million for important ongoing pandemic influenza activities such as safeguarding the Nation's food supply (FDA), global disease surveillance (CDC), and accelerating the development of vaccines, drugs and diagnostics (NIH).

The budget includes a new initiative of \$188 million to fight HIV/AIDS. These funds support the objective of testing for three million additional Americans for HIV/AIDS and providing treatment for those people who are on state waiting lists for AIDS medicine. This initiative will enhance ongoing efforts through HHS that total \$16.7 billion for HIV/AIDS research, prevention, and treatment this year.

The budget maintains the NIH, and includes important increases for important crosscutting initiatives that will move us forward in our battle to treat and prevent disease—\$49 million for the Genes, Environment and Health Initiative and \$113 million for the Director's Roadmap. In addition, it contains an additional \$10 million for the Food and Drug Administration to lead the way forward in the area of personalized medicine and improved drug safety.

One of the most important themes in our budget is that it increases funding for initiatives that are designed to enhance the health of Americans for a long time to come. For instance, the President's Budget calls for an increase of nearly \$60 million in the Health Information Technology Initiative. Among other things, these funds support the development of electronic health records (to help meet President Bush's goal for most Americans to have interoperable electronic health records by 2014); consumer empowerment; chronic care management; and Biosurveillance.

The Budget also includes several initiatives to protect life, family and human dignity. These include, for example, \$100 million in competitive matching grants to States for family formation and healthy marriage activities in TANF. The President's budget also promotes independence and choice for individuals through vouchers that increase access to substance abuse treatment.

In the area of entitlement programs, I want to begin by congratulating you and other Members of Congress for having successfully enacted many needed reforms by passing the Deficit Reduction Act (DRA). DRA supports our commitment to sustainable growth rates in our important Medicare and Medicaid programs. It also strengthens the Child Support Enforcement program. The Deficit Reduction Act also achieves the notable accomplishment of reauthorizing Temporary Assistance for Needy Families (TANF), which has operated under a series of short-term extensions since the program expired in September 2002.

Medicaid has a compassionate goal to which we are committed. Part of our obligation to the beneficiaries of this program is ensuring it remains available well into the future to provide the high-quality care they deserve. With its action on many of our proposals from last year in the Deficit Reduction Act, the Congress has made Medicaid a more sustainable program while improving care for beneficiaries. The President's Budget proposals build on the DRA and include a modest number of legislative proposals, which improve care and will save \$1.5 billion over 5 years in

Medicaid and S-CHIP and several administrative proposals saving \$12.2 billion over 5 years.

This Administration has also pursued a steady course toward Medicare modernization. In just the past 3 years, we have brought Medicare into the 21st century by adding a prescription drug benefit and offering beneficiaries more health plan choices.

Medicare's new prescription drug benefit represents the most significant improvement to senior health care benefits in 40 years. CMS has already exceeded the enrollment target with more than 30 million beneficiaries with drug coverage as of April 18, 2006. In addition, almost 6 million Medicare beneficiaries get drug coverage from other sources such as the Department of Veterans Affairs. This brings the total to approximately 35.8 million Medicare beneficiaries who are now receiving prescription drug coverage. In most cases, their coverage is either completely new or much better and much more secure than it was before.

Savings from the prescription drug benefit have been greater than expected. CMS' Office of the Actuary initially estimated beneficiary premiums averaging \$37 per month. Today, however, the average monthly premium is \$25 a month. And in some parts of the country, beneficiaries are seeing premiums of less than \$2 per month. In 2006, the Federal government is projected to spend about 20 percent less per person than first estimated, and over the next 5 years, payments are projected to be more than ten percent lower than first estimated. So taxpayers will see significant savings and State contributions will be about 25 percent lower over the next decade for beneficiaries who are in both Medicaid and Medicare. All these savings result from the lower expected costs per beneficiary.

Our work to modernize Medicare is not done. Rapid growth in Medicare spending over the long-term will place a substantial burden on future budgets and the economy. The President's fiscal year 2007 Budget includes a package of proposals that will save \$36 billion over 5 years and continue Medicare's steady course toward financial security, higher quality, and greater efficiency.

The bulk of these Medicare savings will come from proposals to adjust yearly payment updates for providers in an effort to recognize and encourage greater productivity. These proposals are consistent with the most recent recommendations of the Medicare Payment Advisory Commission. To ensure more appropriate Medicare payments, the Budget proposes changes to wheelchair and oxygen reimbursement, phase-out of bad debt payments, enhancing Medicare Secondary Payer provisions, and expanding competitive bidding to laboratory services. Building on initial steps in the Medicare Modernization Act, the Budget proposes to broaden the application of reduced premium subsidies for higher income beneficiaries. Finally, the President's Budget proposes to strengthen the Medicare Modernization Act provision that requires Trustees to issue a warning if the share of Medicare funded by general revenue exceeds 45 percent. The Budget would add a failsafe mechanism to protect Medicare's finances in the event that action is not taken to address the Trustees' warning. If legislation to address the Trustees' warning is not enacted, the Budget proposes to require automatic across-the-board cuts in Medicare payments. The Administration's proposal would ensure that action is taken to improve Medicare's sustainability.

President Bush proposes total outlays of nearly \$700 billion for Health and Human Services. That is an increase of more than \$58 billion from 2006, or more than 9.1 percent.

While overall spending will increase, HHS will also make its contribution to keeping America competitive. To meet the President's goal of cutting the deficit in half by 2009, we are decreasing HHS discretionary spending. Our non-emergency request for discretionary budget authority for programs under the jurisdiction of this Subcommittee totals \$61.1 billion, a decrease of \$1.6 billion below fiscal year 2006. The \$2.3 billion for the cost of the next phase of the President's plan to prepare against an influenza pandemic that I discussed earlier is in addition to this amount.

I recognize that every program is important to someone. But we had to make hard choices about well-intentioned programs. I understand that reasonable people can come to different conclusions about which programs are essential and which ones are not. That has been true with every budget I've ever been involved with. It remains true today. There is a tendency to assume that any reduction reflects a lack of caring. But cutting a program does not imply an absence of compassion. When there are fewer resources available, someone has to decide that it is better to do one thing rather than another, or to put more resources toward one goal instead of another.

Government is very good at working toward some goals, but it is less efficient at pursuing others. Our budget reflects the areas that have the highest pay-off potential.

To meet our goals, we have reduced or eliminated funding for programs whose purposes are duplicative of those addressed in other agencies. One example of this is Rural Health where we have proposed to reduce this program in the Health Resources and Services Administration. The Medicare Modernization Act contained several provisions to support rural health, including increased spending in rural America by \$25 billion over 10 years. For example, it increases Medicare Critical Access Hospitals (CAH) payments to 101 percent of costs and broadens eligibility criteria for CAHs. Moreover, recognizing that Congress adopted many of our saving proposals last year, we are continuing to make performance-based reductions.

Our programs can work even more effectively than they do today. We expect to be held accountable for spending the taxpayers' money more efficiently and effectively every year. To assist you, the Administration launched ExpectMore.gov, a website that provides candid information about programs that are successful and programs that fall short, and in both situations, what they are doing to improve their performance next year. I encourage the Members of this Committee and those interested in our programs to visit ExpectMore.gov, see how we are doing, and hold us accountable for improving.

President Bush and I believe that America's best days are still before her. We are confident that we can continue to help Americans become healthier and more hopeful, live longer and better lives. Our fiscal year 2007 budget is forward-looking and reflects that hopeful outlook.

Thank you for the opportunity to testify. I will be happy to answer your questions.

HISTORICAL PANDEMICS

Senator SPECTER. Thank you very much, Mr. Secretary. We'll now go to the questioning by the Senators with 5-minute rounds. In the second round, Mr. Secretary, I intend to go into the budget cuts on the Centers for Disease Control and the National Institutes of Health and others which, as I have outlined earlier, I think totally unacceptable, but let me begin with the issue of the threat of the pandemic flu. There is a draft report, which has appeared publicly, where you are stockpiling 75 million doses of antiviral drugs and 20 million doses of vaccines. There are projections that there could be as much as 40 percent of the workforce absent. There are guidelines to keep people from congregating together. There is even a note about local police departments and National Guard would have the primary responsibility for keeping order, but the military would be available to assist. This sounds like a very, very stark situation. We know that when such disasters have occurred in the past, there have been millions who have been killed. One of the really important matters to be covered is to acquaint the public with what the problems are—that it may be difficult or dangerous to go to the grocery store, that it is important to have a supply of water, that there ought to be provisions made for a worst-case scenario. There have been articles, but they are buried in the newspapers, and I do not think that there is a real public understanding of the seriousness of this program. Now, what you are saying here today is going to be carried in the news media, and this hearing is being covered live on C-SPAN, so it is reaching people as we speak. Stark as it is, I think we ought to be very candid, very frank—brutally frank with the potential nature of the problem. Now, Mr. Secretary, what is the worst-case scenario? If it's as bad as it can be, how bad would that be?

Secretary LEAVITT. Mr. Chairman, pandemics happen. They have happened through all-time. You can date back to ancient Athens—25 percent of that city was wiped out because of disease. You can roll forward, and virtually every century, you will see two or three

pandemics. In the 14th century—Black Death, perhaps the best known, killed 25 million people across Europe.

Senator SPECTER. How many people died in the pandemic in the United States not long into the 20th century?

Secretary LEAVITT. Your point is a very good one. We have had 10 pandemics in the last 300 years. We have had three pandemics in the last 100 years. In 1968 and 1957—a lot of people got sick. Not many people died. In 1918, however, many people got sick and regrettably, millions died. If we were to have a pandemic of equal proportion to that which occurred in 1918, roughly 90 million people in the United States would become ill. About half of those—45 million would become sick enough that they would require some form of serious medical attention, and about 2 million people, regrettably, would die.

Senator SPECTER. Well, those are pretty stark figures—90 million, about one-third—almost one-third of the population, and you say millions would die. What basic precautions should people take?

PANDEMIC INFLUENZA PREPAREDNESS

Secretary LEAVITT. Well, for that reason, the President has asked that we mobilize the country. I have committed that we would hold pandemic summits in all 50 States. So far, we have had 46 of them. We are mobilizing State and local governments. We are also working to develop a global monitoring system.

Senator SPECTER. What should individual citizens do? Should individual citizens stock up on water? Should individual citizens stock up on food?

Secretary LEAVITT. Mr. Chairman, the preparation for a pandemic is essentially the same preparation that needs to occur in any disaster. It's a good idea to have some nonperishable food stored at your home. That would be true for a hurricane or a tornado. It would be a good idea for a bioterrorism event or a nuclear event. It would be true as well for a pandemic. It's a good idea to have a first aid kit and to have prescription drugs stocked up in a way that if you were to need your supply and couldn't get to the drug store that you would have it. It's a good idea to have thought through how you would deal with your children—if you had to alternate going to work with your spouse or if they both needed to stay home and you had to have some kind of caregiving process. It's a good idea to take the same precautions as in any other emergency situation.

Senator SPECTER. The red light went on in the middle of your answer, and I intend to observe the red light meticulously because I ask all the members of the panel to do the same, and now I yield to Senator Harkin.

PANDEMIC INFLUENZA VACCINE STOCKPILE

Senator HARKIN. Thank you very much, Mr. Chairman. Again, welcome Mr. Secretary. Again, I just want to point out that this committee—the Senate went on record 73 to 27 on an amendment offered by Senator Specter on the budget to increase our budget allocation by \$7 billion for health and education programs, much of which would go to this Department to make up for a lot of the cuts that we see in this budget. Of course, we don't have a budget yet.

The House can't seem to pass one. So, I don't know what's going to happen on that later on down the pipe, but I am hopeful that that \$7 billion that Senator Specter and 72 other Senators voted to support stays in there. If that's the case, then we can make up for some of the cuts that are in your budget that I think are just devastating—the cuts to Social Services Block Grants by \$500 million, eliminating the Community Services Block Grant programs, the cuts—as you said, the level funding for NIH, which translates into cuts for some of NIH and for the Centers for Disease Control, the cuts on rural health programs, poison control centers, health professions trainings programs—all of these things all got cuts—all got cuts. Quite frankly, with the needs that we have out there, these cuts cannot stand, and that's why I am hopeful that we can get that \$7 billion. Now, I want to follow up a little bit on the Avian Flu. I want to see if we can clarify the issue of stockpiling of antivirals. The World Health Organization recommended that countries stockpile sufficient antivirals to treat 25 percent of their populations. In your written statement, you concur with that goal. That would equate to about 80 million Americans. I understand that your Department has ordered or has on hand enough antivirals to treat about 26 million individuals, so that leaves about 50 million—60 million short. I understand that you anticipate States will order 30 million courses of antivirals. The Government will subsidize that at 25 percent of the cost. States have been asked to place their orders with you by July—by this July. The final course of treatment will be ordered using pending funds—2007—next year funds. Well now, again, I laid that groundwork to say that—are there any States that have indicated that they will not be able to order these medications because they have a lack of funds or a lack of legislative authority to do so?

Secretary LEAVITT. No State has made that statement to us at this point.

Senator HARKIN. Okay. What is your plan if States don't order these treatments by July?

Secretary LEAVITT. We intend to acquire 50 million courses of antivirals.

Senator HARKIN. You mean 50 million over the 20 you have?

Secretary LEAVITT. Let me reconcile the entire amount and then give you the timeframes. We will have by the end of 2006 the 26 million that you have spoken of. We will have by 2008, 50 million that will have been purchased by Federal money and that will be available for distribution.

Senator HARKIN. Okay.

PANDEMIC INFLUENZA VACCINE DISTRIBUTION

Secretary LEAVITT. We will make a distribution of that 50 million among the States on essentially a proportionate basis. So they will have that available to them in its entirety by the end of 2007. Each of the States then has an opportunity to supplement that—their proportionate share of that 50 million, and we will subsidize it by 25 percent up to their proportionate share of the remaining 31 million. We anticipated originally that we would ask States to make that decision by July. Since that information was provided to you, we have made a decision that we will allow them to buy off of our

order and at the same time, deal directly with the manufacturer so that they could be more efficient rather than go through us.

Senator HARKIN. My time is running out. Mr. Secretary, in the case of a pandemic, State, and local health departments will have to distribute the vaccines. Are you encouraging States to organize mass vaccination exercises during this next flu season to get ready for that?

Secretary LEAVITT. We are.

Senator HARKIN. If so, will you allow the States to use a portion of the \$350 million that we allocated for that to purchase annual flu vaccine?

Secretary LEAVITT. Actually, we would prefer that they utilize the \$350 million to build up the public health infrastructure and to reach deep into the community to be able to do the kinds of things that Senator Specter was talking about.

Senator HARKIN. But isn't one way to do that is to purchase annual flu vaccine and put in place an infrastructure—

Secretary LEAVITT. Oh.

Senator HARKIN [continuing]. To distribute it? That's what I am saying.

That's what I am talking about.

Secretary LEAVITT. I misunderstood your question.

Senator HARKIN. Yeah.

Secretary LEAVITT. At this point, we have not begun to distribute the stockpile of vaccine that we have. It is relatively small, but we will not release it until such time as we have seen person-to-person transmission.

Senator HARKIN. No, now we're—my time is running out, and that's not what I am talking about. What I am talking about is the annual flu vaccine.

Secretary LEAVITT. Oh.

Senator HARKIN. Is we put \$350 million for—to build up State and local structures in case of a pandemic. One of the ways to test that to see if it works, to do it is to buy the annual flu vaccine and say okay, we are going to set up processes and methodologies to get that annual flu vaccine out.

Secretary LEAVITT. Third time is the charm, Senator. You got it.

Senator HARKIN. Okay.

Secretary LEAVITT. I think you finally reached me.

Senator HARKIN. So, my question—would they be allowed to use some of that \$350 million to purchase the annual flu vaccine to test modalities out there to—how to get it out?

Secretary LEAVITT. I hadn't thought of that.

Senator HARKIN. Oh.

Secretary LEAVITT. It's a really interesting idea—

Senator HARKIN. Okay.

Secretary LEAVITT [continuing]. I'd be happy to give it some thought and respond back to you.

Senator HARKIN. I appreciate that. Thanks, Mr. Secretary. All right.

[The information follows:]

PANDEMIC INFLUENZA INFRASTRUCTURE

A major component of the \$350 million allocated to States for pandemic influenza planning is for States to exercise their plans. States are permitted to use Public Health Emergency Preparedness cooperative agreement funds to purchase vaccine in limited quantities for the purpose of conducting drills and exercises. At this time, they are not permitted to purchase annual vaccine with the emergency supplemental funding for pandemic influenza preparedness. However, they may use some of these emergency supplemental funds during the influenza season as an opportunity to exercise mass vaccination plans.

Senator SPECTER. Thank you, Senator Harkin. Senator Craig?

COMMUNITY HEALTH CENTERS

Senator CRAIG. Thank you very much, Mr. Chairman. Mr. Secretary, during the Easter recess when I was back in Idaho, I visited a community health center, and I do that on a regular basis to see how it's working, who they are serving, how they are serving, and it is really one of those kind of unsung success stories out there that some of us fail to recognize. Obviously, this present—President hasn't failed to recognize that to lower income Americans, one way to serve them is making sure the door is open, and community health centers do that very well. This particular community health center in Nampa, Idaho told me that in the year, they had served over 25,000 people, and the place was full, the parking lot was full, and the doctors and nurses there were very pleased with the work they were doing. Should this committee be concerned that expansion of new facilities coupled with a reduction in funds for training personnel to work in those facilities will slow the service—access to service in communities that need these facilities or worse—exacerbate shortages in medical personnel across the country?

Secretary LEAVITT. Mr. Senator, as I indicated earlier, this is one of the President's high priorities, and this budget includes funds to continue forward in his goal of providing 1,200 new or expanded community health center sites. This includes enough for 300, 80 of which will be in the highest poverty counties. This is a passion for the President and for me, and we are working with every asset we have to continue moving it forward.

Senator CRAIG. Okay. So as I said, funds as it relates to the training of personnel, we don't—you don't see that as a problem in relation to standing these up and facilitating them for service?

Secretary LEAVITT. As I speak with those who run and operate these in the same way that you have, there are always needs there.

Senator CRAIG. Yeah.

Secretary LEAVITT. I would not want to say that we will have quenched that, but we do recognize that training is a component of it and want to meet those needs.

WELLNESS AND DISEASE PREVENTION

Senator CRAIG. Okay. Mr. Secretary, myself and other Senators consistently over time have introduced legislation to authorize Medicare to cover medical nutritional therapy services for some beneficiaries. However, there is generally a cost associated with any legislation, and that usually gives us problems in this area. I am one who believes that good health oftentimes brings down costs as it relates to healthcare and that we ought to be increasing advocates of that instead of repairs of broken bodies, if you will, after

the fact. Can you give me your general views based on your experience in implementing programs designed for health and wellness as opposed to programs designed to intervene or respond to long after diseases and ailments have onset?

Secretary LEAVITT. I believe, Senator, it should become our entire focus. When I say entire focus—until we begin to view wellness with the same passion we do treatment, not only will we not see improvement in our health, we will not see improvement in our fiscal health. I believe that is one of the reasons—in fact, one of the primary reasons, why the new Part D prescription drug benefit is such a historic point in time. For the first time, we have begun to provide for seniors the prescription drugs they need to stay healthy as opposed to simply treating them after they are sick. Over and over again, as I have traveled the country meeting with seniors, I have heard stories of people who have had heart operations, ulcer operations, and osteoporosis treatments that could have been prevented with a small amount of prescription drugs at the onset as opposed to the treatment at the end.

MEDICARE PART D ENROLLMENT

Senator CRAIG. Well, my time is up, but you segued nicely from my request for a response as it relates to medical nutritional therapy and to prescription drugs. Could you for a moment give us some of the current figures as to where we are with participation as to where we thought we would be and some of the savings that are now already appearing on the scene?

Secretary LEAVITT. We anticipated that in the first year, we would see 28 to 30 million people enroll. We have now exceeded 30 million. We anticipate between now and the 15 of May that we will have—I don't know exactly of course, but another couple million. If you assume that that's 32 million, there are 42 million in total who are eligible. There are 6 million who are getting coverage from either a private employer or some other source. If you add that 6 to the 32, you get 38. That would mean we have a shot at being able to have enrolled 90 percent of every senior who is eligible for this benefit during the first year. That is a remarkable achievement in my mind, and it's a tribute not just to the Centers for Medicare and Medicaid Services (CMS), but to the thousands of pharmacists, the thousands of volunteers, the tens of thousands of people all over this country who have been involved in reaching out to seniors in their homes, in their places of worship, in their senior centers. The other good news is the cost is coming down. The program is getting better everyday. The cost is coming down, and we are getting people enrolled.

Senator CRAIG. Thank you. It is a success story. We appreciate it.

Senator SPECTER. Thank you very much, Senator Craig. Under the early bird rule, we turn to Senator Durbin.

MEDICARE PART D ENROLLMENT DEADLINE

Senator DURBIN. So, Mr. Secretary, there is more to the story, and here is the rest of the story. The Bush administration says that 35.8 million Medicare beneficiaries will have drug coverage as of mid-April. The truth is 75 percent of those people—more than

26 million—already had prescription drug coverage before January 1 of this year through their employer, the VA or Medicaid. So there were 16 million Medicare beneficiaries who previously did not have drug coverage. Only half or about 9 million have signed up for the benefit. Millions need more time. In my State of Illinois, 606,000 people have not signed up for Part D, and the clock is ticking. It's less than 2 weeks away. Forty-five different plan choices, people—some of whom are flat on their back in nursing homes and in no position to make these choices—I think we have to acknowledge the obvious. Come May 15, the law will impose a penalty on a lot of people who did their best and just couldn't get this done, and I want to ask you point-blank do you think we ought to extend the signup deadline beyond May 15? Number two—should you allow senior citizens a do-over if they picked a bad plan that dropped the formulary, increased the cost? Do you think that that will be a reasonable way to deal with clearly a challenge that has not been met?

Secretary LEAVITT. Senator, millions of people—tens of millions of people—have prescription drug coverage who did not have it before. That is a great step forward, something I believe you would concur with. Let me again say that I believe that when May 15 comes, we will have reached roughly 90 percent of those who are eligible. Of the remaining 10 percent, about half of them will be a population that, granted, is very difficult to reach.

Senator DURBIN. But—

Secretary LEAVITT. We have had that problem—I want to answer your question. About half of them are in a low-income status, and we have granted them the ability if they qualify for the extra help—the people that you are most concerned about—we will not require that they wait until the next enrollment period. They will have no penalty, and they will have no wait.

Senator DURBIN. So increasing monthly premiums of 1 percent for every month past the deadline—are you going to waive that?

Secretary LEAVITT. If you are in fact a low-income eligible person, you will not have a penalty, and you will not be required to wait until the next enrollment period.

Senator DURBIN. Will the administration support extending the deadline beyond May 15?

Secretary LEAVITT. We believe that a deadline is necessary and that it is working. The Government actuary told us if we did not have a deadline, we would have substantially fewer people. We believe that the plan requires the time to mature. We think that the—that half of the people who are—who have yet to enroll will be eligible to enroll during that period once they have qualified for extra help.

Senator DURBIN. I think that we are missing the point here. Of the universe of people who did not have prescription drug coverage on January 1, some 25—let me get the figure correct here—25 percent of the Medicare beneficiaries, about 15 percent of that number will have signed up by May 15, and 10 percent will have not. So 60 percent of our goal will have been reached, but 40 percent not. You are shaking your head, but those are the numbers, and we get the report from your agency county by county. 606,000 people in my State, and we have done our best. What I say to you is I hope that you will understand their predicament, that the administra-

tion will relent and give these seniors a second chance to sign up without penalty. Second, if they have made a bad choice, I hope you will give them a chance to have a do-over, a makeover, support legislation that we have introduced. They can pick a plan that really is better for them. If I might ask one other question—I'm going to run out of time. I am worried about whether or not we are doing what we need to do for our children on our watch. I go to schools across my State, and I ask a simple question—how many here have someone in your family with asthma? You will see more than half the hands go up. You can tell by looking at the children we are dealing with obesity. We know that one out of every 160 children in America have autism at this point. How can we deal with these issues when we are facing a budget that is going to make such significant cuts in the Centers for Disease Control and Prevention, in the National Institutes of Health and that eliminates the NIH National Children's Study? How can we find out what's happening out there and really protect our children against what appears to be an onset of some terrible health challenges?

MEDICARE PART D PLAN CHOICE

Secretary LEAVITT. Senator, we do have an epidemic of obesity, particularly among our young people, and the Centers for Disease Control and Prevention does have a role as would many other agencies at HHS, and we are prepared to join with you in every way we can to assure that that occurs. It is a very serious problem. I would like to just mention one other thing on the choice of plans. A statistic I learned that I think you will find interesting—we did develop a standard plan that was recommended by the Congress. Only 10 percent of the more than 30 million people now have chosen that plan, which tells me that it was very important to people that they have a choice and that they are able to choose a plan that fits their situation. I know from signing a lot of people up that if they had just had to deal with the standard plan, no matter what it was, it would not have served them well. The plan will be simplified in the next version in the same way that the market has allowed for it to become better. We are all going to get better at this as time goes on. In 1965, Medicare became law. It got better in 1966. It got better in 1967. The plans are now maturing. The pharmacies are learning how to use the system. The consumers are now better informed. We are getting better at what we do. This is a very important milestone—undoubtedly the most important thing that's happened in healthcare in the last 40 years.

Senator DURBIN. Thank you.

Senator SPECTER. Thank you, Senator Durbin. Senator Kohl?

FDA GENERIC DRUG APPLICATIONS

Senator KOHL. Thank you, Mr. Chairman. Mr. Secretary, the FDA currently has a backlog of more than 800 generic drug applications, which is an all-time high, and FDA officials expect a record number of generic applications this year and an even larger backlog. The Congressional Budget Office estimates the use of generics provides a savings of \$8 to \$10 billion to consumers every year, and that doesn't include the billions of dollars more of savings to hospitals, Medicare, and Medicaid. I believe it's now more important

than ever that we speed less expensive generic drugs to market, and I would think that you agree. So do you support an increase in the FDA budget to help reduce this backlog, and how much do you believe the FDA needs to efficiently reduce the backlog and pass along the savings to our people and also to the Federal Government?

Secretary LEAVITT. Senator Kohl, I concur with you that there is a need to speed generic drugs to market. It is a good thing for consumers. It's a good thing for healthcare. We are taking steps to do just that—not only to speed them, but to prioritize them. The budget that I have proposed is the budget we have proposed. We think we can accomplish that within the budget that we have suggested.

Senator KOHL. So you are not proposing any increase in the budget to help reduce this backlog?

Secretary LEAVITT. We are putting substantial focus on it, however, I will tell you, at FDA.

Senator KOHL. I'd like to hope that's going to happen, that in fact we will get the kinds of numbers—increases that we need, that I think you believe we need, and you are saying that it's going to happen?

Secretary LEAVITT. Let me suggest one piece of information that might at least give you some insight into this. Of the 800 applications, some of them are essentially for the same chemical or same molecule. So, we have begun to focus on those on in which there is not one generic or two generics. In other words, we want to get new generics into the market as opposed to a repeat of existing molecules that have been made available in some generic form. Now, we think we can do this better, and I think we have to.

ADMINISTRATION ON AGING (AOA) BUDGET CUTS

Senator KOHL. Mr. Secretary, some of the most painful cuts in the budget are programs under the Administration on Aging, which takes a \$28 million hit in programs like Meals On Wheels and family caregiver support services. That means that—well, in my State, Wisconsin senior population continues to grow from 705,000 senior citizens in 2000 all the way up to 1.2 million senior citizens estimated for 2025. The budget does not account for the growth and the need for services. In addition, this budget proposes to eliminate Alzheimer's demonstration grants. In Wisconsin, the Alzheimer's Association is in its first year of a 3-year grant where they are working in Jefferson County on a program to open a dementia care clinic at a hospital in Fort Atkinson in Jefferson County. It is the first of its kind and the only one in the area, and they would lose their funding after this year should this budget prevail. So how do you explain your plan to cut these vital programs while at the same time our aging population is growing?

Secretary LEAVITT. Senator, you have listed a number of different areas, so let me do my best to respond to them and to give you a sense of what was going on in here when I made these decisions. I asked my budget team to essentially use a series of principles. One of them I asked them is to look for one-time funds. So part of that may be one-time funds where the project was completed and hence wasn't repeated. Another principle was looking for programs where purposes were involved in a number of different places at

HHS. So, it's possible that some of those were there. There were also some funds that were carried over from existing programs that I didn't repeat. Now, I can't respond directly. If you'd like me to get to you specifically with those, I'd be happy to respond, but my guess is that we'll find that those principles are the ones that were involved in helping to make the decisions we did.

Senator KOHL. I would like some more information on those particular programs.

Secretary LEAVITT. We'll be happy to respond to that.

[The information follows:]

ALZHEIMER'S DEMONSTRATION GRANTS

For 14 years under the Alzheimer's Disease Demonstration Grant to States Program (ADDGS), demonstrations in almost every State have highlighted successful, effective approaches for serving people with Alzheimer's. Similar to Preventive Health Services, it is time to put these models and the lessons that have been learned to work by moving them in AoA's core services programs—especially the National Family Caregiver Support Program—as a number of States have already done.

The fiscal year 2007 President's budget includes the elimination of ADDGS. This reflects that demonstration projects for individual with Alzheimer's and their caregivers are ready to be incorporated into the core activities of the National Aging Services Network.

RURAL HEALTHCARE

Senator KOHL. There are a number of programs in your Department aimed at bolstering rural health. Wisconsin, one of the biggest beneficiaries in the country, received over \$600,000 from the Rural Hospital Flexibility Grant Program just last year. This funding is used at over 60 rural hospitals that serve anywhere from 10,000 to 12,000 patients every year. The President's budget proposes to eliminate the Rural Hospital Flexibility Grant Program, the rural and community access to emergency devices and area health education centers. So how are rural communities expected to meet their unique healthcare challenges when these very important resources are being severely diminished?

Secretary LEAVITT. I, like you, come from a State where rural medicine is a very important part of the social fabric of our State, and so I have become quite sensitive to this. We have adopted a slightly different strategy and that is to try to bolster the reimbursement rates for providers in those areas. I have also begun to look for places, frankly, where I wasn't able to justify or I wasn't able to see a result. We have invested about \$25 billion through higher reimbursements in rural areas, and that's the way we are intending for many of those funds to be replaced.

Senator KOHL. Thank you, Mr. Chairman.

CDC BUDGET CUTS

Senator SPECTER. Thank you very much, Senator Kohl. On round two, we begin now with Mr. Secretary. With respect to the budget cuts, the Centers for Disease Control and Prevention has been cut by \$67 million this year. They have enormous responsibilities in many many areas which I shall not enumerate, and now we are looking to give them even greater responsibilities if there should be a pandemic flu. Dr. Julie Gerberding, a very distinguished Director of CDC, has sat at your side testifying, preparing on this item. The physical plant of CDC was a shambles when I visited it several

years ago. Prize-winning scientists were sitting in hallways, toxic materials were not under lock and key, and we have carved out funds within our existing budget to fund almost a billion and a half dollars. Immediately, Senator Harkin and I found \$137 million. Now, the budget has been cut from \$159 million to \$30 million—a \$129 million cut. I have been lobbied very heavily by people in the Atlanta community to find the funds, but I can't find money out of thin air. How can CDC be realistically cut and their physical plant not improved given the increased responsibilities that you as Secretary are calling on them to perform?

Secretary LEAVITT. Senator, may I acknowledge that the work that this committee has done to be supportive of CDC is not just noticeable, but revered, and I also acknowledge that the budget that we are presenting to you is reduced by \$179 million. Within that total reduction, the buildings and facilities as far as new construction does make up \$129 million of that. We have felt in a budget with a reduction or a deficit that we have made substantial progress in this area.

Senator SPECTER. Should we stop the rebuilding?

Secretary LEAVITT. Well, we believe that we are capable of pausing on what will be a long-term strategy to continue to improve the facilities. We have made substantial progress. They are remarkable facilities, and I want to express my enthusiasm for how much the campus has been improved, and I want to acknowledge as well the role of you and Senator Harkin in accomplishing that.

Senator SPECTER. Let me ask you to submit the balance of your answer in writing so I can go onto NIH.

[The information follows:]

CDC PHYSICAL PLANT

CDC has made remarkable progress on its Master Plan with \$1.2 billion invested to date to upgrade their facilities. Since 2000, CDC has initiated or completed the construction of more than 2.7 million gross square feet (gsf) of laboratory and facility space. For fiscal year 2007, we have included \$30 million for repairs and improvements of CDC facilities.

Consistent across HHS, our request focuses on finishing projects that are near completion and maintaining existing facilities. No funds are requested to initiate new construction.

NIH RESEARCH GRANTS

Senator SPECTER. NIH tells us that there are going to be more than 800 applications—no, 656 fewer applications, fewer ideas submitted. I am worried that there may be some for breast cancer in that group or prostate cancer or Hodgkin's. How can the crown jewel of the Federal Government—perhaps the only jewel of the Federal Government be cut in funds?

Secretary LEAVITT. Senator, I want to tell you again I agree with you that funding new research ideas is a vital, important priority and that the fiscal year 2007 budget finances 275 more new grants. Now, one of the things you will see is that the actual number doesn't reflect it because a lot of expiring noncompeting grants diminish the number. When we implemented the effort that you instigated in this committee to double the amount of funding, there was a huge amount of new grants. So, what we are in is the first

year where there are not as many non-competing continuation grants.

Senator SPECTER. Well, there will be a lot of grant applications denied and a lot of existing grant applications denied. I get lots of letters, and one illustrates it from Pittsburgh—what am I going to do, Senator Specter, on the tremendous progress I am making if they are going to cut off the funding and the grant's going to be withdrawn? Really, Mr. Secretary, this—these are not issues that can be handled within the purview of the funds which you are allocated. We are going to have to have a fundamental reassessment as to priorities.

My red light just went on, but you—the red light doesn't apply to you, Mr. Secretary, just to my questions.

Secretary LEAVITT. I'd like to acknowledge that we are working to find opportunities for new investigators and for new innovations, and one of the things we are doing, frankly, is reevaluating the grants. After they have been concluded, then people must recompute. In some cases, there are research projects that simply don't stack up to the opportunities because we have essentially been able to get the value from them that the peer review process believes would be to our advantage. So, we have begun to redeploy that into new grants. So, the actual number of new projects is higher than it appears because of the decline in the number of noncompeting grants. The red light's on, and I am sensitive to it.

Senator SPECTER. Well, I turn now to the second round for Senator Harkin, and I am anxious to see if he follows his customary pattern of having really tough questions in the second round.

Secretary LEAVITT. I am going to watch that too.

NIH FUNDING LEVELS

Senator HARKIN. You're putting me on the spot here. Just to follow up on the distinguished chairman's line of questioning on NIH—when we worked hard in a bipartisan fashion with so many others to double the funding for NIH, it was not meant to just double it and then reach a plateau and plateau off. We did this because for years, it had been underfunded, and we wanted to get it back up to where it had been maybe 25 years ago and continue the funding up. It was not meant to get it up and say oh, now we can level off. That's what I see happening, and we are falling into the same pattern that we did 30 years ago when NIH all of a sudden had—it was getting out maybe 4 or 5 peer-reviewed grants per every 10 that came in—30 percent—40 percent—50 percent. Now, we are getting down to 10 percent again. So it's like we're plateauing off again. So we are going to do this, and 10 years from now when we are probably gone, somebody will be kind of like well, we're going to have to double the funding again—not a good way to run things. So, I kind of plead with you use your counsels within the executive branch to tell them this is just not—this is not good. We—and I think that's why we had so much support for the amendment that Senator Specter offered on the \$7 billion. A lot of it had to do with we are not going to let NIH fall into that same rut again. Well, that's a statement, and that's not a question—darn it. Well, I had another statement too.

PANDEMIC INFLUENZA VACCINE

I won't get into that, but on the flu vaccine, I do want to follow up a little bit on that. I have legislation in that would provide for a free flu shot for everyone every year—free flu—the Federal Government just provides a free flu shot. Now, why is that? Well, I am thinking about the vaccines and the—we have to get the infrastructure up for the pandemic flu that may—a lot of signs say is coming. As you point out, we have pandemics every so often. The infrastructure is not there to deliver it. So, if you had a free flu shot for everyone every year, not only do you save 35,000 lives a year perhaps or at least a good portion of those, you save a lot of hospitalizations, you save a lot of money if everyone got a free flu shot every year. Plus you get the States in to think about how you get it out there. You know, how do we start inoculating people in Wal-Marts and sporting centers, high schools, maybe even churches—after church or synagogue, they could get inoculated. In other words, to set up a system so that if a pandemic hits—bang, you have got it there and you can get it out. So I hope that you will take a look at that and see if there is any merit to getting a free flu shot for everyone out there, and I don't know if you want to respond to that or not.

Secretary LEAVITT. I'd love to respond just briefly. I believe one of the side benefits of our pandemic preparedness is the ability to take the annual flu vaccine dilemma off the table forever.

Senator HARKIN. Yeah.

Secretary LEAVITT. We will have to have new capacity developed and have it operating continually to keep our capacity warm—

Senator HARKIN. That's right.

Secretary LEAVITT [continuing]. The best thing to develop—

Senator HARKIN. That's right.

Secretary LEAVITT [continuing]. Would be new annual flu vaccine.

Senator HARKIN. That's right.

Secretary LEAVITT. So, I fully believe that we will see substantial increases in the availability of annual flu vaccine. How we distribute it, what the cost is and so forth will be a matter of policy, but we do need to increase it.

DISEASE PREVENTION

Senator HARKIN. Well, I appreciate that. I will continue to push that idea that we ought to just provide a free flu shot. It's about—I estimated about—well, if you figure the flu shot's about \$10 for 200 million people, that's about \$2 billion a year, but then the lives you save, the decrease in hospitalizations—maybe won't cost that much, so you get a win on the other side. Let me follow up on Senator Craig's comments. I told him when he walked out I was going to follow up on that, and I think I heard you say this was—your primary concern is to get prevention out there. When you mentioned the Medicare, that 8 percent GDP now going to 11 percent, the answer is not just to provide more drugs for the elderly Part D, and I don't mean to get into that contest there, but the answer is just to start getting prevention earlier in life to our kids as they go through life. Now, you know I have been very concerned about

child obesity, diet-related chronic diseases, and one of the areas I am particularly interested in is the junk food marketing that targets kids—its impact. Last December, the IOM report, “Food Marketing to Children: Threat or Opportunity?” was released in December. It outlined a series of policy recommendations for government, the food and beverage industry, schools, parents—designed to limit junk food marketing and instead to utilize the power of marketing to promote healthier diets. What’s that got to do with you? Well, the final recommendation of IOM was for the Secretary of Health and Human Services to designate a responsible agency to formally monitor and report regularly on the progress of all of the recommendations in the report. On March 3 of this year, 14 Members of the Senate wrote to you urging you to implement this final recommendation so that Congress can monitor the progress made or not made toward the goal to see whether we need to do something in that regard. Now again, I am not—don’t want to put you on the spot. We have not heard back from you, but that was only March—that was March 3. But again, Mr. Secretary, does HHS have any plans to take the action recommended by the Institute of Medicine to appoint a monitoring body on food marketing to children? If you don’t have that answer, just—

Secretary LEAVITT. I think I best respond to you—

Senator HARKIN. Respond to me.

Secretary LEAVITT [continuing]. In writing. I have read about your concern about this, and I have begun to make inquiries as to what the current status is.

[The information follows:]

INSTITUTE OF MEDICINE POLICY RECOMMENDATIONS

Obesity prevention is one of my top priorities. I have asked Assistant Secretary for Health, Dr. John Q. Agwunobi, to work with all of the HHS agencies and offices to explore this issue in depth, and consider appropriate actions consistent with existing authorities and available resources.

In addition, last year HHS and the Federal Trade Commission (FTC) sponsored a joint workshop on the effects of food marketing on children. On May 2, HHS and the Federal Trade Commission released a report titled “Perspectives on Marketing, Self-Regulation and Childhood Obesity” that recognizes that advertising and marketing can play a positive role in encouraging sound nutrition and physical activity.

The report includes a series of recommendations for food companies and the entertainment industry to assist Americans in identifying more nutritious, lower-calorie foods; increase efforts to educate parents and children about nutrition and fitness; and to bolster the self-regulatory strategies that are currently employed to monitor the marketing of food and beverages to youth. In addition, the Council of Better Business Bureaus and the National Advertising Review Council recently announced the formation of a working group effort to review and propose changes to the Children’s Advertising Review Unit and its self-regulatory guidelines.

Secretary LEAVITT. Senator, could I just make one other quick statement on a previous matter?

Senator HARKIN. Sure.

NIH RESEARCH

Secretary LEAVITT. I’d just like to acknowledge that—the commitment that I feel to maintain the momentum of the research we have going at NIH. I’ll probably be the only one who will say this is a good performance, but I have worked hard in a deficit reduction budget to make sure that we kept it at least flat. That is maybe good news only to me, but I wanted to tell you I have

worked hard on it and will continue to. I also believe that what Dr. Zerhouni is doing with respect to trans-institute projects with his Roadmap is a very important part of the future. I would like to see a greater percentage of the \$30 billion that we spend there every year for research on inter-institute projects on basic science where all of the Institutes will benefit. I think that's a more efficient way than simply allocating to whatever disease or body part institute it is to have their own project, and I would like at some point to work with this committee to create a means by which that could be accelerated. We need more cross-institute work. We need to have less siloed research, multidisciplinary research is clearly where we will find success in the future.

Senator HARKIN. I appreciate that. That's good.

COMPASSION CAPITAL FUND

Senator SPECTER. Thank you very much, Senator Harkin. Just one final question before we conclude the hearing—Mr. Secretary, I note that you and First Lady Laura Bush were in Pittsburgh to talk about the progress on the initiative in relating to gang control, a Capital Fund—Compassion Capital Fund program—antigang efforts through a community and faith-based organization back on March 7, 2005, and I would be interested to know what your thinking is on any progress there. The problem of gang warfare and shootings is epidemic and endemic. Just this morning, two teenagers were shot straight across from a high school in Philadelphia. The shootings are virtually a daily occurrence. Recently, there was a gunfight. Last week, two men were sentenced to life imprisonment for a massive gunfight outside an elementary school in February 2004 which killed a 10-year-old. Are the funds made available through this new program that you and First Lady Laura Bush announced having any significant impact?

Secretary LEAVITT. We are nearing the point in our process of soliciting proposals. We have an obligation to come up and review it with the committee, and we intend to do that. I think at that point, we'll be in a position to evaluate together the kinds of things those funds are being used for. We are quite optimistic about it and hopeful that we can continue the momentum of the program.

Senator SPECTER. Well, the announcement was sometime ago—March 7, 2005. Have any grants been made under the program in the intervening 15 months?

Secretary LEAVITT. We have not yet received proposals. We have an obligation to come to the committee to review them with you before we do that, and we will do so.

Senator SPECTER. Well, we have put up a fair amount of money last year, and you are asking for \$35 million more this year in a budget where there are cuts on some very vital programs, so we don't want to keep those funds held in abeyance. If they can be directed effectively to juvenile gang problems, we want to do that.

Secretary LEAVITT. Thank you.

Senator SPECTER. But if the money is not going to be awarded so that we can see some positive results from those funds, we want to use them elsewhere. Mr. Secretary, thank you.

Senator Harkin?

AGING SERVICES PROGRAMS

Senator HARKIN. There was one thing I just—thank you, Mr. Chairman—that I wanted to bring up before you left, Mr. Secretary. When we first met when you came into my office when your appointment was scheduled, one of the things I remember we talked about was Systems Change Grants. Shortly after the *Olmstead* decision by the Supreme Court, Senator Specter and I started working to provide funds to help States get deinstitutionalized or to prevent institutionalization, but get people to deinstitutionalize. The *Olmstead* decision said you know, we had to provide the least restrictive environment. So we started this program called Real Systems Change Grants, and we started putting money in it to implement these programs. I believe, from all that I have known about it, it has been a success year after year. But every year, we have to fight to put the money into it. Again this year, the budget eliminates funding for the grants again—once again, so we fight again to put it in. Now, I now read that you have a new program in the area—in the administration on aging called Choices for Independence. Your budget's notes say, "It seeks to reduce the current systemic bias in favor of institutional care." Well, that's what we were doing under Systems Change Grants. So again, what's the difference? Is this new program meant to replace it, to supplement it? I don't understand, and what's the difference between the two programs? Why would you eliminate the Systemic Change programs that we have been funding and now come up with this new program?

Secretary LEAVITT. Our purpose is to continue a portion of it in the Administration on Aging. We do believe, as you have stated, the need for us to deinstitutionalize and to have people served in the communities and homes, and that's the purpose. Perhaps we could provide you with more detail.

Senator HARKIN. Well, provide me with more details because it's not just aging. I mean, these are people with—a lot of the time physical disabilities, sometimes with mental disabilities, sometimes with both, but which has been proven that in many cases can live in a community setting. But a lot of times, it takes an initial expenditure made to get that done. After they get out, they're fine. As you know, there is a bias in Medicaid. Medicaid will pay for someone to be in an institution, but that institution wants to live in a community, they don't get that Medicaid support.

Secretary LEAVITT. Something we'd like to change.

Senator HARKIN. Well, I would like to change that too. That's why we had this program. So I wish you would really look at that. We are mandated—Supreme Court mandated. We got to—they have got to deinstitutionalize. So, we need to change that bias in Medicaid, and I hope we can work with you to do that also to provide that, but I would like to know why this is different. You put it in aging, but it doesn't just cover aging, it covers everybody else. If you don't have it now—

Secretary LEAVITT. I have asked my staff to respond as quickly as possible.

Senator HARKIN. I'd appreciate that. Thank you very much, Mr. Secretary.

Secretary LEAVITT. Thank you.
[The information follows:]

AGING SERVICES PROGRAMS

Thank you for this opportunity to clarify my remarks at the recent hearing. The Choices for Independence program “complements” the Real Choice Systems Change initiative. This is a very important distinction. Allow me to explain further how the two initiatives fit together.

Since fiscal year 2001, Congress has appropriated over \$245 million for the Real Choice Systems Change (RCSC) Grants for Community Living. In implementing the RCSC program, the Centers for Medicare & Medicaid Services (CMS) has awarded over 297 grants to all 50 States, the District of Columbia (DC), and two territories. In fiscal year 2006, Congress appropriated an additional \$25 million to fund a new round of RCSC grants. States and other eligible organizations, in partnership with their disability and aging communities, have the opportunity through RCSC to submit proposals to design and construct systems infrastructure that will result in effective and enduring improvements in community long-term support systems. These system changes are designed to enable children and adults of any age who have a disability or long-term illness to:

- Live in the most integrated community setting appropriate to their individual support requirements and preferences;
- Exercise meaningful choices about their living environment, the providers of services they receive, the types of supports they use, and the manner by which services are provided; and
- Obtain quality services in a manner as consistent as possible with their community living preferences and priorities.

As one component of their RCSC efforts, beginning in fiscal year 2003, CMS began partnering with the Administration on Aging (AoA) to fund States to develop Aging and Disability Resource Centers (ADRC) to streamline access to long-term supports for people with disabilities of all ages. Simplified access to services, as represented through the ADRC initiative, is a key element of a State’s overall systems change efforts. AoA resources for the ADRC initiative have come from the Older Americans Act Title IV Discretionary funding.

Choices for Independence builds on the Older American’s Act unique mission, to help our Nation prepare for the aging of the baby boom generation. Like the Real Choice grants, Choices addresses issues facing Americans who need comprehensive home and community-based systems of long-term care to delay or avoid nursing home placement. Choices for Independence, like RCSC, is designed to promote home and community-based care. Choices will focus mainly on linking Older Americans with available services, improving consumer-directed care, promoting evidence-based disease prevention, and targeting individuals not yet eligible for Medicaid to help prevent them from spending down to eligibility. In this way, Choices will complement the work that Real Choice grants have so effectively begun to improve long-term care (LTC) service delivery systems at the State level. In fiscal year 2007, as CMS works to implement the Deficit Reduction Act of 2005 (DRA), they will continue working with States to reform their LTC delivery systems by building on the successful aspects of Real Choice Systems Change grants.

The fiscal year 2007 budget for AoA essentially folds ADRCs into the Choices for Independence initiative. The fiscal year 2007 budget includes \$28 million for Choices for Independence, including an estimated \$12.5 million for ADRCs; at the same time, CMS is requesting no new funding for Real Choice Systems Change grants. After 5 years, these grants have made great strides in helping States make improvements to their home- and community-based health care delivery service systems. The initiative provided useful lessons that led to the development and implementation of the Money Follows the Person demonstration (focus is consumer-directed care) as well as the State plan options for home- and community-based services in the Deficit Reduction Act (DRA). While Choices for Independence does not currently assume funding from other agencies, AoA will continue to work closely on this initiative with CMS and the other HHS agencies that have been involved in the activities that led to its development.

Senator SPECTER. Thank you very much, Secretary Leavitt. Thank you for what you are doing on the pandemic problem, and I urge you to do more on acquainting America with the nature of the worst-case scenario—how serious it could be and what people ought to be doing individually—and your efforts to stir up activity

by state and local agencies to deal with the problem. I would appreciate your assistance, your thought on what we can do about these budget shortfalls and about what can be done on advocacy within the administration, within the Office of Management and Budget which has the final word here and really with the President himself. I think that there is not a recognition as to what this means on a lot of very difficult very important agencies like the Centers for Disease Control and Prevention. These cuts on so many of the health agencies are just unacceptable. We can't solve that this morning, and you can't solve it, and there may be—have to be some action on Congress somewhere to find something that can give so these cuts are not implemented. Thank you.

ADDITIONAL COMMITTEE QUESTIONS

Senator SPECTER. There will be some additional questions which will be submitted for your response in the record.

[The following questions were not asked at the hearing, but were submitted to the Department for response subsequent to the hearing:]

QUESTIONS SUBMITTED BY SENATOR ARLEN SPECTER

HEALTH PROFESSIONALS TRAINING

Question. Mr. Secretary, I am disappointed that the budget proposal again eliminates funding for health professions training at HRSA, particularly those programs focused on diversity. Why does the administration continue to neglect these programs which play such a vital role in the education of young minority students in the health professions? What do we need to do to get the administration to match the support for these programs that exists in the Congress?

Answer. The administration prioritizes the distribution of health professionals by maintaining funding for the Nation Health Services Corps, which places physicians in underserved areas, at \$126 million. There is no longer a supply problem for physicians. Improving access to health care takes a commitment to improve the distribution of health care providers so that they are serving in areas where there are unmet or under-met healthcare needs. Programs that place people in the communities that need them is the best investment. In fiscal year 2005, only 16 percent of health professionals supported by the Health Professions program entered practice in underserved areas.

MEDICARE ELECTRONIC PAYMENTS

Question. The President's budget includes a proposal to save \$133 million in Medicare by requiring all providers to accept electronic payments, submit electronic claims, and accept more electronic remittance advices. These savings are dependent upon virtually all providers doing this by October 1, 2006. While I laud the goal of increasing Medicare electronic transactions, I question how realistic this is given that the majority of providers in our Nation are in small practices or are solo practitioners. Many of these providers may not have computers in their office or may be reluctant to give up paper. If the savings are not realized, Medicare claims processing contractor budgets will be shortchanged in fiscal year 2007. Given that CMS recently instructed its claims processing contractors to institute a hiring freeze on both new and replacement hires, which I understand could last through the remainder of this year, and possibly into 2007 in order to address current budget shortfalls, I am concerned with any proposal which could put their funding situation in further jeopardy. How does CMS intend to implement this proposal and achieve the estimated Medicare savings? What will the Agency do if the goal is not realized and the savings are not achieved?

Answer. Senator, I appreciate your interest in our administrative processes. This proposal to save \$133 million is part of an overall effort to modernize Medicare operations and administer this program more efficiently. We are working as expeditiously as possible to implement the proposal in 2006. It builds on laws that have already been in effect for several years including the Debt Collection Improvement Act (Public Law 104-134) which requires the government to issue payments elec-

tronically, and the Administrative Simplification Compliance Act or ASCA (Public Law 107–105) which requires most providers to submit Medicare claims electronically.

CMS acknowledges that certain providers are exempt from the requirement to submit electronic claims and will continue to allow these providers to submit paper claims. However, CMS has asked the Medicare contractors to review providers submitting paper claims to see if they are actually entitled to the ASCA exemption. We expect that these reviews will contribute to the savings that CMS expects to realize next year. In addition, CMS has been taking a broad look at the full range of claims-related activities to see which could be streamlined or consolidated. For example, the Medicare contractors currently send beneficiaries a monthly Medicare Summary Notice (MSN) listing services provided. A few of these MSNs include a check to the beneficiary but most do not involve payment. CMS believes it could save between \$15 and \$30 million by sending these “no pay” MSNs quarterly, or maybe semi-annually, instead of monthly. Another potential area for saving resources without placing additional burdens on providers or the Medicare contractors is to require those providers who already bill electronically to receive other claims-related Medicare information and outputs electronically as well. CMS believes that it may be able to save \$10 million from this initiative. While there are substantial amounts at stake, CMS is confident that it can become more efficient without jeopardizing the Medicare contractors’ operations or burdening the providers.

MEDICARE INTEGRITY PROGRAM

Question. CMS partners with private entities to administer the Medicare fee-for-service program. In addition to paying Medicare claims, handling appeals and answering beneficiary and provider inquiries, these contractors are the first line of defense against Medicare fraud and abuse. Unfortunately, the Medicare Integrity Program (MIP)—which is the portion of the budget that funds these critical anti-fraud activities—has been capped by statute since fiscal year 2003. I am pleased the President’s fiscal year 2007 proposal supports an increase for Medicare Part A and B Program Integrity efforts. However, I am concerned with funding for these activities this year. While I understand there are no new dollars right now, I believe it is important to find ways for these contractors to operate more efficiently and effectively. One way to do this is for CMS to give these contractors greater flexibility to manage their MIP budgets. Currently, the Agency does not allow its contractors to transfer funds among MIP program lines if the total funds to be transferred exceed 5 percent of the total funding. In these cases, the contractors must request approval from CMS, which can take months and exacerbate funding problems. This Committee included report language in our fiscal year 2006 spending bill urging CMS to give its contractors this much needed budget flexibility. While CMS has granted its contractors flexibility to manage their program management budgets, they have not done so for MIP. Given the tight budgets contractors are currently facing with MIP dollars, will you consider giving these contractors greater flexibility so they can best manage their budgets to match programmatic needs?

Answer. Although you are correct that the Health Insurance Portability and Accountability Act of 1996 (HIP AA) capped MIP funding at fiscal year 2003 levels, Congress provided an additional \$100 million in 1-year mandatory funding for fiscal year 2006 in the Deficit Reduction Act of 2005 (DRA) for the new Parts C and D workloads. As you stated, the fiscal year 2007 President’s budget includes a proposal to increase MIP funding over the fiscal year 2003 capped level by \$85,634,000 in discretionary funding.

CMS requires all five major MIP functions (Medical Review, Benefit Integrity, Provider Education & Training, Provider Audit, and Medicare Secondary Payer) in order to have a robust arsenal in the fight against fraud, waste, and abuse. As you have noted, CMS is limited in its ability to shift MIP funds since we must ensure that a multi-faceted approach is maintained. In the last couple of years, CMS has increased this flexibility somewhat for the MIP contractors. For example, workload levels in Medical Review and Local Provider Education & Training (LPET) are scalable to a certain extent. During the budget formulation process, contractors determine the type and level of effort they will be able to provide given the available resources. As problem areas/issues surrounding their respective providers change, the contractors can revise their Medical Review and LPET strategies and shift the funding between the two functions as necessary.

As a matter of routine, CMS expects the contractors to keep the agency informed of their changing resource requirements before they are in a deficit situation. CMS is then able to work with the contractors to identify workloads that can be altered

or areas with surplus funding that can be shifted while still achieving CMS' goals and objectives. In limited cases, CMS is even able to provide additional funding.

OFFICE OF MINORITY HEALTH

Question. Mr. Secretary, I am concerned that the budget proposal reduces funding for the Office of Minority Health by \$10 million. In the face of a widening health status gap, how does the administration justify significantly reducing the budget of an office whose mission is to lead the Department in the elimination of health disparities.

Also, in the fiscal year 2006 bill, the legislation calls for a renewed focus on OMH's support for historically black medical schools. Can you tell me the status of this effort?

Answer. The Office of Minority Health (OMH), part of the Office of Public Health and Science (OPHS) in the Office of the Secretary, advises both the Secretary and OPHS on public health program activities affecting racial and ethnic minority populations. The fiscal year 2006 appropriation for OMH included a one-time congressional earmark in the amount of \$10 million, which was not continued in the fiscal year 2007 President's budget.

OMH recognizes the important role that historically black medical schools play in increasing minority representation in the healthcare workforce, and in providing needed services to minority communities. Therefore, OMH encourages minority serving institutions of higher education (including historically black medical schools) to apply for grant programs supported by the Department of Health and Human Services (HHS). In fiscal year 2006, OMH has received proposals from three historically black medical schools; these proposals are currently under review for funding consideration. In addition to its own support, OMH is also working with other HHS Operating Divisions to enhance Departmental opportunities to support these institutions.

NIH SLEEP DISORDERS CONFERENCE REPORT

Question. Mr. Secretary, during the National Institutes of Health's Frontiers of Knowledge in Sleep and Sleep Disorders conference in March 2004, Surgeon General Carmona gave remarks on the profound impact that chronic sleep loss and untreated sleep disorders have on all Americans and that dissemination of the existing body of medical knowledge regarding sleep and sleep disorders is critically important. What are the prospects for development of a Surgeon General's Report on Sleep and Sleep Disorders?

Answer. The Office of the Surgeon General (OSG) is studying this topic as a potential subject for a Surgeon General's Workshop or Surgeon General's Conference. In addition to the comments he made at the March 2004 NIH conference on Sleep and Sleep Disorders, Surgeon General Carmona also provided information regarding healthy sleep habits in a December 29, 2005, press release, "Tips for Parents of Teenagers," as part of The Year of the Healthy Child. In March 2006, OSG staff attended a scientific workshop on "Sleep Loss and Obesity: Interacting Epidemics" to gather more information and identify leaders in this field. In addition, OSG staff members have met with medical intern and resident advocates to discuss their prolonged work hours, and the potential impact on patient safety brought about by sleep loss in this population.

UNDERAGE DRINKING PREVENTION

Question. In February, the Interagency Coordinating Committee on the Prevention of Underage Drinking (ICCPUD), led by SAMHSA, released "A Comprehensive Plan for Preventing and Reducing Underage Drinking." The plan sets three performance targets for 2009: reducing the prevalence of past month alcohol use by those aged 12–20 by 10 percent; reducing the prevalence of those aged 12–20 reporting binge alcohol use in the past 30 days by 10 percent; and increasing the average age of first use from 15.6 to 16.5. These are modest goals, and they expire in just 3 years. It is well recognized, however, that reducing underage drinking will take a concerted effort over many years—certainly more than 3—and no one should be satisfied with 10 percent reductions. Why didn't ICCPUD set more ambitious, longer-term targets? Would you consider doing so in your next annual report?

Answer. The targets set forth in the Comprehensive Plan for Preventing and Reducing Underage Drinking are ambitious, yet achievable, particularly considering underage drinking rates have remained essentially unchanged for over a decade. The targets in the plan, which are to be measured over the 5 year period from 2004 to 2009, represent an ambitious first step in addressing what has been a serious and persistent problem in our country. It is relevant to note that Mothers Against

Drunk. Driving (MADD) has recently adopted targets that are in the same range, including a 3-year goal of reducing the proportion of 16 to 20 year olds who drink alcohol and/or engage in high risk drinking by 5 percent by 2008.

While the Interagency Coordinating Committee on the Prevention of Underage Drinking (ICCPUD) and SAMHSA believe that the current 5-year performance targets set forth in the plan are ambitious, these targets will be revisited during the development of the next annual report.

Question. One of the expected benefits of forming the ICCPUD was that it would result in fewer duplicative efforts in the area of underage drinking. The idea was that as the many Federal agencies with a stake in this problem learned about each other's efforts, they would discover where their efforts overlap and, as a result, eliminate redundancies. Has this occurred? Can you provide concrete examples in which agencies have streamlined their anti-drinking activities?

Answer. Since the Interagency Coordinating Committee on the Prevention of Underage Drinking (ICCPUD) was created in 2004, the member agencies have worked together to conduct an inventory of Federal underage drinking programs, develop the Comprehensive Plan for Preventing and Reducing Underage Drinking and annual report, support a national meeting of the States, support town hall meetings across the country, and create a government-wide website. Through these activities, the member agencies have gained a greater understanding of the science related to underage drinking, as brought to the group by the National Institute on Alcohol Abuse and Alcoholism (NIAAA), and have enhanced their understanding of each other's activities.

The ICCPUD agencies are using this knowledge to support each other's activities, as exemplified by the recent town hall meetings funded by SAMHSA. These meetings were used to distribute research developed by NIAAA, and were strongly supported by a number of key ICCPUD partners, including the Office of Juvenile Justice and Delinquency Prevention (OJJDP), the Office of Safe and Drug Free Schools (OSDFS), and the National Highway Traffic Safety Administration (NHTSA). Several of these agencies encouraged their regional and State counterparts to support and participate in the Town Hall meetings. NHTSA used the meetings broadly to encourage the use of the HBO documentary, *SMASHED: Toxic Tales of Teens and Alcohol* and its accompanying educational package to facilitate and stimulate dialogue about future evidence-based underage drinking prevention action in local communities.

The Centers for Disease Control and Prevention (CDC) and SAMHSA Center for Substance Abuse Prevention (CSAP) were both considering alcohol epidemiological activities in the States. As a result of work with ICCPUD, each agency became aware of the others' plans and avoided duplication of effort. CDC contributed to the development of the request for proposals issued by CSAP. This collaboration ensured that the CSAP funded program will be consistent with CDC's efforts.

Question. It is my understanding that the Surgeon General intends to issue a first-ever "Call to Action" on underage drinking prevention sometime this spring. What is the status of the "Call to Action" and its expected release date?

Answer. A Call to Action working group has developed a draft Call to Action, which will be reviewed by the Interagency Coordinating Committee on the Prevention of Underage Drinking (ICCPUD) member agencies in addition to the Department of Health and Human Services. The Surgeon General is committed to releasing the Call to Action at the earliest possible time.

PANDEMIC INFLUENZA PREPAREDNESS

Question. Congress has appropriated \$350 million for assistance to the States and localities for pandemic preparedness. The goal of that program is to assure that all localities meet a minimal level of preparedness. Is the Department planning to create a single, core set of performance standards that all jurisdictions must strive to achieve with these funds?

Answer. As part of the Public Health Emergency Preparedness Cooperative Agreement, CDC in conjunction with State and local public health agencies and laboratories, national partner organizations, and Federal agencies, developed performance measures for overall public health preparedness. These measures are for all-hazards, including pandemic influenza.

Question. As part of the initial (\$100 million) funding that the Department is allocating to localities for preparedness, grantees are expected to perform some kind of preparedness exercise. Will the Department be reviewing the after action reports from these exercises? And if so, what resources (financial and personnel) has the Department set aside to provide technical assistance to the States to help them mitigate the deficiencies found in these exercises?

Answer. All States submitted draft pandemic influenza preparedness and response plans to CDC in July 2005. As part of the \$100 million emergency supplemental funding, the Department, primarily through CDC project officers and Subject Matter Experts, will assist in developing, conducting, and evaluating various aspects of the pandemic influenza plans through the use of exercises. As part of the award of the remaining \$250 million in pandemic influenza supplemental funding, States will receive funds to “fill gaps” identified during the initial round of support. “Gaps” will be identified through two processes: first, by analyzing a comprehensive assessment conducted by local health departments measuring the many components of comprehensive influenza preparedness, and second, by analyzing results of exercises. Ongoing technical assistance will be provided by CDC.

Question. How much of the \$350 million has been released to the States and localities? By when does the Department expect these jurisdictions to have spent the funds? When will the remaining \$250 million be made available to the States and localities? Is there an expectation that the total \$350 million must be obligated or expended by the end of fiscal year 2006? If so, is this a realistic expectation?

Answer. States were awarded \$100 million on March 7, 2006 to conduct planning for pandemic influenza preparedness. Eighty percent of those funds were restricted pending receipt of their supplemental applications. The applications have been received and evaluated and CDC is in the process of releasing many of the restrictions. We anticipate releasing most of the remaining restrictions by May 17, 2006. The remaining \$250 million will be awarded later this summer. CDC does not anticipate that all funds will be expended by the end of the budget period. Recipients of funding may request for consideration that carryover funds to be awarded the next budget year.

Question. Given that one of the most critical aspects of preparedness will be the ability of local jurisdictions to rapidly distribute a pandemic vaccine, will the Department encourage States to organize mass vaccination exercises during the next flu season to test their distribution plans? If so, will the Department allow the States to use a portion of the \$350 million to purchase annual flu vaccine?

Answer. States are permitted to use Public Health Emergency Preparedness cooperative agreement funds to purchase vaccine in limited quantities for conducting drills and exercises. They are not permitted to purchase vaccine with the emergency supplemental funding for pandemic influenza preparedness. However, they may use some of these emergency supplemental funds during the influenza season as an opportunity to exercise mass vaccination plans.

PANDEMIC INFLUENZA VACCINE

Question. The U.S. Government will be contributing to the expanded production capacity of several manufacturing companies, who will use that capacity to produce and market seasonal flu vaccine in the absence of a pandemic. Given this unprecedented public investment in private corporations, is the Department taking steps to assure that the price charged public programs (e.g., Medicaid, Medicare) for seasonal flu vaccine is reflective of this investment?

Answer. Our goal is to be able to produce enough vaccine for every American within 6 months of a pandemic outbreak. To accomplish this goal, we have focused our efforts on developing a cell-based vaccine for influenza. Without this investment in new technologies, we will not be able to produce enough vaccine in the event of a pandemic. Another key element of our plan is to ensure that manufacturers expand capacity in the United States. It is our hope that these manufacturers will produce seasonal influenza vaccine in the absence of a pandemic, allowing us to provide coverage to more Americans.

PANDEMIC INFLUENZA SURGE CAPACITY

Question. Which HHS agency is in charge of assuring States and localities create the surge capacity for treating people who become ill during a pandemic?

Answer. The Office of Public Health and Emergency Preparedness (OPHEP) is the lead office in HHS for ensuring that States and localities create the surge capacity for treating people who become ill during a pandemic. OPHEP works closely with both HRSA and CDC to ensure that funding through the State and local cooperative agreements enhance surge capacity and pandemic influenza preparedness.

Question. Is the Department providing specific guidance and performance measures with respect to creating surge capacity? Has the Department estimated the cost of creating a minimum level of surge capacity?

Answer. An influenza pandemic in a large number of communities simultaneously would make the need for expanded medical surge capacity critical. The 2005 cooperative agreement guidance for the Health Resources and Services Administration

(HRSA) National Bioterrorism Hospital Preparedness Program provided performance benchmarks on surge capacity, including influenza. Specifically, grantees are required to establish systems that, at a minimum, can provide triage treatment and initial stabilization, above the current daily staffed bed capacity, for the following classes of adult and pediatric patients requiring hospitalization within 3 hours in the wake of a terrorism incident or other public health emergency—500 cases per million population for patients with symptoms of acute infectious disease—especially smallpox, anthrax, plague, tularemia, and influenza.

In addition, the National Strategy for Pandemic Influenza Implementation Plan released on May 3, 2006, includes guidance to Federal departments and agencies, State and local government, the private sector, and the public about how to prepare for a pandemic. With respect to surge capacity, the plan includes a number of actions (with performance measures) on which HHS will collaborate with our partners at the Federal, State, local, and tribal levels and in the private sector. These include developing protocols for changing clinical care algorithms in settings of severe medical surge (action 6.3.4.1), strategies for and protocols for expanding hospital and home health care delivery capacity (action 6.3.4.2), policies and protocols for emergency reimbursement or enrollment in Medicaid and State Children's Health Insurance Program that are appropriate for a pandemic (action 6.3.4.3), and ensuring that Federal medical assets are prepared to deploy to augment State and local capacity (actions 6.3.4.3 to 6.3.4.7). The Department is currently preparing the plan to implement these actions within the timelines specified in the National Strategy for Pandemic Influenza Implementation Plan.

PANDEMIC INFLUENZA PREPAREDNESS PLAN IMPLEMENTATION

Question. While significant funds are being invested in preparedness, when a pandemic hits the costs for Federal, State, and local governments will be significantly higher. Has the Department made an estimate of what the cost would be to implement its pandemic preparedness plans? For example, is there an estimate for what the actual pandemic flu vaccine will cost once it is available? Has the Department asked States and localities to estimate the costs of responding to the pandemic, as opposed to planning for one?

Answer. It will be difficult to estimate with certainty the costs of implementing our pandemic influenza plans because each State and local preparedness plan is unique and because we do not know if we will be responding to a mild or severe pandemic. We are currently focusing our efforts on preparing for a pandemic to mitigate costs during an outbreak by ensuring enough vaccine for every American six months after human-to-human transmission, enough antivirals for 25 percent of the population, and a stockpile of 20 million courses of pre-pandemic vaccine. We are also enhancing domestic and international surveillance to quickly detect a pandemic to slow its spread. We are working closely with States and local communities as they plan for a pandemic and to exercise those plans.

UNINSURED ACCESS TO PANDEMIC INFLUENZA TREATMENT

Question. Hospitals and other health care providers will bear the brunt of costs associated with a pandemic. During a pandemic we need to make sure that those who are uninsured are not deterred from seeking necessary care as early as possible. At the same time we don't want hospitals to have even higher levels of uncompensated care that could threaten their long-term financial viability. Has the Department considered what policies and funding might be needed to address this problem?

Answer. As described in the National Strategy for Pandemic Influenza Implementation Plan, HHS will work with State Medicaid and SCHIP programs to ensure that Federal standards and requirements for reimbursement or enrollment are applied with the flexibilities appropriate to a pandemic, consistent with applicable law. In addition, we are also examining the recommendations of Federal Response to Hurricane Katrina: Lessons Learned report to determine what policies might be needed to respond to public health emergencies, including a pandemic.

PANDEMIC INFLUENZA RESPIRATOR MASKS

Question. Last week the Institute of Medicine issued a report saying the respirator masks and surgical masks should not be re-used. The report also suggested that, as part of a larger strategy of infection control, N-95 respirator masks would offer some protection of health care workers. The WHO recommends use of these masks in a health care setting. How many N-95 masks does the United States now have stockpiled? How many N-95 masks are on order for the stockpile? Does the Department have an estimate of how many masks would be needed in the

healthcare system during a pandemic, when manufacturing and distribution of such masks may be hard to accomplish?

Answer. The Strategic National Stockpile has approximately 9.1 million N-95 masks on hand and 98.4 million N-95 masks on order. The Centers for Disease Control and Prevention estimates that up to 1.5 billion surgical masks and over 90 million N-95 respirators would be needed for the healthcare sector in the event of a severe pandemic. HHS purchased 150 million surgical masks and N-95 respirators in fiscal year 2006. The Federal Government, States, and the private sector share responsibility in ensuring an adequate level of preparedness. States have access to funding from Health Resources and Services Administration's (HRSA) National Bio-terrorism Hospital Preparedness Program to address these surge capacity needs.

MEDICARE INTEGRITY PROGRAM

Question. The Congress has provided significant funding, both mandatory and discretionary, to help CMS combat the unacceptably high payment error rate in the Medicare and Medicaid programs—literally hundreds of millions of dollars even after you have made some progress in reducing the error rate. Reportedly, over 90 percent of the Medicare Integrity Program funds, \$720 million per year have been diverted to fiscal intermediaries and carriers doing routine claims processing, leaving about \$50 million per year for the targeted error rate reduction contracts. What is the rationale for this diversion of resources from fraud and abuse activities?

Answer. MIP funds are not used by fiscal intermediaries and carriers in the performance of routine claims processing. Separate funding under the Program Management account is set aside for that purpose. These contractors, however, have historically been the first line of defense in the fight against fraud and abuse. Under the MIP, they have conducted medical review, fraud review, cost report audit, provider education and other activities identified in the statute. All of these activities are intended to insure that payments are made properly and that inappropriate payments are recovered. Under the medical review/local provider education program, FIs and Carriers are evaluated on their ability to reduce the improper error rate.

Additionally, a significant portion of the \$720 million in MIP funding is used by a host of specialty contractors, most notably the Program Safeguard Contractors, whose sole focus is fraud and abuse activities.

MEDICARE IMPROPER PAYMENTS

Question. The Congress just appropriated \$100 million this year for fraud and abuse activities in the new Part D prescription drug program. What are the Department's plans for using this money to address payment errors in the Part D program? When do you intend to commit funds this fiscal year?

Answer. The \$100 million appropriated in the Deficit Reduction Act (DRA) will be used for many different purposes to maintain the integrity of the prescription drug benefit and fight against fraud and abuse from all sources. CMS is in the process of committing the funds provided in the DRA and plans on using all of the funds by the end of the fiscal year.

CMS has developed a comprehensive plan for a Part D oversight program building off the approach that has worked successfully for Part A and Part B. CMS has established this plan in an effort to ensure that the funding provided in the DRA will help to combat fraud, waste, and abuse associated with the new prescription drug benefit. We have included strong safeguards in areas where we identified vulnerabilities, including eligibility, the bidding process, beneficiary plan, and retail pharmacy fraud, incentives to reduce cost and cost sharing, formulary development (kickbacks), and misuse of Part D beneficiary lists. This program will ensure that Part D contractors and other program stakeholders meet all applicable statutory, regulatory and program requirements.

CMS is expanding its efforts in fighting fraud and abuse in Medicare by using State of the art systems designed to prevent problems and maintain integrity for the new Medicare prescription benefit. A portion of the funding appropriated in the DRA will be used to develop and/or maintain the following program integrity systems:

- Risk Adjustment System (RAS).*—The system intended to vary the Federal share of premiums based on factors that are beyond the control of the drug plan;
- Medicare Advantage Prescription Drug (MARx) System.*—A stand alone system that will include the processing of all enrollment/disenrollment transactions associated with the Part D Program;

—*The Drug Data Processing System (DDPS)*.—The system that collects, maintains, and processes information on all Medicare covered and non-covered drug events for Medicare beneficiaries participating in Part D; and

—*The Medicare Beneficiary Database (MBD)*.—The database that houses Medicare beneficiary enrollment information.

CMS has contracted with program integrity contractors, known as Medicare Drug Integrity Contractors (MEDICs), to assist the Agency in overseeing the Medicare Part D program. Part of the \$100 million will be used to establish and support three MEDICs in the regions, in addition to the Eligibility and Enrollment MEDIC that began on November 15, 2005. The MEDIC contractors will:

- Analyze data to find trends that may indicate fraud or abuse;
- Begin to investigate potential fraudulent activities surrounding enrollment, the determination of eligibility, or the delivery of prescription drugs;
- Investigate unusual activities that could be considered fraudulent as reported by CMS, contractors, or beneficiaries;
- Conduct fraud complaint investigations; and
- Develop and refer cases to the appropriate law enforcement agency as needed.

In addition, CMS will support compliance activities to combat fraud, waste, and abuse in association with the drug benefit. These efforts will include the following strategies: (1) Part D compliance monitoring; (2) accreditation organization validation studies for Medicare Advantage plans; (3) Part D auditing; (4) other compliance and monitoring strategies; and (5) compliance and oversight training for Medicare Advantage plans.

CMS continues to work to ensure the integrity and validity of the data for the prescription drug benefit. The funding provided in the DRA will be used to monitor and evaluate prescription drug plans and Medicare Advantage plans to maintain data integrity. CMS' monitoring activities will include reviewing the plans' pricing and formulary to ensure that they follow the guidelines that have been established. In addition, CMS will review the data by performing payment validation of the plans.

CMS will also use part of the \$100 million to comply with the improper Payments Information Act of 2002 (IPIA). CMS is building on its current program integrity efforts by implementing new steps to analyze program data to detect improper payments and potential areas of fraud and abuse in the Medicare and Medicaid programs more quickly and accurately. CMS is using these analyses to more effectively educate providers and beneficiaries about ways to prevent and minimize waste, fraud, and abuse. CMS' program integrity efforts are being expanded beyond fee-for-service Medicare to encompass oversight of Part D prescription drug benefit and the new Medicare Advantage plans.

The last activity that will be supported by the funding provided in the DRA are audits. These audits will include financial audits of at least one-third of all Part D organizations' financial records including bids, data relating to Medicare utilization and allowable costs as mandated in the MMA. In addition, CMS will use the funding to audit one-third of the Medicare Advantage plans for adjusted community rates and perform various cost plan audits.

Question. The fiscal year 2006 Senate bill and conference report encouraged CMS to move forward on a \$3 million demonstration of the use of data fusion technology to detect payment error and fraud and abuse in the Medicare program. We understand that the agency is moving forward with a data fusion and analysis project to identify improper payments to providers from Medicare using data sources outside of current fraud recovery efforts. What can you do to get this program moving forward more quickly?

Answer. CMS will be competing contracts among the MEDICs to support and develop the Integrated Data Repository and an overall data infrastructure to support CMS fraud, waste and abuse efforts. This effort requires significant resources and will be funded with the \$3 million referenced in the Senate and conference reports and through the 1 year MIP funding provided in the DRA. We anticipate that this effort will integrate Medicare fee-for-service data, prescription drug data, and Medicaid data into one central repository.

CMS—STATUS OF QUALITY DEMONSTRATION PROJECT

Question. Mr. Secretary, last year alone there were over 1.3 million new cases of cancer diagnosed in America—I can't think of a single family who hasn't had a friend or family member affected by this terrible disease. The status quo is simply not acceptable. The last 2 years your department has taken targeted regulatory action to prevent any access disruption through a demonstration project to support the development of quality-based payment policy. I strongly urge you to continue this

important program and begin to move towards a permanent funding solution that will preserve patient access to community cancer care. Do you have any updates for the committee as to the status of the quality demonstration project?

Answer. CMS is very focused on creating a payment system that offers better support for the delivery of high-quality, low-cost care as well as improving the benefits available to America's seniors to prevent disease complications and live longer healthier lives. CMS has worked closely with the AMA, AQA, and MedP AC among others to develop consistent and effective ways to measure the quality of care.

We believe the oncology community is pleased with the improvements made in this year's oncology demonstration project. This project will enable us to capture more specific information about cancer patients including their treatments and whether current cancer care represents best practices and is provided in accordance with accepted practice guidelines.

After reviewing this year's data, we will be able to make decisions about the continuation of the demonstration project and what additional improvements or modifications are necessary for 2007.

CMS—ADEQUATE PROVIDER REIMBURSEMENT

Question. Mr. Secretary, when it enacted MMA, Congress established ASP as the reimbursement metric for prescription drugs covered under Part B of Medicare. My concern is that CMS has continued to resist using its administrative discretion to correct an ASP calculation problem that thwarts the clear legislative intent underlying the shift to ASP-based reimbursement. I am referring to CMS's insistence that it cannot exclude the prompt pay discounts that manufacturers give wholesalers from the calculation of ASP because the term "prompt pay discounts" appears in the list of price concessions that the statute says are to be netted out when ASP is calculated.

Wholesaler prompt pay discounts reward the timely completion of the wholesaler's product purchase from the manufacturer, constitute an integral part of the revenues received by wholesalers for their services, and, in my experience, are not passed on to the wholesalers' customers. By insisting that wholesaler prompt pay discounts be netted out of ASP, CMS has undermined Congress' intent that payment at ASP+6 percent should cover physicians' drug acquisition costs, allow for a reasonable level of pricing variability in the nationwide drug market, and provide compensation for drug-related costs that are not separately reimbursed. In essence, by requiring the inclusion of wholesaler prompt pay discounts in the ASP calculation, CMS has converted physician payments for Part B drugs from the congressionally mandated level of ASP+6 percent to the lesser amount of ASP+4 percent.

Based on the statute and congressional language offered at the time of its adoption, what is CMS' interpretation of congressional intent with regard to adequate provider reimbursement for drug reimbursement, and the application of the prompt pay discount to that reimbursement for oncology services?

Answer. The Congress defined the ASP to be an average measure of sale prices across a broad range of classes of trade and, therefore, established that payments to providers represent average drug acquisition costs and not the actual cost experienced by a particular provider or specific class of trade. Further, in establishing that the payment rates are 106 percent of the ASP, Congress established a corridor above the average acquisition cost to address variations in actual costs.

CMS interprets section 1847A(c)(3) to require manufacturers to deduct prompt pay discounts given on sales included in the ASP calculation from the ASP numerator (ASP=sales in dollars/units sold). The language in section 1847A(c)(3) is plain, "In calculating the manufacturer's average sales price under this subsection, such price shall include volume discounts, prompt pay discounts, cash discounts, free goods that are contingent on any purchase requirement, chargebacks, and rebates (other than rebates under section 1927). For years after 2004, the Secretary may include in such price other price concessions, which may be based on recommendations of the Inspector General that would result in a reduction of the cost to the purchaser."

In the preamble to the CY 2006 Physician Fee Schedule final rule (70 FR 70224), we stated that we lack the statutory authority to permit manufacturers to exclude prompt pay discounts from the calculation of the ASP. We continue to believe the use of "shall" and the limitations on the discretion to include other price concessions in the statutory language do not provide administrative discretion to exclude a statutorily named price concession from the ASP calculation.

CMS—PROMPT PAY DISCOUNT

Question. What evidence is available to CMS that the prompt pay discount is being passed along to the provider of oncology services? If the prompt pay discount is not being passed along to providers, how does CMS achieve the congressional intent to rationalize provider payments with actual costs?

Answer. CMS does not have evidence that prompt pay discounts are or are not being passed along to the providers of oncology services. CMS achieves the congressional intent by implementing the ASP methodology cited in section 1847A(c)(3).

CMS—REGULATORY AUTHORITY FOR REIMBURSEMENT

Question. Congress believes that CMS clearly has the administrative authority to put forward a regulation on provider reimbursement to resolve this issue. Does CMS share this view or is additional legislation necessary?

Answer. CMS does not believe it has the regulatory authority to exclude prompt pay discounts from the ASP calculation. The ASP statutory language is plain and provides limitations on modifying price concessions. We believe the section 1847A(c)(3) authority to adjust the price concessions is limited to those price concessions that would ultimately lower the ASP, whereas removing prompt pay discounts from the ASP calculation would increase Medicare expenditures.

QUESTIONS SUBMITTED BY SENATOR TOM HARKIN

MEDICARE FRAUD

Question. Mr. Secretary, as you know, I have a long record of fighting fraud, waste, and abuse in the Medicare and Medicaid programs. I know that CMS has addressed the issue of fraud in payments to suppliers for power wheelchairs. However, there is still concerns among legitimate suppliers that CMS is not doing enough to root out suppliers that are not legitimate.

I understand that CMS is developing tougher quality and accreditation standards for suppliers. When will these standards be released? And what is CMS doing to make sure that they only issue supplier numbers to legitimate providers? Are CMS's efforts to root out fraud and abuse in this area being hampered by a lack of resources?

Answer. CMS plans on issuing new draft quality standards for suppliers on its website this summer. CMS will then solicit accrediting organizations to review suppliers and assure that they meet the new quality standards. We anticipate that accreditation activities will start before the end of calendar year 2006. Currently, to ensure that only qualified suppliers are issued supplier numbers, we perform site visits prior to enrollment and re-enrollment (which is required every 3 years). We also perform additional reviews of potentially questionable suppliers. These reviews focus on questionable suppliers located in geographic areas where there is a high concentration of fraud and suppliers who have questionable patterns of billing and/or high claims error rates.

CMS—POWER WHEELCHAIRS

Question. On April 6 of this year, CMS published a new final rule that requires that power wheelchairs suppliers review a beneficiary's medical records and determine if a physician's prescription is supported by medical evidence before a power mobility device will be prescribed. What documentation are suppliers required to verify before filling a prescription for a power mobility device? Will CMS issue guidance for suppliers on documentation requirements—including the level of specificity of the documentation—in order to clarify any ambiguities regarding filling a legitimate prescription?

Answer. CMS would like to note that during the comment period of the interim rule, some suppliers noted that they were already experiencing a significant improvement in the timeliness, completeness and substantive content of medical record documentation submitted by physicians since the interim rule became effective. Along with the positive feedback from suppliers, CMS has not received any significant concerns from physician groups or other treating practitioners on this topic. In fact, one professional organization representing over 94,000 physicians and medical students expressed support for the elimination of the certificates of medical necessity (CMNs) for power mobility devices (PMDs).

As you are aware, the CMN for PMDs was eliminated. The CMN was originally designed to improve claims submission by allowing electronic transmission of certain data. Unfortunately, some in the industry saw the CMN as a substitute for evi-

dence of a physician's independent comprehensive examination and analysis of whether a PMD was medically necessary. Despite CMS' and its contractors' statements to the contrary, these suppliers treated the CMN as the ultimate instrument in determining coverage. Some suppliers went so far as to hire physicians to fraudulently complete CMNs. Furthermore, our analysis of claims has found that in approximately 45 percent of cases, statements claimed in the CMNs were not supported by the source information in the patient's medical chart.

Instead of a CMN, the Durable Medical Equipment Regional Carriers (DMERCs) will rely on the patient's medical chart to determine medical necessity. We are concerned that a one-page scripted form would not protect the Medicare program or its beneficiaries in the same way that source information culled directly from a patient's medical record would. The CMN did not help physicians or treating practitioners better document their patients' clinical needs for a PMD, it did not ensure that beneficiaries always received appropriate equipment, and it did not serve as an effective deterrent to fraud and abuse. We believe the beneficiary's physician or treating practitioner is in the best position to evaluate and document the beneficiary's clinical condition and PMD medical needs, and good medical practice requires that this evaluation be adequately documented. Thus, to minimize the documentation requirements for providers while assuring that documentation is adequate, physicians and treating practitioners will now prepare written prescriptions (as required by MMA section 302 and the final rule) and submit copies of relevant existing documentation from the beneficiary's medical record, rather than having to transcribe medical record information onto a separate form such as a CMN.

The rule describes the information that must be included in the written prescription: beneficiary's name, date of the face-to-face examination, diagnoses and condition that the PMD is expected to modify, a description of the item being prescribed, the length of need, the prescribing physician's signature and date of signature. This model provides structure while maintaining appropriate flexibility for the prescribing physician or treating practitioner. Only about 10 percent of physicians and treating practitioners prescribe a PMD for a Medicare beneficiary in any given year, and the majority of those physicians and treating practitioners only prescribe one or two PMDs a year. Given the myriad of forms, brochures, requisitions and similar items in a typical physician's office, a requirement to have a specific prescription form handy in the event that it might be needed would impose an unnecessary burden on the physician and other treating practitioners when that form would only be needed once or twice a year for most prescribers, and never actually needed for the vast majority.

Finally, the physician or treating practitioner must sign the prescription for the PMD and is, therefore, accountable for documentation of the medical need for the device. We believe that this required signature and source documents in the patient's chart effectively document the physician's attestation that the medical need for the device is legitimate.

CMS and the DMERCs have provided extensive educational outreach to both suppliers and the medical community pertaining to the documentation requirements for PMDs. Examples of formal communication include CMS program instructions, Medlearn Matter articles, and DMERC supplier articles explaining the new responsibilities of suppliers. In addition, medical review activities vary depending on the situation under review. CMS cannot develop an all inclusive list of documents or information that Medicare contractors may request during audits. When requesting additional documentation, the DMERCs write to suppliers and ask for the specific documentation or information needed for a review. CMS has defined the circumstances under which contractors request additional information in the Program Integrity Manual. Local Coverage Determinations are issued by our contractors to describe in more detail the conditions under which Medicare payment is made. This additional documentation is only collected during the course of medical review audits and does not need to be collected for all claims.

MEDICAID/SPECIAL EDUCATION BENEFITS

Question. This question concerns Medicaid and special education. I asked Education Secretary Spellings about it at our hearing with her in March, but she said I needed to ask you, so I'd like to do that now.

Under current law, Medicaid pays for the cost of covered services for eligible children with disabilities. School districts can also be reimbursed by Medicaid for the transportation and administrative costs they incur in providing these services. But now the administration wants to prohibit schools from getting reimbursed for those costs. In fiscal year 2007, schools are expected to receive \$615 million from Medicaid for transportation and administrative costs. If this change goes through, they'll have

to pay the \$615 million themselves, and many will have great difficulty doing so. I'm concerned about this, because if schools can't pay the transportation costs to children with disabilities, the children won't end up getting the services.

Does CMS plan to implement this cut? If so, where do you recommend that schools find the money to make up the difference?"

Answer. Appropriate Medicaid services will continue to be reimbursed as allowed under current law. However, claiming for certain Medicaid services in school settings has proven to be prone to abuse and overpayments. Schools provide a wide range of medical services to students, which may or may not be reimbursable under the Medicaid program. Problem areas include but are not limited to school bus transportation and administrative claiming, as well as direct medical services. The fiscal year 2007 budget proposes administrative actions to phase out Medicaid reimbursement for some services, including school bus transportation and administrative claiming related to Medicaid services provided in schools.

According to section 1903(a)(7) of the Social Security Act (the Act), for the costs of any activities to be allowable and reimbursable under Medicaid, these activities must be "found necessary by the Secretary for the proper and efficient administration of the plan" (referring to the Medicaid State Plan). Additional authority derives from section 1902(a)(17) of the Act, which requires that States take into consideration available resources. Through the authority of these statutes, the administration proposes to prohibit Federal reimbursement for transportation provided by or through schools to providers.

HHS has had long-standing concerns about improper billing by school districts for administrative costs and transportation services. Both the Department's Inspector General and the General Accountability Office (GAO) have identified these categories of expenses as susceptible to fraud and abuse. GAO found weak and inconsistent controls over the review and approval of claims for school-based administrative activities that create an environment in which inappropriate claims generated excessive Medicaid reimbursements. Audit findings from States where the OIG conducted administrative claiming audits have shown egregious violations. Proper and accurate claiming for administrative services has not been carried out in compliance with applicable Medicaid regulations. Overall, the leading conclusions from these audits are that most States use an improper allocation methodology and insufficient attention is paid to the details of the claiming process.

The fiscal year 2007 President's budget includes a regulatory proposal that would prohibit Federal Medicaid reimbursement for Medicaid administrative activities performed in schools. It additionally proposes that Federal Medicaid funds will no longer be available to pay for the transportation to and from school related to medical services provided through an Individualized Education Program (IEP) or Individualized Family Service Plan (IFSP).

Schools would continue to be reimbursed for direct Medicaid services identified in an IEP or IFSP provided to Medicaid eligible children, such as physical therapy and occupational therapy that are important to meet the needs of Medicaid-eligible students with disabilities, as long as the providers meet Medicaid provider qualifications. CMS estimates that these proposals will save \$0.6 billion in fiscal year 2007 and \$3.6 over 5 years.

SPECIAL EXPOSURE COHORTS

Question. The Labor HHS Appropriations Act of 2006 (Public Law 109-149) requires NIOSH to prepare a report within 180 days of enactment evaluating whether there are additional radiosensitive cancers not already on the list of 22 cancers eligible for compensation under the Special Exposure Cohort provision of EEOICPA and RECA that should be eligible for compensation. Will NIOSH deliver this report to Congress on schedule?

Will NIOSH solicit comments from experts in radiation epidemiology before submitting this report?

Answer. NIOSH is currently working on finalizing this report and is seeking comments from a set of experts with diverse expertise and perspective, including experts in radiation epidemiology. The report will be peer-reviewed prior to submission. We are working as quickly as possible to obtain comments/edits from the outside reviewers to expedite the process.

Question. The Office of Management and Budget recently issued a "Passback" memo to the Department of Labor, which called for options to "contain the growth in benefits" from new Special Exposure Cohorts under the Energy Employee Compensation law. To accomplish this, the memo outlines options including administration clearance of all Special Exposure Cohorts before a decision is made by you as Secretary of Health and Human Services. Has your Department formulated a legal

and policy response to the OMB memo and if so, could you please share that response with the Committee?

Answer. The National Institute for Occupational Safety and Health (NIOSH) is responsible for receiving and scientifically evaluating petitions from classes of workers seeking inclusion in EEOICP A's Special Exposure Cohort. NIOSH carries out this responsibility under regulations promulgated in May 2004, and amended in December 2005, to make the rule consistent with the amendments to EEOICPA contained in the Ronald W. Reagan National Defense Authorization Act for fiscal year 2005. In fulfilling this duty, NIOSH evaluates the feasibility of scientifically estimating radiation dose for workers in the class that is petitioning for inclusion in the SEC. If a dose estimate is not feasible, NIOSH evaluates whether or not the health of the workers in the proposed SEC class was potentially endangered by their radiation exposure.

NIOSH presents its scientific and technical evaluation findings and recommendations to the Presidentially appointed Advisory Board on Radiation and Worker Health (the Board), a chartered Federal Advisory Committee. The Board considers the NIOSH evaluation and then makes a recommendation to me to either add or not add the class of workers to the SEC. My decision about whether or not to add the class members to the SEC is based on the following: the requirements of the law and the above-mentioned regulations, the NIOSH findings and its recommendation to the Board, and the recommendation of the Board.

QUESTIONS SUBMITTED BY SENATOR DANIEL K. INOUE

HEALTH CENTERS PROGRAM

Question. I would like to express my sincere appreciation to Dr. Elizabeth Duke for her continued support and interest in the extension of health care service delivery networks to the underserved residents in some of the most geographically isolated communities in Hawaii. In particular, I am pleased with consideration to the future establishment of a health center on Lana'i. Through the establishment of these health centers, significant improvements have been noted in access, quality, and continuity of care. All of which are integral to the early detection, diagnosis and intervention in a myriad of potentially debilitating diseases.

Answer. Thank you for your support of our work in the Health Centers program. This program is integral to our mission to enhance the health and well-being of Americans by providing for effective health and human services

EMERGENCY MEDICAL SERVICES FOR CHILDREN

Question. As expressed last year, I am very concerned that once again the Emergency Medical Services for Children (EMSC) program has not been included in your budget. It can not be stressed often enough that the emergency care and resuscitation of children is uniquely different from adult resuscitation. One size does not fit all in the emergency care of children. There is great disparity in the quality and availability of emergency services for children across this country. While other programs are directed at ensuring the adequacy of adult emergency care services, this is the only program specifically directed at saving the lives of children. How does the Department plan to ensure that America's children receive the emergency care they deserve with no targeted funding?

Answer. States, through the Maternal and Child Health Block Grant program, can continue to fund these specialized services.

BACCALAUREATE TO DOCTORAL PROGRAMS

Question. A long-standing supporter of the National Institute for Nursing Research, I am pleased that the administration has continued funding of this program. However, what impact will the \$1 million reduction have on the National Institute of Nursing Research's development of initiative that supports fast-track baccalaureate-to-doctoral programs? These programs were proposed to help increase the number of nursing faculty and in turn decrease the number of qualified nursing school candidates who were turned away in prior years.

Answer. The overall reduction of \$792,000 in the fiscal year 2007 budget request of \$136.6 million for the National Institute of Nursing Research (NINR) will have no impact on its programs that fast-track baccalaureate-to-doctoral nurses to increase the number of nursing investigators. These programs are supported within the Research Training mechanism in NINR, and the fiscal year 2007 President's budget maintains the current level of support of this activity. NINR remains committed to developing the next generation of nurse scientists. NINR encourages and

supports strategies to change the career trajectory of nurse scientists. The Institute emphasizes early entry into research careers, including fast-track baccalaureate-to-doctoral programs, and supports pre-doctoral and postdoctoral nurses who are the future researchers and nursing faculty.

QUESTIONS SUBMITTED BY SENATOR HERB KOHL

GENERIC DRUGS/FDA

Question. The FDA currently has a backlog of more than 800 generic drug applications—an all-time high—and FDA officials expect a record number of generic applications this year and an even larger backlog. The congressional Budget Office estimates the use of generics provides a savings of \$8 to \$10 billion to consumers every year, and that doesn't include the billions of dollars of savings to hospitals, Medicaid and Medicare. It is now more important than ever that we speed less expensive generic drugs to market.

Secretary Leavitt, do you support an increase in the FDA budget to help reduce the backlog? How much do you believe the FDA needs to efficiently reduce the backlog and pass along the savings to Americans and the Federal Government?

Answer. First, let me state that I understand that Congress and the public are concerned about the high cost of prescription drug products. I believe that generic drugs play a very important role in granting access to products that will benefit the health of consumers and the government. Prompt approval of generic drug product applications, also known as abbreviated new drug applications, or ANDAs, is imperative to making generic products available to American consumers at the earliest possible date. This has been a high priority for FDA as it has been for me during my time here at HHS. I believe that the process improvements that FDA is currently implementing along with the investments we continue to make in generic drugs offer the best promise for reducing ANDA review time.

FDA has made significant investments to improve the generic drug review process with the funds appropriated by Congress. In fiscal year 2007, FDA plans to spend \$64.6 million relating to generic drugs, including \$29 million in the Office of Generic Drugs, or OGD. This level represents an increase of more than 66 percent from the comparable fiscal year 2001 amount, which has resulted in a lower median review of 2 months.

FDA has made significant process improvements to increase the efficiency of the ANDA review process. In fiscal year 2005, OGD focused on streamlining efforts and took steps to decrease the likelihood that applications will face multiple review cycles. OGD instituted additional enhancements to the review process such as early review of the drug master file as innovator patent and exclusivity periods come to an end, cluster reviews of multiple applications, and the early review of drug dissolution data.

In fiscal year 2006, FDA is building on these process improvements. FDA began a major initiative to implement Question-based Review for assessment of chemistry, manufacturing, and controls data in ANDAs. This mechanism of assessment is consistent with the International Conference on Harmonization Common Technical Document and will enhance the quality of evaluation, accelerate the approval of generic drug applications, and reduce the need for supplemental applications for manufacturing changes.

FDA's OGD will continue to institute efficiencies in the review process to facilitate the review and approval of ANDAs in fiscal year 2007 and beyond. FDA will also continue to work closely with generic manufacturers and the generic drug trade association to educate the industry on how to submit applications that can be reviewed more efficiently and that take advantage of electronic efficiencies that speed application review. FDA will also work with new foreign firms entering the generic drug industry. It will take time for these new firms to understand the requirements for generic drug product applications. However, in the long-term, these efforts will shorten overall approval time and increase the number of ANDAs approved during the first cycle of review.

With the process improvements stated above and the investments we continue to make in generic drugs, FDA will continue to reduce ANDA review time and deliver safe and effective generic drug products to the American public.

PROGRAMS SERVING OLDER AMERICANS

Question. Some of the most painful cuts in this budget are programs under the administration on Aging, which takes a \$28 million hit in programs like Meals on Wheels and Family Caregiver Support Services. That means that while Wisconsin's

senior population continues to grow—from 705,000 senior citizens in 2000 to 730,000 seniors this year and 1.2 million seniors by 2025—this budget does not account for the growth in the need for services.

In addition, this budget proposes to eliminate Alzheimer Demonstration grants. The Wisconsin Alzheimer Association is in its first year of a 3-year grant, where they are working with Jefferson County to open a dementia care clinic at a hospital in Fort Atkinson. It is the first of its kind and the only one in the area. They would lose their funding after this year should this budget prevail.

How do you explain the administration's plan to cut these vital programs when our aging population is growing?

Answer. The fiscal year 2007 President's budget includes the elimination of the Alzheimer's Disease Demonstration Grant to States Program (ADDGS), Preventive Health Services program, and small cuts to other AoA programs including a reduction of \$906,000 to Home-Delivered Nutrition Services and \$1,980,000 to Family Caregiver Support Services. These reductions reflect an effort to reduce the deficit while focusing on programs that provide needed services most efficiently.

For 14 years under ADDGS, demonstrations in almost every State have highlighted successful, effective approaches for serving people with Alzheimer's. Now, it is time to put these models and the lessons that have been learned to work by moving them into AoA's core services programs—especially the National Family Caregiver Support Program—as a number of States have already done.

Preventive Health Services is a limited, formula-grant funding stream intended to foster the provision of health promotion/disease prevention services in the context of the core community-based long-term care services of the National Aging Services Network. AoA's proposal under the Choices for Independence initiative supports the same type of evidence-based health promotion and disease prevention.

The Home-Delivered Nutrition Services and Caregiver Support Services programs have demonstrated efficiencies in leveraging Federal dollars. In addition, demonstrations such as Choices for Independence are aimed at increasing even further the efficiency of these programs. While reductions in Nutrition and Caregiver services reflect an effort to reduce the deficit, they also reflect an effort to target reductions in programs that have the greatest potential to maintain service delivery with fewer dollars.

RURAL HEALTH

Question. Secretary Leavitt, there are a number of programs within your Department aimed at bolstering rural health. Wisconsin, one of the biggest beneficiaries in the country, received over \$600,000 from the Rural Hospital Flexibility Grant program last year. This funding is used at over 60 rural hospitals that serve anywhere from 10,000 to 20,000 patients per year. The President's budget proposes to eliminate the Rural Hospital Flexibility Grant program, the Rural and Community Access to Emergency Devices, and Area Health Education Centers.

How are rural communities expected to meet their unique health care challenges when their resources are being slashed?

Answer. The Medicare Prescription Drug, Improvement and Modernization Act (MMA) will increase Medicare spending in rural America by \$25 billion over the 10 years following MMA enactment, substantially increasing funding for hospitals and other rural health providers. This Act serves as a catalyst in rural communities by increasing payments to hospitals, health professionals and other services. In addition, the budget includes an additional \$181 million to provide added direct health services to underserved communities through 302 new and expanded health center sites—about half of which are likely to be in rural areas.

MEDICARE DRUG BENEFIT ENROLLMENT DEADLINE

Question. Less than 2 weeks remain for most Medicare beneficiaries to sign up for prescription-drug coverage without penalty. Yet last week a Kaiser Family Foundation poll found that only 55 percent of seniors realize the deadline is May 15, and only 53 percent know enrolling after the deadline will cost 1 percent more per month. Earlier this year, the Senate voted to give you authority to extend the enrollment deadline, but the House has not yet acted. Do you support Congress passing legislation to extend the deadline?

Answer. We are focused on enrolling people now, while the resources are in place to help beneficiaries get the savings and security of prescription drug coverage. According to the Office of the Actuary at CMS, keeping the current May 15th deadline encourages beneficiaries to take action and enroll. The actuaries believe that extending the deadline would likely decrease overall enrollment in 2006 as pressure on beneficiaries to enroll would be diminished. However, in light of the cost effects

on our vulnerable populations, we have recently waived late-enrollment penalties for beneficiaries approved for low-income subsidies if they enroll in a drug plan by the end of 2006.

Proposals to extend the enrollment deadline beyond May 15 include no funding for Medicare to maintain the high level of enrollment support that is available right now. Beneficiaries should be encouraged to take advantage of outreach resources like the 1-800 MEDICARE telephone line. There are short waiting times now and individual, one-on-one counseling is available to help people select a coverage plan.

Tens of thousands of beneficiaries are currently enrolling every day, and there is still time to enroll in a plan.

NATIONAL INSTITUTES OF HEALTH FUNDING

Question. The President's American Competitiveness Initiative states that sustained scientific advancement is the key to maintaining our competitive edge—and I agree with that. The President's fiscal year 2007 budget proposal commits \$5.9 billion to research and education in basic science, that is the physical sciences—and I agree with that as well. What I don't understand is why the President would, in the same budget proposal, flat fund the National Institutes of Health and its research into health sciences and biotechnology. Other industrialized countries are making investments to make sure they get a piece of the growing biotech and health care sectors of the world economy—why aren't we?

Answer. In fiscal year 2003, President Bush fulfilled his commitment to complete the historic doubling of the NIH budget, which grew from \$13.6 billion in fiscal year 1998 to \$27.2 billion in fiscal year 2003. During this 5-year period, NIH was able to fund nearly 11,600 more research grants than it did before the doubling began, representing research ideas that are leading to vaccines, cures, treatments, and other fundamental scientific breakthroughs helping to open up even more new opportunities for improving human health.

With the fiscal year 2007 budget request of \$28.6 billion, the NIH budget will have grown by +\$8.1 billion, or +40 percent, during this administration. While the fiscal year 2007 request for NIH is a straight-line from the fiscal year 2006 level, NIH plans to continue to make strategic investments in trans-NIH initiatives and priorities within its available funds. These include increased support for new investigators, new research project grants, and the NIH Roadmap for Medical Research, a new initiative on Genes, Health and the Environment, and expansion of the Clinical and Translational Science Award program launched in fiscal year 2006. The NIH budget also includes increased investments in national priorities related to developing biodefense countermeasures and pandemic influenza diagnostics, vaccines, and therapeutics. These initiatives will preserve our investment in biomedical research and support medical advancements that will make healthcare more predictive, personalized, and preemptive and thus, improve the length and quality of human life.

NIH welcomes the proposed increase in funding for the physical sciences. Biomedical research is becoming increasingly multi-disciplinary, requiring both science and mathematics to conduct projects in emerging areas of great scientific promise, such as bioinformatics, computational biology, nanotechnology, tissue engineering, and biomedical diagnostic imaging, to name just a few.

SUBCOMMITTEE RECESS

Senator SPECTER. Thank you all very much. The subcommittee will stand in recess to reconvene at 8:30 a.m., Friday, May 19, in room SD-192. At that time we will hear testimony from the Hon. Elias A. Zerhouni, M.D., Director, Department of Health and Human Services.

[Whereupon, at 11:30 a.m., Wednesday, May 3, the subcommittee was recessed, to reconvene at 8:30 a.m., Friday, May 19.]

**DEPARTMENTS OF LABOR, HEALTH AND
HUMAN SERVICES, EDUCATION, AND RE-
LATED AGENCIES APPROPRIATIONS FOR
FISCAL YEAR 2007**

FRIDAY, MAY 19, 2006

U.S. SENATE,
SUBCOMMITTEE OF THE COMMITTEE ON APPROPRIATIONS,
Washington, DC.

The subcommittee met, at 8:31 a.m., in room SD-192, Dirksen Senate Office Building, Hon. Arlen Specter (chairman) presiding.
Present: Senators Specter, Shelby, and Harkin.

DEPARTMENT OF HEALTH AND HUMAN SERVICES

NATIONAL INSTITUTES OF HEALTH

STATEMENT OF ELIAS A. ZERHOUNI, M.D., DIRECTOR

ACCOMPANIED BY:

JOHN E. NIEDERHUBER, M.D., ACTING DIRECTOR, NATIONAL CAN-
CER INSTITUTE

FRANCIS S. COLLINS, M.D., DIRECTOR, NATIONAL HUMAN GENOME
RESEARCH INSTITUTE

ANTHONY S. FAUCI, M.D., DIRECTOR, NATIONAL INSTITUTE OF AL-
LERGY AND INFECTIOUS DISEASES

ELIZABETH G. NABEL, M.D., DIRECTOR, NATIONAL HEART, LUNG,
AND BLOOD INSTITUTE

OPENING STATEMENT OF SENATOR ARLEN SPECTER

Senator SPECTER. Good morning, ladies and gentlemen. The Appropriations Subcommittee on Labor, Health, Human Services, Education, and Related Agencies will proceed with this hearing on the National Institutes of Health, and the funding for these institutes. We have a rather unusual hearing this morning because we have asked representatives of groups advocating research on the major illnesses—heart, cancer, Alzheimer's, Parkinson's—some 20 in total, to underscore the difficulties facing medical research in the United States today.

As it is well known, this subcommittee, Senator Harkin and I, have taken the lead on NIH funding, which has grown from \$12 billion to \$29 billion over the past 10 years. Now we have seen the increases which we had structured by, candidly, robbing Peter to pay Paul. We have a very complex budget on this subcommittee which has to fund not only health but education, labor, worker safety, Head Start, the bulk of the social programs.

Those programs have been cut in the last 2 fiscal years, taking into account actual cuts and inflation, cut by some \$15.7 billion. The NIH, which I frequently say is the crown jewel of the Federal Government, if not the only jewel of the Federal Government, has been cut 10.4 percent in the last 2 years. We find that in fiscal year 2006 there was an actual cut of almost \$66 million.

The funding for fiscal year 2007 is level by the administration. That means with the inflationary increase there is a decrease in the actual dollars which are available. That is just unacceptable in a country with an \$11 trillion gross national product and a Federal budget of \$2.8 trillion.

The advances that have been made by medical science are really remarkable, but it takes funding to accomplish that. Something personal to me is the lack of adequate funding for the National Cancer Institute. In 1970 President Nixon declared war on cancer and if that war had been pursued with the same intensity as our other wars cancer would have been cured long ago.

My chief of staff, Carey Lackman, a beautiful young woman of 48, died of cancer, breast cancer, recently. My son's partner's wife, a beautiful young woman, died of breast cancer. One of my best friends, Judge Edward Becker, one of the most distinguished jurists in America, is suffering great anguish and great pain as we speak from prostate cancer. I had a bout with Hodgkin's last year myself and if you see me dabbing my eyes that is one of the remnants of chemotherapy. Had the Nixon war on cancer been pursued, I think I would not have gotten Hodgkin's and Carey Lackman would not have died, Paula Klein would not have died, Ed Becker would not be in the dire straits he is today.

It is just unconscionable that we are not doing more. That is tied to stem cell research. Again, Senator Harkin and I have taken the lead there with our legislation which would enable, authorize, take the bar away from the Federal Government supporting embryonic stem cell research. We had a meeting yesterday with Senator Frist, the Majority Leader. I believe we are going to have a vote very soon on our issue. It is doubtful that we have 67 to override a presidential veto and we are talking about organizing a march on The Mall. We would like to put 1 million people on The Mall in September, enough people on The Mall to be heard in the living quarters of the White House just a few blocks away, because the estimate of 110 million people being affected directly or indirectly by these ailments is enough to produce two-thirds to override a presidential veto if in fact the President carries out his statement that he will veto the bill.

Well, we have a very long hearing today. We moved the hearing from 9:30 to 9:00 and then we moved it from 9:00 to 8:30 because Senator Harkin has commitments in Iowa. I am a little more flexible. I only have to travel to Pennsylvania. But we have a hearing this afternoon in Philadelphia on campus safety. It is a very, very busy Congress and I think you have seen that from the activities on the confirmation of the Supreme Court justices and the immigration bill, the Patriot Act, and so many other things we are doing.

But I do not believe there is any subject as important as this one. You keep hearing "nothing more important." Well, we may be tied

for first place. I do not think that it is true that there is no subject more important than this one. I do not think there is any subject as important as this one. This is number one. Without health there is nothing.

Senator Harkin.

STATEMENT OF SENATOR TOM HARKIN

Senator HARKIN. Mr. Chairman, thank you very much for your very eloquent opening statement. I would ask that all my statement be made a part of the record. I will just comment on it here.

First, let me thank you, Mr. Chairman, for your courageous leadership in this area of always fighting for the funding we need for NIH. You led the way on building the funding over those years. I was happy to backstop you and support you in that. It was a very courageous effort that you led on that.

I thank you also for your courage in speaking out on the budget earlier this year and your continuing to speak out against the budget as it affects NIH.

Let me also thank you for your own personal courage in battling Hodgkin's lymphoma last year and the example that you set in coming to work every day and holding the hearings in the Judiciary Committee and the Supreme Court nominees and taking it to the floor even while you were undergoing some pretty severe chemotherapy. So it was a great example, I think, of personal courage and we thank you for that.

I would just remind everyone of what Senator Hatfield said. When Senator Hatfield left the Senate, he gave his final speech on the Senate floor. I will never forget. I was over there to listen to it. He said at the time, he said: It is not that the Russians are coming. He said: It is the viruses are coming, the viruses are coming. How prophetic, how prophetic.

We did not work hard to double the funding of NIH to then have it plateau off for another 20 years. The idea was to get it back up where it had been in the 70s, where we had some 40-some percent of our peer reviewed grants approved and funded. That had fallen down and now I think it is down to about—I do not have it in front of me. I think it is down to about 19 percent right now, the lowest ever, the lowest ever.

The problem—not only is it a problem this year in terms of the budget—yes, it is 19 percent right now. About one out of every five is accepted for funding. I think that is having a ripple effect on researchers, it is having an effect on young people who are thinking about research as a lifetime avocation.

But the problem is also looking ahead. As bad as this year's budget is, next year's could be worse. According to OMB projections, the administration will cut NIH by \$800 million in 2008 and make more cuts in 2009 and fiscal year 2010.

Something has got to be done about this. Again, Senator Specter, you have been tremendously courageous in speaking out and trying to get a better deal for us on the budget. But we need to hear from you at NIH, but we also need to hear from the groups that are coming later, to tell the human side and give the human face as to what is happening to so many people in our society.

PREPARED STATEMENT

I have a friend of mine who at this very moment is in the final stages of ALS disease. It is one of the worst things you can imagine. Yet we dither around and we cannot get stem cell research going in this country?

Well, again, Mr. Chairman, thank you. It has been an honor to work with you.

[The statement follows:]

PREPARED STATEMENT OF SENATOR TOM HARKIN

Thank you, Mr. Chairman. You've led the way on NIH funding, and it's been a real honor working with you on this issue.

Good morning, Dr. Zerhouni, and welcome. We're glad to have you back with us today.

We need a strong NIH now more than ever, for so many reasons. First, our security as a Nation depends on it. We often think about security only in military terms. But in today's world, we need to be just as worried about the threats we face from a bioterrorism attack or pandemic flu. NIH research is critically important for protecting us in both of those areas.

We also need NIH to help us through our health care crisis. Consider just one disease—Alzheimer's. It's been estimated that delaying the onset of Alzheimer's by just 5 years could save \$50 billion a year in medical costs. That would go a long way to solving our Medicare problems all by itself.

We need NIH now, because we're on the cusp of so many exciting breakthroughs. Researchers are learning how to match drugs to individual patients, based on their genetic code. They're learning more about stem cell research. They're making discoveries about the interplay between our genes and the environment.

What a shame, then, to get a budget like the one the President has sent us.

His budget would level-fund NIH, one year after the first cut to this agency since 1970. Eighteen of the 19 institutes would get less funding than they did last year. The number of research project grants would drop by about 640. And the success rate for grant applications would remain at a record low of just 19 percent.

We're at a point now where only 1 out of every 5 grant applications is accepted for funding. I'm sure there are a lot of young researchers out there who are wondering, "Why bother applying to NIH? Why bother going into research at all?"

Senator Specter and I didn't work so hard to double NIH funding just so we could watch the President cut it to the bone from then on out. But that seems to be the President's plan. As bad as this year's budget is, next year's will probably be even worse. According to OMB projections, the Administration will cut NIH by \$800 million in fiscal year 2008, and make more cuts in fiscal year 2009 and fiscal year 2010.

We're going to hear firsthand what the President's budget will mean for many diseases from our second group of speakers. I want to thank the representatives of the 20 advocacy groups that are with us today for taking the time to be here.

Mr. Chairman, I look forward to the testimony.

Senator SPECTER. Thank you very much, Senator Harkin. Thank you for your leadership on these issues and the partnership which I think has been very productive for our country.

Senator Shelby.

STATEMENT OF SENATOR RICHARD C. SHELBY

Senator SHELBY. Thank you, Mr. Chairman. Mr. Chairman, I ask that my written statement be made part of the record and I will be brief.

This is a very important hearing and I am here this morning to help you. I think the President, George W. Bush, is going to have to speak out on this issue, that is properly funding NIH medical research. We are falling behind and we cannot, because we have led the world. We continue to lead the world, although we are struggling as far as finances are concerned.

Mr. Chairman, you and Senator Harkin, who are the leaders of this committee, I can tell you I am going to do everything I can. We are challenged in the research everywhere in biomedical, but in autoimmune areas there is a lot of hope there. I am particularly interested in the lupus area. We are challenged there. I am going to do everything I can as a member of the Appropriations Committee to help fund, properly fund, medical research through NIH. You have made a difference and you will make a tremendous difference in the future.

PREPARED STATEMENT

But, as Senators Specter and Harkin both know, it is not going to be easy, but we cannot go backward. We cannot cede this to anybody else in the world. We are the leaders. We have got to stay there.

Thank you, Mr. Chairman.
[The statement follows:]

PREPARED STATEMENT OF SENATOR RICHARD C. SHELBY

Mr. Chairman, thank you for holding this important hearing today. I want to thank all of you for taking the time to be here today. It is vitally important for me to hear directly from you on what your agency's needs are, and the challenges you might face in the coming months. We as a Nation are facing an integral moment in funding critical research. Finding viable treatments and possible cures for many of our common afflictions is our most important goal, but I think early detection of disease is fundamentally important to containing costs in the long-term.

As we begin to move forward in the appropriations process it is of the utmost importance that we ensure adequate funding for these indispensable research institutions. Millions of Americans rely on the life saving work they perform and it is imperative that we as appropriators fully support them.

Federal funding for medical research is critical and while we have worked diligently to increase funding, more is left to do.

I am hopeful that this hearing today will provide a forum to discuss the issues that must be addressed by researchers.

Thank you for your time and I look forward to your testimony.

Senator SPECTER. Thank you very much, Senator Shelby.

We now welcome Dr. Elias Zerhouni, the Director of the National Institutes of Health. He had an illustrious career before coming to be the 15 Director of NIH. He had been executive vice dean at Johns Hopkins University School of Medicine, chair of the Department of Radiology and Radiological Science. He received his medical degree from the University of Algiers School of Medicine and completed his residency in diagnostic radiology at Johns Hopkins.

Thank you for your leadership in this very vital area, Dr. Zerhouni, and we look forward to your testimony.

SUMMARY STATEMENT OF DR. ELIAS A. ZERHOUNI

Dr. ZERHOUNI. Thank you, Mr. Chairman. Thank you, Senator Harkin, Senator Shelby. I submitted a written testimony. What I would like to do really is just summarize the salient points of the testimony, to allow as much time as possible for questions.

Senator SPECTER. Thank you, Dr. Zerhouni.

Dr. ZERHOUNI. What I would like to do is really direct your attention to the screens.

RETURN ON INVESTMENT ON NIH FUNDING

What I would like to address are the fundamental questions that I think all of us would like to have an answer to, to be able to set policy for the future. First and foremost, what is the return on the American people's investment at the National Institutes of Health? Second, what has this NIH budget doubling delivered for the American people? Third, what is our future strategy? Where is NIH heading? When you talk about medical research it is important to understand that it is not a 100-meter dash, it is a marathon, and we have to sustain the effort over time.

First, let me just remind everyone that biomedical research has delivered enormous returns to the American people. I am just going to give two examples here. Many more are in the testimony. In coronary heart disease, if you look at the progress over the past 30 years, there has been a 63 percent decrease in mortality. Over a million early deaths are averted every year because of the research of the past 30 years. Economists tell us that this is worth \$2.6 trillion in economic return because a cohort of individuals who would have died in their 50s now do not and then can produce economic return. We have enormously exciting, effective strategies for not only curing, but preventing and ultimately eliminating coronary heart disease.

Now, you may ask yourself, what was the investment that the American people, that each one of us made to achieve that? Well, over the past 30 years each one of us has spent about \$3.70 per year for medical research related to coronary heart disease. If you look at the total cumulative total over 30 years for heart research, it is \$110 per person. I submit to you that medical research has delivered, for an investment that I think is extremely effective in its return.

Cancer is another example. If you look at cancer—and you mentioned the war on cancer, Senator—for the first time in recorded history, this year we have a lower number of deaths from cancer in the United States, despite an increasing population and an increasing average age of the population. We have 10 million survivors. This is due to the advent of early screening, early detection, new therapies.

What has this cost us? \$8.60 per person per year over the past 30 years. The total investment for each one of us is \$260 over 30 years. I do not think there is an investment that I can describe that any agency can be as proud of as the National Institutes of Health is of its effectiveness. We have delivered not only better cures, but also a healthier life for Americans, who live now longer and healthier lives, with a disability rate that has dropped by 30 percent over the past 22 years because of improvements in bone health, in heart health, and many other advances.

Since 1982 the disability rates have dropped by 30 percent and in the past 30 years American life expectancy has increased by over 6 years, from a total investment cumulative over 30 years, of about \$1,300 per American.

This is not just what we have done in the past. We continue to deliver. If you look at just the advances of the past year—I am just going to take a few examples. If you look at the impact of the

human genome and genomics, we identified over 20 genes just in the past 12 months that relate to prostate cancer and the causes of prostate cancer, in mental health about obsessive compulsive disorder, and one of the most exciting ones is in vision disease, where we have found genes that may explain over 70 percent of cases of what we call age-related macular degeneration, the fastest rising cause of blindness in American seniors.

Vaccines: We have the first global candidate vaccine on HIV/AIDS, that Dr. Fauci and his team developed. Yesterday the FDA approved the first preemptive cancer vaccine against cervical cancer. We have expanded the Avian Flu trials. We have one vaccine in trial and a second one in development. This would not have been possible without the support of Congress and your support here on this committee.

But we realize that biomedical research must continue to deliver and we have a challenge in front of us. We all know that the rising cost of health care and the burden of disease is going to be a challenge for all of us. We see the curve. We see that it is not sustainable. Society spends about \$7,100 per American per year on health care costs. The total NIH spending, \$95 per American per year, has to do something, must do something, to change that picture.

This is the vision of NIH. Our vision, all of us as scientists at NIH, is to use our investment and deliver a complete transformation of medicine, because if we keep practicing medicine the way we know it today, 25 years from now it just will not be sustainable. So discoveries and new ways of not only curing disease, but preventing disease, preempting disease altogether, is the key.

We will do this through what we call the four P's of medicine. It will be more predictive because of our understanding of molecular events. It will be more personalized because we know that every one of us reacts differently to different diseases. It will have to be increasingly preemptive because this is where it is the least costly. But we cannot do this without the participation of everyone, and this is why we say the fourth P is, in the context of chronic diseases like diabetes or obesity, it will require us to include the patients as partners in this new medicine.

PREPARED STATEMENTS

So my message is very simple. We have delivered, we continue to deliver, and we will deliver, and the return on investment is in my view one of the most remarkable returns that anyone can describe, and we will continue to do so. I am happy to take any questions.

[The statements follow:]

PREPARED STATEMENT OF DR. ELIAS A. ZERHOUNI

Mr. Chairman and distinguished members of the subcommittee, it is an honor and a privilege to appear before you today to present the National Institutes of Health (NIH) budget request for fiscal year 2007 and discuss the priorities of NIH for this year and beyond.

BUDGET REQUEST

The request for NIH is \$28.4 billion in fiscal year 2007, the same as the fiscal year 2006 level for the Agency. The budget request will support the research programs managed by NIH's Institutes and Centers. At this budget level, NIH will in-

crease the biodefense research program by \$110 million for Advanced Development. Support for the Pandemic Influenza Preparedness Plan will increase by \$17 million. We have also chosen to carefully invest in several trans-NIH strategic initiatives. The NIH Roadmap, an incubator for new ideas and initiatives that will accelerate the pace of discovery, increases by \$113 million. We allocated \$40 million to the Institutes and Centers to launch the Genes, Environment and Health Initiative to accelerate discovery of the major genetic and environmental factors for diseases that have a substantial public health impact. We have also directed \$15 million to the new "Pathway to Independence" program to increase our support of new investigators.

I will focus my testimony on the return of the investment in NIH for the American people. In particular, I will discuss how discoveries fueled by this investment are transforming the practice of medicine. We can now clearly envision an era when the treatment paradigm of medicine will increasingly become more predictive, personalized and preemptive. We will strike disease before it strikes us with the hope of greatly reducing overall costs to society. We expect to move away from the costly and predominantly curative model of today, which requires us to wait for the disease to occur before intervening. I will share with you the strategic vision of NIH and discuss the many management innovations we have implemented to ensure optimal stewardship of taxpayers' resources.

SELECTED ACCOMPLISHMENTS OF NIH AND THEIR IMPACT ON HEALTH

The achievements of NIH and our private sector partners in medical research are difficult to overstate. According to the latest report on the Nation's health from the Centers for Disease Control and Prevention (CDC), life expectancy continues to rise, now at an unprecedented 78 years for the total U.S. population. Since 1950, the age-adjusted death rate for the total population declined by a remarkable 43 percent. Life expectancy has increased by one year in every five for the past 30 years. Americans are not only living longer, they are healthier. For instance, the disability rate of American seniors dropped by almost 30 percent in the past 20 years, owing to a range of scientific advances.

The following are samples of the many advances driven by the investment in NIH.

ADVANCES IN CARDIOVASCULAR DISEASE AND STROKE

Thirty years ago, it was common for a man or woman to suddenly die of a heart attack or stroke between the ages of 50 and 60. Had this trend continued unabated, today more than 1.6 million lives would have been lost per year. Fortunately, today the toll is much less. The death rates from cardiovascular disease have declined by 63 percent and by 70 percent for stroke. Were it not for the ground-breaking research on the causes and treatment of heart disease, supported in large part by NIH, including recent developments such as drug coated stents, safe levels of blood pressure and cholesterol lowering therapies, heart attacks would still account for 1.2 to 1.3 million deaths per year instead of the actual 515,000 deaths experienced today. The estimated total cumulative investment in cardiovascular research at the NIH per American over the past 30 years, including the doubling period, is about \$110, or about \$4 for each American per year over the entire period.

ADVANCES IN CANCER

The mortality rates of cancer, the second leading cause of death in the United States, have been falling for several years, and this year, for the first time in history, the absolute number of cancer deaths in the United States has decreased. More effective therapies have led to improved outcomes for more than 10 million American cancer survivors. With the increase in budgets between 1999 and 2003, the National Cancer Institute has stimulated a paradigm shift in cancer therapy. We are seeing the emergence of targeted therapies, with the unprecedented ability to use specific molecular targeting to treat tumors with novel agents. We can also detect and treat cancer at earlier stages. The National Cancer Institute's (NCI) Early Detection Research Network (EDRN), launched in 1999, has identified a number of biomarkers that allow for the earlier detection of breast, prostate, colon, lung and other cancers. This year, NCI, in collaboration with the Human Genome Research Institute, has launched a cancer genome pilot project to help further our understanding of the basic biology of cancer and identify additional treatment targets. The estimated total cumulative investment at the NCI per American over the past 30 years, including the doubling period, is about \$258, or about \$9 per American per year over the entire period.

ADVANCES IN HIV/AIDS

Without the development and testing of antiretroviral drugs, there would be no hope for patients with HIV/AIDS. The development of Highly Active Antiretroviral Therapies primarily resulted from the work of a large cadre of NIH-supported scientists and their counterparts in the pharmaceutical industry. Their discoveries about the cellular mechanisms of the disease have transformed AIDS into a manageable disease, preventing hundreds of thousands of hospitalizations and early deaths. To date, 21 antiretroviral drugs and 4 combination formulations have been approved by the FDA. Many more less toxic AIDS drugs are currently in development. Today, fewer than 50 HIV-infected babies are born each year in the United States, sparing 16,000 to 20,000 children from AIDS through the use of antiretroviral drugs to prevent mother-to-child transmission. Mother-to-child transmission rates in developing countries have declined by 40 percent with the use of drug therapy. With the introduction of these new drugs, economists estimate the aggregate potential value of improved survival has been nearly \$400 billion for those infected through 2000. They estimate the aggregate potential value for all past and future cohorts of individuals infected with HIV is almost \$1.4 trillion.

With the additional resources provided during the doubling of the NIH budget, we launched the Vaccine Production Program (VPP) Laboratory to efficiently translate candidate research vaccines, including HIV vaccines, into useable products. Since its inception in 2001, this program has overseen the manufacture of over 29 bulk pharmaceutical compounds formulated into 14 different vaccine products for HIV, as well as West Nile, SARS and Ebola Virus, and expanded our network of clinical trial sites across the globe. This program is enabling NIH to serve the needs of the American people in an age of global risks of infectious diseases.

ADVANCES AGAINST THE THREAT OF PANDEMIC INFLUENZA

Thanks to fundamental advances in viral genomics and genetic engineering, NIH has been able to help in the development of countermeasures against both seasonal and pandemic influenza viruses. We now have a vaccine against the H5N1 virus and will develop a second one in conjunction with CDC. Without such a vaccine, and others under development and testing, we would be completely defenseless against the potential pandemic that threatens the entire world. We are investing in research and development to hasten the production process by converting from egg-based to cell culture-based vaccines. We are developing novel vaccine approaches using a variety of molecular biological techniques, and we launched discovery efforts for new anti-viral compounds against pandemic flu. We initiated a project to identify the genomes of thousands of human and avian influenza viruses, and, to date, 831 influenza genome sequences from human isolates have been deposited in NIH's GenBank, allowing researchers across the world to better understand influenza viruses and develop countermeasures.

DEVELOPMENT OF BIODEFENSE RESEARCH

Since 2001, NIH has directed more than \$10 billion toward protecting the American public from bioterrorism. The 2001 intentional release of anthrax underscored the reality of a bioterrorism threat posed by other Category A agents such as smallpox, plague, tularemia, hemorrhagic fevers, and botulinum toxin. NIH responded swiftly. Promising vaccine candidates for Ebola and smallpox are currently in clinical trials. Identification of the three-dimensional structure of the anthrax toxin complex is fueling the search for compounds that block the toxin's effects, and the discovery of the key mechanism of Ebola virus cell entry prompted experiments demonstrating that Ebola infection could be blocked in laboratory tests. We continue to build a national biodefense research infrastructure that will position the Nation to respond even more quickly and precisely to bioterrorism.

ADVANCES IN DIABETES AND RELATED ILLNESSES

Nearly 21 million Americans have diabetes, a disease that can cause damage to multiple organs and lead to death. Without NIH research, the improvements of the past two decades in the therapies for diabetes would not have occurred. Through large prospective trials, made possible by the doubling of our budget, we have assessed the relative value of drug based approaches versus weight loss and physical activity, and showed it is possible to reduce the risk of type 2 diabetes by 58 percent with lifestyle modifications alone.

Diabetes can also result in vision loss. Four million American adults suffer from diabetic retinopathy, the outcome of damage to the tiny blood vessels in the light-sensitive retina lining the inside of the eye. Nearly a million have the advanced vi-

sion-threatening stage of the disease. The National Eye Institute completed a series of landmark clinical trials to develop novel treatments for diabetic retinopathy. Without these new treatments, 450,000 patients who have advanced disease today would otherwise likely be blind in 5 years. As a consequence, of those currently at risk, only 27,000 would progress to legal blindness, and only 9,000 would become blind today. In addition to reduced suffering and disability, the economic savings from these treatments will reach as much as \$1.6 billion per year.

As another example of payoff from recent NIH research, end-stage renal disease (ESRD)—kidney failure requiring dialysis or transplantation, a complication of diabetes and high blood pressure—results in direct federal expenditures of approximately \$20 billion per year. Through the 1980s and 1990s, the incidence of ESRD nearly doubled each decade, but in the last five years overall rates have stabilized—and even declined in certain population groups. This improvement has been driven by monitoring for proteins in urine to prevent kidney disease or detect it in its early stages. Compared with earlier projections, the savings in federal health care expenditures are approximately \$1 billion dollars per year.

Without the investment in medical research, people with diabetes would be living shorter, less productive, and less hopeful lives.

ADVANCES IN IMAGE-GUIDED MICROSURGERY

Increases in the NIH budget allowed new investments in the use of imaging technologies like CAT scanning, MRI or ultrasonography for the development of new microsurgical techniques. These minimally invasive therapies are changing the fate of many patients, including patients with Parkinson's disease, through deep brain stimulation. These new techniques are also promising to revolutionize the treatment of epilepsy, a disease that affects over 2.7 million Americans. As we move forward with such research, we expect that surgery will become less invasive, more precise and less dangerous, with far less operative complications.

ADVANCES IN HEALTH INFORMATION FOR SCIENTISTS AND THE PUBLIC

The National Library of Medicine of the NIH provides the American public with high quality, reliable information. The NIH web sites (www.nih.gov) are now recognized by independent organizations as the most successful health related web sites, with over 2 million queries per day. Millions of patients and their families regularly consult NIH web sites for up to date information in English and Spanish, a capability made entirely possible by the doubling of the NIH budget. The web-based ClinicalTrials.gov represents a landmark effort to provide information to patients and physicians across the country on NIH-funded clinical trials.

NIH also leads the research field in developing information technology for biomedical research. No biomedical scientist develops a project without first consulting the suite of powerful informational research tools available through the NIH National Library of Medicine's PubMed, a growing digital archive of peer-reviewed research articles and scientific databases.

NEW RESEARCH TOOLS

NIH researchers have pioneered powerful new research tools and methods such as high throughput DNA sequencing, protein identification with mass spectrometry, gene expression arrays, the determination of thousands of new protein structures, and imaging technologies which were simply unavailable before the doubling of the NIH budget. A great illustration of the impact of these advances has been the identification of the cause of the SARS virus in less than a month and the current tracking of pandemic flu viruses. These tools have greatly accelerated the research process itself, spurred progress and spawned new discoveries in all areas of biomedical research. Perhaps nowhere else have these technological advances in imaging and genotyping elicited more excitement than in the field of mental and behavioral health, elucidating genes linked to schizophrenia, depression, bipolar disorder and anxiety. These discoveries are allowing for the first time direct visualization of brain structure and function to study the brain circuitry involved in thinking and a range of behaviors.

NEW DIAGNOSTIC AND THERAPEUTIC TECHNOLOGIES

Some of NIH's successes can be measured in new medical technologies. Advances in research are driving an increase in the number of technologies being licensed to companies for commercialization. In fiscal year 2004, there were thousands of active licenses between federally funded research institutions and companies worldwide. Out of these technologies, several thousand companies are making many new prod-

ucts that have an immeasurable impact on public health. Today, from NIH funded research, more than 300 new drug products and vaccines targeting more than 200 diseases—including various cancers, Alzheimer’s disease, heart disease, diabetes, multiple sclerosis, AIDS and arthritis—are in clinical trials. These outcomes are accomplished through the on-going network of successful collaborations with our colleagues in private industry.

CHANGING LANDSCAPE OF DISEASE

Disease and injury are constant threats to humankind and are never static. New diseases can emerge at any time, such as HIV/AIDS, SARS, Pandemic Flu, obesity or many other conditions. Bioterrorism did not figure significantly in the NIH agenda in 2001, but is now a top priority of the agency. Twenty years ago the impact of Alzheimer’s disease was not fully appreciated, nor were its causes known.

As the result of our success in preventing and treating acute and short term conditions such as heart attacks, stroke, cancer and many infectious diseases, we are living longer. Our increasingly older population faces the new challenge of multiple chronic conditions which now consume about 75 percent of healthcare expenditures. This shifting burden of health care from acute to chronic diseases is perhaps the greatest challenge we face.

Health care costs in the United States have risen to more than \$2 trillion. The amount spent on health care per person has doubled, from \$3,461 in 1993 to \$7,110 today. The causes of health care inflation are varied and complex, requiring different, nation-wide solutions.

We are in a race against the overwhelming human and economic consequences of disease. We can win this race, but only if we use research discoveries to transform medicine as we know it. Thanks to recent research advances, we can foresee a future of more effective medical treatment that might be less expensive than current practices.

STRATEGIC VISION FOR NIH: FROM CURATIVE TO PREEMPTIVE CARE

We are in an era of great scientific opportunity. Advances in our understanding of basic human biology allowed NIH to sequence the human genome by 2003, two years ahead of schedule, and to complete the Haplotype Map, showing the variation between individual humans, in October 2005, also ahead of plans. One of the greatest scientific achievements in history, the genome blueprint, along with work in systems biology and proteomics, are driving a revolutionary period in the life sciences. We are on the brink of transforming medical treatment in the 21st Century. Our hope is to usher in an era where medicine will be predictive, personalized and preemptive.

Toward this goal, NIH is strategically investing in research to further our understanding of the fundamental causes of diseases at their earliest molecular stages so that we can reliably predict how and when a disease will develop and in whom. Because we now know that individuals respond differently to environmental changes according to their genetic endowment and their own behavioral responses, we can envision the ability to precisely target treatment on a personalized basis. Ultimately, this individualized approach, completely different than how we treat patients today, will allow us to preempt disease before it occurs.

Consider, for instance, how better predictive and personalized treatments could improve the safety and effectiveness of drugs. As we know, drugs do not fall into the “one size fits all” category. The same drug can help one patient and harm another. Recent research shows that we will be increasingly able to know which patients will benefit from treatment and which patients might be harmed. This field of study is known as pharmacogenetics. Using the latest genomic data, enabled by the doubling of the NIH budget, the NIH established a Pharmacogenetic Research Network which is studying the interactions of drugs and molecules as well as the biological processes that eliminate compounds from the body. In the first five years of this program, the researchers in this network made numerous discoveries.

For example, they learned that 10 percent of the North American population exhibits a genetic variation that puts them at high risk for life-threatening reactions to irinotecan, a cancer drug. We now know that patients with this variation should be given lower than prescribed doses of this successful drug, thus potentially saving their lives.

NIH researchers also discovered variations in a gene involved in the body’s response to more than half of all medications. Understanding these differences could explain critical individual as well as racial and ethnic differences in drug responses. Other genetic variations discovered by the NIH network will have an impact on

asthma treatment, the risk of sudden death from irregular heartbeats and the proper use of blood thinning medications to avoid deadly bleeding complications.

In another example of emerging personalized medicine, cancer researchers have developed a test that helps determine the risk of recurrence for women who were treated for early stage, estrogen-dependent breast cancer. This information can help a woman and her doctor decide whether she should receive chemotherapy in addition to standard hormonal therapy. This test has the potential to change medical practice by sparing tens of thousands of women each year the unnecessary and harmful side effects associated with chemotherapy at large potential cost savings.

RAPID ADVANCES IN THE GENOMIC ERA

Because of a hundred fold reduction in the cost of genomic technology, we can now study, at affordable costs, the differences between patients who have a disease and their normal counterparts. Recently, this revolutionary approach led to the discovery of two previously unsuspected factors that can identify who is at risk and how to protect patients from age-related macular degeneration, an increasing cause of blindness in our aging population, with over 7 million Americans at risk. Last month, a key transcription factor that may be responsible for a large percentage of cases of diabetes was discovered.

These breakthroughs form the basis of our budget request for the Genes and Environment Initiative, supported by Secretary of Health and Human Services Michael Leavitt, because it will give us the unprecedented ability to discover, over the next three years, the potential causes of the 10 most common diseases afflicting the U.S. population. With this funding, if approved, we will also launch a technology development effort for enabling scientists to measure many types of environmental exposures at the individual level. Taken together, these efforts will lead to better understanding of the environmental and genetic factors in the development of many diseases.

Imagine a world where we will be able to tell each patient whether they need to take action to preempt altogether the development of costly and painful diseases. Imagine telling them that they do not need to take expensive medications for life because they are not at risk of disease. A more predictive, personalized and preemptive form of medicine is no longer just a dream, but a vision to strive for as rapidly as we can.

MANAGEMENT INNOVATIONS

NIH has an enormous and growing scope of mission. We conduct or support research on over 6,600 diseases and conditions, from the most common to the rarest. In 2005, more than 43,000 research grant applications went through our rigorous two-tiered review process, with about 22 percent of applications ultimately receiving funding.

More than 80 percent of the NIH budget supports extramural research at 3,100 institutions around the world, employing about 200,000 scientists and other research personnel. Another 10 percent of the budget goes into the NIH intramural program, consisting of approximately 6,000 scientists, where work is focused on public health priorities and cutting edge research. The hub of the intramural program, the NIH Clinical Center on the Bethesda campus, is the world's largest dedicated clinical research complex.

NIH is spending \$95 per American this year on medical research, and we need to make every dollar count. With the growth and increasing complexity of the agency, NIH has aggressively moved to transform its management strategies and decision-making processes. To streamline, harmonize and better coordinate decisions that affect the entire agency, in 2003, I established the NIH Steering Committee, composed of nine Institute Directors who serve on a rotating basis. Six working groups support the Steering Committee. This new governance structure has enabled greater coordination and harmonization between the 27 Institutes and Centers at NIH.

NIH has addressed the need for more robust means to oversee the vast NIH research portfolio, and plan and launch trans-NIH initiatives. While the NIH successfully developed important trans-NIH initiatives such as the Roadmap for Medical Research, the Strategic Plan for Obesity Research, and the Neuroscience Blueprint, the agency is now implementing even more rigorous and transparent processes and developing cutting-edge tools to analyze, assess and manage the array of research it supports. This will provide better information to support planning and priority-setting in areas of shared Institute and Center interests. To reinforce these accomplishments, NIH is establishing a new office within the Office of the Director—the Office of Portfolio Analysis and Strategic Initiatives (OPASI).

Review of our programs by the Office of Management and Budget under the congressionally mandated Government Performance and Results Act (GPRA) provides evidence that our programs are effective. We have been rated in the top 15 percent of federal organizations.

NIH's effective performance is reflected in recent scores as measured by the OMB Program Assessment Rating Tool (PART). In the fiscal year 2007 PART, the Buildings and Facilities Program and the Intramural Research Program both received the highest possible rating of effective, with scores of 96 percent and 90 percent, respectively. On the fiscal year 2006 PART, the NIH Extramural Research Program achieved a similarly high 89 percent. These high scores demonstrate exemplary management and substantial progress toward meeting NIH performance measures. To date, approximately 90 percent of NIH's budget has been PARTed and rated effective.

TRANSLATING DISCOVERIES INTO BETTER MEDICAL TREATMENT

Rapidly translating our discoveries from the bench to the bedside is a top priority of the NIH. The opportunities have never been greater to use modern research methodologies such as genomics, proteomics, metabolomics, high sensitivity biochemical methods and other novel strategies to bring new insights to the study of human populations and more rapidly achieve the goal of making medicine predictive, personalized and preemptive.

To accelerate progress, NIH recently introduced the institutional Clinical and Translational Science Award (CTSA). The CTSA program will stimulate institutions across the country in transforming Clinical and Translational Science in the U.S.A. to (1) captivate, advance, and nurture a cadre of well-trained multi- and inter-disciplinary investigators and research teams; (2) create an incubator for innovative research tools and information technologies; (3) synergize multi- and inter-disciplinary clinical and translational research; and (4) accelerate the application of new knowledge and techniques to clinical practice at the front lines of patient care.

TRAINING A NEW GENERATION OF SCIENTISTS

New visions require new talent. In times of constrained budgets the most important action NIH needs to take is to preserve the ability of young scientists with fresh ideas to enter the competitive world of NIH funding. To that effect, NIH has launched the new "Pathway to Independence" program which will support, for each of the next five years, 150 to 200 recently trained scientists conducting independent, innovative research.

IN SUMMARY

Our Nation's investment in biomedical research has dramatically improved health outcomes. The return on the investment of the American people at NIH is nothing short of spectacular. Thanks to the support of Congress, we are able, through our science, to respond in record time to emerging threats such as SARS, Pandemic Flu and biodefense needs. We have learned how to decrease the incidence of many diseases and other disabilities for old and young Americans. The estimated total cumulative investment at the NIH per American over the past 30 years including the doubling period is about \$1,334 or about \$44 per American per year over the entire period. In return, Americans have gained over six years of life expectancy and are aging healthier than ever before.

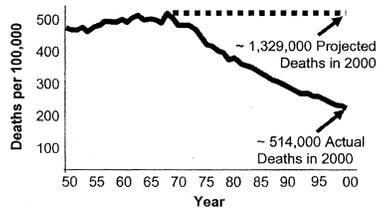
The President and Congress have wisely invested in biomedical research. We are acutely aware that NIH research is often the only hope for millions of people afflicted by disease. In the battle for health, NIH also believes that it needs to accelerate the pace of progress, as it is only through a fundamental transformation of medicine that solutions to the rising burden of healthcare will be found.

I will be happy to answer any questions you may have.

- **What is the return on the American people's investment in the National Institutes of Health?**
- **What has the NIH budget doubling delivered?**
- **What is the NIH strategy for the future?**



Biomedical Research Has Delivered
Coronary Heart Disease

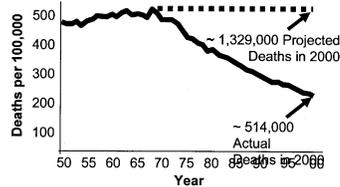


- **63% decrease in Mortality**
- **~ 1 million early deaths averted per year**
- **\$2.6 trillion in economic return**
- **New, effective treatments and prevention strategies**



Biomedical Research Has Delivered Coronary Heart Disease

Average investment
per American
~\$3.70
per year

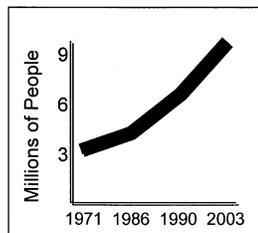
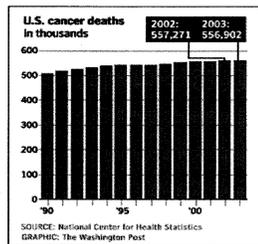


30-year investment
per American:
~\$110
Total

- 63% decrease in Mortality
- ~ 1 million early deaths averted per year
- \$2.6 trillion in economic return
- New, effective treatments and prevention strategies



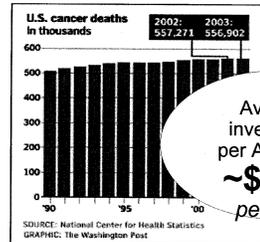
Biomedical Research Has Delivered Cancer



- For the first time in recorded history, annual cancer deaths in the United States have fallen
- 10 million survivors
- Advent of early detection and screening



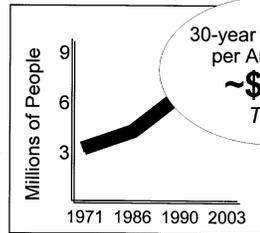
Biomedical Research Has Delivered Cancer



Average investment per American
~\$8.60
per year

- For the first time in recorded history, annual cancer deaths in the United States have fallen

- 10 million survivors



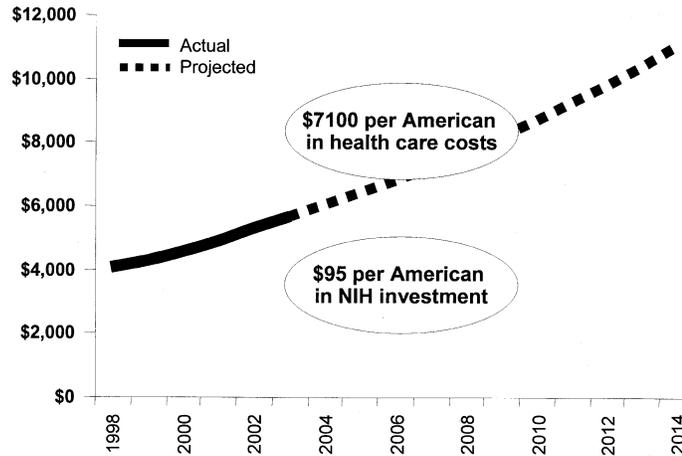
30-year investment per American:
~\$260
Total

- Advent of early detection and screening



Facing the Rising Challenge

U.S. Health Expenditures per capita



Source: <http://new.cms.hhs.gov/NationalHealthExpendData/downloads/nheprojections2004-2014.pdf>

Biomedical Research Has Delivered *Americans Live Longer, Healthier Lives*



Improvements in:

- Recovery from heart disease, stroke
- Deafness
- Vision impairment
- Osteoporosis
- Arthritis



Biomedical Research Has Delivered *Americans Live Longer, Healthier Lives*



Since 1982,
disability rate for
elderly Americans
declined by 30%

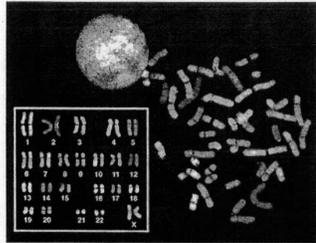
In past 30 years,
American life
expectancy
increased by ~6
years

Improvements in:

- Recovery from heart disease, stroke
- Deafness
- Vision impairment
- Osteoporosis
- Arthritis



Biomedical Research Is Delivering *NIH Advances in the Past Year*



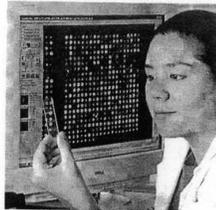
- Genomics:
 - Identified >20 genes influencing diseases, including:
 - Prostate Cancer
 - Obsessive Compulsive Disorder
 - Age-related Macular Degeneration



- Vaccines:
 - First “global” HIV/AIDS vaccine
 - First Cervical Cancer vaccine
 - Expanded Avian Flu vaccine clinical trials



Biomedical Research Will Deliver *Transforming Medicine through Discovery*



Predictive ↔ Personalized ↔ Preemptive





NIH *Transforming medicine through discovery*



PREPARED STATEMENT OF DR. JOHN E. NIEDERHUBER

Mr. Chairman and Members of the Committee: I am please to present the fiscal year 2007 President's budget request for the National Cancer Institute (NCI). The fiscal year 2007 budget includes \$4,753,609,000, a decrease of \$39,747,000 below the fiscal year 2006 enacted level of \$4,793,356,000 comparable for transfers proposed in the President's request.

OUR GOAL REMAINS THE SAME

Four years ago, we put the NCI on a trajectory towards the Challenge Goal of eliminating suffering and death due to cancer as early as the year 2015. Since that time, we have vigorously and aggressively managed NCI's portfolio of investments in cancer research across that entire continuum of the process of cancer, whether we've been focusing on understanding genetic mutations that were responsible for susceptibility to cancer or focusing on issues that have to do with survivorship and living with, rather than dying from, cancer.

NCI has been a major leader in the molecular metamorphosis of biomedical medicine that has benefited all fields of medical research. Without the Nation's support of NCI's pioneering role in funding research—including basic science, clinical trials, and translational investigations—into the molecular and genetic processes that underlie all disease and the training of new cancer researchers, it is unlikely that the advances we are seeing today in many health areas—from AIDS to macular degeneration—would have occurred at the pace they have. These leadership efforts must be sustained going forward.

The Nation's past commitment to cancer research has proven its worth: mortality rates have declined for all cancers combined while incidence rates have stabilized or increased slightly, detection and treatments have improved, new therapeutic options offer startling promise. Today there are nearly 10 million cancer survivors in the United States compared to approximately 3 million cancer survivors in 1971 when the National Cancer Act was established. Also, in 1971 fewer than half of those found to have cancer lived 5 years beyond their diagnosis; today the 5 year survival rate is 64 percent for adults and 79 percent for children aged 14 or younger. The latter figure is truly remarkable given how few children survived even a couple of years after being diagnosed in the early 1970s. NCI's continued commitment is manifested today in far-reaching programs that have advanced our basic understanding of the genetic changes responsible for this dreaded disease. The Nation's investment and the actions of Congress are directly responsible for the devel-

opment of a nation-wide network of 61 NCI-designated cancer centers and a highly successful Community Clinical Oncology Program (CCOP), founded in 1983. Through the network of 64 CCOP grantees, community investigators participate actively in NCI-sponsored cancer prevention, control, and treatment clinical trials. These programs place cutting-edge research directly in communities and put access to cancer clinical trials into the hands of local physicians. Because of their participation in NCI trials, community clinicians more readily adopt new regimens, ensuring that these advances are rapidly made part of the standard of care.

Recently, NCI's leadership team has initiated a series of site visits to innovative community-based cancer centers as potential models for a new NCI initiative, the Community Cancer Centers Program (CCCP). The CCCP would help foster replication of successful community models across the country, set the standards for multi-specialty state-of-the-art care, provide access to early phase clinical trials, and ultimately improve cancer care and outcomes. This program is especially designed to bring academic standards of care and clinical trials directly to the segments of our population who either through age or resources cannot leave their community.

A RECORD OF REAL SUCCESS

The past year in cancer research shows a record of substantial and heartening achievement. We are expanding our foundation of knowledge and the technical tools with which rapid advances can be made in understanding the mechanisms of cancer. We are exponentially increasing the opportunities to manage this lethal disease. Building on NCI-funded research, large-scale clinical trials in 2005 yielded results that will have profound effects in preventing and treating many cancers.

For example, three different clinical trials showed that adding trastuzumab (Herceptin®) to standard adjuvant chemotherapy significantly reduced the risk of recurrence in women with the early-stage breast cancer, HER-2/neu positive, which has an over expression of protein in the gene. Approximately 50,000 women in the United States are diagnosed with HER-2/neu positive breast cancer each year, representing about 20 percent of invasive breast cancers.

Equally stunning results were seen in the trial of a vaccine that protects against two strains of human papillomavirus (HPV) that cause over 70 percent of cervical cancers, a disease that kills more than 200,000 women each year, including many in developing countries. Study results concluded that women who received the vaccine during a 2-year study were protected against precancerous lesions caused by HPV. NCI made the initial discoveries linking HPV to cervical cancer, which led to creation and testing of HPV vaccines that are based on technology also developed at the Institute. It is an outstanding exemplar in this era of molecular medicine of how NCI's knowledge about the etiology of the disease enabled creation of a vaccine against a specific cancer.

In January, an NCI-sponsored trial reported that women who received chemotherapy directly in their abdomens as part of treatment for advanced ovarian cancer lived more than a year longer than women who received the same chemotherapy intravenously. The findings confirm and expand recent research showing that intraperitoneal (IP) chemotherapy, which delivers drugs directly to the abdominal cavity through a catheter, can significantly increase survival for some women with the disease. As the results were made public, NCI issued a rare clinical announcement to raise awareness about IP chemotherapy for ovarian cancer among physicians and patients. The NCI announcement—the first since 1999—was warranted because IP chemotherapy is widely regarded as an old technology and previous trials have generated little interest among physicians. Ovarian cancer causes the most deaths of any gynecological cancer in the United States and frequently goes undetected until tumors spread beyond the ovaries.

Another notable advance came last September with the announcement of results from the NCI-sponsored Digital Mammographic Imaging Screening Trial (DMIST). The study found that digital mammography is more accurate than film mammography for women with dense breasts, as well as for several other groups of women, including women under 50 and pre- and perimenopausal women. Overall, DMIST offers a model case study of how NCI can be an agent of change, pursuing new approaches to research, partnering with the private and public sectors, and fueling the development of technologies to achieve an important advance. It is particularly noteworthy that NCI and the American College of Radiology Imaging Network (ACRIN) secured the involvement in DMIST of four companies that developed and manufactured digital mammography machines for our use in clinical trials: Fischer Medical, Fuji Medical, General Electric Medical Systems, and Hologic.

Finally, NCI has made strides to address the widespread disparities in cancer screening, treatment, and care for disadvantaged, mostly minority populations. One

approach to closing this access gap is NCI's Patient Navigator Research Program, which relies on personal guides to shepherd disadvantaged cancer patients into standard care. NCI supports a number of Patient Navigator Program pilot projects in minority communities and about \$24 million in grants will be awarded over the next 5 years as part of the program.

ADVANCED TECHNOLOGIES ACCELERATE PROGRESS

The technology revolution is speeding up and enabling the discovery process. Nanotechnology has emerged as a key strategy for imaging molecular features of cancer and will ultimately lead to personalized medicine. NCI's investment in nanotechnology is a powerful example of leveraging resources from the private sector through our Centers of Cancer Nanotechnology Excellence.

Of equal significance, in December 2005 NCI and the National Human Genome Research Institute (NHGRI) launched The Cancer Genome Atlas (TCGA) Pilot Project, a comprehensive effort to accelerate understanding of the molecular basis of cancer and which evolved from the Human Genome Project (HGP). The TCGA Pilot Project will develop and test the science and technology needed to systematically identify the genetic changes in a small number of cancers.

Additionally, NCI's cancer Biomedical Informatics Grid (caBIG™) is creating a unifying technology platform or "world-wide web" for cancer research. caBIG™ is well on the way to its goal to create a network of interconnected data, applications, individuals, and institutions that will redefine how cancer research is conducted and care is provided. This initiative has also whetted considerable commercial interest.

INTERAGENCY COLLABORATIONS

Addressing the cancer problem requires that NCI work across institutional and sector boundaries, share knowledge, and bring together the diverse members of the Department of Health and Human Services (DHHS) family of agencies, as well as other federal offices, that can help develop systems-based solutions to the cancer problem.

The NCI and FDA Interagency Oncology Task Force (IOTF) continues to remove bottlenecks in the process of developing and approving safe, more effective cancer interventions. During 2005, IOTF helped foster the creation of two important initiatives: the Exploratory Investigational New Drug (IND) process to streamline the early clinical development of new drugs and biologics; and the NCI Regulatory Affairs Liaison position to help NCI-funded researchers navigate through FDA's IND application process. Both will help eliminate obstacles to the rapid development of promising new anticancer agents.

DHHS Secretary Mike Leavitt announced last month the Oncology Biomarker Qualification Initiative (OBQI)—an unprecedented interagency agreement among NCI, FDA, and the Centers for Medicare and Medicaid Services (CMS) to collaborate on improving the development of cancer therapies and the outcomes for cancer patients through biomarker development and evaluation.

CONCLUSION

We must do more to continue the acceleration of discovery, development, and delivery of the interventions that will hasten the transformation of our traditional view of cancer as a death sentence into a disease that we can prevent, eliminate, or control. This will be the legacy we leave our children.

While progress is evident, there is much that remains to be accomplished. We are committed to face the challenge of making difficult choices between those programs that we will continue to grow and nurture and those that have already advanced our knowledge. The decisions will be science driven. This is an unprecedented era of discovery. The opportunities to apply powerful new technologies to advance our knowledge and the opportunities to change the course of cancer have never been greater.

PREPARED STATEMENT OF DR. FRANCIS S. COLLINS

Mr. Chairman and Members of the Committee: I am pleased to present the fiscal year 2007 President's budget request for the National Human Genome Research Institute (NHGRI). The fiscal year 2007 budget includes \$482,942,000, a decrease of \$3,107,000 from the fiscal year 2006 enacted level of \$486,049,000 comparable for transfers proposed in the President's request.

On October 26, 2005, an international consortium of dedicated scientists from six countries, led by the NHGRI, published a new map of the human genome called

“HapMap” that may prove even more powerful than the human genome sequence because of its medical applications.

The Human Genome Project (HGP) spelled out the letters of the 99.9 percent of the DNA code that we all share. The haplotype map, or HapMap for short, provides detailed knowledge of the 0.1 percent that represents variation in the genome. The HapMap reveals the way in which this genetic variation is organized into chromosomal neighborhoods and provides a powerful tool to uncover those spelling differences in the human instruction book that predispose some people to diabetes, Alzheimer’s disease, heart disease, or cancer. As with the HGP, all of the data has been placed in the public domain.

Since early deliberations about the HGP 20 years ago, scientists and physicians have dreamed of the day when we would be able to apply the tools of genomics to the diagnosis, treatment, and prevention of those common diseases that fill up our hospitals and clinics, causing untold suffering, misery, and premature death. The completion of the HapMap brings us a major step closer to the realization of that dream.

The HapMap project could not have succeeded without the support of multiple NIH institutes, the U.S. Congress, and the dedication of more than 2,000 scientists across the world who delivered on every promise of the project. In fact, in its brief three-year life, this project produced a map three times more detailed than originally thought possible. The NHGRI and other NIH institutes can now move quickly to build on this success to discover the genetic and environmental factors that cause disease, and to utilize this information to develop better means of individualized prevention and treatment.

ONGOING NHGRI INITIATIVES

Use of Comparative Genomics to Understand the Human Genome

The NHGRI continues to support the sequencing of the genomes of non-human species such as the chimpanzee, dog, and mouse because of what they tell us about the human genome. The first comprehensive comparison of the genetic blueprints of humans and chimpanzees, published in *Nature* to wide acclaim in September 2005, shows our closest living non-human relatives share identity with 96 percent of the human DNA sequence. The sequence of the dog genome was published in December 2005, revealing many interesting details about the remarkable diversity of man’s best friend, and greatly empowering the ability to track down the genes involved in many chronic illnesses (like cancer) where dogs are excellent models for human disease.

Sequencing technology advances, on the way to the \$1,000 genome

DNA sequencing enables a detailed description of the order of the chemical building blocks, or bases, in a given stretch of DNA, and is a powerful engine for biomedical research. Though DNA sequencing costs have dropped by three orders of magnitude since the start of the HGP, sequencing an individual’s complete genome for medical purposes is still prohibitively expensive. Two bold new advances in sequencing technology recently developed by NHGRI-funded researchers promise to greatly reduce this cost. Ultimately, the NHGRI’s vision is to cut the cost of whole-genome sequencing to \$1,000 or less. If achieved, this would enable the sequencing of individual genomes as part of routine medical care, providing health care professionals with a more accurate means to predict disease, personalize treatment, and preempt the occurrence of illness.

Knockout Mouse Project

The technology to “knockout” or inactivate genes in mouse embryonic stem cells has led to many insights into human biology and disease. However, information about knockout mice have only been published and made available to the research community for about 10 percent of the estimated 20,000 mouse genes. Recognizing the wealth of information that mouse knockouts can provide, the NHGRI coordinated an international meeting in 2003 to discuss the feasibility of a comprehensive project. These discussions have now resulted in a trans-NIH, coordinated, five-year cooperative research plan that will produce knockout mice for every mouse gene and make these mice available as a community resource.

Chemical Genomics—Roadmap—Molecular Libraries and PubChem

The NHGRI has taken a lead role in developing a trans-NIH chemical genomics initiative. This is part of the NIH Roadmap, and now offers public-sector researchers access to high throughput screening of libraries of small organic compounds that can be used as chemical probes to study the functions of genes, cells, and biochemical pathways. This powerful technology provides novel approaches to explore

the functions of major components of the cells in health and disease. All the data generated for this project is stored in the new PubChem database at the National Library of Medicine.

Bench-to-Bedside in Intramural Research—The Example of Progeria

As just one example of the focus of the NHGRI intramural program on translational research, rapid advances have recently been achieved in the study of progeria, a rare genetic disease of childhood characterized by dramatic acceleration of aging. In 2003, NHGRI researchers discovered that progeria is caused by a single letter misspelling in a gene known as *lamin A*. The *lamin A* protein undergoes a particular modification known as farnesylation. That same modification activates the protein product of the famous ras oncogene; ten years of hard work has made available a class of cancer drugs that blocks this step. Remarkably, cell culture and mouse model experiments suggest these drugs may also have benefits for children with progeria. Serious consideration of a clinical trial is now underway, just three years after gene discovery.

The Surgeon General's Family History Initiative

Family medical history is a source of genetic information that can help more accurately determine an individual's risk for specific diseases. However, to date, this resource has been underutilized in health. To address this, Surgeon General Richard Carmona established the U.S. Surgeon General's Family History Initiative, a collaborative effort between a number of Department of Health and Human Services agencies, with leadership from NHGRI. The second annual National Family History Day was celebrated on Thanksgiving Day 2005, when a new and improved version of the software tool called "My Family Health Portrait" was released to help individuals compile their own family history information. This initiative should have an impact on patient-healthcare provider interaction, facilitating the development of more accurate family history information for patient medical records, and leading to more personalized and effective disease prevention and treatment strategies.

NEW NHGRI INITIATIVES

The Genes and Environment Initiative (GEI) and the Genetic Association Information Network (GAIN)

Just this February, the Department of Health and Human Services announced the creation of two related groundbreaking initiatives in which NHGRI will play a leading role, to speed up research on the causes of common diseases such as asthma, arthritis, the common cancers, diabetes, and Alzheimer's disease.

The Genes and Environment Initiative (GEI) is a trans-NIH research effort to combine comprehensive genetic analysis and environmental technology development to understand the causes of common diseases. NIH will invest \$68 million in GEI in fiscal year 2007. Using the newly derived HapMap, GEI will search for the specific DNA variations that are associated with an increased risk of common illnesses. For the more than a dozen disorders chosen for investigation under GEI, NIH will study roughly 1,000 cases and 1,000 controls will be studied. Finding the variants that predispose a person to common disease is one of the highest priorities of current biomedical research, as this will enable developing personalized medicine and identifying new drug targets.

To ensure that GEI takes advantage of the wide breadth of expertise that is available on DNA variations for common disorders, NIH has begun partnering under the Genetic Association Information Network with the Foundation for the NIH, Pfizer, and Affymetrix to begin research on seven diseases during this fiscal year.

But genes alone do not tell the whole story. Recent increases in chronic diseases like diabetes, childhood asthma, obesity or autism cannot be due to major shifts in the human gene pool as those changes take much more time to occur. They must be due to changes in the environment, including diet and physical activity, which may produce disease in genetically predisposed persons. Therefore, GEI will also invest in innovative new technologies/sensors to measure environmental toxins, dietary intake and physical activity, and using new tools of genomics, proteomics, and understanding metabolism rates to determine an individual's biological response to those influences.

The Cancer Genome Atlas (TCGA)

In December, the National Cancer Institute (NCI) and the National Human Genome Research Institute (NHGRI) jointly launched a very important new effort to accelerate our understanding of the molecular basis of cancer through the application of genome analysis technologies, including large-scale genome sequencing. Thanks to the tools and technologies developed by the Human Genome Project and

recent advances in using genetic information to improve cancer diagnosis and treatment, it is now possible to envision a comprehensive effort to map the changes in the human genetic blueprint associated with all known forms of cancer. The overall effort, called The Cancer Genome Atlas, will begin in 2006 with a three year, pilot project totaling \$100 million to determine the feasibility of a full-scale effort to explore the universe of genomic changes involved in all types of human cancer. This atlas of genomic changes will provide: (1) new insights into the biological basis of cancer which in turn will lead to new tests to detect cancer in its early, most treatable stages; (2) new ways to predict which cancers will respond to which treatments; (3) new therapies to target cancer at its most vulnerable points; and (4) ultimately, new strategies to prevent cancer altogether.

OTHER AREAS OF INTEREST

Education of Health Care Professionals

To enable the translation of basic genetic discoveries into health care practice, the NHGRI has developed numerous educational programs to prepare health care professionals for this revolution. Specifically, the NHGRI continues to play a lead role in the National Coalition for Health Professional Education in Genetics (NCHPEG), which is leading a national effort to achieve genetic literacy amongst health professionals. NHGRI also worked closely with the American Academy of Family Physicians, who featured genomic medicine as their educational focus for 2005.

Minority Outreach Activities

The NHGRI has been at the forefront of ensuring that minority scientists and students are equipped to meet the new challenges of genome research for the 21st century. The institute has sponsored new initiatives to reach out to diverse populations including research, education, and outreach collaborations on the role of genetic factors in health disparities. In conjunction with the National Council of La Raza, NHGRI has developed a community-based model education program for provision of genetics information to underserved Latino communities. NHGRI is also working with Alaska Native communities and the University of Washington to expand community-based education programs in Alaska Native communities.

Genetic Nondiscrimination

The NHGRI remains very concerned about the impact of potential genetic discrimination on research and clinical practice. Through many surveys and research projects funded by the Ethical, Legal, and Social Implication (ELSI) program of the Institute, it is clear many Americans remain concerned about the possible misuse of their genetic information by insurers or employers. In February 2005, the Senate unanimously passed the Genetic Information Nondiscrimination Act of 2005 (S. 306), which would address these concerns; the companion bill H.R. 1227 is now pending in the House. The Bush Administration has issued a Statement of Administrative Policy in support of the legislation. This issue remains a high priority for the Institute.

PREPARED STATEMENT OF DR. ANTHONY S. FAUCI

Mr. Chairman and Members of the Committee: I am pleased to present the President's budget request for the National Institute of Allergy and Infectious Diseases (NIAID) of the National Institutes of Health (NIH). The fiscal year 2007 budget of \$4,395,496,000 includes an increase of \$12,195,000 over the fiscal year 2006 appropriated level of \$4,383,301,000, comparable for transfers proposed in the President's request.

The mission of NIAID is to conduct and support research to understand, treat, and prevent infectious and immune-related diseases. Infectious diseases include well-known killers such as HIV/AIDS, malaria, and tuberculosis; emerging or re-emerging threats such as influenza; and "deliberately emerging" threats from potential agents of bioterrorism. Immune-related disorders include autoimmune diseases such as type 1 diabetes and rheumatoid arthritis as well as asthma, allergies, and problems associated with transplanted tissues and organs.

NIAID has a two-fold mandate. First, NIAID must plan and execute a comprehensive and long-term basic and clinical research program on well-recognized endemic infectious and immune-mediated diseases. Second, and in this case it is unique among the NIH Institutes, it must respond quickly with targeted research to meet new and unexpected infectious disease threats as they arise, often in the form of public health emergencies. Part of the expansion of the NIAID research portfolio in recent years has been driven by unprecedented scientific opportunities in the core

NIAID scientific disciplines of microbiology and immunology. Advances in these key fields have led to a better understanding of the human immune system and the mechanisms of infectious and immune-mediated diseases. But the scope of NIAID programs also has grown because of a growing realization that biomedical research is a key component of a successful response to new challenges posed by emerging and re-emerging infectious diseases such as pandemic influenza and HIV/AIDS, the threat of bioterrorism, and the increase in asthma prevalence among children.

EMERGING AND RE-EMERGING INFECTIOUS DISEASES

Despite advances in medicine and public health such as antibiotics, vaccines, and improved sanitation, the World Health Organization (WHO) estimates that infectious diseases still account for approximately 26 percent of all deaths worldwide, including about two-thirds of all deaths among children younger than five years of age. Moreover, the pathogens we face are not static, but change dramatically over time as new microbes emerge and familiar ones re-emerge with new properties or in unusual settings.

Influenza is perhaps the most pertinent example of a re-emerging disease. Influenza viruses continually accumulate small changes such that a new vaccine must be made for each influenza season. When a totally new influenza virus against which the global population has no natural immunity emerges, a worldwide pandemic can result if the new viruses are able to transmit efficiently between people. Three such pandemics occurred in the 20th century, in 1918, 1957, and 1968. The pandemics of 1957 and 1968 were severe infectious disease events that killed approximately two million and 700,000 people worldwide, respectively. The 1918–1919 pandemic, however, was catastrophic. Public health experts estimate that the 1918 pandemic killed more than 500,000 people in the United States and more than 50 million people worldwide.

The highly pathogenic H5N1 avian influenza virus currently found in domestic and migratory birds in Asia, Africa, the Middle East, and Europe is of great concern. Although H5N1 is primarily an animal pathogen, it nonetheless has infected more than 170 people; more than half of all confirmed H5N1 patients have died. At this time, the virus is not able to spread efficiently from animals to humans and is extremely inefficient in spreading from person to person, but the feared human influenza pandemic could become a reality if the H5N1 virus mutates further or mixes its genes with human influenza viruses, remains highly virulent, and acquires the capability to spread efficiently from person to person.

It is imperative that we prepare for the possibility that a new influenza virus will emerge to cause a 1918-like pandemic among human beings. It is important to note, however, that our ability to cope with a pandemic—with a sufficient supply of effective vaccines and antiviral drugs, effective infection control, and clear public communication—will to a large extent depend on how well we cope with seasonal influenza. It is clear that we have not yet optimized our preparedness and responsiveness to this recurring disease, which, according to estimates of the Centers for Disease Control and Prevention (CDC), kills an average of about 36,000 people in the United States each year. The serious vaccine shortage that occurred in the 2004/05 influenza season underscored the difficulties we face in annually renewing the influenza vaccine supply, and highlights the pressing need to move toward adoption of newer vaccine manufacturing techniques and other strategies that can improve the surge capacity, flexibility and speed with which vaccines are made.

NIAID supports numerous research projects that lay the foundation for improved influenza vaccine manufacturing methods, new categories of vaccines that work against multiple influenza strains, as well as the next generation of anti-influenza drugs. Some of these are basic research projects intended to increase our understanding of how animal and human influenza viruses replicate, interact with their hosts, stimulate immune responses, and evolve into new strains. Other projects are more targeted, such as a program to screen compounds for antiviral activity against influenza viruses. One particularly important effort is to develop a vaccine that raises immunity to parts of the influenza virus that do not vary from season to season. Not only would such a vaccine provide continued protection over multiple influenza seasons, it might also offer considerable protection against a newly-emerged pandemic influenza virus and thereby substantially improve our preparedness for pandemic threats.

The Department of Health and Human Services (DHHS) Pandemic Influenza Response and Preparedness Plan designates NIAID as the lead agency for research and development efforts related to pandemic influenza. In this capacity, NIAID has developed and is clinically evaluating several candidate H5N1 vaccines, including inactivated and live-attenuated vaccines, as well as other strategies such as recom-

binant subunit and DNA vaccines. The potential benefits of NIAID research to the American public have been clear and immediate. The pre-pandemic H5N1 vaccine that is currently being stockpiled by DHHS was shown in clinical trials by NIAID to be safe and capable of inducing an immune response that would be predictive of being protective against the H5N1 virus. The dose of vaccine required for this protection, however, is high; and current NIAID studies are aimed at enhancing the response to lower doses of the H5N1 vaccine, particularly with the use of adjuvants, which are compounds that have been shown to enhance the immune response to vaccines. NIAID also conducts surveillance for the molecular evolution of influenza viruses among animals and humans in Asia and elsewhere, and tracks changes in the virus that might allow it to be transmitted more easily among people. The Institute also is evaluating new antiviral drugs against H5N1 influenza as well as combinations and varied doses of existing drugs. In addition, NIAID is working to establish a clinical trials network in Southeast Asia to conduct research on emerging infectious diseases, with an initial emphasis on influenza.

Influenza is by no means the only emerging and re-emerging infectious disease threat that the world faces. For example, malaria is a substantial and growing problem compounded by the emergence of drug-resistant malaria parasites and insecticide-resistant mosquito vectors. NIAID supports a large malaria research portfolio; one recent study identified a specific parasite gene that is essential for full maturation of the parasites in mice. Disrupting this gene not only prevented the onset of disease in mice, but injection of the modified parasites stimulated an immune response that protected them from subsequent infection with unmodified, fully-virulent malaria parasites. This indicated that genetically attenuated parasites might be useful as a malaria vaccine in the future.

Tuberculosis (TB) is an example of a microbial disease that has reemerged in recent years. Infection with *Mycobacterium tuberculosis* is estimated to be prevalent in one-third of the world's population and is especially common among persons infected with HIV. NIAID supports a large portfolio of research to develop new drugs, vaccines, and diagnostics for TB and to evaluate improved treatment and preventive regimens. Recently, two novel, engineered TB vaccines developed with NIAID support entered Phase I clinical trials in the United States. These promising candidates are the first new TB vaccines to be tested in people in more than 60 years. In addition, the Global Alliance for TB Drug Development and NIAID have collaborated to develop a promising new TB drug candidate, which is now being tested in clinical trials. NIAID also has made substantial research progress on West Nile Virus, multi-drug resistant tuberculosis (MDR-TB), SARS, and other new or re-emerging infections.

HIV/AIDS RESEARCH

HIV/AIDS was first recognized as an emerging disease only 25 years ago. Today it is a global catastrophe. According to the Joint United Nations Program on HIV/AIDS (UNAIDS), approximately 40 million people worldwide are living with HIV/AIDS, and their number is increasing by more than 5 million people every year—about 14,000 each day. In the United States, more than one million people are living with HIV/AIDS, and approximately 40,000 new infections occur annually. Worldwide, more than 25 million people with HIV have died since the pandemic began, including more than 520,000 in the United States. In 2004, there were 3 million deaths worldwide due to HIV/AIDS. These statistics are grim reminders of the physical and emotional devastation to individuals, families, and communities coping with HIV/AIDS, and of the terrible impact of HIV/AIDS on regional and global security and the global economy.

Development of a vaccine that protects against HIV/AIDS is one of the highest priorities of the NIAID. The scientific challenges that must be overcome, however, are extraordinary. Because the immune system, with rare exceptions, has not been shown to contain HIV on its own, an HIV vaccine will have to elicit an even stronger immune response than elicited by natural HIV infection if it is to prevent infection. To help meet these challenges, NIAID established the Center for HIV/AIDS Vaccine Immunology (CHAVI) in June 2005. CHAVI's mission is to tackle the fundamental immunological obstacles in HIV vaccine research and to design, develop, and test novel HIV vaccine candidates. The establishment of CHAVI complements NIAID's continued support of other innovative research projects conducted through a highly cooperative and collaborative global research and development program.

Among many HIV vaccine research efforts, NIAID scientists have developed a two-part vaccination strategy, consisting of an initial (prime) vaccination followed by a later (boost) vaccination. The priming dose is a "naked" DNA vaccine, and the boost is a recombinant adenovirus vaccine, which is based on a highly attenuated

version of a common cold virus. Both components contain genes from three different subtypes of HIV that together cause about 85 percent of all HIV infections around the world. An initial Phase I clinical trial showed that the pair of vaccines was well-tolerated and induced substantial immune responses. Building on these promising findings, NIAID recently launched a second phase of testing of this “prime-boost” strategy. This project is a collaboration between three international clinical trial networks—NIAID’s HIV Vaccine Trials Network, the non-profit International AIDS Vaccine Initiative, and the U.S. Military HIV Research Program—and expands the safety and immunogenicity testing of the prime-boost strategy in the Americas, South Africa, and Eastern Africa. Also underway and slated to complete enrollment this year is the evaluation of a candidate adenoviral vaccine administered without a DNA vaccine to determine whether it may be useful alone in preventing HIV infection or disease.

The use of potent combinations of anti-HIV drugs, many of which were developed with NIAID support, has dramatically reduced the numbers of AIDS deaths in industrialized countries. Most recently these drugs have had a major impact on several developing countries in sub-Saharan Africa, the Caribbean, South America and Asia, as drugs have become available to them. Indeed, these drug regimens have transformed the complexion of HIV/AIDS throughout the world, saving the lives of millions of people. These results are some of the most cogent examples of the practical benefits of NIH-supported research. But we cannot be complacent in our success. Anti-HIV drug regimens often cause serious side effects and frequently lose their effectiveness due to the emergence of resistant forms of HIV within a patient. Clinical research is moving new classes of AIDS drugs closer to market and defining how to optimally use currently licensed medications. Basic HIV research continues to uncover additional viral and cellular targets for therapy. For example, several potential drug targets have been identified by determining the mechanisms that HIV uses to gain entry into host cells. These include fusion inhibitors, the first of which was recently approved by the Food and Drug Administration (FDA). In addition, several inhibitors of the HIV enzyme that allows the virus to enter and integrate into an infected cell’s genes have shown great promise in clinical trials.

BIODEFENSE RESEARCH

The potential use of biological agents in a terrorist attack is a serious threat to the citizens of our nation and the world. Research to mitigate this threat is a key focus of NIAID. The NIAID Strategic Plan for Biodefense Research, developed shortly after the terrorist attacks of 2001, outlines three essential pillars of the NIAID biodefense research program: infrastructure needed to safely conduct research on dangerous pathogens; basic research on microbes and host immune defenses that serves as the foundation for applied research; and targeted, milestone-driven development of medical countermeasures to create the vaccines, therapeutics and diagnostics that we would need in the event of a bioterror attack. Implementation of this plan enhances not only our preparedness for bioterrorism, but also for naturally occurring endemic and emerging infectious diseases. In addition, NIAID was recently given the role of coordinating and facilitating NIH research into countermeasures to mitigate harm to civilians from chemical and radiological/nuclear weapons. Other NIH Institutes and Centers will also contribute substantially to these efforts. The NIH Strategic Plan and Research Agenda for Medical Countermeasures against Radiological and Nuclear Threats was released in June 2005, and the NIH Strategic Plan and Research Agenda for Medical Countermeasures against Chemical Threats is scheduled to be released in mid-2006.

Perhaps the most tangible signs of NIAID’s biodefense research progress are the biocontainment research facilities now under construction, which will be capable of safely containing dangerous pathogens, enabling scientists to study such agents. For example, through its extramural program, NIAID is supporting the construction of two National Biocontainment Laboratories—capable of safely containing the most deadly pathogens—as well as thirteen Regional Biocontainment Laboratories nationwide. In addition, three intramural biocontainment labs—on the NIH campus, on the National Interagency Biodefense Campus at Fort Detrick in Frederick, MD, and at the NIAID Rocky Mountain Laboratories in Hamilton, MT—are either complete or under construction. NIAID also has established a nationwide network of Regional Centers of Excellence (RCEs) for Biodefense and Emerging Infectious Diseases Research; two new RCE awards were announced on June 1, 2005, bringing the total number of RCEs nationwide to ten.

The investment in biodefense research has already yielded substantial dividends, some of which are of immediate benefit while others provide considerable promise for the future. Our basic research and clinical trials have already greatly increased

our ability to respond to the threats of smallpox, anthrax, and Ebola with new and improved vaccines. For example, in November 2004, DHHS awarded a contract for the acquisition of 75 million doses of a new anthrax vaccine to be held in the Strategic National Stockpile. NIAID's support of the development of this vaccine was instrumental in making this initiative possible. In addition, NIAID-supported scientists recently discovered that a poxvirus infection may be halted by a cancer drug aimed not at the virus, but at the host cellular machinery that the virus needs to spread from cell to cell. Although much work remains, this research provides a lead to not only a new therapeutic approach to poxviruses such as smallpox, but also a means of circumventing antiviral drug resistance for other viruses. In another example of critical new discoveries, NIAID-supported scientists demonstrated that host cell proteins called cathepsins play an essential role in the Ebola virus' ability to enter and infect cells, and that inhibitors of cathepsin activity block viral entry and reduce the production of infectious Ebola viruses. This suggests that drugs that inhibit the activity of cathepsins might be useful as anti-Ebola therapies.

NIAID's implementation of its Strategic Plan for Biodefense Research has been aided by the enactment of the Project BioShield Act of 2004. Project BioShield provides NIH additional flexibility in awarding contracts, cooperative agreements, and grants for research and development of critical medical countermeasures. The BioShield Act also provides NIH with streamlined personnel authority, which has allowed NIAID to hire highly-qualified individuals to fill key positions related to product development. Lastly, Project BioShield provides NIAID with additional authority for the construction of research facilities, which NIAID used to award grants in fiscal year 2005 for the construction of four Regional Biocontainment Laboratories.

RESEARCH ON IMMUNE-MEDIATED DISEASES

Autoimmune diseases, allergic diseases, asthma and other immunologic diseases are significant causes of chronic disease and disability in the United States and throughout the world. Autoimmune diseases affect 5 to 8 percent of the U.S. population; asthma and allergic diseases together are the sixth leading cause of chronic disease and disability in this country; and asthma is the leading cause of hospitalizations and school absences among children. A promising strategy to treat and prevent immune-mediated diseases is known as immune tolerance. Immune tolerance therapies are designed to preprogram immune cells in a highly specific fashion to eliminate injurious immune responses, such as those seen in autoimmune diseases, while preserving protective responses needed to fight infection. The NIAID has established a comprehensive program in immune tolerance research, including basic research, preclinical testing of promising strategies in nonhuman primates, and clinical evaluation through the Immune Tolerance Network (ITN), a consortium of more than 80 investigators in the United States, Canada, Western Europe, and Australia. Currently, NIAID is supporting more than 40 clinical trials of immune tolerance strategies to treat autoimmune diseases, allergic diseases, and transplant rejection.

NIAID-supported research in immune-mediated diseases has led to significant advances in our understanding of how to manage these diseases. For example, NIAID-supported scientists recently identified novel ways to non-invasively assess the risk of kidney graft rejection by using immunologic and genetic biomarkers present in urine. If validated in larger studies, these biomarkers would allow physicians a non-invasive way to monitor transplant recipients for organ rejection, and intervene before organ injury, a significant advance in the clinical management of transplant patients.

NIAID also remains committed to improving the health of children with asthma, particularly those who live in our Nation's inner cities. For example, NIAID-supported researchers recently published the results of a study on the effect of home-based interventions that reduce exposure to common allergens such as cockroaches, house dust mites, and tobacco smoke. The study found that the interventions resulted in 20 percent fewer days with asthma symptoms and 14 percent fewer unscheduled clinic visits through the intervention year. We anticipate that our extensive research portfolio will continue to illuminate the causes of asthma and other immune-mediated conditions, and lead to new interventions to reduce the burden of these serious diseases.

CONCLUSION

The research conducted at NIAID and at NIAID-sponsored laboratories encompasses a broad array of basic, applied and clinical studies. This research has resulted in tangible benefits to the American public and to individuals throughout the world. By supporting talented researchers and emphasizing a balance of basic stud-

ies and targeted research, we hope to continue to develop innovative technologies and treatments to combat a wide range of important diseases that afflict humanity.

PREPARED STATEMENT OF DR. ELIZABETH G. NABEL

Mr. Chairman and Members of the Committee: I am pleased to present the fiscal year 2007 President's Budget request for the National Heart, Lung, and Blood Institute (NHLBI). The fiscal year 2007 budget includes \$2,901,012,000, a decrease of \$20,745,000 over the fiscal year 2006 enacted level of \$2,921,757,000.

The NHLBI was established as the National Heart Institute in 1948 with a mandate "to improve the health of the people of the United States" through research on diseases of the heart and circulation. And that is exactly what we have done. I believe it is no exaggeration to claim that, over the past decades, biomedical research has made more progress in cardiovascular disease than in any other major chronic health problem. The impact on death rates alone constitutes a monumental validation of this country's public investment in the NIH and the NHLBI.

The United States experienced an epidemic of coronary heart disease (CHD) during the twentieth century and, had the trend continued unabated, more than 1.6 million lives would be lost to CHD this year. In actuality, the toll will be less than 500,000 deaths, reflecting a 63 percent decline in age-adjusted mortality since 1950.¹ Mortality from stroke, the third most common cause of death in the United States, declined 70 percent over that time. The effect on longevity has been remarkable—looking just at recent data, we can see that between 1970 and 2000 the life expectancy of the average American increased by 6 years, and nearly 4 years of that gain was due to reductions in deaths from cardiovascular disease.

Much of the reduction in death rates has come from improved treatments for CHD. Not so long ago, atherosclerosis followed an inexorable course and, once an artery became occluded, blood flow could not be restored. Increasingly sophisticated technological developments in revascularization—coronary artery bypass surgery (1968), balloon angioplasty (1977), stents (1994), and now "drug-eluting" stents—coupled with vastly improved diagnostic procedures and new medications, have literally given many patients a new lease on life. NHLBI-supported basic and applied research studies, as well as carefully designed clinical trials, have enabled scientists to develop these interventions, to assess their utility and safety, and to determine the characteristics of patients most likely to benefit from them. Millions of Americans suffer from cardiovascular disease, and this research has contributed enormously to our ability to help them live longer and healthier lives.

We are equally pleased to reflect on improvements that have occurred in our ability to treat acute heart attacks. In past generations, doctors could only stand by while a heart attack ran its course and they had little to offer the patient but bed rest and a prognosis of rapid death or severely restricted life as a "cardiac cripple." All that changed in the 1980s when scientists determined that most heart attacks occur because of a blood clot in an artery that feeds the heart. The development of thrombolytic—"clot-busting"—therapy followed. NHLBI-sponsored clinical trials of thrombolysis demonstrated that the procedure could limit the area of damaged heart muscle and decrease mortality. This was revolutionary, and it rapidly influenced how heart attack is treated.

The greatest benefit of thrombolysis, however, accrues in the initial minutes and hours after onset of the attack and, unfortunately, many patients do not reach the emergency room in time. In the 1990s the NHLBI initiated a successful trial of community-based interventions to reduce delays in seeking and receiving treatment for heart attack symptoms. The knowledge gained was used to develop Act in Time to Heart Attack Signs, a far-reaching public education campaign launched by the NHLBI during the NIH budget doubling. Also during the doubling, the Institute began a pilot program at Suburban Hospital to test a new approach to diagnosing heart attack patients who may be candidates for thrombolytic therapy. For many patients arriving at the emergency room with chest pain, diagnosis requires measurement of enzymes that appear in the bloodstream only hours after the heart attack has occurred—too late for effective thrombolysis. The experimental program is having great success in using MRI (magnetic resonance imaging) technology to provide a diagnosis in about 35 minutes, and we believe it may form the basis for a better approach to delivering prompt therapy to patients who are likely to benefit from it. In light of recent evidence that thrombolytic therapy may benefit patients who experience a clot-based stroke, we have also teamed up with the National Insti-

¹Data in this statement regarding mortality and life expectancy are from U.S. Vital Statistics.

tute of Neurological Disorders and Stroke to use MRI in evaluating patients who come to the emergency room with stroke symptoms.

Let me mention some special efforts to improve treatment of coronary heart disease in a highly vulnerable population—patients with obesity and type II diabetes. Although there is near-universal optimism that a cure for diabetes will ultimately be found, in the meantime the majority of patients are suffering and dying from cardiovascular disease. We are working to identify approaches to prevent and treat these complications, and I am happy to note that the budget doubling enabled us to move forward with full funding of two major new clinical trials in this area. The ACCORD trial is testing the extent to which control of blood pressure, cholesterol, and glucose levels to thresholds beyond those that are currently recommended will reduce the occurrence of cardiovascular problems. The BARI-2D trial, focused on diabetic patients who already have coronary heart disease, is weighing the merits of revascularization versus medical treatment and, in addition, studying two different approaches to controlling blood sugar. These trials are effortful and expensive because they involve multiple complex issues in diabetes management. However, they address a critical public health need, given the escalating prevalence of obesity and diabetes in the United States, and many among us are likely to benefit from their findings.

Much as we celebrate these advances in treatment, let me assure you that we have never lost sight of our ultimate objective—prevention. Indeed, we have had considerable success in identifying risk factors such as high blood pressure and cholesterol, developing and evaluating methods to control them, and translating the research findings into messages for health-care professionals, patients, and the general public. During the budget doubling, we launched The Heart Truth, an education campaign to raise awareness that heart disease is the leading cause of death in American women and call women to take action to reduce their risk of developing heart disease. Already we have evidence that the campaign's message, "Heart disease doesn't care what you wear—it's the #1 killer of women," has raised awareness throughout the nation. Last June we launched We Can! (Ways to Enhance Children's Activity and Nutrition), a national education program to help children 8–13 years of age stay at a healthy weight. We Can! offers parents and families tips and activities to encourage healthy eating, increase physical activity, and reduce sedentary or screen time. It also provides resources to help community groups and health professionals work toward these goals.

Much of what we know about factors that put people at risk of developing cardiovascular diseases has come from the multigenerational Framingham Heart Study, begun in 1948. I am delighted to announce that the NHLBI, in conjunction with Boston University, recently unveiled a plan to take this study to the next level. Our new Framingham Genetic Research Study will entail up to 500,000 analyses of the DNA of 9,000 study participants. By identifying genetic variations that relate strongly to participant characteristics (e.g., blood pressure and cholesterol levels, overweight and obesity) and to outcomes (e.g., stroke, congestive heart failure, diabetes), we hope to refine our understanding of individual risk and identify carefully focused new strategies for treatment and prevention. We at the NHLBI share Dr. Zerhouni's vision of an approach to medical care that is predictive, personalized, and preemptive and we believe this new endeavor constitutes a major step toward realizing that goal.

PEDIATRIC HEART AND LUNG DISORDERS

Tremendous progress has been made in treating congenital cardiovascular malformations, the most common type of birth defect in the United States. Many of us remember when these conditions constituted a death sentence, but today we have an array of surgical and medical treatments, as well as reliable and effective methods for providing monitoring and support. As a result, more than 90 percent of these babies live to celebrate a first birthday. Indeed, the prognosis has improved so much that there are now more adults than children living with congenital heart defects, according to data from the Adult Congenital Heart Association. Nonetheless, congenital heart disease is still a major contributor to infant mortality and many challenges remain. Thanks to the budget doubling, we have been able to expand significantly our efforts in this area by funding two additional Specialized Centers of Research in Pediatric Cardiovascular Disease, establishing a clinical research network to enable rapid evaluation of new treatment approaches, and soliciting research proposals to develop devices for infants and children who experience cardiopulmonary failure and circulatory collapse.

As recently as 35 years ago, many premature infants died within hours of birth from neonatal respiratory distress syndrome (RDS), a condition caused by lack of

a substance called surfactant that keeps the lung's air sacs open for breathing. The NHLBI's long-term investment in basic, applied, and clinical research has nearly relegated neonatal RDS to history. With development of special ventilation techniques to sustain babies until their lungs matured, introduction of a prenatal test for lung maturity, and demonstration that antenatal corticosteroid treatment could accelerate lung maturation, U.S. deaths from this disorder fell 60 percent between 1970 and 1984—from 10,000 to 4,000 per year. Then, in the 1980s, NHLBI-supported studies of surfactant structure, function, and regulation and efforts to identify the genes for surfactant proteins culminated in development of surfactant replacement products for testing in clinical trials. Since 1990, when two surfactant treatments were approved for widespread clinical use, neonatal RDS mortality has fallen more than 75 percent, to about 1,000 deaths per year.

ASTHMA

For centuries, asthma was viewed a bronchial spasm problem and treated—with limited success—as such. Our intensive research effort in recent years led to the realization that asthma is a manifestation of chronic inflammation and immune dysfunction. This insight revolutionized treatment, the mainstay of which now is anti-inflammatory medications to treat the underlying disease, with bronchodilators used chiefly for quick relief of symptoms. The NHLBI has also been a pioneer in development of self-management strategies and their application, especially for inner-city minority children; evidence indicates favorable effects on emergency room visits and school absences in this vulnerable population. Results of all these efforts are rapidly incorporated into national guidelines that set the standard for modern asthma management. Clinical research networks have proven invaluable for rapidly assessing new treatment strategies, and during the budget doubling we were able to renew our highly productive adult Asthma Clinical Research Network and initiate the Childhood Asthma Research and Education Network, which addresses pediatric asthma. We also began a program focused on severe asthma. These efforts are enabling us to make good on our promise to patients, “Your asthma can be controlled—expect nothing less.” And we are now talking with increasing confidence about curing asthma, going beyond the initial promise of asthma control.

SICKLE CELL DISEASE

As recently as 1970, the average patient with sickle cell disease died in childhood. Today, life expectancy is about 45 years. NHLBI research has led to a standard of care that begins with screening of newborns, provides prophylaxis for potentially lethal childhood infections, and offers transfusion therapy to prevent stroke in high-risk children. A clinical trial demonstrated the value of the drug hydroxyurea in preventing painful crises, acute chest syndrome (a life-threatening respiratory complication), and need for transfusions in adult patients. With the budget doubling, we have been able to undertake a hydroxyurea trial in children, and also to assess the value of stem cell transplantation as a possible cure. Our hope and expectation is that further gains in longevity and quality of life will be achieved.

I would be pleased to respond to any questions that the Committee may have.

PREPARED STATEMENT OF DR. DUANE ALEXANDER, DIRECTOR, NATIONAL INSTITUTE OF CHILD HEALTH AND HUMAN DEVELOPMENT

Mr. Chairman and Members of the Committee: I am pleased to present the fiscal year 2007 President's budget request for the National Institute of Child Health and Human Development (NICHD). The fiscal year 2007 budget includes \$1,257,418,000, a decrease of \$7,351,000 over the fiscal year 2006 enacted level of \$1,264,769,000 comparable for transfers proposed in the President's request.

The mission of the NICHD is vital to the NIH goal of ensuring the overall health and well-being of the American people. Our research focuses on both child health and human development. Increasingly, researchers are confirming that lifelong health and well-being are strongly influenced by events occurring early in life.

Understanding human development evolves from understanding normal growth and change processes before birth through adulthood. It begins at the most basic molecular and cellular levels and encompasses cognitive, behavioral, physical and social development. By understanding what goes “right,” NICHD research provides clues as to what may go “wrong,” laying the critical scientific foundation not only for understanding many disease processes, but also for preventing them altogether.

FETAL DEVELOPMENT: JUMP START ON LIFE

We now know that both undernourished and obese mothers have children with increased risk of chronic disease later in life. This is a problem world wide and it is an increasing problem in the United States.

To understand and reverse the epidemic of type 2 diabetes among young people, we need to look beyond their diet. The health and nutrition of the mother during fetal development influences not only how children function but also the later development of diabetes, high blood pressure, heart disease and other conditions. To better understand fetal origins of adult disease, researchers recently discovered links between birth weight and stress hormone (cortisol) levels in boys and girls who were small at birth, but healthy term babies. Cortisol helps to regulate blood pressure, energy production, and response to stress. The researchers found that the lower birth weight boys had higher levels of cortisol under stressful conditions compared to the higher birth weight boys. They found that the lower birth weight girls had higher cortisol levels at the beginning of the day. This discovery demonstrates how low birth weight can have lasting, yet different, effects on stress hormone levels in girls and boys. These alterations in cortisol may predispose children to obesity, hypertension, and glucose intolerance later in life.

PREDICTING PREECLAMPSIA

Preeclampsia is a sudden, dangerously high increase in high blood pressure that threatens the health of a pregnant woman and her fetus. Preeclampsia strikes without warning and can result in maternal seizures and even death. The researchers studying this condition found that women who, in mid-pregnancy, have a lower level of a substance known as placental growth factor were more likely to develop preeclampsia. This advance may lead to a screening test for preeclampsia and a treatment to help women avoid the condition.

OBSTETRIC PHARMACOLOGY—TREATMENT FOR PREGNANT WOMEN

Most drugs used to treat pregnant women are prescribed without full knowledge about safety and efficacy. In many cases, no data exists to predict how the drug's dynamics may interfere with a woman's pregnancy. To fill this knowledge gap, the NICHD has established the Obstetric-Fetal Pharmacology Research Units (OFPRU) Network to develop improved safety and efficacy drug information for pregnant women. One drug currently being studied is used to control gestational diabetes. Gestational diabetes affects up to 15 percent of all pregnancies according to the March of Dimes. The condition results from a sudden inability of the body to remove sugar from the blood. Untreated, gestational diabetes results in large, stocky babies who may cease breathing unexpectedly, have difficulty feeding, and must eat frequently to avoid seizures. Children of mothers with gestational diabetes are also likely to become obese during childhood and adulthood.

For many years, physicians treated gestational diabetes with injections of insulin. Recently, however, physicians began treating pregnant women with glyburide, which stimulates the pancreas to gradually release small quantities of insulin. Many patients preferred the convenience of taking a pill to giving themselves an injection. Although many pregnant women have taken glyburide, no studies have ever tested the drug's effectiveness in treating gestational diabetes. A new study is examining the use of glyburide in pregnancy, to determine if the current dosing schedule is the most effective means to treat the disorder.

PREMATURE BIRTH RESEARCH

Reducing preterm birth (PTB) is a major public health priority and a major research priority for this Institute. One out of eight infants in the United States is born preterm. This amounts to about 476,000 infants a year. The March of Dimes estimates that babies born too soon or too small cost the U.S. health system \$18.1 billion a year. Preterm infants face a number of serious health problems and life-threatening conditions. PTB accounts for nearly half of the neurological problems among newborns who are at risk of having learning disabilities and mental retardation. When preterm infants reach adulthood, they also face much higher risks of cardiovascular disease and diabetes.

The NIH investment in preterm birth research is paying dividends. For the first time, we now have a method to reduce the risk of PTB for some women. One of our studies found that weekly injections of a synthetic form of progesterone reduces the chances of preterm delivery in women who had already given birth prematurely. For the first time, this research gives doctors an intervention that has been shown to be both safe and effective in reducing the risks of preterm birth. This discovery also

illustrates how quickly research can be turned into practice. Shortly after this research was published, The American College of Obstetricians and Gynecologists recommended that all of their members use progesterone to prevent PTB for women with previous PTB. Another study found that pregnant women who have a condition known as bacterial vaginosis have a greater likelihood of delivering prematurely. For many years, these women have been treated with antibiotics. Contrary to existing clinical thinking, treating the infection with an antibiotic during pregnancy did not reduce the incidence of preterm birth. Still another NICHD study found that women with a condition known as trichomoniasis are also at increased risk for preterm delivery. The study found that giving antibiotics does not reduce the risk of preterm birth associated with infection; moreover, this treatment actually increased the preterm birth rate.

The new knowledge gained from each of these three studies was created by one of the multidisciplinary clinical research networks supported by the NICHD. With these networks in place, NICHD scientists working with researchers around the country can answer important scientific questions quickly, and work through professional organizations to help clinicians translate the new knowledge into practice.

The NICHD recently established the Genomics and Proteomics Network for Pre-mature Birth Research. This new network will focus on the hereditary information in DNA and the structure and function of proteins to understand the underlying processes that lead to preterm birth.

GENES MAY HOLD THE KEY TO TREATING UTERINE FIBROIDS

Each year, more than 200,000 women in the United States undergo a hysterectomy to treat the chronic pain and abnormal bleeding caused by fibroids. Scientists are exploring alternative ways to treat fibroids without surgery. Previously, these researchers identified a molecule called transforming growth factor beta (TGF- β) that helps to regulate several processes including the growth of uterine fibroids. Using a powerful new technology, the researchers identified the different genes influenced by the growth factor in both normal and fibroid cells. The researchers then tested a gene therapy that appeared to block production and action of TGF- β . This insight may lead to novel, non-surgical therapeutic approaches, not only to prevent uterine fibroid growth, but also to treat other reproductive conditions.

BUFFERGEL SHOWN TO BE SAFE CONTRACEPTIVE

Researchers have made a major step forward in developing contraceptives that protect women against HIV. One product, BufferGel, can be used with a diaphragm, much like a conventional spermicide. The results of a recent study demonstrate that BufferGel is as effective at preventing pregnancy as is currently available spermicides. A study is now in progress to determine if BufferGel can reduce transmission of the AIDS virus.

GENE PROGRAMS EARLY DEVELOPMENT AND NEURAL MIGRATION

NICHD researchers made a significant advance in understanding dyslexia. In an article that Science Magazine called one of the 10 major breakthroughs in 2005, the researchers linked the developmental gene DCDC2 to dyslexia. This gene functions to control nerve cell migration in early brain development. This work suggests that genetic miscues alter brain biology in the womb in a way that predisposes people to problems later in life.

FUTURE RESEARCH: NEWBORN SCREENING

The NICHD Newborn Screening Initiative is moving forward in its effort to develop and employ the latest technology for improving the availability, accessibility, and quality of genetic and other diagnostic laboratory testing for rare diseases and conditions affecting newborns. Ultimately, this research could help identify at-risk infants as early as possible and provide the data needed to develop therapies for many of these conditions. As a cornerstone activity, the NICHD funded a major grant for developing and refining a newborn screening test for spinal muscular atrophy (SMA), a common fatal neuromuscular disease in children. The NICHD will soon be funding additional grants to increase understanding of conditions such as SMA or other genetic conditions.

MATHEMATICS AND SCIENCE COGNITION AND LEARNING

The NICHD is enhancing its program to better understand the underlying developmental processes that allow children to learn math and science. One goal is to

help researchers understand the developmental and cognitive processes needed to help children transition successfully from arithmetic to algebraic reasoning, a fundamental skill needed to allow children to advance their understanding of mathematical concepts. In turn, mastering math-related concepts such as recognizing patterns, representing relationships, and making generalizations is key to learning and understanding science. These critical program activities fill a major research need to clarify the cognitive factors needed for scientific thinking and learning.

COMMUNITY-BASED REHABILITATION INTERVENTION

The aging of the baby-boom generation and expected pressures on the U.S. health care system make research into effective therapies in community settings a high priority. Clinical trials of rehabilitation therapies have demonstrated the efficacy of novel interventions in preventing or significantly lessening disabling conditions associated with stroke, traumatic brain injury, and other disorders and conditions. Little is known, however, about whether and how well such therapies will work in less-controlled community practice settings. Scientists do not know whether—or how—efficacious rehabilitative therapies and even clinical trial design may need to be modified for community settings. To address these critical questions, the NICHD will solicit applications for clinical trials by scientists partnering with persons with disabilities, practitioners, and others in the community.

Mr. Chairman and members of the Committee, the support you have shown for medical research has allowed scientists in research centers around the country to make discoveries that advance the health of women, children and families. I will be pleased to answer any questions.

PREPARED STATEMENT OF DR. BARBARA M. ALVING, ACTING DIRECTOR, NATIONAL CENTER FOR RESEARCH RESOURCES

Mr. Chairman and Members of the Committee: It is a privilege to present to you, for the first time, as the Acting Director of the National Center for Research Resources (NCRR), the President's budget request for NCRR for fiscal year 2007, a sum of \$1,098,242,000, including support for AIDS research, which reflects a net decrease of \$859,000 over the comparable fiscal year 2006 appropriation.

By developing and funding essential research resources, NCRR connects scientists with one another, as well as with patients and communities across the nation. These connections bring together innovative research teams and the power of shared resources, multiplying the opportunities to improve human health.

These connections can be seen in the new institutional Clinical and Translational Science Awards program, launched in fiscal year 2006, which enables researchers to train and collaborate in new ways to move findings in the laboratory more quickly to patients. NCRR also is bringing patients, advocacy groups, and researchers together to fight rare diseases—a unique opportunity to combine patient information and support with research knowledge. Other programs are helping investigators to create technologies that will make research information more accessible and precise through various software tools and Internet connections.

In addition, NCRR-supported technologies help researchers—located in isolated regions—share information that benefits underserved populations across the country. And at NCRR-supported primate research centers, investigators come together to study AIDS vaccines, Parkinson's, Alzheimer's, and many other diseases. Perhaps our most wide-ranging connections are made through science education—programs that reach young and old—on a diverse range of health-related issues.

These are just a few of the programs that comprise NCRR's portfolio, but they illustrate how we are investing research dollars in order to bring the power of shared resources to communities and researchers across the nation and ultimately improve the health of Americans. I would now like to provide you with additional details about each of these exciting programs.

INTEGRATING CLINICAL AND TRANSLATIONAL SCIENCE

Recognizing that a well-integrated collaborative effort is needed to transform basic discoveries into improved medical care, NCRR has launched an important new initiative—the Clinical and Translational Science Awards (CTSAs)—on behalf of the NIH Roadmap for Medical Research. The CTSA Program was initiated to break existing barriers between basic and clinical sciences and, above all, to get people to work together to speed the delivery of improved health care to the public. Developed with extensive input from the scientific community, the CTSAs will help research institutions nationwide create an academic home for clinical and translational re-

search, essentially generating what NIH Director Dr. Elias Zerhouni calls the “glue” that fills the gaps among scientists in multiple disciplines and thus forms a bridge between basic and clinical research.

In ongoing dialogues with the scientific community, researchers also have told us that the CTSA initiative will allow them to strengthen the career development pipeline for clinical and translational researchers. At the same time, it will build partnerships with communities that will ensure that diverse populations, and clinical practitioners serving those populations, play an integral part in addressing the unique health challenges that they face. With the community’s participation, the CTSAs will help to deliver improved medical care that meets the needs of these diverse patients and their communities.

CREATING PARTNERSHIPS: RARE DISEASES NETWORK

Another NCRR initiative—the Rare Diseases Clinical Research Network—illustrates the importance of bringing patients and researchers together. Headed by NCRR in partnership with the NIH Office of Rare Diseases, the network is truly a trans-NIH activity, with funding coming from five additional NIH institutes. The need for such a network is best appreciated when one considers the emotional toll a family faces when they find out that their child has a rare disease and the desperation they face when they search for medical resources. For example, Trish Hertzog, a mother from Philadelphia who agreed that we could tell her story to help others, can vividly recall the day her son Mathew was born more than a decade ago. Unbeknownst to anyone, including his doctors, this seemingly healthy newborn lacked a critical gene that helps to remove toxic substances from the body. Within two days of his birth, Mathew fell into a coma, as lethal levels of ammonia built up in his brain, and died within hours.

Mathew Hertzog had inherited a rare condition known as a urea cycle disorder, which affects only about 1 in 30,000 children. Collectively, rare diseases affect about 25 million Americans, according to the National Organization for Rare Diseases. Research on rare diseases is especially challenging since few patients with the same condition can be recruited from any one clinical site.

To improve outcomes and outreach, the Rare Diseases Clinical Research Network unites the efforts of researchers from multiple institutions and their patients nationwide. The Network’s web site has become a source of information for the public, physicians, patients, and investigators about rare diseases. The site also contains a unique web-based contact registry for patients who wish to learn about clinical studies. With this Network now available, parents like Trish can obtain information about rare diseases and learn about participating in one of the initial clinical trials.

WIDENING THE NET: UNDER-REPRESENTED POPULATIONS AND AREAS

NCRR is using the latest advances in technology to promote greater inclusion of under-represented minority and rural populations in research by boosting capacity in institutions and regions of the country that lack high-capacity, broad-bandwidth Internet connections. Some states—including Montana, Wyoming, Alaska, Idaho, Nevada, and Hawaii—lack access to advanced Internet applications, such as virtual laboratories, digital libraries, distance education, as well as advanced networking capabilities. This lack of resources hinders the ability of the institutions in these states to conduct collaborative, data-intensive biomedical studies. In the first phase of a national effort called IDeANet, NCRR is enhancing high-speed network connectivity in these five rural Western states and Hawaii, which will bring these areas on par with connectivity in the other parts of the country.

This effort is part of the Institutional Development Award (IDeA) Program, which broadens the geographical distribution of NIH funding for biomedical research. Ultimately, IDeANet will expand to include NCRR’s Research Centers in Minority Institutions Program, which enhances the research capacity and infrastructure at minority colleges and universities that offer doctorates in health sciences.

SPURRING ADVANCES THROUGH DATA SHARING

Through the Biomedical Informatics Research Network (BIRN), NCRR supports the integration of data, expertise, and unique technologies to spur scientific advances that would be difficult or impossible in the context of individual laboratories. To illustrate this point, five volunteer research participants traveled across the country to nine different sites to have their brains imaged via magnetic resonance imaging (MRI). The data that was collected contributed to a first-of-its-kind neuroimaging dataset that will enhance large-scale, multisite imaging studies for years to come. Scientists found that brain images from a single individual appeared surprisingly different when collected at different MRI centers—such variance would

greatly hamper multi-site imaging studies. Through BIRN, scientists have recently developed software tools to standardize data and reduce this type of inter-site variability in brain scans. This collaboration is just one example of how BIRN contributes to solving complex health-related problems. While initial efforts are focusing on neuroimaging data, the tools and technologies developed by BIRN ultimately may be applied to other disciplines.

PROVIDING CRITICAL LINKS: NONHUMAN PRIMATE RESEARCH

Studies of nonhuman primates are indispensable to translational research, providing a critical link between small laboratory animals and human subjects. Many of today's life-saving interventions—including polio vaccines, AIDS-fighting drugs, and heart surgery techniques—depended on preliminary evaluation in nonhuman primates like the rhesus macaque. To support such studies, NCRP funds eight highly specialized research facilities known as the National Primate Research Centers, which bring together researchers with a variety of expertise, thereby contributing to studies of major human health issues, including cancer and neurodegenerative disorders.

Because the nation currently lacks a sufficient number of clinically trained primate veterinarians, NCRP plans to support an initiative to attract and train graduate-level veterinarians in the procedures for conducting primate research. A well-trained veterinary research corps will enhance the country's capacity to respond to the emergence and spread of potentially deadly human diseases, such as severe acute respiratory syndrome (SARS), influenza, and hepatitis.

PROMOTING SCIENCE AND HEALTH LITERACY

By supporting collaborations among educators, researchers, community groups, museums, and other organizations, NCRP's Science Education Partnership Award program increases the public's understanding of medical research and delivers information about healthy living and career opportunities in science to children and the general public. For instance, a novel project at the University of Maryland is infusing physical education classes in grades 3–5 with science-enriched curriculum to enhance children's knowledge of the heart and other muscles and the importance of physical fitness. Another project, a partnership involving the University of Hawaii and culturally diverse local communities, is designed to enhance biomedical education and mentoring for children and their teachers on isolated Hawaiian islands. By providing students with opportunities to participate in hands-on, inquiry-based research projects, NCRP hopes to demystify science and make it more accessible to individuals throughout the nation.

CONCLUSION

The future of medical care will depend on our commitment to bring together scientists with diverse expertise and to support research institutions with varying strengths and research capacities. At the same time, we must ensure the participation of researchers and patients who are from ethnically and geographically diverse communities and share the importance of medical research with educators and students. Our goal in the coming year is to enhance these collaborations, partnerships, and networks in order to bring the power of shared resources to researchers across the nation and maximize our research investments.

PREPARED STATEMENT OF DR. JEREMY BERG, DIRECTOR, NATIONAL INSTITUTE OF GENERAL MEDICAL SCIENCES

Mr. Chairman and Members of the Committee: I am pleased to present the fiscal year 2007 President's budget request for the National Institute of General Medical Sciences (NIGMS). The fiscal year 2007 budget includes \$1,923,481,000, a decrease of \$12,137,000 from the fiscal year 2006 enacted level of \$1,935,618,000 comparable for transfers proposed in the President's request.

NIGMS supports a broad spectrum of research central to the National Institutes of Health's mission of improving the nation's health. Over the years, this foundational work has led to important breakthroughs and treatments. Biophysical studies sparked the development of life-saving drugs for AIDS. Inventive burn and trauma research yielded the first artificial skin to treat severely burned patients. Most recently, research in pharmacogenetics led the Food and Drug Administration (FDA) to change the label of irinotecan, a drug approved in 1996 for colorectal, lung, and other cancers. The label now indicates that people with a certain genetic vari-

ation are at a greater risk for life-threatening reactions to the drug and encourages doctors to use a lower starting dose for those patients.

In other areas, such as chemistry, groundbreaking basic research helped support drug development by the pharmaceutical industry. NIGMS' investment in this area was recognized with the 2005 Nobel Prize in chemistry, bringing the number of laureates whose research we have funded to 57. Long-time grantees Robert H. Grubbs, Ph.D., of the California Institute of Technology and Richard R. Schrock, Ph.D., of the Massachusetts Institute of Technology were honored for developing a revolutionary way of synthesizing new molecules. Their discoveries transformed a seemingly esoteric process into a practical tool that is now routinely used in the pharmaceutical industry and in other areas of the economy, including the plastics industry.

STRENGTHENING THE PIPELINE

In addition to providing stable research support to these chemists, NIGMS provided funds to support their transition from trainees to independent researchers. The Institute has a number of structured programs that offer thousands of trainees access to state-of-the-art resources, rigorous curricula, and high-quality ethics training. Each year, many scientists receiving NIGMS support launch independent careers and join the ranks of top-notch researchers in a wide range of scientific disciplines.

Many creative contributions like the few I have highlighted above are the work of individual bright minds. However, as biomedical research converges and scientific fields meld together in new ways, researchers working in different areas need to combine their talent and expertise. Recognizing the dual need for teamwork and individual intellectual contribution, NIGMS has invested its resources wisely. In addition to funding a substantial number of individual investigators, we have broadened our investment by funding large, multidisciplinary scientific teams. These programs have served a truly catalytic role in tackling issues of great importance to public health, and I would like to describe some of their recent advances.

DAWN OF PERSONALIZED MEDICINE

The NIGMS-led Pharmacogenetics Research Network (PGRN), a trans-NIH project consisting of 12 scientific teams, has just completed its first 5 years of work with an impressive track record. For example, the treatment of childhood leukemia is improving due to the discovery that variations in two genes can predict which patients with the most common form of the disease have a higher risk of relapse. On the horizon is safer dosing of the widely used blood-thinning medicine Coumadin® (also known as warfarin) due to the discovery that normal variation in two genes can put some patients at risk for excessive bleeding or for heart attacks and strokes. PGRN researchers have also made important strides in unraveling disparities in response to treatments for asthma, a disease that affects roughly 20 million Americans, according to the American Lung Association. Recent findings show that variation in just a few genes affects responses to two mainstay asthma therapies, inhaled steroids and beta-agonists. Genetic tests to detect these variations may be available within a year.

Other payoffs from NIGMS investments in pharmacogenetics extend beyond implications for individual drug dosing. PGRN research has unexpectedly uncovered knowledge that can predict disease risk in subsets of patients, including those taking tamoxifen for breast cancer and beta-blockers for heart disease. Finally, NIGMS-sponsored research in pharmacogenetics is having an impact on policy. PGRN studies have played a role in the FDA's recent decision to develop new guidelines for personalized medicines. For example, an FDA program that allows manufacturers to submit pharmacogenetic data for review has seen a jump from six submissions to 25 in the space of 1 year.

TEAMING SCIENCE FOR PUBLIC HEALTH GAINS

NIGMS' innovative "glue grant" program is a novel approach that brings together scientists from different disciplines to attack problems beyond the scope of an individual investigator but crucial to the future of the public health enterprise. One example of a recent glue grant advance is the discovery that genes can help explain why patients can have dramatically different reactions to traumatic injury. The NIGMS-funded Inflammation and the Host Response to Injury research group, which performed this study, will also release this year a set of standard operating procedures for the care of critically injured patients. This work, while still in the early stages, is moving ahead rapidly and will likely improve standards for treatment across the nation as well as facilitate the conduct of high-quality research in this important field.

Many areas of basic biomedical research require an incubation period before results emerge and new knowledge is translated into the clinic. Both pharmacogenetics and much of the complex biology being investigated with glue grants are good examples, and the recent achievements I've described offer evidence that the wait has been worth it. However, in other circumstances NIGMS has invested basic research expertise in areas quite ripe for practical development. A case in point is the Models of Infectious Disease Agent Study (MIDAS), not yet 2 years old, which has already made an important mark on the public health policy landscape. Several key papers have emerged from this highly interdisciplinary effort, and the program continues to be fluid, evolving to match public health needs. The MIDAS network is focusing on modeling the spread of influenza, and its models are providing key inputs to policy makers and health officials engaged in preparing for possible influenza pandemics.

VALUE OF A SYSTEMS APPROACH

The ready application of MIDAS research to current flu preparedness efforts is apparent, but I'd like to point out that this research is a shining example of what may seem a more esoteric concept: systems biology. In fact, systems biology is a powerful and promising approach for investigating how to control the progression of diseases worldwide.

Systems biology addresses how the parts of a complex network work together to produce the behavior of the overall system. The threads of systems biology are apparent in pharmacogenetics, which goes beyond the consideration of a drug and its target to examine other molecules that affect drug action and determine how apparently subtle variations in these molecules can affect drug efficacy and safety. In infectious disease modeling, the properties of an infectious agent are superimposed on the structure of society, from transportation networks to human behavior. Systems biological approaches require interdisciplinary teams of scientists working together toward a common goal that is often closer to practical applications than are the powerful, "one component at a time" approaches that have driven biomedical research so successfully over the past decades.

POWER OF THE MIND

Let me finish by returning to the contributions of individual minds. I'll highlight two relatively young scientists who have been recognized by the NIH Director's Pioneer Award program for their exceptional potential to make major breakthroughs.

The first is Sunney Xie, Ph.D., of Harvard University. He is a pioneer in the development of methods that can see single biological molecules in action. Most biomedical experiments examine millions or more molecules, revealing the average behavior of all of them. While this information can be highly useful, many details are lost. Dr. Xie's methods, developed through an inspired application of techniques from physics and chemistry, look at the behavior of one molecule at a time. This is like being able to hear one conversation clearly rather than hearing the din of a room full of people all talking at once. As these methods mature, they have the potential to transform our understanding of how gene expression is controlled in normal and diseased cells.

The second NIH Director's Pioneer Award winner I will mention is neurobiologist Erich Jarvis, Ph.D., of Duke University. Dr. Jarvis, an African American who grew up amid poverty, drugs, and violence in Harlem, seeks to unravel the mysteries of vocal learning. He is investigating this question using songbirds as a model system, and he has already made important strides in unlocking some of the complexity of one of biology's unexplored frontiers: the brain. Although his research falls outside the realm of the NIGMS mission and Dr. Jarvis is not currently an Institute grantee, I tell you his story for a different, very important reason. He is a terrific example of what we stand to lose if we do not continue to invest in the creative individual sparks of young scientists in our diverse society. At least part of Dr. Jarvis's rise to success can be attributed to chances he got in school. He participated in the NIGMS Minority Biomedical Research Support and Minority Access to Research Careers programs as an undergraduate at the City University of New York, Hunter College, where he received a bachelor's degree in biology and mathematics. He later earned a Ph.D. in molecular neurobiology and animal behavior from the Rockefeller University and today works at the forefront of an exciting discipline at the intersection of biomedical and behavioral research.

The creative energies of potential biomedical researchers—not just those in fields traditionally related to biomedicine but also those in associated fields in the physical, mathematical, behavioral, and social sciences—will drive advances leading to improvements in human health for many years to come. Nurturing a diverse sci-

entific workforce will enhance the vitality of our nation and improve the health of our children and their children.

Thank you, Mr. Chairman. I would be pleased to answer any questions that the Committee may have.

PREPARED STATEMENT OF DR. PATRICIA A. GRADY, DIRECTOR, NATIONAL INSTITUTE OF NURSING RESEARCH

Mr. Chairman and Members of the Committee: I appreciate the opportunity to present the fiscal year 2007 President's budget request for the National Institute of Nursing Research (NINR). The fiscal year 2007 budget includes \$136,550,000, a decrease of \$792,000 over the fiscal year 2006 enacted level of \$137,342,000 comparable for transfers proposed in the President's request.

I am pleased to describe some of the exciting research of the National Institute of Nursing Research (NINR). NINR is charged with supporting research that establishes the scientific basis of quality patient care regardless of disease or health status. We fund research that affects individuals across the lifespan and all health care settings, especially the underserved.

NINR is currently celebrating the 20th anniversary of its establishment at NIH. We have used this occasion not only to take stock of our accomplishments, but more importantly, to look toward the future role of NINR's research in today's increasingly complex health care environment. We are faced with an aging population at a time when our Nation is experiencing a shortage of nurses. We are also in an era of new technologies, which demands that nurses be technologically-savvy and able to adapt these new methods to a variety of patient populations and settings. This dynamic health care environment provides many opportunities for nursing research to address a variety of challenges and improve health care for all patients.

Let me give you a few examples of how our research has improved lives and the promise it holds for the future.

HEALTHY MOTHERS AND HEALTHY CHILDREN

Sleep and Healthy Pregnancies.—Women often complain of fatigue and difficulty sleeping during pregnancy, especially as they approach delivery. Researchers studied women who slept less than 6 hours per night or who experienced frequent sleep disturbances during their pregnancy. These women had significantly longer labors and were 3–4 times more likely to have a cesarean delivery than women who slept 7–8 hours a night with fewer disruptions. These results highlight the importance of adequate sleep during pregnancy, and suggest a need for care providers to stress better sleeping habits to their pregnant patients.

Children and Health Disparities.—In fiscal year 2007, NINR will solicit new intervention research proposals aimed at reducing health disparities among children. NINR is committed to reducing disparities in health care, but current research in this area often targets adults. Children who live in poverty have little access to health care, and these children are disproportionately from minority populations. NINR's effort to reduce disparities in child health will target such areas as: developing culturally-sensitive interventions to promote physical activity and healthy diets in children, reducing health risk factors in children that lead to poor health outcomes, and studying how gender and immigrant status affect child health and access to health care.

STAYING HEALTHY THROUGHOUT ADULTHOOD

Culturally-sensitive Diet Intervention.—Diabetes is prevalent among rural African-Americans, and compliance with dietary self-management guidelines is often poor. In one study, NINR researchers tested a dietary intervention for diabetic African-Americans living in rural South Carolina. Through culturally-tailored classes that taught healthy food choices and low-fat cooking techniques, participants successfully lowered their body weight and fat intake. Other community-based interventions that include culturally-relevant components show similar successes. These types of programs may be important tools in promoting health and reducing health disparities.

Heart Disease in Women.—Heart disease, the number one cause of death in the United States, is sometimes more difficult to diagnose in women than in men, because women can exhibit different symptoms of heart disease than men. Better ways of detecting heart disease are therefore needed. NINR investigators are currently developing and testing a new screening tool that could predict whether or not certain women are at risk for serious heart disease. The test takes into account the

different symptoms that women with heart disease experience, and its factors in the diverse symptoms experienced by women of different races.

UNDERSTANDING AGING AND CARING FOR THE ELDERLY

Improving Self-management for the Elderly.—The aging American population has tremendous implications for our health care system. Better tools are needed to prevent and treat the health problems experienced by the elderly in a cost-effective manner. Improving self-management strategies is one way to decrease hospital and long-term care costs. Health professionals have developed telehealth programs that allow elderly patients to monitor and manage their symptoms at home by communicating with their providers over the phone or the internet. However, the effectiveness of telehealth interventions has not been well-studied. NINR investigators are currently testing a self-management telehealth intervention for patients with heart failure. The investigators will study questions such as: Is the intervention more effective than traditional methods of treatment? Are elderly patients willing to use the new technology? Do these techniques save money? Findings from these studies may help providers better use technology in self-management. This could ultimately lead to a higher quality of life for patients, and lower health care costs for consumers.

Caregivers and Depression.—An aging population also means that an increasing number of spouses and children will be caring for their infirm partners or parents. In addition to significant economic and societal costs,¹ caregiving may also have serious negative health impacts. Caregiving can often be a stressful and time-consuming experience for those who take on the responsibility. NINR has funded a wide range of studies to analyze the burdens experienced by caregivers and develop methods to alleviate these burdens. One group of NINR researchers surveyed over 2,000 female caregivers of elderly veterans with dementia and found that over one-third of the caregivers exhibited symptoms of depression. However, less than one in five of those with depression were using antidepressants; Caucasians were twice as likely as African-Americans to be taking such medications. These results suggest that caregivers should be routinely screened for depression and that better efforts may be needed to educate informal caregivers about the potential benefits of antidepressant therapy.

PATIENTS AND FAMILIES AT THE END OF LIFE

The final stage of life is a challenging time for everyone involved, from the patient, to attending physicians and nurses, and to bereaved family and friends. NINR is the lead NIH institute for end-of-life research. We are charged with finding ways to improve end-of-life care for all involved and ensure that patients experience death with as much dignity and comfort as possible. We fund research on such topics as: better management of symptoms prior to death; improving communication between doctors, patients, and family members; and examining factors that influence end-of-life decision-making. NINR researchers continue to make important findings in these areas.

Communicating with Families at the End of Life.—One study found that physicians in intensive care units often fail in communicating with family members when discussing the withholding or withdrawal of care from a dying patient. Problems included failures to listen to the concerns or address the emotions of the family members. Physicians also failed to properly explain the uses and purpose of palliative care or the ethical basis for deciding to remove life-prolonging therapies. A better awareness of these gaps can help physicians and nurses improve their communication skills for talking to families in difficult times.

NURSING SHORTAGES AND TRAINING NURSE RESEARCHERS

The current aging of our population comes at a time when the supply of nurses in the United States cannot meet the demand. In addition, new advances in medical technology require a more technologically-savvy nursing workforce. There was a shortage of approximately 168,000 registered nurses in the United States in 2003, and this shortage is expected to top 1 million by 2020. The field of nursing research is experiencing the effects of this shortage. Fewer nurses mean fewer nurse researchers, and that means fewer nursing faculty.

NINR continues to fund innovative initiatives to train new nurse researchers. Our Nursing Partnership Centers to Reduce Health Disparities partner research-inten-

¹Langa KM, Chernew ME, Kabeto MU, Herzog AR, Ofstedal MB, Willis RJ, Wallace RB, Mucha LM, Straus WL, Fendrick AM, National Estimates of the Quantity and Cost of Informal Caregiving for the Elderly with Dementia. *J Gen Intern Med* 16: 770–778, 2001.

sive universities with minority-serving institutions to increase the number of researchers from underserved populations. We also continue to collaborate with universities on training students in fast-track baccalaureate-to-doctoral programs to speed the process of developing new nurse scientists and faculty.

NINR AND THE NIH ROADMAP

NINR has incorporated two key themes of the NIH Roadmap into its research agenda: Interdisciplinary Research Teams of the Future and Re-engineering the Clinical Research Enterprise. Historically, NINR has maintained a focus on interdisciplinary research, but increased collaborations made possible by the Roadmap have fully introduced nursing science to the rest of the scientific community. They have also enabled nurse scientists to expand the breadth of their own work. Because of the strongly clinical emphasis of the NINR research portfolio, the Roadmap's clinical research initiatives are ideally suited to NINR. We will actively pursue Roadmap initiatives that seek to develop new technologies to measure patient symptoms and quality of life, and others that strive to develop skilled clinical investigators with strong multidisciplinary backgrounds.

CONCLUSION

In conclusion, NINR continues to discover effective approaches to meeting the challenges of today's dynamic health care environment, while looking ahead to meet the health care needs of tomorrow. We will strive to improve the quality of care and quality of life for all individuals, especially the underserved, regardless of age or disease. We will also train the next generation of leaders in nursing research. The past twenty years have demonstrated the power of nursing research. The future holds endless opportunities.

Thank you, Mr. Chairman. I will be happy to answer any questions that the Committee might have.

PREPARED STATEMENT OF DR. RICHARD J. HODES, DIRECTOR, NATIONAL INSTITUTE ON AGING

Mr. Chairman and Members of the Committee: The NIA is requesting an fiscal year 2007 budget of \$1,039,828,000, a decrease of \$6,803,000, or .6 percent below the fiscal year 2006 enacted level.

Thank you for this opportunity to participate in today's hearing. I am Dr. Richard Hodes, Director of the National Institute on Aging, and I am pleased to be here today to tell you about our progress making and communicating scientific discoveries that will improve the health and well-being of older Americans.

There are today approximately 35 million Americans ages 65 and over, according to the U.S. Bureau of the Census, and this number is expected to rise dramatically in the coming decades as members of the Baby Boom generation reach retirement age. These older Americans are more likely than at any other time in history to enjoy good health and an active lifestyle: Data from the National Long Term Care Survey (NLTC) indicate that the rate of disability among older Americans dramatically declined from the 1980s through the mid 1990s, even among the "oldest old," people age 85 and older. At the same time, however, the downward trend in disability among the elderly may be in danger of reversal. Data from the National Health Interview Survey show that, over the same period, the disability rate actually rose significantly for people ages 18-59, with the growing prevalence of obesity an important factor in this trend. Now, in fact, some demographers are forecasting a complete leveling-off of the disability decline in the coming decade.¹

The mission of the National Institute on Aging (NIA) is to improve the health and well-being of older Americans through research. In support of its mission, the Institute conducts and supports an extensive program of research on all aspects of aging, from the basic cellular and molecular changes that occur as we age, to the prevention and treatment of common age-related conditions, to the behavioral and social aspects of growing older, including the demographic and economic implications of an aging society. In addition, the NIA is the lead Federal agency for research related to the all-important effort to prevent and treat Alzheimer's disease (AD). Finally, our education and outreach programs provide vital information to older people

¹Goldman DP et al. Consequences of Health Trends and Medical Innovations for the Future Elderly. Health Affairs online special issue "Health and Spending of the Future Elderly." R5-R17, 2005.

across the Nation on a wide variety of topics, including living with chronic conditions, maintaining optimal health, and caregiving.

ALZHEIMER'S DISEASE AND THE NEUROSCIENCE OF AGING

Alzheimer's disease is a devastating condition with a profound impact on individuals, families, the health care system, and society as a whole. Approximately 4.5 million Americans are currently battling AD, with annual costs for the disease estimated to exceed \$100 billion.² Moreover, the rapid aging of the American population threatens to increase this burden significantly in the coming decades: By 2050, the number of Americans with AD could rise to some 13.2 million, an almost three-fold increase.³

Dr. Zerhouni has told this Committee about the NIH's new paradigm for biomedical research that is "predictive, personalized, and preemptive." This vision greatly informs the NIA's comprehensive program of Alzheimer's disease research. NIA-supported investigators conduct research on topics across the spectrum of AD-related inquiry, from basic brain biology to clinical trials of potential interventions. Through these studies, we are uncovering new predictors of individual risk for AD, and using this information, along with a greater understanding of specific pathways mediating disease processes, we are developing new approaches to prevention and treatment.

Risk Factors and Early Diagnosis.—Population studies suggest that conditions affecting the circulatory system may be associated with higher risk for dementia, or that the presence of vascular disease may influence the progression of AD. One recent report indicated that AD dementia may be exacerbated by other cerebrovascular problems such as small strokes, while another linked untreated high blood pressure in mid-life with increased risk of dementia in later life. The possible association of diabetes, insulin resistance, and AD is garnering increased attention as well; recent findings from at least four long-term studies link diabetes with decline in cognitive function. The NIA recently funded two clinical trials to examine directly whether diabetes-related interventions might be effective in preventing or delaying cognitive decline or development of Alzheimer's disease.

Research suggests that the earliest AD pathology begins to develop in the brain long before clinical symptoms yield a diagnosis; the ability to make an accurate early diagnosis of AD would be highly beneficial. Improvements in brain imaging, coupled with the development of more sensitive cognitive tests, are enabling us to diagnose AD in the research setting with greater precision than ever before. Imaging techniques may become important for a number of other reasons, particularly in helping investigators understand events unfolding in specific regions of the brain in the very early stages of Alzheimer's disease and in assessing the effectiveness of potential therapeutic strategies. To speed both the development of imaging techniques and the discovery of biological markers to detect Alzheimer's disease, the National Institute on Aging and other Federal partners, in conjunction with nine pharmaceutical/biotech companies, the Institute for the Study of Aging, and the Alzheimer's Association, announced the Alzheimer's Disease Neuroimaging Initiative in October 2004. The study will test whether serial MRI, PET, or other biological markers can be used in conjunction with clinical and neuropsychological assessment to measure earlier and with greater sensitivity the development and progression of mild cognitive impairment (MCI) and early Alzheimer's disease. This major public-private partnership could help researchers and clinicians develop new treatments and monitor their effectiveness as well as lessen the time and cost of clinical trials. The study, which is taking place at approximately 50 sites across the United States and Canada, began recruitment in late 2005; approximately 800 people ages 55 to 90 will participate over the five years of the study.

Prevention and Treatment.—Results of a growing number of studies are suggesting that diet and exercise may have significant benefits on not only physical but also cognitive health. For example, in one recent study, researchers related fruit and vegetable consumption among 13,388 older women over a 10–16 year period to subsequent cognitive performance and found that women consuming the most green leafy vegetables experienced slower decline than women consuming the least amount. Long-term epidemiologic studies now also suggest that exercise may have a specific influence on aspects of cognitive decline, and researchers are hoping that

²Data from the Alzheimer's Association. See also Ernst, RL; Hay, JW. "The U.S. Economic and Social Costs of Alzheimer's Disease Revisited." *American Journal of Public Health* 1994; 84(8): 1261–1264. This study cites figures based on 1991 data, which were updated in the journal's press release to 1994 figures.

³Hebert, LE et al. "Alzheimer Disease in the U.S. Population: Prevalence Estimates Using the 2000 Census." *Archives of Neurology* August 2003; 60 (8): 1119–1122.

clinical trials will be able to directly test the therapeutic value of exercise and diet for improved cognitive performance and, eventually, for reduced risk of AD. Small clinical trials currently are ongoing to test the effects of exercise on cognitive decline, both in older adults with normal cognition and in persons with mild cognitive impairment with memory decline; a larger trial that would include a cognitive component is in the planning stages. In addition, the planned Lifestyle Interventions and Independence for Elders (LIFE) study, which has been designed to determine whether physical exercise is effective for preventing major mobility disability or death, will include a cognitive component. Clinical trials are also ongoing to test the effects of a variety of dietary supplements, including antioxidants and alpha-lipoic acid, on cognition.

Investigators are also searching for drugs that will be effective in stopping the progression of AD or, ultimately, preventing the disease altogether. Recently, investigators announced the discovery of the first agent shown to delay the clinical diagnosis of Alzheimer's in people with amnesic mild cognitive impairment, an MCI subtype strongly correlated with the later development of AD. The investigators found that individuals who took the drug donepezil (Aricept®) were at reduced risk of progressing to a diagnosis of Alzheimer's disease during the first year of the trial, but by the end of the three-year study there was no benefit from the drug. Although donepezil's effects were limited, the results are nonetheless encouraging. And although too little is known about donepezil's long-term effects to support a recommendation for its routine use to forestall the diagnosis of AD in people with mild cognitive impairment, these findings do suggest that chemoprevention of AD is possible and support our hope that future clinical studies will lead to more significant progress.

OTHER AGING-RELATED RESEARCH

Diseases of aging continue to affect many older men and women, seriously compromising their quality of life. Diseases and conditions currently under study at the NIA include:

Obesity.—Overweight and obesity are widespread in the United States and are associated with an array of health problems, including heart disease, stroke, osteoarthritis, adult-onset diabetes, certain types of cancer and physical disability. NIH has assigned a high priority to research on obesity.

These activities range from basic research on the genetic and biological mechanisms of overweight and obesity to human intervention studies. For example, recent studies of *C. elegans*, tiny worms frequently used for genetic studies, are providing important insights about fat regulation and storage that may be applicable in humans. NIA-supported researchers used RNA interference (RNAi), a technique in which genes are inactivated one at a time to determine their function, to screen the worm's genome and found some 417 genes involved with fat regulation and storage. Many of the genes they found have human counterparts, a number of which had not been previously implicated in the regulation of fat storage. The genes identified in *C. elegans* may ultimately suggest new targets for treating human obesity and its associated diseases.

Research has also shown that many of the disabling conditions affecting older people could be diminished through regular exercise and that fitness affects mortality risk regardless of an individual's body fat. One study, which followed men 30–83 years of age for an average of eight years, found that within each category of body fatness, “fit” men—as measured by exercise testing—were at a lower risk of death. In addition, among fit men, obesity was not significantly related to risk of death. In another study, low fitness increased mortality risk in men approximately fivefold for cardiovascular disease and threefold for all-cause mortality. Low fitness was associated with higher mortality in all weight groups.

At a 2004 NIA and Centers for Medicare and Medicaid Services (CMS) sponsored workshop, researchers used published findings and trends to postulate that if the United States were able to prevent obesity until a person reaches 65 years of age by adjusting the body mass index for all cohorts entering Medicare, we could realize a significant decline in the percent with heart disease and diabetes, a significant increase in the percent without disability, and a cost savings to Medicare on the order of \$10 billion annually over the subsequent 30 years.⁴

⁴Lakdawalla, DN et al. The Health and Cost Consequences of Obesity Among the Future Elderly. Health Affairs on line special issue “Health and Spending of the Future Elderly.” R30–41.

Heart disease.—Each year over 1 million Americans undergo angioplasty,⁵ a procedure in which a long, thin tube attached to a tiny balloon is used to access and widen a blood vessel at the site of narrowing or blockage. However, a significant number of these individuals go on to experience restenosis, or gradual narrowing of the artery at the site of the blockage; this condition is aggravated by the implanting of stents (tiny metal scaffolds placed inside the artery to hold it open). Restenosis usually occurs within six months of angioplasty and results from the migration of cells from the middle of the arterial wall into the inner layer of the artery, where they multiply and block normal blood flow. Recognizing that cell division is crucial to the development of restenosis, NIA scientists tested the anticancer drug paclitaxel (Taxol®), which arrests cell division, as a means of preventing the tissue growth that leads to vessel narrowing, and found that stents coated with paclitaxel can delay restenosis both safely and effectively. The investigators obtained a patent for these paclitaxel-coated stents, and a cooperative research and development agreement was established with private industry partners to begin clinical testing. Today, paclitaxel is one of only two drugs that, when applied to stents, have been shown to safely reduce the incidence of restenosis in humans. FDA approval of paclitaxel-coated stents was granted in March 2004, and currently over 70 percent of the drug-eluting stents used worldwide are paclitaxel-coated. Approximately 1.8 million patients worldwide have received paclitaxel-coated stents to date.

Diabetes.—NIH investigators searching for potential treatments for type 2 diabetes conducted a study of the compound exendin-4, an analog of a hormone that is naturally released after eating and that can lower blood sugar in people with diabetes. The investigators found that exendin-4 is safe and effective, and in April 2004, the Food and Drug Administration approved exenatide (Byetta™), a synthetic derivation of exendin-4, for the treatment of type 2 diabetes.

HEALTH COMMUNICATIONS AND PROMOTION

The NIHSeniorHealth website continues to be a major initiative that enables the growing number of “wired seniors” to find credible aging-related health information in an online format that is compatible with their cognitive and visual needs, as evidenced by NIH-supported research. Conceived by NIA and jointly developed with the National Library of Medicine (NLM), the website now includes 26 health topics developed by eleven NIH Institutes. Each month, 52,000 unique visitors browse over a half a million pages. NIHSeniorHealth serves as a model for web designers seeking to make sites accessible to older adults. To increase the number of older adults skilled in searching for health information online, NIA has developed and is evaluating a senior-friendly Internet training curriculum geared around NIHSeniorHealth and NLM’s MedlinePlus web site for those who train older individuals to use computers.

Changes in public health policy may necessitate the development of new communications strategies and techniques targeted at older Americans, as was demonstrated with the passage of Medicare Part D, the “prescription drug benefit” for U.S. seniors. NIA-supported researchers are currently using established datasets to rapidly collect information and analyze patterns of use under Medicare Part D; their findings have been communicated to the CMS on an ongoing basis and will inform the creation of new strategies for tailored communications that will assist older Americans in understanding and maximizing use of this important new program.

Thank you for the opportunity to testify before this Subcommittee. I would be happy to answer any questions you may have.

PREPARED STATEMENT OF DR. SHARON HRYNKOW, ACTING DIRECTOR, FOGARTY INTERNATIONAL CENTER

Mr. Chairman and Members of the Committee: I am pleased to present the fiscal year 2007 President’s Budget for the Fogarty International Center (FIC). The fiscal year 2007 budget includes \$66,681,000, which reflects an increase of \$303,000 over the fiscal year 2006 enacted level of \$66,378,000 comparable for transfers proposed in the President’s request.

Forty-seven years ago, Congressman John E. Fogarty noted, “Time and time again, it has been demonstrated that the goal of better health has the capacity to demolish geographic and political boundaries and to enter the hearts and minds of men, women, and children in the four corners of the earth. It is an issue which serves as a forceful reminder of the oneness, the essential brotherhood of man.” Congressman Fogarty, the visionary namesake of the National Institutes of Health’s

⁵Data from the National Heart, Lung, and Blood Institute.

(NIH's) John E. Fogarty International Center for Advanced Study in the Health Sciences (Fogarty), recognized that when it comes to disease, we are truly one world. His words and those of his Congressional colleagues implored us to work for "a healthy America, in a healthier world."

Today, Fogarty works to meet this goal in two ways: by supporting the whole of the NIH mission via international partnerships, and through the support of global health research and training programs aimed at improving the health of citizens in the United States and around the globe. As a nation, our interest in global health stems not only from humanitarian concerns, but also from an enlightened self-interest. Such interests involve protecting our nation from imported diseases, and political and economic considerations—healthy, stable countries make strong allies and trading partners. In addition, through partnerships with scientists from around the world, we are able to identify new strategies and new understandings of disease processes, including HIV/AIDS, tuberculosis, and chronic diseases such as heart disease, that affect us all. I welcome this opportunity to relate Fogarty's progress over the past year and proposed plans for fiscal year 2007. While Fogarty's programs span over 20 topical areas, I will focus on three exemplars in this summary.

BATTLE AGAINST HIV/AIDS

Fogarty continues to place a high priority on combating HIV/AIDS the deadliest pandemic of modern times. According to UNAIDS, an estimated 4.9 million people worldwide became newly infected with HIV in 2004—the highest number of new cases reported in any single year since the beginning of the pandemic. As the United States works to combat the spread of AIDS domestically and globally, trained scientists in countries hard-hit by AIDS are crucial allies in our fight. In the 18-year history of Fogarty's flagship AIDS program, the AIDS International Research and Training Program (AITRP), Fogarty has helped train 2,000 health scientists, including Ph.D. and Masters level researchers from developing countries working on AIDS. More than 50,000 have received short-course training in their home countries through this program. These scientists represent a substantial increase in the global capacity to fight AIDS and provide a wealth of allies in our international struggle.

Haiti has the largest number of people living with AIDS in the Caribbean. For almost two decades, Fogarty has invested in research and public health infrastructure to combat the HIV/AIDS crisis there. Haiti has now begun to "turn the corner on AIDS," according to Dr. Jean Pape, Haiti's leading AIDS researcher and long-standing Fogarty collaborator. As a result of Fogarty's work and that of partner agencies, HIV seroprevalence at a key sentinel site in Haiti dropped from 6.3 percent in 1993 to 2.9 percent in 2003.

Due to this strong research base, Dr. Pape's institution received a grant from the President's Emergency Plan for AIDS Relief (PEPFAR), allowing 2,000 patients to receive antiretroviral therapy. An analysis of the first 1,000 patients at the one-year follow-up indicates outcomes comparable to those achieved in the United States in terms of survival; other indicators show reduced amounts of HIV in the blood of AIDS patients, as well as increased amounts of cells that are critical to staving off the impacts of HIV. None of this would have been possible without the vision and foresight of Fogarty, working hand in glove with NIH partners, including the National Institute of Allergy and Infectious Diseases.

In fiscal year 2007, Fogarty plans to expand both major AIDS programs in its portfolio. The AITRP expansion would involve new U.S. universities, including minority institutions, important partners as we work to address global health challenges and the range of U.S. challenges on AIDS. In addition, Fogarty's new training program in clinical, operational and health services research would be expanded to build much needed capacity in monitoring and evaluating AIDS programs abroad.

ADDRESSING THE THREAT OF EMERGING AND RE-EMERGING INFECTIOUS DISEASES: PREDICTION AND PREEMPTION

Little is known about the ecological factors that lead to the emergence or re-emergence of infectious diseases, including potentially pandemic diseases such as avian flu. We do know that most new diseases come from animals, both wild and domesticated. But beyond that we have little ability to predict the emergence of new diseases, or how new or existing diseases spread among animals, and from animals to humans. To better understand the relationships between ecological factors that drive emergence and transmission of infectious agents, and to develop predictive models that would suggest practical modes to interrupt disease spread, Fogarty led the development of a unique interagency program on the Ecology of Infectious Dis-

eases (EID). The EID program fills a critical gap in our national effort to protect the health of the public—both in the United States and globally—against the threat of epidemic and emerging infectious diseases. The program links microbiologists, veterinarians, physicians, ecologists, geospatial scientists, and mathematical modelers together into transdisciplinary teams to create new knowledge and new methods to predict and prevent the spread of infectious disease. In its first years of operation, the EID program has already linked experts from 23 countries and has supported publication of over 200 scientific articles on dozens of human and wildlife diseases, including schistosomiasis, Hanta virus, cholera, and severe acute respiratory syndrome (SARS).

SARS was first reported in southern China in the winter of 2002–2003, and within a few months it had spread to over two dozen countries. Within a month of its discovery, SARS was recognized as a viral respiratory illness caused by a newly identified coronavirus (CoV), yet the origin of the virus and how it was initially transmitted to humans remained a mystery. Preliminary evidence suggested that the palm civet (a raccoon-like mammal common in live animal markets in southern China) might have spread the virus to humans. However, the occurrence of related viruses in bats led some to think these animals may have been involved. A team of Fogarty-funded researchers from the United States, China, and Australia collected and analyzed specimens from nine species of bats in their native habitats in southern China. The team studied the presence of antibodies to the SARS virus and performed genome sequencing of viral isolates from positive tissues, comparing these genome sequences to that of the SARS virus. Study results indicate that bats are the natural reservoir of the SARS virus, suggesting that palm civets played an intermediary role in human infections. These findings have major implications for development of public health strategies to combat the spread of SARS. In fiscal year 2007, FIC expects to expand the EID program in terms of the number of projects supported and their scope, simultaneously increasing the focus on supporting translation of research findings and predictions into action.

As we consider the daunting challenge of pandemic avian influenza, programs such as the EID can provide a critical component in our ability to predict and prevent emergence and transmission of this and other disease threats. The United States and its global partners will be better poised to make effective interventions to prevent the spread of avian flu through understanding of migration patterns of reservoir bird species, the interactions between humans, domestic animals and birds, and the pathogen dynamics in and among these hosts. We cannot predict the spread of this disease, in its current zoonotic form, using mathematical or statistical models if we do not support the fieldwork necessary to sample wild and domesticated birds (work done by ornithologists, veterinarians, and ecologists). The field data are useful only for post field analysis if we integrate them into predictive models. The interagency EID program is unique in its integration of these methods into interdisciplinary teams to understand the biology and predict disease emergence and transmission.

GLOBAL BURDEN OF TRAUMA AND INJURY

According to the World Health Organization (WHO), the numbers and the global burden due to trauma and injury are on the rise: more than 1.2 million people are killed in traffic accidents annually, and up to 50 million more are injured or disabled. If current trends continue, the number of people killed and injured on the world's roads will rise by more than 60 percent between 2000 and 2020. Almost 90 percent of deaths due to injuries take place in poorer countries—this is true for all forms of such trauma including road accidents, war, homicides, and suicides. And, according to the Association for Safe International Road Travel, road traffic accidents are the second leading cause of death for Americans abroad.

To address this growing challenge, Fogarty, working closely with the Centers for Disease Control and Prevention, WHO, the Pan American Health Organization, and eight other NIH institutes, initiated a research training program to build the capacity of developing country investigators and institutions to conduct human trauma and injury research. The International Collaborative Trauma and Injury Research Training (ICTIRT) program involves collaborators from United States and developing country institutions to train the next generation in basic and applied science, the epidemiology of risk factors, acute care and survival, rehabilitation, and the long-term mental health consequences of trauma and injury, including civil strife. Benefits of this program will accrue not only to developing countries but, as low-cost and effective strategies are identified, to communities around the world. This program was initiated with awards in fiscal year 2005 and fiscal year 2006. We anticipate new awards in fiscal year 2006 and fiscal year 2007.

CONCLUSION

The programs and international initiatives of the Fogarty International Center are a living testament to the vision of Congressman John E. Fogarty. As we consider the daunting global challenges of AIDS, avian influenza and chronic problems, including obesity and mental health disorders, we understand the interconnectedness of the United States and the global community. These challenges require us to move forward with efficiency and diplomacy, for the benefit of the American people and the global community.

PREPARED STATEMENT OF DR. THOMAS R. INSEL, DIRECTOR, NATIONAL INSTITUTE OF MENTAL HEALTH

Mr. Chairman and members of the Committee: I am pleased to present the fiscal year 2007 President's budget request for the National Institute of Mental Health (NIMH). The fiscal year 2007 budget includes \$1,394,806,000, which reflects a decrease of \$8,709,000 under the 2006 enacted level of \$1,403,515,000 comparable for transfers proposed in the President's request. In my statement, I will call to your attention our Nation's most prevalent mental and behavioral disorders and include a brief review of our research activities and accomplishments.

BURDEN AND COST OF MENTAL ILLNESS

Mental disorders are common, chronic, and disabling. They cause more disability than any other class of communicable medical illness in American adults under age 45, according to the World Health Organization's Global Burden of Disease report. The National Comorbidity Survey Replication (NCS-R), funded by NIMH and released in May 2005, documents the prevalence and severity of specific mental disorders in the United States. The study shows that half of all lifetime cases of mental illness begin by age 14, making these the chronic diseases of the young. About 6 percent of the U.S. population is afflicted with a severely disabling mental disorder in a given year. Most troubling, this landmark study has demonstrated that despite effective treatments, there are long delays—sometimes decades—between first onset of symptoms and when people seek and receive treatment.

The cost in human suffering from these mental diseases is compounded further by their economic burden. According to the President's New Freedom Commission on Mental Health (2003), individuals with serious mental illnesses represent the single largest diagnostic group (35 percent) on the Supplemental Security Income (SSI) rolls. Medicaid is the largest single payer of mental health services, with more than 50 percent of all mental health expenditures paid for by the public sector (including Medicaid, Medicare, state and local governments).

The good news is that there now are some extraordinary new tools and technologies, such as neuroimaging and genomics, with which to address these urgent public health needs. Our major challenge is to integrate and translate basic research discoveries and technological advances into practical strategies that can help all communities, including children, the socioeconomically disadvantaged, and others facing barriers to mental health care.

ENVISIONING PERSONALIZED CARE

Research efforts stemming from former President George Bush's proclamation of the 1990s as the Decade of the Brain established that mental disorders (autism, bipolar, depression, schizophrenia, and others) are brain disorders. The current decade is one in which many major candidate molecules, cells, and circuits for normal and abnormal brain function are being identified for the first time. Through these discoveries research will definitively identify the specific brain pathways that underlie each of the major mental disorders. By identifying the features of the brain that go awry in mental illnesses, we will have clear new targets to test how biological, behavioral, and environmental factors affect illness and to develop more effective interventions with the ultimate vision of delivering personalized care through pre-emptive treatments and strategic preventions.

Currently, there are effective treatments for many mental disorders such as depression and anxiety disorders. Studies show that even from a business standpoint, treating these disorders is highly cost-effective; national business groups are encouraging employers to support such treatments in order to reduce healthcare costs while also improving productivity and reducing absenteeism.

Not all treatments work for everyone, however, and clearly there remains room for improvement in both diagnosis and treatment. In mental disorders, just as in the rest of medicine, diagnosis should rely on detection of biomarkers of the specific

disease, and treatments should be based on medication and/or behavioral interventions targeting specific brain regions and processes. For a person with mental illness, one can imagine that a future clinician would use a cognitive task together with neuroimaging and genetics to diagnose and select a specific treatment, just as a contemporary cardiologist uses a stress test and echocardiogram to diagnose ischemic heart disease and select the proper intervention.

It is critical to realize that this vision does not mean designing exotic technologies for a few privileged patients. The ultimate goal is personalized or individualized care for a broad spectrum of people with mental disorders. Now, specific treatments for any given patient are largely developed through trial and error. As researchers learn more about the brain pathophysiology of mental disorders and related behavioral and environmental factors, treatments will become more specific. Early detection of mental illnesses will require a thorough understanding of the range of risks that affect brain processes, which in turn is based on a comprehensive understanding of genetics and experience.

PRACTICAL CLINICAL TRIALS

As noted above, we have treatments that are helpful for nearly all of the mental disorders. But these treatments are not optimal; recovery is often slow, incomplete, and compromised by adverse effects. Since we do not know who will respond completely and who will develop adverse effects, each clinician depends on trial and error with each patient. The Institute has developed practical clinical trials in more than 10,000 patients to help clinicians individualize treatments. Practical clinical trials, or “effectiveness studies,” are designed to examine changes in symptoms and functioning, changes which are vital to determining whether a treatment improves quality of life, caregiving burden, or health service use. The designs of practical clinical trials help increase relevancy to real-world clinical practice to help clinicians answer the question: what is the best treatment for my patient? Each of the following NIMH-funded practical clinical trials provides results from the largest and longest studies of their kind.

In the Clinical Antipsychotic Trials of Intervention Effectiveness (CATIE) Study, 1,432 schizophrenia patients from 56 sites, including private practices, community health care centers, and state facilities, were randomly assigned to treatment with one of five medications for 18 months. In the first phase of analysis the study found that newer, “atypical” antipsychotics are not much more effective than older, conventional antipsychotics; however all the medications studied have unique side effect profiles, some of which include significant weight gain and metabolic side effects, thus increasing risk for diseases such as diabetes. Later phases of this study will examine crucial issues including effects of switching from one treatment to another, use of health services, and cost-effectiveness.

Another example is the Treatment for Adolescents with Depression Study (TADS), which compared short- and longer-term effectiveness of medication and psychotherapy for depression in 439 adolescents. TADS was designed to test best-practice care for depression and was carried out by 13 academic and community clinics across the country. Researchers found that fluoxetine (a selective serotonin reuptake inhibitor) in combination with cognitive behavioral therapy was more effective against adolescent depression than either one alone. In addition, clinically significant suicidal thinking was greatly reduced in all four treatment groups, with those receiving medication combined with cognitive therapy showing the greatest reduction. This is an especially important finding, considering recent concerns that the use of antidepressant medications themselves may induce suicidal behavior in youths. This study shows that treatment leads to a significant improvement of depression overall. It is vital that all patients being treated for depression be closely monitored.

The Sequenced Treatment Alternatives to Relieve Depression Trial (STAR-D) examines 4,041 adults with major depression, particularly those who previously showed poor outcomes to treatment, to see if switching medications or augmenting the initial drug be more likely to achieve a remission. The study, conducted at 41 sites coordinated by 14 regional centers, will also answer how the side effects of the various medications compare and how psychotherapy compares with medication for treatment-resistant depression.

In the Systematic Treatment Enhancement Program for Bipolar Disorder (STEP-BD) trial, 4,360 participants with bipolar disorder from 20 private, state, and community practice sites underwent various treatment pathways to find the most effective long-term and acute treatments and ways to prevent relapse. In the first phase, slightly more than half of the first group of 1,469 participants (58 percent) achieved recovery. In addition, almost half of the recovery group had a recurrence during the

follow-up period, and the majority (70 percent) of recurrences was characterized by a return to a depressive state. In the following phases of the trial, not yet published, various treatments will be tried such as mood-stabilizing medications, antidepressants, atypical antipsychotics, and various “talk” therapies, to see which is best for acute treatment, long-term treatment, and prevention of relapse.

NIMH INITIATIVES FOR FISCAL YEAR 2007

To further advance the vision of personalized mental health care, NIMH will pursue two collaborative initiatives in fiscal year 2007. The first is the Autism Phenome Project, in collaboration with the NIH Autism Coordinating Committee, the Centers for Disease Control and Prevention, and the Department of Energy. Just as the Human Genome Project identified the sequence and organization of human DNA, the phenome project seeks to identify the various clinical characteristics (phenotypes) and subtypes of autism and autism spectrum disorders. Identifying specific phenotypic subtypes will aid research on genetic and other potential causes and suggest more specific approaches to treatment.

The second collaborative initiative is with the Department of Defense (DOD) and the Department of Veterans Affairs (VA) to study the mental health needs of active duty, National Guard, and Reserve personnel including their transition to VA health services. In particular, representative groups of men and women will be studied over time to assess post-deployment adjustment difficulties (including post-traumatic mood and anxiety disorders, and substance use and abuse disorders), the development and effectiveness of early detection and intervention methods, and the possibility of decreasing the risk of developing chronic conditions, disability, and death in those with adjustment difficulties.

These initiatives, in conjunction with the exciting research already underway, will enable NIMH to make significant gains in the upcoming years. We intend to realize our vision of translating basic research and technologies to improved diagnosis, treatment, and preventive strategies that will allow development of personalized mental health care for the millions of Americans affected by mental illnesses.

PREPARED STATEMENT OF DR. STEPHEN I. KATZ, DIRECTOR, NATIONAL INSTITUTE OF ARTHRITIS AND MUSCULOSKELETAL AND SKIN DISEASES

Mr. Chairman and Members of the Committee: I am pleased to present the fiscal year 2007 President's budget request for the National Institute of Arthritis and Musculoskeletal and Skin Diseases (NIAMS). The fiscal year 2007 budget includes \$504,533,000, a decrease of \$3,399,000 below the fiscal year 2006 enacted level of \$507,932,000.

The NIAMS was created by an Act of Congress nearly 20 years ago, and since its inception, the Institute has contributed to significant research progress in areas of public health importance across diseases that are common, costly, and have a major impact on quality of life, disability, and mortality. Research milestones in the history of the Institute include the development of life-saving treatments for kidney failure in patients with lupus, and ground-breaking work to uncover the genetic bases of periodic fever syndromes that affect both children and adults, among many others.

Most recently, investments that NIAMS made as a result of the NIH budget doubling are bringing results that will directly benefit patients. These include support for large-scale clinical trials in areas of high public health impact, such as osteoporosis and back pain; efforts in biomarkers research and epidemiology studies for common conditions such as osteoarthritis, as well as uncommon, but often devastating, disorders such as scleroderma; and new initiatives in translational research for diseases such as muscular dystrophy. Looking to the future, NIAMS will continue its commitment to fund outstanding science across a broad spectrum to enable us to better understand, treat, and, ultimately, prevent diseases of the bones, joints, muscles, and skin.

PREVENTIVE MEDICINE

The NIAMS has made significant investments in studies to identify risk factors and biomarkers of disease, in an effort to facilitate the early identification of signs and symptoms, and to develop interventions that are more effective. This is particularly important from a public health perspective for common conditions such as osteoporosis and osteoarthritis that already afflict tens of millions of Americans, and will affect even more as the U.S. population ages in the coming decades.

In the area of osteoporosis, the NIAMS, along with the National Institute on Aging, has provided steady support for the Study of Osteoporotic Fractures (SOF), a multi-site clinical investigation to determine the risk factors for osteoporotic fractures in older women. Begun in 1986, SOF scientists recruited 9,704 white women aged 65 and older from 4 metropolitan areas for this study. In 1997, an additional 662 African American women who are now seen with the original cohort were enrolled. Major contributions from this long-term study include the findings that bone mineral density (BMD) of the hip is the best predictor of all types of fractures, and that weight loss and parental history of hip fractures are among the most important risk factors for this condition. SOF investigators have also learned that the relationship of BMD and fracture risk is similar in white and African American women, but that at every level of BMD, fracture rates are 30 to 40 percent lower in African American women. These insights are providing clinicians with important information about which women are at most risk for this debilitating disease, so that prevention strategies may be used more effectively. Similar epidemiological studies have now been launched to learn about risk factors for osteoporosis in men.

With respect to osteoarthritis, the NIAMS partnered with the National Institute on Aging, several other NIH components, and four pharmaceutical companies in establishing the Osteoarthritis Initiative, a public-private partnership aimed at developing clinical research resources that support the discovery and evaluation of biomarkers and surrogate endpoints for osteoarthritis clinical trials. For the first time, a public-private partnership is bringing together new resources and commitments to help find biological markers for the onset and progression of osteoarthritis. Recruitment of participants is actively underway, and by the end of fiscal year 2005, more than 3,800 participants have been recruited. One year follow-up measurements have been carried out on over 1,000 participants, and will continue for the next 4 years. All data and images collected will be available to researchers worldwide to help quicken the pace of scientific studies and biomarker identification. This consortium serves as a model for future endeavors that link the public and private sectors.

COMPLEX GENETICS

The NIAMS is taking full advantage of the explosion of information related to genetics, genomics, and proteomics to pursue the causes of complex diseases, and how best to treat them. This includes recent work which identified a genetic variation that doubles the risk of developing rheumatoid arthritis. Scientists have long suspected that autoimmune diseases such as rheumatoid arthritis result from a combination of genetic and environmental factors. Now, a NIAMS-funded research team has identified a specific genetic variation, called a single nucleotide polymorphism or SNP, that increases rheumatoid arthritis risk twofold. The SNP is located within a gene that codes for a particular enzyme that is known to be involved in controlling the activation of white blood cells, called T cells, that play an important role in the body's immune system. Under normal conditions, the enzyme works as a negative regulator: it inactivates a specific signaling molecule which, in turn, interrupts the communications and keeps immune cells from becoming overactive. However, in cases where the SNP is present in one or both copies of a person's genes for this enzyme, the team found that the negative regulation by the enzyme appears to be inefficient, allowing T cells and other immune cells to respond too vigorously, causing increased inflammation and tissue damage. The implications of this finding go beyond a better understanding of rheumatoid arthritis risk. It may also help explain why different autoimmune diseases tend to run in families, since this gene variant is also found in diabetes and lupus.

In other efforts, researchers have recently made breakthroughs in understanding the genetics underlying psoriasis, a chronic skin disease characterized by scaling and inflammation. This disorder occurs when skin cells rapidly pass from their origin below the surface of the skin and pile up on the surface before they have a chance to mature. Usually this movement (also called turnover) takes about a month, but in psoriasis it may occur in only a few days. Recent studies funded by the NIAMS are helping scientists and doctors to understand the disease process at the molecular level, and what role genes play in predisposing people toward psoriasis. In one such project, researchers investigated the role of both genes and the environment in psoriasis, psoriatic arthritis, and atopic dermatitis, another inflammatory skin condition. The researchers found similarities in genetic susceptibility for psoriasis and atopic dermatitis. As for psoriatic arthritis—a condition in which inflamed joints produce symptoms of arthritis for patients who have or will develop psoriasis—they found that the presence of modifier genes can indicate which people with psoriasis are also at risk for psoriatic arthritis.

TRANSLATIONAL RESEARCH

A key ingredient in research success is translation: work to bring insights from the laboratory bench to the patient bedside, and back again, with the ultimate goal of improving patient care and public health. In this vein, NIAMS has recently launched a new program to bring together basic and clinical scientists in a targeted and organized way. The Centers of Research Translation (CORT) program emphasizes the translation of results from basic to clinical studies, as well as translating findings from clinical research to enhance and focus the approaches used in basic studies—all with the goal of improving public health.

This commitment to translational research is bringing results in many areas, including the field of muscular dystrophy research. NIAMS supports two of the six Senator Paul D. Wellstone Muscular Dystrophy Cooperative Research Centers: the first, at the University of Pittsburgh, focuses on gene and stem cell therapies to treat muscle disease; and the second, located at the University of Pennsylvania, is examining strategies to inhibit muscle degeneration and promote muscle growth. These centers promote side-by-side basic, translational, and clinical research; provide resources that can be used by the national muscular dystrophy and neuromuscular communities; and provide training and advice about muscle diseases for researchers and clinicians.

The Institute has also launched new initiatives to encourage translational research in all forms of muscular dystrophy, and to stimulate career development opportunities for muscle disease researchers. These efforts are designed to facilitate the development of new and more effective treatments for muscular dystrophy, and to increase the number and quality of investigators in basic, translational, and clinical research focused on this disease.

REGENERATIVE MEDICINE

Regenerative medicine—a multidisciplinary field that involves the life, physical, and engineering sciences—is an emerging area of research that cuts across several NIAMS programs. For example, important advances have been made recently in the development of promising new polymers for cartilage repair. Cartilage is a tissue that lacks capacity for self-repair. However, multidisciplinary studies by biologists, engineers, physicians, and other are providing new strategies for treating degenerative cartilage that may result in treatments for articular cartilage lesions. Researchers funded by the NIAMS have developed a class of injectable materials based on a biodegradable polymer, OPF (oligo-polyethylene glycol fumarate), for cartilage tissue engineering. Short-term studies in experimental animals demonstrated excellent tissue filling and integration resulting from implantation of these materials into cartilage defects. The polymers were also designed to deliver bioactive molecules (such as growth factors) as well as cells (such as chondrocytes or progenitor cells) to cartilage lesions to enhance tissue repair. Early results show that chondrocytes remain viable, proliferate, and synthesize cartilage matrix components in these polymer gels. Taken together, these results indicate that OPF gels are promising materials for cell delivery in cartilage repair strategies.

CONCLUSION

The scientific advances and innovative initiatives highlighted above paint a picture of research progress that has benefited millions of American children and adults. In the coming fiscal years, NIAMS will focus on strategic collaborations by building partnerships to pursue shared goals across public, academic, and private research entities. A primary example of such a coordinated effort is the Collaborative Initiative on Bone Strength. NIAMS—in conjunction with other NIH components, the Food and Drug Administration, and industry partners—is exploring a potential public-private collaboration on bone strength. The main goals of such an initiative would be to provide data supporting the use of new bone strength markers as surrogate endpoints for fractures in clinical trials, and to find measurements that predict risk of fracture more accurately than does bone density. This would facilitate the continued development and approval of new treatment alternatives to prevent fractures through the support of clinical trials that are smaller, shorter, and less expensive than current studies.

Finally, NIAMS is placing a high priority on strengthening the pipeline of well-trained investigators across the Institute's areas of research interest. This commitment includes funding for the new NIH award program, "Pathway to Independence," to support young investigators, as well as an enhanced emphasis on basic, translational, and clinical training at the major research centers supported by NIAMS. All of these activities are driven by our dedication to fulfill the mandate

that Congress gave the Institute when it created NIAMS; namely, to reduce the burden of illness and to enrich the quality of life for all Americans affected by diseases within our mission.

PREPARED STATEMENT OF RAYNARD KINGTON, DEPUTY DIRECTOR, OFFICE OF THE DIRECTOR

Mr. Chairman, Members of the Committee: I am pleased to present the fiscal year 2007 President's budget request for the Office of the Director (OD). The fiscal year 2007 budget includes, \$667,825,000, an increase of \$140,259,000 over the fiscal year 2006 appropriation of \$527,566,000 comparable for transfers proposed in the President's request. The OD provides leadership, coordination, and guidance in the formulation of policy and procedures related to biomedical research and research training programs. The OD also is responsible for a number of special programs and for management of centralized support services to the operations of the entire NIH.

The OD guides and supports research by setting priorities; allocating funding among these priorities; developing policies based on scientific opportunities and ethical and legal considerations; maintaining peer review processes; providing oversight of grant and contract award functions and of intramural research; communicating health information to the public; facilitating the transfer of technology to the private sector; and providing fundamental management and administrative services such as budget and financial accounting, and personnel, property, and procurement management, administration of equal employment practices, and plant management services, including the implementation of environmental and public safety regulation. The principal OD offices providing these activities include the Office of Extramural Research (OER), the Office of Intramural Research (OIR), and the Offices of: Science Policy; Communications and Public Liaison; Legislative Policy and Analysis; Equal Opportunity; Budget; and Management. This request contains funds to support the functions of these offices. In addition, the OD also maintains several trans-NIH offices and programs to foster and encourage research on specific, important health needs. I will now discuss the budget request for the OD in greater detail.

NIH ROADMAP FOR MEDICAL RESEARCH

Responding to 21st Century biomedical challenges, the NIH Roadmap for Medical Research serves as a test bed for trans-NIH programs designed to accelerate the pace and translation of biomedical discovery. Derived from stakeholder input, Roadmap initiatives are bearing fruit with infrastructure, tools and training programs that serve and intersect the needs of NIH research disciplines and missions. Several large initiatives follow a "hub-and-spoke" model that connects projects and research centers to one another and to the research community at large. For example, the National Centers of Biomedical Computing have created a networking 'hub' to cooperatively develop a number of computing resources that are being followed quickly by investigator-initiated projects (spokes) that will use and assess these resources. Recognizing that gaps in scientific knowledge can be filled in many types of ways, the Roadmap invests in people with innovative, high-risk ideas and in programs and training to foster the development of new research teams and disciplines. Re-engineering of clinical research is also underway with efforts to harmonize research policies, develop tools to examine patient-reported outcomes, integrate clinical research networks, and accelerate multidisciplinary and translational research training. The NIH Roadmap for Medical Research is lowering barriers to biomedical research and harnessing the collective knowledge from multiple disciplines to make the next great leap forward in biomedical discovery. The fiscal year 2007 budget request for NIH Roadmap for Medical Research is \$110,700,000, an increase of \$28,530,000 over the fiscal year 2006 level.

OFFICE OF AIDS RESEARCH

The Office of AIDS Research (OAR) plays a unique role at NIH, establishing a roadmap for the AIDS research program. OAR coordinates the scientific, budgetary, legislative, and policy elements of the NIH AIDS research program. Our response to the AIDS epidemic requires a unique and complex multi-institute, multi-disciplinary, global research program. Perhaps no other disease so thoroughly transcends every area of clinical medicine and basic scientific investigation, crossing the boundaries of the NIH Institutes and Centers. This diverse research portfolio demands an unprecedented level of scientific coordination and management of research funds to identify the highest priority areas of scientific opportunity, enhance collaboration, minimize duplication, and ensure that precious research dollars are invested effec-

tively and efficiently, allowing NIH to pursue a united research front against the global AIDS epidemic. OAR oversees the development of the annual comprehensive trans-NIH AIDS-related research plan and budget, based on scientific consensus about the most compelling scientific priorities and opportunities that will lead to better therapies and prevention strategies for HIV disease. The Plan serves as the framework for developing the annual trans-AIDS research budget; for determining the use of AIDS-designated dollars; and for tracking and monitoring those expenditures. OAR also identifies and facilitates multi-institute participation in priority areas of research and facilitates NIH involvement in international AIDS research activities. The fiscal year 2007 budget request for OAR is \$59,290,000, which is a decrease of \$1,000,000 below the fiscal year 2006 level.

OFFICE OF RESEARCH ON WOMEN'S HEALTH

The Office of Research on Women's Health (ORWH), the focal point for women's health research for the Office of the Director, strengthens, enhances and supports research related to diseases, disorders, and conditions that affect women, and sex/gender studies on differences/similarities between men and women; ensures that women are appropriately represented in biomedical and biobehavioral research studies supported by the NIH to facilitate analyses by sex/gender; and develops opportunities for the advancement of women in biomedical careers and investigators in women's health research. ORWH is developing a novel initiative, entitled Advancing Novel Science in Women's Health Research (ANSWHR), with the NIH ICs to support innovative research in women's health and sex/gender issues. ORWH will continue funding for new or continuing programs through new RFAs for its highly successful interdisciplinary programs: Specialized Centers on Research (SCORs) Affecting Women's Health and Building Interdisciplinary Research Careers in Women's Health (BIRCWH). Reissuance of these interdisciplinary programs will insure the continuation of advances in sex and gender factors in women's health research and the mentored development of junior faculty by bridging advanced training with research independence resulting in more clinical researchers performing in women's health research. The fiscal year 2007 budget request is \$40,949,000, which is the same as the fiscal year 2006 level.

OFFICE OF BEHAVIORAL AND SOCIAL SCIENCES RESEARCH

The NIH's long history of funding behavioral and social sciences research has contributed significantly to our understanding, treatment, and prevention of disease and to the promotion of health and well-being. To further NIH's ability to capitalize on such opportunities, Congress established the Office of Behavioral and Social Sciences Research (OBSSR) to provide leadership in developing research programs that are likely to improve our understanding of processes underlying health and disease and to provide directions for intervention. OBSSR works to ensure that behavioral and social sciences research is integrated into the greater NIH health research enterprise.

As Secretary Leavitt's announcement of the Genes, Environment and Health Initiative (GEHI) made clear, very little is known about how various characteristics of the environment interact with genetics to influence susceptibility to illness. The GEI's focus is interactions among genetics, environmental toxins and individual behaviors (dietary intake and physical activity) that influence the risk of developing a number of common diseases. Based on recommendations from an OBSSR-supported Institute of Medicine study examining the state of the science on gene-social environment interactions, OBSSR is collaborating with ICs to develop research initiatives at the interface of social and genetic factors and health. Moreover, the office is initiating training institutes in genetics for behavioral and social scientists to provide them with the expertise they need to function in interdisciplinary research teams working in this area.

Another area of trans-NIH emphasis has been effective design, communication and implementation of health and clinical information to ensure optimal outcomes across groups of diverse stakeholders. OBSSR's participation in the "Dissemination and Implementation Research in Health" program will help identify and overcome many barriers to the widespread adoption of evidence-based social and behavioral interventions to treat and prevent illness. The promise of these efforts lies in their potential to improve treatment and prevention of illness, the use of these tools to address disparities in health outcomes, and the possibility of demonstrating opportunities for more cost-effective health policy and practice.

To continue such groundbreaking work in the behavioral and social sciences, the fiscal year 2007 budget request for OBSSR is \$26,121,000, the same amount as the fiscal year 2006 level.

OFFICE OF DISEASE PREVENTION

The primary mission of the Office of Disease Prevention (ODP) is to stimulate disease prevention research across the NIH and to coordinate and collaborate on related activities with other federal agencies as well as the private sector. There are several other offices within the ODP organizational structure.

The Office of Medical Applications of Research (OMAR) has as its mission to work with NIH Institutes, Centers, and Offices to assess, translate and disseminate the results of biomedical research that can be used in the delivery of important health interventions to the public. The ODP has two additional specific programs/offices that place emphasis on particular aspects of the prevention and treatment of disease the Office of Dietary Supplements (ODS) and the Office of Rare Diseases (ORD).

In fiscal year 2007, the ODS requests a budget of \$26,807,000, the same amount as the fiscal year 2006 level. ODS promotes the scientific study of the use of dietary supplements by supporting investigator-initiated research, and stimulating research through the conduct of conferences and presentations at national and international meetings. Other current ODS efforts include:

- Sponsorship of systematic reviews on the efficacy and safety of dietary supplements in reducing the risk of chronic diseases such as cancer and heart disease.
- Collaborations for the development, validation, and dissemination of analytical methods and reference materials for dietary supplements.
- Support for and development of databases of dietary supplement information including:
 - National Health and Nutrition Examination Survey (NHANES);
 - Collaboration with USDA to develop an analytically-based database of dietary supplement ingredients;
 - Plan to develop a dietary supplement label database;
 - International Bibliographic Information on Dietary Supplements (IBIDS);
 - CARDS, a database of federally funded research on dietary supplements.
- Collaboration with other federal agencies to develop a coordinated approach to assessment of the health effects of bioactive factors in food and dietary supplements.
- Publishing Fact Sheets on dietary supplements for consumers.

Another component of ODP, the ORD, was formally established through the Rare Diseases Act of 2002, Public Law 107–280. The budget request for fiscal year 2007 for ORD is \$15,548,000, the same amount as the fiscal year 2006 level. The following are highlights of ORD activities: (1) An Extramural Rare Diseases Clinical Research Network that involves 10 consortia with 70 sites, and 30 patient support organizations for almost 50 rare diseases. Twenty-two clinical protocols have been approved and another 25 will be developed during 2006. (2) ORD provides support for 20 Bench-to-Bedside research projects in the NIH Intramural Research Program and supports collaborative research efforts with the National Human Genome Research Institute. (3) ORD also co-funds with the NIH institutes and centers approximately 80 to 100 scientific conferences per year to identify scientific opportunities or stimulate research where it is lagging or lacking. (4) To assist the rare diseases research community and patients with rare diseases, ORD initiated a pilot program to develop genetic tests from gene discoveries in the research laboratories to the clinic. (5) ORD is developing a Web-based database of rare diseases bio-specimen repositories in the United States to facilitate access to human biomaterials for research.

OFFICE OF SCIENCE EDUCATION

The Office of Science Education (OSE), within the Office of Science Policy, develops science education programs to enhance efforts to attract young people to biomedical and behavioral science careers and to improve science literacy in both adults and children. The OSE creates programs to improve science education in schools (the NIH Curriculum Supplement Series); creates programs that stimulate interest in health and medical science careers (LifeWorks Web site); creates programs to advance public understanding of medical science, research, and careers; and advises NIH leadership about science education issues. Programs target diverse populations including under-served communities, women, and minorities, with a special emphasis on the teachers of students from Kindergarten through grade 12. The OSE Web site is a central source of information about available education resources and programs, <http://science.education.nih.gov>. The fiscal year 2007 budget request for OSE is \$3,839,000, the same as the fiscal year 2006 level.

LOAN REPAYMENT AND SCHOLARSHIP PROGRAM

The NIH, through the Office of Loan Repayment and Scholarship (OLRS), administers the Loan Repayment and Undergraduate Scholarship Programs. The NIH Loan Repayment Programs (LRPs) seek to recruit and retain highly qualified physicians, dentists, and other health professionals with doctoral-level degrees to biomedical and behavioral research careers by countering the growing economic disincentives to embark on such careers, using as an incentive the repayment of educational loans. There are loan repayment programs designed to attract individuals to clinical research, pediatric research, health disparities research, and contraception and infertility research, and to attract individuals from disadvantaged backgrounds into clinical research. The AIDS, intramural Clinical, and General Research Loan Repayment Programs are designed to attract investigators and physicians to the NIH's intramural research and research training programs. The NIH Undergraduate Scholarship Program (UGSP) is a scholarship program designed to support and enhance the training of undergraduate students from disadvantaged backgrounds in biomedical research careers and employment at the NIH. For fiscal year 2006, the UGSP plans to award scholarships and provide funding for summer internship service pay-back for twenty (20) individuals and provide funding for twenty-one (21) individuals performing one-year service payback at a cost of \$768,000. In fiscal year 2006, the Loan Repayment Program for Research Generally (GR-LRP) plans to award contracts to fifty-one (51) individuals entering into initial three-year contracts, and forty (40) contracts to individuals entering into one-year renewal contracts at a cost of \$5,286,000. Lastly, the NIH Clinical Research Loan Repayment Program for Individuals from Disadvantaged Backgrounds (CR-LRP) plans to award contracts to two (2) individuals entering into initial two-year contracts, and ten (10) contracts to individuals entering into one-year renewal contracts at a cost of \$483,000 in fiscal year 2006. The fiscal year 2007 budget request for OLRS is \$7,141,000, the same as the fiscal year 2006 level.

OFFICE OF PORTFOLIO ANALYSIS AND STRATEGIC INITIATIVES

In fiscal year 2005, the NIH established a new office within the Office of the Director, the Office of Portfolio Analysis and Strategic Initiatives (OPASI). The OPASI is made up of three divisions, focused on (1) resource development and analysis (including the development and deployment of knowledge management; (2) strategic coordination; and (3) evaluation and systematic assessments. Collectively, these three divisions identify and integrate information to support the planning and implementation of trans-NIH initiatives that address exceptional scientific opportunities and emerging public health needs. More specifically, OPASI is facilitating a "functional integration" of strategic planning and evaluation activities across the agency. The fiscal year 2007 budget request for OPASI is \$3,000,000, an increase of \$1,020,000 over the fiscal year 2006 level.

When fully staffed by fiscal year 2008, OPASI will have approximately 72 FTEs. Thirteen existing FTEs transferred to OPASI in fiscal year 2006, and approximately 16 FTEs will be recruited during fiscal year 2006. The NIH is in the process of recruiting for a Director, OPASI and expects to fill this position in 2006. Funding for fiscal year 2007 will cover additional recruitments and Office operations in an amount consistent with OPASI's structure and responsibilities. In addition to salaries to support the FTEs, funding will be used to pay for contractual services, supplies, equipment, office rent and other services.

Through these efforts, the NIH Director and the IC Directors will have access to more consistent information to improve coordination and facilitate collaboration across the agency, and to inform priority setting and budget decisions. The governance process for OPASI will likely be carried out by a new working group of the NIH Steering Committee, as described above. The group will be charged with monitoring the overall effectiveness of the office, advising on policy and planning issues, and forecasting the need for changes in OPASI's activities, among other areas.

Thank you, Mr. Chairman for giving me the opportunity to present this statement; I will be pleased to answer questions that the Committee may have.

PREPARED STATEMENT OF DR. STORY C. LANDIS, DIRECTOR, NATIONAL INSTITUTE OF NEUROLOGICAL DISORDERS AND STROKE

Mr. Chairman and Members of the Committee, I am Story Landis, Director of the National Institute of Neurological Disorders and Stroke (NINDS). I am pleased to present the fiscal year 2007 President's budget request for NINDS.

The mission of the NINDS is to reduce the burden of neurological disorders by developing ways to prevent or to treat these diseases. Epilepsy, autism, cerebral palsy, muscular dystrophy, spinal muscular atrophy (SMA), and hundreds of other disorders are first evident in infancy or childhood. Multiple sclerosis, spinal cord injury, migraine, and traumatic brain injury are among the many nervous system diseases that are prevalent in young adults. Stroke, dementias, chronic pain, and Parkinson's disease will increase, if unchecked, with the aging of our population. The impact of neurological disorders on people, on their families, and on our economy is immense.

CLINICAL RESEARCH

The NINDS currently supports more than 1,000 clinical research projects, of which more than 125 are clinical trials of interventions to prevent or treat disease. Ongoing clinical trials are testing drugs, natural biological molecules, surgery, deep brain stimulation, hypothermia, radiation, immunotherapy, and behavioral therapies for disorders including amyotrophic lateral sclerosis (ALS), brain tumor, cerebral palsy, epilepsy, headache, Huntington's disease, multiple sclerosis, muscular dystrophy, myasthenia gravis, pain, Parkinson's disease, spinal muscular atrophy, stroke, Tourette syndrome, and traumatic brain injury.

Last year an NINDS clinical trial showed that aspirin prevents stroke effectively for the many people with partially blocked arteries in the brain who have had a previous stroke or TIA (mini stroke). Aspirin works as well as warfarin, a drug that requires monthly monitoring and carries the risk of major hemorrhage and heart attack. This trial is another step in a long march of advances that guide physicians in preventing stroke in particular risk groups. The U.S. Centers for Disease Control and Prevention estimated that the death rate from stroke declined by 18.5 percent for the U.S. population from 1993 to 2003, and progress is continuing with results like these.

Each year also brings results from several NINDS preliminary clinical trials. Current drugs for Parkinson's disease ultimately fail because they do not halt the progressive death of brain cells that causes this disease. The Neuroprotection Exploratory Trials in Parkinson's Disease (NET-PD) is a network of 50 clinical centers throughout the United States that efficiently tests drugs to slow the underlying disease. NET-PD has completed phase II trials of four drugs that had been rigorously selected for testing from candidates suggested by scientists around the world, and just published the results of the first two. NET-PD will move quickly to a large, definitive clinical trial to test the safety and effectiveness of at least one of these drugs in preventing Parkinson's disease.

In addition to clinical trials, other types of clinical studies lead to new treatment or prevention strategies. An epidemiological study this year found that men who exercised vigorously as young adults had a 50 percent lower risk of developing Parkinson's disease in later life than men who had low levels of physical activity. Other studies determined how to predict which patients with glioblastoma, a common and deadly brain tumor, will respond to a new class of anti-cancer drugs, and discovered why infant seizures do not respond to drugs that are effective in adults and what other drugs might work better.

The NINDS Clinical Research Collaboration (CRC), now under development, will extend the reach of clinical research into more communities across the United States. The CRC engages community practice and academic neurologists to speed clinical studies; minimize costs; make clinical trials more accessible to diverse participants; facilitate trials of rare diseases; and improve transfer of research results to clinical practice in the community. Complementing the CRC, the NINDS is building a network to develop emergency treatments for neurological disorders. Stroke, seizures, traumatic brain and spinal cord injury, and other neurological disorders account for perhaps 5 to 10 percent of all medical emergencies. This program brings together specialists in emergency medicine, neurological disease and clinical trials.

GENES AND NEUROLOGICAL DISORDERS

In December, the journal *Science* chose the discovery of a gene defect that can cause Tourette syndrome as one of the 10 most important scientific advances of the year. Since the NIH budget doubling began, scientists have identified more than 100 genes associated with neurological diseases including ALS, ataxias, Batten disease, dyslexia, dystonia, epilepsy, muscular dystrophies, Parkinson's disease, peripheral nerve diseases, and spinal muscular atrophies.

Gene discoveries often have a rapid impact on patients and families. They yield definitive DNA diagnostic tests that are faster, cheaper, and more accurate, and allow genetic counseling and attention to special risks of people with particular in-

herited disorders. For example, patients with ataxia used to undergo MRI brain scans, withdrawal of spinal fluid for analysis, tests for amino acids and organic acids, lipoprotein electrophoresis, urine heavy metal screens, thyroid function tests, and sometimes painful nerve or muscle biopsies to get a diagnosis, costing thousands of dollars over several months. Today, a commercially available DNA test can often give a definitive diagnosis of a genetic neurological disorder within a week for a few hundred dollars.

Gene findings also jumpstart therapy development. Over the last year, studies of therapies in animal models, another benefit from gene discoveries, have shown promise for neurofibromatosis, muscular dystrophy, Fragile X syndrome, Huntington's disease, hereditary ataxias, and several other disorders. Therapies are already moving from animal models into NIH or private sector clinical trials, including ceftriaxone for ALS, anti-oxidants for ataxia-telangiectasia, myostatin inhibitors and gentamicin for muscular dystrophy, and coenzyme Q10 for Huntington's disease. The pace is remarkable after decades without progress for many of these diseases.

Knowing where and when genes are active is key to understanding the nervous system in health and disease. Most genes are active at some time and place in the brain, yet only a small fraction of these have been well characterized, so the NINDS initiated the GENSAT (Gene Expression Nervous System Atlas) to map gene activity in the brain across development. GENSAT also generates valuable research tools including strains of mice in which a visible marker is turned on where and when the gene of interest is active. Using these mice, scientists this year found new insights into Parkinson's disease that could not have been revealed without this resource. The studies showed that one of two previously undistinguishable types of nerve cells is selectively affected in Parkinson's disease, helped explain why brain movement control circuits malfunction, revealed the molecular mechanism that kills those cells, and identified a potential new target for drugs to slow Parkinson's disease.

TRANSLATIONAL RESEARCH

With the budget increases, the NINDS implemented major programs to move insights from basic research to practical therapies ready for testing in clinical trials, that is, translational research. The Cooperative Program for Translational Research supports research teams in academia and small companies. These milestone-driven, investigator-initiated projects are developing drug, stem cell, or gene therapies for Batten disease, Parkinson's disease, Huntington's disease, tuberous sclerosis, Duchenne muscular dystrophy, traumatic brain injury, and stroke, among other disorders.

In another translational effort, the NINDS developed the SMA Project as a model program to expedite therapy development. The contract-based project is making encouraging progress towards its ambitious goal—having a drug for SMA ready for clinical trials by the end of 2007. A steering committee, with drug development expertise from industry, the FDA, academia, and the NIH, first developed a detailed drug development plan. To carry out the plan, the project then created a virtual drug development company with the tools and facilities for identifying “lead compounds,” chemically modifying leads into potentially improved compounds, testing drug candidates in cell and animal models, and coordinating the overall drug development scheme. More than 300 compounds have been prepared and are in testing. In 2007, the NINDS will address a major barrier in the development of drugs for other neurological diseases by extending the contract-based medicinal chemistry resource from the SMA Project. Medicinal chemists modify weakly active compounds so that drug development teams can test the new drugs for improved safety and effectiveness.

NIH basic science stimulates therapy development in the private sector, as well as by the NIH. In the past year, private sector clinical studies of clotting Factors VII and VIIa have shown promise for serious and hard to treat strokes caused by bleeding in the brain. NIH research motivated those studies by showing that these strokes are followed by continued expansion of blood filled pockets in the brain, called hematomas, which contribute profoundly to disability and death. Private sector clinical trials in gene and cell therapies for Parkinson's disease begun this year also build upon NINDS research.

Longstanding NINDS targeted therapy development programs also catalyze private sector efforts. For three decades, the Anticonvulsant Screening Program (ASP) has fostered industry development of drugs for epilepsy, including six drugs in widespread use and several more now in clinical testing. Drugs that emerged from the ASP testing program are also among the most effective treatments for chronic pain. NINDS initiatives begun last year and to begin in 2007 focus on animal models for

testing drugs that block the development of epilepsy, work for treatment resistant epilepsy, and meet the special needs of pediatric and geriatric populations.

COLLABORATIVE RESEARCH

The NINDS strongly encourages cooperative efforts among scientists and physicians from diverse disciplines, and works closely with other parts of the NIH, other government agencies, and non-governmental organizations, as well as with companies. As may be evident from the discussions of the Clinical Research Consortium, NET-PD, GENSAT, the Cooperative Program in Translational Research, and the SMA Project, most NINDS programs, whether focused on a particular disease or a scientific problem, emphasize collaboration. Other examples include research centers on muscular dystrophy, Parkinson's, autism, spinal cord injury, stroke and health disparities, and resources including the Human Genetics Repository and the Microarray Consortium.

The NIH Neurosciences Blueprint, begun in 2005, presents a framework to enhance cooperation across the NIH institutes that share an interest in diseases of the nervous system. Blueprint initiatives have focused on neuroscience tools, training in the neurobiology of disease for basic scientists, genome analysis, neuroimaging, genetic mouse models, core research facilities, and clinical assessment tools. In 2007, the Blueprint will focus on neurodegeneration, which contributes to many diseases.

Among government agencies, the NINDS is working closely with the U.S. Army Medical Research Institute of Chemical Defense (USAMRICD) because many potential chemical terrorist agents affect the nervous system. Cooperative projects with the Veterans Administration include a major clinical trial of deep brain stimulation for Parkinson's disease. The NINDS also meets regularly with the FDA on stem cells and other biological therapies and works with the National Science Foundation on common interests including computational neuroscience and informatics.

More than 300 non-governmental organizations (NGOs) focus on diseases within the mission of the NINDS. The World Parkinson Conference, held for the first time this February, and a major conference on epilepsy planned for March 2007 are two of many recent examples of cooperative efforts between NGOs and the NINDS. In June 2005, the Institute brought together 75 representatives of NGOs at the NIH for a day of presentations, informal interaction, and group discussions. Based on the strong positive feedback from participants, the NINDS will hold similar meetings in the future to explore how we can work together in the future.

Thank you, Mr. Chairman. I would be pleased answer questions from the Committee.

PREPARED STATEMENT OF DR. TING-KAI LI, DIRECTOR, NATIONAL INSTITUTE ON ALCOHOL ABUSE AND ALCOHOLISM

Mr. Chairman and members of the Committee: I am pleased to present the fiscal year 2007 President's budget request for the National Institute on Alcohol Abuse and Alcoholism (NIAAA). The fiscal year 2007 budget includes \$433,318,000, which reflects a decrease of \$2,612,000 over the fiscal year 2006 enacted level of \$435,930,000 comparable for transfers proposed in the President's request.

Alcohol consumption kills or disables thousands of Americans each year. The Centers for Disease Control and Prevention (CDC) reported in 2005 that, in the mid-1990s, alcohol use and abuse were among the top ten causes of death and disability in the United States. CDC also ranked excessive alcohol consumption as the third leading preventable cause of death in 2001. Motor vehicle crashes are among the most visible consequences of alcohol use; CDC estimates that in 2003, 40 percent of traffic deaths were alcohol-related. However, death and disability also result from alcohol-related diseases, such as liver cirrhosis, heart disease, stroke, dementia, and certain cancers.

Despite these consequences, the majority of people who drink are able to do so without harm to themselves or others. One of the fundamental goals of alcohol research is to determine why some individuals cannot limit their drinking. Research has shown clearly that half of the risk for developing alcohol use disorders is a function of genes, while the other half can be traced to factors in the environment, such as family, friends, and culture. The measure of risk is not an either/or situation; genes and environmental factors interact and influence one another, even at the molecular level.

Investigating the interplay of genes and environment is an important focus across the NIH, with implications for many of the most widespread, life-threatening, and costly health conditions affecting Americans. One of the exciting areas of research I would like to describe today has to do with how new tools we are developing to

investigate this interaction between genes and environment can contribute to an understanding of alcohol dependence.

As a starting point, we have already identified several genes that can raise or lower the risk of developing alcohol dependence. Variants in two families of genes that are involved directly in alcohol metabolism, for example, can lower risk. These genes encode enzymes that break down alcohol. Some people inherit enzyme variants that will result, if a person drinks, in especially high levels of a toxic by-product of alcohol metabolism. These individuals feel sick when they drink; as a result, they are at lower risk of developing alcohol use disorders.

Other genes that play a role in alcoholism risk encode the communication circuitry of brain messenger molecules, the receptors of neurotransmitters, a number of which have been linked to alcoholism and psychiatric disorders that co-occur frequently with alcoholism. Research suggests, for example, that genes for neurotransmitters involved in depression and anxiety are also, in some groups, related to alcoholism risk. Among the neurotransmitter systems for which research has reported a relationship between genes and alcoholism risk: GABA, a neurotransmitter that slows the pace of brain signaling and is known to be involved in the alcohol response; NPY, a brain protein involved in stress responses and memory; serotonin, a neurotransmitter involved in the regulation of mood; and brain opioids, which play a role in the sensation of pleasure.

Variants in these neurotransmitter genes influence alcoholism risk by shaping how the brain responds to alcohol, regulating how pleasant the experience is, or how sedating. An important new direction of research has to do with investigating how the opposite can occur: alcohol can make lasting changes in genes in ways that can have profound effects on health.

Epigenetics refers to heritable and long-term changes in gene function that occur without a change in DNA sequence. Such changes could be caused, for example, by elements in the environment, such as alcohol, changing how genes are translated into proteins, in other words, how the genes are expressed. Epigenetics can help us understand how alcohol has lasting effects on health.

One of the ways alcohol and its metabolites can change gene expression is by modifying histones—proteins that intertwine with DNA. Stable modification of DNA can also occur. Both of these reactions can activate or silence the expression of genes. Alcohol through its metabolism contributes to or alters the level of at least two specific metabolites that are required for these chemical modifications.

Epigenetic modifications may be transmitted as the cell divides. Thus, these modifications may persist throughout the lifespan. Epigenetic changes also have the potential to be passed on to the next generation, producing abnormalities in offspring. This research, at the forefront of progress in genetics and molecular biology, gives us an opportunity to understand the complex mechanisms by which an external environmental factor like alcohol interacts with biology. It promises to help explain why repeated exposure to alcohol can change permanently how a person responds thereafter to the substance, setting the stage for dependence. It can help explain why drinking during pregnancy can cause irreversible damage to the brain of a fetus. And it may help explain what underlies alcohol's destructive effects on such organs as the liver, pancreas, and brain, as well as its role in cancers associated with heavy alcohol exposure.

Epigenetics research may also provide a means for investigating the long-term effects of alcohol consumption on adolescents. Alcohol is the drug most commonly used by youth. Adolescents who drink tend to do so intensively; according to 2005 data from the Monitoring the Future study, 11 percent of 8th graders, 21 percent of 10th graders, and 28 percent of 12th graders report drinking 5 or more drinks in a row in the past two weeks. This "binge" drinking is a particularly hazardous pattern of drinking at any age. But during adolescence, when the brain is still undergoing developmental change, binge drinking may have particular dangers.

Preliminary studies suggest that alcohol has the potential to disturb normal brain development in adolescence and young adulthood. NIAAA research has established that youth who begin to drink in their early teens are at greater risk later of developing alcohol dependence. This increased risk can be explained only partly by inherited biological risk factors, suggesting that early drinking itself causes changes that manifest themselves in future behavior. Data from NIAAA's National Epidemiologic Survey on Alcohol and Related Conditions has shown that most cases of alcoholism are established by age 25. This suggests that alcoholism, rather than being a disease of middle age, is a developmental disorder that has its roots in youth.

An important NIAAA initiative is aimed at investigating the effects of alcohol, including epigenetic effects, on developing brain structures and systems that regulate behavior. It will address the mechanisms that underlie alcohol-related changes during brain development, the dosage and drinking patterns that result in changes, and

the factors that promote or protect against these changes. An important aim of this research is to determine whether and how alterations in brain function influence lifetime risk for alcohol use disorders, particularly in vulnerable individuals.

Improving our fundamental understanding of how the environment interacts with genes has many potential benefits. For example, knowledge of the genes that are related to risk for alcohol problems—and how variants of these genes might be manifest in physical or behavioral traits—can be used to assist in the identification of individuals at risk or, in other words, predict who is vulnerable. Understanding how alcohol interacts with genes will help define how an individual makes the transition from casual drinking to dependence; and how long term heavy drinking causes disease.

Our growing body of knowledge about genes and the cellular processes they encode is providing targets for medications development. Genetics research is helping to show why no one medication will work in every person. The ultimate goal will be to personalize treatment—similar to the approach in diseases like hypertension or depression—by choosing from an array of medications the agent that is most effective for a given individual.

Finally, among its most important potential benefits, the investigation of genes and environment will give us a clear picture of the impact of alcohol on the long-term health and behavior of adolescents. Understanding the mechanisms behind these persistent effects will make even more compelling the imperative to identify effective ways of preventing adolescents from consuming alcohol, not only to safeguard their health and well-being in youth, but to preempt the development of alcohol use problems in adulthood.

Thank you Mr. Chairman. I would be pleased to answer any questions that the Committee may have.

PREPARED STATEMENT OF DR. DONALD A.B. LINDBERG, DIRECTOR, NATIONAL LIBRARY OF MEDICINE

Mr. Chairman and Members of the Committee: I am pleased to present the President's budget request for the National Library of Medicine (NLM) for fiscal year 2007, a sum of \$313,269,000, which is \$1,641,623 less than the comparable fiscal year 2006 appropriation.

Only a few years ago we frequently described the role of the National Library of Medicine almost entirely in the context of the medical literature—NLM collected and organized the books and journals that were then used in the process of making new discoveries that would be reported in yet more books and journals. That paradigm, although accurate as far as it goes, is no longer sufficient to describe the Library's role. Today, the NLM is at the hub of an interconnected world of an amazing amount of information, ranging from the published literature, to molecular sequence and genomic data, to descriptions of clinical trials, to still and moving medical images, to maps of chemical spills and other information used for emergency preparedness, and to authoritative research-based information prepared especially for the general public—for patients and their families and caregivers.

The range of persons and institutions with which the Library interacts is staggering. A National Network of Libraries of Medicine, with more than five thousand members, extends the reach of NLM's services. Many medical organizations, publishers, academic institutions, government agencies, and libraries make data available to the world through the National Library of Medicine. The NLM, with a staff of experienced medical librarians, scientists, and health professionals, creates databases and other Web resources to ensure that high quality information is available to all, easily and without restriction. The bottom line of all this is that the Library operates the most-consulted scientific medical Web site in the world: two million people come to the Library's Web site—to learn about diseases, search the literature, connect with other information providers, and to download terabytes of data—every day.

As a key member of the NIH research team, the Library works closely with scientists on the Bethesda campus and around the country. A prime example of this is the work of NLM's National Center for Biotechnology Information (NCBI) and the panoply of databases with genomic information contributed by NIH and NIH-supported scientists. This collaboration extends around the world, with partners at institutions in other nations contributing sequence and other data to the NCBI's databases. Another example of extensive collaboration is that several thousand public and private organizations have agreements with NLM to use the Visible Human Project datasets of anatomical information to create techniques and software used in teaching and research.

But the Library is also a bricks and mortar facility on the campus of the National Institutes of Health. NLM has two reading rooms that are open to the public—one that serves the Library's remarkable collection of historical materials and a main reading room. An exhibition, "Visible Proofs: Forensic Views of the Body," has just been opened in the Library's public area and will be visited by many thousands, including students from grade school up. Previous exhibitions are now touring the country, extending greatly the work of our history of medicine curators.

A basic function of the National Library of Medicine is to serve as a "court of last resort" for seekers of medical information. With the world's largest collection—eight million items—the NLM is relied on by institutions and individuals around the globe.

INFORMATION SERVICES FOR THE PUBLIC

The Library's main portal for consumer health information is MedlinePlus, available in both English and Spanish. Much of this material is based on research done or sponsored by the NIH Institutes. MedlinePlus has more than 700 "health topics," containing, for example, overview information, pertinent clinical trials, alternative medicine, prevention, management, therapies, current research, and the latest news from the print media. In addition to the health topics, there are medical dictionaries, a medical encyclopedia, directories of hospitals and providers, and interactive "tutorials" with images and sound. The newest addition to MedlinePlus is a series of surgical videos that show actual operations of common surgical procedures. Another new aspect of MedlinePlus is "Go Local," that is, a service to link users from the MedlinePlus health topics to the health and social services in their community that are related to that topic.

There are other popular NLM Web sites for the public. ClinicalTrials.gov was created to give everyone easy access to information about human research studies. The site contains information on more than 25,000 federally and privately supported trials. It includes summaries of the purpose of each study, the recruiting status, criteria for patient participation, location(s) of the trial and specific contact information. NIHSeniorHealth.gov is maintained by the Library in collaboration with the National Institute on Aging and other NIH Institutes. At present there are 22 topics of interest to seniors, including, for example, Alzheimer's Disease, balance problems, macular degeneration, shingles, and stroke. NIHSeniorHealth.gov contains information in a format that is especially usable by seniors, with, for example, large type, and it also has a "talking" function that allows users to listen as the text is read to them.

NLM's Genetics Home Reference provides consumer-friendly summaries of genetic conditions and related genes and chromosomes. This information resource bridges consumer health information and scientific bioinformatics data, and it links to many existing resources, both at NLM and at other reliable sites. The Household Products Database provides easy-to-understand data in consumer-friendly language on the potential health effects of more than 2,000 ingredients contained in more than 6,000 common household products. The Household Products Database has proved to be popular with the media, and there have been a number of newspaper and magazine articles about it. Another consumer health site is the colorful Tox Town, which looks at an ordinary town and points out many harmful substances and environmental hazards that might exist there. Users can click on a town location, like a school, office, factory, or park and find information about the toxic chemicals that may be encountered there. Other versions are available for a big city, a farm, and the U.S.-Mexico border area. There is also a new special section with information on toxic chemicals and disaster health concerns in the wake of Hurricane Katrina and Hurricane Rita.

INFORMATION SERVICES FOR THE SCIENTIFIC COMMUNITY

The most frequently consulted online medical resource in the world is PubMed/Medline, an easily searchable database of more than 15 million references and abstracts for medical journal articles from the 1950s to the present. Usage of PubMed/Medline by the scientific and lay communities has grown considerably since it became free on the Web in 1997, to over two million searches per day. PubMed also links to the sites of participating publishers so that users can retrieve full-text articles from 5,000 journals. Where links to electronic full text are not available, the user may use PubMed to place an online order for an article directly from a library in the National Network of Libraries of Medicine.

PubMedCentral (PMC) is a Web-based repository of biomedical journal literature providing free and unrestricted access to the full-text of articles. This repository is based on a natural integration with the existing PubMed/Medline biomedical lit-

erature database of references and abstracts. Currently, PMC contains nearly 600,000 full-text articles. Recent additions have come from newly published material as well as from digitizing back issues that previously were only available in printed form. NIH's Public Access policy encourages scientists whose work is funded by the NIH to submit their manuscripts to PubMed Central. NLM's National Center for Biotechnology Information designed and implemented the NIH Manuscript Submission system, a quick and easy-to-use system for scientists to submit their manuscripts. Creating such digital archives as PubMedCentral to ensure that the world's biomedical literature is properly recorded and available for future generations, is an important NLM responsibility.

Another heavily used scientific resource is a database of all publicly available DNA sequences, called GenBank. The NCBI, which maintains GenBank, has also created integrated retrieval tools that allow seamless searching of the sequence data and provide links to related sequences, bibliographic citations, and other resources. Such features allow GenBank to serve as a critical research tool in the analysis and discovery of gene function as well as discoveries that lead to identification and cures for a number of diseases. One recent example of the use of NCBI sequence databases was to identify the first polio case in the United States since 1999. The state health laboratory in Minnesota had isolated an unknown virus from a hospitalized child from an Amish community. The laboratory staff went to the Web, searched against the 55 million DNA sequences at NCBI, and found a match to the polio virus used in the Sabin oral vaccine. "Bingo," said the laboratory's director, "It was a 98 percent match. We knew we had nailed it."

A critical need in biomedical research, as identified in the NIH Roadmap Initiative, is a repository for what are called "small molecules" that are crucial in drug development. Small molecules are responsible for the most basic chemical processes that are essential for life and they often play an essential role in the attack of a pathogen, or in the cell's response to the attack. The new PubChem database, developed by the NCBI, links the small molecules to their biological functions and to the macromolecules with which they interact. At present, PubChem includes over 7.5 million records for small molecules with over 5 million molecular structures. These data have been contributed by public, academic, and commercial resources.

The NCBI is also doing important work on other issues of current public concern. One of these is to provide an Influenza Virus Resource that links researchers working on vaccines to genomic data about the influenza virus. As the data accumulate and the analyses progress, the discoveries made will ultimately lead to better prediction of large-scale outbreaks, more effective vaccine design, and the saving of many human lives. Another area of NCBI work of topical interest is their development, in the aftermath of 9/11, of sophisticated software called OSIRIS. The software is now being tested within five collaborating forensic DNA laboratories to assist in the analysis and validation of forensic data and help identify victims from the Gulf Coast states in the aftermath of Katrina.

A recently announced series of initiatives by several NIH Institutes directed at understanding the genetic factors underlying human disease will require the NCBI to play a key role. Several large-scale, long-term studies, such as the Framingham Heart Study, will be adding genetic information from participants to the clinical data already collected. NCBI has been selected by the Institutes to build the databases that will incorporate the clinical and genetic data, link them to the molecular and bibliographic resources at the NCBI and, for the first time, make these data available to the scientific and clinical research community.

NLM remains the principal source of support nationally for research training in the field of biomedical informatics. This support is especially important as rapidly moving technology in health care and biomedical research requires investigators who understand biomedicine as well as fundamental problems of knowledge representation, decision support, and human-computer interface. Five-year institutional training grants from NLM support some 300 pre-doctoral, post-doctoral, and short-term trainees across the country.

OTHER AREAS OF INTEREST

The Library has an important role in developing standards for Electronic Health Records. As part of its Unified Medical Language System (UMLS) project, NLM creates vocabulary databases and software tools to assist informatics researchers and system developers in automated interpretation and integration of medical knowledge and health data. Chief among the UMLS resources is the Metathesaurus, which links and provides 4.7 million concept names for 1.2 million concepts from 114 vocabularies in a single database format. The UMLS serves as a common distribution vehicle for standard code sets and vocabularies needed for administrative

transactions and electronic health records, as well as a resource for advanced natural language processing, automated indexing, and enhanced information retrieval. Building on its two decades of UMLS experience, the Library also serves as an HHS coordinating center for standard clinical vocabularies, such as the SNOMED CT clinical terminology. The Library works closely with the Office of the National Coordinator for Health Information Technology and other organizations to align health data standards into an effective interlocking set and to promote more rapid adoption of standards-based electronic health records to facilitate patient care, public health surveillance, and clinical research.

Twenty years ago the National Library of Medicine published a long range plan that has proved to be of enormous benefit to the institution. Out of it grew such initiatives as the Visible Human Project, the National Center for Biotechnology Information, and the recommendation that the Library engage in an outreach campaign to reach minority and other underserved health professionals. The Library is now engaged in a similar planning exercise for the next decade. Leaders from across the spectrum of health and medicine are meeting at the Library to consider four major themes relating to resources and infrastructure, outreach to the underserved, support for clinical and public health systems, and support for genomics. The plan, which will be issued by the NLM Board of Regents and published later in 2006, will point the Library in the direction in which it can make its maximum contribution to society.

PREPARED STATEMENT OF JUANITA M. MILDENBERG, ACTING DIRECTOR, OFFICE OF RESEARCH FACILITIES DEVELOPMENT AND OPERATIONS

Mr. Chairman and Members of the Committee: I am pleased to present the President's budget request for the Buildings and Facilities (B&F) Program for fiscal year 2007, a sum of \$81,081,000.

ROLE IN THE RESEARCH MISSION

State-of-the-art facilities for scientific research and research support facilities are a vital part of the research enterprise. The National Institutes of Health's (NIH) Buildings and Facilities (B&F) program designs, constructs, repairs and improves the agency's portfolio of laboratory, clinical, animal, administrative and support facilities at its six installations in four states. These facilities house researchers from the NIH Institutes' and Centers' (ICs) intramural basic, translational, and clinical research programs; science administrators who oversee NIH's grants; the NIH leadership, and various programs that support agency operations. The fiscal year 2007 B&F budget request focuses on the need for responsible utilization and stewardship of NIH's past and recent investments in the "bricks and mortar" of the research enterprise. In order to stay abreast of the changing needs of the NIH programs, it is imperative that we provide reliable, safe and secure research support facilities that are appropriately equipped, operated and maintained.

The B&F budget request is the product of a comprehensive, corporate capital facilities planning process. This process begins with extensive consultation across the research community and the NIH's professional facilities staff. It works through the Facilities Working Group, an advisory committee to the NIH Steering Committee, and the HHS Capital Investment Review Board. Through this process, the program demand for more effective and efficient facilities designed to support current and emerging investigative techniques, technologies, and tools is integrated with, and balanced against, the need to repair, renovate, and improve the existing building stock to keep it in service and to optimize its utility.

The fiscal year 2007 request provides the necessary funding support for the ongoing safety, renovation and repair, and related projects that are vital to proper stewardship of the entire portfolio.

The fiscal year 2007 B&F budget request is organized among three broad Program Activities: Essential Safety and Regulatory Compliance, Repairs and Improvements and Construction. The fiscal year 2007 request provides funds for specific projects in each of the program areas. The projects and programs enumerated are the end result of the aforementioned NIH facilities planning process and are the NIH's capital facility priorities for fiscal year 2007.

FISCAL YEAR 2007 BUDGET SUMMARY

The fiscal year 2007 budget request for Buildings and Facilities is \$81.1 million. The B&F request contains a total of \$14.5 million for Essential Safety and Regulatory Compliance programs composed of \$2 million for the phased removal of asbes-

tos from NIH buildings; \$5 million for the continuing upgrade of fire and life safety deficiencies of NIH buildings; \$1.5 million to systematically remove existing barriers to persons with disabilities from the interior of NIH buildings; \$1 million to allow for environmental remediation activities at NIH sites; and \$5 million for the continued support of the rehabilitation of animal research facilities. In addition, the fiscal year 2007 request includes \$65.9 million in Repairs and Improvements for the continuing program of repairs, improvements, and maintenance that is the vital means of maintaining the complex research facilities infrastructure of the NIH; and \$700,000 in Construction for pre-project planning including concept development studies and analyses of NIH-wide facility projects proposed in the facilities plan.

My colleagues and I will be happy to respond to any questions you may have.

PREPARED STATEMENT OF DR. RODERIC I. PETTIGREW, DIRECTOR, NATIONAL INSTITUTE OF BIOMEDICAL IMAGING AND BIOENGINEERING

Mr. Chairman and Members of the Committee: I am pleased to present the fiscal year 2007 President's budget request for the National Institute of Biomedical Imaging and Bioengineering (NIBIB). The fiscal year 2007 budget includes \$294,850,000; a decrease of \$1,960,000 over the fiscal year 2006 enacted level of \$296,810,000 comparable for transfers proposed in the President's request.

BRIDGING THE PHYSICAL AND LIFE SCIENCES

The mission of the NIBIB is to improve human health by leading the development and accelerating the application of biomedical technologies. The Institute is committed to integrating the engineering and physical sciences with the life sciences to advance basic research and medical care. To demonstrate our commitment, the NIBIB gives special consideration for funding to research grant applications that bridge and integrate the life and physical sciences.

TRANSLATING TECHNOLOGY INTO CLINICAL PRACTICE

Ultimately, the NIBIB seeks to translate research findings made in the laboratory into solutions that advance human health by reducing disease burden and improving quality of life. One highly successful example of a research and commercialization effort supported in part by the NIBIB is an automated, digital-imaging device called the "array microscope." The system utilizes an array of 100 miniaturized objectives to produce a single, seamless sweep of a microscope slide of a histopathology sample. The result is a microscopic-level resolution, multi-colored digitized image of the pathology sample. The most immediate impact of this technology is expected to be in medical pathology. These "virtual slides" can be easily stored in a patient's record and can also be viewed over the Internet, providing immediate on-line access to expert second opinions.

The recently released "Quantum Project" initiative is another example of how the NIBIB strives to support a more integrated and focused research agenda using multidisciplinary approaches to develop innovative and marketable technologies. The goal of this unique program is to make a "quantum" advance in healthcare by funding research on a specific project or projects that will translate into new technologies and modalities for the treatment, prevention and cure of disease or resolve a major health care problem within a reasonable time frame. In these "bench to bedside" partnerships, a team of interdisciplinary scientists will conduct collaborative research that will result in a prototype product that can be translated into clinical practice.

TECHNOLOGIES TO IMPROVE HEALTH CARE DELIVERY

With the advent of miniaturized devices and wireless communication, the way in which doctors care for patients has changed dramatically. Empowering clinicians to make decisions at the bedside, or the "point-of-care," has the potential to significantly impact health care delivery and help address the challenges of health disparities. The success of such a shift relies on the development of portable diagnostic and monitoring devices for near-patient testing. The NIBIB has contributed to advances in this area by funding the development of sensor and microsystem technologies for point-of-care testing. These instruments combine multiple analytical functions into self-contained, portable devices that can be used by non-specialists to detect and diagnose disease, and can enable the selection and monitoring of optimal therapies. These advances limit the reliance on submission of samples to centralized laboratories and will make results more readily available within minutes as opposed to several hours or days, enabling clinicians to make decisions regarding treatment

when these decisions can have the greatest impact. An example under development at the NIBIB is a handheld system for the rapid detection and identification of bacteria which cause urinary tract infections. The research team anticipates this test could become available in the next two to three years. To further capitalize on these advances, the NIBIB is planning an initiative to support research on critical areas for the development of other hand-held, diagnostic devices. These systems could reduce the cost of health care, much as integrated electronics have reduced the cost of computing, and greatly simplify and improve patient delivery of care.

NEXT GENERATION MINIMALLY-INVASIVE TECHNOLOGIES

Advances in imaging technologies have spurred new minimally-invasive procedures to accurately identify the site of disease and injury, provide tissue for a definitive diagnosis, administer treatment with minimal trauma, and monitor treatment responses. Image-guided interventions are not only more efficient in terms of time and cost, but their less invasive nature may result in fewer complications and less damage to tissue. For example, NIBIB investigators are developing new magnetic resonance imaging (MRI) techniques to detect and treat organ rejection non-invasively. The current standard for diagnosing and staging rejection is the biopsy, which is invasive, painful, and prone to sampling errors that can yield false negative results. The development of a non-invasive imaging-based method that can replace the biopsy is highly desirable.

Over the next year, the NIBIB intends to expand its image-guided interventions program by supporting research on the development of technologies that allow the surgeon to visualize the patient seamlessly, in three-dimensional preoperative images; track intraoperative changes with real-time imaging; and restore a normal sense of touch through robotic tools with sensors for touch feedback, or haptics. This research may lead to new minimally-invasive surgical procedures with fewer complications, shorter hospital stays, and reduced costs. To plan for future initiatives in this area, the NIBIB recently organized an interagency retreat to identify high priority challenges that can serve as short- and long-term goals. Eight Federal agencies and nine NIH Institutes and Centers (ICs) participated in this retreat.

SMEDICAL ROBOTIC

First generation surgical robots are already being installed in a number of operating rooms around the country. Although these robots can't perform surgery on their own, they are certainly lending a mechanical hand. Robots are being used in medicine because they allow for unprecedented control and precision of surgical instruments and reduce trauma to the patient, dramatically improving surgical outcomes and lowering health care costs. Robots are also being used in rehabilitation as they provide considerable opportunities to improve the quality of life for physically disabled people. For example, one of the most common stroke disabilities is a paralyzed arm. The NIBIB and the National Institute of Child Health and Human Development are jointly funding the development of two robotic devices that could accelerate rehabilitation of patients with paralyzed arms and reduce the cost of physical therapy. These devices can also treat people who have experienced catastrophic events, such as war injuries resulting in limb loss. Testing with stroke patients is expected to begin this year using one device.

Traumatic injury or neurological diseases can also significantly alter or impair the lifestyle of an individual. To help patients lead more productive lives, NIBIB scientists are developing a non-invasive brain-computer interface to provide both communication and control functions. By recording brain waves from the scalp and then decoding them, this system allows people to move a cursor to spell words, and even to control a robotic arm. Initial efforts to test this new technology in the field are underway.

NANOTECHNOLOGY FOR DISEASE DETECTION AND DRUG DELIVERY

Detection of dormant metastatic tumor cells is a critical but elusive goal in cancer treatment. To find these cells, NIBIB researchers are developing non-invasive optical imaging techniques that are less costly and more accessible than MRI-based techniques and are free of the side effects associated with radioactive imaging agents. Microscopic or nanoscale "bubbles," called polymerosomes, containing embedded fluorescent materials are the key to this new approach. These labeled bubbles are injected directly into a tumor and then imaged. Also in development are polymerosomes that would deliver chemotherapy agents directly to a tumor. The surface of the bubble can carry a molecule that would bind to tumor cells, and its membrane would also hold fluorescent molecules for detection by optical imaging, with the chemotherapy "payload" carried in the interior. One investigator has developed

a special device which improves drug release by ultrasonic fragmentation of the bubble.

ENHANCED SUPPORT FOR NEW INVESTIGATORS

New investigators are the innovators of the future—they bring fresh ideas and technologies to existing biomedical research programs, and they pioneer new areas of investigation. Entry of new investigators into the ranks of independent, NIBIB-funded research is essential to the health of the biomedical imaging and bioengineering research enterprise. The NIBIB is specifically targeting new investigators for special funding consideration. This proved to be quite successful in the first year of this policy, and a continuation of this program is planned.

TRAINING FOR THE FUTURE

An important goal of the NIBIB is to train a new generation of researchers equipped to meet the modern needs of interdisciplinary and transdisciplinary research. Researchers trained in biomedical imaging and bioengineering must be able to demonstrate technical competency in multiple fields as well as the ability to think independently, communicate ideas effectively, work in teams, and contribute to a strong vision that transcends a narrow discipline. To this end, the NIBIB will work with the community to develop new programs that cross-train research scientists in the biological and quantitative sciences. For example, the NIBIB's Research Supplements to Promote Clinical Resident Research Experiences program has been very successful. This novel training mechanism is designed to serve as a "first step" in attracting outstanding clinicians into research careers related to the mission of the NIBIB by providing a one to two-year research opportunity during residency training.

The NIBIB has also developed several public and private collaborations to catalyze research at this interface. For example, the NIBIB and the Howard Hughes Medical Institute partnered in a novel public-private partnership to stimulate the development of new interdisciplinary graduate training programs that integrate the physical, quantitative, and engineering sciences with the life sciences. This program will train a new generation of researchers, equipped to meet the challenges of the 21st Century.

NIH ROADMAP FOR BIOMEDICAL RESEARCH

An overarching goal of the NIH Roadmap is to facilitate the development of broad-based innovative, novel and multidisciplinary science and technology that has the potential to further advances in health care. This goal is well aligned with the NIBIB mission and is actively supported on a number of fronts. For example, over the last year NIBIB has been the lead Institute in a Roadmap initiative entitled "Innovation in Molecular Imaging Probes." Molecular imaging approaches can be used to study cellular events and biochemical abnormalities. The major roadblocks to in vivo clinical applications of molecular imaging are the poor sensitivity and potential toxicity of the current probes. This initiative supports research programs that will circumvent these roadblocks.

NIH BLUEPRINT

The Neuroscience Blueprint is a framework designed to enhance cooperative activities among the NIH ICs that support research on the nervous system. During the last year, NIBIB contributed to the development of a number of initiatives, leading or participating in three project teams. These initiatives aim to support research and development of imaging technology for high resolution imaging of neural activity that is reflected in electrophysiological signals; and to develop a framework to address the critical need for neuroimaging data and software tools sharing and integration. The NIBIB also participated in the development of neuroscience training initiatives.

PREPARED STATEMENT OF DR. GRIFFIN P. RODGERS, ACTING DIRECTOR, NATIONAL INSTITUTE OF DIABETES AND DIGESTIVE AND KIDNEY DISEASES

Mr. Chairman and Members of the Committee: I am pleased to present the fiscal year 2007 President's budget request for the National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK) a sum of \$1,844,298,000, which includes \$150,000,000 for the Special Appropriation for Research on Type 1 Diabetes through Sec. 330B of the Public Health Service Act. The NIDDK transfers some of these funds to other institutes of the NIH and to the Centers for Disease Control and Pre-

vention (CDC). Adjusted for mandatory funds, this is an decrease of \$10,627,000 from the fiscal year 2006 enacted level of \$1,854,925,000 comparable for transfers proposed in the President's request.

The NIDDK supports research to combat a wide range of chronic health problems, including diabetes and other endocrine and metabolic diseases; diseases of the digestive system, kidneys, urinary tract; and blood; nutritional disorders; and obesity. Through vigorous research, initiated both by investigators and by the Institute, the NIDDK will continue to elucidate the fundamental biology underlying health and disease. We are pursuing new strategies for disease diagnosis, treatment, and ultimately, prevention and cure.

PREEMPTING CHRONIC DISEASES AND THEIR COMPLICATIONS

Chronic diseases pose some of the greatest health challenges to the Nation today. These diseases and their symptoms range in severity, but are often debilitating and sometimes fatal. Some impair fundamental body processes, such as metabolism, while others target the kidneys, liver, and other vital organs and systems. Though their causes and ultimate effects on health may differ, chronic diseases share the grim features of constant affliction and impaired quality-of-life. The burden of chronic diseases within NIDDK's research purview is immense. Recent estimates using national health survey data reveal that diabetes (type 1 and type 2) affects nearly 21 million Americans.¹ About 20 million Americans have chronically impaired kidney function, which places them at increased risk for irreversible kidney failure (end stage renal disease) and death.² Digestive diseases, such as irritable bowel syndrome (IBS), inflammatory bowel disease (IBD), and liver and biliary diseases, wreak havoc with people's lives. "Benign" diseases of the bladder and lower urinary tract, including urinary incontinence and prostate diseases, can be devastating. These chronic diseases also exact a heavy economic toll. For example, the healthcare and indirect costs of diabetes and its complications totaled \$132 billion in 2002.³ The painful, debilitating symptoms of IBS and the bladder disease interstitial cystitis (IC) result in loss of work and increased medical costs. Costs of chronic diseases that strike the digestive system, kidneys, and bladder run into the tens of billions of dollars.

The tremendous human and monetary costs of chronic disease are matched only by the extraordinary interventions often needed just to preserve life. Organ transplantation and kidney dialysis are but two examples. Although these are extreme measures for the sickest patients, they represent some of the victories achieved by biomedical research in reducing morbidity and mortality from advanced chronic disease. Our goal is to improve these treatments, while we simultaneously seek prevention strategies. For example, whole liver transplantation from deceased donors is a successful treatment for liver failure, but is limited by a shortage of donor organs. A new NIDDK clinical network (A2ALL) is maximizing this treatment option in adults by assessing the safety and outcomes, for both patients and donors, of new procedures that use partial liver transplants from living donors—thereby increasing the potential donor pool. Similarly, we are addressing the diminished quality-of-life and low five-year survival rates under current dialysis treatment, which is typically administered three times weekly. A new clinical trial will evaluate the effectiveness of daily dialysis.

IMPORTANCE OF EARLY INTERVENTION

For persons already suffering from chronic disease, improved treatments will have great benefits. However, it is imperative that researchers find ways to intervene at the earliest possible stage of a disease. The goals for such research are to: (1) identify and use biological information, such as "biomarkers," that can predict an individual's susceptibility to disease, disease progression, or disease complications—thereby enabling more tailored use of interventions; (2) find the most effective interventions to preempt the onset or course of disease; and (3) ensure that these predictive tools and interventions can be precisely targeted for the benefit of patients. New advances in science, technology, and public health research are making these goals realizable, with the prospect of significant improvements in public health. Ex-

¹National Institute of Diabetes and Digestive and Kidney Diseases. National Diabetes Statistics fact sheet: general information and national estimates on diabetes in the United States, 2005. Bethesda, MD: U.S. Department of Health and Human Services, National Institute of Health, 2005

²The National Kidney Foundation <http://www.kidney.org/kidneyDisease/>. Accessed February 14, 2006.

³Hogan P, et al, Diabetes Care 26:917–932, 2003.

amples of potential research payoffs include hepatitis C and diabetes complications. In the United States, hepatitis C infection affects an estimated 4 million people and is the leading cause of both liver cancer and liver failure due to end-stage cirrhosis. Patients who do not respond to standard medical therapy with interferon and ribavirin are at high risk of developing these severe health problems. Ideally, physicians should be able to predict likely “non-responders” to current therapy and those at risk for disease progression, and then tailor interventions to them. While this is not yet possible, ongoing studies will help to move the field forward, including a major clinical trial (HALT-C) aimed at preventing end-stage cirrhosis and lowering risk of liver cancer in “non-responders” with advanced disease.

Likewise, physicians would welcome new, precise methods for tailoring interventions to individuals with diabetes so as to reduce complications in those at greatest risk, while also lessening treatment burden. Landmark clinical trials have demonstrated that tight control of blood sugar levels in type 1 diabetes patients significantly reduces their overall risk of eye, kidney, nerve, and cardiovascular disease. Unfortunately, current therapies to achieve tight control also increase the risk of potentially life-threatening bouts of low blood sugar. If a simple method existed to identify patients who could tolerate “looser” control of blood sugar levels without an increased risk of complications, then therapy could be tailored accordingly. Pinpointing the underlying causes of diabetes complications will pave the way to such targeted interventions.

Developing a more personalized approach to medical therapy requires a robust toolkit forged from research advances. Therefore, the NIDDK is continuing with new initiatives to accelerate translation of fundamental research into clinically useful applications. For example, we want to be able to stop early scarring of the liver and kidney—known as fibrosis—before it ignites a series of events leading to irreversible organ failure. The NIDDK is fostering new, non-invasive imaging methods to reveal fibrosis. Such techniques will enable physicians to diagnose, monitor and treat liver and kidney disease more effectively. For diseases within the NIDDK mission, we are also committed to the discovery of biomarkers—factors, such as molecules, that can be measured and used to monitor a patient’s disease or response to therapy. A new translational initiative encourages research to develop and validate these biomarkers for clinical use.

Critically important for predicting and preempting chronic diseases—such as polycystic kidney disease (PKD), focal segmental glomerulosclerosis (FSGS), kidney stones, IC, IBD, IBS, non-alcoholic steatohepatitis (NASH), and hepatitis B and C—is a thorough understanding of their natural history. For example, discovery of PKD genes has led to insights into the molecular defect underlying most cases of this disease. Promising new medical therapies are being explored to prevent or reduce cyst formation, and new trials (HALT-PKD) will now test approaches for preventing progressive kidney damage. In the kidney disease FSGS, we do yet know all the causative factors, but a better understanding of FSGS progression has enabled the NIDDK to undertake a trial of therapies to prevent or delay kidney failure in patients. A new international patient registry should increase our understanding of inherited causes of calcium oxalate kidney stones. The cause(s) of the bladder disease IC remains unknown, but studies of a promising biomarker from urine may lead to improved diagnosis and treatment for patients, as well as to new therapeutic options.

Our efforts in digestive diseases will be guided by a long-range strategic research plan to be developed by a new National Commission, as well as by a recently completed Liver Disease Action Plan. We are already making progress on several fronts. In IBD, studies of a recently identified Crohn’s disease susceptibility gene are pointing the way to new therapeutic options. Researchers are exploring the multiple physical and cognitive factors that appear to play a role in IBS. A new clinical research network is studying the biological basis of progression from a less serious form of non-alcoholic fatty liver disease to the fatty liver, liver inflammation and scarring of NASH, and will test strategies to prevent disease progression in both adults and children. Studies of the hepatitis B virus continue in order to optimize treatment options. A new system to replicate (“grow”) hepatitis C virus in the laboratory will significantly enhance research to test potential therapeutic targets and open the door to vaccine development—complementing ongoing trials such as HALT-C.

Strikingly, research has revealed that obesity, with its comorbidities, is at the nexus of many chronic diseases. The high prevalence of obesity in the U.S. population, with nearly 31 percent of adults affected,⁴ bears directly on the millions affected with chronic diseases. Obese individuals are at increased risk of type 2 diabe-

⁴Flegal KM et al, JAMA 2002;288:1723–1727.

tes, and obesity is linked to increased risk of NASH, as well as of ESRD via type 2 diabetes and high blood pressure. However, not all overweight and obese individuals will develop obesity-associated diseases. Age, gender, race, ethnicity, socio-economic status, and individual genetics are among the many factors that may influence risk. Through initiatives developed by the NIH Obesity Task Force and through NIDDK-led efforts, we are encouraging research studies to promote prevention and to identify which subsets of obese individuals are at risk for developing particular comorbidities, and, in turn, to tailor interventions accordingly.

Recent data offer promise that we may be able to stem the tide of obesity-related health problems. For example, analyses by the United States Renal Data System (USRDS) indicate that overall incidence rates of ESRD have stabilized in the United States, following a 20 year period of annual increases. This finding suggests that there has been a successful translation into medical practice of research-based knowledge important to preventing ESRD—the use of medications (ACE inhibitors) and the benefits of controlling blood sugar and blood pressure levels. Unfortunately, this positive result has not yet been seen across the entire U.S. population, in that ESRD continues to affect minority groups disproportionately. The National Kidney Disease Education Program (NKDEP) has a major campaign aimed at reducing the burden of kidney disease in African Americans, for whom the risk factors of high blood pressure, diabetes, and a family history are dangerous red flags. Through its working groups, the program is also promoting the standardized, routine reporting of serum creatinine—an indicator of kidney function. Use of this simple approach can facilitate early detection and treatment of impending or active chronic kidney disease in patients. Along the same lines, the National Diabetes Education Program (NDEP) has translated into a multi-faceted campaign for multiple audiences the impressive results of the Diabetes Prevention Program (DPP) clinical trial. This trial demonstrated that lifestyle changes—relatively moderate weight loss and increased physical activity—can reduce the risk of type 2 diabetes by 58 percent in persons at risk for the disease.

Such hopeful results spur our efforts to further reduce the health burden of these chronic conditions through interventions to prevent obesity as early as possible. Prevention research needs to address the alarming rise in rates of pediatric overweight and obesity nationwide over the past three decades. A recent study indicates that approximately two million American adolescents have a prediabetic condition (IFG) strongly linked to obesity and overweight. Children and adolescents are being increasingly diagnosed with type 2 diabetes, NASH, and other obesity-associated conditions once found mainly in adults. To address key points of vulnerability early in life, the NIDDK is spearheading several initiatives, such as defining mechanisms by which maternal obesity and diabetes during pregnancy affect the future risk of obesity and other chronic diseases in offspring. Another initiative is focused on finding ways to prevent or manage weight gain in children. Moreover, the new “HEALTHY” trial will investigate whether a concerted, integrated program in middle schools will help reduce the prevalence of obesity-related harbingers of type 2 diabetes by improving cafeteria lunches, vending machine offerings, and physical education and promoting behavioral change. The tremendous success of the intensive lifestyle intervention for adults in the Diabetes Prevention Program provides hope that the HEALTHY trial may do the same for children.

The Nation’s investment in NIH-funded research offers enormous benefits, particularly the opportunity to preempt disease and reduce its lifelong costs, both human and economic. To this end, the NIDDK is harnessing new technologies, maximizing research investments, and capitalizing on new opportunities to achieve early, effective intervention for the many chronic diseases within its mission. Thank you, Mr. Chairman. I would be pleased to answer any questions that the Committee may have.

PREPARED STATEMENT OF DR. JOHN RUFFIN, DIRECTOR, NATIONAL CENTER ON
MINORITY HEALTH AND HEALTH DISPARITIES

Mr. Chairman and Members of the Committee: I am pleased to present the President’s budget request for the National Center on Minority Health and Health Disparities (NCMHD) for fiscal year 2007, a sum of \$194,299,000, which represents a decrease of \$1,106,000 over the comparable fiscal year 2006 appropriation.

The overall health of the general American population has improved; yet as a Nation we continue to be challenged by disparities in health among racial and ethnic minority and other health disparity populations. There continues to be a disproportionate burden of illness, disability and premature death resulting from diseases

and health conditions such as cancer, cardiovascular disease, HIV/AIDS, stroke, obesity, mental illness and diabetes, in these communities.

The cause of health disparities is multi-factorial in nature. The complexity of health disparities merits a strategic, innovative, and multi-faceted attack. Genes, biology, culture, race environment, socioeconomic, and health behaviors all contribute to this complex public health crisis. Biomedical research is essential in transforming the health of this Nation. In order to have the greatest impact on improving the health of America's underserved populations, at NIH, we believe a new biomedical research paradigm is needed—one that is predictive, personalized and preemptive. We need a well-coordinated, interdisciplinary effort involving traditional as well as non-traditional partners to get to the crux of the health disparities crisis.

The National Center on Minority Health and Health Disparities was established in 2000 to lead the Federal effort in health disparities research, research capacity building, and outreach. The NCMHD has always recognized the significance of partnerships in resolving health disparities. Our programs embody a strategy that emphasizes our efforts to build a biomedical research enterprise that is diverse, predictive, personalized, and preemptive.

The NCMHD is committed to training a diverse biomedical research workforce to examine issues relevant to the disparities in health of America's rapidly increasing racial and ethnic minority populations. More than 600 promising research scientists across the country have received NCMHD loan repayment awards to conduct health disparities research and clinical research. Institutional capacity building has been an important area of focus. Through our endowments and research infrastructure program, we have funded almost 40 academic institutions—more than half being minority-serving institutions. The funding is helping to equip the institutions, their faculty and students to engage in avant-garde biomedical research and training. Another integral element of our strategy is community participation. Our aim is to empower the community to address its own health problems. Our communities should include individuals other than patients, who must be actively engaged in research intervention and ultimately the translation and dissemination of research results into practical community tools.

Advancements in science and technology offer hope for the future. The NCMHD has supplied more than 100 individuals, institutions, and small businesses with resources to conduct research to help answer some of the perplexing issues in health disparities. NCMHD is one of the few NIH Institutes or Centers (IC) that focuses on populations and not specific diseases or health conditions. Consequently, we have had the unique opportunity of partnering with all of the ICs over the past five years in our quest to eliminate health disparities. Our partnerships and our programs have allowed us to support research into many of the diseases and health conditions affecting racial/ethnic minority and other health disparity populations. It is through these programs and partnerships, that the NCMHD has been able to have far reaching effect in improving the health of the Nation's health disparity populations. We have made progress, but there is much more to be achieved.

HEALTH DISPARITIES RESEARCH AGENDA

A national health disparities research agenda is fundamental in eliminating health disparities. Healthy People 2010, the prevention strategy for the Nation, identified a number of health objectives to be achieved over a 10-year period. The elimination of health disparities among different segments of the population in the United States is one of the goals. We have five years left as a Nation to demonstrate how far we have come in attaining that goal. The NIH through the leadership of the NCMHD has been a principal player in advancing the goals of Healthy People 2010. The NCMHD coordinates the development of the evolving NIH health disparities research agenda—the NIH Health Disparities Strategic Plan. The Plan represents the trans-NIH health disparities vision and strategy. Through the Strategic Plan, the NIH can aggressively address health disparities by fostering pioneering partnerships and initiatives. The NCMHD, through the Institute of Medicine (IOM), initiated the five-year evaluation of the NIH Health Disparities Strategic Plan. The NCMHD, in collaboration with NIH leadership and the Secretary of Health and Human Services will address the recommendations of the IOM report in implementing and reshaping the NIH health disparities research agenda.

NCMHD HEALTH DISPARITIES EFFORTS

At the NCMHD, we are working to build an inclusive, collaborative, and adaptive biomedical and behavioral research enterprise to identify innovative diagnostics, treatments, and preventive strategies that will eliminate health disparities. NCMHD activities have been numerous and far-reaching. The newest NCMHD ini-

tiative is the Community-Based Participatory Research (CBPR) Program, which supports 25 institutions nationwide. The CBPR exemplifies a predictive, personalized and preemptive approach to eliminating health disparities. It is a three-part program that engages the community in all phases of the research process and is directed to a specific disease/health condition in a particular minority population. It starts with a three-year planning grant, followed by a five-year grant to conduct intervention research, and concludes with a three-year grant to disseminate the research information. The CBPR is a novel approach for the biomedical research enterprise, and we anticipate its potential in addressing health disparities through projects such as: Project GRACE: A Participatory Approach to Address Health Disparities in HIV/AIDS among African American Population; Partnership to Overcome Obesity in Hawaii; Project AsPIRE (Asian American Partnership in Research); The Healing of the Canoe (is aimed at planning, implementing and evaluating a community-based and culturally competent intervention to reduce health disparities and promote health in the Suquamish Tribe reservation community); and Partnership for a Hispanic Diabetes Prevention Program in Washington.

The Centers of Excellence Program, "Project EXPORT" has been key in leading our effort in supporting the advancement of medical research and the transformation of the health care system. The program is creating new partnerships to enable institutions at all levels of capability to maximize their health disparities research, research training and community outreach efforts. The 73 Project EXPORT grantees have had a tremendous influence on creating more than 100 unique partnerships focused on health disparities. We have created an array of partnerships with entities such as hospitals; tribal groups; health plans; health centers; community and faith-based organizations; civic and non-profit health organizations; and local, city, and state governments. Biomedical research is important in understanding the underlying causes of health disparities, and how to prevent, diagnose and treat disease and disability. The research conducted by our Centers of Excellence will help to increase that understanding through projects such as: Perceived Discrimination in Healthcare among American Indian/Alaska Natives; Religious Outlook on Organ and Tissue Sharing; Inflammation and Asthma; Impact of Coronary Heart Disease Risk Perception on Health Behaviors and Physical Activity Assessment in Multi-Ethnic Women.

The NCMHD Loan Repayment Programs support the goals of the new NIH Pathway to Independence Program by increasing the number of qualified health care professionals who conduct health disparities and clinical research. The programs promote a diverse and strong scientific workforce. Since its establishment, the Loan Repayment Program has made more than 600 new awards to researchers in research disciplines such as epidemiology, pharmacology, linguistics, etiology, health policy, and behavioral science. The program is fulfilling its Congressional intent with the majority of award recipients being from a health disparity population. The NCMHD is training research scientists and health professionals not only to deal with health disparities on the domestic level, but also globally. Through the Minority Health and Health Disparities International Research Training Program (MHIRT), 24 academic institutions have developed international training opportunities in health disparities research for faculty and students. MHIRT participants will be exposed to research areas including cancer epidemiology, reproductive biology, parasitology, and ethnopharmacology in countries such as Ethiopia, Ghana, Jamaica, Dominican Republic, Australia, and Spain.

The NCMHD commitment to enhancing research capacity at academic institutions is best demonstrated through its Research Endowment Program and its Research Infrastructure in Minority Institutions (RIMI) Program. The RIMI program is building research capacity in 21 predominantly minority-serving academic institutions. The NCMHD provides endowment grants to eligible institutions to build minority health and other health disparities research and training capacity. The Endowment program has funded 16 institutions to strengthen teaching programs in the biomedical and behavioral sciences; establish endowed chairs and programs; obtain state-of-the-art equipment for instruction and research; and enhance the recruitment and retention of student and faculty from health disparity populations.

RESEARCH COLLABORATIONS

The health disparities phenomenon is almost incomprehensible until it is humanized. Hurricane Katrina demonstrated the underlying national health crisis that continues to plague America's racial and ethnic minority and low-socio economic communities. In some cases, evacuees received medical treatment for the first time for chronic and life-threatening diseases, such as hypertension, cardiovascular diseases, diabetes, and mental health disorders.

Community involvement and partnerships are critical to redress the devastation experienced by individuals caught in the path of Hurricane Katrina. The NCMHD is collaborating with the HHS Office of Minority Health on a HHS \$12 million initiative to bring desperately needed health care services, information, and hope to racial and ethnic minority populations in the Gulf Coast region. The NCMHD provided \$5.2 million in funding to support that initiative. Our Centers of Excellence have also been mobilized to participate in the initiative to create a Regional Coordinating Center to build a research infrastructure for on-going efforts to eliminate health disparities in the hurricane-ravaged communities. Such an infrastructure would integrate research-based academic facilities, public health, primary care, and specialty care officials to engage in innovative approaches to relief activities, including developing and testing culturally relevant telemedicine response to mental health needs, and other acute and chronic diseases; instituting electronic health records for individuals in the region through partnerships with academic experts in practice-based research; and establishing effective community-based screening and surveillance systems to monitor health needs of individuals evacuated from hurricane-ravaged communities, as well as those returning to communities as they are re-built, with a special focus on exacerbations of existing health disparities.

The NCMHD Visiting Faculty Program is a new program that is assisting researchers displaced by the hurricane. The program will help to bring displaced scientists who were employed at institutions in the Gulf Coast states to the NIH, so that they can continue their research efforts.

CONCLUSION

During its initial five years the NCMHD has strived to be inclusive, creative, and adaptable to changing circumstances. The programs highlighted are but some examples of what is being done to eliminate health disparities. We need to build on these successes and further our activities. Toward this end, the NCMHD will sustain and expand its primary strategies. Research capacity building will continue to extend beyond academia to involve community and faith-based organizations, individuals, and businesses at the local and grassroots level. Training and the diversification of the health, scientific, and technological workforce will remain key areas of focus in developing innovative projects. Prevention, treatment, cultural competency, and healthcare delivery for urban and rural communities will continue to be approached aggressively.

Through our vision of the future embodied in the NIH Health Disparities Strategic Plan, the NCMHD renews its commitment to build a solid and diverse national biomedical research enterprise of individuals and institutions dedicated to eliminating health disparities. With our NIH Institute and Center collaborations and our partnerships with scientific institutions and community-based organizations across the Nation, the NCMHD will advance scientific discovery to ensure the health of all Americans. All citizens should have an equal opportunity to live long, healthy and productive lives.

PREPARED STATEMENT OF DR. DAVID A. SCHWARTZ, DIRECTOR, NATIONAL INSTITUTE OF ENVIRONMENTAL HEALTH SCIENCES

Mr. Chairman and Members of the Committee: I am pleased to present the President's budget for the National Institute of Environmental Health Sciences (NIEHS) for fiscal year 2007, a sum of \$637,323,000 which reflects a decrease of \$3,809,000 from the fiscal year 2006 appropriation.

INTRODUCTION

As the Director of NIEHS, I am grateful for this opportunity to present our vision for the Institute and environmental health sciences. Our vision at NIEHS is to prevent disease and improve human health by using environmental sciences to understand human biology and human disease. Environmental agents contribute to many conditions of public importance, including cancer, neurodevelopmental disorders, autoimmune diseases, and chronic lung disease. While many of our investigators are focused on understanding the causes of disease, we are also involved in studies of susceptibility, basic mechanisms of disease, and identifying novel approaches to intervention and disease prevention.

Recent NIEHS-supported research illustrates the range of our Institute's science. In studying asthma, NIEHS scientists examined the mechanisms controlling the body's own system for achieving balance between airway constriction and airway relaxation. They discovered a natural bronchodilator, deficient in asthmatics, that re-

laxes the airway; absence of this enzyme in mice increases the development of allergen-induced asthma. In other work, investigators studied the role of supplements in preventing birth defects. While folate has been shown to prevent spina bifida, a defect in the spinal column, epidemiologists have now discovered that women who take folate supplements during pregnancy are at reduced risk of giving birth to a child with cleft lip and palate birth defects. Finally, NIEHS-supported studies have shown that short-term exposure to ozone can increase mortality rates. These studies demonstrated that a 10-part per billion (ppb) increase in the previous week's ozone was associated with a significant increase in cardiovascular and respiratory mortality.

CURRENT CHALLENGES

Today, we find ourselves at a critical junction where new tools and opportunities for substantial scientific achievement intersect with our growing understanding of cellular and molecular mechanisms by which environmental exposures exert their effects. Our challenge is to take advantage of these advances and to forge new frontiers to improve our nation's health. To help ensure that the best opportunities are identified and funded, we have made several programmatic and scientific changes at the Institute since last April. Importantly, these changes are consistent with our strategic plan that we initiated ten months ago and have involved the efforts of many talented individuals across the country. Concurrently, we are engaged in developing critical partnerships to address areas of public health concern that involve the missions of multiple organizations.

INTEGRATIVE RESEARCH ON HUMAN DISEASE

Environmental health science is not limited to an organ system, disease or population, but spans the full spectrum of human health and disease. The interdisciplinary nature of our work requires the right mix of specialists. As NIEHS increases its focus on common human diseases, interdisciplinary teams of scientists will be needed to integrate clinical, epidemiological, and toxicological research with basic mechanistic studies. To optimize the creation of these interdisciplinary research teams, I have begun a number of programmatic changes. I have created an Office of Translational Biomedicine that will re-focus the NIEHS intramural and extramural programs so that our basic research discoveries can be rapidly applied to improvements in human health. In our division of extramural research, I have initiated a new program, DISCOVER (Disease Investigation for Specialized Clinically Oriented Ventures in Environmental Research), that brings together extramural scientists with expertise in basic, clinical, and population-based research to focus on a disease related to environmental exposures. Among intramural investigators, I have developed a new program, the Director's Challenge, that also supports multidisciplinary research teams to attack basic problems, like inflammation and oxidative stress, that can be induced by environmental exposures and can influence the development of many different diseases. I am re-engineering our Environmental Health Science Research Centers so that they include a clinical component in their research, thus enhancing the disease focus and relevance of these centers. I have also directed funds to build a new clinical research unit on campus so that our intramural research program can be integrated into human biology and human disease.

RECRUIT AND TRAIN THE NEXT GENERATION

A more integrative approach to understanding complex human diseases will require innovative scientists with the type of training that can take advantage of new technologies and research opportunities. NIEHS has initiated a number of changes that address our future workforce needs. We have re-engineered our existing training programs so that we can better identify and encourage promising students at all levels to pursue careers in environmental health research. The existing T32 training grants program will be broadened to include other training opportunities in interdisciplinary research and genetics and genomics. We will also train physician-scientists by expanding our MD, PhD training program and by supporting young investigators in their transition to early faculty positions (developed a K12 training program). We have also instituted the Outstanding New Environmental Scientist, or ONES, award to help young, talented investigators make the transition from mentored to independent research. These grants will assist young scientists in launching innovative research programs focusing on problems of environmental exposures and human biology, human pathophysiology, and human disease by providing support for both the research and the start-up costs that are needed to establish a laboratory.

EXPAND COMMUNITY-LINKED RESEARCH

The likelihood of exposure to environmental agents increases in economically disadvantaged communities and is associated with an excess disease burden in these communities. The NIEHS traditionally supports research relevant to understanding those health disparities and community concerns. We will continue to support research, both domestically and globally, that can offer insights into how to reduce exposures and disease in these settings. We will also be involved in developing quick responses to emerging environmental health issues, such as arose in the aftermath of Hurricane Katrina, when NIEHS launched a website that used a Global Information System to assess environmental hazards caused by the storm, as well as coordinated a local team of physicians and support staff to deliver medical care. Beginning in fiscal year 2006, NIEHS is planning to support a research program to investigate the health consequences of Hurricane Katrina. This project will examine the role of genes, the environment, and gene-environment interaction in the exacerbation of airway disease from exposure to mold and microbial toxins in New Orleans following Hurricane Katrina.

RE-EVALUATE PROGRAMMATIC INVESTMENTS

We have decided that investigator-initiated research needs to be prioritized at NIEHS and are rigorously re-evaluating other existing programs and approaches to determine if we need to re-conceptualize or eliminate some of these efforts. We have developed two new programs aimed at using environmental agents to understand basic mechanisms in human biology. One is the Epigenetics Initiative which explores intrauterine environmental and nutritional factors that can alter gene expression and generate developmental abnormalities or functional changes. The other is the Comparative Biology of Environmental Disease which uses novel “-omics” technologies and comparative biology approaches to study environmentally-relevant disease pathways. These studies will help us understand why people exposed to the same environmental stressors respond differently. Finally, we have reorganized the National Center for Toxicogenomics to insure a more timely and relevant product. In order to achieve these new programs and priorities, I have decided that the Comparative Mouse Genomics Centers Consortium has fulfilled its mission of infrastructure development and will not be re-competed.

GENE, ENVIRONMENT AND HEALTH INITIATIVE—A NOVEL PARTNERSHIP

Currently, we have inadequate techniques to precisely measure environmental exposures. This situation is in marked contrast to the robust tools that have been recently developed for the fields of genetics and genomics. To be able to assess the role that environmental exposures and genetic variation play in the risk of developing disease, we simply need more robust tools to measure the environmental exposures and the biological responses to these agents. While these tools are absolutely vital in moving the field of environmental health sciences forward, these tools will be invaluable to investigators in all areas of biomedical research. To further this goal, the NIH, with the support of the Secretary, has developed the Gene, Environment and Health Initiative. Our goal in this initiative is to develop tools to precisely measure individual biological responses to changes in our environment, diet, and activity level so that we can understand the relationship between various environmental exposures and human health and disease.

NIEHS STRATEGIC PLAN—A NEW OUTLOOK

The NIEHS recently embarked on a strategic planning exercise, the final version of which can be viewed on our website and will soon be distributed in hardcopy. This document represents the efforts of many scientists and advocacy groups. I have been gratified by the intense interest and involvement from citizens and scientists throughout the country. This document is truly a national plan that represents our collective wisdom of where environmental health sciences needs to go in order to reap full benefit of our investments and opportunities. Many of the suggestions have already been incorporated into our new programs and we will continue to design programs that are responsive to this plan.

SUMMARY

The opportunities within environmental health sciences are greater than they have ever been. With our recent nationally supported strategic plan and the exciting partnerships that we are developing, it is my belief that environmental health sciences will continue to strengthen. With an improved relevance to major public health concerns, better technology for teasing out important environmental contrib-

utors to disease, an integrated approach to research, and a re-energized workforce, I expect the NIEHS to provide many of the important scientific advances of the future. Ultimately, this knowledge will be used to reduce the burden of many important diseases both in this country and abroad. I would be happy to answer any questions you might have.

PREPARED STATEMENT OF DR. PAUL A. SIEVING, DIRECTOR, NATIONAL EYE INSTITUTE

Mr. Chairman and Members of the Committee: I am pleased to present the fiscal year 2007 President's budget request for the National Eye Institute (NEI). The fiscal year 2007 budget includes \$661,358,000, which reflects a decrease of \$5,398,000 under the fiscal year 2006 enacted level of \$666,756,000 comparable for transfers proposed in the President's request.

As the Director of the NEI it is my privilege to report on the progress laboratory and clinical scientists are making in combating blindness and visual impairment and about the unique opportunities that exist in the field of vision research.

RETINAL DISEASES

Retinal diseases are a diverse set of sight-threatening conditions that include age-related macular degeneration (AMD), diabetic retinopathy, retinopathy of prematurity, retinitis pigmentosa, Usher's syndrome, ocular albinism, retinal detachment, uveitis (inflammation) and cancer (choroidal melanoma and retinoblastoma).

Of these diseases, AMD is the most frequent cause of vision loss and legal blindness in older-age Americans, making it a research priority for the NEI. AMD causes degeneration of the macula, the central part of the retina that gives us fine, sharp visual detail. AMD is thought to result from the confluence of genetic predisposition and chronic exposure to environmental risk factors.

On the genetic side of the equation, identifying subtle alterations in a gene or genes in AMD and other late onset diseases has been complicated by the fact that traditional genetic research strategies and tools are either inadequate or too cumbersome in their application. The development of more sophisticated genetic tools has enabled scientists to scan the entire human genome more quickly and efficiently. Using data from the Human Genome Project and the International HapMap Project, four different NEI supported laboratories identified a common variation in a gene called complement factor H (CFH) that accounts for an estimated 50 percent of the risk of developing AMD.

The CFH protein regulates an inflammatory response that is typically triggered by infectious microbes. Alterations in the CFH gene are postulated to poorly regulate this response, leading to chronic, localized inflammation and ensuing damage to cells in the center of the retina, the macula, and its neighboring tissues. Inflammation is thought to play a role in many other common diseases such as Alzheimer's disease, Parkinson's disease, multiple sclerosis, kidney disease, stroke, and atherosclerosis. Although the cells, tissues, and molecular events in these diseases are diverse, they may share some common disease mechanisms that present an opportunity to cross pollinate findings from diverse research areas.

The discovery of the CFH gene will allow researchers to create animal models and evaluate therapies that control chronic inflammation. The CFH gene also illustrates the potential of a new paradigm for medicine in the 21st century. This new paradigm holds that the practice of medicine should be preemptive, personal and predictive. The CFH gene presents the possibility to one day identify at-risk patients and intervene well before pathology is clinically detectable.

STRABISMUS, AMBLYOPIA AND VISUAL PROCESSING

Developmental disorders such as strabismus (misalignment of the eyes) and amblyopia (commonly known as "lazy eye") are among the most common eye conditions that affect the vision of children. It is estimated that 20 percent of preschool children ages 3-4 have these and other treatable eye conditions.¹

In an effort to identify children with treatable eye conditions, many states are developing guidelines for preschool screening programs. However, none of the commonly used vision tests have been evaluated in a research-based environment to establish their effectiveness. To address this issue, the NEI supported a large, multi-center study called the Vision in Preschoolers (VIP) Study to determine which tests and test conditions can effectively identify preschoolers in need of a comprehensive

¹ Comparison of preschool vision screening tests as administered by licensed eye care professionals in the Vision in Preschoolers Study. *Ophthalmology* 111(4):637-50, 2004.

eye exam. Previously VIP Study researchers found that in the hands of licensed eye care professionals, the best performing tests were able to detect 90 percent of children with the most severe visual impairments. This year, VIP Study investigators found that specially trained nurses and lay people can achieve results that are comparable to screenings performed by licensed eye care professionals. Given that most eye screening programs rely on lay people and nurses, this finding validates the effectiveness of this approach.

GLAUCOMA AND OPTIC NEUROPATHIES

Glaucoma is a group of eye disorders that causes optic nerve damage that can lead to severe visual impairment or blindness. Elevated intraocular pressure (IOP) is frequently, but not always, associated with glaucoma. Glaucoma is a major public health problem and published studies find that the disease is three times higher in African Americans than in non-Hispanic whites.²

The defining event that leads to vision loss in all forms of glaucoma is the degeneration of retinal ganglion cells (RGC) in the back of the eye. These cells relay visual information to the brain through the optic nerve and their loss effectively severs the neural network that allows us to process visual information. However, little is known about the molecular events that result in RGC degeneration. Using high dose radiation and bone marrow rescue to explore inflammatory responses in an animal model of glaucoma, researchers unexpectedly discovered that this procedure prevents the loss of RGCs. The neuroprotection offered by this procedure was complete, highly reproducible, and lasting. Normally, by 12–14 months, these glaucoma susceptible mice have complete RGC loss. At 14 months, treated mice had no detectable signs of disease. Although the mechanism that offers neuroprotection is not yet known, researchers speculate that it is due to radiation, because the transferred bone marrow was genetically identical to the original bone marrow the mice were born with. This highly novel treatment protocol offers a tool to understand neurodegeneration and, with refinement, could have important implications for the treatment and prevention of neurodegenerative diseases.

CORNEAL DISEASES

The cornea is the transparent tissue at the front of the eye. Corneal disease and injuries are the leading cause of visits to eye care professionals, and are some of the most painful ocular disorders. In addition, approximately 25 percent of Americans have a refractive error known as myopia or nearsightedness that requires correction to achieve sharp vision; many others are far-sighted or have astigmatism.³

Inflammation is a common immune response to injury and infection in the body. In the cornea, however, inflammation can cause extreme discomfort and result in vision loss. Nonetheless, the cornea retains a remarkable capacity for wound repair while actively suppressing an inflammatory response. Scientists have recently discovered that two lipids, lipoxin A₄ (LXA₄) and docosahexaenoic acid-derived neuroprotectin D1 (NPD1), are formed in the cornea and act as anti-inflammatory agents during corneal infection and wound healing. Topical treatment with LXA₄ and NPD1 in mice with corneal injuries increased the rate of tissue repair and inhibited inflammation without impairing the recruitment of key immune leukocytes, which are normally associated with inflammation, into the wounded tissue. Moreover, a transgenic mouse that lacks these lipids exhibited delayed wound healing and attenuated leukocyte recruitment. The identification of these anti-inflammatory lipids in the cornea and their enhancement of wound healing by topical application suggest their use as therapeutic agents to overcome aberrant and damaging inflammatory responses in the eye.

CATARACT

Cataract, an opacity of the lens of the eye, interferes with vision and is the leading cause of blindness in developing countries. In the United States, cataract is also a major public health problem. The enormous economic burden of cataract will worsen significantly in coming decades as the American population ages.

The lens is a dense, compact structure containing two cell types: metabolically active epithelial cells and quiescent fiber cells. Throughout the life-time of an individual, the lens carries out a process of continued growth with epithelial cells divid-

²The Eye Diseases Prevalence Research Group: Prevalence of open-angle glaucoma among adults in the United States. *Arch Ophthalmol* 122:532–538, 2004.

³The Eye Diseases Prevalence Research Group: The prevalence of refractive errors among adults in the United States, Western Europe, and Australia. *Arch Ophthalmol*. 122:495–505, 2004.

ing and differentiating into fiber cells. During this process, the emerging fiber cells become denuded of organelles such as the nucleus and mitochondria. This process in part helps the lens achieve the high transparency needed for clear vision. Scientists have previously found that the lens uses proteins involved in a biological process called programmed cell death or apoptosis to rid lens fiber cells of their organelles. This past year, vision researchers have discovered the biologic process that regulates apoptosis such that it allows for the elimination of organelles without resulting in cell death.

The process is termed Apoptosis-related Bcl-2 and Caspase-dependent (ABC) differentiation. In this process, a number of proteins that normally lead to cell death such as caspases—proteins that break-down internal cellular structures—are expressed to denude organelles. The caspase proteins are balanced by the simultaneous induction of pro-survival molecules such as bcl-2, a protein that binds to cell death proteins and inhibits further damage or death to fiber cells. The discovery of ABC differentiation in the lens will allow researchers to better understand lens cell renewal and determine whether faulty mechanisms in this process might lead to cataract formation.

NIH ROADMAP

A goal of the NIH Roadmap Nanomedicine Initiative is to characterize quantitatively the molecular scale components or nanomachinery of cells and to precisely control and manipulate these molecules and supramolecular assemblies in living cells to improve human health. The NEI has a leadership role in implementing the NIH Roadmap Nanomedicine Initiative. Under this initiative, a Request for Applications (RFA) was prepared to award Nanomedicine Center Concept Development Awards. These concept development awards were created to allow applicants time and resources to develop the concept for a Nanomedicine Center that would address various issues in nanomedicine including, biomolecular dynamics, intracellular transport, and protein-protein interactions. Understanding these fundamental biologic processes at the nanoscale level will allow scientists to engineer molecular structures, assemblies, and organelles for treating diseased or damaged cells and tissues. Of the applications, four Nanomedicine Centers were awarded in fiscal year 2005. The Centers will be dedicated to understanding the nanobiology that underlies protein folding machinery; ion channels and ion transport proteins; synthetic signaling and motility systems; and mechanical biology. The NIH expects to fund additional Nanomedicine Centers in fiscal year 2006. The Nanomedicine Initiative will also benefit eye research in a more direct way. Current NEI grantees are exploring the use of nanotechnology to assist in corneal wound healing and drug delivery to the retina. Increased support of nanomedicine through the NIH Roadmap will undoubtedly speed progress in these areas.

NIH NEUROSCIENCE BLUEPRINT

The NIH Neuroscience Blueprint is a collaborative effort among 15 NIH institutes and centers to accelerate the pace of discovery and understanding in neurosciences research. In an effort to better understand all elements of the nervous system, the Blueprint will focus on the development of tools and resources that will facilitate research on the processes of development, neurodegeneration, and plasticity that underlie the health and disorders of the nervous system. One of the approaches to develop these tools and resources is a cellular level approach to discovering the key molecules involved in nervous system function. There is still a need to identify the location, the developmental timing, and the cellular function of most of the genes and proteins expressed in the brain. Mapping of the neurogenome is being conducted by creating and analyzing transgenic mice to map gene expression and activity to different cell types and regions of the mouse central nervous system. The NEI component of this effort will be to ensure that the genes involved in neurons of the complete visual system are included in the neurogenome map.

Mr. Chairman, this concludes my prepared statement. I would be pleased to respond to any questions you or other members of the committee may have.

PREPARED STATEMENT OF DR. STEPHEN E. STRAUS, DIRECTOR, NATIONAL CENTER
FOR COMPLEMENTARY AND ALTERNATIVE MEDICINE

Mr. Chairman and Members of the Committee: I am pleased to present the President's fiscal year 2007 budget request for the National Center For Complementary And Alternative Medicine (NCCAM). The fiscal year 2007 budget includes

\$120,554,000, a decrease of \$911,000 over the comparable fiscal year 2006 appropriation of \$121,465,000.

NCCAM has made significant progress in discovering the potential of complementary and alternative medicine (CAM) to prevent and treat disease. During NCCAM's first 7 years, the Center has formed a research enterprise that addresses the challenges of conducting CAM research as well as training investigators, conducting outreach, and facilitating the integration of proven CAM therapies into the health care that Americans receive.

SETTING THE COURSE

Through national surveys, we know that two-thirds of Americans are using some form of CAM each year. We are gaining understanding of which Americans use the various CAM modalities and for which health purposes. These patterns of CAM use will inform NCCAM's research priority setting in fiscal year 2007, along with guidance from two key documents:

- The NCCAM Strategic Plan for 2005–2009 (developed with input from the public and scientific and medical communities nationwide); and
- The Institute of Medicine's 2005 report, "Complementary and Alternative Medicine in the United States."

In fiscal year 2007, NCCAM will again collaborate with the Centers for Disease Control and Prevention to support the National Health Interview Survey to capture changes in trends of the American public's use of CAM.

FURTHERING THE RESEARCH MISSION

Seven years of NCCAM investments in CAM research translate to the support of more than 1,200 projects (in research, training, and career development) at over 260 U.S. institutions. There has been a 20-fold increase in the number of CAM papers published in leading scientific journals by NCCAM grantees. In fiscal year 2007, building upon this strong foundation, NCCAM plans to further enhance CAM research in the following areas.

A Flourishing Centers Program

NCCAM has expanded and refined its approach to research centers. As a result, the Center now has a diverse cadre of multidisciplinary research centers at conventional and CAM institutions nationwide.

- Centers of Excellence for Research on CAM.*—Six centers with outstanding research records direct teams of CAM and conventional investigators to explore, using cutting-edge technologies, how CAM therapies may work.
- Developmental Centers for Research on CAM.*—Scientists and practitioners at 18 CAM and conventional institutions have forged research partnerships. In fiscal year 2007 there will be new Phase I developmental centers for CAM institutions just launching programs of research, and Phase II developmental centers for CAM institutions prepared to undertake more sophisticated research studies.
- International Centers for Research on CAM.*—Two centers support U.S. investigators who collaborate with experts in the traditional medical systems of their own countries, building research expertise and capacity abroad and providing foreign researchers with valuable experience in navigating the NIH grants system.
- Botanical Research Centers.*—Seven dietary supplement research centers focusing on studies of botanical products are funded by NCCAM and the NIH Office of Dietary Supplements. Research conducted by these centers will advance the scientific base of knowledge about the safety, effectiveness, and mechanisms of action of botanicals.

Studies of Herbs and Other Dietary Supplements

Herbs and other dietary supplements are widely used by the American public and they are a research priority for NCCAM. Studying botanicals, however, has presented special research challenges related to product characterization, standardization, and dosage. With the advice of experts in herbal medicine and leaders of the dietary supplement industry, NCCAM is improving product consistency for research studies and thus increasing the probability that the studies NCCAM funds will yield accurate findings.

In this regard, the Center has developed research-quality cranberry products to use in studies of urinary tract infections and standardized an extract of milk thistle (silymarin), for study in patients with chronic viral hepatitis and non-alcohol-related steatohepatitis, a collaborative project with the National Institute of Diabetes and Digestive and Kidney Diseases.

NCCAM has worked with several NIH partners to design, conduct, and fund large clinical trials of dietary supplements. The largest of these was reported in February 2006 in the *New England Journal of Medicine*: a 4-year study (co-funded by the National Institute of Arthritis and Musculoskeletal and Skin Diseases) of glucosamine and chondroitin sulfate, two dietary supplements widely used by people with knee osteoarthritis. In this study, the two supplements combined did not provide statistically significant pain relief for all the participants, compared to placebo. However, a small subset of participants with moderate-to-severe pain had significant pain relief. An ancillary study is continuing to determine whether the combination of these supplements can prevent or delay further joint deterioration, a common long-term outcome for people with osteoarthritis.

A Broad Research Portfolio

There are hundreds of different practices, products, and approaches that comprise CAM. Thus, the research that NCCAM funds is wide-ranging. Areas that NCCAM will emphasize further in fiscal year 2007 include:

- Manual therapies.*—The mechanisms of action underlying the effects of manipulative and body-based therapies such as chiropractic and massage are little understood. Therefore, NCCAM is launching an initiative in fiscal year 2007 on the biology of manual therapies to better understand the effects of these techniques on the body.
- Mind-body medicine.*—One recent NCCAM-funded study found that tai chi combined with standard medical care benefits patients with chronic heart failure. Studies of meditation and mindfulness-based stress reduction in various health conditions are under way. NCCAM is also redirecting the focus of its intramural research program to emphasize studies of mind-body medicine.
- Echinacea.*—Research on echinacea is being done both because of the public health burden of the common cold and the public's widespread use of this natural product. A study of a single dosage of *Echinacea purpurea* to treat viral colds in healthy children was recently completed by an NCCAM grantee. A larger study is being undertaken in which a range of doses of this popular herb will be assessed for its ability to prevent colds in children.
- Immune responses.*—Many CAM interventions are believed to affect the immune system, either by enhancing its ability to thwart infection or by suppressing an overactive response, as occurs in autoimmune diseases. NCCAM is exploring the immune effects and basic mechanisms of action of various CAM modalities such as traditional Chinese herbal mixtures, ginseng, green tea, and *Ginkgo biloba*.

EXPANDING TRAINING AND CAREER DEVELOPMENT

There can be no significant CAM research progress without a sufficient cadre of investigators who are both skilled in rigorous research and knowledgeable about CAM practices. NCCAM has increased the number, quality, and diversity of the CAM research community using a variety of approaches and grant mechanisms. In fiscal year 2007, NCCAM will offer three new training opportunities: supplements to existing research grants, in order to attract more CAM practitioners into research endeavors; the CAM Practitioner Research Career Development Award, for CAM practitioners interested in research; and the NCCAM Career Transition Award, to help outstanding postdoctoral research fellows in their transition to an independent career in CAM research.

DISSEMINATING INFORMATION

From the outset, NCCAM has made it a priority to help practitioners, patients, and the public make informed decisions about CAM. The Center conducts outreach to public and professional audiences through a variety of channels: information clearinghouse, website, quarterly newsletter, conferences, Distinguished Lecture Series, and online continuing education. With the National Library of Medicine, the Center publishes CAM on PubMed, an online database of more than 400,000 research papers on CAM.

FACILITATING INTEGRATION

NCCAM is committed to facilitating the integration of safe and effective CAM therapies into conventional medicine. One example of this effort is within the NIH itself. The Center is establishing a new Integrative Medicine Consult Service at the NIH Clinical Center, to provide integrative medical consultations and enrich patient care. In addition, NCCAM continues to provide CAM curriculum development grants to conventional medical, dental, and nursing schools.

COLLABORATING ACROSS NIH

NCCAM continues its collaborations with other NIH Institutes and Centers, as a contributing member of the biomedical research community. For example, NCCAM is a partner in several of the NIH Roadmap for Medical Research initiatives, including the Exploratory Centers for Interdisciplinary Research. Also, by participating in efforts like the NIH Neuroscience Blueprint, the NIH Pain Consortium, and the Trans-NIH Obesity Initiative, NCCAM can accelerate efforts to unlock the potential of CAM therapies through these multidisciplinary research initiatives.

LOOKING TOWARD THE FUTURE

Mindful of the lessons learned in our first 7 years as an NIH Center, and with growing understanding of the scientific opportunities and public health priorities to be addressed with CAM approaches, NCCAM will continue to explore options to sustain and improve the health and well-being of the American people.

Thank you, Mr. Chairman. I would be pleased to answer any questions that the Committee may have.

 PREPARED STATEMENT OF DR. LAWRENCE A. TABAK, DIRECTOR, NATIONAL INSTITUTE OF DENTAL AND CRANIOFACIAL RESEARCH

Mr. Chairman and Members of the Committee: I am pleased to present the President's budget request for the National Institute of Dental and Craniofacial Research (NIDCR) for fiscal year 2007. The fiscal year 2007 budget includes \$386,095,000, a decrease of \$3,241,000 from the fiscal year 2006 level of \$389,336,000, comparable for transfers proposed in the President's Request.

STRENGTHENING THE EVIDENCE BASE IN DENTAL CARE

Health care decisions should be guided by the preponderance of clinical research data, or evidence, whenever possible. This approach is known as "evidence-based medicine", a concept that has evolved into a driving force in healthcare.

Recognizing the concept's value, dentistry also has embraced an evidence-based approach. Yet, having sufficient clinical data from which to build that base can be challenging. For some oral health problems, evidence-based approaches are possible; for many others, knowledge gaps must be filled before an evidence-based approach can take root. As the nation's leading supporter of oral, dental, and craniofacial research, the NIDCR is uniquely positioned to fill those gaps while continuing its efforts in the laboratory to develop new and even more effective ways to prevent, diagnose, and treat dental diseases. I would like to highlight over the next few minutes how the NIDCR is sowing the clinical seeds of progress to advance evidence-based dentistry in America and, above all, improve the nation's oral health.

PRACTICE-BASED RESEARCH NETWORKS

Healthcare providers sometimes comment that too often they are not included as participants in research, noting that their clinical experience and insight are significant assets to understand and address patients' most pressing health concerns. I believe that there is much to be gained from engaging clinical practitioners in research. That is why the NIDCR recently established three regional practice-based research networks (PBRNs) to investigate everyday issues in oral healthcare.

Each PBRN involves 100 or more oral health practitioners who will propose and conduct studies of common dental procedures across a range of patient and clinical conditions. For example, some of the early investigations will gather data on methods dentists use to restore teeth with deep decay, and to assess caries risk. Each network will conduct 15 to 20 clinical studies over the next seven years. The PBRNs also will collect information to generate data on disease, treatment trends, and the prevalence of less common oral conditions.

While the PBRNs aim high, their success will be rooted in their focus on real-world clinical issues and their ability to generate information that will be of immediate value to practitioners and patients alike. The studies will involve topics and procedures that clinicians themselves identify as relevant and in need of systematic research to help guide clinical decisions. I believe the PBRNs have the potential to generate a body of high quality clinical research data in a relatively short period of time. Most importantly, their research will substantially enhance the base of evidence clinicians can use to inform treatment decisions, translate newer information into daily practice, and directly affect and improve routine dental care.

GREATER EMPHASIS ON LARGE CLINICAL STUDIES

The nation's progress against heart disease, cancer, and infectious diseases has been accelerated by large clinical studies yielding results that can be generalized and can clarify the interplay of many variables. In dentistry, clinical research traditionally has involved smaller studies with fewer participants. The NIDCR is changing this trend by supporting larger clinical studies whose outcomes have the potential to fundamentally change dental practice and improve public health. I would like to tell you about some examples.

PERIODONTAL DISEASE AND PRETERM BIRTH

In the United States, about one in eight babies is born prematurely.¹ Preterm babies can be so small and underdeveloped that they must remain hospitalized for months and, if they survive, spend years battling chronic health problems. This heartbreaking situation has spurred scientists to identify risk factors associated with premature births. Risk factors such as smoking, hypertension, and diabetes allow doctors to identify women who are more likely to deliver prematurely and to tailor their prenatal care. However, identification of risk factors is a work in progress. One in four of preterm births (more than 125,000 per year) occurs without any known explanation.² Scientists have assembled an intriguing body of preliminary evidence to suggest that women who have severe gum, or periodontal, disease during pregnancy are at increased risk of preterm delivery. This raises the question: Does treatment for periodontal disease during pregnancy help women reach full term and give birth to healthy babies?

The NIDCR is supporting the first large, controlled Phase III clinical trials to answer this important public health question. Two studies involve over 2,600 women of various racial, ethnic, and economic backgrounds. The first, called the Obstetrics and Periodontal Therapy (OPT) trial, will soon report its findings, providing for the first time the clinical data needed to offer sound scientific advice on this issue. The results of the second study, called the Maternal Oral Therapy to Reduce Obstetric Risk (MOTOR) trial, should be forthcoming next year.

BETTER PAIN TREATMENTS FOR JAW CONDITION

Temporomandibular joint and muscle disorder (TMJMD) is an umbrella term for conditions affecting the area in and around the temporomandibular joint, or TMJ. The TMJs connect the jaw to the skull. Common symptoms of TMJMD include persistent pain in the jaw muscles, restricted jaw movement, and jaw locking.

Although TMJ disorders vary in their duration and severity, for some people the pain becomes severe and permanent. NIDCR recently launched a large, seven-year clinical study to accelerate research on better pain-control treatments for TMJMDs. The study, called Orofacial Pain: Prospective Evaluation and Risk Assessment (OPPERA) will collect data on 3,200 healthy volunteers for three to five years to see how many develop TMJMD, opening a largely unexplored window from which to observe the early stages of the disorder. With this unique vantage point, they can gather data on key genetic, physiologic, and psychological variables involved in TMJMD pain, ultimately weaving the information into more effective treatments.

Only a decade ago, a large study tracking the development of TMJMD over time would have been scientifically problematic, because little was known about the basic mechanisms of human pain. However, because progress in the basic sciences has fed the knowledge pipeline, pain researchers have now better defined the molecular circuitry involved in pain transmission, thereby providing the conceptual framework for this important clinical study.

MOLECULAR MEDICINE AND ORAL CANCER

In the fight against cancer, future weapons of choice likely will fall within the therapeutic category of molecular medicine. The concept builds on world-wide efforts to design cancer treatments targeting the precise molecules that drive the tumor process, leaving normal cells unscathed. As envisioned, molecular medicine will increase the benefits of treatment and limit greatly the unwanted side effects that now afflict cancer patients. For the vision to become reality, scientists first must learn to correctly identify distinctive features of the genetic and/or protein profiles of developing tumors. Much progress has been made in the laboratory, but the

¹Martin JA, Hamilton BE, *et al.* Births: Final data for 2003. National vital statistics reports; vol. 54 no 2. Hyattsville, MD: National Center for Health Statistics. 2005.

²Offenbacher S, Katz V, *et al.* Periodontal infection as a possible risk factor for preterm low birth weight. *J Periodontol*, vol. 67(10) p. 1103–13.

promise of molecular diagnostics remains largely unready for translation to patient care.

An NIDCR-supported project that has successfully taken that critical step is a partnership between scientists, dental educators, and a community clinic in British Columbia. The partners have integrated molecular techniques with existing screening tools by combining certain molecular discoveries with clinical use of toluidine blue, a chemical dye used to determine whether or not to biopsy an abnormal growth. The technique hinges on laboratory work that showed an association in early oral lesions between toluidine blue retention and the presence of cells with distinct, cancer-predisposing chromosomal abnormalities. The program already has identified several people requiring treatment for oral cancer and pre-cancerous lesions.

DRY MOUTH AND RADIATION THERAPY

Persistent dry mouth often occurs in head and neck cancer patients because radiation from the therapy damages the salivary glands. This irreversible, chronic dryness makes normal chewing and swallowing difficult, and leads to a range of painful oral diseases. Recently, NIDCR scientists teamed with researchers at the National Cancer Institute to develop an important new lead in protecting the salivary glands during radiation therapy to the head and neck. Their work involves a synthetic chemical called Tempol, which possesses a unique ability to protect cells against radiation. In mice, administration of Tempol 10 minutes prior to radiation therapy to the head and neck provided significant protection to the salivary glands. Critically, Tempol did not protect tumors from radiation, and thus did not diminish the beneficial effects of the radiation therapy. Future clinical trials in people are likely.

REDUCING DISPARITIES IN THE NATION'S ORAL HEALTH

Although the Nation's oral health has improved greatly over the past several decades, this progress has not been equally shared by millions of low income and underserved Americans. To help reverse this trend, the NIDCR supports five Centers for Research to Reduce Oral Health Disparities. The centers are designed to explore, understand, and improve the oral health of those who reside in underserved communities. The researchers seek creative but practical approaches that are inexpensive, can be easily applied, and are exportable to other underserved communities.

This year, the Disparities Centers reported several noteworthy findings. For example, after a two-year clinical study, San Francisco researchers found that infants and small children who receive at least one fluoride varnish treatment per year can cut their dental caries rate in half. Fluoride varnish is a concentrated fluoride in a resin or synthetic base that is applied directly onto the teeth. The treatment is inexpensive and is more easily used with very small children than other preventive measures, such as dental sealants and mouth rinses.

Meanwhile, the Disparities Center at the University of Washington is evaluating the oral health benefits of gum and candy sweetened with xylitol rather than caries-promoting sugars. Xylitol, a natural substance found in certain fruits, has been shown to fight tooth decay. The team is refining the optimal dose to satisfy taste and fight decay. Xylitol use exemplifies an easily adopted, self-administered, scientifically validated approach that may be useful in underserved populations.

IMPROVING THE NATION'S ORAL HEALTH

As these highlights demonstrate, the NIDCR has made a strong commitment to expand clinical research and to build the evidence base that will inform better clinical practice. At the same time, progress in basic science continues to provide new and exciting leads that can translate into large clinical trials, yielding results with the potential to transform dentistry and public health. Above all, the NIDCR seeks to find practical solutions to intractable problems and, in so doing, improve the Nation's oral health.

PREPARED STATEMENT OF DR. NORA VOLKOW, DIRECTOR, NATIONAL INSTITUTE ON DRUG ABUSE

Mr. Chairman and Members of the Committee: I am pleased to present the fiscal year 2007 President's budget request for the National Institute on Drug Abuse (NIDA). The fiscal year 2007 budget estimate is \$994,829,000, a decrease of \$5,200,000 from the fiscal year 2006 enacted level of \$1,000,029,000, comparable for transfers proposed in the President's request.

INTRODUCTION

The National Institute on Drug Abuse, within the National Institutes of Health (NIH), is once again pleased to report continuing declines in overall drug use among our Nation's youth. NIDA has focused much of its research on the vulnerable adolescent period of development, since this is when drug abuse typically takes hold and can bend a young life toward long-term drug abuse problems or addiction. Research findings elucidating the mechanisms of action and destructive consequences of drugs of abuse on the brain and body appear to be getting through to this population. For example, the 2005 Monitoring the Future (MTF) Survey of 8th, 10th, and 12th graders shows a dramatic 19 percent reduction in use since 2001. However, areas of significant concern remain, including the alarmingly high rates of non-medical use of painkillers among 12th graders, the high rates of stimulant abuse among 12th graders, and the spread of methamphetamine abuse to new geographic areas of the country.

Therefore, while we can acknowledge and appreciate the positive effects of evidence-based prevention and treatment efforts, we also recognize the need to keep pace with emergent problems. To this end, ongoing support of leading edge research by NIDA scientists continues to enhance innovative prevention and treatment interventions, while collaborations with other Institutes and public and private partners make optimal use of our research infrastructure.

PRESCRIPTION DRUG ABUSE—THE PROBLEM WITH PAINKILLERS

According to the 2004 National Survey on Drug Use and Health, nearly three-fourths of the estimated 6 million people aged 12 and older who reported non-medical use of prescription psychoactive drugs said they abuse pain relievers in particular, with young adults (18–25) showing the greatest increases in lifetime use from 2002–2004. Even younger populations are involved, revealed by findings from NIDA's 2005 MTF Survey.

NIDA is tackling this growing problem from multiple angles, seeking to understand the factors that have brought us to this point so that we may reverse negative trends and stop new ones from emerging. Underlying factors include the fact that opioids are now among the most commonly prescribed medications, that society is more accepting of using medications to treat all kinds of health problems, and that the Internet provides greater access to prescription drugs.

In response to these concerns, NIDA's new initiative on prescription opioids and treatment of pain is soliciting a broad range of preclinical and clinical studies from across the sciences. We will examine the basic mechanisms involved in pain and how their interaction with prescription painkillers influences addiction potential—for example, whether opiates are equally addictive to an individual in pain versus one who is not in pain. Research on the basic interactions between pain and opioid systems is needed to inform physicians about associated abuse risks and to guide their prescribing practices.

Other strategies for reducing prescription painkiller abuse include developing alternative pain medications and promoting better delivery systems for painkillers to minimize abuse potential. Recent studies have identified a subset of cannabinoid receptors (i.e., CB2 receptors) as promising new targets for treating chronic pain from nervous system injury. In addition, because of their lack of activity in brain reward centers and diminished abuse liability, novel CB2-based medications present an attractive alternative for treating chronic pain. Buprenorphine/naloxone, a recently approved medication for the treatment of opioid addiction, represents another approach. Acting on the same brain receptors as drugs like heroin and morphine, buprenorphine does not produce the same high, physical dependence, harsh withdrawal symptoms, or dangerous side effects. Further, its unique formulation with naloxone, an opioid antagonist, produces severe withdrawal symptoms in addicts who inject it to get high, thereby lessening the likelihood of diversion while maintaining desired therapeutic properties. NIDA is planning a multiple trial study to evaluate the effectiveness of buprenorphine in the treatment of the pain patient who is addicted to his/her pain medication and to help develop guidelines on how to treat these types of patients.

GENES, ENVIRONMENT, AND BEHAVIOR

A person's individual genome, or genetic makeup, plays an important role in determining his or her vulnerability to or protection against addiction. Studies of heredity have shown that about 40–60 percent of predisposition to substance abuse can be attributed to genetics, with environment impacting how those genes function or are expressed. Addiction is a quintessential gene-x-environment interaction dis-

ease: that is, a person must be exposed to drugs (environment) to become addicted, yet exposure alone is not determinative—genes interact with this environment to create a vulnerability to addiction. Growing knowledge about the dynamic interactions of genes with the environment confirm addiction as a complex and chronic disease of the brain with many contributors to its expression in individuals.

NIDA is studying these interactions to see what they reveal about vulnerability to addiction and to other adverse effects of abused drugs. For example, one recent study found that carriers of a common variant of the COMT gene were more likely to exhibit psychotic symptoms and to develop schizophreniform disorder if they used marijuana.

Thus, people with particular genes may suffer more harmful effects from drugs of abuse.

To expedite the translation of findings that could help identify the location of genes that confer vulnerability or protection, NIDA is supporting innovative research to help design, develop, and market technology to conduct rapid behavioral throughput screens for identifying genetic vulnerability using animal models of drug abuse and addiction. This information could then become part of a database of candidate genes for drug abuse, for eventual mapping and for targeted therapeutic application. Advances in genetics research in addiction are already suggesting ways to tailor our interventions to have the greatest impact. For example, a recent study showed that distinct alleles of the dopamine receptor gene led to different outcomes according to the type of smoking cessation therapy used—bupropion or nicotine replacement therapy. Such findings provide a glimpse of a future in which a patient's genetic background will be a major factor in selecting the most appropriate therapeutic course of action.

Other NIDA studies are also helping to unravel the ways in which environmental factors, such as stress, induce brain changes that interact with drugs of abuse and alter behavior. It is well known that stress is a major cause of relapse to drug abuse in recovering addicts and can prompt the release of a neurochemical, corticotrophin releasing factor (CRF). Recent research showed that in cocaine-exposed animals, stress-induced CRF triggered drug-seeking behavior, even as long as 3 weeks after exposure. This research highlights the concept of persistent brain changes leaving individuals vulnerable to certain relapse triggers like stress. Moreover, stress may be common to a variety of conditions, including depression, anxiety, and some forms of overeating and obesity. By revealing the precise brain mechanisms involved in stress, our research can lead to treatments that for these conditions.

We are also learning how environmental factors not only alter the expression but the structure of genes involved in brain function, which then influences an individual's behavior. Known as "epigenetics," this field gives researchers an opportunity to investigate gene-environment interactions, including the deleterious changes to brain circuits resulting from drug abuse. Understanding how drugs of abuse effect epigenetic changes may help in developing interventions to counter or prevent such changes. A recent study of demonstrated that cocaine caused significant structural changes to the DNA in regions containing genes implicated in shaping the brain's response to drugs of abuse; furthermore, in animals genetically engineered to minimize those changes, the rewarding effects of cocaine were dramatically reduced. These results show how gene-environment interactions can change the brain and drive behaviors associated with drug addiction. NIDA is supporting innovative research to help design, develop, and market technology to conduct rapid behavioral throughput screens for identifying gene/environment interactions.

SOCIAL NEUROSCIENCE

NIDA is targeting the influence of social factors both in individual and group decision-making. This focus is critical not just to understanding drugs of abuse but other health behaviors as well. For instance, a social neurobiological perspective is being applied in NIDA studies investigating the mechanisms underlying adolescents' increased sensitivity to social influences (i.e., peers) and decreased sensitivity to negative consequences of their behavior that together make them particularly vulnerable to drug abuse.

A recent NIDA request for research in the emerging field of social neuroscience is soliciting studies from basic to clinical science as we work to examine how neurobiology and the social environment interact in abuse and addiction processes (e.g., initiation, maintenance, relapse, and treatment). We now have the tools to see how genetics, epigenetics, and brain chemistry can change social behavior and how the social interactions of an individual can change his or her brain. For example, studies of early maternal behavior in animals demonstrated that offspring receiving low levels of care during their first week of life developed an over-responsive stress

system that lasted a lifetime. In this case, genes responsible for regulating stress responses were “silenced” by environmental manipulation. Some of these changes can be reversed in adulthood by targeted intervention, making this research area ripe for developing approaches to counteract the effects of adverse environmental impacts, which in the case of stress are known to increase the risks for substance abuse.

We are also committed to efforts to better characterize “phenotypes” of social environments and to understand their interaction with other vulnerabilities, such as genetics. One approach could include strategies such as mapping community risk factors for drug use (e.g., parental practices, family structure, school systems, socio-economic status, neighborhood characteristics, and drug availability) and to use that knowledge to inform us about mediators of the social stressors that elevate risk for drug abuse. A better understanding of this relationship is relevant both for the treatment of drug addiction and for psychotherapeutic interventions for mental illnesses, which also involve social aspects of human behavior.

DRUG ADDICTION TREATMENT WORKS

NIDA’s research findings have demonstrated that drug addiction treatment works. Moreover, comprehensive treatments (i.e., those that include a combination of available medications, behavioral treatments, and job training and referral services) tailored to the needs of the individual patient have the highest success rates. We continue to work with the private sector to develop medications to use with behavioral therapies to treat drug addiction, and are pursuing collaborations with pharmaceutical companies to move novel and promising compounds forward to clinical evaluation. In addition, NIDA’s initiative focusing on pilot clinical trials of new addiction medications will invigorate the field by helping investigators generate sufficient safety and efficacy data to support full-scale clinical trials and expedite the possible progression of novel medications to real-world use.

Over the past year, we have made great progress in identifying potential medications for treating drug addiction, including addiction to stimulants such as cocaine and methamphetamine. Several promising compounds have been identified in animal studies, and initial clinical efficacy for drug abuse has been demonstrated for medications marketed for other uses: disulfiram, prescribed for alcoholism; modafinil, for treatment of narcolepsy; and gamma-vinyl GABA (not marketed in the United States) and topiramate, both used to treat seizure disorders. Progress is also being made in the area of vaccine development for cocaine and nicotine addiction, and Rimonabant, a cannabinoid receptor blocker is a promising candidate for treating marijuana addiction. Close to being approved for marketing by the pharmaceutical industry as a weight loss aid, Rimonabant may also have the potential to prevent relapse to cocaine, heroin, and methamphetamine abuse, and nicotine addiction. Marinol, another cannabinoid receptor agonist, may also show promise as a treatment for marijuana withdrawal symptoms.

Interventions are also needed to treat comorbid mental disorders and addiction. For example, given that an estimated 15–30 percent of patients with substance abuse problems also suffer from comorbid ADHD, as found in research studies, NIDA has launched a large clinical study in our Clinical Trials Network (CTN) to test whether treatment of ADHD with methylphenidate, in parallel with treatment for substance abuse, will improve outcomes in those who suffer from both conditions.

We are also developing drug abuse treatments for use in the criminal justice system. Our research findings show that drug treatment works even for people who enter it under legal mandate, with outcomes as favorable as for those who enter treatment voluntarily. To illustrate, in a Delaware Work Release study sponsored by NIDA, those who participated in prison-based treatment followed by aftercare were seven times more likely to be free of drugs after 3 years than those who received no treatment. Moreover, nearly 70 percent of those in the comprehensive drug treatment group remained arrest-free after 3 years—compared to only 30 percent in the no-treatment group. We are helping to integrate drug treatment into the criminal justice system and improve outcomes for offenders through our comprehensive Criminal Justice Drug Abuse Treatment Studies (CJ-DATS) initiative, undertaken in collaboration with Federal, state, and local criminal justice partners.

NIDA research has demonstrated the value of drug addiction treatment programs in helping patients recover from the complex disease of addiction. Faith-based and community-centered programs are often part of long-term recovery, yet their effectiveness and role in delivering treatment needs to be studied more extensively. NIDA is conducting research to examine this role.

HIV/AIDS AND MINORITY DISPARITIES

The latest data from the Centers for Disease Control and Prevention (CDC) suggest that the HIV/AIDS epidemic is evolving, with drug abuse still a major vector in its spread. Progress in treating injection drug abuse has helped to decrease HIV transmission among this highly vulnerable population, influenced by a multi-pronged approach including community-based outreach to reduce risky behaviors and development of medications such as methadone and buprenorphine to treat injecting drug users. But while this approach has helped reduce U.S. cases from this route of transmission, other countries, such as Russia and Southeast Asia, continue to report that injection drug abuse accounts for a large proportion of their HIV/AIDS cases. Thus NIDA is supporting international studies to promote HIV prevention practices and use of medications to treat drug addiction. Depot-Naltrexone is one such possibility, since it is a long-acting opioid antagonist medication expected to soon receive approval for treatment of alcohol addiction. Because efforts to decrease drug abuse also modify the behaviors that can lead to HIV transmission, we believe strongly that drug abuse treatment is HIV prevention.

Early detection of HIV helps prevent HIV transmission and increase health and longevity. NIDA-supported research indicates that routine HIV screening, even among populations with prevalence rates as low as 1 percent, is as cost effective as screening for other conditions such as breast cancer and high blood pressure. These findings have important public health implications, but require efforts to increase HIV screening acceptability (similar to mammography) in order to be effective.

We are also deeply concerned about the disproportionate impact of HIV/AIDS on African Americans. For while they represent just 13 percent of the U.S. population, African Americans account for 42 percent of AIDS cases diagnosed since the start of the epidemic, according to CDC. In fact, data from the CDC's National Vital Statistics Report published in 2003 show that HIV/AIDS is the leading cause of death among all African Americans 25–44 years old, ahead of heart disease, accidents, cancer, and homicide.

To address these disparities, NIDA is encouraging research on the nexus of drug abuse and HIV/AIDS among African Americans to understand the risk factors and the pathways between them and to develop culturally sensitive prevention and treatment programs for drug abuse and HIV/AIDS. We are committed to making sure this research is translated in a meaningful way.

FROM BENCH TO BEDSIDE TO COMMUNITY

NIDA is proud of our myriad efforts to translate the results of our basic and clinical research on the brain and body effects, getting new treatments into the hands of providers who will use them, disseminating prevention messages to people who will hear them, and raising the awareness of people who can help change the course of drug abuse treatment in this country. Our audiences are many and include physicians, teens, teachers, judges, parents, and others.

Through our physician outreach initiative, we are funding efforts to develop strategies for primary care physicians to better identify and serve drug abusing patients through use of science-based screening and brief interventions. We are also supporting development of a pilot judicial training curriculum in Cook County, Illinois, to help criminal court judges understand the neurobiology of addiction and the effectiveness of treatment. The goal of this program is to better inform judicial decision-making with regard to substance-abusing offenders. These efforts will be applied to the Federal court system as well. We also support grants to evaluate results from drug courts to achieve optimal dissemination and improve outcomes, and we will soon publish a book of treatment principles for application with individuals involved in the criminal justice system.

Our education portfolio continues to grow and includes a wealth of materials, such as our NIDA Goes Back to School Initiative, a science education campaign to provide middle school students with information about how drugs work in the brain. An interactive website complements this effort, allowing students and teachers to easily obtain additional information about drugs of abuse. To help young people understand the risks of drug abuse leading to HIV infection, NIDA and our partnering organizations—including the American Academy of Child and Adolescent Psychiatry, the AIDS Alliance for Children, Youth, and Families, and the United Negro College Fund Special Programs Corporation—recently launched a multimedia educational campaign, including a public service announcement and website, to help young people “learn the link” between drug abuse and HIV infection. We are translating these materials into Spanish and making them culturally relevant for different populations.

We are also collaborating with our sister agency, the Substance Abuse and Mental Health Services Administration (SAMHSA) and with the National Institute of Mental Health on a new initiative to enhance the capacity of community-based providers of drug abuse treatment services. We continue to work with SAMHSA, supporting the development and dissemination of research-based products through their Addiction Technology Transfer Centers across the country, applying findings from our Clinical Trials Network and other research. And because addictive, psychiatric, and neurological disorders emerge from common neural substrates, a tremendous amount of inter-Institute collaboration has taken place—an approach we will continue to emphasize, given its ability to produce sharable findings and cost efficiencies.

CONCLUSION

Our investment in basic and clinical research has changed the way people view drug abuse and addiction in this country. We now know how drugs work in the brain, their health consequences, how to treat people already addicted, and what constitutes effective prevention strategies. As science advances, NIDA's comprehensive research portfolio is strategically positioned to capitalize on new opportunities. We continue to make great strides in translating and disseminating the products of our research, so they can be used in real communities by people who need them, providing front-line clinicians around the country with the tools needed to reduce drug abuse and addiction in our Nation. To make the most of scarce resources, we depend on a rigorous planning and priority-setting process that not only supports our strong commitment to reducing drug abuse and HIV transmission in this country, but extends to other health fields represented by NIH. Sustaining the momentum of our efforts will lead to even more discoveries that will improve the health and safety of all Americans.

Thank you, Mr. Chairman. I will be pleased to answer any questions the Committee may have.

IMPACT OF BUDGET CUTS

Senator SPECTER. We will now proceed with questioning by the Senators, 5 minutes each.

Dr. Zerhouni, you say you will continue to deliver. How is that possible when you have had more than a 10 percent decrease, considering inflation, which amounts to about \$3 billion? The comments that I hear relate to there being a panic, panic among the applicants for NIH research. How can you continue to deliver with that kind of a budget?

Dr. ZERHOUNI. It is very important to realize that medical research cannot be funded through ups and down. We have to sustain the investment over time, and it is clear that medical research requires support for scientists. What is happening right now is that through the doubling we have generated a new generation of scientists. We have over a 50 percent increase in the number of scientists.

Senator SPECTER. What is the consequence of the cut?

Dr. ZERHOUNI. The consequence of the cut is very simple. If you keep investing below and lose purchasing power, the most important impact on research is loss of scientists. This is what we have seen in the past and this is what may happen again if we do not sustain our investment in medical research.

PREPAREDNESS FOR PANDEMIC INFLUENZA

Senator SPECTER. Dr. Fauci, there is a great concern, as we all know, about pandemic influenza. This subcommittee has held a series of hearings on the subject. How are we doing? What are the prospects for being prepared if that wave should strike us in the United States?

Dr. FAUCI. From the standpoint of the scientific preparation for developing vaccines and drugs, from the last time I testified before you, Mr. Chairman, which was just a couple of months ago, we have made even more progress. We have, as you know, as Dr. Zerhouni alluded to, we have a vaccine that is currently in clinical trial in different age groups and demographic groups. We have tested it and published the results in healthy young adults. We have tested it in the elderly and in children. As I mentioned to you at the last hearing, the vaccine appears to be very well tolerated and induces an immune response that would be predictive of being protective.

There is a big problem with it, though. The problem relates to the fact that the dose that is required to induce the level of immunity that you would predict would be protective is prohibitively high, which is leading us to the studies that are ongoing now, namely the use of what we call adjuvants, or compounds which expand the capability of the immune system to respond. Those studies are ongoing right now.

FUNDING FOR PANDEMIC INFLUENZA

Senator SPECTER. Is the funding adequate?

Dr. FAUCI. We could do more with more funding, there is no doubt about that. I would be—

Senator SPECTER. How much do you need?

Dr. FAUCI. It is difficult to put a number on it, except to say that—

Senator SPECTER. Well, if you cannot put a number on it, we cannot.

Dr. FAUCI. Well, we need—for example, if I could bring one component up that I think would be of interest to this committee, is that we are currently pursuing rather aggressively the concept of what we call a universal influenza vaccine, namely a vaccine that cross-reacts from season to season and would also be protective against the pandemic flu.

Senator SPECTER. Dr. Fauci, I am reluctant to cut off a witness with your distinctive record. Give us in writing what funding you need.

Dr. FAUCI. Okay, I could do that for you.

[The information follows:]

FUNDING FOR PANDEMIC INFLUENZA

The National Institute of Allergy and Infectious Diseases (NIAID) supports a robust and diverse portfolio of research on influenza, including pandemic influenza. Many opportunities to accelerate the research and development of medical countermeasures against influenza as well as to advance our understanding of influenza viruses could be pursued in fiscal year 2007 and fiscal year 2008 should additional funds become available. In its professional judgment that is outside the context of other competing priorities, NIAID estimates that it could obligate an additional \$212 million in influenza research in fiscal year 2007 above the budget request and an additional \$458 million in fiscal year 2008.

NIAID could use such funds to accelerate research and development of antiviral drugs, vaccines, adjuvants, and diagnostics for influenza. For example, NIAID could accelerate the development and clinical testing of promising universal vaccine candidates, which could offer protection against multiple influenza virus strains, and the development of new and improved vaccine strategies for influenza such as recombinant subunit vaccines and gene-based vaccines that may allow for more rapid production of a vaccine against a pandemic strain of influenza, should one emerge.

These additional funds also could facilitate the expansion of critical research resources, such as animal models and clinical trials infrastructure that are essential for the development of medical countermeasures against influenza.

Underpinning efforts to develop medical interventions against pandemic influenza is research into the basic biology and disease-causing mechanisms of influenza viruses. With additional funding, NIAID could expand basic research in the areas of influenza virology, pathogenesis, epidemiology, immunology, genomics, proteomics, and systems biology as well as to expand international animal surveillance activities. This research is crucial to the development of antiviral drugs, vaccines, and diagnostics for influenza.

CANCER GENOME ATLAS

Senator SPECTER. Let me turn now to Dr. Niederhuber with respect to the cancer-genomics initiative. Can that be implemented with the current funding? What do we need to successfully prosecute the war against cancer?

Dr. NIEDERHUBER. Well, Senator Specter, thank you. We are very committed, the National Cancer Institute, with our partner, the National Human Genome Research Institute, to initiate a pilot project on the Cancer Genome Atlas. Each Institute has committed \$50 million from our existing resources to do that. This will be a pilot project which is helping us understand the technology needs, the technology advancements, and our ability to do this project.

Senator SPECTER. Dr. Niederhuber, would you supplement your testimony today with a memorandum as to what you need as to that program and as to the war on cancer overall?

Dr. NIEDERHUBER. Absolutely, sir.

Senator SPECTER. Give us a winning strategy for that war?

Dr. NIEDERHUBER. Absolutely.

[The information follows:]

CANCER GENOME ATLAS

The Cancer Genome Atlas program is the product of several years of investment by the NCI in the Cancer Genome Anatomy Project (C-GAP) and other large scale genomics programs, some of which were performed in collaboration with the NHGRI. These efforts culminated in 2003 with a report from the NCI's National Cancer Advisory Board (NCAB) which recommended that the two Institutes undertake a pilot program to determine the feasibility of systematically developing an "atlas" of all genetic alterations involved in cancer.

Active planning for The Cancer Genome Atlas, or TCGA, began in the latter half of 2002 as a consequence of progress and convergence of science and advanced technologies in three distinct areas. First, the completion of the sequencing of the human genome provided for the first time in history a benchmark to begin to understand the effect of genetic changes on the etiology and progression of diseases such as cancer. Second, our years of investment in understanding cancer at the molecular level resulted in the discovery of some very important genetic changes in cancer cells that led to the development of targeted drugs such as Gleevec and Herceptin. Based on an understanding of the specific genetic alterations driving specific tumors, these targeted drugs allowed oncologists for the first time to target specific genetic alterations in patients with chronic myelogenous leukemia (CML) and breast cancer, respectively. Finally, the pace of technology development in analyzing all aspects of genes and their products is accelerating—setting the stage for large scale interrogation of the genome to understand the role of genetic mutation in diseases such as cancer. Interestingly, one of the major requirements for this project is the development of an unprecedented data management system and ultimately an accompanying database; NCI's investment in the Cancer Bioinformatics Grid (caBIG) over the past several years provides the advanced technology platform needed to meet this need.

Cancer is a disease of changes in genes that occur over an individual's lifetime. Three kinds of genetic alterations contribute to cancer—those that occur in the DNA of egg or sperm and are passed from a parent to offspring (germline mutations),

those that occur as a result of exposure to the environment (somatic mutations) and changes in DNA that lead to changes in genes that control proteins involved in transcription and translation. Additionally, changes in gene function can occur without a change in the sequence of DNA (epigenetic changes). TCGA will finally facilitate an in-depth understanding of how these types of genetic changes differ in terms of their role in an individual's inherited risk vs. those changes that arise from environmental exposure. It is the latter category of mutations that will allow scientists to obtain a clear picture of the impact of these somatic mutations on the major pathways that appear to drive many of the major hallmarks of cancer cells. Overall, the TCGA pilot project, much like the Human Genome Project, has the potential to create an unparalleled knowledge base, drive a new era of discovery by scientists from all fields of biomedical research and ultimately provide a new paradigm for the prevention, detection and treatment of chronic diseases such as cancer.

The NCI and NHGRI believe strongly that TCGA is one of the most important projects undertaken in medicine to date. It leverages all that has gone before and for the first time will allow scientists to apply our understanding of the human genome sequence to cancer—a disease that will strike over 1.4 million Americans this year and kill over 560,000 at a cost of well over \$190 billion. We are committed to getting this project underway within current budget constraints. The NCI has identified funds for redeployment from other projects, and the NHGRI will dedicate a large portion of its sequencing capacity to performing this first-ever large scale effort in medical sequencing.

The information generated by the TCGA pilot project will provide the necessary scientific data by which the Institutes and the scientific community can evaluate the preliminary outcomes of the research.

The convergence of our understanding of cancer at the molecular level, advanced genome analysis technologies, especially bioinformatics, and experience gained in the Human Genome Project, allow us to now undertake TCGA, a project that promises to contribute significantly to the development of 21st century medicine. Both the NCI and the NHGRI are committed to leveraging these strengths to ensure that we move forward toward our goal of personalized medicine for cancer and all diseases.

A WINNING STRATEGY AGAINST CANCER

NCI has developed a Strategic Plan to reduce and eliminate the suffering and death due to cancer with the help of the scientific community. The Plan sets forth a framework within which NCI can use its funding, infrastructure, tools, and intellectual resources to lead and work with others. We set forth eight strategic objectives in the Plan and these will be instrumental in guiding our operational level plans and serve as an organizer for measuring and reporting progress. A complete description of the Strategic Plan can be found on NCI's web site at <http://www.cancer.gov/aboutnci/2015>.

There are two basic tactics—preempting cancer and ensuring the best outcomes for all—embodied in the Plan's objectives.

To preempt cancer at every opportunity, there are four strategic objectives:

- Understand the causes and mechanisms of cancer;
- Accelerate progress in cancer prevention;
- Improve early detection and diagnosis; and
- Develop effective and efficient treatments.

To ensure the best outcomes for all, there are four strategic objectives:

- Understand the factors that influence cancer outcomes;
- Improve the quality of cancer care;
- Improve the quality of life for cancer patients, survivors, and their families; and
- Overcome cancer health disparities.

To achieve these objectives requires numerous funding vehicles and support mechanisms throughout the cancer research community. The steps we could take in order to accelerate progress to eliminate the suffering and death due to cancer include:

- Rapid development of an integrated technology initiative;
- Deployment of a modern integrated clinical trials infrastructure;
- Expansion and integration of the Cancer Centers program; and
- Mechanisms and Flexibilities—streamlined procurement and review processes to acquire materials and services and coordination of licensing and patenting activities.

An integrated advanced technology initiative for cancer could provide a linkage between the National Cancer Program and R&D initiatives being developed in selected national laboratories and advanced technology facilities located in more than 40 states and regions. Connected in real-time through a common bioinformatics

grid, forming a “network of networks” of science, technology, and treatment, such an initiative could serve to accelerate the emerging discipline of molecular oncology. This would create a pipeline of new personalized cancer diagnostics and therapeutics from bench concept to bedside and community delivery. In the next few years, such an initiative could:

- Accelerate the implementation of a nationwide high-end information technology grid for bioinformatics that could be uniquely adapted for real-time data sharing. NCI’s pilot version, called caBIG, is slated for full-scale implementation this year and, during the pilot phase, was implemented among 50 Cancer Centers, FDA, and other organizations.
- Develop a comprehensive biomarker discovery and validation program.
- Foster the application of emerging technologies, such as nanotechnology, and integrate molecular agents with advanced imaging devices.
- Accelerate a nationwide real-time medical information electronic system for research and medical data sharing using technologies and devices currently employed by the banking industry and large-scale commercial enterprises.
- Enhance the discovery and validation of new targets of genes and proteins critical to cancer development.

NCI could deploy a more modern and integrated infrastructure for cancer clinical trials. This clinical research infrastructure could:

- Strengthen collaborations with industry, FDA, Centers for Medicare and Medicaid Services, and other public, private, academic, and patient advocacy organizations to oversee the conduct of cancer clinical trials.
- Develop new infrastructure and procedures to standardize, coordinate, and track clinical trials development and accrual across all NCI-supported clinical trials.
- Increase utilization of imaging tools in screening and therapy trials, evaluate new imaging probes and methodologies, enable access to the imaging data from trials in an electronic format, and facilitate evaluation of image-guided interventions.
- Expand access and improve the timeliness for completion of the highest priority clinical studies.
- Foster the development of a cadre of established clinical investigators who could work between bench and bedside.
- Pilot new approaches and develop prototypes for clinical trials networks that could improve the efficiency, coordination, and integration of our national efforts.
- Develop a common clinical trials informatics platform that could be made available to the full range of investigators working within the cancer clinical trials system.

NCI plans to accelerate the expansion and integration of the NCI-designated Cancer Centers program, including the addition of 14 new Cancer Centers, increasing the number of centers to 75. The Cancer Centers program could:

- Implement progressive bioinformatics and communication systems to achieve horizontal integration.
- Fund additive programs in collaborative, multidisciplinary research, and require integration and sharing of results.
- Broaden the geographic impact of the centers, networks, and consortia and vertically integrate them with community and regional health care delivery systems.
- Improve the access of minority and underserved populations to state-of-the-art research and resources.
- Create and strengthen partnerships with government agencies and community organizations.
- Broadly provide expertise and other resources to caregivers, patients and families, and appropriate health agencies.

In addition to appropriations, flexible legislative authorities related to exemptions from specific parts of current procurement, grant review and processing, and licensing and patenting rules could also help accelerate progress. A streamlined procurement process could facilitate the acquisition of materials and services to support the R&D activities. Technology development could also be enhanced by sufficient flexibility and integration to enable interactions among a wide array of laboratories and other entities. Expedited review procedures and workflow processing could help to award funds in sequence as needed. Coordination of the licensing and patenting activities among grantees, contractors, and the intramural program could also be useful for many of the multicomponent technology platforms that could be created through an advanced technology effort.

WOMEN'S HEART DISEASE

Senator SPECTER. Let me turn now to Dr. Nabel. What have the results been with the Women's Health Study? With respect to heart disease, we know that women are affected differently. I want the record to note that my question ends with no red light, but you can proceed.

Dr. NABEL. Thank you, Mr. Chairman.

The women's health initiative was an important study conducted over 15 years with 161,000 women in this country ages 50 to 79 participating. We gathered important information about heart disease, the number one killer of women in this country.

From other studies, we realize that heart disease often manifests itself in women differently than men. We have come to recognize what those symptoms are. We have come to recognize that some of the diagnostic tests have to be different and we have come to recognize that some of the treatments have to be specifically focused towards women.

These studies have given us a tremendous amount of information. We now have engaged in a very large public awareness education campaign and we are in the midst of helping women to understand what their risks are for heart disease and how to seek help when they need it.

Senator SPECTER. Thank you.

Senator Harkin.

NATIONAL CHILDREN'S STUDY

Senator HARKIN. Thank you, Mr. Chairman.

Dr. Zerhouni, of all the proposed cuts in the budget there is one that I think may be discouraging than all the rest, and that is the planned elimination of the National Children's Study. We passed this legislation back in 2000. It was going to be the largest long-term study of children's health ever conducted in the United States. It was going to involve 100,000 children from before birth to adulthood. The idea was to better understand the link between the environments where the children are raised and their physical and emotional health and development.

We have already spent about \$50 million planning the study, 4 to 5 years of planning on it. Now I understand that the study is going to stop. Why is that?

Dr. ZERHOUNI. Well, the study has had a pilot phase to evaluate feasibility. The issue really is, you are talking about a very long study with a large budgetary impact, and at the end it was just a matter of budgetary priorities which led to the decision of not completing the pilots at this time, but to look at other times when the budgets will be easier.

Senator HARKIN. I understand that the budgetary impact was \$70 million. Is that correct or not?

Dr. ZERHOUNI. If you look at—the \$70 million is not just a 1-year expenditure. In fact, you have to continue that expenditure. If you committed to that expenditure, Senator, then you have committed to the \$3.2 billion or thereabouts total over the total study. Why? Because once you launch the study you have to continue recruitment of the 100,000 children, the parents, and so on.

So if you look on the screen that tries to describe the evolution, it is \$69 million in 2007, \$111 million in 2008, \$192 million, \$194 million, and so on. So this is what led to the budgetary conclusion for these tight fiscal times. Committing to 2007 meant not just 2007, but a whole series of budgetary commitments, and in the context of projections it was very hard to see how it would fit in.

WOMEN'S HEALTH INITIATIVE

Senator HARKIN. Well, as you know, it was supposed to start by the end of this fiscal year.

Dr. NABEL. How long was the women's health initiative study?

Dr. NABEL. 15 years, Mr. Senator.

Senator HARKIN. 15 years.

Dr. NABEL. Yes.

Senator HARKIN. Obviously, we got a lot of good information out of it.

Dr. NABEL. We sure did.

Senator HARKIN. What did that cost, do you know?

Dr. NABEL. In total, about \$710 million.

Senator HARKIN. For the 15 years. How many women did it cover?

Dr. NABEL. 161,000 women.

Senator HARKIN. This is 100,000 children and it was supposed to be how many years study? About 20—

Dr. ZERHOUNI. 21 plus 4, so about 25 years, and about \$3.2 billion is the number I remember, but upwards of that.

Senator HARKIN. Well, it seems to me from the women's health initiative we learned the benefits of long-term studies, long-term longitudinal studies. It seems to me with everything that is impacting on obesity, to diabetes to mental health, kids and how they grow up, there is just a lot of things that need to be taken into account. If you do these studies, then you would be able to factor some of these things in after a longer period of time.

I just find this very disturbing that we are cutting this program. I am hopeful that we can put this back in the budget. Maybe this is another result of the President's budget. I do not know. Is that what it is? I am just asking it rhetorically. I do not expect an answer, but I am just asking this rhetorically. If that is what it is, then we have got to find the money to put back in there.

This did not just come up. This is something that we had talked about for a long time with your predecessor and others, about getting this very long-term study done. We just assumed, at least I did anyway, that it was on track and that we were going to do it, and all of a sudden this year it pops up and it is going to be eliminated. EPA was coming in on the study, I think, also CDC was also going to partner in the study, if I am not mistaken.

Dr. ZERHOUNI. No, you are not mistaken, Senator. It was a trans-governmental study. It was not just an NIH study. It really involved 14 different departments. Environmental health was important, genetic health was important. Education was involved as well. So 14 Federal agencies were involved.

Senator HARKIN. Well, I am just wondering what kind of a priority would this be in the scheme of things. Is this just something

that we can just drop out the bottom, or is this really an important study to be done? Is it important or not?

Dr. ZERHOUNI. So the issue is really an issue of prioritization, and you have a pilot phase study so we can evaluate whether or not to go forward. But you mentioned yourself the critical factor of sustaining success rates, and so in the context of those decisions you can see where, in a constant sum budget, studies like this will have a large impact on success rates across the board. Therefore, when you look at the investments that medical schools and others have made over the doubling period, what we are seeing is a large increase in demand for grants at the time when the supply for grants is sort of flattening.

So the real tension right now is, how do you sustain a vibrant research enterprise across the board and at the same time look at issues like this one, which is a very valid issue to look at? That is what the tension is and that is where the budgetary decisions came up.

Senator HARKIN. Thank you, Dr. Zerhouni.

Thank you, Mr. Chairman.

Senator SPECTER. Thank you very much, Senator Harkin.

Senator Shelby.

AUTOIMMUNE DISEASES

Senator SHELBY. Thank you, Mr. Chairman.

I want to, doctor, focus on the area of autoimmune, specifically lupus. It is estimated that 1.5 million Americans suffer from lupus. Ninety percent of those being diagnosed are women. This is a terribly painful disease, as you well know. It has been about 40 years, it is my understanding, since a new drug has been developed and approved for treatment of lupus. Is there any hope in sight for new treatment, because this is in the area, as I understand it, of autoimmune, in which you do a lot of research?

So how do we—first, what do you see down the road there?

Dr. ZERHOUNI. This is an excellent, excellent question, in a field of research, autoimmune disease, that affects 5 to 8 percent of Americans. It is not just lupus, Senator.

Senator SHELBY. It is all autoimmune, is it not?

Dr. ZERHOUNI. Right, it is all autoimmune. It is a whole category of diseases that we are now beginning to understand. Breakthroughs over the past year indicate that we may have actually developed technologies where we could develop—we could detect years before the disease really starts the markers of the disease and maybe intervene earlier.

What I would like to do is ask my colleague Dr. Fauci, who is the Director of the National Institute of Allergy and Infectious Diseases, who has a lot of knowledge in autoimmune diseases, to perhaps address some of that.

Senator SHELBY. That would be good. Thank you, doctor.

Dr. FAUCI. Thank you, Dr. Zerhouni.

Senator Shelby, there are some very promising areas in the whole arena of autoimmune diseases. There is still a long way to go, but, very briefly, as Dr. Zerhouni mentioned in his opening statement, it falls within that area of predictive and ultimately pre-emptive and preventive, in the sense that we now are developing

rapidly, not only with lupus, much more sensitive diagnostic tests that can give you a feel for the ultimate evolution of an autoimmune disease.

One among many therapeutic modalities that I would just submit for your consideration that we are very excited about is the whole area of what is called immune tolerance. Immune tolerance means that you manipulate the immune system to get it to not respond to a particular antigen. In other words, you tolerize it to it.

This has been something that has been very exciting in animal studies. Now, with a network involving multiple institutes within the NIH, the immune tolerance network, we have been able to tolerize the body against rejecting transplanted organs. We found very rapidly that that can be applied to diseases of autoimmunity.

PREDNISONE

Senator SHELBY. Is that what Prednisone does?

Dr. FAUCI. Well, Prednisone is a drug that dampens globally the immune system. But we are talking about when we talk about tolerance, specifically training the body either not to reject an organ that is transplanted or not to respond to tissues that are self tissues. Patients should not respond to self antigens, but for reasons that relate to genetic, environmental, and other factors, they inappropriately react against their own tissues.

So now we try to tolerize them and dampen the immune response only specifically for the particular tissue that they are attacking, not general immunosuppression, because one of the real problems with treating any autoimmune disease, if you induce a global immunosuppression you have a lot of complications that relate to immunosuppressive therapy, much the way cancer patients have complications related to chemotherapy.

LUPUS

Senator SHELBY. What could you say to the 1.5 million or more lupus sufferers out there right now in the pipeline?

Dr. ZERHOUNI. Well, if I may, Dr. Fauci, I would like to show you the evolution of our investments in lupus research.

What I want to tell you is that there is really hope because, one, we have made advances in genomics that allow us to now identify some genetic factors in patients with lupus. Two, we really understand the immune response very specifically and we believe that the T-cells that respond in lupus may be a target for treatments. We also have research that suggests that perhaps a viral connection exists as well.

So over the past 2 years, 3 years, there has been a multiplication of new ideas thanks to the doubling and many people looking at it. What we intend to do is sustain it. We have ideas of how to in fact focus on autoimmune diseases across NIH and do the basic research across all institutes that will serve every one of these diseases.

So, Senator, it is a difficult disease. It is not an easy disease. If you have known anyone with lupus—

Senator SHELBY. My wife.

Dr. ZERHOUNI. I am sorry, Senator. I did not know about that. It is something that we really care about.

Senator SHELBY. Thank you very much.
Mr. Chairman, thank you.

PROGRAM FUNDING

Senator SPECTER. Thank you, Senator Shelby.

Obviously, we would like to have a lot more time to go into greater detail on many subjects. But what we would appreciate your doing is giving us a supplemental memorandum as to what the cuts will mean for your ongoing programs. I would like to share that with all of our colleagues in the House. Second, what it would take to adequately fund the issues you are working on and what you could accomplish with the figure you put on as being adequate.

Dr. Zerhouni, your statistics are very impressive and the showing of a trillion dollars in savings compared to a modest investment, that is the kind of things Congress needs to hear. That is the kind of things which impresses the Congress.

[The information follows:]

PROGRAM FUNDING

Within the context of a deficit-reduction budget, the President's Budget request had to weigh many competing priorities, and still proposed to hold spending for NIH at a straightlined level for fiscal year 2007. In fiscal year 2006, NIH reduced all noncompeting Research Project Grant (RPG) awards by -2.35 percent, and the average cost of competing RPGs was held at the fiscal year 2005 level. The fiscal year 2007 President's Budget Request provides no inflationary increases for non-competing continuation awards and holds the average cost of competing RPGs to the fiscal year 2006 level, which could lead to an erosion of the research buying power of NIH research projects. Within its available funds, however, NIH is supporting the highest priority research activities, including making strategic investments in bio-defense, the NIH Roadmap, a new program for new investigators, and the Clinical and Translational Sciences Award program.

If additional funds were available above these priorities, such as an increase for fiscal year 2007 above the Biomedical Research and Development Price Index inflator of 3.8 percent, NIH would be able restore the buying power of its research program, and fund additional projects, from basic, translational, and clinical research to therapeutic development and advanced technologies. All of these activities could serve to advance our understanding of the mechanisms underlying human health and disease and contribute to improving human health. Examples of projects that were not funded in the President's Budget Request, but could be undertaken are as follows:

Large-scale Genome Study for Serious Mental Disorders.—This study could speed development of new effective treatments for the 13 million Americans suffering from seriously debilitating mental disorders that prevent people from participating in daily life at home, work, or social settings for over 80 days per year and results in early death or suicide for 30,000 individuals each year.

Schizophrenia Treatment Research.—This proposed study could build on recent advances in schizophrenia treatment to determine whether an early intervention of aggressive pharmacotherapy, combined with focused rehabilitative efforts, can prevent long-term disability and suffering of schizophrenia, devastating mental illness affecting 2.4 million adult Americans.

Protocols for Treating Autism Spectrum Disorders Early.—These studies could bolster efforts to determine the most effective treatment regimens to improve outcomes for children and families struggling with the life-long disability and pain of autism spectrum disorders.

The Atherosclerosis Prevention Trial.—Although drugs to lower low-density lipoprotein (LDL) cholesterol levels are known to reduce the risk of major adverse cardiovascular events, it is not yet known whether additional benefits can be realized by lowering LDL cholesterol beyond current treatment guidelines. A multi-center, randomized clinical trial could determine whether aggressive lowering of low-density lipoprotein cholesterol beyond current treatment guidelines further reduces major adverse cardiovascular events.

Program to Reduce Cardiovascular Disease Risk in Young Adults by Preventing Weight Gain.—Studies could develop and evaluate promising intervention ap-

proaches for preventing weight gain in young adults, which is a major risk factor for cardiovascular disease (CVD) and associated CVD risk factors including elevated cholesterol, high blood pressure, and diabetes.

Systolic Blood Pressure Intervention Trial.—Although drug treatment to lower blood pressure, both systolic and diastolic, is known to reduce CVD mortality, it is not yet known whether additional benefits can be realized by lowering systolic pressures beyond current treatment guidelines. A multi-center trial could determine whether treating systolic blood pressure to a lower goal than currently recommended further reduces cardiovascular disease mortality and morbidity, particularly for those aged 50 years and older in whom systolic blood pressure is more strongly associated with CVD risk than diastolic blood pressure.

PREPAREDNESS FOR PANDEMIC INFLUENZA

Senator SPECTER. Dr. Fauci, if you would supplement what you have testified to on pandemic flu. There is enormous concern in this country today and we would like to know to what extent are we prepared. Being prepared is a tough subject to answer, but to what extent are we prepared. When you say that more funding would be of material assistance, I think there is something that we are prepared to fund.

Senator Harkin took the lead and put a figure of \$7 billion. We came close to \$6 billion, and contracts have been let for five big companies for a billion dollars. It is scary. It could be devastating. So let us know, and this subcommittee is prepared to take the lead again.

[The information follows:]

PREPAREDNESS FOR PANDEMIC INFLUENZA

The Department has made great strides to improve the Nation's preparedness for a pandemic influenza outbreak. For example, HHS has stockpiled roughly 8 million doses of vaccine against one H5N1 virus strain. Given, a two-dose vaccination schedule, this would allow vaccination of 4 million people. The Department also recently invested more than \$1 billion in the development of cell-based vaccine technology; shifting from the current egg-based technology is critical to quickly producing vast quantities of vaccine should a pandemic develop. Our goal is to build the capacity to vaccinate all 300 million Americans within 6 months of a pandemic outbreak. The Strategic National Stockpile now contains sufficient antivirals to treat nearly 7 million people, and with another 19 million courses on order, it should contain 26 million courses by the end of 2006. HHS is also enabling States and other entities to purchase up to 31 million antiviral treatment courses off of the Federal contract. Our goal is to have enough antivirals on hand for 25 percent of the population, or approximately 75 million individuals. In addition, we have purchased 150 million N95 respirators, surgical masks and other personal protective equipment. Planning summits have been held in all but two States, and almost every State has either a draft or final pandemic flu plan in place. As Secretary Leavitt has stated, "Preparation is a continuum. Every day we prepare brings us closer to being ready. We are better prepared than we were yesterday. And we must be better prepared tomorrow than we are today."

The National Institute of Allergy and Infectious Diseases (NIAID) is a major component of these preparation efforts. For example, NIAID has made progress in the development of an H5N1 influenza vaccine. NIAID-supported researchers at St. Jude Children's Research Hospital obtained a clinical isolate of a highly virulent H5N1 influenza virus in Vietnam in early 2004, and used a technique called reverse genetics to create a non-virulent vaccine reference strain from this isolate. NIAID then contracted with sanofi pasteur and Chiron Corporation (now Novartis) to manufacture pilot lots of the inactivated virus vaccine for use in clinical trials. The sanofi pasteur vaccine has been tested in healthy adults and is currently in clinical testing in healthy elderly people and children. The Chiron vaccine is currently in clinical testing in healthy adults.

Results from the trial of the sanofi pasteur vaccine in healthy adults provide both good and sobering news. The good news is that the vaccine is well-tolerated, and induces an immune response that augurs well for protecting people against the H5N1 virus. The sobering news is that larger doses of the H5N1 vaccine than typi-

cally used for yearly influenza vaccine are needed to elicit immune responses in the majority of people that would be predictive of protection. However, preliminary results from a Phase I clinical trial of an H9N2 influenza vaccine candidate made by Chiron suggest that addition of an adjuvant—a vaccine component that increases the immune response—may help to reduce the required dose. Clinical trials of H5N1 candidates using adjuvants and other strategies to improve immune responses at lower doses of vaccine are ongoing or imminent.

In addition, NIAID intramural researchers are working with colleagues from MedImmune, Inc. under a Cooperative Research and Development Agreement (CRADA) to produce and test multiple vaccine candidates for potential pandemic influenza strains, including H5N1 strains. The researchers have developed three live-attenuated H5N1 vaccine candidates, designed for nasal spray delivery, that have been shown to be protective in mice. The CRADA capitalizes on the long history of NIAID research and development of respiratory virus vaccines, including fundamental research that was key to the development of FluMist®, the licensed nasal spray influenza vaccine manufactured by MedImmune. The researchers have produced a clinical lot of a candidate H5N1 vaccine based on a strain isolated in Vietnam in 2004, and clinical trial of this vaccine is expected to begin later this year.

NIAID also supports a number of basic and applied research projects that could lead to significant advances in the development and production of vaccines against potential pandemic strains of avian influenza. This includes investigation of cell culture-based vaccine production as an alternative to chicken egg-based vaccine production—as noted above, an endeavor to which the Department of Health and Human Services recently committed \$1 billion that was awarded to several pharmaceutical companies. In addition, NIAID conducts and supports research into new vaccine platforms, including recombinant subunit vaccines, in which cultured cells are induced to make various influenza virus proteins that are then purified and used in a vaccine; gene-based vaccines, in which influenza genetic sequences are injected directly into a person to stimulate an immune response; and vector approaches that insert the genes of influenza virus into another non-virulent virus (the vector) and inject the vector vaccine as a carrier to present the influenza proteins to the vaccine recipient. For example, a gene-based influenza vaccine developed by researchers at the NIAID Vaccine Research Center is expected to enter Phase I clinical trials later in 2006.

In addition to efforts to develop vaccines against potential pandemic influenza strains, NIAID is supporting basic and applied research to develop improved antiviral drugs against influenza. These efforts include a screening program for new drugs, as well as targeted drug development and clinical trials. NIAID-supported researchers are conducting studies of varying doses and combinations of existing antiviral medications, developing and testing long-acting next-generation antivirals, and evaluating novel drug targets for potential prevention and treatment of influenza using *in vitro* and animal models.

Because a pandemic influenza virus could emerge anywhere in the world, NIAID helps to conduct global surveillance and molecular analysis of circulating influenza viruses. For example, NIAID funds a long-standing program to detect the emergence of influenza viruses with pandemic potential, in which researchers in Hong Kong and at St. Jude Children's Research Hospital collect and analyze influenza viruses from wild birds and other animals in Asia and North America and generate candidate vaccines against them.

NIAID is also supporting a collaborative effort to release full genomic sequence information for several thousand influenza viruses to the public domain. More than 1,000 influenza viruses have been sequenced. Readily available sequence data will allow researchers to further study how influenza viruses evolve, spread, and cause disease, which may ultimately lead to improved methods of treatment and prevention; identify specific characteristics of previous pandemic strains, which may help focus preparedness efforts; and identify genes that are highly conserved among various strains, and therefore act as possible targets for broadly protective therapeutics or vaccines.

Lastly, NIAID is collaborating with Oxford University, the Wellcome Trust and the World Health Organization to establish a small network of clinical sites in Southeast Asia to conduct clinical research on avian influenza and other emerging infectious diseases. A key purpose of the effort is to build an independent clinical research capacity in these countries. Five sites in Vietnam, four sites in Thailand and two in Jakarta will be established.

Senator SPECTER. I had thought it would be helpful if you stayed to hear the other testimony, but now that we have given you this

homework your time is too valuable. So we will stay and forge on alone.

Thank you very much for coming in. Thank you for what you are doing for America and the world.

Senator SHELBY. Mr. Chairman, can I just take 1 second?

Senator SPECTER. Certainly.

Senator SHELBY. I just want to commend you for bringing all these people together. This is a blue ribbon panel if I have ever seen one and I have seen a lot of panels in the Congress, as you have. We appreciate what NIH has done and we will be ashamed of ourselves if we do not properly fund you for the benefit of the American people.

Senator SPECTER. That is high praise coming from Senator Shelby because he usually deals with bankers.

Senator SPECTER. Senator Harkin.

MULTI-BUG APPROACH ON VACCINES

Senator HARKIN. Mr. Chairman, I want to thank the panel and all the people from NIH for coming down here today.

Dr. Fauci, in your supplement that the chairman spoke to you about, I wanted to delve a little bit into the multi-bug approach on vaccines that I understand you are working on, rather than just the one bug, one vaccine approach. So I would like to know a little bit more about that and where that stands.

Dr. Collins, in regards to—there is some interesting work going on in terms of the relating of genes and environment. I know you are doing some stuff on that and I would also like to be kind of brought up to speed on that, too, if you could submit that.

Thank you.

[The information follows:]

MULTI-BUG APPROACH ON VACCINES

The National Institute of Allergy and Infectious Diseases (NIAID) is supporting research and development of alternate approaches to dealing with the threat of emerging and re-emerging infectious diseases such as influenza.

For example, NIAID is pursuing the development of a "universal vaccine" that protects against multiple virus strains such as those resulting from antigenic drift associated with seasonal influenza and antigenic shift associated with pandemic influenza. As influenza viruses circulate, the genes that determine the structure of their surface proteins undergo small changes. Sometimes the change in the genes results in a slight change in the antigenic properties of the protein, a process commonly referred to as "antigenic drift". Antigenic drift is the basis for the changes in seasonal influenza observed during most years, and is the reason that we must update influenza vaccines annually. Influenza viruses also can change more dramatically. For example, viruses sometimes emerge that can jump species from natural reservoirs, such as wild ducks, to infect domestic poultry, farm animals, or humans. When an influenza virus jumps species from an animal, such as a chicken, to infect a human, the result is usually a "dead-end" infection that cannot readily spread further in the human population. However, mutations in the virus could develop that allow human-to-human transmission. Furthermore, if an avian influenza virus and another human influenza virus were to simultaneously co-infect a person or animal, the two viruses might swap genes, possibly resulting in a virus that is readily transmissible between humans, and against which the population would have no natural immunity. These types of significant changes in influenza viruses are referred to as "antigenic shift." When an "antigenic shift" occurs, a global influenza pandemic can result. Historically, pandemic influenza is a proven threat. In the 20th century, influenza pandemics occurred in 1918, 1957, and 1968.

The NIAID is supporting a number of research projects to develop a vaccine that induces a potent immune response to the common elements of the influenza virus

that undergo very few changes from season to season and from strain to strain. Although this is a difficult task, such a “universal” influenza vaccine would not only provide continued protection over multiple seasons, it might also offer protection against a newly emerged pandemic influenza virus and thus substantially reduce the susceptibility of the population to infection by any influenza virus—making the country far less vulnerable to influenza viruses emerging from avian and other animal sources.

One relatively stable element of the influenza virus is a protein called M2. The external portion of the M2 protein is very similar in influenza viruses from year to year and from strain to strain. A “universal” influenza vaccine targeting the M2 protein, or other conserved elements, could be protective against a range of influenza strains. NIAID-supported researchers have demonstrated that vaccines made with bioengineered versions of M2 can protect mice from lethal influenza virus. The scientists now are testing cross-reactivity between different species and strains of influenza, examining how long the immunity provided by these vaccines lasts, and evaluating whether the influenza viruses can evade these vaccines by developing mutations in their M2 proteins.

In addition, researchers at the NIAID Vaccine Research Center (VRC) are developing and testing gene-based influenza vaccines that will protect against multiple strains of influenza. As a first step, initial candidate vaccines, each containing the gene encoding the hemagglutinin (H) surface protein of an influenza virus isolated from a recent human outbreak of influenza (H1N1, H3N2 or H5N1), have already shown promise in animal studies. VRC researchers plan to develop additional gene-based vaccines for all common variants of hemagglutinin, as well as other influenza viral proteins, such as nucleoprotein and the M2 protein. In future, the VRC will incorporate both conserved and variable genes from multiple influenza strains into DNA and adenovirus vectors that can readily be produced by existing manufacturing processes.

A second approach, while not technically a vaccine, is an immune enhancer which specifically targets a component of the immune system and enhances one’s ability to respond to a broad range of microbial threats. Studies of the human innate immune system, which is comprised of “first responder” cells and other defenses that provide a first line of defense against a wide variety of pathogens, have been moving forward rapidly. These advances suggest it may be possible to develop a relatively small set of fast-acting, broad-spectrum countermeasures that can boost innate immune responses to many pathogens or toxins, including influenza. The capability to boost the innate immune system also could lead to the development of more powerful vaccine additives, called adjuvants, that can increase vaccine potency. The concept of immune enhancers has been demonstrated in early stage clinical studies, but requires further research and development to be applied to pandemic influenza vaccination.

GENES, ENVIRONMENT, AND HEALTH INITIATIVE

On February 8, 2006, HHS Secretary Leavitt announced that the President’s budget proposal for fiscal year 2007 included \$68 million for the Genes, Environment and Health Initiative (GEI), a research effort by the National Institutes of Health (NIH) to combine a type of genetic analysis and environmental technology development to understand the causes of common diseases such as asthma, arthritis, many types of cancer, diabetes, and Alzheimer’s disease. This represents a \$40 million increase above the \$28 million already planned for such efforts by the NIH for fiscal year 2007.

If approved by Congress, \$26 million of the requested \$40 million increase in funding would go to genetic analysis and \$14 million to the development of new tools to measure environmental exposures that affect health. The discoveries made through these efforts can potentially lead to profound advances in disease prevention and treatment. By seizing the historic opportunity provided by the Human Genome Project and the International HapMap Project, this initiative would speed the discovery of genetic risk factors for common diseases. But, as it has been said, genetics loads the gun; environment pulls the trigger. GEI will also provide markedly improved ways to measure and analyze the environmental contribution to disease, so that we can understand the complex interplay among genes and environment that is responsible for all human health and disease.

The NIH has recently formed a Coordinating Committee of representatives from 13 Institutes and Centers that would develop the content, priorities, and implementation of the initiative, should it be approved by the Congress. Similar to the management of NIH Roadmap initiatives, specific functions of the Coordinating Committee include: (a) identification of research priorities and opportunities relevant to

the program, (b) guidance and support of the development and implementation of specific research initiatives related to the program, (c) evaluation of proposals for specific activities to be conducted under the auspices of the program, and (d) facilitation of appropriate NIH-wide communication of program goals, initiatives, and findings. Two subcommittees have been formed, one to focus on the genetics component of GEI and the other to focus on its environmental component. These subcommittees will do the necessary planning for the proposed program during the current year and will be prepared to help administer the initiative, provided fiscal year 2007 funds are made available. Attached is a breakdown of the proposed budget for the initiative. Since the initiative is so early in its planning stages, the number of grants that would be awarded eventually is not known at this time.

Through initiatives such as GEI, we stand on the threshold of creating a future that would revolutionize the practice of medicine by allowing us to predict disease, identify environmental triggers, develop more precise therapies and, ultimately, prevent the development of disease in the first place.

Senator SPECTER. Thank you all very much.

We turn now to our next panel: Dr. Knapp, Dr. Auerbach, Dr. Chao, Dr. Comstock, Dr. Emerson, Ms. Eng, and Dr. Fox.

We have taken the unusual step of inviting 20 witnesses to this hearing to give us a bird's eye view or a thumbnail sketch, to mix metaphors, as to what is happening in specific lines of medical research. We have allocated as much time as we can, consistent with the schedule. It is not enough.

Dr. Knapp represents the entire group on medical research and there has been an allocation of 3 minutes for him and an allocation for every other witness, regrettably, of only a minute and a half. But that is the best we can do, and you have submitted written statements, all of which will be made a part of the record, and that will give us an opportunity to have some insights on your views and what is happening in your specific fields.

We are going to just indicate the group you are associated with, as opposed to going over your curriculum vitae's, which are all very, very impressive. Dr. Knapp, we start with you, representing the Ad Hoc Group for Medical Research.

STATEMENT OF RICHARD M. KNAPP, M.D., CHAIR, AD HOC GROUP FOR MEDICAL RESEARCH

Dr. KNAPP. Good morning. My name is Dick Knapp and I chair the Ad Hoc Group for Medical Research.

Mr. Chairman, all Americans owe you and Senator Harkin an enormous debt of gratitude for your unwavering commitment to medical research and your continued leadership in the support of the NIH, and we applaud your efforts to add funds to the 2007 budget to permit a \$2 billion increase in NIH funding.

The President's budget claims to freeze NIH at the 2006 level, but for almost all NIH institutes and centers this budget represents a cut, not a freeze. This budget proposal represents the fourth consecutive year that NIH funding has failed to keep pace with inflation. In inflation-adjusted dollars, as you pointed out, Mr. Chairman, this budget represents a loss of almost 11 percent of purchasing power since 2003.

Mr. Chairman, we are well on our way to undoubling the NIH budget that you and your colleagues fought so hard to achieve. As you heard from Dr. Zerhouni, NIH-funded research is driving the transformation of the practice of medicine. At a time of unparalleled scientific opportunities and unprecedented health challenges, NIH should be positioned to support more research, not less. Yet,

under this President's budget NIH would fund 10 percent fewer competing research project grants in 2007 than 4 years ago.

Because new investigators are essential to NIH's future, as Dr. Zerhouni pointed out, NIH-sponsored training should be supported as a top priority. However, due to fiscal constraints, the NIH has been unable to meet the stipend recommendations it made in 2001, and the President's budget proposes no stipend increases in 2007.

The flattening of the NIH budget also undermines the Nation's biomedical research infrastructure. Mr. Chairman, and you Senator Harkin have emphasized the need for increased support for the renovation and construction of extramural research facilities and the acquisition of state of the art laboratory instrumentation. Yet this budget again fails to request funds for the NIH extramural facilities program and the budget proposes to cut funding for shared instrumentation grants by nearly 8 percent below the level of 2005.

This morning's witnesses will describe how NIH research has safeguarded and improved the lives of all Americans while at the same time serving as a catalyst for new products and technologies, creating skilled jobs and contributing to the Nation's economic growth.

PREPARED STATEMENT

We share your concern that the continued flattening of the NIH budget threatens further progress in all of these areas. Thank you for the chance to be here.

[The statement follows:]

PREPARED STATEMENT OF RICHARD M. KNAPP

Mr. Chairman and members of the subcommittee, my name is Dick Knapp, and I chair the Ad Hoc Group for Medical Research Funding, a coalition of more than 300 patient and voluntary health groups, medical and scientific societies, academic and research organizations, and industry. The Ad Hoc Group is pleased to have the opportunity to provide an overview of the President's fiscal year 2007 budget for the National Institutes of Health (NIH).

Mr. Chairman, the members of the Ad Hoc Group, and indeed, all Americans, owe you and Senator Harkin an enormous debt of gratitude for your unwavering commitment to medical research and your continued leadership in support for the NIH. We share your belief that much of what has been accomplished in the past half century to help save lives and improve the health of all Americans can be attributed, directly or indirectly, to the NIH. And we applaud your efforts to add funds to the fiscal year 2007 budget resolution to permit a \$2 billion increase in the NIH budget. In January, the Ad Hoc Group joined four other major medical research advocacy groups in calling for the NIH budget to be increased by a minimum of \$1.4 billion (5 percent) in fiscal year 2007.

The President's budget for fiscal year 2007 proposes \$28.35 billion in budget authority through this subcommittee for the NIH, which is an increase of less than \$1 million over the current year's level. Much has been made of this proposal for flat funding. But for most areas of research, this budget represents a cut, not a freeze. Under the President's proposal, the fiscal year 2007 budgets for almost all NIH institutes and centers would be reduced below the fiscal year 2006 levels.

In addition, it is important to recognize that this year's budget is not a one-year aberration. The President's overall request is \$64.5 million less than what NIH received in fiscal year 2005, and the proposed budgets for most institutes and centers are between 1 and 1.5 percent lower than two years ago. If adopted, the President's budget would represent the fourth consecutive year that NIH funding has failed to keep pace with inflation as measured by the Biomedical Research and Development Price Index. In fact, in terms of inflation-adjusted dollars, the President's budget represents a loss of 11 percent of purchasing power since 2003, as shown in the attached graph. Mr. Chairman, we are well on our way to "undoubling" the NIH budget that you and your colleagues fought so hard to achieve.

It is the cumulative effect of this multi-year “flattening” of the NIH budget that is cause for concern. The flattening has had and would continue to have a severe impact across the pillars of NIH: basic research, translational and clinical research, research training, and the research infrastructure.

NIH-funded researchers have blazed new trails for medical research. Basic research forms the knowledge foundation needed to achieve continued scientific advancement. And as you have heard from Dr. Zerhouni, the discoveries resulting from the investment in NIH-funded research are driving the transformation of the practice of medicine through the development of novel and personalized therapies, cures, and prevention strategies.

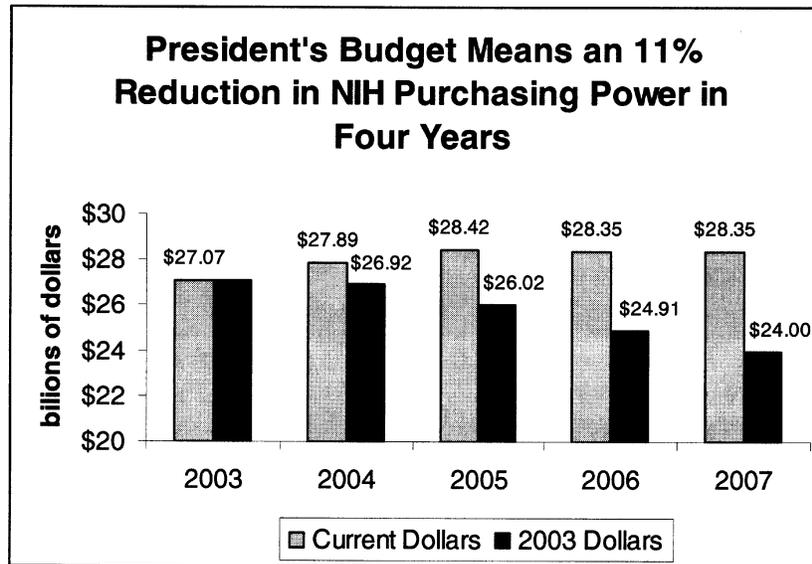
According to the Congressional Justification accompanying the President’s budget, in fiscal year 2007 NIH will be able to support 37,671 total research project grants (RPGs). This is 1,570 fewer RPGs than NIH funded in fiscal year 2004. What is more critical is the reduction in the number of new and competing RPGs. Under the President’s budget, NIH will be able to award 9,337 competing RPGs in fiscal year 2007, a decrease of 1,074 compared to fiscal year 2003. This is 10 percent reduction in just four years. At a time of unparalleled scientific opportunities and unprecedented health challenges, NIH should be positioned to support more research, not less.

In addition, a key function of NIH is to support training awards to encourage new investigators into basic and clinical medical research careers. Because an influx of new investigators is essential to NIH’s future, NIH-sponsored training opportunities should be supported as a top priority, with realistic funding levels for stipends, tuition, and benefits. Under the President’s budget, the NIH will be able to support 17,499 full-time training positions (FTTPs) in the Ruth L. Kirschstein National Research Service Award (NRSA) program. This is a reduction of 139 since fiscal year 2005. Furthermore, in 2001 the NIH recommended increased stipend support for NRSA recipients; however, the agency has been unable to meet these objectives due to fiscal constraints. For example, stipends for pre-doctoral students and post-doctoral fellows have fallen significantly short of NIH’s targets, and the President’s budget provides no increases for stipends above the fiscal year 2006 levels. How are we to continue to attract the best and brightest students with stipends that are unduly low in view of the high level of education and professional skills involved in biomedical research?

The flattening of the NIH budget also undermines the nation’s biomedical research infrastructure. NIH extramural research infrastructure grants are essential if research institutions are to update or replace aging research laboratories. Senator Harkin recognized the critical importance of the research infrastructure to the continued leadership of the United States in medical research when he championed the Twenty-First Century Research Laboratories Act, which was enacted in 2000. This legislation emphasized the need for increased support for the renovation and construction of extramural research facilities and the acquisition of state-of-the-art laboratory instrumentation. Yet once again, the President’s budget fails to request funds for the peer-reviewed, competitively awarded, extramural research facilities grant program administered through NIH’s National Center for Research Resources.

Federal funding also is critical to equip core facilities at biomedical research institutions with state-of-the-art technologies. NIH administers two competitive grant programs that award funds to institutions to purchase present and emerging technologies: the Shared Instrumentation Grant Program for groups of NIH-supported investigators to obtain commercially-available equipment that costs more than \$100,000; and the High-End Instrumentation Grant Program to acquire more expensive equipment, such as structural and functional imaging systems, electron microscopes, and supercomputers. These grants maximize the utility of federal research funds by allowing a number of scientists with similar instrumentation needs to share such equipment, and promote interactions among scientists, frequently across scientific disciplines, thereby catalyzing mutually rewarding new research collaborations. Yet, the President’s budget proposes to reduce funding for these programs to \$64.4 million, which is 7.7 percent below the fiscal year 2005 level.

This morning’s witnesses will give specific examples of how the research supported and conducted by NIH has had a profound and far-reaching impact on society in many important ways, serving as a catalyst for new products and technologies, creating skilled jobs, contributing to the nation’s economic growth, and most importantly, safeguarding and improving the lives of all our citizens. Mr. Chairman, we share your concern that the continued flattening of the NIH budget as proposed by the President threatens further progress in all of these areas.



Senator SPECTER. Thank you, Dr. Knapp.

Dr. Judith Auerbach, representing the Foundation for AIDS Research.

STATEMENT OF JUDITH AUERBACH, Ph.D., VICE PRESIDENT, PUBLIC POLICY AND PROGRAM DEVELOPMENT, AMFAR, THE FOUNDATION FOR AIDS RESEARCH

Dr. AUERBACH. Good morning, Mr. Chairman, and thank you very much. I am Judy Auerbach from amFAR and I will speak very quickly since we have only 90 seconds.

There are now more than 1 million HIV-infected people in the United States and the rates of HIV infection have risen dramatically among vulnerable populations, including racial and ethnic minority women and men. To make headway in the fight against AIDS, we need a strong Federal commitment to research leading to more effective treatment and prevention methods.

During the doubling of NIH's budget, the Agency was able to expand the knowledge base in basic research focusing on human immunology, macromolecular biology, structural biology, and behavioral research. This led to a dramatic increase in the number of vaccine and therapeutic candidates in the pipeline and to the implementation of crucial HIV prevention trials in populations most at risk of infection.

But much of this progress is in jeopardy with current and proposed cuts. Factoring in the recent recalculation, AIDS research at NIH was cut by about 2.4 percent between 2005 and 2006 and will be cut another 6 percent under the President's 2007 request. This has grave consequences for grants overall, for expanded trials of promising prevention technologies and therapeutics, and for new and seasoned investigators.

The number of R01's in AIDS research decreased by 5 percent in both numbers and dollars from 2005 to 2006 and would decrease even further in 2007. Under current budget constraints, it is anticipated that the AIDS clinical trials networks will be allocated only about 54 percent of what it is estimated they will need over the next 7 years. This means important effectiveness trials of new prevention technologies and new therapeutics will not be launched. Research institutes are losing potential new investigators and more experienced ones are demoralized, knowing that the majority of submissions are triaged and unscored and that funding is not likely until resubmission, even if then.

So altogether this means that important AIDS research will not be undertaken and people at risk for or living with HIV and AIDS will not have access to lifesaving interventions.

My time is over, so I will stop there. Thank you.

Senator SPECTER. Thank you, Dr. Auerbach.

Dr. Moses Chao, Christopher Reeve Foundation.

STATEMENT OF MOSES CHAO, M.D., CHRISTOPHER REEVE FOUNDATION

Dr. CHAO. Thank you, Mr. Chairman.

In the past 10 years we have witnessed a remarkable turnaround in neuroscience research. It used to be dogma that the adult spinal cord could not regenerate or recover from serious injury. But now through basic research we know of specific genes, proteins, and cells that can stimulate the repair of the spinal cord, and we are now ready to convert these findings into new therapies.

But the United States is falling behind because of the decrease in NIH funding. The decrease has affected many scientists, including my own lab, because the level of funding has actually dropped to 10 percent. What that means is 1 out of 10 grants is being funded and that has produced some drastic consequences, because many innovative applications and promising experiments are not supported or carried out.

More distressingly, there is a huge negative impact on the recruitment of our next generation of young scientists because of this discouraging situation. So we believe that this is the time to invest in basic research to advance the progress that we have made in this area. Christopher Reeve often argued that what we learn about spinal cord regeneration has direct implications to many diseases, including glaucoma, Alzheimer's disease, and Parkinson's disease. Therefore, to put the brakes on funding basic research will interfere with new scientific discoveries that will be aimed at improving the health of all Americans.

Thank you.

Senator SPECTER. Thank you, Dr. Chao.

Ms. Amy Comstock, Parkinson's Action Network.

STATEMENT OF AMY L. COMSTOCK, CHIEF EXECUTIVE OFFICER, PARKINSON'S ACTION NETWORK

Ms. COMSTOCK. Good morning. Thank you, Chairman Specter and Senators Harkin and Shelby. I am Amy Comstock, the Chief Executive Officer of the Parkinson's Action Network, and I am here on behalf of Parkinson's patients, their families, and all of the national Parkinson's organizations.

Parkinson's disease is now listed among the 15 leading causes of death in this country. Yet there is still no cure and no known treatments that even slow the progression of the disease. In fact, since the introduction of dopaminergic treatments nearly 50 years ago, our community is still struggling with mere variations of that treatment for this progressive disease.

Even with the introduction of deep brain stimulation for Parkinson's disease, we are still only responding to the symptoms of the disease and not doing that very well sometimes, and certainly not for a long duration.

So I am here this morning, quite frankly, to use the word that we are terrified of flat funding at NIH. Not only will flat funding eat into all forms of research currently under way at NIH, but we are particularly fearful that it will have a disproportionate impact on clinical and translational research, which is exactly the kind of research that we need the most.

Clinical research is very expensive to conduct, but it is what we have to have in order for treatments to make it through the drug development pipeline and become available to patients. For example, there is a handful of drugs slated for clinical trials right now at NIH that in fact may be what we need so badly. They may be compounds that can slow the progression of the disease.

PREPARED STATEMENT

We have to have these trials, but we cannot have them without funding. With flat funding, even if those trials are conducted—we have to do the math—other research would be cut at NIH. Therefore, we strongly support a minimum of 5 percent increase for NIH.

Thank you.

[The statement follows:]

PREPARED STATEMENT OF AMY L. COMSTOCK

Thank you Chairman Specter, Ranking Member Harkin, and distinguished members of the Subcommittee for convening this hearing on NIH appropriations. I am the Chief Executive Officer of the Parkinson's Action Network (PAN). PAN represents the Parkinson's community, including the more than one million Americans currently fighting Parkinson's disease (PD), and their families, and the national Parkinson's organizations, such as The Michael J. Fox Foundation for Parkinson's Research, Parkinson's Disease Foundation, National Parkinson Foundation, Parkinson Alliance, and American Parkinson Disease Association.

As I am sure you all you know, PAN was instrumental in helping garner Congressional support for this Subcommittee's doubling of the NIH budget over five years during the late 1990's and early in this decade. We continue to work in conjunction with so many to prevent the proposed freeze in funding for NIH. Flat-funding would, in effect, constitute a significant cut, as the Biomedical Research and Development Price Index (BRDPI) is estimated to have increased by 5.5 percent for fiscal year 2005, and will likely increase by 4.1 percent for fiscal year 2006, and 3.8 percent in fiscal year 2007. Accordingly, in order to not lose ground in ongoing research, we support the medical research advocacy community's recommendation for a 5 percent increase above the fiscal year 2006 funding level for the National Institutes of Health.

We cannot turn our backs on our most promising research, which may happen if this funding is not provided. The Parkinson's community is particularly concerned with several clinical trials that may be eliminated without sufficient funding and direction.

These clinical trials are a part of a study going on at NIH right now that embody the kind of translational research most promising to the Parkinson's community and is desperately needed. NET-PD (Neuroprotection Exploratory Trials in Parkinson's Disease) is a trial to study compounds that may slow the progression of Parkinson's

disease. Research into treatments that might slow progression is particularly important as current treatments for PD alleviate some symptoms but do not slow progression of the disease. Despite the potential value, this program may be halted or cut back if NIH does not receive adequate funding. Yet, NET-PD is exactly the kind of translational research that we strongly support NIH aggressively pursuing.

We believe that there is hope for today's Parkinson's disease patients and their families. There are emerging therapies that should be pursued—even therapies that could potentially reverse the progression of the disease. These are the neuro-restorative therapies, such as neural growth factors, gene therapies, and tissue transplants including stem cells, which ultimately may restore function in patients suffering from Parkinson's disease as well as other neurodegenerative disorders. However, if this important research is not aggressively pursued it may take many more years than necessary to determine if this hopeful research may become much-needed therapies for today and tomorrow's Parkinson's patients.

On behalf of the Parkinson's community, I thank you for your continued interest in Parkinson's disease issues and your support for better treatments and a cure for Parkinson's. I would be happy to answer any questions you may have.

Senator SPECTER. Thank you, Ms. Comstock.

We turn now to Dr. Steven Emerson on the cancer issue. Give my regards and thanks to Dr. John Glick, my oncologist.

STATEMENT OF STEPHEN EMERSON, M.D., ASSOCIATE DIRECTOR FOR CLINICAL RESEARCH, ABRAMSON CANCER CENTER, UNIVERSITY OF PENNSYLVANIA HOSPITAL

Dr. EMERSON. Good morning, Chairman Specter, Senators Harkin and Shelby. My name is Steve Emerson. I am the associate director for clinical research at the Abramson Cancer Center at Penn. Our outgoing director, Dr. Glick, sends his regards. He is no stranger to this committee.

First off, I want to thank you all for your continued support for the health and welfare of this country by means of health care research over the past several years. Without your support, we could not have done what we have done. In the area of cancer where I work, I have seen in the 25 years I have been working a change where 25 years ago a cancer diagnosis was uniformly and relatively quickly fatal, to now where over half the patients who walk in my office know that they will live at least 5 years, if not be cured of their cancer.

But still we are only partway there and at this point cancer is still the largest cause of death in all Americans under the age of 85. It is still a huge killer. We have a long way to go.

Now, you have heard a lot about the issues with the doubling of the budget and yet where we are with the flat budgets going forward. I want to concentrate on just one part of that. One of my roles at Penn is head of training and the mentoring of the next generation of investigators. What you see with the budget being flat is actually a reduction in all new R01's being funded to this year the eleventh percentile, next year much lower. This is one-third the level of funding in terms of numbers of grants and chances of getting funded that it was even 3 years ago, and that is going to get worse next year.

Worse than that, the money per grant is being cut 30 percent off even the best grants. So the funds going in for new research have plummeted. That is the source of the panic you are talking about. So for new investigators that we have all invested in, the outlook for them for careers, for taking care of all of us and for finding new cures, it is hard to convince them what the future is. If we do not correct this, all of the goodwill and investment we have made in

the infrastructure with the road map, all the collaborative work, all the genomics and cancer that we have put this investment into will go to waste because we will not have a next generation of scientists to take advantage of it.

PREPARED STATEMENT

So thank you all again in the past and in the future for your efforts on preserving the NIH budget and its mission. Thanks again. [The statement follows:]

PREPARED STATEMENT OF DR. STEPHEN EMERSON

Good Morning, Chairman Specter, Senator Harkin, and Members of the Subcommittee. I am Stephen Emerson, Associate Director for Clinical Research at the University of Pennsylvania's Abramson Cancer Center, one of NIH's original comprehensive cancer centers funded by the National Cancer Institute three decades ago. Our outgoing Director, Dr. John Glick, no stranger to this Subcommittee, extends his regards and regrets his schedule did not permit him to appear this morning.

Thank you for the opportunity to speak with you today about efforts by scientists and clinicians in the ongoing fight against cancer, a disease that is the leading cause of death for Americans 85 years of age and younger. In the United States last year, 1 of every 4 deaths was from cancer. This illness claimed the lives of about 563,700 Americans, with approximately 1.4 million new cancer cases diagnosed.

These staggering figures should not, however, diminish the hope that exists for all those who fall victim to this disease from the dramatic progress we have made in this fight. When the Abramson Center opened its doors three decades ago, a cancer diagnosis was a near certain, imminent death sentence. But through the efforts of millions of people, and as a direct result of the steadfast support of this Subcommittee in robust funding for cancer research over the years, today about 60 percent of cancer patients can expect to live more than five years after diagnosis. Working with our colleagues in partnership with organizations like the American Cancer Society and the Friends of Cancer Research, there is an aggressive, day-to-day battle to reverse the devastating effect that cancer has on the lives of so many individuals and families—through research, prevention efforts and treatment.

That effort, however, is under assault, and at great risk, if the President's fiscal year 2007 budget for the National Institutes of Health, and its proposed allocation for the National Cancer Institute, is not reversed. In the Bush 2007 budget proposal, the NCI is slated to receive \$4.75 billion—a cut of nearly \$40 million, or almost 1 percent, below NCI's fiscal year 2006 level. That is a reduction of \$70 million cut from the fiscal year 2005 level and approximately \$186 million less than what the Congressional Budget Office estimates is necessary to maintain current projects, infrastructure and spending adjusted for inflation and other factors.

Within the proposed levels for the NCI, virtually every major activity, other than activities for the NIH Roadmap initiative, would be reduced. Cancer research activities would be cut \$50 million below the 2006 level, which itself was slightly reduced from the level allocated for 2005. Cancer biology research would be cut nearly \$41 million and research into the causes of cancer would be reduced more than \$6 million. Overall support for the cancer centers would be reduced by more than \$2 million, capping a two-year period of real decline in the NIH investment for its cancer centers. Even cancer control and prevention, one of the single most important areas in our efforts to combat this disease, is scheduled to be hit with a nearly \$2.5 million reduction, reductions that amount to a cumulative decline of nearly \$17 million over two years.

These proposed reductions, which I know you oppose Mr. Chairman, completely contradict the Administration's stated goal of ending suffering and death from cancer by 2015. They fly in the face of the spiraling cost of cancer treatment, pegged at more than \$72 billion annually in the United States, nearly five percent of all health care expenditures. And they send the wrong message to the nation at a time when the economic burden, excluding the costs for treatment, from cancer morbidity and premature mortality is a staggering \$120 billion annually.

For the community of scientists and clinicians who have dedicated their lives to the prevention, diagnosis and treatment of cancer, and who are the members of the team working in every state in our nation to meet that 2015 goal, these proposed cuts are both alarming and highly discouraging. If enacted, these funding levels would drop success rates for scientists proposing research project grants to the NCI

to just 16 percent—that is a 1 in 6 chance of obtaining funding. Such a level would mean a drop in the NCI grant success rate of more than 50 percent since 1998, and a drop of 43 percent since 2002. For NCI's R01 grants, the bread and butter mechanism for most NIH funded scientists, the payline for last year is even worse—just 11 percent. Reductions in 2007 would only erode that level further.

While older, more established research scientists will likely find a way to hold on to most of their core funds, the effect on young investigators—the seed corn of our future in this battle—is nothing short of devastating. The NIH New Investigators Committee presented data last December that showed the average age of a typical new NIH R01 awardee with an M.D. degree had reached 44. At the same time, the percentage of new investigators in competing R01 Awards across NIH continues to decline to just 20 percent. For the NCI, the first-time investigator success rate for all grant mechanism is worse—just 11 percent. For R01's, the success rate is again just 17 percent. The message these proposed cuts send is that for promising young biomedical professionals, a career focused on tackling cancer—whether in the fundamental study of genomics, proteomics, and biomarkers, or the more applied disciplines directed at generating new diagnostic or treatment regimes and devices—is not worth pursuing. The President's budget runs the risk of beginning the effective elimination of a whole generation of cancer scientists—at the very time when we are turning the corner on the fight against this disease.

Those of us who have spent our lives focused on ending the scourge of this disease know that this Subcommittee—more so than any other in the U.S. Congress—led the fight for funds to double the NIH budget. And there has been tremendous progress against cancer as the number of people who died from cancer between 2002 and 2003 decreased for the first time, the year corresponding to the last of the large NIH budget increases. The Director of the NCI, in his testimony to this Committee last month, outlined a number of significant scientific breakthroughs in the treatment and diagnosis of breast, ovarian and cervical cancers in just the last year. These continue the remarkable success we have had in fighting the number two cause of death in the United States.

The proposed 2007 budget cuts would help to unravel the progress this Subcommittee fought so hard to achieve in the doubling of NIH from 1998–2003. We urge you to redouble your efforts to stop them, and provide a modest increase—perhaps an additional \$300 million for the NCI in the coming year—to help offset declines enacted in 2006 and provide for most increases to sustain the pool of young scientists whose careers will hopefully be marked by the end of cancer as a scourge on so much of our nation and our world.

Thank you for the chance to present my views to the Subcommittee. We would be happy to prepare responses to any questions you might have for the record.

Senator SPECTER. Thank you, Dr. Emerson.

Ms. Lauren A. Eng, Spinal Muscular Atrophy Foundation.

STATEMENT OF LAUREN A. ENG, PRESIDENT, SPINAL MUSCULAR ATROPHY FOUNDATION

Ms. ENG. My daughter is one of the 33,000 American children suffering from spinal muscular atrophy, the most common genetic killer of young children. One missing gene causes nerves and muscles to wither away and most children die by the age of 2. But there are many terrible diseases. What makes SMA remarkable is the imminence of treatment. SMA represents both the problem and the opportunity of drug development for orphan diseases. Half of Americans with illness suffer from rare diseases and for the vast majority of rare diseases, especially pediatric ones, money and scientific advances are wasted because discoveries do not move from the bench to the bedside.

Because of scientific breakthroughs, NINDS chose SMA from its 600 diseases for a groundbreaking drug discovery program. The SMA project is a shining example that NIH can develop treatments and invest in further and basic science that is ripe and pays off. With less than \$5 million a year, a group of potential drugs have already been identified. NIH has been a catalyst of advancing re-

search and drug companies are interested. It achieved in 3 years what might have otherwise taken 10.

PREPARED STATEMENT

But running an astonishing race is useless if you stop short of the finish line. Under the proposed budget, continuation of the program is at risk. There is funding to pursue one drug, but scientists believe at least three should be advanced, each costing \$15 million to bring to trials. If NIH cannot fund this next step, it will have catastrophic effect. Academic and industry research will stop. We will have wasted the enormous investments and progress made in biomedical research, and for my child all of this is the difference between life and death.

[The statement follows:]

PREPARED STATEMENT OF LOREN A. ENG

I am Loren Eng, president of the Spinal Muscular Atrophy (SMA) Foundation and am here on behalf of the SMA Coalition. Most importantly, I am the mother of Arya Singh, who is one of the 30,000 children in America dying from Spinal Muscular Atrophy.

As you may know, SMA is a terrible disease. It is the most common genetic killer of babies and young children in America, and it is untreatable and fatal. It is often described as a genetic version of polio, or the children's equivalent of ALS. In children with SMA, one missing gene, and one missing protein causes motor neurons to die. Muscles weaken and wither away, leaving the bright minds of its young victims trapped by their failing bodies. Most children with SMA die within the first few years of life. Some are "lucky" and live longer, but face extreme disability and suffering.

But there are many terrible diseases. What makes SMA remarkable is the ability to truly make a difference with a modest amount of money and smart strategy.

SMA is a poster child for both the problem and the opportunity of drug development for rare pediatric diseases.

For large diseases, the historical focus on basic science works well—large drug companies take that basic science and translate it into treatments that save lives.

However, half of Americans with illness have smaller diseases, and for them the system has not worked. Breakthroughs are often achieved in basic science, but there are no large drug companies waiting to turn those breakthroughs into treatments. For a handful of smaller diseases, drug companies will only get involved at later stages where perceived risk is lower. But for most small diseases, the basic science is wasted because of the challenges of advancing research from the bench to the bedside. This is especially true for rare pediatric diseases. Money is spent, but children still die.

In the past decade, scientists studying SMA have achieved incredible breakthroughs, creating a unique opportunity to develop treatments. To its credit, NINDS has recognized the opportunity and taken steps to advance basic science with a revolutionary translational research effort.

Just three years ago, the NINDS designated SMA, from among 600 diseases, as the best candidate for a model new program to translate basic science into actual drugs and treatments. The SMA Project combined academic and industry expertise, and was a focused and strategic effort to translate remarkable science into real solutions.

In just three years, and for less than \$5 million per year, the SMA Project has brought us within reach of an effective treatment. Investigators have identified a group of potential drugs that may slow the progression of the disease. Despite a minuscule budget for the project, NINDS has made incredible strides in harnessing the community's efforts toward a near term treatment.

Unfortunately, running a brilliant race is useless if you stop before the finish line, and that is what we fear is at risk of happening.

I am not an expert in the federal budget but I do know that:

- this model SMA program would never have been initiated under this budget,
- the existing funding of just \$5 million a year is at risk, and
- the very success of the program is at risk.

The next phase of the project is pre-IND studies but there is only enough funding to study JUST one compound. Project scientists say we need at least two to three, and each costs \$2 million. For clinical trials we will need \$10 to \$15 million each.

The leadership of the NIH has been a catalyst of incredible progress—it expects to advance research to a point when they can be “handed off” to drug companies to fully develop. For a fraction of the vast amounts spent on caring for SMA victims, we could develop treatments that would save them. With a modest amount of money and continued focus, we can save lives, and money.

If NIH can not provide for these critical next steps, it will have a domino effect elsewhere:

- Young investigators will not focus on SMA,
- Existing non-government research will stall,
- Industry will surely not engage, and
- Other diseases like ALS and DMD will not reap the benefits of SMA research.

The SMA Project has been a revolutionary effort and a shining example of how NIH cannot only fund basic research but actually DEVELOP TREATMENTS for deadly diseases.

Through a solution driven approach, the NIH has achieved in 3 years what might have taken a decade. “Smart investment” could pay off in treatments that save lives. This is an incredible example of finding solutions, not just spending money. Of course, in this case, a “solution” means treatment that could save the lives and reduce the suffering of 30,000 children.

We urge you not to stop short now when we are so close. Reducing funding for NIH, and for projects like the SMA Project will have devastating consequences—we will waste the enormous amounts of money that have been spent and progress that has been made. For our daughter, it could mean the difference between life and death.

Senator SPECTER. Thank you, Ms. Eng.

We turn now to Dr. Philip Fox, American Association for Dental Research.

STATEMENT OF DR. PHILIP C. FOX, DIRECTOR OF CLINICAL RESEARCH, DEPARTMENT OF ORAL MEDICINE, CAROLINAS MEDICAL CENTER ON BEHALF OF THE AMERICAN ASSOCIATION FOR DENTAL RESEARCH

Dr. Fox. Thank you, Mr. Chairman. I am Dr. Phil Fox and I am really representing the dental research community.

I would like to highlight this morning some advances in salivary diagnostics, an area you have not heard much about. Diagnosis of most health conditions requires a blood or a urine sample and that may be invasive or painful to obtain. But now, after many years of research, saliva is poised to be used as a noninvasive diagnostic fluid for a number of oral and systemic conditions.

Dental researchers have been able to amplify molecular signals that are present in saliva, heralding the advent of new tests that allow for earlier diagnosis than is currently possible. Saliva is already being used routinely for rapid noninvasive HIV diagnosis and saliva-based tests will soon be available to detect oral cancer. Further, saliva has the potential to detect exposure to chemical and biological weapons and is being looked at in autoimmune diseases as well.

Now, most of this research is funded by the National Institute of Dental and Craniofacial Research, the NIDCR. However, as you have heard, the investment that is made in the NIH doubling is now at risk. I think that we have the research equivalent now of being all dressed up and nowhere to go.

As a result of your past investment, there are many unprecedented opportunities in dental research. But the austere budget of the last 4 years has resulted in a steady decrease in new research grants and many young investigators who are leaving the field.

Imagine a future in which a saliva sample is used for quick, painless and less expensive diagnostic tests and to monitor many systemic health conditions and exposure to chemical and biological weapons. Early diagnosis could save thousands of lives. We need you to sustain your commitment to NIH and to dental research in order to realize these unprecedented scientific opportunities.

Thank you for your interest and support.

Senator SPECTER. Thank you very much, Dr. Fox.

Unless there is some question from the panel, we will turn now to our next group of experts.

Thank you all very, very much.

Dr. KNAPP. Thank you.

Dr. EMERSON. Thank you.

Senator SPECTER. We now call on Ms. Patricia Furlong, Dr. Sam Gandy, Ms. Ann Gibbons, Dr. Robert Goldstein, Dr. Lawrence Holzman, and Dr. Steven Houser.

Thank you all very much for joining us. As is the situation with all of the witnesses, your full statements will be made a part of the record. We turn first to Ms. Patricia Furlong, who represents the Project on Muscular Dystrophy. Ms. Furlong.

STATEMENT OF PATRICIA FURLONG, CO-FOUNDER AND CHIEF EXECUTIVE OFFICER, PARENT PROJECT MUSCULAR DYSTROPHY

Ms. FURLONG. Thank you very much, Senator Specter, Senator Harkin, and Senator Shelby. I so appreciate this opportunity to talk about NIH funding.

I thought I would start by giving you three examples. In 1999 a scientist from the University of Pennsylvania with NIH support looked at aminoglycosides to suppress premature stop codons. Premature stop codons in a genetic sentence could be interpreted as a period in the middle of a genetic sentence, creating the loss of a significant protein. These aminoglycosides are found to suppress a premature stop.

This particular scientist went to industry and, again with his own NIH support, began high throughput screens. Today we have a drug in trial called PTC-124. This drug has implications for all genetic diseases in terms of a subset of the population with premature stops. It is currently in trial and demonstrating pharmacological activity in cystic fibrosis and in Duchenne muscular dystrophy we do not have the data. But this drug has sweeping potential results across the rare genetic disease community.

In 2000 a scientist from Johns Hopkins University looked at muscle regulators and found that inhibiting myostatin would improve the bulk of the muscle and potentially the strength. This drug is currently in trial in muscular dystrophies FSH, Becker, and myotonic.

In the year 2001, the Bowman-Burke inhibitor compound was looked at. It is a protease inhibitor that can slow or halt muscle degeneration in muscular dystrophy. It had been in trial in the National Cancer Institute and was halted, not because of any risk to the patient, but primarily due to lack of material. This drug is now going into trial through NIH funding in muscular dystrophy in January.

PREPARED STATEMENT

It is these cures, potential treatments for all of us, that make such a difference in our lives. We ask you to commit to NIH funding to supply that NIH, that research enterprise, with the funding it needs to help all of us, to give us time with the people we love, and to help not only the American people but people across the world.

Thank you.

[The statement follows:]

PREPARED STATEMENT OF PAT FURLONG

Good morning/afternoon Mr. Chairman and Members of the Committee, and thank you for this opportunity to testify on the NIH budget.

My name is Pat Furlong, Co-Founder and CEO of Parent Project Muscular Dystrophy and the mother of two sons who battled Duchenne Muscular Dystrophy.

Thanks to the significant amount of basic research funded by NIH in recent years, we are making encouraging progress in our quest to develop effective treatments for this always-fatal disease. Right now, we are in a Phase II clinical trial on a promising drug for a subset of patients with Duchenne muscular dystrophy, and potentially a subset of patients with many other genetic conditions.

It's basic NIH-funded research that served as a foundation and provided the spark for this drug, and many other promising therapies that are in the works. Without adequate NIH funding to support basic research, the medical research tower will rise much lower before eventually buckling due to the tremendous strain placed on too few resources.

We are particularly concerned about the negative impact the budget crunch will have on young investigators seeking to enter the field of Duchenne MD research. The budget limitations we have seen over the past few years have made it tremendously more difficult for young, first-time investigators with meritorious submissions to secure an R01 grant.

I urge your panel and the entire Senate to continue to lead the way in restoring critically needed dollars to support basic NIH research.

Senator SPECTER. Thank you very much, Ms. Furlong.

We now turn to Dr. Sam Gandy, representing the Alzheimer's Association.

STATEMENT OF SAM GANDY, M.D., Ph.D., CHAIR, MEDICAL AND SCIENTIFIC ADVISORY COUNCIL, ALZHEIMER'S ASSOCIATION

Dr. GANDY. Mr. Chairman, members of the subcommittee: As a direct result of this subcommittee's leadership and foresight, scientists supported by the NIH have made enormous strides towards understanding Alzheimer's, a disease that affects 4.5 million Americans today and will affect as many as 16 million in a few decades.

For the first time in the history of medicine, we have Alzheimer's genes in hand and we can now contemplate rational therapy for Alzheimer's. With adequate resources, scientists will be able to develop medications that modify Alzheimer's pathology in as few as 3 years. Achieving that goal will relieve a major bottleneck and attract every major pharmaceutical company to begin bringing new drugs into human clinical trials.

The current trajectory of NIH cuts threatens to arrest progress and devastate the upcoming generation of scientists. Current grants are now routinely cut by 18 percent. In my institution this is already causing layoffs and I see my students turning away from research careers. Budget cuts also mean that some of the most promising drug targets will go unstudied. An important new molecule was discovered just last month. Where will we find the resources to study its potential therapeutic value?

PREPARED STATEMENT

The inescapable conclusion is that Federal budget cuts are killing more than programs. These cuts are killing the minds of millions of Americans. The threat of Alzheimer's is staggering in its scope. I urge you and your colleagues to act now to reverse the disastrous path upon which we find ourselves.

Thank you very much for providing me with this opportunity to testify.

[The statement follows:]

PREPARED STATEMENT OF SAM GANDY

Mr. Chairman and members of the Subcommittee, I appreciate the opportunity to be here to discuss Alzheimer's disease, a disease that, as we speak today, is robbing 4.5 million Americans of their abilities to form memories and thoughts. The disease will ultimately take the life of every one of these 4.5 million. Within a few decades, as many as 16 million Americans will have Alzheimer's, all of whom will eventually succumb to the disease, unless we all, together, take up the fight toward a cure or means of prevention.

As a direct result of the leadership and foresight of this Subcommittee, the National Institutes of Health have played essential roles in developing and maintaining a cadre of American scientists such as myself who have made enormous strides toward understanding Alzheimer's and, for the first time in the history of medicine, contemplating rational interventions aimed at the underlying disease process. We now know that Alzheimer's is a disease and not an inevitable consequence of aging. We have identified several key genetic mistakes that are so malignant that one single mistake in the DNA is sufficient to cause the complete picture of Alzheimer's. These DNA mistakes have been both necessary and sufficient to supply us with essential information that has eluded scientists for the century since Alois Alzheimer presented his landmark paper in Munich in 1906. For the first time in the history of medicine, we are now able to mimic the earliest steps in the disease using chemicals, cells, or, most valuably, the lowly laboratory mouse. Human Alzheimer genes have enabled us not only to create in the laboratory a living brain with Alzheimer's, but, astoundingly, we are also now able to cure experimental Alzheimer's in the laboratory. These experimental therapies are now entering human trials so that we might translate these experimental cures into practical medicines for humans.

To date, four drugs have been approved for treating the symptoms of Alzheimer's, but these drugs only help a few patients, and even then, only modestly and temporarily. Current Alzheimer drugs leave the basic underlying disease untouched and the natural progression from amnesia to death proceeds along the standard, predictable, inevitable, and cruel path that we know all too well. Yet, from the laboratory, for the first time, scientists and physicians see genuine, tangible, quantifiable hope. Most experts agree that with adequate resources, scientists will be able to develop medications that will modify Alzheimer's pathology within the next three years. If the prevailing wisdom about the root cause of the disease is validated, a major bottleneck will be relieved, and every major pharmaceutical company will begin bringing new drugs into human clinical trials.

But that can only happen if you and your colleagues sustain the Alzheimer research enterprise. Alzheimer's drug development will certainly be stymied if Congress adopts the President's proposal, where for the fourth consecutive year the NIH budget fails to even keep pace with inflation.

The NIH doubling process is directly responsible for the progress of Alzheimer's research as a field of study: the field has moved from a backwater of obscurity into perhaps the single most visible, most competitive, and most exciting research field in experimental neurology. Within three years after this Subcommittee first appropriated funds for Alzheimer's, the number of scientists drawn into this field of study increased three-fold. But because of budget cuts over the past three years we are already seeing talented scientists turning to other fields.

The current trajectory of cuts threatens to devastate the upcoming generation of scientists. NIH funding of the scientists who populate the faculties of our universities is not simply used to buy test tubes and chemicals: those funds directly pay the salaries of scientists on these faculties. Draconian cuts will render these scientists and professors unemployable. And with the loss of this talent, we are postponing the day that we can eradicate this deadly disease.

But perhaps most importantly, persistent budget cuts are shutting out opportunities to find ways to cure or prevent Alzheimer's disease. In 1998, NIH was funding 30 percent of top-rated grant applications. Today, the percentage of Alzheimer projects that actually receive funding is down to 18 percent. Some institutes are struggling to maintain 10 percent funding. This means that most scientific opportunities are being left on the table. It also means that some of the most promising clinical trials—the tools we need to translate basic research findings into effective clinical treatments—will be delayed or scrapped altogether. The inescapable conclusion, for me, at least, is that federal budget cuts are killing more than programs; they are killing the minds of millions of Americans.

Mr. Chairman and Senator Harkin, I am certain that you both realize that we cannot be a strong nation unless we are a healthy nation. In fiscal year 2007, spending on all Medicare beneficiaries benefits will total \$449.2 billion. Unless we find a way to prevent or cure Alzheimer's disease, in less than 25 years, the care of Medicare beneficiaries that is attributed to Alzheimer's alone will cost over \$400 billion, roughly equivalent to today's entire Medicare budget. The threat is so enormous that the temptation is to just give in to nihilism and cynicism. I urge you and your colleagues to join us in resisting this temptation and act now to reverse the disastrous path upon which we find ourselves.

Thank you for the opportunity to testify.

Senator SPECTER. Thank you. Thank you, Dr. Gandy.

Our next witness is Ms. Ann Gibbons, representing Autism Speaks.

STATEMENT OF ANN GIBBONS, MEMBER, BOARD OF DIRECTORS, AUTISM SPEAKS

Ms. GIBBONS. I am the mother of a 17-year-old boy with autism and I am a member of the board of directors of Autism Speaks, and I am here to speak for those who cannot.

Autism is our Nation's fastest growing developmental disorder, affecting 1 in 166 children, up more than tenfold from a decade ago and costing our Nation approximately \$35 billion annually. Autism has no known cause, no known cure, and few effective treatments. The incidence of autism has increased at epidemic proportions, but NIH funding for autism research has been frozen over the past 2 years and will remain so in the President's 2007 budget.

Specifically, the first lost opportunity is developing new treatment standards for autism. This would support research on new or existing early interventions to establish common methods of verifiably effective treatment. Early intervention provides children with the best possible opportunity to develop in the most normal way possible, but not with the President's budget, where this critical research will not be funded.

Another lost opportunity is defining the core features of autism, when it begins, its long-term course, and subtypes of the disorder that may exist on the autism spectrum. Understanding the common features of autism will lead to identification of its causes, both genetic and environmental, and identify better treatments or even prevention of the disease. The President's proposed budget will not fund this research.

PREPARED STATEMENT

The incidence of autism will continue to grow, but funding for autism research will not. With the President's budget, opportunities will be lost, but the pain and suffering of autistic children and their families will continue to grow, as will the cost to society.

I just want to thank you all for what you are doing for biomedical research.

[The statement follows:]

PREPARED STATEMENT OF ANN GIBBONS

Mr. Chairman, I am Ann Gibbons, a resident of Bethesda, Maryland, a member of the Board of Autism Speaks, and the mother of a 17-year-old son with autism.

Autism Speaks was launched to help find a cure for autism by raising the funds to facilitate and quicken the pace of research, to raise public awareness of autism, and to give hope to all those who suffer from this disorder. Autism Speaks' goal is to give a voice to an entire community, to every family dealing with the hardships of autism. With its mergers with the National Alliance for Autism Research and the Autism Coalition for Research and Education, Autism Speaks now represents our nation's largest autism advocacy organization.

In both of my roles, in my public capacity as an Autism Speaks board member and in my private role as a mother of an autistic child, I commend you, Mr. Chairman, for your leadership in promoting funding for biomedical research and support you in your efforts to secure increased funding for the National Institutes of Health this year.

Funding for understanding the causes of and finding treatments for autism is sorely needed. Autism is our nation's fastest-growing developmental disorder, now affecting 1 in 166 children in the United States, up more than tenfold from just a decade ago. A Harvard School of Public Health professor, in a recent book, estimates that it can cost \$3.2 million to care for an autistic person over the course of his or her lifetime, and by conservative estimates autism costs our society \$35 billion annually in direct and indirect costs.

Autism has no known cause, no known cure, and few effective treatments. And while NIH funding for autism may have tripled in the past decade to \$100 million, that amount pales in comparison to the money spent for research on other diseases and disorders that affect fewer individuals.

Autism research is poised at a turning point. While diagnoses are skyrocketing at epidemic rates, many areas of autism research stand on the verge of important findings. If adequately funded, this research could yield real progress on the diagnosis, treatment and cure for this disorder. The President's proposed freeze on NIH funding falls short on all counts, and would seriously impede the progress and promise of autism research.

One turning point is the development of new treatment standards for autism spectrum disorder. This program would support research on new or existing interventions with the goals of establishing common methods of treatment and measurements of treatment efficacy. This study could hasten the ability to use existing treatments early to improve outcomes for children and families struggling with the disability of autism spectrum disorders. When autistic children do receive evidence-based early intervention service between ages 3 and 5, from 20 to 50 percent of them are able to go onto mainstream kindergarten. Early intervention is critical in order to provide children with autism the optimum opportunity to develop in the most normal way possible.

Unfortunately, Mr. Chairman, the President's proposed budget for fiscal year 2007 will freeze funding for autism, and research leading to advances in autism intervention will not be possible.

Another turning point is the need to define core features of autism, including when it begins, its long-term course, and subtypes of the disorder that may exist on what is known as the autism spectrum.

Defining the features of autism could lead toward the long-term goal of finding genetic and non-genetic causes of autism and offering the possibility of providing better treatments or even prevention of the disease. It's also urgent that we better understand the genetic associations with autism so that research into the interaction of genes with the environment can be understood.

With the budget proposed by President, this research will not be funded, and these advances cannot be made.

With the President's budget, progress in understanding brain development and autism, one of the most devastating disorders affecting hundreds of thousands of children, will be slowed or halted. Scientists will be unable to realize the full potential of the latest scientific techniques, in neuroimaging and genetics technology.

Mr. Chairman, autism, which the Centers for Disease Control and Prevention estimates now affects 300,000 American children between ages 4 and 17, will continue to grow, with 3 children now being diagnosed every hour. The pain and suffering of autistic children and their families will continue, as will the costs to society. But research on this devastating disorder will be stymied, progress on potential treat-

ments and cures will be stymied as a result of the President proposed freeze on spending for biomedical research and on research on autism.

Moreover, we will lose the opportunity to save an entire generation of children from this devastating disorder, which can lock people in their own worlds, unable to communicate with, and sometimes unable to experience the affection of those who love them.

Mr. Chairman, thank you for giving me the opportunity to speak for those with autism and their families.

Senator SPECTER. Thank you. Thank you very much, Ms. Gibbons.

Our next witness is Dr. Robert Goldstein, representing the Juvenile Diabetes Research Foundation.

STATEMENT OF ROBERT GOLDSTEIN, M.D., Ph.D., CHIEF SCIENTIFIC OFFICER, JUVENILE DIABETES RESEARCH FOUNDATION

Dr. GOLDSTEIN. Thank you, Senators Specter, Harkin, and Shelby for this opportunity to testify. I am Robert Goldstein, the chief scientific officer for the Juvenile Diabetes Research Foundation.

Without an increase in Federal funding for diabetes research, there will be a disproportionate impact on clinical translation research. Islet cell transplantation, a procedure that has been successfully done experimentally in nearly 600 diabetes patients, will delay the—the NIH-sponsored clinical trials to expand this proven treatment out into the community will be seriously delayed.

In the area of hypoglycemia, dangerously low blood sugar can lead to convulsions, coma, or even death. The Diabetes Research and Children's Network's efforts to assess new glucose monitoring technology will impact on the management of type 1 diabetes in children.

Diabetic retinopathy. Anti-angiogenesis drugs that can reverse diabetic retinopathy have been discovered, but clinical trials to extend and expand these findings to test new classes of drugs would be delayed or halted.

Treatment of new onset of type 1 diabetes. Clinical trials using monoclonal antibodies have shown that insulin-secreting cells can be protected for up to 2 years. Support studies to determine how to prolong this effect, whether treatment prior to the onset can prevent diabetes, and whether these therapies can be given years after onset would be delayed or curtailed. Since type 1 diabetes is an autoimmune disease, this will impact understanding of other autoimmune diseases.

PREPARED STATEMENT

Causes of type 1 diabetes. NIH-supported efforts to identify the genes responsible for susceptibility will be curtailed and delay our ability to effectively prevent disease in at-risk populations.

Thank you for the opportunity to testify.

[The statement follows:]

PREPARED STATEMENT OF ROBERT GOLDSTEIN

Chairman Specter, Ranking Member Harkin and Members of the Subcommittee, thank you for the opportunity to testify before you today regarding the many opportunities that will be lost without an increase in federal funding for diabetes research at the National Institutes of Health. I am Robert Goldstein, the Chief Scientific Officer for the Juvenile Diabetes Research Foundation International.

In the past 25 years, the number of people with diabetes has more than doubled, so that today approximately 20.8 million Americans have diabetes. Evidence sug-

gests that 1 in 3 Americans born in 2000 will develop diabetes during his or her lifetime. Diabetes is the 6th leading cause of death in the United States. The disease cost this country \$132 billion in 2002, which is almost 5 times NIH's annual budget. Only research to better prevent, treat and cure diabetes will significantly impact these numbers.

The Diabetes Research Working Group recommended \$1.6 billion in fiscal year 2004—the last year of their study—to take advantage of the many diabetes research opportunities. We have used appropriations to build critical momentum for accelerating the delivery of therapies to people with diabetes. There have been major advances (see attached) and more importantly programs have been put in place that will insure continued advances. Yet funding today is \$600 million short of this recommendation. Absent an increase in federal funding, this momentum will be lost and progress and solutions will be delayed. Specifically, the following areas of diabetes research will be seriously impacted:

Islet Cell Transplantation.—Nearly 600 diabetes patients worldwide have now received islet transplants, and enough patients have been transplanted that long-term benefits can be documented. Islet cell transplants have resulted in significant benefits to people with very complicated forms of type 1 diabetes: for instance, at least half of the transplant recipients exhibit stabilization or reversal of their diabetic eye and nerve diseases. Overall, islet transplant patients report a significant improvement in their quality of life. However, challenges remain, and we need additional funding for NIH programs and NIH/CMS sponsored clinical trials to test new protocols and fully understand how to maximize this proven treatment so it is an appropriate therapy for all who suffer from type 1 diabetes.

Hypoglycemia.—Hypoglycemia—episodes of dangerously low blood sugar—is the most feared acute complication of diabetes and can lead to shaking, convulsions, coma, or even death in extreme cases. Young diabetic children who may not be able to recognize or communicate the signs of impending hypoglycemia are especially vulnerable. Technologies coming onto the market in the near term have the ability to warn patients of hypoglycemia, and it is critical that the technology is suitable for use in children. The NIH has established the Diabetes Research in Children Network (DirecNet) to provide independent assessments of glucose monitoring technology and its impact on the management of type 1 diabetes in children, and this important work would be delayed without additional funds.

Diabetic Retinopathy.—Diabetes is the leading cause of new blindness in working age adults; more than 8.5 million people in the United States have diabetic retinopathy or eye disease. Significant progress being made on the causes and pathogenesis of diabetic retinopathy is generating renewed hope for the prevention or reversal of eye disease. For the very first time anti-angiogenesis drugs that can actually reverse diabetic retinopathy, as opposed to simply halting further progression by means of laser treatment, have been discovered. The NIH-supported Diabetes Retinopathy Clinical Research Network (DRCR.Net) includes more than 150 collaborating physicians across the United States, and provides an organized platform for rapidly translating new therapeutic ideas from the research community into clinical testing in human patients. Clinical trials to test the pipeline of potential new drugs would be delayed, curtailed or halted without continued funding.

Treatment of New Onset Type 1 diabetes.—By the time type 1 diabetes is diagnosed, patients have already suffered a devastating autoimmune attack that has destroyed most of the insulin-producing beta cells of the pancreas. Research has shown that a patient's level of residual beta cell activity correlates with the ability to more easily maintain glucose levels close to normal and reduces the amount of insulin that must be injected. A prime research goal is to develop new therapies that will help newly diagnosed type 1 diabetes patients preserve remaining beta cells and possibly even dampen the immune system enough to allow the pancreas to regenerate new beta cells. Researchers have identified a drug that can effectively alter the clinical course of the disease. A short 1–2 week course of treatment with an antibody—named anti-CD3—helps patients maintain or increase their ability to produce insulin naturally for up to 18 months after diagnosis compared to a placebo. This treatment demonstrates the proof of principle that the clinical source of an established autoimmune disease can be significantly altered. This work could not have been done without the major advances in clinical trial platforms from several NIH sponsored programs, including:

—Immune Tolerance Network, whose goals are to develop new therapies to treat/prevent autoimmune disease and to prevent or treat graft rejection in transplantation by inducing immune tolerance. Among the diseases under investigation by this collaborative effort include type 1 diabetes and islet transplantation; and

—TRIAL NET which also supports studies aimed at both preventing further destruction of insulin secreting cells in new onset type 1 diabetes, as well as developing the means to prevent disease.

More extensive studies to determine how long this effect can be maintained, and whether the addition of specific antigen therapy or other drugs can prolong this effect, will not occur without continued support. Similarly, large studies to determine whether early treatment prior to disease onset can prevent diabetes or whether these therapies can be given years after disease should be supported.

Genetics and Environmental Causes of Type 1 Diabetes.—The best way to attack type 1 diabetes is to stop it before it ever starts, but this requires sophisticated knowledge of the underlying causes of disease. Ground breaking NIH efforts (T1DGC, TEDDY, TRIGR) to identify the genes responsible for susceptibility to type 1 diabetes coupled with the identification of environmental triggers (viruses, toxins, dietary factors) will be curtailed or abandoned without continued funding, and delay our ability to effectively prevent disease in at-risk populations.

Diabetes research has demonstrated a strong return on the federal investment. Continued strong federal commitment is needed.

Thank you again for the opportunity to appear before you today. I am happy to answer any questions you may have.

NIH AND DIABETES RESEARCH—A STRONG RETURN ON FEDERAL INVESTMENT

Diabetes affects more than 20 million adults and children in the United States, up to 7 percent of the population. In 2001, approximately \$3.8 billion was spent on inpatient care for diabetes; two-thirds of those costs could have been saved with appropriate primary care for complications. A 2002 study estimated that diabetes—both type 1 and type 2—caused the U.S. economy \$132 billion in direct medical costs and indirect costs such as disability, work loss, and premature mortality. The disease accounts for more than 30 percent of Medicare expenditures. Total diabetes costs are predicted to climb to as much as \$192 billion per year by 2020.

Beyond the economic impact is the personal toll that diabetes exacts. Individuals with diabetes have twice the prevalence of disability as persons without diabetes. In 2002, more than 176,000 cases of permanent disability were attributed to diabetes at an estimated cost of \$7.5 billion. That same year diabetes accounted for 88 million disability days. Persons with diabetes are at greater risk for stroke, heart attack, blindness, kidney failure, limb amputation, nerve damage, severe dental disease, and complications of pregnancy. Type 1 diabetes can reduce a person's expected lifespan by as much as 15 years.

The Diabetes Control and Complications Trial (DCCT), a clinical trial of 1,441 people with type 1 diabetes, demonstrated that tight control of blood glucose through intensive insulin therapy could significantly reduce or delay many diabetic complications. This landmark finding spurred a shift in the daily management of type 1 diabetes and energized research in the field. In 1996, at the conclusion of the DCCT, it was estimated that implementation of intensive insulin management in the entire U.S. diabetic population would save 920,000 years of sight, 691,000 years free from end stage kidney disease, 678,000 years free from amputation, and 611,000 years of life.

Since the discovery of insulin more than 80 years ago, biomedical research has continued to improve the health and lives of diabetes patients. The research listed below demonstrates that the field of juvenile diabetes research is making advances worthy of a continued strong federal investment.

—*Advances in Islet Cell Transplantation.*—Since 1999, almost 600 diabetes patients worldwide have received islet transplants, and enough patients have been transplanted that long-term benefits are beginning to emerge. This procedure involves isolating the insulin-producing cells, called islet cells, from a donor pancreas, and injecting them into an adult who has juvenile diabetes. Islet cell transplants have resulted in significant benefits to people with very complicated forms of type 1 diabetes: for example, at least half of patients exhibit stabilization or reversal of their diabetic eye and nerve diseases. Overall, islet transplant patients report a significant improvement in their quality of life. Unfortunately this procedure cannot be used in children because the medications that need to be taken to prevent the body from rejecting these donated cells can have many side effects. Researchers are working to improve this procedure and to develop new techniques so that one day the procedure can be suitable for children with juvenile diabetes.

—*Treatment in new Onset Type 1 Diabetes.*—Researchers have identified a drug, a monoclonal antibody, that can effectively alter the clinical course of type 1 diabetes: a short 1–2 week course of treatment with the antibody—named anti-

CD3—helps patients maintain or increase their ability to produce insulin naturally for up to 18 months after diagnosis compared to a placebo. Treated patients required reduced insulin dosage, and better hemoglobin A1c levels. A larger phase II trial of this procedure is underway. These findings are significant because residual beta cell activity correlates with the ability to more easily maintain glucose levels close to normal, and to prevent the development of the devastating complications of diabetes. Anti-CD3 is at the leading edge of a robust pipeline of potential therapies for reversing new onset type 1 diabetes. The Type 1 Diabetes TrialNet was established in 2001 to “fast track” potential diabetes therapies into clinical trials.

- Advances in Preventing Hypoglycemia.*—Significant advances in glucose monitoring technology help patients to determine whether their blood sugars are falling (signaling the need to eat to avoid hypoglycemia) or rising (indicating the need for an insulin dose). Researchers have evidence that patients who use continuous glucose monitoring systems spend more time in the normal glucose range; a critical finding because short term variability in glucose levels may be as important as overall, long-term glucose control in predicting the risk of complications. In 2005, an NIH-funded study validated that newer-generation home blood glucose meters demonstrated a high degree of accuracy over a broad range of glucose concentrations in children with type 1 diabetes. The study was conducted by Diabetes Research in Children Network (DirecNet), a network of clinical centers that provides an independent assessment of glucose monitoring technology and its impact on the management of type 1 diabetes in children. DirecNet is now testing the new continuous glucose monitors, which will be the next wave in diabetes care and represent an essential step toward an artificial pancreas.
- Reversing of Diabetic Retinopathy.*—Diabetes is the leading cause of new blindness in working age adults. Laser treatment can reduce the risk of severe vision loss by 20 to 50 percent and saves up to \$1.6 billion per year by preventing or treating diabetic eye disease. New research has discovered anti-angiogenesis drugs that can actually reverse diabetic retinopathy, as opposed to simply halting further progression by means of laser treatment. These and other new classes of drugs make up a pipeline that must be tested in clinical trials.
- Preventing Cardiovascular Disease.*—Adults with diabetes are two to four times more likely to have a stroke or to die from heart disease than adults without diabetes. Indeed, heart disease or stroke is the leading cause of death among patients with diabetes, accounting for 65 percent of deaths in this population. Blood pressure control reduces the risk of heart attack and stroke by 33 to 50 percent and the risk of other complications by as much as 33 percent. Nevertheless, additional research is necessary to understand the factors that contribute to increased cardiovascular risk. New findings to design new diagnostic tools that predict or detect the early onset of cardiovascular disease, develop new drugs or devices to reverse cardiovascular damage due to diabetes, and clinically test new therapies in large, randomized trials.
- Slowing Onset and Progression of Kidney Disease.*—Diabetes is the leading cause of kidney failure in the United States, accounting for 44 percent of new cases in 2002. Based on NIH-funded research, scientists have made great progress in developing methods that slow the onset and progression of kidney disease in people with diabetes. Drugs used to lower blood pressure (antihypertensive drugs) can slow the progression of kidney disease significantly. Two types of drugs, angiotensin-converting enzyme (ACE) inhibitors and angiotensin receptor blockers (ARBs), have proven effective in slowing the progression of kidney disease. Drugs that lower blood pressure, including ACE inhibitors or angiotensin receptor blockers (ARBs), decrease the onset of kidney disease by 30 to 70 percent.
- Gaining an Understanding of Kidney Disease Susceptibility.*—Some diabetic patients seem to be particularly susceptible to developing diabetic nephropathy, while others show no signs of kidney damage even after many years of living with diabetes. Researchers are actively investigating the genetic factors that influence an individual’s susceptibility or resistance to diabetic nephropathy. The Genetics of Kidneys in Diabetes (GoKinD) Study has gathered more than 2,600 participants for the study of the genetic risk factors for type 1 diabetes and diabetic kidney disease. This sample and data collection will provide a resource to facilitate investigator-driven research into the genetic basis of diabetic kidney disease. Furthermore, GoKinD participants form the core of a population registry that could be recruited for future clinical trials.
- Reducing Incidence of Diabetic Neuropathy.*—Two-thirds of all diabetes patients suffer from some degree of nerve damage affecting organs throughout the body.

This condition—known as diabetic neuropathy—results in loss of sensation, weakness, or pain in hands or feet, carpal tunnel syndrome, pain in the eyes or face, pain in the chest or abdomen, profuse sweating, loss of balance or coordination, slowed digestion of food or related gastrointestinal problems, urinary incontinence, erectile dysfunction, and a variety of other nerve problems. The inability to feel pain coupled with impaired wound healing often leads to non-healing foot ulcers and, ultimately, amputation of some part of the foot or leg. For this reason, diabetic neuropathy is the most common cause of non-traumatic lower limb amputation. Comprehensive foot care programs to detect and treat skin ulcers before they progress can reduce the rate of amputation by 45 to 85 percent.

- Understanding Susceptibility to Disease.*—The Type 1 Diabetes Genetics Consortium (T1DGC) will identify the genes responsible for susceptibility to type 1 diabetes, leading to a better understanding of pathways to disease. Researchers recently confirmed the discovery of a new gene that contributes to susceptibility to disease. The pathway controlled by this gene implicates it in other autoimmune diseases, not just type 1 diabetes, underlining that common pathways may be involved in the development of autoimmunity. This understanding may lead to better diagnosis and new therapies to stop diabetes before it ever starts.
- Identifying Environmental Causes of Type 1.*—The Triggers and Environmental Determinants of Diabetes in Youth (TEDDY) study has screened more than 6,000 newborns to identify the environmental causes of type 1 diabetes in genetically susceptible individuals. Once completed, the TEDDY study will have amassed the largest data set and samples on newborns at risk autoimmunity and type 1 diabetes anywhere in the world.
- Investigating Vaccine to Prevent Type 1.*—Recent studies in animal models have raised the possibility that a “vaccine” may be able to prevent type 1 diabetes.
- Monitoring Progression of Type 1 Onset.*—Researchers have developed a means to non-invasively monitor the start and progression of insulinitis, the inflammation of insulin producing cells, in mice, which may allow researchers to predict whether and when individual people will develop type 1 diabetes in the future.
- Regenerating of Insulin Producing Cells.*—Replacement of the lost beta cells through either transplantation of islets from an external source or regeneration of islets within a patient’s own pancreas is required to restore physiological control of glucose and cure type 1 diabetes. Development of regenerative treatments to restore beta cells without transplantation will require researchers to understand how beta cells are normally formed in the adult pancreas, and then use that information to identify molecular targets for drugs that can induce that process in diabetic patients. Researchers supported by the NIH Beta Cell Biology Consortium are now uncovering multiple pathways by which new beta cells are formed in the body. The work should help clarify how pancreatic beta cells develop, and it could potentially lead to successful treatments for both type 1 and type 2 diabetes.
- Identifying Animal Models for Complication Studies.*—The Animal Models of Diabetic Complications Consortium (AMDCC) has identified more than 70 animal models for the study of diabetic complications, including a number of promising models for type 1 diabetic cardiomyopathy, nephropathy and neuropathy.

Senator SPECTER. Thank you, Dr. Goldstein.

We now turn to Dr. Lawrence Holzman, representing the NephCure Foundation.

STATEMENT OF LAWRENCE B. HOLZMAN, M.D., CHAIRMAN, SCIENTIFIC ADVISORY BOARD, NEPHCURE FOUNDATION

Dr. HOLZMAN. Mr. Chairman and members of the subcommittee: Despite advances in dialysis and kidney transplantation, kidney failure remains a devastating diagnosis, carrying a survival prognosis similar to patients diagnosed with cancer and assuring a lifetime of severe medical complications.

NIH-sponsored investigators have been really remarkably successful in advancing our understanding of kidney disease, with the goal of preserving and preventing kidney functional loss. For example, a recent revolution in our knowledge of the biology of the kidney filter has allowed the identification of several inherited dis-

eases and promises to provide tools that will better allow us to diagnose and treat kidney failure in general.

However, cutting the NIH budget for kidney disease research or even failing to keep up with inflationary costs threatens present research momentum. As an investigator and as a member of an NIH peer review committee that evaluates scientific proposals, I can assure you that the effects of a restricted NIH budget are already being felt. Threatened by a pay line at which only 12 percent of grant applications are funded, investigators are reluctant to take risks necessary to dramatically advance the field. Delays in funding outstanding proposals retard progress and result in loss of uniquely trained research personnel.

PREPARED STATEMENT

Finally, despite NIH set-asides designed to protect junior investigators, our next generation of talented young people observe the anxiety created by funding uncertainty, make rational economic decisions, and turn away from a career in biomedical science.

Therefore, we ask you to provide an increase of 5 percent in fiscal year 2007 to the NIDDK and to the NIH budget overall.

Thank you for your attention.

[The statement follows:]

PREPARED STATEMENT OF LAWRENCE HOLZMAN

Mr. Chairman, and members of the Subcommittee, thank you for giving me this opportunity to come before you today. I am Dr. Lawrence Holzman, Associate Professor of Internal Medicine and Director of the NIH-sponsored Nephrology Training Program at the University of Michigan Medical School. I also serve as Chairman of the Scientific Advisory Board of the NephCure Foundation (NCF), a non-profit organization dedicated to fighting idiopathic nephrotic syndrome and focal segmental glomerulosclerosis (FSGS).

Fifteen million Americans have significantly impaired kidney function and are at risk of losing their kidney function entirely. Another 400,000 have already lost their kidney function. Despite NIH-sponsored advances in dialysis and kidney transplantation, kidney failure—due to common diseases such as diabetic kidney disease or hypertension, or due to relatively rare diseases such as focal segmental glomerulosclerosis—remains a devastating diagnosis. Kidney failure carries a shortened survival similar to that of many cancers and assures a lifetime of severe medical complications. The American people spend nearly \$20 billion per year to provide medical care for these individuals alone. Undeniably, there remains a critical need to prevent patients from losing kidney function.

Recognizing this need, NIH-sponsored investigators have made great strides in the basic science and clinical science of kidney disease, progress that has begun to slow the incidence of kidney failure. For example, during the past decade, a revolution in our understanding of the biology of the kidney filter sparked by initial successes in molecular genetics has allowed the identification of several inherited diseases of the kidney filter and promises to provide tools that will much better guide diagnosis and treatment of the patients who are likely to lose their kidneys. Dramatic advances in our understanding of the biology of cystic diseases of the kidney such as polycystic kidney disease has led to promising clinical trials of medications that might slow or prevent these diseases. For those patients that have already lost their native kidneys to disease, NIH-sponsored research has improved our understanding of the immune system, providing hope for kidney transplant patients who suffer the dangerous side effects of present day anti-rejection medications and who suffer from the knowledge that the average kidney transplant lasts only 11 years. Moreover, dialysis patients have improved quality of life because NIH sponsored clinical research has taught nephrologists how to better care for their patients.

Cutting the NIH-budget for kidney disease research, or even failing to keep up with the inflation in costs for doing this research, immediately threatens the research momentum that was attained by doubling the NIH budget. As an independent investigator, and as member of an NIH peer review committee that evalu-

ates independent-investigator initiated scientific proposals, I can assure you that the affects of a restricted NIH budget are already being felt in a real but difficult to quantify fashion. Threatened by a “pay line” at which only 12–14 percent of grant applications are funded (rather than 24 percent just three years ago), investigators have become reluctant to take risks that must be taken in their research that would dramatically advance a field. Delays in funding outstanding proposals (because they must be recycled through the application process several times before they are funded) retard progress and result in the loss of talented and uniquely trained research personnel that cannot be readily replaced. Finally, despite NIH set asides designed to protect junior investigators, our next generation of talented young people observe the anxiety created by funding uncertainty, make rationale economic decisions, and turn away from a career in biomedical science, leaving the future of this science in jeopardy.

NIH sponsored biomedical research is an American treasure that reaps multifold benefits; it is a treasure that must be nurtured and protected. Therefore, we ask you to provide an increase of 5 percent in fiscal year 2007 for the National Institute of Diabetes, Digestive, and Kidney Diseases (NIDDK), and the NIH overall.

Thank you.

Senator SPECTER. Thank you, Dr. Holzman.

Our final witness on the panel is Dr. Steven Houser, representing the American Heart Association.

STATEMENT OF STEVEN R. HOUSER, Ph.D., DIRECTOR, CARDIOVASCULAR RESEARCH CENTER, TEMPLE UNIVERSITY SCHOOL OF MEDICINE ON BEHALF OF THE AMERICAN HEART ASSOCIATION

Dr. HOUSER. Thank you, Senator Specter and Senators Harkin and Shelby. I am an American Heart Association volunteer for the last 30 years. My day job is at a cardiovascular research group at Temple University School of Medicine in North Philadelphia. My NIH-funded research focuses on how we can fix broken hearts so that people can live healthier, happier lives.

Thanks to your investments, I believe we are on the threshold of making wonderful discoveries that can be translated into novel therapies. My lab group works on a very simple concept. We have found that in every one of your hearts there are stem cells that are making new myocytes and blood vessels all the time. I believe that we have the opportunity to figure out ways to take these cells from each of your hearts, expand them, prime them to repair your heart, and save them in case you ever need them if your heart becomes damaged.

PREPARED STATEMENT

Unfortunately, the NIH cuts are limiting my ability and the ability of my collaborators in Pennsylvania, Iowa, which I just visited last week, and Alabama, where I will visit in about a month, to pursue these ideas. It is forcing me to cut my staff, train fewer people, lay off local workers. I think this has impact not just on science and medicine, but on the economies of the communities and the States that we are charged to serve.

So thank you so much for all your hard work with respect to these issues, and I would be happy to answer any questions.

[The statement follows:]

PREPARED STATEMENT OF STEVEN R. HOUSER

SUMMARY OF RECOMMENDATIONS

Agency	Amount
National Institutes of Health	\$29,800,000,000
National Institutes of Health Heart Research	2,200,000,000
National Institutes of Health Stroke Research	357,000,000
National Heart, Lung, and Blood Institute	3,100,000,000
National Institute of Neurological Disorders and Stroke	1,600,000,000
Agency for Healthcare Research and Quality	440,000,000
Centers for Disease Control and Prevention (plus funding for pandemic influenza preparedness)	8,500,000,000
Heart Disease and Stroke Prevention Program	55,000,000
Health Resources and Services Administration: Rural and Community Access to Emergency Devices Program	8,900,000
Department of Education: Carol M. White Physical Education Program	100,000,000

An estimated 71 million American adults suffer from heart disease, stroke, and other forms of cardiovascular disease. Nearly 2,500 Americans die of cardiovascular disease each day—an average of one death every 35 seconds. Heart disease and stroke remain the first and third leading causes of death, respectively, for both men and women in the United States today and more than half of men and nearly 40 percent of women will develop cardiovascular disease during their lifetime. As the baby boom generation ages, the prevalence of cardiovascular disease will increase dramatically, because although this disease can strike at any stage of life—the likelihood increases with age. Deaths from heart disease alone are projected to increase by about 130 percent between 2000 and 2050, according to one report.

Cardiovascular disease also costs Americans an estimated \$403 billion in medical expenses and lost productivity in 2006—more than any other disease and more than the projected budget deficit for that year. As the population ages, the combination of demographics and high costs will result in a cardiovascular disease crisis with staggering implications for health care costs and quality of care.

Although progress has been made in the treatment of cardiovascular disease, there is no cure. In fact, studies suggest that increased rates of diabetes, obesity and other risk factors may reverse four decades of declining mortality. The most prudent way to address this looming crisis is to simultaneously invest in prevention and in the development of more cost-effective treatments. Regrettably, the funding levels proposed by the President undermine efforts in both of these areas.

When adjusted for biomedical research inflation, the proposed NIH budget for cardiovascular disease research is estimated to be 15 percent lower in 2007 than in fiscal year 2003. Funding levels proposed in the budget for the CDC's Heart Disease and Stroke Prevention Program remain flat at a time when only 14 states receive the resources necessary to implement prevention programs and strategies. In addition, the Rural and Community Access to Emergency Devices Program, administered by the Health Resources and Services Administration, is terminated in the President's budget. This program provides grants to rural areas and communities to purchase and place AEDs in schools, churches, fire stations, and other locations to save the lives of cardiac arrest victims.

Now is the wrong time to reduce our nation's investment in programs that prevent and treat America's leading and most costly cause of death. Solving a problem of this magnitude will require a significant public investment in these fiscally challenging times, but if we fail to take aggressive and deliberate action now—we will pay a terrible cost later—both in terms of health care expenditures and human lives. The following recommendations from the American Heart Association address this problem in a comprehensive but fiscally responsible manner.

INCREASE FUNDING FOR THE NATIONAL INSTITUTES OF HEALTH (NIH)

NIH-sponsored research has revolutionized patient care and holds the key to an eventual cure for all forms of cardiovascular disease. Research funded by the NIH also fuels innovation that generates economic growth and preserves our nation's role as a world leader in the biomedical and biotechnology industries. For fiscal year 2006, NIH funding was cut below the previous year's level for the first time in 35 years. The President preserved this cut in his fiscal year 2007 budget and reduced NIH further over the next five years by nearly 20 percent. This five year cut reduces NIH resources in inflation adjusted terms by more than one-third from its peak in fiscal year 2003—the end of the historical five-year doubling of the NIH budget.

Recommendation.—The AHA joins the research and patient advocacy community in recommending an fiscal year 2007 appropriation of \$29.8 billion for the NIH. This level, which represents a 5 percent increase over 2006, covers the increased costs of biomedical research inflation and provides additional resources to investigate emerging research opportunities.

INCREASE FUNDING FOR NIH HEART AND STROKE RESEARCH

From 1993–2003, death rates from cardiovascular diseases have fallen by 22 percent, death rates from coronary heart disease have declined by 30 percent, and death rates from stroke have fallen by 19 percent. NIH sponsored heart and stroke research has improved health outcomes and in some cases, lowered health care costs. Examples of recent NIH-supported research follow.

Aspirin Prevents Another Type of Stroke.—Aspirin is as effective as, and safer than, the blood thinning drug warfarin in preventing intracranial arterial stenosis—which accounts for roughly 10 percent of all strokes. Aspirin is a low cost therapy that does not require the intricate and costly monitoring like the drug warfarin. Researchers estimate that use of aspirin rather than warfarin could cut health care costs by \$20 million each year.

Blood Test to Screen for Stroke Wins FDA Approval.—A blood test to screen for heart disease gained approval to predict stroke risk. The test scans the blood for levels of the enzyme lipoprotein-associated phospholipase A2, which are higher in potential stroke victims.

Diuretics Again Initial Therapy for High Blood Pressure.—Continuing analyses of the Antihypertensive and Lipid-Lowering Treatment to Prevent Heart Attack Trial (ALLHAT) for diabetics, blacks and non-blacks with high blood pressure confirms, the initial conclusion that diuretics should be the initial high blood pressure treatment instead of newer, more costly drugs.

Antibiotics do not Prevent Second Cardiovascular Events.—Results of clinical trials have shown that antibiotics are ineffective in preventing second events like heart attack, unstable chest pain and stroke in patients with existing heart disease. This finding was unanticipated.

Slightly Elevated Blood Pressure Triples Heart Attack Risk.—Examining data from the Framingham Heart Study, researchers found that the 59 million Americans with prehypertension, blood pressures ranging from 120–139 over 80–89 mm Hg, are three times more likely to suffer a heart attack and nearly twice as likely to experience heart disease than those with normal blood pressure. Scientists estimate that aggressive treatment would prevent 47 percent of heart attacks.

Although cardiovascular disease is the leading cause of death in the United States, the NIH heart and stroke research budget remains disproportionately underfunded compared to the burden of these diseases on society. Cardiovascular disease meets NIH's priority setting criteria (public health needs, scientific quality of research, scientific progress potential, portfolio diversification and adequate infrastructure support), yet only 7 percent of the NIH budget is invested in heart research and a mere 1 percent is dedicated to stroke. Adjusted for medical research inflation, resources for cardiovascular research will decline 15 percent since fiscal year 2003 if the President's budget is enacted. These declining resources are insufficient to support and expand current activities and to invest in promising initiatives to aggressively advance the battle against heart disease and stroke. Additional funds would be used in the following areas:

Atherosclerosis Prevention Trial Network.—Atherosclerosis is a major risk factor for heart disease and stroke. With increased funding, the National Heart, Lung, and Blood Institute (NHLBI) could initiate a clinical trial to determine whether reducing low-density lipoprotein cholesterol, so-called "bad" cholesterol, to a level lower than currently recommended, reduces major cardiovascular disease events in healthy patients at high risk of heart disease and or stroke.

Systolic Blood Pressure Intervention Trial.—High blood pressure is a major risk factor for heart disease, heart failure and stroke. More funding would allow the NHLBI to conduct a multicenter clinical trial to determine whether reducing systolic blood pressure to a lower level than currently recommended could prevent heart attacks and strokes.

Preventing Weight Gain in Young Adults.—Young adults are at a high risk for weight gain. With more resources, NHLBI could develop and test innovative practical, cost-effective ways to prevent weight gain in young adults to prevent cardiovascular disease.

Stroke is the No. 3 killer of Americans and a major cause of permanent disability. In addition to the elderly, stroke also strikes newborns, children and young adults. An estimated 700,000 Americans will suffer a stroke this year, and nearly 158,000

will die. Many of America's 5.5 million stroke survivors face debilitating physical and mental impairment, emotional distress and huge medical costs; about 1 in 4 survivors are permanently disabled.

As a result of fiscal year 2001 Congressional report language, the National Institute of Neurological Disorders and Stroke (NINDS) convened a Stroke Progress Review Group. A report from this group provides a long-range stroke strategic plan for stroke research that includes 5 research priorities and 7 resource priorities. Multiple scientific programs initiated since the report have made impressive progress; however, additional funding is needed to implement the plan. The fiscal year 2007 estimate for NINDS stroke research falls 50 percent short of the target for implementation of that year of the plan. Additional funds would be used to conduct stroke research in the following areas:

Stroke Translational Research.—Translational studies are vital to providing cutting-edge stroke treatment and prevention. Due to budget shortfalls, the NINDS has been forced to compress its Specialized Programs of Translational Research in Acute Stroke (SPOTRIAS) from the planned 10 extramural centers to the five currently funded. SPOTRIAS researchers facilitate translation of basic research into patient care and evaluate and treat victims rapidly after the onset of stroke symptoms.

Neurological Emergencies Treatment Trials Network.—Limited resources will also force the NINDS to scale back its Neurological Emergencies Treatment Trials Network. This initiative is designed to develop a clinical research network of emergency medicine physicians, neurologists and neurosurgeons to develop more and improved treatments for acute neurological emergencies, such as stroke, through clinical trials.

Stroke Education.—As a member of the Brain Attack Coalition—a group of organizations devoted to fighting stroke—the AHA works with the NINDS to increase public awareness of stroke symptoms and the need to call 9–1–1. Together, we initiated a public education campaign, Know Stroke: Know the Signs, Act in Time, and we are striving to develop systems to make tPA available to appropriate patients. In partnership with the CDC, the NINDS extended this campaign to launch a grass-roots program called Know Stroke in the Community to enlist the aid of “Stroke Champions” who educate communities about stroke signs and symptoms. When these measures are implemented, stroke treatment will shift from supportive care to early brain-saving intervention. Additional funds are needed to educate the public and health providers about stroke.

Recommendation.—The AHA recommends an fiscal year 2007 appropriation of \$2.2 billion for NIH heart research. We advocate for an appropriation of \$3.068 billion for the NHLBI. And, we recommend \$357 million for NIH stroke research. We advocate for an appropriation of \$1.612 billion for the NINDS. These appropriations represent a 5 percent increase over fiscal year 2006—commensurate with the Association's overall recommended funding increase for the NIH.

INCREASE FUNDING AT THE CENTERS FOR DISEASE CONTROL (CDC)

Basic research must be translated into easy-to-understand guidance so that people can apply it to their daily lives. Prevention is the best way to protect Americans' health and ease the financial burden of disease. Although the clinical literature indicates that increased and improved cardiovascular disease interventions can be highly successful, investigators have concluded that well-established strategies for combating cardiovascular disease are often not being implemented. Recent studies suggest that not smoking, maintaining a healthy weight, and avoiding diabetes, high blood pressure and high cholesterol, may add 10 years to life.

The AHA commends Congress for supporting CDC's new Division for Heart Disease and Stroke Prevention, which provides funding to 33 states to create programs to educate and prevent first and second instances of heart disease and stroke. These state-tailored programs facilitate collaboration among public and private sector partners to help individuals control high blood pressure, lower elevated cholesterol, learn heart disease and stroke signs and symptoms, call 9–1–1, improve emergency response and quality of care, and eliminate treatment disparities. Many of these programs have been successful in reducing risk factors—like high blood pressure.

In fiscal year 2006, only 14 states received funding to implement these prevention programs. The remaining 19 states received funds for planning; which is now largely complete. Because cardiovascular disease remains the No. 1 killer in every state, each state needs basic implementation money for this program. However, current funding levels will not allow for the expansion of this program.

Recommendation.—For fiscal year 2007, the AHA recommends an appropriation of \$8.5 billion plus funding for pandemic influenza preparedness for the CDC, including a 10 percent increase over current funding to return chronic disease preven-

tion to the same level as fiscal year 2002. Within that total, we recommend \$55 million to expand the Heart Disease and Stroke Prevention Program. This funding level would allow the CDC to add up to 4 states to the program, allowing them to conduct a state-tailored plan, and elevate 4 more states from planning to program implementation, maintain the Paul Coverdell National Acute Stroke Registry, and start the development of a state-based cardiac arrest registry.

RESTORE FUNDING FOR THE RURAL AND COMMUNITY ACCESS TO EMERGENCY DEVICES PROGRAM

The Rural and Community Access to Emergency Devices Program provides grants to states to train lay rescuers and first responders to use AEDs and buy and place them where cardiac arrests are likely to occur. During the first year of the program, 6,400 AEDs were purchased and 38,800 individuals were trained. AEDs have been placed in schools, faith-based and recreation facilities, nursing homes, and other locations in communities across our nation.

About 94 percent of cardiac arrest victims die outside of a hospital. Immediate CPR and early defibrillation using an automated external defibrillator (AED) can more than double a victim's chance of survival. Small, easy-to-use AEDs can shock the heart back into normal rhythm. Placing AEDs in more public settings could save thousands of lives each year. Communities with comprehensive AED programs that include training of anticipated rescuers have achieved survival rates of 40 percent or higher.

The Rural and Community Access to Emergency Devices Program is terminated in the President's fiscal year 2007 budget. The budget justification asserts that much of the demand for AEDs has been met, although between fiscal year 2002 and fiscal year 2004 less than half of the grant dollars requested by states for this life-saving program were actually awarded.

Recommendation.—For fiscal year 2007, the AHA recommends that the Subcommittee allocate \$8.927 million for HRSA's Rural and Community Access to Emergency Devices Program to restore funding to its fiscal year 2005 level.

INCREASE FUNDING FOR THE AGENCY FOR HEALTHCARE RESEARCH AND QUALITY (AHRQ)

The AHRQ is a critical partner with the public and private health care sectors. This agency helps develop evidence-based information needed by consumers, providers, health plans and policymakers to improve health care decision making. Through its Effective Health Care Program, AHRQ supports research focusing on outcomes, comparative clinical effectiveness, and appropriateness of pharmaceuticals, devices and healthcare services for a number of conditions, including ischemic heart disease, stroke, and high blood pressure. The new research and comparative effectiveness reviews conducted and funded under this program will help address issues raised in the Institute of Medicine's (IOM) report: *Crossing the Quality Chasm*.

The AHRQ's initiative on health information technology (HIT) is a key element to the nation's strategy to bring health care into the 21st century. This initiative includes more than \$166 million in grants, and through these and other projects, AHRQ and its partners will help to identify challenges to HIT adoption and use, solutions and best practices, and tools that will help hospitals and clinicians successfully incorporate new HIT. To facilitate this effort, the AHRQ's National Resource Center for HIT provides the health care community with technical assistance and consulting services to HIT projects, and particularly focus on addressing challenges to HIT implementation in rural and small community settings.

Recommendation.—The AHA joins with the Friends of AHRQ in advocating for an appropriation of \$440 million for the AHRQ to advance health care quality, cut medical errors and expand the availability of health outcomes information.

INCREASE FUNDING FOR THE CAROL M. WHITE PHYSICAL EDUCATION PROGRAM (PEP)

Physical inactivity is a key risk factor for heart disease and stroke, but Youth Risk Behavior Surveillance data indicates that almost half of 12–21 year olds do not participate in any vigorous physical activity on a regular basis. Despite recent studies by Action for Healthy Kids and the Robert Wood Johnson Foundation showing that almost 80 percent of parents support daily physical education (PE) in schools to help combat physical inactivity and teach life long skills, only 6–8 percent of schools nationally offer daily PE. One of the primary barriers to providing PE is adequate financial resources for equipment, program development, and staff training. The Carol M. White Physical Education Program helps schools overcome this barrier by providing money for school-based physical education activities that teach

life-long physical activity habits. PEP is the only federal program that directly supports PE in schools.

Recommendation.—For fiscal year 2007, the AHA recommends an appropriation of \$100 million for the Carol M. White Physical Education Program. This level of funding will allow the Department of Education to expand the program to more districts while maintaining funding for the duration of previously awarded grants.

Although heart disease, stroke, and other cardiovascular disease are largely preventable, these diseases continue to exact a deadly toll on our nation. As baby boomers age, our nation faces an expanding cardiovascular disease crisis unless significant steps are taken. We urge the subcommittee to consider these recommendations for the fiscal year 2007 budget. Adequate funding of research, treatment and prevention programs will save lives and reduce rising health care costs.

Senator SPECTER. Thank you very much, Dr. Houser.

Senator Harkin, do you have any comment or question?

Senator HARKIN. Just one. I have a lot of questions for the panel, but just one that I just want to ask Dr. Goldstein. Give us just a few seconds on your view on the potential of stem cell, embryonic stem cell research to benefit juvenile diabetes, type 1 diabetes?

Dr. GOLDSTEIN. We are extremely bullish, Senator Harkin, on the potential to create insulin-secreting cells that are fully functional and respond to glucose. Work has already carried the human embryonic stem cell work to the point of producing endoderm, which is the tissue that then can create the pancreas. Investigators in animal studies can instruct endoderm to make pancreas. If we can make pancreas, that will give us the precursor cells for beta cells and insulin-secreting cells.

So we are extremely, extremely optimistic and wish the work could go forward with full speed.

Senator HARKIN. Thank you.

Senator SPECTER. Senator Shelby, any comment or question?

Senator SHELBY. Yes.

Is anyone on the panel dealing in the autoimmune area, especially dealing with lupus or lupus-related? Dr. Holzman, do you want to comment on where we are going? You heard the first panel earlier.

Dr. HOLZMAN. Actually, in this regard I am more the clinician dealing with patients on the front lines.

Senator SHELBY. That is very important, the clinical work.

Dr. HOLZMAN. I am a nephrologist, a person who deals with kidney disease, and see many of the most complicated patients with lupus and kidney disease. I can tell you first that these are patients who suffer dramatically, that their lives are spent worrying about not only dealing with the current flare, the current problem, but the probability that the disease will recur.

I should say that, thanks to big investments by the NIH in clinical trials, there actually have been some new drugs, drugs that have actually been around for a while but now are proven safer and actually as effective as earlier, more dangerous drugs, such as cyclophosphamide. We are now using microphenalate moftil as a first-line drug for kidney lupus and with I think fairly good success.

Senator SHELBY. So you see a lot of hope there?

Dr. HOLZMAN. I see a lot of hope there. I think that we need to further invest using the latest technology and translational studies in this area.

Senator SHELBY. Thank you.

Thank you, Mr. Chairman.

Senator SPECTER. Thank you, Senator Shelby.

Thank you very much, ladies and gentlemen.

Senator SHELBY. I think Dr. Goldstein was going to say something.

Dr. GOLDSTEIN. Real quickly, Senator Shelby. I would just like to repeat something that Dr. Fauci said: the support of the Immune Tolerance Network, which is a clinical trial translation platform for autoimmune diseases, including lupus, type 1 diabetes, and others. We learn from each other, from the science. Choking that funding off is going to eliminate the possibility to do those cutting edge clinical trials.

Senator SHELBY. Thank you.

Thank you.

Senator SPECTER. Thank you very much, ladies and gentlemen. We very much appreciate your coming in.

We now turn to panel three: Dr. Daniel Koo, Dr. Phil Landrigan, Mr. Emeran Mayer, Dr. Peter McDonnell, Ms. Sandra Raymond, Mr. Herman Taylor, Ms. Suzanne Vogel-Scibilia.

Our first witness is Dr. Daniel Koo, represent the Deaf and Hard of Hearing Alliance, and Dr. Koo is accompanied by an interpreter. Dr. Koo, we begin with you.

STATEMENT OF DANIEL KOO, M.D., ON BEHALF OF THE DEAF AND HARD OF HEARING ALLIANCE

Dr. KOO [speaks through a sign language interpreter]. Mr. Chairman, members of the Subcommittee of Senate Appropriations: On behalf of the member organizations of the Deaf and Hard of Hearing Alliance—

Senator HARKIN. Excuse me. Could you speak into that just a little bit louder. I am having a hard time.

Senator SPECTER. Senator Thurmond always would say: Bring the machine a little closer.

Dr. KOO. Mr. Chairman and members of the Senate Appropriations Subcommittee: On behalf of the member organizations of the Deaf and Hard of Hearing Alliance, a coalition of professional and consumer organizations serving and representing people who are deaf and hard of hearing, it is my pleasure to be here with you this morning to discuss the President's budget request for NIH's National Institute on Deafness and Other Communication Disorders.

My name is Dr. Koo. I am a postdoctoral fellow at Georgetown University conducting neuroimaging studies on language and literacy, supported by NIDCD.

Fiscal year 2007's budget request for NIDCD is \$1.9 million less compared to the fiscal year 2006 appropriation. The DHHA strongly urges Congress not to impose further cuts in NIH or NIDCD research funding and that Congress and the administration work together to ensure appropriate funding that does not compromise current and future research efforts. The DHHA applauds current research being conducted related to people who are deaf and hard of hearing, specifically the strategies to protect hearing, diagnose and prevent hearing loss, and explore genetic modifiers.

However, we urge the NIDCD to continue to pursue and support studies that delve into the acquisition and learning of oral and-or

visual languages, the various communication modes and educational settings.

Cutting the funding most assuredly will prevent the expansion of research in this critical area of need. Funding support for NIDCD to date has allowed many scientists, like myself, to make significant advances in hearing research as well as related sensory and cognitive areas. With congressional support, the NIDCD can continue its important research that aids in preventing hearing loss as well as assisting those who are deaf or hard of hearing.

PREPARED STATEMENT

With hearing loss expected to reach 40 million Americans within the next generation, scientific work taking place at NIH and NIDCD is too critical to the human condition to take a step backward at this time.

Thank you.

[The statement follows:]

PREPARED STATEMENT OF DANIEL KOO

On behalf of the member organizations of the Deaf and Hard of Hearing Alliance, a coalition of professional and consumer organizations serving and representing people who are deaf or hard of hearing, it is my pleasure to be here with you this morning to discuss the President's budget request for the National Institutes of Health, specifically the National Institute on Deafness and Other Communication Disorders (NIDCD).

My name is Daniel Koo. I am a post-doctoral fellow at Georgetown University conducting neuron-imaging studies on language and literacy supported by NIDCD.

The fiscal year 2007 budget request for NIDCD is \$391,556,000, a decrease of \$1,902,000 compared to the fiscal year 2006 Appropriation. The DHHA strongly urges Congress not to impose further cuts in NIH or NIDCD research funding, and we ask that Congress and the Administration work together to ensure appropriate funding to ensure that current and future research efforts are not compromised. With hearing loss expected to affect 40 million within one generation, there has never been a time when research has been needed so much.

The DHHA applauds the current research being conducted related to people who are deaf or hard of hearing, specifically the strategies to protect hearing, diagnose and prevent hearing loss, and explore genetic modifiers. However, we urge NIDCD to continue to pursue and support studies that delve into the acquisition and learning of oral and/or visual languages the necessary precursor to a variety of communication modes and settings. Cutting the funding will most assuredly prevent the expansion of research in this critical area of need.

Funding support for NIDCD to date has allowed many scientists like myself to make significant advances in hearing research, as well as related sensory and cognitive areas that impact the human condition. With Congressional support the NIDCD can continue its important research that aids in preventing hearing loss as well as assisting those who are deaf or hard of hearing. The work taking place at NIH and NIDCD is too critical to the human condition to take a step backward at this time.

Members of the Deaf and Hard of Hearing Alliance include: Alexander Graham Bell, Association for the Deaf & Hard of Hearing, American Academy of Audiology, American Academy of Otolaryngology-Head and Neck Surgery, American Speech-Language-Hearing Association, Conference of Educational Administrators of Schools & Programs for the Deaf, Council of American Instructors of the Deaf, Cued Language Network of America, Deafness Research Foundation, Hearing Loss Association of America, Media Access Group at WGBH, National Association of the Deaf, National Cued Speech Association, Registry of Interpreters for the Deaf, Testing, Evaluation, and Certification Unit, and Telecommunications for the Deaf, Inc.

Senator SPECTER. Thank you very much, Dr. Koo.

We now turn to Dr. Philip Landrigan, representing the Campaign for American Children's Health. Dr. Landrigan.

**STATEMENT OF PHILIP J. LANDRIGAN, M.D., MSc, FAAP, PRESIDENT,
CAMPAIGN FOR AMERICAN CHILDREN'S HEALTH**

Dr. LANDRIGAN. Good morning, Senator Specter, Senator Harkin, Senator Shelby. I'm Philip Landrigan, pediatrician at Mount Sinai Medical School in New York City, and I thank you for inviting me here this morning to come to speak in support of the National Children's Study.

I'd like first of all to thank all of you for the great support that you've given the National Children's Study over the past 6 years since its inception in 2000, and thanks most particularly for the discussion that you had in support of the study just a few minutes ago this morning.

The reason that this Nation needs the National Children's Study is that the children's study will give us information on the preventable environmental causes of the major diseases that afflict American children today—asthma, which has more than doubled; childhood brain cancer has gone up 40 percent; autism, you heard a few minutes ago has gone up remarkably; other learning disabilities.

It's been said that the study is expensive and it is. But the diseases, the chronic diseases that the study will address, cost this Nation more than \$600 billion a year. The very same logic that Dr. Zerhouni invoked this morning when he spoke of the great declines that have been achieved in heart disease because of the Framingham study, the women's health initiative, that same logic applies to the National Children's Study, and it's ironic that I chose to include the same image in my testimony as he used in his screen presentation this morning.

PREPARED STATEMENT

If we fail to fund the National Children's Study it will be a major opportunity lost. The National Children's Study is our generation's best hope, indeed probably our only hope, to get on top of the chronic diseases in America's children.

I thank you.

[The statement follows:]

PREPARED STATEMENT OF PHILIP J. LANDRIGAN

Good morning, Mr. Chairman and Members of the Subcommittee. I am Dr. Philip J. Landrigan. I am a pediatrician, Professor and Chairman of Community & Preventive Medicine, and Professor of Pediatrics at the Mount Sinai School of Medicine. I am Principal Investigator for the Queens, New York Vanguard Center of the National Children's Study. I am also President of the Campaign for American Children's Health, a not-for-profit organization committed to preserving the health of America's children by sustaining the National Children's Study.

Why Do We Need the National Children's Study? The United States needs the National Children's Study because we desperately need the information the Study will provide on preventable causes of the major diseases that confront America's children today. Information from the National Children's Study will provide a blueprint for prevention. The diseases of greatest current concern in American children are:

- Asthma, which has more than doubled in frequency since 1980 and become the leading cause of pediatric hospitalization and school absenteeism;
- Birth defects, which are now the leading cause of infant death. Certain birth defects, such as hypospadias, have doubled in frequency;
- Neurodevelopmental disorders—autism, dyslexia, mental retardation, and attention deficit/hyperactivity disorder (ADHD). These conditions affect 5–10 percent of the 4 million babies born each year in the United States. Reported rates of autism are increasing especially sharply—more than 20 percent per year;

- Leukemia and brain cancer in children and testicular cancer in adolescents. Incidence rates of these malignancies have increased since the 1970s, despite declining rates of mortality. Testicular cancer has risen by 55 percent, and primary brain cancer by 40 percent. Cancer is now the second leading cause of death in American children, surpassed only by traumatic injuries;
- Preterm birth, which has increased in incidence by 27 percent since 1981;
- Obesity and its consequence, type 2 diabetes. Obesity has trebled in prevalence in the United States. Obesity has become common in even the youngest of our children, and for example, 41 percent of 5-year-olds entering kindergarten in the five boroughs of New York City in 2005 were overweight or frankly obese. The future toll of disease and premature death in these youngsters—from diabetes, heart disease, stroke and probably cancer—will be fearsome.

We have a responsibility to safeguard our children. They are the most vulnerable among us, our most precious resource, and the hope for our future. But these rapidly rising rates of chronic disease threaten the health of our children and the future security of our nation.

Indeed, concern is strong among the pediatric community that these rapidly rising rates of disease may create a situation unprecedented in the 200 years of our nation's history, in which our current generation of children may be the first American children ever not to enjoy a longer life span than the generation before them. In other words, if we do not support the necessary research—especially the National Children's Study—and if we fail to take needed preventive action, we are actually at risk of losing hard-won ground in children's health.

What is the National Children's Study?—The National Children's Study is a prospective multi-year epidemiological study that will follow 100,000 American children, a nationally representative sample of all children born in the United States, from conception to age 21. The study will assess and evaluate the environmental exposures these children experience in the womb, in their homes, in their schools and in their communities. It will seek associations between environmental exposures and disease in children. The diseases of interest include all those listed above. The principal goal of the Study is to identify the preventable environmental causes of pediatric disease and to translate those findings into preventive action and improved health care.

The National Children's Study was mandated by Congress through the Children's Health Act of 2000. The lead federal agency principally responsible for the Study is the National Institute of Child Health and Human Development. Other participating agencies include the National Institute of Environmental Health Sciences, the Environmental Protection Agency, and the Centers for Disease Control and Prevention.

By working with pregnant women and couples, the Study will gather an unprecedented volume of high-quality data on how environmental factors acting either alone, or in combination with genetic factors, affect the health of infants and children. Examining a wide range of environmental factors—from air, water, and dust to what children eat and how often they see a doctor—the Study will help develop prevention strategies and cures for a wide range of childhood diseases. By collecting data nationwide the study can test theories and generate hypotheses that will inform biomedical research and the care of young patients for years to come. Simply put, this seminal effort will provide the foundation for children's healthcare in the 21st Century.

The Unique Strengths of the National Children's Study.—Six aspects of the architecture of the National Children's Study make it a uniquely powerful tool for protecting the health of America's children:

1. *The National Children's Study is prospective in its Design.*—The great strength of the prospective study design is that it permits unbiased assessment of children's exposures in real time as they actually occur, months or years before the onset of disease or dysfunction. Most previous studies have been forced to rely on inherently inaccurate retrospective reconstructions of past exposures in children who were already affected with disease. The prospective design obviates the need for recall. It is especially crucial for studies that require assessments of fetal and infant exposures, because these early exposures are typically very transitory and will be missed unless they are captured as they occur.

2. *The National Children's Study Will Employ the Very Latest Tools of Molecular Epidemiology.*—Molecular epidemiology is a cutting-edge approach to population studies that incorporates highly specific biological markers of exposure, of individual susceptibility and of the precursor states of disease. Especially when it is embedded in a prospective study, molecular epidemiology is an extremely powerful instrument for assessing interactions between exposures and disease at the level of the individual child.

3. *The National Children's Study Will Incorporate State-of-the-Art Analyses of Gene-Environment Interactions.*—Recognition is now widespread that gene-environment interactions are powerful determinants of disease in children. These interactions between the human genome and the environment start early in life, affect the health of our children, and set the stage for adult disorders. The heroic work of decoding the human genome has shown that only about 10–20 percent of disease in children is purely the result of genetic inheritance. The rest is the consequence of interplay between environmental exposures and genetically determined variations in individual susceptibility. Moreover, genetic inheritance by itself cannot account for the sharp recent increases that we have seen in incidence of pediatric disease.

4. *The National Children's Study Will Examine a Nationally Representative Sample of American Children.*—Because the 100,000 children to be enrolled in the Study will be statistically representative of all babies born in the United States during the five years of recruitment, findings from the Study can be directly extrapolated to the entire American population. We will not need to contend with enrollment that is skewed by geography, by socioeconomic status, by the occurrence of disease or by other factors that could blunt our ability to assess the links between environment and disease.

5. *Environmental Analyses in the National Children's Study will be conducted at the Centers for Disease Control and Prevention.*—The CDC laboratories in Atlanta are the premier laboratories in this nation and the world for environmental analysis. Because the testing will be done at CDC it will be the best available, and the results will be unimpeachable.

6. *Samples Collected in the National Children's Study Will be Stored Securely and Will be Available for Analysis in the Future.*—New tests and new hypotheses will undoubtedly arise in the years ahead. Previously unsuspected connections will be discovered between the environment, the human genome and disease in children. The stored specimens so painstakingly collected in the National Children's Study will be available for these future analyses.

The Current State of the National Children's Study.—Congress has already laid a firm foundation for the National Children's Study. Between 2000 and 2005, the Congress invested more than \$55 million to design the study and begin building the nationwide network necessary for its implementation.

Seven Vanguard Centers and a Coordinating Center were designated in 2005 at sites across the nation—in Pennsylvania, New York, North Carolina, Wisconsin, Minnesota, South Dakota, Utah and California—to test the necessary research guidelines—with plans to expand the program to 38 states and 105 communities nationwide.

The tough job of designing and organizing is nearly complete. Funding for the Study this year will permit researchers to begin achieving the results that will make fundamental improvements in the health of America's children.

To abandon the Study at this point would mean forgoing all of that dedication, all of that incredible effort, and all of the logistical preparation.

The Study Will More Than Pay for Itself.—The National Children's Study will yield benefits that far outweigh its cost. It will be an extraordinarily worthwhile investment for our nation, and it can be justified even in a time of fiscal stress such as we face today.

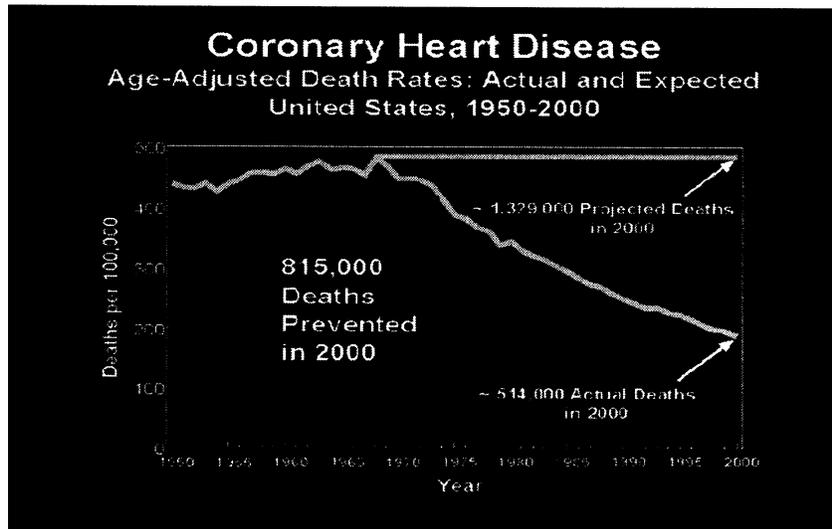
Six of the diseases that are the focus of the Study (obesity, injury, asthma, diabetes, autism and schizophrenia) cost America \$642 billion each year. If the Study were to produce even a 1 percent reduction in the cost of these diseases, it would save \$6.4 billion annually, 50 times the average yearly costs of the Study itself.

But in actuality, the benefits of the National Children's study will likely be far greater than a mere 1 percent reduction in the incidence of disease in children. The Framingham Heart Study, upon which the National Children's Study is modeled, is the prototype for longitudinal medical studies and the benefits that it has yielded have been enormous.

The Framingham Study was launched in 1948, at a time when rates of heart disease and stroke in American men were skyrocketing, and the causes of those increases were poorly understood. The Framingham Study used path-breaking methods to identify risk factors for heart disease. It identified cigarette smoking, hypertension, diabetes, elevated cholesterol and elevated triglyceride levels as powerful risk factors for cardiovascular disease. These findings contributed powerfully to the 42 percent reduction in mortality rates from cardiovascular disease that we have achieved in this country over the past 5 decades (see Figure, next page).

The data from Framingham have saved millions of lives—and billions of dollars in health care costs. The National Children's Study, which will focus on multiple childhood disorders, could be even more valuable.

The Health Benefits of the Framingham Heart Study



The National Children's Study will Yield Benefits in the Near-Term Future.—We do not need to wait 21 years for benefits to materialize from the National Children's Study. Valuable information will become available in a few years' time, as soon as the first babies in the Study are born.

Consider, for example, data on premature births. The rate of U.S. premature births in 2003 was 12.3 percent, far higher than the 7 percent rate in most western European countries. Hospital costs associated with a premature birth average \$79,000, over 50 times more than the average \$1,500 cost for a term birth. Just a 5 percent reduction in rates of prematurity would cut hospital costs by \$1.6 billion annually. Within just two years, that savings would match the full cost of the Study.

The Study Enjoys Broad Support.—The Study enjoys a broad group of supporters, including The American Academy of Pediatrics; Easter Seals; the March of Dimes; the National Hispanic Medical Association; the National Association of County and City Health Officials; the National Rural Health Association; the Association of Women's Health, Obstetric and Neonatal Nurses; United Cerebral Palsy; the Spina Bifida Association of America; and the United States Conference of Catholic Bishops, just to name a few. This broad and diverse group recognizes the overwhelming benefits this Study will produce for America's children.

Congress Should Fully Fund the National Children's Study.—Congress first authorized the National Children's Study in 2000, and has appropriated \$55 million since then to design the Study, complete preparatory research, and designate the seven Vanguard sites that will conduct preliminary testing.

This has been a wise investment that should not be abandoned just as the Study is about to bear fruit. Unfortunately, the Administration has not provided continued funding in the fiscal year 2007 budget, a decision which threatens to squander the investment already made and to throw away the multi-generational benefits the Study will yield.

Funding for the Study this year requires a commitment of \$69 million. These funds will be used to begin enrolling children in the study. They will enable the NIH to continue establishing the 105 study sites around the country. We urge Congress to fully fund the National Children's Study. It is an investment in our children—and in America's future.

The National Children's Study will give our nation the ability to understand the causes of chronic disease that cause so much suffering and death in our children. It will give us the information that we need on the environmental risk factors and the gene-environment interactions that are responsible for rising rates of morbidity

and mortality. It will provide a blueprint for the prevention of disease and for the enhancement of the health in America's children today and in the future. It will be our legacy to the generations yet unborn.

Thank you. I shall be pleased to answer your questions.

Senator SPECTER. Thank you very much, Dr. Landrigan.

We now turn to Dr. Emeran Mayer, representing the Digestive Disease National Coalition. Dr. Mayer.

STATEMENT OF EMERAN A. MAYER, M.D., ON BEHALF OF THE DIGESTIVE DISEASE NATIONAL COALITION

Dr. MAYER. Thank you, Senators Specter, Harkin, and Shelby, for this opportunity. I'm here on behalf of the Digestive Disease National Coalition, representing the International Foundation for Functional Gastrointestinal Disorders. I'm a gastroenterologist and director of an NIH-funded research center at UCLA dedicated to the study of functional gastrointestinal disorders.

These disorders, specifically irritable bowel syndrome, or IBS, are the most common GI disorders in society. They're characterized by chronic abdominal pain and discomfort and affect women disproportionately. IBS's health care costs are \$2 billion annually and exceed \$20 billion when indirect costs are included. Yet the cause of this disorder remains incompletely understood.

During the past 10 years, NIDDK has helped advance biomedical research in the field, bringing us within reach for the first time of several IBS treatments with great potential. The NIDDK is embarking on a strategic planning process for digestive diseases in which IBS will be a critical component. This is essential to advance our understanding, improve treatments, and recruit new investigators for the disease.

The President's proposed cuts to NIH will have a detrimental impact on research advancements in digestive diseases and specifically in IBS. Such cuts would slow our understanding of pathophysiological mechanisms and effective treatments, slow or eliminate pivotal clinical trials, and prevent the pharmaceutical industry to develop new treatments, and most importantly reduce the number of established investigators and send a shock wave to young investigators considering entering into this field.

PREPARED STATEMENT

It is therefore essential to continue our investment into these programs that hold such promise at this point. I urge you therefore to prevent the proposed NIH budget cuts and to prevent the likely unraveling of all the progress that has been made during the past decade.

Thank you for the opportunity to testify.

[The statement follows:]

PREPARED STATEMENT OF EMERAN A. MAYER

Chairman Specter and members of the Subcommittee, thank you for the opportunity to present testimony before you today on the effect that the President's fiscal year 2007 budget for the National Institutes of Health (NIH) will have on functional gastrointestinal and motility disorders research. My name is Dr. Emeran A. Mayer and I am here today representing the International Foundation for Functional Gastrointestinal Disorders' (IFFGD) Board of Directors and the IFFGD Advisory Board on behalf of the Digestive Disease National Coalition (DDNC). I am the Director of the UCLA Center for Neurovisceral Sciences & Women's Health (CNS), a

translational research program recently funded by the NIH that is currently viewed as the leading integrated research program in the world in the area of functional digestive disorders.

Functional gastrointestinal disorders, specifically irritable bowel syndrome or IBS, and motility disorders are the most common gastrointestinal disorders experienced in society and are present in about 25 percent of the U.S. population. The impact on the healthcare system and society in general is substantial. These disorders comprise about 40 percent of gastrointestinal problems for which patients seek health care and the frequency of work absenteeism as a result of these disorders is second only to the common cold. IBS health care costs to society are \$2 billion annually and exceed \$19 billion when indirect factors such as loss of work and productivity are considered. Although the cause of IBS is incompletely understood, we do know that this disorder needs a multidisciplinary approach in research and often treatment, in order to help the millions of patients suffering across the country.

New knowledge on the mechanisms of these disorders, in particular in terms of dysregulation of the elaborate interactions between the nervous system and the digestive system, has resulted in neurophysiological and neuropharmacological investigations which have the potential to produce new pharmaceutical agents as well as disease management programs for treatment of these disorders.

The National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK) has been supporting research into the basic and translational mechanisms of functional GI disorders including IBS, in terms of individual research grants (R-01), career development grants to young investigators (K awards), and major support of two research centers, including our own at UCLA. These efforts during the past 10 years have been essential in advancing biomedical research in the field and, for the first time, bringing us within reach of several novel pharmacological treatments with great potential for IBS. The NIDDK is in the process of embarking on a strategic planning process for digestive diseases, and IBS will be a critical component of this plan. Strategic planning is essential to advancing our understanding of this disease, determining improved treatment options for IBS sufferers, and assisting in the recruitment of new investigators to conduct IBS research.

Cutting the budget for the NIH, as is proposed in the President's fiscal year 2007 budget, will have a detrimental impact on the research advancements in this important disease area that have been accomplished during the past several years. Specifically, such cuts would have an immediate impact in the following areas:

- It will slow the elucidation of pathophysiological mechanisms and identification of novel targets, which will have a ripple effect on drug development by the pharmaceutical industry. There will be no new drug development without NIH funded basic and translational research.
- It will slow or eliminate the execution of pivotal clinical trials of novel treatments for IBS.
- Most importantly, it will slow strategic planning and reduce the number of young investigators dedicated to the field by starting an exodus of such individuals into jobs in the pharmaceutical industry and private practice. Such a reduction in the research base will take years to undo.

Biomedical research, sponsored by the NIH, has advanced our understanding of countless diseases and disorders. It is important to continue our investment in these vital programs that hold such promise for our nation's future. Therefore, we ask you to provide an increase of 5 percent in fiscal year 2007 for the National Institute of Diabetes and Digestive and Kidney Diseases and for the NIH overall.

Senator SPECTER. Thank you, Dr. Mayer.

Our next witness is Dr. Peter McDonnell, representing the National Alliance for Eye and Vision Research. Dr. McDonnell.

STATEMENT OF PETER McDONNELL, M.D., ON BEHALF OF THE NATIONAL ALLIANCE FOR EYE AND VISION RESEARCH

Dr. McDONNELL. Thank you, Chairman Specter, Senator Harkin, Senator Shelby.

The President's proposed fiscal year 2007 budget would cut National Eye Institute funding by 0.8 percent, or \$5.3 million. This will have a significant detrimental impact on the entire NEI research portfolio, especially research programs into age-related macular degeneration, AMD. As Dr. Zerhouni mentioned this

morning, this is the leading cause of blindness now in the United States. It robs our seniors of their independence.

I offer three examples. The NEI has identified variants of a gene associated with the body's inflammatory response responsible for 50 percent of the risk of developing AMD. Without adequate funding, NEI will not be able to develop diagnostics for early detection of at-risk individuals and conduct clinical studies with promising therapies, as well as study the impact of the inflammatory response and other degenerative eye diseases.

The NEI has demonstrated that dietary zinc and anti-oxidant vitamins actually reduce vision loss in individuals at risk of developing AMD. Without adequate funding, NEI will not be able to proceed with follow-up clinical studies to identify additional dietary supplements used singly or in combination to demonstrate even greater protective effects against progression to advanced disease.

NEI's research has resulted in the first generation of FDA-approved drugs to treat abnormal blood vessel growth in the wet form of AMD, halting further vision loss. NEI's ability to conduct clinical studies of these therapies in patients with macular edema associated with diabetes and diabetic retinopathy would also be jeopardized.

Thank you, Mr. Chairman, and we appreciate the subcommittee's efforts to increase NIH and NEI funding in the fiscal year 2007 budget.

Senator SPECTER. Thank you very much, Dr. McDonnell.

We now turn to Ms. Sandra Raymond, representing the Lupus Foundation of America.

STATEMENT OF SANDRA RAYMOND, ON BEHALF OF THE LUPUS FOUNDATION OF AMERICA

Ms. RAYMOND. Good morning, Mr. Chairman, Senator Harkin, Senator Shelby.

Lupus is the prototypical autoimmune disease, so an investment in lupus research may in fact produce answers to many other autoimmune diseases affecting more than 23 million Americans. In recent years, NIH has had funded studies that give us great hope that we are on the brink of major breakthroughs in lupus research.

For example, one study, an adult stem cell transplantation study, is carried out on only the most severely ill of lupus patients, for whom all other treatments have failed. Fifty percent of these patients having the procedure had disease-free survival for 5 years.

In another NIH-funded study, researchers identified a gene that plays a role in one of the immune system pathways meant to fight infection. In people with lupus, this pathway turns on, but never turns off.

Mr. Chairman, should NIH appropriations be curtailed there may not be a future generation of scientists to do lupus research. Already the hint that funding may be reduced has caused leaders in our field to consider better funded areas. Cuts in NIH funding could bring to a standstill support of clinical trials and large observational studies in lupus and could limit research on those at highest risk for lupus, women of color.

PREPARED STATEMENT

NIH-funded research currently in progress will lead to new and improved treatments for lupus. There has not been a new FDA-approved drug for lupus in almost 40 years and the drugs that our patients are currently taking are very harsh chemotherapies, chemotherapies in lupus as well as in cancer.

Thank you.

[The statement follows:]

PREPARED STATEMENT OF THE LUPUS FOUNDATION OF AMERICA, INC.

I am Dr. Michael Madaio, Chief of Nephrology, Professor of Medicine, Temple University School of Medicine and a lupus researcher. The Lupus Foundation of America, Inc. (LFA) appreciates the opportunity to submit written comments for the record regarding funding for lupus related programs for fiscal year 2007. The LFA is the nation's leading non-profit voluntary health organization dedicated to improving the diagnosis and treatment of lupus, supporting individuals and families affected by the disease, increasing awareness of lupus among health professionals and the public, and finding the causes and cure. As you may know, lupus is a debilitating, chronic autoimmune disease that causes inflammation and tissue damage to virtually any organ system; it can cause significant disability or even death. Lupus is the prototypical autoimmune disease; therefore, finding answers to questions about lupus may also provide understanding about other autoimmune diseases that affect 22 million Americans. The leaders and members of the LFA and the 1.5 to 2 million people suffering from lupus respectfully request for fiscal year 2007 \$29.7 billion for the National Institutes of Health (NIH) to support lupus research. Specifically, we urge Congress to direct NIH to support and bolster lupus research across all relevant institutes, centers, and offices.

I have been funded for lupus research for over 20 years. I am proud to be affiliated with the Lupus Foundation of America as a member of the Medical Scientific Advisory Board and Chairman of the Medical Advisory Board for the Southeastern Pennsylvania Chapter of the LFA. While I am a nephrologist, since my research and clinical practice is focused on lupus, I really work day-to-day within the realms of nephrology and rheumatology as well as other medical specialties and subspecialty areas. I understand the importance of biomedical research funding and the impact that federal research funding has had, does have, and can have on the lives of the 1.5 million people living with lupus and the 22 million Americans with other autoimmune diseases.

After a tragic 40 year dearth of new treatments to manage this often debilitating and devastating disease, the good news is that we finally are on the brink of major breakthroughs, thanks to research sponsored by the National Institutes of Health. Exciting research and strides in treatments for people with lupus are on the horizon and a sustained investment now in lupus research will speed the day to better treatments and a cure. One exciting study, adult stem cell transplantation, was carried out on only the most severely ill of lupus patients for whom all other treatments have failed. Fifty percent of the patients having the procedure had disease free survival at 5 years. In another NIH funded study researchers identified a gene that plays a role in one of the immune system pathways meant to fight infection. In people with lupus this pathway turns on and never turns off. These findings and others will lead to effective ways of treating lupus and other autoimmune diseases affecting 23 million Americans.

Specifically, I am conducting extensive research on lupus nephritis, which is kidney involvement in lupus disease. My field is advancing rapidly, due in large part to factors directly dependent on NIH funding:

- the burgeoning growth in the number of new animal models, including a wealth of informative transgenic and gene-targeted mutants;
- increased access to improved powerful technologies such as gene and protein arrays, now available at many institutions and to many investigators through NIH core facilities;
- new technologies that permit successful query of the very small amounts of human tissue typically available from patients and, collaboration across disciplines and across institutions to bring crucial expertise together;
- new insights into underlying biology and pathophysiology in immunity and lupus are constantly emerging;
- technologies to identify biomarkers are improved and accessible; and

—new approaches to therapy are being explored.

These endeavors are bearing fruit but they are highly dependent on NIH funding. If funding for the NIH is cut or level funded, it could cripple or paralyze current lupus research efforts.

As lupus is a systemic disease that can affect any organ or tissue elucidating pathogenesis (or cause) and treatments of lupus will have direct impact on many other autoimmune diseases (e.g. results and treatments translating to other diseases). Providing adequate resources to support lupus research will help the nation turn the corner on finding better treatments or a cure for lupus while also supporting breakthroughs and progress for other disease states. It is important to note that the corollary is true: cuts in lupus research funding also will have an adverse effect on progress for lupus and for progress in related diseases. Cuts in NIH funding could bring to a standstill support of clinical trials and large observational studies, and could curtail research on those at highest risk for lupus, women of color; it also could negatively impact pediatric research at a time when researchers have just begun to undertake studies in important new areas. Furthermore, insufficient federal funding also could slow much-needed genetic research when we are just discovering the critical components that may contribute to lupus and its effects. Therefore, it is critical that biomedical researchers be provided the necessary resources to continue seeking answers to the questions that will lead to better lupus treatments. Increased research funding will help deliver much-needed breakthroughs from the laboratory to patients in need.

The National Institute of Arthritis and Musculoskeletal and Skin Diseases (NIAMS), the institute most involved in lupus research, is one of the smallest institutes at NIH. In the past 2 years there has been a decrease in research funding for NIAMS overall, with a 10 percent decrease in new research grants. Currently, only 12–15 percent of the grant applications submitted to NIAMS receives funding. Further cuts will cause this rate to drop precipitously to below 10 percent next year. Just 2 or 3 years ago, funding levels were at 25–30 percent. Cuts in research funding, coupled with the rate of biomedical research inflation (3–4 percent per year), further erode NIAMS' ability to fund lupus research grant applications at the rate necessary to begin making real progress. As such, an increase above the rate of biomedical research inflation is necessary to allow NIH to sustain and build on its research progress resulting from the recent budget doubling while avoiding the severe disruption to that progress that would result from a lesser increase or cut.

Furthermore, in the proposed budget for NIAMS for 2007 there will be a loss of 10 training grants; each grant funds training for four physicians, mostly rheumatologists. Young and senior investigators alike are moving into other fields because of the lost of funding. Exacerbating the situation, medical schools are struggling financially due to public funding cuts thus eliminating any safety net for researchers that may have previously existed. As a result, young investigators are not attracted to lupus research which means there will be not be a future generation of lupus scientists and clinicians to do research. Moreover, after having attracted scientists to translational immunology in the last 5 to 10 years, when funding was increasing, there is now a possibility we could lose both the current and next generation of young investigators. Increased funding is necessary to support an adequate number of training grants. Without research and training funds lupus researchers might be forced to become private practice physicians instead, leading to an imbalance in the health care system: sufficient numbers of physicians to treat lupus patients, but no new treatments with which to care for them, and no researchers to develop the cures of tomorrow.

We recognize and appreciate that Congress and the nation face unprecedented fiscal challenges; however, we cannot afford to lose ground in biomedical research at such a promising time. The LFA looks forward to working with the subcommittee and others in Congress to reduce and prevent the suffering caused by lupus. We stand ready to serve as a resource for any information you may need in this regard and thank you for this opportunity to submit written testimony for the record concerning fiscal year 2007 lupus related funding.

Senator SPECTER. Thank you very much, Ms. Raymond.

Our next witness is Dr. Herman Taylor, representing the Jackson Heart Study. Dr. Taylor.

STATEMENT OF HERMAN A. TAYLOR, JR., M.D., ON BEHALF OF THE JACKSON HEART STUDY

Dr. TAYLOR. Thank you, Mr. Chairman, and good morning, Senator Harkin, Senator Shelby. I am Herman Taylor, professor and

cardiologist at the University of Mississippi Medical Center and also with appointments at Jackson State and Talugu College.

I am proud this morning to come to you on behalf of the largest study of cardiovascular disease ever undertaken in the African American population. It is called the Jackson Heart Study. The NHLBI and the National Center for Minority Health and Health Disparities are the NIH entities that fund this groundbreaking work. We are not only doing research, but we are actively involved in training young people to be scientific leaders for tomorrow.

We are accomplishing much, but our challenges are huge. A well documented and widening gap has opened up between blacks and other citizens of this country with respect to cardiovascular health. While most Americans have enjoyed a 40-year decline in death rates from cardiovascular disease, there has been virtually no change in the death rate from cardiovascular disease for African Americans in the State of Mississippi and certain other urban areas in other parts of the country share these equally dismal statistics.

So while the Jackson Heart Study is a very heartening and wonderful undertaking, if the intent is to approach these disparities what we have done thus far can be compared to throwing a 10-foot rope to a man at the bottom of a 40-foot well. It is a great idea, it is a good intention, but it comes up short.

PREPARED STATEMENT

If we consider the question of health disparities an important national priority, you have to ask yourself what if we were equal. Dr. David Satcher asked that question in a recent publication and he concluded, looking at CDC statistics, that last year 80,000 African Americans died unnecessary deaths compared to their white counterparts. In our State 1,200, our small southern State, 1,200 African Americans died unnecessarily.

To reverse this trend, we must support research and extend the work of the Jackson Heart Study. Thank you.

[The statement follows:]

PREPARED STATEMENT OF HERMAN A. TAYLOR, JR.

I am proud to come to you today on behalf of the largest and most comprehensive study of CVD in the African American community ever conducted—the JHS. Through the generous support of 2 NIH components—NHLBI and the NCMHD—this ambitious and multifaceted project is emerging as a leading study on CV disease among African Americans. Besides its establishing a growing database of detailed health information and test results ranging from advanced images of the heart to genetics to measures of stress and psychological parameters, the JHS is also an incubator for the scientific leaders of tomorrow through our education and training programs that involve minority students in didactic classroom sessions and practical research experiences. And while we search for answers and train future leaders, we also are taking action NOW—to serve the community with important health information from our study as well as others.

We are relatively new, born during the period of NIH budget doubling, and already we have accomplished much within the Jackson community and beyond. However, despite the promise of the JHS and our optimism over its impact, I come to you with a deep concern, summarized in the arresting quotes below.

“It has been discovered that the health of [blacks] in [parts of] Mississippi is deteriorating while the health standards for the nation are improving”—The Wall Street Journal

“Cardiovascular deaths in MS seem to be rising while they have fallen for the past 30 years for the rest of the country.”—Circulation (the official organ of the American Heart Association)

These 2 quotes are distressing, whether you are African American or not, whether you are Mississippian or not. However, the magnitude of the problem they summarize becomes clearer when you consider that the two statements were made 32 years—a full generation—apart. The notion that in the richest country in the history of man, one location or group within its borders can be so singularly and peculiarly burdened from a largely preventable disease is barely credible. But it is true, and it has the status quo for around forty years.

So while the JHS represents an inspired, timely effort of the NHLBI and the NCMHD, to freeze research efforts at the current levels of funding would be like throwing a 10 foot rope to a man at the bottom of a 40 foot hole. We come up short, and despite the right idea and a noble attempt, the problem of disparate CV health remains unsolved. To extend the reach of the JHS to its full potential, our Study and other complementary studies—and the investigators driving them—must thrive, and have support for their approaches and new ideas.

The JHS contributes to extending the research lifeline in several important ways. First there is the core JHS Study itself. Classically designed in the pattern of the world famous Framingham Study, it offers a chance to Study a wide list of possible causes for poorer cardiovascular health among African Americans, to inform precise interventions that will reduce disparities. Funded through 2013 by NHLBI and NCMHD, it is a landmark undertaking. The JHS also is innovative in its list of partnering institutions. Besides the guidance and support of the NHLBI and the NCMHD, 3 local Jackson Institutions of higher learning take active part in making the JHS work—Jackson State University, University of Mississippi Medical Center, and Tougaloo College all have unique and vital roles in the Study. Comprising a team of 2 Historically Black institutions and a third predominantly minority-serving institution, this combination has been ground-braking and synergistic in the service of this population-based study of an African American population. Training of promising young talent from the affected population and participation of HBCU’s in epidemiological research at the highest level is bearing fruit for the Nation in terms of a rising cadre of leaders in the relevant fields.

However, the potential impact of the JHS is bigger than even this important core Study will provide. This is because not only is the JHS a Study in its own right, it is a platform for critical spin-off studies. These “Ancillary Studies” require secondary funding that is NOT a part of the JHS contract funding. A flat or declining NIH budget threatens these important studies, where much of the truly innovative work on health disparities could occur. For instance, nearly all of the genetics studies of heart disease in the JHS require this ancillary funding. The genetics of CVD may be the key in the lock of our understanding of much of the current epidemic. Implications of these studies may be huge for not only African Americans, but all people threatened by the nation’s number one killer. Flat budget lines severely limit the opportunities for such important studies. This is especially devastating to new investigators, those who apply for the career development (K) awards that NHLBI has been so committed to funding. These young people are the cadre of scientists in whom we are investing our future hopes of American world leadership in health research, and the ultimate resolution of health disparities.

The future of innovative science from the JHS is therefore tied in important ways to Ancillary studies (R01’s) and career development (K) awards for new investigators. Holding the line on the NIH budget is to worsen a palpable threat scientists now feel—that of being squeezed out of a zero-sum game where more and more scientists are fighting each other and the rising cost of research in order to launch and sustain promising careers. This is especially devastating to new investigators, in whom we are investing our future hopes of American world leadership in health research.

Therefore, the JHS at this point in its evolution can be thought of as a major platform for scientific discovery—an incredible growing database that is a national resource. If the growing brain trust of scientists—in Jackson as well as Boston, Bethesda, Minneapolis, Baltimore, New York, Chicago and elsewhere—who are showing active interest, receive funding for meritorious ideas, the JHS stands to produce important breakthroughs in our understanding of the CVD patterns seen in AA and others. However, if flat pay lines prevent the funding of new ideas for using this unparalleled resource, the trajectory of discovery will be blunted, the pace of advance slowed, and important scientific opportunity, squandered. And the wisdom shown by NCMHD and NHLBI in building this platform for discovery will be in many ways betrayed.

We cannot afford to squander any opportunities to improve health overall and eliminate health disparities. I witness the impact of failed promises everyday. Among my patients, I see the end result of our incomplete understanding of heart disease: in young mothers whose hearts fail after childbirth for no good reason—though we have a name for it—peripartum cardiomyopathy—we don't understand it, and we don't understand why it afflicts Blacks more than other Americans. I see it in fathers with no known risk factors, but develop coronary disease anyway. I see it in people suffering from morbid obesity who not only are at increased risk for disease, but because of their size, therapeutic and diagnostic interventions themselves are technically much more difficult. Standard operations are often riskier, and sometimes impossible to perform. With 1,200 unnecessary deaths from CVD among AA in our small Southern state alone, deferring the dream of health equality only adds to our regional tragedy of health disparities. With 80,000 unnecessary deaths nationally among African Americans in 2004 (most from CVD) research retrenchment in the form of flat lining or cutting the research budget only defers finding answers that were needed yesterday for our Nation's health. An act of national compassion and strong resolve is necessary. I pray that this Congress and President will engage this great threat to the dream of a healthy, vigorous nation. It is in our compelling national interest to do so.

Thank you, Mr. Chairman. I would be pleased to answer any questions that the Committee may have.

Senator SPECTER. Thank you very much, Dr. Taylor.

Our final witness is Dr. Suzanne Vogel-Scibilia, representing the National Alliance for Mental Illness.

STATEMENT OF SUZANNE VOGEL-SCIBILIA, M.D., PRESIDENT, NATIONAL ALLIANCE ON MENTAL ILLNESS

Dr. VOGEL-SCIBILIA. Greetings from Beaver County, Pennsylvania, Senator Specter.

I'm a volunteer with—

Senator SPECTER. Whereabouts? Where?

Dr. VOGEL-SCIBILIA. Beaver.

Senator SPECTER. Thank you.

Dr. VOGEL-SCIBILIA. I'm a volunteer at NAMI and the president of the National Alliance on Mental Illness, and I have been a practicing psychiatrist and a family member of persons with mental illness as well as a consumer with bipolar disorder myself. I have had periods of severe illness, but I have had a good recovery.

Unfortunately, though, many people in our country have not yet achieved recovery. If Congress cuts funding at the NIMH as the President has suggested, we will have to continue to have millions of people in this country with chronic disability and a \$40 billion loss in economic productivity each year alone for schizophrenia, not to mention other illnesses.

Because of the past doubling of the research budget, NIMH has brought forth vitally important real world trials to impact the treatment of all persons with schizophrenia, bipolar disorder, and depression. Unfortunately, though, the future gains in medication and treatment options for this vital research will not be realized unless further medical support is given to these important studies. We will be unable to fund the United States whole genome studies for serious mental illness, which could transform the understanding of causes and risk factors for these devastating illnesses and open up new avenues of effective treatment.

Last, we will be unable to advance schizophrenia and bipolar research progress. One example is in the understanding if early intervention and medication therapy and rehabilitation will prevent disability and morbidity for persons with new onset schizo-

phrenia. We will also be unable to address and prevent the epidemic of suicide in this country, including a substantial number of our young people who die or are disabled before their life has truly started, and the elderly who are cheated from their retirement years.

For myself, my children, and the people who belong to over 1,100 affiliates of NAMI in the United States of America, we humbly thank you for all your reform to express our concerns and hope that research dollars will be provided to help those of us who suffer.

Thank you very much.

Senator SPECTER. Thank you very much, Dr. Vogel-Scibilia.

One question, Dr. Taylor. When you say “unnecessary deaths,” how would you define that?

Dr. TAYLOR. Yes. The term, sir, refers to deaths that you would not expect, given statistical projections, given the current level of care and our understanding of risk factors for cardiovascular disease. So these are people who—a certain number of people are expected to die, of course, from certain diseases, like heart disease, every year. Well, these are people who you would not expect to have died. Dr. Satcher and others have termed these “unnecessary deaths.”

Senator SPECTER. You are saying in effect that that is higher for blacks, African Americans, than others?

Dr. TAYLOR. Senator, it is substantially higher. Again, the national prediction is that 80,000 of these deaths occur from a variety of causes and the lion’s share of those deaths are due to cardiovascular causes.

Senator SPECTER. What is the reason for the higher incidence of deaths among blacks?

Dr. TAYLOR. Well, this is the principal focus of the Jackson Heart Study and studies like it, to figure that out. Clearly there are higher levels of risk factors, such as obesity, hypertension, diabetes. But one must ask the question, why are those risk factors higher? We cannot simply say, well, there is more hypertension, therefore we expect more deaths. The question is why is there more hypertension and related problems?

Also, access to care clearly is a major part of this. But historically, African Americans as a group have been understudied with regards to what are the true determinants of poor health. Studies like the Jackson Heart Study and studies related to it I think will help unravel these questions and give us detail that we might not even suspect at this point. The Jackson Heart Study, for instance, includes studies into genetic underpinnings of various illnesses. But on the opposite end perhaps of the spectrum, we look very carefully at psychological determinants of ill health, at social and behavioral parameters that may also impact how well people do in terms of their overall health.

Senator SPECTER. Senator Shelby.

Senator SHELBY. Thank you, Mr. Chairman.

Ms. Raymond, what funding do we really need to sustain research into lupus at NIH in your judgment?

Ms. RAYMOND. Well, presently the amount of funding now allocated is around \$66 million. In order to really sustain and break through, I think we need \$200 million.

Senator SHELBY. That is a lot of money.

Ms. RAYMOND. A lot of money.

Senator SHELBY. But a lot of promise, too.

Ms. RAYMOND. I think so. We have many deaths due to lupus.

Senator SHELBY. Absolutely.

Ms. RAYMOND. It is a fatal disease. It is prototypical because it affects any organ system, any tissue system in the body.

Senator SHELBY. 90 percent of them are women, are they not?

Ms. RAYMOND. 90 percent are women and a majority are women of color, African American, Hispanic, Asian, and Native Americans.

Senator SHELBY. Dr. McDonnell, macular degeneration. What is the real promise once you are diagnosed in that area?

Dr. MCDONNELL. Well, Senator, this is now with the tidal wave of aging Americans, this has taken over from diabetes as the major cause of Americans to go blind. It is a progressive disease involving—it is almost our Alzheimer's or Parkinson's—a neurodegenerative condition of the cells of the retina, of the back of the eye. The eye is part of the brain, and this progression occurs.

Now we believe we have some dietary supplements that may slow the progression.

Senator SHELBY. What are these?

Dr. MCDONNELL. Anti-oxidant vitamins and zinc have been shown, thanks to an NEI-funded study, to delay the progression to severe forms of the macular degeneration. Now, we have some treatments that can treat severe forms with blood vessels that are causing leakage and bleeding and scarring in the back of the retina. We also hope to be able to begin and expand upon studies of regenerative medicine using stem cells, such as would be done in other fields, to restore the cells that are lost or damaged from this disease.

Senator SHELBY. So there is great promise everywhere in biomedical research. It has just got to be properly funded. Is that the bottom line?

Dr. MCDONNELL. I agree with that. As you heard, lupus also damages the eye. The eye is part of the brain. Fortunately, not all patients are afflicted in the eye, but we have patients go blind and we need the same treatments that would improve the kidney damage and brain damage of lupus also for our eye patients.

Senator SHELBY. Thank you.

Mr. Chairman, thank you.

Senator SPECTER. Thank you, Senator Shelby.

Senator Harkin.

Senator HARKIN. Thank you, Mr. Chairman.

Dr. Landrigan, thank you for bringing up the children's study. That is why I brought it up earlier. You talked about the benefits to children, but would it not also benefit adults also? I mean, obviously obese children have later complications as they grow older. Many of the things that happen to you in childhood you carry with you, especially mental health. If you have mental health problems early in life and they are not attended to, it can manifest itself later on.

So I just wanted to draw you out a little bit on that in terms of the benefits of the children's study, not just to kids, but I think across the spectrum.

Dr. LANDRIGAN. Yes, Mr. Harkin, that is absolutely true. There is an expanding body of research, called the early origins of adult disease hypothesis. For example, slow fetal growth of the baby still in the mother's womb is associated in young adult life with an increased risk of diabetes, hypertension, and heart disease. There are some intriguing clues, more from animal studies than human at the moment, that early exposures to toxic chemicals may cause brain damage that does not become manifest in childhood, but shows up four, five, six decades later in the form of dementia or Parkinson's disease.

So I think it is both to protect America's kids as well as future generations of adults that we are seeking the full funding for the study to be restored in fiscal year 2007, which would be \$69 million, and also assurances that the study will continue to be funded in the years ahead. It will not succeed unless the funding for it is sustained.

Senator HARKIN. Thank you very much.

Mr. Chairman, I do not have any further questions. I would just again for the record state, Mr. Chairman, that you and I and others on this committee had planned for this children's study. It was passed in 2000. A lot of planning went into this and forethought went into it to set up this long-term study, and I just cannot believe that we are just going to just stop it at this point in time.

So we have just got to do everything we can to mandate, if we have to, mandate—I do not know if there is anyone here from OMB, but mandate—that this funding go forward this next year.

Thank you very much.

Senator SPECTER. Thank you. Thank you, Senator Harkin.

I thank all of you. We are fighting. We put up a Specter-Harkin amendment and added \$7 billion to the budget in the Senate. Unfortunately, that has not been accomplished in the House. We have added from that \$7 billion \$2 billion for the National Institutes of Health.

But this is a battle that really has to be engaged in by 110 million Americans who are suffering directly or indirectly from the kinds of illness which we have heard about here today.

We thank you for coming in. This has been an impressive hearing because it puts a face on these ailments. They are sort of abstractions. They are not abstractions if your wife is suffering from them or a close relative or a close friend or you are suffering from them. They are not abstractions at all. But there has to be a very intense advocacy effort. We call it lobbying around here. It is really advocacy. Your organizations are very, very important in this advocacy effort. We thank you for what you are doing. But you have to contact your counterparts everywhere.

The amendment which Senator Harkin and I sponsored won 73 to 27, but there were 27 Senators who voted no and you ought to identify them and you ought to march on them in their cities, in their States, seriously, very, very seriously. It is a little hard, with all that Senator Harkin and I have to do—he has got to bounce out of here and go to Iowa for a meeting later today and I have got

to conduct a hearing on campus violence in Philadelphia at 2 o'clock. I have not been in my office all week. I have been on the floor managing the immigration bill. Before that I was fully occupied with the Supreme Court nominations.

But your groups are advocates and I would like to see that million person march. But it has got to be done. We are a democracy and people in Washington pay attention to people in their home States. If I get seven letters, I have got 12 million constituents, I think it is significant. You have really got to be more politically active, not Democrat or Republican active, but active for these issues, active for NIH, active for stem cells.

I am convinced there are cures for all of these ailments and we have the resources to do it. It is a question of how many doctors and hospitals and research scientists and dedicated people you have. It is not a matter of how many dollars you have. It is a matter of what your resources are. The money flow comes out of Washington to a large extent, also out of your State capitals.

ADDITIONAL COMMITTEE QUESTIONS

There will be some additional questions which will be submitted for your response in the record.

[The following questions were not asked at the hearing, but were submitted to the Department for response subsequent to the hearing:]

QUESTIONS SUBMITTED BY SENATOR ARLEN SPECTER

LIVER DISEASE RESEARCH BRANCH

Question. Dr. Zerhouni, 3 years ago, the NIDDK established a Liver Diseases Research Branch within its Division of Digestive Diseases and Nutrition. Please explain the benefits of having a Research Branch dedicated to a specific area of research and describe how this Liver Disease Research Branch has succeeded in its mission.

Answer. Research on diseases of the liver is a trans-NIH effort involving 19 institutes, centers, and offices. The National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK) has lead responsibility for liver disease research at the NIH. Within the NIDDK, liver disease research is under the purview of the Division of Digestive Diseases and Nutrition. The Federal liver disease research effort has benefited greatly from the establishment in 2003 of an organizational entity within the NIDDK—the Liver Disease Research Branch—dedicated exclusively to this very important area. This new Branch was formed to focus and coordinate research efforts on critical areas relevant to liver and biliary disease, such as hepatitis and liver transplantation.

Following a national search, Jay H. Hoofnagle, M.D., an internationally recognized authority in liver disease research, was appointed as Chief of this Branch. The NIDDK recruited an additional scientific Program Director with expertise in liver diseases to further support the efforts of the Branch. The Branch also includes scientific experts in the areas of viral hepatitis, clinical trials, epidemiology and data systems, genetics and genomics, and research training and career development.

The Liver Disease Research Branch has accelerated research on liver disease supported by the NIDDK and has helped to coordinate and stimulate liver-related research efforts across the NIH and within other Federal agencies, such as the Centers for Disease Control and Prevention, the Department of Defense, the Bureau of Prisons, the Food and Drug Administration, and the Department of Veterans Affairs. An initial important task set for the Branch was to prepare the trans-NIH Action Plan for Liver Disease Research. The Plan provides an overview of the current burden of liver disease in the United States, the current level of NIH research funding in liver disease, and recent research advances. Importantly, the Plan also summarizes challenges to advancing liver disease research and delineates the major goals for future research. Specific goals for the next 10 years are defined for each of 16 topic areas in liver disease research.

One mission of the Branch is to oversee the conduct of the Plan, which includes annual Progress Reviews to aid in its implementation through an ongoing assessment of progress and the need for further efforts to promote liver and biliary disease research. The Progress Review for 2005, the first year following release of the Action Plan, is available at: http://www.niddk.nih.gov/fund/divisions/ddn/ldr/Progress_reviews.htm. The Branch also develops and coordinates future NIH efforts in liver disease research aimed at reaching the goals defined in the Plan.

Thus, the Branch is succeeding in its mission to plan and direct the NIH program of liver research, as evidenced by an impressive array of initiatives that include major clinical trials and special program announcements in the areas of proteomics of the liver, biomarkers for liver disease, non-invasive tests for diagnosis and staging of liver disease, and ancillary studies linked to specific clinical trials, databases and cohort studies on liver disease (<http://www.niddk.nih.gov/fund/program/DDN-list.htm#Liverprograms>).

UROLOGY RESEARCH STRATEGIC PLANNING

Question. Our conference report last year “urged the NIDDK to continue to support and develop the ‘Urologic Diseases in America’ report and to include urological complications as well as diabetes and obesity research initiatives.” This language was included in response to concern that the NIH-wide Obesity Strategic Plan did not address urological issues such as, stress urinary incontinence or erectile dysfunction (ED), two conditions highly associated with obesity. These conditions severely affect quality of life and result in high medical costs. How do you ensure that all disciplines are represented in strategic planning?

Answer. The NIH acts to ensure that its strategic planning efforts for research are comprehensive, inclusive, and evidence-based. Currently, strategic planning is conducted by the individual Institutes, Centers, and Offices of the NIH, as well as through trans-NIH and interagency mechanisms, as appropriate. The NIH Office of Portfolio Analysis and Strategic Initiatives, which I established recently, will have an instrumental role in facilitating both individual and trans-NIH strategic planning efforts through its planned activities.

To ensure effective planning processes, the NIH seeks input from a wide array of stakeholders, including scientific experts, representatives from professional organizations, and patient advocates. For example, most strategic planning for urologic diseases research is conducted by the National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK). In two major planning efforts, the NIDDK assembled large, multidisciplinary groups of scientists and medical professionals prominent in their fields and active in patient and professional societies related to bladder disease in 2002, and in pediatric urology in 2006. These groups were thus able to bring multiple perspectives to bear when reviewing progress in bladder disease and pediatric urology research, and to provide broad-based assessments of research needs and recommendations for future action, including recommendations regarding the impact of obesity and diabetes on certain urologic diseases. As a result, these groups’ 2002 and 2006 reports have served as a model for NIH planning for urologic diseases research and for trans-NIH collaborations in this area. Moreover, the NIDDK has continued to gather multidisciplinary expert groups to assist in more focused areas of research planning, such as prostate disease, and urologic diseases in women. All of these efforts are bolstered by the Urologic Diseases in America report, which has provided significant information related to major urologic diseases. The NIDDK is strongly committed to maintaining this program, and a research solicitation is being developed for the next phase of Urologic Diseases in America that will include assessment of the impact of diabetes and obesity on urologic diseases. Additional, ongoing assessments of research progress in urologic diseases through advisory group meetings, scientific conferences, and stakeholder input allow flexibility, capitalization on new research advances, and the opportunity to strategically address research gaps and barriers that may emerge or become evident over time.

The Strategic Plan for NIH Obesity Research, developed by the NIH Obesity Research Task Force, similarly drew upon a broad base of scientific expertise within and external to NIH. The plan focuses, in part, on goals and strategies to break the link between obesity and its associated health conditions. Recommendations from this and other plans and from ongoing strategic planning efforts are reflected in NIH action. For example, the NIDDK has funded the Program to Reduce Incontinence by Diet and Exercise (PRIDE) study, which is examining the impact of weight loss on urinary incontinence in overweight and obese women. The benefits of considering multiple disciplines in research planning can be seen in research results. For example, the NIH-funded Diabetes Prevention Program recently found that weight loss improves bladder control in women with prediabetes. This new knowledge, that

an intervention proven to reduce risk of type 2 diabetes can also reduce episodes of urinary incontinence, has the potential to improve health and quality of life for the large number of older American women who have both prediabetes and bladder control problems. The NIH has also been supporting a similar study in patients with type 1 diabetes who are participating in the Epidemiology of Diabetes Interventions and Complications study, to determine whether intensive control of blood sugar levels—an intervention proven to reduce risk of developing eye, kidney, nerve, and cardiovascular complications of diabetes—also reduces risk of urologic complications.

OPASI TRANS-NIH FUNDING PROGRAM

Question. Dr. Zerhouni, you have initiated a new trans-NIH funding program, which requires each Institute and Center to contribute a fixed portion of their appropriations for cross-cutting research initiatives. Can this program move forward as planned in an environment of no real increases in NIH funding?

Answer. The Administration has focused resources on our highest priority: protecting the citizens and our homeland. This underscores the importance of being as strategic as possible with NIH dollars to catalyze high-impact research. The time is right for NIH to take a more coordinated approach to the development and funding of trans-agency initiatives by asking each IC to pool a very small proportion of their appropriation in a Common Fund for shared needs. This is true not only because of the difficult budgets, but also because many of the most exciting scientific opportunities and pressing public health challenges we now face cut across the mission areas of multiple institutes and centers. Thus, the creation of this new trans-NIH funding stream will actually enable the NIH to be more proactive in addressing emerging scientific needs and opportunities; to fund high-risk, high-impact science; and to incubate and launch pilot efforts that have transforming potential for all of science.

THE HEART TRUTH ROAD SHOW

Question. As a member of the Congressional Heart and Stroke Coalition, I am concerned that heart disease remains the leading cause of death of women in the United States, but many women do not realize this fact. I know that for the past several years, the NIH has been working with the fashion industry in your Heart Truth Campaign to increase women's knowledge about their No. 1 killer and that the Heart Truth Road Show stopped in Pittsburgh recently. Please explain to the Committee about the progress of this initiative?

Answer. The National Heart, Lung, and Blood Institute's (NHLBI) The Heart Truth campaign continues to flourish, extending the reach of the campaign in a variety of ways.

- As the campaign ambassador, First Lady Laura Bush is leading the federal effort to give women a personal and urgent wake-up call about their risk of heart disease, participating in more than a dozen Heart Truth events around the nation over the past 3 years.
- Corporate partners, including General Mills, Minute Maid, and DermaDoctor, have featured the campaign's Red Dress (emblematic of the message "Heart disease doesn't care what you wear; it's the killer of women") on more than 60 million product packages. Johnson & Johnson, L'eggs hosiery, Benecol, Starkist Tuna, and Celestial Seasonings have promoted The Heart Truth campaign and Red Dress logo in newspaper advertising inserts, resulting in a combined circulation of 370 million.
- The Red Dress Collection 2006 Fashion Show took place on the third annual National Wear Red Day—Friday, February 3, 2006. People throughout the country participated in the day's celebration to increase awareness of women's heart disease.
- The Heart Truth Road Show visited shopping malls in Pittsburgh, Memphis, and Washington, DC, in the spring of 2006 to raise awareness about women and heart disease by helping participants learn about risk factors; providing free health screenings including blood pressure, body mass index, total blood cholesterol, and blood glucose; and disseminating educational materials.
- The campaign launched "Know The Heart Truth" in April 2006, an initiative that is recruiting and training health advocates and educators in local communities to increase awareness about women and heart disease. The Heart Truth has also formed partnerships with leading organizations representing women of color to engage in national and local activities, including a faith-based initiative, to help women reduce their risk for heart disease.

The impact of The Heart Truth campaign is already becoming apparent. Awareness of heart disease as the leading cause of death among American women in-

creased from 34 percent in 2000 to 46 percent in 2003 to 55 percent in 2005. A 2005 survey commissioned by WomenHeart found that 60 percent of U.S. women agreed that the Red Dress makes them want to learn more about heart disease. Twenty-five percent of women recalled the Red Dress as the national symbol for women and heart disease awareness and 45 percent agreed that it would prompt them to talk to their doctor and/or get a check-up. A Lifetime Television Women's Pulse Poll released in February 2006 showed that women are increasingly aware of the dangers of heart disease. Thirty-nine percent of survey participants recognized the Red Dress as the national symbol for women and heart disease awareness, up from 25 percent in 2005.

STROKE

Question. Following up on language from last year's congressional report, please provide this Committee with highlights of implementation progress on the Stroke Progress Review Group report.

Answer. In 2001, the NINDS convened the first meeting of the Stroke Progress Review Group (SPRG) to identify and prioritize scientific opportunities and needs in stroke research. One hundred forty prominent scientists, clinicians, patient advocates, and industry representatives participated and developed a set of scientific and resource recommendations that the NINDS assembled in a Report of the SPRG in 2002. In 2003, the chairs of the SPRG meeting reprioritized their recommendations and identified a subset of high priorities for stroke research in an Implementation Report. Many of the following research activities address the scientific research and resource priorities identified by the SPRG in its 2002 Report and 2004 Implementation Report.

The NINDS is funding a wide range of studies on the basic biology of stroke, including the role of the blood-brain barrier (BBB; the cellular barrier that controls the exchange of substances between the blood and the nervous system) and the neurovascular unit (NVU; the functional "unit" comprised by brain blood vessels, glial support cells, and neurons). Understanding the function of the NVU and the BBB in stroke is critical to developing strategies for treating and preventing stroke and related conditions such as vascular cognitive impairment (VCI). NINDS is supporting a variety of stroke-related studies focused on the roles of the NVU and the BBB under two recent Program Announcements with set-aside funding. To more fully understand the biological basis of VCI, the Institute held a workshop in June 2006 to discuss the cell biology of VCI and develop recommendations to accelerate research in this area.

To facilitate the translation of basic research findings into the clinical setting, NINDS is planning to expand its Specialized Programs of Translational Research in Acute Stroke to include seven programs across the country participating in clinical trials, training of research fellows, and translational research on stroke. In addition, NINDS released two new grant solicitations to address barriers to translational research in stroke.

The NINDS also continues to fund many clinical trials involving potential interventions and preventive strategies for stroke. To improve outcomes for stroke patients in emergency-room settings, the NINDS is developing a Neurological Emergencies Treatment Trials (NETT) Network of emergency medicine physicians, neurologists, and neurosurgeons, and plans to fund the clinical coordinating center component of the NETT in fiscal year 2006. The Institute is also supporting research on the causes of stroke among high risk groups, improved methods for diagnosing stroke, and a range of educational outreach programs to increase awareness of stroke risk factors and symptoms.

In September 2006, the NINDS will sponsor another meeting of the SPRG to assess research progress in stroke, evaluate current priorities, and identify new opportunities for advancing stroke research. Prior to the meeting, 16 working groups will assess progress and develop recommendations for future priorities on topics ranging from genetics of stroke to recovery and rehabilitation. NINDS solicited information from the stroke research community on research progress and remaining needs and research gaps, and will provide this feedback to the SPRG participants prior to their deliberations. Following the September meeting, the SPRG will produce a mid-course implementation report that reflects the current status of stroke research and identifies new priorities.

CLINICAL AND TRANSLATIONAL SCIENCE AWARDS

Question. You have announced that by the year 2010, the GCRC program will have been phased out and the funding transferred to a new program. How are you going to assure that the CTSA's maintain or enhance services currently provided by

the GCRCs including specialty nursing care, patient facilities, laboratory testing, and specialized monitoring and diagnostic capabilities?

Answer. Applicants for the Clinical and Translational Science Awards (CTSAs) are asked to propose a center, department, or institute for clinical research that will transform the clinical and translational research environment at their institution. Up to \$6 million additional funds may be requested in addition to certain National Center for Research Resources (NCRR) and NIH Roadmap awards held by the institution at the time of application. These additional funds may be used to transform the local, regional, and national environment for clinical and translational science, thereby increasing the efficiency and speed of clinical and translational research. By introducing CTSAs as an increase in support, NIH is allowing applicants to retain such services as are currently provided by the General Clinical Research Centers (GCRCs) that they deem needed for their clinical research, such as inpatient and outpatient facilities, laboratory testing, and specialized monitoring and diagnostic capabilities.

Question. You have announced that by the year 2010, the GCRC program will have been phased out and the funding transferred to a new program. How will you monitor the impact on the vitally important clinical research support currently provided to patients and investigators through the GCRCs?

Answer. NIH staff review GCRC Annual Reports, communicate frequently with grantees, and attend annual meetings with Center grantees in Washington, DC. Clinical and Translational Science Awards likewise will submit Annual Reports and will establish Steering Committees on which NIH will be represented. These various tools and forums provide opportunities to assess the impact of the Clinical and Translational Science Awards and General Clinical Research Centers and will assure NIH of the requisite monitoring for impact on clinical research support.

Question. You have announced that by the year 2010, the GCRC program will have been phased out and the funding transferred to a new program. Will institutions that lose their existing GCRC funding and do not receive CTSA awards be able to support patient-oriented research facilities and services?

Answer. The 60 CTSAs that NIH plans to award could support over 90 percent of the institutions that currently have GCRCs. Researchers that perform patient oriented research at institutions that do not receive CTSAs may apply for investigator-initiated NIH research supported by a variety of NIH grant mechanisms including Research Project and Research Program Projects and Centers grants. Additional sources of research support for investigators may come from Research Foundations, partnerships with industrial sponsors and institutional funds.

Question. You have announced that by the year 2010, the GCRC program will have been phased out and the funding transferred to a new program. Will researchers in these institutions have to cancel planned patient-oriented research projects because of inadequate facilities? Certainly, the NIH budget is too constrained to provide this support through other competitive mechanisms.

Answer. Researchers in the institutions that do not receive Clinical and Translational Science Awards may apply for investigator initiated NIH research supported by numerous NIH grant mechanisms including Research Project and Research Program Projects and Centers grants. Research Foundations, partnerships with industrial sponsors, and institutional funds may also provide additional sources of research support for investigators.

Question. The K12 training mechanism is required for the CTSA award. Why isn't the GCRC M01 mechanism required? The RFA appears to marginalize the GCRCs and their functions, and I am concerned about that. Why not require the M01 mechanism in the CTSA award RFA in 2007?

Answer. Applicants for a CTSA are required to include a Mentored Clinical Research Scholar Award (K12) component in their proposal so as to promote clinical and translational research as a distinct discipline. There is no requirement for applicants to be K12 awardees for them to apply for a CTSA. NCRR has not made an M01 award an eligibility requirement for a CTSA application in the expectation that certain new affiliations amongst institutions that do not currently hold an M01 award would be strong enough to compete successfully. CTSAs will support the discipline of clinical and translational science and the needs of its researchers, so applicants are encouraged to look beyond the constraints of M01 awards and to propose novel concepts, methodologies, and approaches that could be integrated into a comprehensive, effective, and efficient researcher-, trainee-, and participant-centered clinical research program.

Question. Could NIH maintain a GCRC or mini-GCRC program for institutions that have had strong GCRCs, historically, but do not receive CTSA awards.

Answer. NCRR has received wide support for the new CTSA program, so we believe that the purposes of clinical research will best be served by a smooth and unin-

errupted transition. Several new consortia are expected to apply for CTSA and clinical research at those sites that compete well in the peer review process should not be delayed by prolongation of the GCRC program. Retaining the GCRC program would limit the funding available for the CTSA program and NIH believes that this would be detrimental to the needs and interests of the majority of clinical investigators.

Question. Have you considered the possibility of a “pause” after the second year of implementation to evaluate the effectiveness and impact of the new CTSA program before proceeding with additional awards?

Answer. The combination of Annual Reports with Clinical and Translational Science Award Steering Committees will assure NIH of the requisite evaluation opportunities during their implementation. In the event that changes are required to optimize the award functionality, they can be made without the delays that would be incurred through a “pause” in making awards.

Question. Do you have a fall-back plan if the budget is not sufficient to accommodate the implementation of the CTSA program as you envision it?

Answer. Transformation of Clinical Research infrastructure programs from GCRCs to CTSA will be funded principally by NCRF appropriated funds, with additional funds from the NIH Roadmap for Medical Research. The project period for CTSA grants is 5 years, and NIH is planning for an additional 5-year competitive renewal of these awards. The fiscal year 2006 funding level for the combined CTSA/GCRC program is \$322,740,000 and their estimated fiscal year 2007 funding level is \$361,200,000. NIH plans to award four to seven CTSA in fiscal year 2006, to increase the number of awards annually, and to have 60 CTSA in place by 2012. While changes in Congressional Appropriations would affect both the GCRC and CTSA programs in parallel, the transformation of the GCRC program to CTSA is occurring in response to user demand.

POLYCYSTIC KIDNEY DISEASE

Question. The Food and Drug Administration has granted “Fast Track” designation for Tolvaptan, a promising drug therapy designed to retard disease progression in polycystic kidney disease (PKD) and thus prevent kidney failure. What does the NIH plan to do to make the most of this discovery and foster the development of further PKD therapies?

Answer. The NIH is committed to research that will pursue opportunities to combat polycystic kidney disease (PKD)—a serious, burdensome, and costly disease. Within the NIH, the National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK) supports a diverse portfolio of basic and clinical research into the underlying biology of and possible therapies for PKD. The Interdisciplinary Centers for Polycystic Kidney Disease Research are important components of this research portfolio. The NIDDK recently renewed funding for four Centers for five additional years. Three of the Centers focus on the more common autosomal dominant PKD (ADPKD), and will explore extensively the basic and clinical functional changes seen in ADPKD. The fourth is a Research and Translational Core that focuses on autosomal recessive PKD (ARPKD) and will make available to investigators in the field a broad range of model research systems and reagents for the study of ARPKD.

The Institute also has two other major research projects related to PKD—the HALT-PKD trial network, and the Consortium for Radiologic Imaging Studies of PKD (CRISP) cohort study. CRISP was established to develop innovative and standardized imaging techniques and analyses that would allow clinicians to reliably follow disease progression of ADPKD. This four-year study followed 240 PKD patients with annual glomerular filtration rate evaluation (a measure of kidney function), and magnetic resonance imaging to assess changes in kidney volume over time. The first phase of CRISP was recently completed, and the primary study results were published in the *New England Journal of Medicine* in May 2006 (NEJM 354: 2122–2130, 2006). Although the preliminary findings show promise for use of imaging methods and structural endpoints for tracking progression of ADPKD, the NIDDK has extended the CRISP cohort study for another five years, in order to collect additional structure and function data on enrolled subjects. Additional data from CRISP II will enable investigators to assess how reliably structural changes can predict functional kidney changes over time in ADPKD. The CRISP II investigators are currently developing the protocol for the next phase of the study.

The Polycystic Kidney Disease Clinical Trials Network, co-funded by the PKD Foundation, is conducting two phase III-type studies in the HALT-PKD trial—one in patients with early kidney disease and another in patients with more advanced disease. HALT-PKD is testing whether blockade of the renin-aldosterone-angiotensin system, with angiotensin-converting enzyme inhibitor monotherapy or

combination angiotensin-converting enzyme inhibitor and angiotensin receptor blocker, will slow the progression of ADPKD. A partnership was also negotiated with industry to provide medications for testing in these studies. The HALT-PKD trial in subjects with early kidney disease is novel in that it is implementing the CRISP imaging methods in order to determine how reliable the methods are for interventional studies in ADPKD. The ability to reliably implement imaging methods for trials of ADPKD will have a significant impact on planning future interventional studies of new therapeutics in this disease. The HALT-PKD studies began enrolling patients in January 2006, and will be the largest interventional trial ever conducted in ADPKD.

NATIONAL PRIMATE RESEARCH CENTER

Question. The fiscal year 2006 Labor-HHS-Education Appropriations bill provided the NIH Office of AIDS Research with up to \$4 million to spend for construction or renovation necessary to expand a breeding colony for non-human primates for AIDS research, which is intended to be collaborative effort amongst the National Primate Research Centers. What progress has been made on that effort, and what is the expected completion date?

Answer. Although the fiscal year 2006 bill allows the Office of AIDS Research (OAR) to utilize funds for construction for the national breeding resource facility, funds will not be used for that purpose in fiscal year 2006. In late fiscal year 2005, the Tulane National Primate Research Center successfully competed for the first phase of a national breeding resource facility project. However, construction capability in this region has been limited in the aftermath of Hurricane Katrina. Thus the second phase of this project has not proceeded as scheduled. Consequently, OAR cannot use this provision of the fiscal year 2006 appropriations bill this year. Instead, OAR provided funds to NCRP to support AIDS-related research infrastructure needs and increased operating expenses, such as unanticipated high energy costs, at the National Primate Research Centers (NPRCs). A timeline for completing the national breeding resource facility project is being reassessed.

QUESTIONS SUBMITTED BY SENATOR TOM HARKIN

COLLABORATION AMONG INSTITUTES

Question. Dr. Zerhouni, one of the most common complaints I hear from advocacy groups is that they can't get multiple NIH institutes and centers (ICs) to work together on common goals. Consider diseases like scleroderma, neurofibromatosis or epilepsy, all of which fall under the jurisdictions of more than one IC. In each case, one IC might be designated as taking the lead on the disease, but other ICs also share the responsibility for conducting research on it. Too often, unfortunately, patients complain that the ICs don't collaborate. Sometimes the patients themselves practically have to drag a researcher from one institute into a meeting with a researcher from another institute, just to get them to talk.

I know you're well aware of this problem. It's an issue that the National Academies addressed in its report on NIH's structure in 2003. What are you doing to improve the situation?

Answer. In 2002, I began a process called the Roadmap for Medical Research that was designed to identify major opportunities and gaps in biomedical research that no single institute at NIH could tackle alone to make the biggest impact on the progress of medical research. A primary accomplishment of the Roadmap was internal "functional integration" of the 27 institutes and centers (IC) to plan, implement and fund initiatives that go beyond the mission of any one IC. These accomplishments led to creation of the Office of Portfolio Analysis and Strategic Initiatives (OPASI) which has begun to institutionalize these processes. The establishment of OPASI represents a major organizational change at NIH aimed primarily at addressing challenges in the coordination of biomedical research of benefit to every IC. Using a combination of approaches such as agency-encompassing portfolio analysis and establishment of a common fund for shared needs, OPASI will synergize diverse components of the NIH toward the attainment of common goals more efficiently. Continuing the tradition of the NIH Roadmap, this office will also support well-developed initiatives that address areas of science which do not clearly fall within the mission of any one IC or program office. This makes OPASI a natural space for NIH ICs to work together on broad-reaching opportunities which will impact multiple aspects of public health and disease intervention.

CONFLICTS OF INTEREST

Question. Last August, NIH announced the final ethics rules on conflicts of interest. What impact are they having on employee retention and recruitment, and on interactions between NIH scientists and outside associations, such as trade groups and scientific associations?

Answer. Regarding Employee retention and recruitment. In the preamble to the final rule (published in August 2005), we stated that we would review the rule to “evaluate continued adequacy and effectiveness in relation to current agency responsibilities.” We are particularly interested in learning about any effects that the prohibited holding and outside activities provisions of the rule have had on hiring and retention. We are currently in the process of conducting a survey of current NIH employees, collecting their feedback related to the new regulations. In separate surveys in the coming months, we intend to ask former employees (those who left the NIH after January 1, 2005) and potential employees their opinions as well.

Interactions between NIH scientists and outside associations, such as trade groups and scientific associations. The regulations do not affect official duty interactions that scientists may have with trade groups or scientific associations.

PANDEMIC FLU

Question. We are all concerned about how long it would take between the time that we detected a pandemic flu virus in the United States and when we could create a vaccine for it. Right now, if a pandemic were to occur, I understand that it would take almost six months to produce a vaccine, using our current egg-based methods.

HHS recently invested \$1 billion in the development of new cell-based technologies to produce a pandemic vaccine. We’re all looking forward to the results. But even if successful, a cell-based vaccine would not be immediately available at the time of a pandemic.

The current methods of vaccine development are commonly referred to as the “one drug, one bug” philosophy—develop a vaccine for each flu strain or strains. But that means that you have to identify the “bug” or flu strain before you can begin to manufacture a vaccine. However, I have heard that there is work being done to develop a vaccine that would address all strains of the flu—a “one drug, many bugs” plan. Is NIH supporting this type of research? Does it have promise?

Answer. The National Institute of Allergy and Infectious Diseases (NIAID) is supporting research and development of alternate approaches to dealing with the threat of emerging and re-emerging infectious diseases such as influenza.

For example, NIAID is pursuing the development of a “universal vaccine” that protects against multiple virus strains such as those resulting from antigenic drift associated with seasonal influenza and antigenic shift associated with pandemic influenza. As influenza viruses circulate, the genes that determine the structure of their surface proteins undergo small changes. Sometimes the change in the genes results in a slight change in the antigenic properties of the protein, a process commonly referred to as “antigenic drift.” Antigenic drift is the basis for the changes in seasonal influenza observed during most years, and is the reason that we must update influenza vaccines annually. Influenza viruses also can change more dramatically. For example, viruses sometimes emerge that can jump species from natural reservoirs, such as wild ducks, to infect domestic poultry, farm animals, or humans. When an influenza virus jumps species from an animal, such as a chicken, to infect a human, the result is usually a “dead-end” infection that cannot readily spread further in the human population. However, mutations in the virus could develop that allow human-to-human transmission. Furthermore, if an avian influenza virus and another human influenza virus were to simultaneously co-infect a person or animal, the two viruses might swap genes, possibly resulting in a virus that is readily transmissible between humans, and against which the population would have no natural immunity. These types of significant changes in influenza viruses are referred to as “antigenic shift.” When an “antigenic shift” occurs, a global influenza pandemic can result. Historically, pandemic influenza is a proven threat. In the 20th century, influenza pandemics occurred in 1918, 1957, and 1968.

The NIAID is supporting a number of research projects to develop a vaccine that induces a potent immune response to the common elements of the influenza virus that undergo very few changes from season to season and from strain to strain. Although this is a difficult task, such a “universal” influenza vaccine would not only provide continued protection over multiple seasons, it might also offer protection against a newly emerged pandemic influenza virus and thus substantially reduce the susceptibility of the population to infection by any influenza virus—making the

country far less vulnerable to influenza viruses emerging from avian and other animal sources.

One relatively stable element of the influenza virus is a protein called M2. The external portion of the M2 protein is very similar in influenza viruses from year to year and from strain to strain. A “universal” influenza vaccine targeting the M2 protein, or other conserved elements, could be protective against a range of influenza strains. NIAID-supported researchers have demonstrated that vaccines made with bioengineered versions of M2 can protect mice from lethal influenza virus. The scientists now are testing cross-reactivity between different species and strains of influenza, examining how long the immunity provided by these vaccines lasts, and evaluating whether the influenza viruses can evade these vaccines by developing mutations in their M2 proteins.

In addition, researchers at the NIAID Vaccine Research Center (VRC) are developing and testing gene-based influenza vaccines that will protect against multiple strains of influenza. As a first step, initial candidate vaccines, each containing the gene encoding the hemagglutinin (H) surface protein of an influenza virus isolated from a recent human outbreak of influenza (H1N1, H3N2 or H5N 1), have already shown promise in animal studies. VRC researchers plan to develop additional gene-based vaccines for all common variants of hemagglutinin, as well as other influenza viral proteins, such as nucleoprotein and the M2 protein. In the future, the VRC will incorporate both conserved and variable genes from multiple influenza strains into DNA and adenovirus vectors that can readily be produced by existing manufacturing processes.

A second approach, while not technically a vaccine, is an immune enhancer which specifically targets a component of the immune system and enhances one’s ability to respond to a broad range of microbial threats. Studies of the human innate immune system, which is comprised of “first responder” cells and other defenses that provide a first line of defense against a wide variety of pathogens, have been moving forward rapidly. These advances suggest it may be possible to develop a relatively small set of fast-acting, broad-spectrum countermeasures that can boost innate immune responses to many pathogens or toxins, including influenza. The capability to boost the innate immune system also could lead to the development of more powerful vaccine additives, called adjuvants, that can increase vaccine potency. The concept of immune enhancers has been demonstrated in early stage clinical studies, but requires further research and development to be applied to pandemic influenza vaccination.

QUESTIONS SUBMITTED BY SENATOR DANIEL K. INOUE

TRADITIONAL HEALING PRACTICES

Question. Last year, at my request, Dr. Donald Lindberg, Director of the National Library of Medicine, visited one of our Native Hawaiian Healing programs at Papa Ola Lokahi for the purpose of conducting “listening circles” to discuss the needs for preservation and documentation of traditional cultural healing practices. I am very interested in a report of his findings from this visit. I am most appreciative of the National Library of Medicine’s continued interest and support of Native Hawaiian issues.

Answer. Early this year NLM convened a working group to examine both the feasibility of an exhibition on Native health and healing, and NLM’s role in collecting and preserving information about traditional medicine. As a result of this working group, NLM has reviewed its collection to develop policies, as well as examined its collection in these areas. Subsequently, the Library has made an effort to collect modern publications such as all the items in the Bishop Museum’s (Honolulu, HI) current catalog as well as their out of print materials.

In addition to purchasing standard published materials, NLM is also obtaining input from Native American (including Native Hawaiian) healers, leaders, educators, and others, on appropriate collection and preservation policies. Over the past year, since the series of Listening Circles the NLM participated in with different Native Peoples, NLM staff have met with many such individuals to gain insight into the issues of collecting and preserving information about traditional healing practices. For example, in February, NLM staff met with librarians and curators from the Bishop Museum, Hawaiian Historical Society, The Hawaiian Mission Children’s Society Library, and the University of Hawaii to gather information to planning a larger follow-up meeting.

This meeting, to include NLM staff, occurred in July 2006, and a report of findings from this visit will be prepared.

DEVELOPING NURSE RESEARCHERS

Question. A long-standing supporter of the National Institute for Nursing Research, I am pleased with the extensive array of research initiatives that have been undertaken by the Institute. I am particularly pleased with those endeavors that are directed at developing the pool of nurse researchers who also become nurse faculty. Another important initiative is training support for fast-track baccalaureate to doctoral program participants. I welcome news of the Institute's progress in facilitating research projects in rural areas that serve minority students via community colleges.

Answer. NINR considers the development of nurse researchers and nurse faculty to be a fundamental component of its research mission. Indeed, developing nurse investigators will be an overarching goal in the Institute's new strategic plan for 2006–2010.

Approximately 7 percent of NINR's budget supports the Institute's Centers programs, which are used to develop the nursing research infrastructure and train new investigators. In addition to our ten Core and nine Exploratory Centers, we have co-sponsored a joint initiative with the National Center on Minority Health and Health Disparities that supports partnerships between established, research-intensive institutions and growing, minority-serving institutions. These Nursing Partnership Centers on Reducing Health Disparities, involving 17 schools of nursing, will increase health disparities research and broaden the diversity of the nurse scientist pool. Several of these Centers are located in rural areas or serve rural and other underserved populations. These Centers represent a major investment aimed at expanding the cadre of nurse scientists involved in health disparities research.

BACCALAUREATE TO DOCTORAL PROGRAMS

Question. A long-standing supporter of the National Institute for Nursing Research, I am pleased that the Administration has continued funding of this program. However, what impact will the \$1 million reduction have on the National Institute of Nursing Research's development of initiative that supports fast-track baccalaureate-to-doctoral programs? These programs were proposed to help increase the number of nursing faculty and in turn decrease the number of qualified nursing school candidates who were turned away in prior years.

Answer. The overall reduction of \$792,000 in the fiscal year 2007 budget request of \$136.6 million for the National Institute of Nursing Research (NINR) will have no impact on its programs that fast-track baccalaureate-to-doctoral nurses to increase the number of nursing investigators. These programs are supported within the Research Training mechanism in NINR, and the fiscal year 2007 President's Budget maintains the current level of support of this activity. NINR remains committed to developing the next generation of nurse scientists. NINR encourages and supports strategies to change the career trajectory of nurse scientists. The Institute emphasizes early entry into research careers, including fast-track baccalaureate-to-doctoral programs, and supports pre-doctoral and postdoctoral nurses who are the future researchers and nursing faculty.

CANCER CENTERS

Question. The National Cancer Institute has had great success and demonstrated value in its system of cancer centers across the country. When awarding core grants for cancer research, is attention paid to geographic and ethnic diversity to ensure that results will capture the often significant differences in outcomes among various ethnic groups and lifestyles?

Answer. The NCI-designated Cancer Centers are vital parts of a national strategy to reduce the suffering and death due to cancer. The NCI Cancer Centers Program provides critical infrastructure for academic and research institutions throughout the United States that provide broad based, coordinated, interdisciplinary programs in cancer research. These institutions are characterized by scientific excellence and a capacity to integrate various research approaches focused on the problem of cancer. Generally, in order to become an NCI-designated Cancer Center, an institution must have a large cancer-relevant grant funding base; substantial institutional commitment in the form of space, resources, and authorities provided to the Center Director; a synergistic organization of transdisciplinary research across all scientific areas of the institution; and, specifically for comprehensive centers, community outreach, education, and training activities.

While the NCI designation is based solely on an evaluation of the science, Centers deliver medical advances to patients and their families; provide state-of-the-art care and access to clinical trials; serve as the major training ground for new clinicians

and researchers; and have the strong links with national, state, and local agencies and advocacy groups needed to address cancer issues most relevant to their communities.

Examples of strategies focused on the geographic reach of Cancer Center services include:

- Minority Institution/Cancer Center Partnership Programs (MI/CCP).*—The MI/CCP, which partner Minority-Serving Institutions (MSIs) with existing NCI-designated Cancer Centers, was established in 2000 to take maximum advantage of their respective expertise and experience. The program is designed to foster development of independent cancer research programs and minority career scientists in MSIs and to improve minority-focused outreach and training efforts in NCI-designated Cancer Centers. Participation in this program better positions MSIs to compete for independent NCI designation and/or to form equal and permanent research alliances with existing NCI-designated Cancer Centers. These partnerships are expected to enable the NCI-designated Cancer Centers to realize substantial progress in their efforts to implement effective research, outreach, and education programs that truly benefit minority populations.
- Affiliations and Consortia.*—Realizing that many institutions serving minorities may not have the research capability or the desire to apply for NCI designation independently, NCI revised the Cancer Center guidelines to encourage the development of affiliations and consortia. We specifically encourage consideration of partnerships that address cancer in minority and other underserved populations.
- Emphasized Integration.*—Through NCI's "Discovery, Development, Delivery" continuum, we expect the continued development of links between existing Cancer Centers, their affiliates and partners in research; as well as state, municipal, and community-based private organizations. NCI is actively seeking mechanisms to foster both vertical integration (i.e., from the Cancer Centers through the community layers they serve) and horizontal integration (i.e., across Cancer Centers and a nationwide network of public and private partners) of the benefits of cancer research. This integration provides a more unified approach to reducing cancer and cancer risk, and more uniform delivery of the benefits of cancer research into all communities.

NCI recognizes that the Cancer Research Center of Hawaii is unique in the community it serves. NCI program staff regularly consults with existing NCI-designated centers on approaches for enhancing representation of underserved populations, and provides support and direction to Center and institutional leadership on how to maintain NCI designation; the latter activities are viewed as particularly critical for Centers with significant minority and other underserved populations.

NCI continues to pay close attention to the Cancer Centers geographic placement. The latest planning grants for NCI Cancer Research Centers (an initial step to gaining designation) have gone to areas without an NCI-designated Center (University of Louisville, University of Oklahoma, Emory University, Medical University of South Carolina, and Howard University). The University of New Mexico, a former planning grant recipient, received Cancer Center designation last year. NCI also continues to advise emerging centers in a number of other underrepresented areas around the country on an informal basis.

Additionally, the Cancer Centers themselves are increasingly establishing their own networks with community hospitals and private oncology practices and extending the benefits of care and clinical trials further into communities not previously reached.

CONSULTATION PROTOCOL

Question. I am pleased that the National Library of Medicine and the National Cancer Institute have made substantial efforts to incorporate, within their program areas, resources to address Native Hawaiian health issues and concerns. The Secretary's latest directive on consultation directs the Intra-Department Council on Native American Affairs to incorporate Native Hawaiian health needs and concerns within the consultation framework for agencies within the Department of Health and Human Services similar to that afforded American Indians and Alaska Natives.

Would the National Institutes of Health be willing to engage in discussions with Papa Ola Lokahi (Native Hawaiian Health Board) on how best the lessons learned working with the National Library of Medicine and the National Cancer Institute can be incorporated within all the Institutes of the National Institutes of Health to develop an agency-wide consultation protocol for the National Institutes of Health and Native Hawaiians similar to that afforded to American Indians and Alaska Natives?

Answer. The NCMHD has established a trans-NIH Committee to work on the NIH implementation of the Department of Health and Human Services' tribal consultation policy. As the committee prepares the NIH-wide tribal consultation protocol, it will look at various best practice models among the Institutes and Centers, including the National Library of Medicine and National Cancer Institute's models for lessons learned that could be incorporated into the protocol and be beneficial to Papa Ola Lokahi and other Native Hawaiians. The NIH recognizes the importance of listening, dialoguing, and developing relationships prior to developing programs and services, and would be willing to hear the suggestions of Papa Ola Lokahi.

QUESTIONS SUBMITTED BY SENATOR HARRY REID

CHRONIC FATIGUE SYNDROME (CFS)

Question. How many Chronic Fatigue Syndrome (CFS) specific grant applications were received, reviewed and funded for fiscal year 2004 and fiscal year 2005?

Answer. In fiscal year 2004, 17 CFS-specific grant applications (R01) were received and reviewed; 2 were awarded. One P50, a specialized center, was received and awarded. One R13, a conference grant, was received and awarded. In fiscal year 2005, eight CFS-specific grant applications (R01) were received and reviewed; one was awarded. One K12, Physician Scientist Award, was received but not awarded.

Question. Please provide a detailed list of the studies, institutions, lead researchers and individual grant amounts for all CFS studies funded in fiscal year 2004 and fiscal year 2005.

Answer. The information requested is included in the following tables compiled by the OD Budget Office.

NATIONAL INSTITUTES FOR HEALTH—FUNDING FOR CHRONIC FATIGUE SYNDROME FISCAL YEAR 2004

[Whole dollars]

IC	Project number	Principal investigator	Institution	State	Project title	Amount
NHLBI	5 R01 HL045462	COLLINS, TUCKER O	CHILDREN'S HOSPITAL (BOSTON)	MA	TRANSCRIPTIONAL REGULATION OF E-SELECTIN	\$177,750
NHLBI	5 R01 HL054926	ISCHIROPOUL OS, HARRY	CHILDREN'S HOSPITAL OF PHILADELPHIA	PA	REACTIVE SPECIES IN VASCULAR DISEASE-INJURY MECHANISMS.	170,000
NHLBI	5 R01 HL055591	LOWASNEY, JON W	NORTHWESTERN UNIVERSITY	IL	MOLECULAR BASIS FOR PROTEIN-PHOSPHOLIPID INTERACTION	148,500
NHLBI	5 R01 HL056850	CLEMMONS, DAVID R	UNIVERSITY OF NORTH CAROLINA CHAPEL HILL	NC	MECHANISMS BY WHICH IGF-1 STIMULATES SMOOTH MUSCLE CELLS.	203,694
NHLBI	5 R01 HL059459	FREEMAN, ROY	BETH ISRAEL DEACONESS MEDICAL CENTER.	MA	ORTHOSTATIC INTOLERANCE IN CFS	392,186
NHLBI	2 R01 HL061388	CRANDALL, CRAIG G	UNIVERSITY OF TEXAS SW MED CTR/DALLAS.	TX	HEAT STRESS AND CIRCULATORY CONTROL	61,066
NHLBI	5 R01 HL066007	STEWART, JULIAN M	NEW YORK MEDICAL COLLEGE	NY	CIRCULATORY DYSFUNCTION IN CHRONIC FATIGUE SYNDROME.	252,000
NHLBI	5 R01 HL067422	CRANDALL, CRAIG G	UNIVERSITY OF TEXAS SW MED CTR/DALLAS.	TX	SKIN COOLING TO IMPROVE ORTHOSTATIC TOLERANCE	131,500
NHLBI	5 R01 HL070215	CALDWELL, ROBERT W	MEDICAL COLLEGE OF GEORGIA	GA	ENDOTHELIAL CELL DYSFUNCTION IN OXIDATIVE STRESS MODELS.	125,562
TOTAL, NHLBI						1,662,258
NINDS	1R13NS047105-01	HORTOBAGYI, TIBOR	EAST CAROLINA UNIVERSITY	NC	INTERNATIONAL SYMPOSIUM ON MOTOR CONTROL USING TMS.	2,250
NINDS	5Z01NS02979-06	GOLDSTEIN, DAVID	NINDS	MD	CLINICAL NEUROCARDIOLOGY: CATECHOLAMINE SYSTEMS IN STRESS AND DISEASE.	531,506
TOTAL, NINDS						533,756
NIAD	1 R01 AI05601401A1	SULLIVAN, PATRICK F	UNIVERSITY OF NORTH CAROLINA CHAPEL HILL	NC	MICROARRAYS & PROTEOMICS IN MZ TWINS DISCORDANT FOR CFS.	255,301
NIAD	5 R01 AI042403-07	BARANIUK, JAMES N	GEORGETOWN UNIVERSITY	DC	MECHANISMS OF RHINITIS IN CFS	232,800
NIAD	5 R01 AI049720-05	JASON, LEONARD	DE PAUL UNIVERSITY	IL	ACTIVITY INTERVENTION FOR CHRONIC FATIGUE SYNDROME.	266,169
NIAD	5 R01 AI051270-03	TAM, PATRICIA E	UNIVERSITY OF MINNESOTA TWIN CITIES.	MN	VIRAL DSRNA AS A MEDIATOR OF CHRONIC MUSCLE DISEASES.	334,125

NIAD	2 R01-AI054478-02	NATLSON, BENJAMIN H	UNIV OF MED/DENT NJ NEWARK	NJ	SLEEP AND CYTOKINES IN CHRONIC FATIGUE SYNDROME	334,904
TOTAL, NIAD						1,423,299
NICHD	R01HD043301-02	TAYLOR, RENE E R	UNIVERSITY OF ILLINOIS AT CHICAGO	IL	CHRONIC FATIGUE SYNDROME IN ADOLESCENTS	267,009
TOTAL, NICHD						267,009
NIAAMS	5-R01-AR-47678-03	BUCHWALD, DEDRA S	UNIVERSITY OF WASHINGTON	WA	ARE FIBROMYALGIA AND CHIARI I MALFORMATION RELATED?	146,712
TOTAL, NIAAMS						146,712
NIMH	5K23MH001961-04	FRIEDBERG, FRED	STATE UNIVERSITY NEW YORK STONY BROOK	NY	PSYCHIATRIC COMORBIDITY IN CHRONIC FATIGUE SYNDROME	148,923
TOTAL, NIMH						148,923
NINR	R01-AI049720-05	LEONARD, JASON	DE PAUL UNIVERSITY	IL	ACTIVITY INTERVENTION FOR CHRONIC FATIGUE SYNDROME	100,000
TOTAL, NINR						100,000
NCRR	2M01RR000037-44	SMITH, MARK	UNIVERSITY OF WASHINGTON	WA	THE EFFECT OF PARENTAL CHRONIC FATIGUE SYNDROME ON OFFSPRING	29,494
NCRR	3P41RR002305-20S1	MCCULLY, KEVIN	UNIVERSITY OF PENNSYLVANIA	PA	CHRONIC FATIGUE SYNDROME	5,742
NCRR	5M01RR000039-44	PAPANICOLAOU, DIMITRIS A	EMORY UNIVERSITY	GA	EFFECTS OF CORTICOTROPIN-RELEASING HORMONE INFUSION IN NORMAL FEMALES	179,251
NCRR	5M01RR000042-44	WILLIAMS, DAVID A	UNIVERSITY OF MICHIGAN AT ANN ARBOR	MI	SUBJECT REGISTRY: INTERDISCIPLINARY STUDIES OF CHRONIC MULTI-SYMPTOM ILLNESSES	9,149
NCRR	5M01RR000046-44	LIGHT, KATHLEEN C	UNIVERSITY OF NORTH CAROLINA CHAPEL HILL	NC	FACTORS IN ARTHRITIS, CFS, FIBROMYALGIA & TEMPOROMANDIBULAR DISORDERS	74,144
NCRR	5M01RR000052-43	ROWE, PETER C	JOHNS HOPKINS UNIVERSITY	MD	DISORDERED RESPONSES TO ORTHOSTATIC STRESS IN . . . GULF WAR SYNDROME SYMPTOMS	7,991
NCRR	5M01RR000052-43	SCHWARTZ, CINDY	JOHNS HOPKINS UNIVERSITY	MD	MOVEMENT RESTRICTION AND FATIGUE IN CANCER SURVIVORS	157
NCRR	5M01RR002635-20	ADLER, GAIL	BRIGHTMAN AND WOMEN'S HOSPITAL	MA	IMMUNONEUROENDOCRINE RESPONSE TO TETANUS TOXOID	4,821

NATIONAL INSTITUTES FOR HEALTH—FUNDING FOR CHRONIC FATIGUE SYNDROME FISCAL YEAR 2004—Continued
 [Whole dollars]

IC	Project number	Principal investigator	Institution	State	Project title	Amount
NCRR	5M01RR010710-07	FRIEDBERG, FREDRICK	STATE UNIVERSITY NEW YORK STONY BROOK	NY	PSYCHIATRIC COMORBIDITY IN CHRONIC FATIGUE SYNDROME	159,869
NCRR	5M01RR010710-07	FRIEDBERG, FREDRICK	STATE UNIVERSITY NEW YORK STONY BROOK	NY	WHY DO PEOPLE DROP OUT OF SUPPORT GROUPS FOR CHRONIC FATIGUE SYNDROME?	6,401
NCRR	5M01RR016587-03	HURWITZ, BARRY	UNIVERSITY OF MIAMI-MEDICAL	FL	RBC MASS/AUTONOMIC NERVOUS SYSTEM/INTEGRITY/SYNDROME IN CHRONIC FATIGUE SYNDROME.	142,237
NCRR	5P20RR011145-10	FRIEDMAN, THEODORE C	CHARLES R. DREW UNIVERSITY OF MED & SCI.	CA	USE OF VIAGRA TO ALTER SYMPTOMS IN PTS WITH CFS	118,851
NCRR	5P41RR008119-12	TARASOV, SERGEY G	UNIVERSITY OF MARYLAND BALT PROF SCHOOL	MD	SPECT & DNA BINDING OF NAPHTHYLMIDO IMIDAZOACRIDONE WMC79 & RELATED COMPOUND.	43,966
NCRR	5P51RR00168-43	MADRAS, BERTHA K	HARVARD UNIVERSITY (MEDICAL SCHOOL)	MA	MOLECULAR TARGETS OF THE ANTI-NARCOLEPTIC DRUG MODAFINIL	14,843
NCRR	5R13RR017508-03	LAKOWICZ, JOSEPH R	UNIVERSITY OF MARYLAND BALT PROF SCHOOL	MD	CFS COURSE ON FLUORESCENCE SPECTROSCOPY: MICROCOPY, DATA ANALYSIS, FLUOROMETRY.	4,084
TOTAL NCRR						801,000
OD	1R01HD43301-02	TAYLOR, RENEE	UNIVERSITY OF ILLINOIS, CHICAGO	IL	CFS	400,000
TOTAL OD						400,000
GRAND TOTAL						5,482,957

NATIONAL INSTITUTES FOR HEALTH—FUNDING FOR CHRONIC FATIGUE SYNDROME FISCAL YEAR 2005
 [Whole dollars]

IC	Project number	Principal investigator	Institution	State	Project title	Amount
NHLBI	5 R01 HL045462	COLLINS, TUCKER O	CHILDREN'S HOSPITAL BOSTON	MA	TRANSCRIPTIONAL REGULATION OF E-SELECTIN	\$177,750
NHLBI	5 R01 HL054926	ISCHIROPOUL OS, HARRY	CHILDREN'S HOSPITAL OF PHILADELPHIA	PA	REACTIVE SPECIES IN VASCULAR DISEASE-INJURY MECHANISMS.	170,000

NHLBI	5 R01 HL055591	LOMASNEY, JON W	NORTHWESTERN UNIVERSITY	IL	MOLECULAR BASIS FOR PROTEIN-PHOSPHOLIPID INTER-ACTION.	148,500
NHLBI	5 R01 HL056850	CLEMMONS, DAVID R	UNIVERSITY OF NORTH CAROLINA CHAPEL.	NC	MECHANISMS BY WHICH IGF-I STIMULATES SMOOTH MUSCLE CELLS.	209,541
NHLBI	5 R01 HL059459	FREEMAN, ROY	BETH ISRAEL DEACONESS MEDICAL	MA	ORTHOSTATIC INTOLERANCE IN CFS	403,952
NHLBI	5 R01 HL061388	CRANDALL, CRAIG G	UNIVERSITY OF TEXAS SW MED	TX	HEAT STRESS AND CIRCULATORY CONTROL	47,164
NHLBI	5 R01 HL067422	CRANDALL, CRAIG G	UNIVERSITY OF TEXAS SW MED	TX	SKIN COOLING TO IMPROVE ORTHOSTATIC TOLERANCE	131,500
NHLBI	5 R01 HL070215	CALDWELL, ROBERT W	MEDICAL COLLEGE OF GEORGIA (MCG).	GA	ENDOTHELIAL CELL DYSFUNCTION IN OXIDATIVE STRESS MODELS.	125,562
TOTAL, NHLBI						1,413,969
NINDS	5Z01NS002979-07	DAVID, GOLDSTEIN	NINDS INTRAMURAL RESEARCH PROGRAM	MD	CLINICAL NEUROCARDIOLOGY: CATECHOLAMINE SYSTEMS IN STRESS AND DISEASE.	559,424
NINDS	9L30NS054198-02	FRANTOM, CATHERINE G	LOAN REPAYMENT		NEURO-REHAB MEASUREMENT	3,058
TOTAL, NINDS						562,482
NIAID	5 R01 AI051270-04	TAM, PATRICIA E	UNIVERSITY OF MINNESOTA TWIN CITIES	MN	VIRAL DSRNA AS A MEDIATOR OF CHRONIC MUSCLE DISEASES.	349,860
NIAID	5 R01 AI054478-03	NATELSON, BENJAMIN H	UNIV OF MED/DENT OF NU-NU MEDICAL SCHOOL	NJ	SLEEP AND CYTOKINES IN CHRONIC FATIGUE SYNDROME	673,289
NIAID	1 R01 AI055735-01A2	JASON, LEONARD A	DE PAUL UNIVERSITY	IL	RISK FACTORS ASSOCIATED WITH CFS AND CF PROGNOSIS.	541,703
NIAID	5 R01 AI056014-02	SULLIVAN, PATRICK F	UNIVERSITY OF NORTH CAROLINA CHAPEL HILL.	NC	MICROARRAYS & PROTEOMICS IN MZ TWINS DISCORDANT FOR CFS.	518,667
TOTAL, NIAID						2,083,519
NICHD	R01HD043301-03	TAYLOR, RENE E R	UNIVERSITY OF ILLINOIS AT CHICAGO.	IL	CHRONIC FATIGUE SYNDROME IN ADOLESCENTS	268,159
TOTAL, NICHD						268,159
NIAAMS	5-R01-AR-47678-04	BUCHWALD DEDRA S	UNIVERSITY OF WASHINGTON	WA	ARE FIBROMYALGIA AND CHIARI I MALFORMATION RELATED?	127,983
TOTAL, NIAAMS						127,983

NATIONAL INSTITUTES FOR HEALTH—FUNDING FOR CHRONIC FATIGUE SYNDROME FISCAL YEAR 2005—Continued
 [Whole dollars]

IC	Project number	Principal investigator	Institution	State	Project title	Amount
NIMH	5K23MH001961-05	FRIEDBERG, FRED	STATE UNIVERSITY NEW YORK STONY BROOK	NY	PSYCHIATRIC COMORBIDITY IN CHRONIC FATIGUE SYNDROME.	157,316
TOTAL, NIMH						157,316
NCRR	1M01RR020359-01	BARANIUK, JAMES N	CHILDREN'S RESEARCH INSTITUTE	DC	RHINITIS IN CHRONIC FATIGUE SYNDROME (CFS)	3,236
NCRR	2M01RR000052-44	SCHWARTZ, CINDY	JOHNS HOPKINS UNIVERSITY	MD	MOVEMENT RESTRICTION AND FATIGUE IN CANCER SURVIVORS.	1,246
NCRR	2P20RR011145-11	FRIEDMAN, THEODORE C	CHARLES R. DREW UNIVERSITY OF MED & SCI.	CA	USE OF VIAGRA TO ALTER SYMPTOMS IN PTS WITH CFS	19,782
NCRR	2P41RR002305-21A1	MCCULLY, KEVIN	UNIVERSITY OF PENNSYLVANIA	PA	CHRONIC FATIGUE SYNDROME	16,453
NCRR	5M01RR000037-45	SMITH, MARK	UNIVERSITY OF WASHINGTON	WA	THE EFFECT OF PARENTAL CHRONIC FATIGUE SYNDROME ON OFFSPRING.	6,418
NCRR	5M01RR000042-45	WILLIAMS, DAVID A	UNIVERSITY OF MICHIGAN AT ANN ARBOR.	MI	SUBJECT REGISTRY: INTERDISCIPLINARY STUDIES OF CHRONIC MULTI-SYMPTOM ILLNESSES.	77,197
NCRR	5M01RR000046-45	LIGHT, KATHLEEN C	UNIVERSITY OF NORTH CAROLINA CHAPEL HILL	NC	FACTORS IN ARTHRITIS, CFS, FIBROMYALGIA & TEMPOROMANDIBULAR DISORDERS.	17,907
NCRR	5M01RR000048-44	TAYLOR, RENEE	NORTHWESTERN UNIVERSITY	IL	A PROSPECTIVE STUDY OF CHRONIC FATIGUE SYNDROME IN ADOLESCENTS.	26,247
NCRR	5M01RR000071-42	MATHEW, SANJAY	MOUNT SINAI SCHOOL OF MEDICINE OF NYU.	NY	MRS NEUROMETABOLITES IN CHRONIC FATIGUE SYNDROME, GENERALIZED ANXIETY DISORDER.	10,871
NCRR	5M01RR010710-08	FRIEDBERG, FREDRICK	STATE UNIVERSITY NEW YORK STONY BROOK	NY	PSYCHIATRIC COMORBIDITY IN CHRONIC FATIGUE SYNDROME.	48,251
NCRR	5M01RR010710-08	FRIEDBERG, FREDRICK	STATE UNIVERSITY NEW YORK STONY BROOK	NY	WHY DO PEOPLE DROP OUT OF SUPPORT GROUPS FOR CHRONIC FATIGUE SYNDROME?	42,683
NCRR	5M01RR016587-04	HURWITZ, BARRY	UNIVERSITY OF MIAMI-MEDICAL	FL	RBC MASS/AUTONOMIC NERVOUS SYSTEM/INTEGRITY/SYNDROME IN CHRONIC FATIGUE SYNDROME.	28,827
NCRR	5P41RR008119-13	NOWACZYK, KAZIMIERZ	UNIVERSITY OF MARYLAND BALT PROF SCHOOL.	MD	CFS COMPUTERS	20,687
NCRR	5P51 RR000168-44	MADRAS, BERTHA K	HARVARD UNIVERSITY (MEDICAL SCHOOL).	MA	MOLECULAR TARGETS OF THE ANTI-NARCOLEPTIC DRUG MODAFINIL.	120,481

Question. NIH is expected to announce later this month the awards made in response to the 7/14/05 RFA for CFS. Will the studies funded under this RFA yield a true increase in the level of NIH research funding for CFS?

Answer. Yes. The 7 new grants funded will infuse an additional several million dollars into the bottom line for CFS funding that has remained relatively constant in the \$5.5–\$6 million range over the past years. A projected \$2 million is derived from the redirected funds of the ORWH budget to fund and co-fund studies through the ICs. The remainder will be provided by the NIAAA, NIAMS, NIEHS, and NINDS. Additionally, individual letters sent from the Trans-NIH Working Group for Research on Chronic Fatigue Syndrome encouraged the unsuccessful applicants to revise and submit their proposals under the standing CFS Program Announcement. Many have been in touch for advice and plan to resubmit. The announcement resulted in increased interest from many researchers who had not previously conducted research on CFS. They are now aware that NIH interest in CFS is broad based and that many disciplines can contribute. It is expected that this RFA, information on the new website, and contacts established with members of the CFSWG will lead to a further increase in investigator initiated submissions.

Question. You have been a strong advocate for more centralized power and discretion within the NIH Office of the Director for the Roadmap Initiative to identify major opportunities and gaps in research that no single institute at NIH can tackle alone but that the agency as a whole must address. CFS is a complex illness that affects the brain and multiple body systems and thus is an example of a condition that must be addressed by multiple institutes. The CDC is expected to announce that CFS affects more than four million adults in the United States. In 1999, responsibility for CFS was moved to the Office of the Director. What progress in NIH's approach to the study of CFS has been made since this move?

Answer. Tremendous progress has been and will continue to be made in pursuing and further stimulating CFS research. This is accomplished through a trans-NIH Working Group for Research on CFS (CFSWG) that is chaired by the Office of Research on Women's Health (ORWH) in the Office of the Director and includes members from 13 different ICs. The CFSWG was established in April 2001 to develop an action plan to enhance the status of CFS research at the NIH and among the external scientific community. The Working Group first issued a program announcement based on recommendations from the Chronic Fatigue Syndrome, State of the Science Conference held in October 2000 that encouraged innovative and interdisciplinary CFS research. The CFSWG updated and reissued this announcement in 2005 based on the results of a second NIH-sponsored scientific workshop. This workshop, Neuro-Immune Mechanisms and Chronic Fatigue Syndrome: Will understanding central-mechanisms enhance the search for the causes, consequences and treatment of CFS?, was held in June 2003. Its proceedings were published in 2004 (NIH Publication No. 04–5497) and disseminated widely among the scientific community. The first issue of the new ORWH Science Series for the Public, informational fact sheets, is also derived from these proceedings. Also based on these proceedings, the ORWH and the CFSWG developed a request for applications (RFA) to explicate how the brain, as the mediator of the various body systems involved, fits into the schema for understanding CFS (RFA OD–06–002). This RFA specifically solicited proposals from multidisciplinary teams of scientists to develop an interdisciplinary approach to the mechanisms involved in CFS in men and women across the life span. Twenty-nine applications were received and are in process. All documents mentioned above as well as complete information about the NIH CFS program are available at <http://orwh.od.nih.gov/cfs.html>. All of the above demonstrate concerted trans-NIH efforts coordinated by an OD program office that is the focal point for research on women's health, ORWH, to engage the scientific community in addressing the many aspects of and increasing knowledge of CFS.

Question. Has the move to the Office of the Director led to any real progress in multidisciplinary research? If so, what specifics can you point to?

Answer. Yes. Collaborative achievements that include the development of an action plan to enhance the status of CFS research at the NIH and the products of this plan, such as trans-NIH Program Announcements, Requests for Applications, Scientific Workshops would not have been possible without the formation of a trans-NIH CFSWG chaired by the ORWH in the Office of the Director. The ORWH has had a long and successful track record for developing and leading interdisciplinary research and training initiatives on women's health and sex and gender factors in human health through its Coordinating Committee for Research on Women's Health (CCRWH), which brings together representatives from every institute and center to facilitate collaborative efforts. Similarly, the CFSWG, supported and led by the ORWH, is composed of representatives from 13 NIH institutes and centers with an interest in facilitating collaborative efforts to invigorate CFS research at the NIH.

Question. How does the current status of CFS research within the NIH serve as a model for progress, based on more centralized authority within the Office of the Director or as a model for multidisciplinary approaches and the Roadmap.

Answer. NIH has made steady progress towards an interdisciplinary approach to CFS through the efforts and function of an OD program office that was established to serve as the NIH focal point for the OD on women's health research. Therefore, the OD, through ORWH, was able to bring together diverse institutes to collaborate effectively in a trans-NIH initiative to enhance research on CFS. The ORWH also contributed staff and budget to these expanded research activities. This ORWH effort for CFS serves as an example of how an office within the OD can facilitate trans-NIH scientific initiatives that manifest real progress in research.

QUESTIONS SUBMITTED BY SENATOR HERB KOHL

ALZHEIMER'S DISEASE

Question. In April, the National Center for Health Statistics reported that the life expectancy of Americans has risen to 78 years—the highest it has ever been. However, they also reported that the death rate from Alzheimer's disease is increasing among the top 10 causes of death in the United States. In light of the fact that the Baby Boom generation is entering the age of highest risk for Alzheimer's, shouldn't NIH be increasing, rather than reducing, its investment in Alzheimer's research?

Answer. It should be noted that our fiscal year 2007 funding level for Alzheimer's disease is an estimate and reflects a reduction that is comparable to the reductions in the total budgets of the NIH ICs supporting research in this important area. At this time, it is not possible to be precise as to where available funding will be allocated. Funding decisions will be based on public health need, scientific and technological opportunity, and the peer review of research applications.

As the Senator points out, with current trends, Alzheimer's disease will become an increasingly critical public health concern over the coming decades. To reverse this trend, it is critical that we explore all promising avenues of discovery and promote the translation of research results into interventions for the successful prevention, detection, diagnosis, and treatment of Alzheimer's disease. Alzheimer's disease research continues to be a high priority for NIH, and scientific opportunities in this area will be actively pursued within available resources.

EPILEPSY

Question. As you know, for years I have pushed NIH to work harder to develop better treatments and a cure for epilepsy. I have supported efforts by the National Institute of Neurological Disorders and Stroke to fund epilepsy research. However, many experts think we need a broader approach, with greater collaboration between NINDS and the National Institute on Mental Health, the National Institute on Child Health and Human Development, and other Institutes. What are you doing to guarantee that multi-Institute studies on epilepsy are developed and funded in the coming year?

Answer. As the lead NIH Institute for epilepsy research, the National Institute of Neurological Disorders and Stroke (NINDS) coordinates epilepsy research efforts through the InterAgency Epilepsy Working Group. The Epilepsy Working Group is composed of scientific program staff from the NINDS, eight other Institutes, including the National Institute of Mental Health (NIMH) the National Institute of Child Health and Human Development (NICHD), and staff members from the Centers for Disease Control and Prevention. The Working Group facilitates coordination and collaboration among NIH Institutes. For example, NINDS and NIMH Epilepsy Working Group members collaborated with the American Epilepsy Society to sponsor an international workshop in May 2005 on treatment of nonepileptic seizures (NES), a neuropsychiatric seizure disorder. As a result of this meeting, the NIMH and the NINDS issued a request for applications on "Collaborative Research on Mental and Neurological Disorders."

This initiative focused on co-morbidities between mental health and neurological disorders, including epilepsy.

The NINDS and the NICHD have a long history of collaboration on epilepsy research. The NICHD funds the Mental Retardation Research Centers Program, a network of regional centers developed for research on mental retardation and related aspects of human development, including epilepsy. Many of the Centers also provide infrastructure for NINDS-supported epilepsy research projects. Both Institutes fully expect this successful collaboration to continue in the future.

The NIMH, NICHD, and NINDS also collaborate in funding the Autism Research Network (ARN). The ARN is made up of eight collaborative research centers that focus on the causes, diagnosis, early detection, prevention, and treatment of autism. One of the network studies, "A Longitudinal Assessment of Behavior Problems, Puberty, and Epilepsy" is designed to investigate which children with autism develop seizures and whether there are changes in behavior that either precede or follow the development of seizures.

Question. As you know, NINDS held a successful epilepsy conference in 2000, where research benchmarks were developed and used to create a research agenda in epilepsy. It's my understanding that NINDS is planning a follow-up conference on Curing Epilepsy in March 2007. Will you ensure that representatives from other Institutes participate in the 2007 conference? What steps will you take after the conference to ensure that collaborative research is pursued in order to have the greatest impact for epilepsy patients?

Answer. The NINDS has invited all the organizations represented on the Inter-Agency Epilepsy Working Group (IAEWG) to participate in planning and co-sponsoring the Curing Epilepsy 2007 conference. Co-morbidities, such as cognitive and psychological issues in children and adults with epilepsy, will be one of the major themes of the conference. Epilepsy co-morbidities often include behavioral problems, learning and memory difficulties, and depression. The NINDS expects that the conference will draw attention to the importance of these issues and will stimulate interdisciplinary investigation into the causes, treatment and prevention of epilepsy and its co-morbidities. The IAEWG will also consider the potential for collaborative activities in response to any recommendations that result from the Curing Epilepsy 2007 conference.

AGE-RELATED MACULAR DEGENERATION

Question. You have publicly cited as an NIH "breakthrough" the discovery of a gene strongly associated with age-related macular degeneration (AMD). As you know, AMD is the leading cause of blindness in the United States, especially among our seniors, robbing them of their independence and quality of life. What does this finding mean for new treatments to stop or reverse this blinding eye disease? How will the National Eye Institute follow up on this exciting breakthrough when the President's budget proposes to cut NEI funding?

Answer. National Eye Institute-sponsored investigators have made considerable progress since the recent discovery of the complement factor H (CFH) gene in age-related macular degeneration (AMD). NEI intramural researchers are initiating a phase I clinical trial to evaluate anti-inflammatory agents that may inhibit damaging immune responses potentially resulting from alterations in the CFH gene. NEI extramural and NIH intramural scientists discovered that alterations in a second gene in the inflammatory pathway, complement factor B, are also associated with AMD. Variations in these two genes can predict the clinical outcome in 74 percent of individuals with AMD. In addition, the NEI launched a new research initiative to further investigate the role of inflammation in AMD and other common eye diseases such as diabetic retinopathy and uveitis.

IRRITABLE BOWEL SYNDROME

Question. For the last several years, the Appropriations Committee has asked the National Institute of Diabetes and Digestive and Kidney Diseases to develop a strategic plan for research into Irritable Bowel Syndrome. NIDDK has explained that the Institute [is] creating an overall digestive disease action plan and that IBS will be a significant part of it. Can you update us on NIDDK's progress on the digestive disease plan and explain how much attention IBS will receive?

Answer. The NIH established a National Commission on Digestive Diseases in August 2005, based on the shared interest of the NIH and the Congress in advancing research on digestive diseases. One of the Commission's primary purposes is to develop a Long-Range Research Plan for Digestive Diseases, which will include plans for stimulating research on functional gastrointestinal (GI) and motility disorders such as irritable bowel syndrome (IBS). Within the NIH, the NIDDK has lead responsibility for digestive diseases research and supports a research portfolio in IBS and other types of functional GI and motility disorders. The NIDDK is providing leadership and support for this federally chartered Commission.

As NIH Director, I appointed members of the Commission after a broad call for nominees with diverse scientific, professional, and personal experiences related to digestive diseases from within the academic and medical research and practice communities, patient and patient advocacy community, and the NIH and other Federal health agencies. The perspective of individuals with personal or professional interest

in IBS and other types of functional GI and motility disorders is represented within the Commission.

Commission members recently convened for their first meeting on June 12, 2006, and are currently finalizing topics for chapters of the Research Plan, one of which is expected to focus on IBS and related GI motility disorders research. The ultimate goal of the Commission's Research Plan is to improve the nation's health through advancing research on digestive diseases, such as IBS. The Research Plan will include: (1) information on the burden of disease on individuals and society; (2) examples of research advances that are generating new knowledge vital to understanding, treatment, and prevention; and (3) compelling opportunities for future NIH-funded research, which offer promise for reducing the burden of disease. This Research Plan will recommend promising research directions relevant to IBS and other types of functional GI and motility disorders, which will help guide the NIDDK, the NIH, and the investigative and lay community in the pursuit of the most productive research avenues.

The Commission will rely on broad stakeholder input from members of the digestive diseases community to inform the Research Plan throughout its development. For example, Commission members are currently establishing Working Groups composed of individuals with expertise related to specific areas of digestive diseases research, who will provide input necessary for crafting a well-informed Research Plan. One of these Working Groups is expected to focus on functional GI and motility disorders, such as IBS, in addition to potential overlapping and synergistic efforts in this area on the part of other Working Groups. Other opportunities for broad stakeholder input into the Commission's activities will include public Commission meetings and an open comment period for public input on the draft Research Plan. Additional information on the Commission's ongoing activities can be found on its website at: <http://NCDD.niddk.nih.gov>.

CONCLUSION OF HEARINGS

Senator SPECTER. So thank you for what you are doing. We appreciate your thanks to us, and we are going to do more and we ask you to do more. That concludes our hearings.

[Whereupon, at 10:14 a.m., Friday, May 19, the hearings were concluded, and the subcommittee was recessed, to reconvene subject to the call of the Chair.]

DEPARTMENTS OF LABOR, HEALTH AND
HUMAN SERVICES, EDUCATION, AND RE-
LATED AGENCIES APPROPRIATIONS FOR
FISCAL YEAR 2007

U.S. SENATE,
SUBCOMMITTEE OF THE COMMITTEE ON APPROPRIATIONS,
Washington, DC.

DEPARTMENT OF LABOR
OFFICE OF THE SECRETARY

THAD COCHRAN, MISSISSIPPI, CHAIRMAN

TED STEVENS, ALABAMA
ARLEN SPECTER, PENNSYLVANIA
PETE V. DOMENICI, NEW MEXICO
CHRISTOPHER S. BOND, MISSOURI
MITCH MCCONNELL, KENTUCKY
CONRAD BURNS, MONTANA
RICHARD C. SHELBY, ALABAMA
JUDG GREGG, NEW HAMPSHIRE
ROBERT F. BENNETT, UTAH
LARRY CRAIG, IDAHO
KAY BAILEY HUTCHISON, TEXAS
MIKE DEWINE, OHIO
SAM BROWNBACK, KANSAS
WAYNE ALLARD, COLORADO

ROBERT C. BYRD, WEST VIRGINIA
DANIEL K. INOUE, HAWAII
PATRICK J. LEAHY, VERMONT
TOM HARKIN, IOWA
BARBARA A. MIKULSKI, MARYLAND
HARRY REID, NEVADA
HERB KOHL, WISCONSIN
PATTY MURRAY, WASHINGTON
BYRON L. DORGAN, NORTH DAKOTA
DIANNE FEINSTEIN, CALIFORNIA
RICHARD J. DURBIN, ILLINOIS
TIM JOHNSON, SOUTH DAKOTA
MARY L. LANDRIEU, LOUISIANA

J. KEITH KENNEDY, STAFF DIRECTOR
TERRENCE E. SALVAIN, MINORITY STAFF DIRECTOR

United States Senate

COMMITTEE ON APPROPRIATIONS
WASHINGTON, DC 20510-6025
<http://appropriations.senate.gov>

June 16, 2006

Honorable Elaine Chao
Secretary
U.S. Department of Labor
Washington, D.C.

Dear Madam Secretary,

Due to the press of Senate business and the particularly heavy schedule of the Judiciary Committee, it has been necessary to postpone, several times, your appearance before the Subcommittee on Labor, Health and Human Services and Education. At this late date, neither your schedule nor mine will permit a hearing in time to obtain the information needed to mark-up the Labor-HHS bill.

I am therefore requesting that you answer, in writing, the enclosed series of questions pertaining to the Department of Labor's fiscal year 2007 budget request. Please provide your responses not later than July 7, 2006. "

My best,

Sincerely,



Arlen Specter
Chairman
Subcommittee on Labor, Health and Human
Services and Education Appropriations

[The following questions were submitted to be answered for the record:]

(273)

QUESTIONS SUBMITTED BY SENATOR ARLEN SPECTER

MINE SAFETY

Question. Congress has now passed bi-partisan mine safety legislation that contained many of the provisions in a bill I introduced on February 16, 2006. Congress has also passed a pending supplemental appropriations bill containing \$35,600,000 to augment inspections of coal mines and to expand research to develop mine safety technology. How do you intend to implement these authorization and appropriation measures? What additional appropriations are necessary to fully implement the new authorization?

During the hearing this Subcommittee held on January 23, 2006, on the Sago Mine disaster, I questioned the policy of the requiring mine representatives to be present during accident investigation interviews with miners. Although the legislation I introduced would prohibit this practice, it was not included in the consensus bill reported last week. Do you support such a provision?

Answer. \$25.6 million of the \$35.6 million contained in the supplemental appropriation was appropriated to MSHA. The supplemental appropriation contains a provision requiring MSHA to submit a spending plan for these funds to the appropriations committees by July 15, 2006, and MSHA will comply with this provision. The remaining \$10 million in supplemental funding was appropriated to NIOSH for expansion of research and mine safety technology, therefore NIOSH is the appropriate entity to answer questions regarding their plans for the use of those funds. With regard to additional appropriations necessary to fully implement the MINER Act, the MINER Act contains authorization for new grant programs but no funding for these programs has been appropriated. Many of the new MINER Act provisions do not require any additional funding. For example, the increase of the maximum civil penalty for flagrant violations and the implementation of minimum penalties for unwarrantable citations and orders, as well as the provision requiring every mine to have an Emergency Response Plan do not require any increases in funding.

With regard to MSHA accident investigations, the Mine Act gives MSHA discretion to determine who may be present during accident investigation interviews with miners and other persons who may have relevant information. As you are aware, MSHA's longstanding past practice regarding interviews has generally included participation by the mine operator and the representative of miners. However, we have come to the conclusion that this process should be changed to conform to the process used by virtually all other law enforcement investigative agencies. We believe that witness interviews should be conducted with only federal, and where applicable, state authorities. Of course, witnesses would continue to have the option of having a personal representative of their choosing present during the interview. We believe that the time proven technique of interviewing witnesses separately and without additional persons present is the best method of eliciting useful information without fear of intimidation, and minimizes the ability of witnesses to modify their testimony in light of the knowledge gained from other witnesses. In fact, recent experience has demonstrated that the presence of third-parties could compromise the investigation, make witnesses less likely to cooperate, and result in premature release of information before all witness interviews are complete. Thus, we agree that participation in interviews by non-government personnel should be limited to a personal representative of the witness. Of course, MSHA will continue its practice of releasing all witness transcripts, except those requested under the Mine Act to be confidential, once the investigation has reached a stage where release would not impede or interfere with the investigation.

JOB CORPS FUNDING

Question. It has been more than 45 calendar days of continuous session of the Congress since the President proposed rescinding \$75 million of Job Corps construction and renovation funds. Have these funds now been released as required by the Congressional Budget and Impoundment Control Act?

Answer. The \$75 million in Construction, Rehabilitation, and Acquisition funds were not withheld from obligation, as noted in our May 30, 2006 letter to GAO on this matter, and remain available for obligation by the Office of Job Corps.

Question. Your budget proposed to cut \$62,578,000 from the Job Corps budget for program year 2007, which would result in 3,614 fewer students enrolled than in 2005. This would reduce funding, on inflation-adjusted basis, 8.5 percent below the level in 2005. How far below capacity would this put the 122 existing Job Corps centers?

Answer. With the requested 2007 operating budget of \$1,401,602,000, Job Corps will be able to maintain 42,863 year-around training slots, which represents 95.5 percent of the peak level that could be accommodated by our physical infrastructure.

REINTEGRATION OF YOUTHFUL OFFENDERS

Question. Your budget once again zeroes out the program I was instrumental in creating, for training and employing of youthful offenders. Even after last November's conference agreement restored \$49 million for this program, the Administration immediately offered it up as an offset to help pay for December's Katrina supplement. Do you think this was an appropriate way to respond?

Answer. The impacts of the Katrina and Rita hurricanes were unprecedented and the Administration carefully prioritized the use of available resources across government to fund relief and recovery efforts. The Youth Offender appropriation was only one of many offsets the Administration presented to Congress, and this is consistent with the Administration's proposal in the fiscal year 2007 and previous budgets to replace the Responsible Reintegration of Young Offenders program with the Prisoner Reentry Initiative, thereby increasing the program's overall scope and reach.

ELIMINATION OF MIGRANT JOB TRAINING

Question. Both the House and the Senate appropriations committees have repeatedly rejected your proposal to eliminate the Migrant and Seasonal Farmworkers Program under the Workforce Investment Act. I think it's fair to say that Congress recognizes that it is unrealistic to expect states and localities to be responsible for a unique and difficult-to-serve migratory population that, from their point of view, is "here today and gone tomorrow." It is also unfair to shift this burden to states when you are proposing to reduce the already limited job training resources that states have to serve their eligible local residents. If Congress understands this, why doesn't the Department?

Answer. The Administration's fiscal year 2007 Budget proposal seeks to tap the workforce investment system's potential to serve more migrant and seasonal farmworkers by providing job training services to them through the One-Stop Career Center system, and turning to other, appropriate agencies to provide supportive services, housing, and other related assistance. Currently, the section 167 program provides employment and training services to only 10,000 of an estimated two million farmworkers, which demonstrates the need for a wider system approach.

The Administration believes that providing services to farmworkers through the One-Stop system will increase the number served and have a positive employment and earnings impact on those who receive services.

IMPACT OF JOB TRAINING CUTS

Question. Your budget is based on the assumed enactment of a new Workforce Investment Act reauthorization proposal calling for Career Advancement Accounts, to be run through a consolidated workforce system, cutting nearly \$700 million. Until the authorization legislation is changed, this Committee acts on the basis of extending current law. In the absence of law change, what impact will your budget proposals have on existing programs for youth, adults, dislocated workers, and the Employment Service? For example, the Pennsylvania Association of Workforce Investment Boards estimates the President's Budget would result in a 17 percent cut from current levels for the youth, adult and dislocated worker block grants. Do I have your assurance that you will not proceed administratively to implement proposals such as consolidated Career Accounts without Congressional approval?

Answer. The President's Budget request does assume enactment of the Career Advancement Account (CAA) proposal, which would reduce overhead and administrative costs and focus more funding on training, thereby tripling the number of individuals receiving job training through the workforce investment system.

In the absence of any legislation passed by Congress, states will continue to operate Workforce Investment Act programs and the Employment Service as currently authorized. The appropriation level provided by Congress is a separate issue from job training reform. We feel that CAAs are a more effective approach than the current workforce investment system, regardless of the funding level provided by Congress.

Several states and local areas have expressed interest in piloting CAAs. We will work with these areas to develop a limited pilot that can be carried out under current law. However, statutory changes are necessary to achieve all of the reforms envisioned under the CAA proposal.

WORKFORCE TRAINING CUTS

Question. Your budget for workforce programs contains cuts of \$506 million for state grant programs, while increasing funding under national control by \$107 million. How does this square with your legislative proposal to shift greater control of resources to the States?

Answer. The President's fiscal year 2007 Budget proposes a minimal increase for programs under "national control." The only activity that falls under this category that is proposed for additional funding is Unemployment Insurance National Activities, whereby an increase of \$600,000 is requested to pay for activity related to processing separation documents and unemployment claims of former military service personnel.

Furthermore, the fiscal year 2007 Budget request proposes initiatives that give greater control of funding to states and local areas. The Career Advancement Account proposal promotes state and local flexibility by streamlining and strengthening the One-Stop Career Center system and removing or simplifying statutory requirements that create rigidity and hinder flexibility in providing education and training opportunities to American workers. Also, the Administration included a streamlined program structure in its Older Americans Act reauthorization proposal, which would give states greater control over the Senior Community Service Employment Program (SCSEP) funds.

ASBESTOS EXPOSURE

Question. Madame Secretary, the fiscal year 2006 appropriation contained \$2 million for the Employment Standards Administration to facilitate the expeditious startup of a system to resolve the claims of injury caused by asbestos exposure. How are these funds being used to shorten the lead-time for implementation of pending asbestos legislation?

Answer. If the Asbestos legislation is enacted as currently written, the Department of Labor will be expected to manage a new and very substantial national benefits program involving the disbursement of billions of dollars in compensation to hundreds of thousands of individual asbestos claimants. The proposed time frame for implementing this legislation is extremely short, requiring immediate preparatory work and the up-front expenditure of resources to ensure that payments can begin being made to compensable claimants as quickly as possible.

Given the status of the pending legislation, the \$2 million is being used to analyze the proposed legislation and plan how to implement it in the event that it is passed. In the next phase, funding will be used for initial program start-up expenses in the areas of program design, acquisition of specialized expertise, technology, and infrastructure.

OSHA PENALTIES FOR ASBESTOS VIOLATIONS

Question. I have introduced legislation (S. 668) to subject employers who willfully violate OSHA asbestos standards to fines at levels set by the Uniform Criminal Code as well as imprisonment of up to five years, or both. Currently OSHA provides for criminal penalties only in those cases where a willful violation of standards results in the death of a worker within six months after the violation is discovered. Do you agree that stronger enforcement action is needed against parties that violate OSHA asbestos enforcement rules?

Answer. Currently, the OSH Act provides for criminal fines and imprisonment of up to six (6) months against an employer only where the employer's willful violation of a standard caused the death of an employee. In addition, criminal penalties exist against employers who make false statements to OSHA investigators or who unlawfully interfere with OSHA investigations. S. 668 provides that any willful violation of a standard issued under OSH Act section 6 with respect to control of occupational exposure to asbestos is punishable by fines under section 3571 of Title 18, United States Code, and imprisonment in the case of a first offense, of up to five years. While we agree that occupational exposure to asbestos is a very serious health issue, we believe the current OSH Act and penalty structure provide the means and flexibility to address instances where penalties are warranted.

IMMIGRATION BILL

Question. The Senate passed immigration legislation, S. 2611, contains a provision requiring the Secretary of Labor to certify that no United States workers are available for a specified position before employers can hire an alien for the job. Do you support this provision, and does your Department have sufficient resources to administer it?

Answer. The Department supports the need to enact comprehensive immigration reform that creates a guest worker program and enhances the security of our borders. In his various speeches on immigration reform, the President has repeatedly noted that foreign workers should be allowed to take only those jobs that no U.S. worker is willing or available to perform. To implement this important program design feature, the Department will need to either establish a labor market test for domestic worker interest or create a mechanism whereby employers can attest that they have tested the labor market and been unable to find a U.S. worker to fill the job. If an attestation system is created, the Department would randomly audit employer attestations to ensure program integrity. We agree that the S. 2611 provision is consistent with the President's position and we support it accordingly. The administration will work with Congress as immigration legislation moves forward to ensure that the need for resources is addressed.

Question. Your Department has the responsibility to prevent employer exploitation of undocumented workers, by enforcing minimum wage and overtime laws. To what extent is this effort discouraging illegal immigration?

Answer. The strong enforcement of basic labor standards for all employees weakens the incentive to hire undocumented workers. Although it is difficult to quantify the extent to which labor standards enforcement deters or dissuades employers from hiring undocumented workers, most studies on the impact of illegal immigration acknowledge the importance of such enforcement as a key component in an overall strategy for addressing the problem.

Question. What actions do Labor Department inspectors take when they come across evidence that a business unlawfully employs illegal immigrants?

Answer. When the Wage and Hour Division (WHD) performs an investigation a complaint-based investigation, it does not seek evidence of the complainant's immigration status. WHD instituted this policy to avoid discouraging complaints from undocumented workers who might otherwise be reluctant to complain to WHD because of their immigration status.

However, WHD investigators do perform directed investigations (non-complaint cases) to determine employers' compliance with their employment eligibility verification obligations (Forms I-9). In cases where it appears that violations have been committed, WHD refers the matter to DHS pursuant to a Memorandum of Understanding.

MEDICAL LEAVE PROGRAM

Question. At your last appearance before this Committee on March 15, 2005 you stated no final decision has been made with respect to revising regulations implementing the Family and Medical leave Act. What progress has been made addressing concerns of workers and employers that have resulted in so many lawsuits on the interpretation of when employers are eligible for leave under the law?

Answer. The Department continues to review the issues raised by the Supreme Court's decision in *Ragsdale v. Wolverine World Wide, Inc.*, as well as other court decisions, and the possibility of revisions to the FMLA regulations remains an item on the Department's regulatory agenda. No final decisions have yet been reached as to what, if any, changes might actually be proposed. If changes are proposed, the public will be provided ample opportunity to comment through the formal notice and comment rulemaking process.

RE-ALLOCATION OF UNSPENT FUNDS

Question. Your budget proposed bill language that would take money away from states that have more than 30 percent unspent job training funds, yet you do not propose applying this principle to Dislocated Worker national reserve funds, which currently have unspent funds exceeding 50 percent. What is your justification for this?

Answer. The Department always obligates all National Reserve monies to states during the program year for which such money was appropriated. Any unspent funds are unspent at the state and local level, not at the national level. This indicates that even more funds are available for expenditure by states and grantees.

RAPID RESPONSE FUNDS

Question. Currently, states use rapid response funds to provide immediate service to workers affected by a mass layoff, often before the workers are even laid off. Under your legislative proposal, states will need to apply to the Employment and Training Administration for rapid response funds as events occur. What are the reasons for keeping these funds at the national level, and having states apply for them each time they are faced with mass layoffs?

Answer. The Department does not contemplate that a state would have to apply for funds each time there is a mass layoff or to only sporadically fund a state rapid response coordinator. Early intervention to provide information and assistance to workers to decrease the amount of time between actual layoff and re-employment is a key principle of the dislocated worker program. Rapid response is a key element of this early intervention strategy.

States could demonstrate need and apply for rapid response funds at the beginning of the program year or throughout the program year. We will not propose that a state be required to submit an application for funding each time a dislocation event occurs.

In spite of all the good work that has been done over the past fifteen years with dislocated worker rapid response funds, the Department has found that most company executives do not know about the type and quality of assistance available to them and their employees when closures or layoffs are contemplated. They have also reported that where they have layoffs in several states simultaneously, the levels and quality of assistance varies dramatically. ETA, in collaboration with state and local partners, has undertaken several initiatives in the auto, textile and defense industries recently to try to integrate services and develop more consistency. We believe a nationally-coordinated approach to delivering rapid response assistance by states can help bring the services to more workers and employers.

The proposed mechanism will assist both the Department and the states to better manage scarce taxpayer resources by directing the bulk of the funds to the areas of need. For example, not all states experience major layoffs every year. Analyses of dislocated worker program expenditures reported by states have shown that the funds reserved for rapid response are consistently under-expended. In the aggregate, the rapid response carry-in funds from program year 2003 to 2004, and from 2004 to 2005, was \$136.7 million and \$166 million, respectively. Through March 31, 2006, states reported accrued expenditures of just over \$176 million of a total available of more than \$342.5 million, or 51.4 percent of the total funds available. States are not required to retain the up to 25 percent authorized to be reserved for rapid response activities. They may include a portion of the funds in the amount allocated to local workforce investment boards for core, intensive and training services for dislocated workers, or they may award additional funds from the reserved amount to local areas that experience disasters, mass layoffs, plant closings or other events that precipitate substantial increases (defined by the state) in the number of unemployed workers.

COMMENTS ON CECIL ROBERTS TESTIMONY

Question. Mr. Cecil Roberts, President of the United Mine Workers of America, testified to this Committee that the penalties assessed by the Labor Department are designed to insure that mining remains profitable, even if the conditions are so hazardous the mine should be shut down. Do you believe that keeping a mine operating is more important than the safety of the miners?

Answer. No, we do not believe that keeping a mine operating is more important than the safety of the miners who work in that mine. The Mine Act states in its opening section that “the first priority of all in the coal or other mining industry must be the health and safety of its most precious resource—the miner.” That is the premise on which the Mine Act is based and the reason for the existence of MSHA. The Mine Act contains provisions to withdraw miners until the hazard or violation is abated when there is an imminent danger to the health and safety of miners or an unwarrantable failure of an operator to comply with a mandatory health and safety standard. MSHA uses its withdrawal authority vigorously and appropriately.

Under the Mine Act, MSHA has the authority to propose penalties for violations of the Act. MSHA does so in accordance with the six statutory criteria enacted by Congress in the Mine Act, including consideration of the effect of the proposed penalty on the operator’s ability to stay in business. Consistent with the Administration’s last three budget requests, Congress included a provision in the MINER Act to increase the maximum civil penalty for flagrant violations of the Mine Act to \$220,000. Minimum penalties were also included for unwarrantable failure violations. The Department has announced that MSHA will be revising its regulations and proposing a new penalty formula to raise penalties for mine safety and health violations across the board. These higher penalties should provide a greater incentive to mine operators to comply with MSHA’s safety standards.

OLDER WORKER EMPLOYMENT PROGRAM

Question. The Department has launched another national grant competition process for the Senior Community Service Employment Program despite not having the essential performance data that will not be available for new performance goals until September 2006. Since the current law directs that re-competition be conducted for non-performance by a grantee, on what basis do you deem this new round of competition to have sound data for assessing current or future grantee performance or capacity?

Answer. The Department has been collecting performance data since the inception of the program, and has been collecting additional data on the new common performance measures since July 2004.

Furthermore, according to the Title V of the Older Americans Act, competition is not limited to when grantees fail performance measures. Section 514(a) limits the award of SCSEP grants to no more than three years, thus requiring a selection of grantees within three years of the first competition. The issue of whether the Department can compete the SCSEP grants has also been addressed by the courts. The U.S. District Court of the District of Columbia held recently in *Experience Works v. Chao*, 267 F.Supp. 2d 93 (D.D.C. June 17, 2003), “[t]he use of competitive procedures is a time-honored method for obtaining the most highly qualified awardees of government funds, for allowing new and innovative ideas and organizations to receive those funds, and for assuring public confidence in the integrity of the process to distribute government funds.”

Finally, the current Solicitation for Grant Applications (SGA) clearly identifies the criteria against which applicants are assessed. All applicants will be rated using a ranking criterion based on points. This SGA requires that responses be thoughtful and reflect a strategic vision.

The SGA evaluation criteria are as follows:

1. Design and Governance—15 points
2. Program and Grant Management Systems—10 points
3. Financial Management System—10 points
4. Program Service Delivery—40 points
5. Performance Accountability—25 points

Question. When the program was competed in 2003, this whole competition process—application, grading and transition—took almost 6 months—including over 6 weeks for transitioning the participants affected. This time the new competition rules are much more complex, yet the whole process has been shortened to 4 months, leaving barely 3 weeks for transition of these vulnerable participants—why the rush to get this done this way this year?

Answer. This year’s competition is not rushed. Applicants were given nearly the same amount of time this year as in the 2003 competition to respond to the Solicitation for Grant Applications (SGA). In 2003, grantees were given 90 days to respond to the SGA, a time period which included Christmas. This year, the competition was announced in the Federal Register on March 2, and grantees were given until May 26 to respond, or 85 days.

Further, once grants are awarded, grantees have 2 months in which to transition participants among grantees, a longer transition period than in 2003. As specified in the SGA, the transition period follows a 1-month extension of current grants and will take place August 1-September 30, 2006. This means that the period from publication of the SGA (March 2) until the transition period ends (September 30) is approximately 7 months, 1 month longer than the 2003 competition.

Question. The cost of transitioning thousands of participants nationwide among old and new sponsors will be significant. Subsequent to publication of the SGA in the Federal Register, the DOL website was amended to say, “Transition cost should be submitted as an integral part of the budget and reflected on the other’ cost category with a narrative explanation. Can you assure the Committee that services to enrollees will not be diminished as a result of incurred transitions costs?”

Answer. All current grantees were required to build transition costs into their budgets in the 2003 competition, and all applicants under the 2006 competition have also budgeted for transition costs. Further, the Department is prepared to assist grantees with additional costs associated with the transition, as it did following the transition after the 2003 competition. Program Year 2004 recaptured funds are available for this purpose.

At the time of the 2003 competition, many participants and grantees were concerned about the transition effects upon participants. The Department can say with authority that every single participant was transitioned successfully. Competition does not need to cause any disruption among services participants receive.

DOL has identified specific responsibilities for itself, national grantees and state grantees to ensure a smooth transition. DOL will provide orientation to all national grantees to provide information on program administration and management. DOL will begin regular conference calls between federal and regional DOL staff and national grantees to quickly address any transition issues. DOL will also provide assistance through a national call center, and provide on-site technical assistance as needed.

Question. Your budget proposes to save \$44 million in the Community Service Employment for Older American program through “efficiencies related to program streamlining.” What exactly is being proposed to save this amount?

Answer. The Administration proposes that reauthorization of the Title V SCSEP program be based on five key reform principles: (1) helping meet employers’ demands for skilled workers by attracting more older workers into the labor force, encouraging others to remain in the workforce, and by offering opportunities for older workers to update their skills; (2) making the One-Stop Career Center system effective for older individuals seeking to work or upgrade their skills, including better integrating services for older workers and assisting more older workers, regardless of income, to gain skills that are in demand; (3) tailoring services to meet the needs of individual older workers by providing a range of training experiences, including community service employment, on-the-job training and classroom training, depending on the individual’s background and experience; (4) targeting SCSEP resources to those older workers most in need (primarily low-income older workers who lack the basic skills for private sector employment), while ensuring that others receive services through the One-Stop Career Center system; and (5) streamlining the program to make it easier to administer in order to improve program performance, serve more participants, and receive a return on investment for the federal taxpayers’ dollar.

In fiscal year 2007, savings from streamlining administration and other reforms will amount to an estimated \$44 million in the first year of implementation. Specifically, we expect that savings will be achieved from the following reforms:

- Revamping the SCSEP program structure so that states conduct a competition every three years to run the program in the state, which will simplify administration, eliminate duplication, and create a more comprehensive program.
- Eliminating fringe benefits for program participants (except accident insurance or benefits that may be required by law) to reinforce the training aspect of the program.
- Allowing SCSEP funding to be used for training (as opposed to wages) and allowing more flexible training options in addition to community service work experience.

In addition to savings from reforms through reauthorization, savings will also be realized through the current grant competition. The current Solicitation for Grant Applications encourages a regional service delivery architecture that will reduce redundancy and fragmentation of service delivery areas by requiring that applicants apply to serve an entire county instead of a portion, and generally requiring that applicants apply to serve contiguous counties if multiple counties are served.

It is important to note that the fiscal year 2007 request will continue to support 92,300 low-income elderly individuals, the same level as fiscal year 2006.

ADMINISTRATION AND MANAGEMENT

Question. Provide appropriations and full time equivalent staff for each of fiscal years 2003 through 2005 enacted, fiscal 2006 comparable, and fiscal 2007 budget request, for each of the components of the Administration and Management activity within the Departmental Management account, including: Department Budget Center; Center for Program Planning and Results; Human Resources Center; Information Technology Center; Civil Rights Center; Office of Security and Emergency Management and Business Operation Center. Provide the source, by Department of Labor agency and activity, of the FTE and funding for Working Capital Fund Programs, comparing fiscal year 2006 comparable with the fiscal year 2007 request.

Answer. The information for Administration and Management follows:

ADMINISTRATION AND MANAGEMENT BUDGET ACTIVITY DEPARTMENTAL MANAGEMENT SALARIES AND EXPENSES

[Amount in thousands]

Agency	Fiscal year 2003 enacted		Fiscal year 2004 enacted		Fiscal year 2005 enacted		Fiscal year 2006 comparable		Fiscal year 2007 request	
	AMT	FTE	AMT	FTE	AMT	FTE	AMT	FTE	AMT	FTE
Center for Program Planning and Results	\$6,352	4	\$6,076	9	\$5,537	8	\$5,438	8	\$5,562	8
Human Resources Center	3,650	23	3,473	23	3,502	24	3,445	24	3,573	24
Information Technology Center	12,414	60	12,954	56	11,624	50	9,346	37	9,755	37
Business Operation Center	2,652	16	2,026	14	1,959	11	1,778	11	1,825	11
Office of Security and Emergency Mgmt. ¹	6,944	6,875	1,893
Department Budget Center ²	1,776	15	2,362	19	2,056	18	2,116	18
Library	714	2	719	2	754	1	754	1	782	1
Federal Executive Board	170	2	173	2	176	2	206	2	210	2
Assistant Secretary for Administration and Management	4,239	5	5,956	5	6,500	10	7,590	10	7,923	10
Civil Rights Center ³	5,930	48	6,144	48	6,237	46	6,451	46	6,735	46

¹Represents funding for Frances Perkins Building security enhancements. The fiscal year 2007 Request includes a comparative transfer of \$5 million from this budget activity to the Working Capital Fund for upgrading security and continuity of operations capabilities for the Department.

²Department Budget Center was transferred to Administration and Management budget activity from the Chief Financial Officer budget activity in fiscal year 2004.

³CRC is funded from the Civil Rights Activity, rather than the Administration and Management Activity.

The information for Working Capital Fund follows:

DOL AGENCY WORKING CAPITAL FUND ASSESSMENTS

[In thousands of dollars]

	Fiscal year	
	2006 estimate	2007 request
ETA	14,987	17,942
ETA/TES	9,326	9,922
ESA	37,620	44,021
OSHA	22,851	25,235
EBSA	10,054	11,463
BLS	16,009	19,353
OIG	4,097	4,685
OSEC	14,458	16,730
VETS	2,832	3,207
SOL	6,396	6,646
ILAB	1,984	2,228
MSHA	11,237	13,564
ODEP	1,250	1,305
FPB repairs	915	833
Total	154,016	177,134

PROGRAM DIRECTION

Question. Provide appropriations and full time equivalent staffing for each of fiscal years 2003 through 2005 enacted, fiscal 2006 comparable, and fiscal 2007 budget request, for each of the following components of the Program Direction and Support activity within the Departmental Management account: Office of the Secretary; Office of the Deputy Secretary; Office of Public Affairs; Office of the Assistant Secretary for Policy; Office of Congressional and Intergovernmental Affairs; Office of Small Business Programs; Office of Public Liaison; Office of the 21st Century Workforce; and the Center for Faith-Based and Community Initiatives.

Answer. The information for Program Direction follows:

PROGRAM DIRECTION AND SUPPORT

[Amount in thousands]

PDS components	Fiscal year 2003 enacted		Fiscal year 2004 enacted		Fiscal year 2005 enacted		Fiscal year 2006 ¹ comparable		Fiscal year 2007 request	
	AMT	FTE	AMT	FTE	AMT	FTE	AMT	FTE	AMT	FTE
Office of the Secretary	\$3,669	17	\$3,015	12	\$4,639	21	\$4,859	17	\$5,068	20
Office of the Deputy Secretary	1,173	8	1,270	8	1,260	9	1,234	8	1,293	9
Office of Small Business Programs	1,021	9	1,097	9	1,289	8	1,344	7	1,659	8
Office of Public Liaison	840	8	895	7	949	6	1,004	6	1,072	6
Office of Congressional and Intergovernmental Affairs	4,232	32	4,456	32	4,420	27	4,651	24	5,258	27
Office of Public Affairs	4,003	26	5,861	35	3,612	28	3,772	26	4,812	28
Office of the Assistant Secretary for Policy ²	10,423	53	8,975	46	8,903	40	7,222	35	8,741	40
Office of the 21st Century Workforce	1,019	8	1,049	8	1,041	6	1,040	6	1,092	6
Center for Faith-Based & Community Initiatives	593	5	605	6	633	6	800	6

¹ \$28.5 million was appropriated in ETA Program Administration for Job Corps program salaries and expenses. These funds have been allotted to the Office of the Secretary to be used for the Job Corps program in accordance with Section 102 of Public Law 109-149.

² Includes ASP drug-free workplace funds.

BUILT-IN AND PROGRAM CHANGES

Question. Provide a table for each discretionary appropriation account, identifying by line-item, the built-in changes from the fiscal year 2006 adjusted level, and each program increase, to arrive at the fiscal year 2007 budget request level.

Answer. The attached table reflects built-in increases and decreases, program increases and decreases, and finance changes, affecting each discretionary appropriation account from the fiscal year 2006 adjusted level to the fiscal year 2007 budget request level.

DEPARTMENT OF LABOR—Continued
[In thousands of dollars]

Discretionary Appropriation Account	Fiscal year 2006 adjusted level	Built-in		Program		Finance changes	Transfer	Fiscal year 2007 budget request cur- rent law
		Increases	Decreases	Increases	Decreases			
Metal/Nonmetal	68,227	1,879						70,106
Standards Development	2,485	173						2,658
Assessments	5,405	161						5,566
Educational Policy and Development	31,749	1,177						32,926
Technical Support	25,609	804		1,000				27,413
Program Eval & Info Resources	15,532	203				1		5,735
Program Administration	11,938	1,099						13,037
Total—MSHA	278,408	8,428		1,000				287,836
BUREAU OF LABOR STATISTICS:								
Employment & Unemployment Statistics	165,683	5,373						171,056
Labor Market Information (Trust Funds)	77,066	1,960						7,026
Prices and Cost of Living	173,515	5,566		8,000				187,081
Compensation and Working Conditions	81,052	2,808						83,860
Productivity and Technology	10,777	341						11,118
Executive Direction & Staff Services	30,235	912						31,147
Total—BLS	538,328	16,960		8,000				563,288
DEPARTMENTAL MANAGEMENT:								
Program Direction and Support	25,759	1,320		2,868				29,795
Departmental IT Cross Cut	29,462		-152					29,405
Departmental Management Cross Cut	1,683							1,108
Legal Services	80,416	3,246		1,204				84,866
Trust Funds	308	14						322
International Labor Affairs	72,567	651						12,363
Administration & Management	30,613	1,237						31,746
FPB Security Enhancements	1,875	18						1,893
Adjudication	27,243	1,700						28,931
Women's Bureau	9,763	456						9,348
Civil Rights Activities	6,451	284						6,735

WOMEN IN APPRENTICESHIP

Question. The conference agreement on the fiscal year 2006 Labor Department appropriations legislation specified \$982,000 for carrying out Public Law 102-530, the Women in Apprenticeship and Non-Traditional Occupations Act.

What action is being taken to issue grants to community based organizations to encourage employment of women in apprenticeable occupations and nontraditional occupations?

Answer. The Employment and Training Administration and the Women's Bureau have worked collaboratively to develop a Solicitation for Grant Applications (SGA). The SGA is currently going through Departmental clearance and we expect a notice announcing the SGA to be published in the Federal Register in August 2006.

APPALACHIAN COUNCIL/WORKING FOR AMERICA INSTITUTE

Question. This subcommittee held a hearing on July 22, 2004, on the funding of the Appalachian Council and Working for America Institute. Despite that hearing, the Labor Department did not renew the contracts for these organizations, forcing Congress to earmark \$2.2 million and \$1.5 million, respectively, for their continued operation. I understand that funding has now run out, and I urge you to renew the contracts. Will you take another look at the organizations, and see what can be done to provide renewed funding?

Answer. On February 1, 2005, the Department of Labor executed a \$1,500,000 grant to the Working for America Institute (WAI). This grant will remain active until February 3, 2007. The Department of Labor continues to work closely with WAI to support the deliverables of their grant, including developing resources to support a well-skilled advanced manufacturing workforce.

Job Corps funded the Appalachian Council for \$2.2 million in February, 2005 and then renewed the funding in the amount of \$2.2 million in April, 2006. That funding is through March 31, 2007. An evaluation will be done to determine if additional funding will be provided based upon performance and funding availability.

JOB TRAINING STAFF

Question. Your budget request for federal administration of Employment and Training Administration programs provided for 1,158 direct full-time equivalent staff, compared to the current level of 1,194 staff.

Why are you requesting only a reduction of 14 federal staff when you are proposing to consolidate several job training programs into a single block grant to states?

Answer. The Employment and Training Administration (ETA) fiscal year 2006 FTE level supported by appropriated funds is 1,180 (with an additional 16 FTE supported by fees and reimbursements). The ETA fiscal year 2007 Legislative Proposal FTE level (excluding FTE supported by fees and reimbursements) is 1,158. Compared with fiscal year 2006 staffing, ETA's fiscal year 2007 Legislative Proposal represents a net reduction of 22 FTE—an addition of 7 FTE within Youth Services to support the proposed transfer of Youthbuild from the Department of Housing and Urban Development to ETA, and a reduction of 29 FTE in Workforce Security in anticipation of the enactment of a Foreign Labor Certification Permanent Program fee.

ETA does not anticipate that the implementation of the Career Advancement Accounts (CAA) will have an immediate impact on ETA staffing levels. Assuming the passage of authorizing legislation in fiscal year 2007, a significant amount of effort by ETA staff will be required to transition from the current Workforce Investment Act (WIA) structure to a new CAA structure. Moreover, during the transition and until it is complete, the same or a similar level of effort that is currently provided will be necessary to continue national and regional Federal oversight required to administer WIA. The time necessary to implement the transition to a new CAA structure will also provide ample time for an orderly transition to an FTE level appropriate for the level of Federal oversight required to administer CAAs.

SAFE PLACES IN MINES

Question. The Commonwealth of Pennsylvania has begun an analysis of locating safe places in the mines for workers to seek refuge in case escape routes are blocked. These safe places could be permanent or portable. Do you intend to conduct a similar analysis nationwide?

Answer. Section 13 of the MINER Act requires NIOSH to study various refuge alternatives in an underground coal mine environment and issue a report not later than 18 months after enactment of the Act. Not later than 180 days after the receipt

of this report, the Secretary of Labor is required to provide a response to the two authorizing committees describing what actions, if any, the Secretary intends to take based on the report. The Department will comply with this statutory requirement.

COMPETITIVENESS AGENDA

Question. You propose cutting \$653 million from workforce investment programs and another \$27 million from the Employment Service, despite the fact that funding for workforce programs is \$1 billion below the funding level than when the President took over and there are one million more unemployed workers than there were in 2001. Isn't that approach inconsistent with a competitiveness agenda that is supposedly going to help America, and its workers, compete in the global economy?

Answer. Although the President's fiscal year 2007 Budget request for the Employment and Training Administration is below the fiscal year 2006 appropriation, it is a responsible budget that reflects the competitive demands for very limited resources for domestic programs and the need to eliminate waste and redundancy. The proposed reforms align with the competitiveness agenda by reforming the workforce investment system so that many more workers are trained, equipping them with the skills necessary to succeed in the 21st Century.

The public workforce investment system could be structured to better meet the training challenges presented by the increased need for skills and competencies by workers. There exists a lack of integration, which causes too much money to be spent on competing bureaucracies, overhead costs, and unnecessary infrastructure, and not enough on meaningful skills training that leads to job growth and economic prosperity.

Career Advancement Accounts, relative to the existing workforce investment system, will be more effective and flexible in meeting the demands of the global economy and in addressing the nation's workforce challenges. Career Advancement Accounts would mean a streamlined workforce investment system that gets more training dollars in the hands of workers and reduces costs by eliminating duplication across employment and training programs and lowering overhead costs. The greater efficiency from this redesign of the system will result in cost savings that account for much of the reduction in ETA's budget. More than triple the number of workers currently being trained would be trained under this proposal.

VOUCHER PROPOSAL

Question. You have proposed a new WIA reauthorization proposal calling for Career Advancement Accounts, i.e. vouchers, to be run through a consolidated workforce system overseen by the Governor, allowing him or her to choose to eliminate the local workforce system and the One Stop network. This is the third different reauthorization proposal you have made to the Congress, your previously two attempts to create a block grant for the Governor have been resoundingly rejected in both the House and Senate, which have consistently protected the local workforce delivery system as essential to helping our workers receiving training for jobs in the local economy. Knowing that this approach has been rejected twice before, isn't your budget proposal just a smokescreen to provide a rationale for deep budget cuts to the workforce system?

Answer. No. Under the Administration's proposal for Career Advancement Accounts, states can maintain One-Stop Career Centers to provide employment services to job seekers and employers, as well as access to Career Advancement Accounts, at these sites. Career Advancement Accounts are a more efficient and effective way to deliver job training that will result in more workers getting the skills they need with less overhead costs. We believe that with the constraints on discretionary spending and the promise of more than tripling the number of workers trained with this innovative new approach, Congress will take this proposal seriously. This proposal is consistent with the "innovation" agenda that has bi-partisan support in Congress.

Workforce Investment Act (WIA) reauthorization has been pending in Congress for three years. No proposals have been either formally accepted or rejected. H.R. 27, which was passed by the House on March 2, 2005, does consolidate the WIA Adult, WIA Dislocated Worker, and Employment Service funding streams, indicating interest on the part of Congress in streamlining programs as the Administration proposed.

RATIONAL FOR WORKFORCE TRAINING

Question. You claim that only 200,000 are trained annually by the workforce system; however your data provides the smallest data pool possible to make your claim,

as it only measures participants leaving training during a fiscal year. GAO estimates that over double this number, 416,000 receive training annually. Your own data provided in the Budget Justifications shows that over 15 million participants receive an array of training, intensive, or basic employment assistance annually through the workforce system. Isn't your budget request another example of using selective data to block grant and cut program funding?

Answer. The important point is that 200,000 people complete and exit training per year with a \$4 billion investment, meaning that too much money is being spent on low-cost services with little value to the customer. ETA uses actual data collected from the states in referencing number of people trained. The GAO study indicates that 40 percent of funds are used for training adults and dislocated workers, whereas ETA estimates this figure at 26 percent. This discrepancy occurs due to two primary differences in the measurements: (1) ETA is measuring exiters, or those that have actually completed training, while GAO is measuring training costs of all participants receiving training (meaning that people are "double counted" because their training may have occurred over two program years); and (2) ETA includes expenditures, while GAO includes both expenditures and obligations—obligations which may not result in someone actually being trained. The estimates by ETA and GAO are different because they look at distinctly different sets of cost estimates and individuals included in the count.

The question also refers to the number of individuals served by the workforce investment system. The large majority of these participants are receiving only basic employment services, including self-services. The Career Advancement Accounts proposal would increase the number of individuals trained through the workforce investment system, while still providing basic employment services to job seekers.

ELIMINATION OF MIGRANT PROGRAMS

Question. For the third year in a row, you have proposed eliminating the Migrant and Seasonal Farmworker program authorized under WIA. You first proposed to work with states and local areas to ensure that migrant and seasonal farmworkers could access services through One-Stop Career Centers; despite the fact that your Department's data show that the program met its performance goals. Now you propose to give governors the flexibility to design how individuals will access information and Career Advancement Accounts or vouchers. How does the Administration propose to ensure that these individuals—some of America's neediest adults and their families—will be able to successfully navigate among service delivery systems that will differ from state to state and secure the job training and employment services that they need?

Answer. The Administration's fiscal year 2007 Budget proposal seeks to tap the workforce investment system's potential to serve more migrant and seasonal farmworkers by providing job training services to them through the One-Stop Career Center system, and turning to other, appropriate agencies to provide supportive services, housing, and other related assistance. Currently, the section 167 program provides employment and training services to only 10,000 of an estimated 2 million farmworkers, which demonstrates the need for a wider system approach.

The Administration believes that providing services to farmworkers through the One-Stop system will increase the number served and have a positive employment and earnings impact on those who receive services.

The Administration's fiscal year 2007 budget proposal seeks to take advantage of the One-Stop system's potential to better serve more migrant and seasonal farmworkers by helping them access the full array of employment and training services available from the seventeen federal programs delivered through the One-Stop system. While the proposal is to increase the amount of funding spent on training utilizing Career Advancement Accounts as the vehicle, the proposal also includes continued funding for core service delivery, including career guidance and job referrals, to any job seeker. Career Advancement Accounts can be used for a combination of remedial training leading to a diploma or GED in addition to post secondary education. We believe this combination of career guidance and training in the context of the One-Stop delivery system that connects workers to a wide array of services, including supportive services, can result in increased services to farmworkers and more positive employment and earnings impact on those farmworkers who receive services.

EMPLOYMENT SERVICE CUTS

Question. You propose to cut the Employment Service by about \$27 million in fiscal year 2007 over and above a \$96 million reduction in fiscal year 2006. You would give states the flexibility to determine how to provide basic employment services to

America's workers and at the same time, absorb other costs that you propose to divest from the federal level—in labor market information products and services and dedicated professionals to help the disabled obtain employment. Past shortfalls in federal support have forced states to close local offices. With these deep cuts, states will be forced to shut down many more One Stop Career Centers that help match job seekers and employers seeking workers. How do you expect governors to be able to help an expected 14 million workers who need jobs and the thousands of employers looking for workers?

Answer. The Department proposes to consolidate the Workforce Investment Act (WIA) programs for adults, dislocated workers, and youth, and the Wagner-Peyser funding stream into a single flexible grant that enables governors to utilize these resources strategically to both drive their economies and provide maximum training and employment opportunities for their citizens.

The public workforce investment system, as currently constituted, is ill-equipped to meet the workforce challenges presented by the increased need for advanced skills and competencies in the 21st century economy. As one researcher has noted, "As it now stands, employment services (and by extension the One-Stop system) is very far from being an effective labor exchange capable of assisting people surmount the challenges of today's job market.¹ This is due, in part, to the lack of integration, which causes too much money to be spent on competing bureaucracies, overhead costs, and unnecessary infrastructure, and not enough on meaningful skills training that leads to job growth and economic prosperity. For example, while the Employment Service is intended to be the cornerstone of the One-Stop system under WIA, many states continue to have a separate network of Employment Service offices that offer the same "core services" that are available under WIA through One-Stop Career Centers.

Furthermore, large amounts of state unexpended carryover funds still remain. In fiscal year 2004, unexpended funds from the WIA Adult, Dislocated Worker, and Youth programs totaled almost \$1.2 billion and a similar amount is projected for fiscal year 2005, which ends on June 30, 2006. Therefore, it is the Administration's position that through more efficient administration, integration of existing funding, and the effective use of currently available resources, states will not face the need to reduce services to the citizens generally or to populations with barriers to employment.

NATIONAL RESERVE FUND

Question. Your proposal indicates that the Department would retain at the national level a portion of funds for a National Reserve Fund for unexpected emergencies before allocating funds for Career Advancement Accounts. What is the Department's estimate for this fund? And how would we distinguish the uses of these funds from the pilot, demonstration, and research account?

Answer. Under the Career Advancement Account (CAA) proposal, the Department proposes to set aside funds for a National Reserve in a manner similar to the current Dislocated Worker National Reserve structure. The Department would reserve 7.5 percent of the appropriation provided by Congress for Career Advancement Accounts for the National Reserve. The Secretary would have the discretion to use this funding to quickly address unanticipated events, such as natural disasters, mass layoffs and plant closings, and the impacts of foreign trade. The National Reserve would also be used to provide technical assistance and for demonstration activities.

The proposed use of Career Advancement Account National Reserve funds for demonstrations in addition to those carried out under pilots, demonstration and research budget authority is no different than the current structure. Under WIA section 171(d), up to ten percent of the National Reserve is used for dislocated worker projects. These demonstrations are in addition to the pilots, demonstrations and research authorized under WIA section 171(b). As it does now, the Department will maintain rigorous financial controls that track fund sources for all programs and activities.

RAPID RESPONSE SERVICES

Question. Your consolidation proposal eliminates state resources set aside specifically for states to respond rapidly with information and services to workers who have received word of pending layoffs. You would require states to apply for funds from the National Reserve Account to provide such services. What justification do you provide states about requiring them to go through extra steps to provide rapid

¹Osterman, Paul. "Employment and Training Policies: New Directions for Less Skilled Adults." Paper prepared for the Urban Institute. October 2005. p.16.

response services and gaining their confidence that the Department can respond to such requests in a timely manner?

Answer. The Department does not contemplate that a state would have to apply for funds each time there is a mass layoff or to only sporadically fund a state rapid response coordinator. Early intervention to provide information and assistance to workers to decrease the amount of time between actual layoff and re-employment is a key principle of the dislocated worker program. Rapid response is a key element of this early intervention strategy.

States could demonstrate need and apply for rapid response funds at the beginning of the program year or throughout the program year. We will not propose that a state be required to submit an application for funding each time a dislocation event occurs.

In spite of all the good work that has been done over the past fifteen years with dislocated worker rapid response funds, the Department has found that most company executives do not know about the type and quality of assistance available to them and their employees when closures or layoffs are contemplated. They have also reported that where they have layoffs in several states simultaneously, the levels and quality of assistance varies dramatically. ETA, in collaboration with state and local partners, has undertaken several initiatives in the auto, textile and defense industries recently to try to integrate services and develop more consistency. We believe a nationally-coordinated approach to delivering rapid response assistance by states can help bring the services to more workers and employers.

The proposed mechanism will assist both the Department and the states to better manage scarce taxpayer resources by directing the bulk of the funds to the areas of need. For example, not all states experience major layoffs every year. Analyses of dislocated worker program expenditures reported by states have shown that the funds reserved for rapid response are consistently under-expended. In the aggregate, the rapid response carry-in funds from program year 2003 to 2004, and from 2004 to 2005, was \$136.7 million and \$166 million, respectively. Through March 31, 2006, states reported accrued expenditures of just over \$176 million of a total available of more than \$342.5 million, or 51.4 percent of the total funds available. States are not required to retain the up to 25 percent authorized to be reserved for rapid response activities. They may include a portion of the funds in the amount allocated to local workforce investment boards for core, intensive and training services for dislocated workers, or they may award additional funds from the reserved amount to local areas that experience disasters, mass layoffs, plant closings or other events that precipitate substantial increases (defined by the state) in the number of unemployed workers.

ADULT TRAINING FUNDS

Question. We need to upgrade the skills of our current workforce, including the low skilled on a broad base to increase economic growth and incomes. Recent data released from the National Assessment of Adult Literacy indicates that 14 percent of American adults had less than basic literacy skills—meaning they had a hard time locating easily identifiable information on commonplace material or following written instructions in simple documents. Your proposal would reduce adult training funds and turn the funds that are left into Career Advancement Accounts. It appears that low skilled adults who would compete with other workers for these vouchers may require combinations of assessment, career planning and developmental education services prior to being able to benefit from technical training. How will these individuals really fare under a system of capped vouchers and high pressure sales from many training providers?

Answer. We agree there is a need to upgrade the skills of our current workforce, including those with low skills and literacy. State and local workforce systems set service priorities, and this will continue to be the case under the CAA proposal. These priorities will differ across the country, since demographics, labor markets and regional economies differ. By combining funding streams, our proposal will allow a more flexible response to these differences. Our proposal will triple the number of workers who currently are being trained by the workforce investment system.

Assessment, career planning and developmental education services will continue to be accessed through One-Stop Career Centers, provided either through Workforce Investment Act funding or One-Stop partner programs. States will be responsible for determining eligible training providers within the state, as well as determining policies that govern those providers, such as policies to prevent false advertising and other abuses.

ECONOMIC GROWTH EFFORTS

Question. Your consolidation proposal, combined with sizable cuts and program eliminations, ironically puts states in the position of not being able to jump start or continue to nurture regional economic growth planning and collaboration activities that integrates economic development, workforce development and education systems. These activities are similar to those you are promoting through your new WIRED initiative. What do you say to states that want to move forward with such integrated economic growth efforts if they don't qualify for funds under federal rules?

Answer. The proposals for consolidation of workforce programs are intended to provide maximum flexibility for states and regional economies to implement the type of workforce investment services that are needed in that specific region. We believe that our traditional thinking about how individual programs are funded is contributing to the persistent problem of siloed program services, with excessive funds being spent on overhead and bureaucracy, rather than addressing the workforce needs of a regional economy. If regional economic needs are to be effectively and comprehensively addressed, it will take many sources of funding, including funding from economic development agencies and educational institutions, and coordination across these funding streams. Therefore, the approach of making Federal funding for workforce services more flexible will contribute to integrated economic development efforts and the maximum leveraging of resources. Finally, the transformation of a regional economy is not dependent on Federal demonstration funding. What drives transformation is the collaborative leadership and strategic planning of economic development, research and development, capitalization, entrepreneurship and workforce development visionaries.

ELIMINATION OF YOUTH TRAINING GRANTS

Question. Your proposal to redesign the workforce delivery system eliminates WIA training grants for disadvantaged youth that are aimed at improving their education, employment, and earnings prospects. It is difficult to reconcile your proposed request when the President and you as well have focused on the need to raise the skills of young people in order to maintain our competitive edge in this new global economy. And from research—much funded by your Department, we know that an array of services is necessary to help disadvantaged youth complete their education, mature into solid citizens, and make the successful transition to work. By making these young people compete with adults for Career Advancement Accounts, aren't you really limiting their changes for future success?

Answer. We agree that there should be an emphasis on raising the skills of young people in order to maintain our competitive edge in the global economy. Career Advancement Accounts will be available to out-of-school youth. Furthermore, states and localities will still be able to provide career counseling and other services to these out-of-school youth, and workforce information will be available to assist them in choosing careers in high growth industries and in determining appropriate training for those careers.

Targeted programs and set-asides have led to multiple program silos, excessive overhead and bureaucracy, lack of coordination and integration, and only a modest number of people trained for the size of the workforce system investment. States and local areas will still be able to serve targeted groups, such as out-of-school youth, but will have more flexibility in using resources and not be subject to the often conflicting requirements of multiple programs or funding streams. Furthermore, consolidating funding streams will enable states and localities to better focus on the needs of their distinct populations, since labor force demographics and labor markets vary considerably across the country. The substantial number of requests for waivers to allow transfer of funds between programs indicates the need for more flexibility in this area than the current legislation allows.

CAREER ADVANCEMENT ACCOUNTS

Question. A recent ETR article on the fiscal year 2007 budget request noted "ETA officials said their legislative analysts believe this program—the consolidated Career Accounts proposal—can be implemented under current authorizing statutes, but would be easier for states to embrace with program consolidation that would occur under the WIA reauthorization package put forward by House Republicans, HR 27." It's my understanding that HR 27 has passed the House and is awaiting conference with the Senate. Please explain how, if the House already has a bill that is not consistent with your Career Advancement Accounts proposal, how you plan to accomplish this.

Answer. As you indicate, the House has passed H.R. 27 and the Senate recently passed its version of Workforce Investment Act reauthorization legislation. H.R. 27 would implement many key components of the President's job training reform proposal, such as merging funding streams. We believe CAAs can be built upon this piece of legislation.

ELIMINATION OF JOB BANK PROGRAM

Question. The elimination of America's Job Bank is particularly troubling. It is the backbone for more than 20 state job banks as well as the electronic version of a national employment service. Thousands of job seekers get their work through AJB and thousands of employers use it. By your own Department's last count, over 138 million job searches were conducted on AJB for the year ending June 3, 2005 and over 9 million resume searches were conducted by employers during the same period. There were about 7.8 million job postings originated on AJB during that year, over 700,000 new resumes posted, and 55,000 new employer registrations. All of these activity counts are increases over the prior year. How can the United States have a modern public employment service without an electronic exchange?

Answer. The Department of Labor considered numerous factors in coming to the decision to phase out America's Job Bank (AJB), which included looking at the larger environment in which AJB is operating and weighing the costs associated with running the system. Since the launch of AJB, the number of private sector Internet-based job banks (Career Builder, Monster, Yahoo! Hot Jobs, etc.) has proliferated, calling into question the need for a Federal government-sponsored national job bank. These private-sector electronic labor exchange systems are continuously improving and most, if not all, of these sites offer free services to job seekers. Current trends in the industry seem to indicate that some level of free service will also be offered to businesses/employers in the future and many employers who currently use AJB are already using these other job banks simultaneously to advertise their openings.

In addition, it has been increasingly difficult, if not impossible, to keep America's Job Bank updated as technology has advanced. Also, as Internet technology and technical resources have become widespread and the costs associated with them have declined, state and local areas that previously relied on AJB for their Internet self-service labor exchange presence have built and operate job banks of their own that are not based on AJB and promote them to their job seeker and business customers rather than AJB.

AJB is not the backbone for 20 state job banks, nor is there any evidence of widespread job gains as a result of using AJB. In fact, AJB is not used in most One-Stop Career Centers across the country.

PROPOSED WORKFORCE LEGISLATION

Question. The Administration plans to introduce legislation to reform the workforce investment system and create the Career Advancement Accounts (CAAs). If this legislation is not passed before fiscal year 2007, what would be the impact on services of the proposed 15 percent funding reduction for workforce development programs?

Answer. The President's Budget request assumes enactment of the Career Advancement Account (CAA) proposal, which would reduce overhead and administrative costs and focus more funding on training, thereby tripling the number of individuals receiving job training through the workforce investment system. In the absence of CAA legislation passed by Congress, the workforce investment system will continue to have siloed funding streams that result in duplicative costs.

While states will be able to continue operating Workforce Investment Act programs and the Employment Service at the lower funding levels proposed by the Administration, these reduced levels, without the accompanying reforms, may result in decreases in the number of participants served through these programs, compared to the President's proposal.

Question. States could administer the CAAs through "community career centers" at community colleges, public libraries, senior centers, and other locations, as well as through existing one-stop centers. Could this approach lead to the creation of a parallel system of job search and career assessment services, that duplicates what is already available through the one-stop centers? Could it lead to confusion among potential customers of the system, about where to go to access services?

Answer. Under our proposal, states can maintain One-Stop Career Centers to provide employment services to job seekers and employers, as well as access to Career Advancement Accounts. States and localities would have the option of making em-

ployment services and access to Career Advancement Accounts available at additional sites in the community.

Question. Will the existing state and local workforce boards have any role in administering the new program, or will they be disbanded? Similarly, will the programs that are currently mandatory partners in the one-stop system have any role in administering the CAAs?

Answer. State and local Workforce Investment Boards will continue to exist and retain roles and functions similar to what they have under the current Workforce Investment Act. Similarly, the required partners will continue to participate in the One-Stop service delivery system, and have a role in setting local policy and providing oversight for the service delivery system. The specific role of the partner programs in administering Career Advancement Accounts (CAA) would be worked out under policies set by the state in setting up the CAA system.

Question. How will the Labor Department calculate the amount of funds each state will receive for CAAs? Will there be a formula?

Answer. There will be a formula for allotting Career Advancement Account funds to states, similar to the formulas that have been used to allot funds to states under current law. The specific formula proposal has not been finalized, but the final formula would be worked out between the Administration and Congress.

Question. The CAA proposal assumes that individuals need minimal assessment and case management services to make good decisions about whether and how to use training funds. However, in implementing reform of the Trade Adjustment Assistance (TAA) program, you have emphasized the need to co-enroll TAA participants in WIA for case management, so that their training needs can be properly assessed. What is the basis for your decision to provide training funds with minimal case management funds, in the CAA proposal?

Answer. The Department's ongoing evaluation of the Individual Training Account activity under the Workforce Investment Act shows that when an individual is provided more choice in training and counseling services, the individual is more likely to use an ITA for training and to enter training more quickly. Further, the individual's training selection tends to be similar to training programs selected by similar individuals who are required to receive counseling services and approval.

We believe that up-front assessment (as contrasted with ongoing and costly case management) is what workers need, including those served under the TAA program. Assessments can be provided under the CAA proposal if needed, with over \$700 million set aside for such services to complement training (22 percent of the total consolidated resources per state, roughly equivalent to the current Wagner-Peyser amount for core services). The purpose of such assessments is to properly gauge marketable skills and assist workers to reenter employment or identify training to fill gaps in marketable skills. Our demonstrations show that with this "informed choice" more people can receive actual training for jobs in the local labor market.

Question. The new system would be designed based on lessons from the implementation of the Individual Training Account and Personal Reemployment Account (PRA) programs. What lessons specifically have been drawn from the implementation of those programs? What evaluations exist to support giving more control over training funds to individuals?

Answer. CAAs provide individuals with increased customer choice and flexibility for selecting training and other services that are appropriate for them and are based in part on lessons learned from Individual Training Account (ITA) and Personal Reemployment Account (PRA) demonstrations.

The ongoing evaluation of the ITA Experiment explored the use of increasing customer choice in the delivery of ITAs. Initial analysis from eight local boards participating in the experiment showed that when an individual was provided more customer choice in training and counseling services, the individual was more likely to accept an ITA for training, the individual's training selection tended to be similar to training programs selected by individuals required to receive counseling services and approval of programs, and the individual was more likely to enter training quickly. The final report, to be completed later this year, will provide a more in-depth analysis of the impacts of the three different ITA service approaches.

The goals of PRAs are to provide individuals who are identified as most likely to exhaust Unemployment Compensation with a quicker return to work, direct access to training, greater customer choice and control, and better economic outcomes. Initial observations from the PRA Demonstration show that participating states were able to implement the PRAs generally as planned, with the first accounts offered in March 2005. The evaluation of the PRA Demonstration is underway. An interim report, to be completed this year, will provide a more in-depth understanding of the implementation process. In the meantime, reports from states on best practices

show that account mechanisms can be implemented, appropriate oversight can be maintained, and individual choice can provide greater access to needed services.

Question. The CAA proposal includes performance measures that are similar to those now used to assess the adult and dislocated worker programs. However, with CAA funds going directly to individuals, who would be held accountable for performance outcomes—states or the local community career centers? Does it make sense to apply performance measures designed for adults (that focus on employment outcomes) to CAAs that are also used by youth? Currently, youth performance measures also consider educational goals.

Answer. States will continue to negotiate performance targets and report to the Department of Labor on three primary outcome measures: (1) entered employment, (2) retention in employment, and (3) earnings. In addition, attainment of a degree or certificate, entry into training and education, and literacy and numeracy gains would be tracked as intermediate outcomes.

RAPID RESPONSE FUNDS

Question. Currently, states use rapid response funds to provide immediate service to workers affected by a mass layoff, often before the workers are even laid off. Under your legislative proposal, states will need to apply to The Employment and Training Administration for rapid response funds as events occur. What are the reasons for keeping these funds at the national level, and having states apply for them each time they are faced with a mass layoff? What effect will this approach have on states' ability to provide immediate rapid response services for mass layoffs?

Answer. The Department does not contemplate that a state would have to apply for funds each time there is a mass layoff or to only sporadically fund a state rapid response coordinator. Early intervention to provide information and assistance to workers to decrease the amount of time between actual layoff and re-employment is a key principle of the dislocated worker program. Rapid response is a key element of this early intervention strategy.

States could demonstrate need and apply for rapid response funds at the beginning of the program year or through the program year. We will not propose that a state be required to submit an application for funding each time a dislocation event occurs.

In spite of all the good work that has been done over the past fifteen years with dislocated worker rapid response funds, the Department has found that most company executives do not know about the type and quality of assistance available to them and their employees when closures or layoffs are contemplated. They have also reported that where they have layoffs in several states simultaneously, the levels and quality of assistance varies dramatically. ETA, in collaboration with state and local partners, has undertaken several initiatives in the auto, textile and defense industries recently to try to integrate services and develop more consistency. We believe a national approach to delivering rapid response assistance by states can help bring the services to more workers and employers.

The proposed mechanism will assist both the Department and the states to better manage scarce taxpayer resources by directing the bulk of the funds to the areas of need. For example, not all states experience major layoffs every year. Analyses of dislocated worker program expenditures reported by states have shown that the funds reserved for rapid response are consistently under-expended. In the aggregate, the rapid response carry-in funds from program year 2003 to 2004, and from 2004 to 2005, was \$136.7 million and \$166 million, respectively. Through March 31, 2006, states reported accrued expenditures of just over \$176 million of a total available of more than \$342.5 million, or 51.4 percent of the total funds available. States are not required to retain the up to 25 percent authorized to be reserved for rapid response activities. They may include a portion of the funds in the amount allocated to local workforce investment boards for core, intensive and training services for dislocated workers, or they may award additional funds from the reserved amount to local areas that experience disasters, mass layoffs, plant closings or other events that precipitate substantial increases (defined by the state) in the number of unemployed workers.

FOREIGN LABOR CERTIFICATION

Question. There is an inherent unfairness to having some employers' applications from six years ago pending at the BEC and having new applications adjudicated in two months. These inordinate delays have caused and are causing serious prejudice to employers and employees alike. With this as background, please address the following issues:

Answer. The Department published a final regulation implementing a new re-engineered Permanent Labor Certification Program effective March 28, 2005. This regulation created a new faster and more efficient method for employers to have their applications processed. The regulation applies to all applications filed after its effective date. However, for applications previously filed up until March 27, 2005, those applications must be processed under the previous regulation. The process prescribed by the previous regulation takes considerably more time than the new one, despite efficiency measures we have introduced, e.g., technology, to streamline it as much as possible.

Question. Congress has expressed a clear intention in the Child Status Protection Act to prevent government delays from separating families by having children turn 21 during the permanent residence processing. At the time Congress passed the CSPA, the existing scope of the DOL backlog was unanticipated. In light of the clear Congressional intention, why has the Department of Labor refused to expedite long-pending backlogged applications based upon a showing that the impact of the delay will forever prevent a child from becoming a permanent resident with his or her parents?

Answer. We understand the Child Status Protection Act applies only to cases pending before the Department of Homeland Security. The Department of Labor strongly supports efforts to keep families together. The Department has determined this goal can best be accomplished by minimizing the amount of time it takes to process foreign labor certification applications. For this reason, the Department has consistently applied a first in/first out (FIFO) policy to cases in the Program Electronic Review Management (PERM) program. The FIFO policy prevents the need to make subjective decisions regarding which, if any, cases merit special consideration for expedition, thereby conserving resources and substantially reducing the amount of time that is required to process applications. It is ETA's longstanding policy to also process cases in the permanent labor certification program backlog on a "First-In/First-Out" basis within that system's various processing categories; for example Reduction in Recruitment (RIR) cases are in a separate processing queue from cases being handled through the traditional recruitment process (TR), but cases in each queue are processed on a "First-In/First-Out" basis. It has been ETA's established policy never to expedite cases based on the specific circumstances of individual employers or aliens.

Question. In addition to children aging out, other significant detriments to employers and employees exist in specific cases. Examples include inability to promote employees, loss of tuition benefits, inability to travel, inability for spouses to work, etc. Given that the delays are through no fault of the employer or the employee, why has the Department of Labor failed to establish a system for expediting worthy cases?

Answer. The Department's policy of not expediting cases saves an enormous amount of limited resources since we do not have to evaluate the merits of each request to expedite across what potentially could be tens of thousands of cases. Furthermore, we believe some of the concerns you note arise from visa restrictions over which the Departments of State and Homeland Security have jurisdiction and not from any DOL permanent labor certification rules or requirements.

The most equitable response to this complicated issue is to require strict adherence to our first-in/first-out policy under which all applicants are treated consistently. For every case considered for expedited consideration, an older case would be further delayed. Unlike the Department of Homeland Security, the Department of Labor does not have the legislative authority for a fee structure which allows for "premium processing."

Currently, employers do not pay a fee to DOL for the processing of permanent foreign labor certification applications. Employers benefit significantly from the admission of foreign workers, and the efficient review of applications they receive under the new, streamlined process. The backlog system is not fully automated and therefore continues to function through a FIFO process. The Administration has included a proposal in the fiscal year 2007 budget to create a fee structure for the Permanent Labor Certification Program. We anticipate revenue from such fees would permit the assignment of additional staff, such that there should be no backlogs in the new PERM system.

Question. Why has the Department of Labor made it so difficult and risky for employers to convert cases from the BEC to PERM? Seemingly, DOL has created the most restrictive rules possible to discourage these conversions, resulting in an unexpectedly low number of conversions and an unexpectedly high number of cases remaining at the BECs? Will DOL amend its rules to encourage conversions? Examples of improvements include eliminating the risk of the loss of priority date if a case is not eventually adjudicated to be "identical"; eliminating the risk of loss of

the ability to obtain seventh year H-1B extension if the case is not considered to be "identical"; removing the "identical" standard entirely; changing present procedures which involve audits of most or all of the conversion cases; eliminating the very extensive delays in adjudicating PERM conversion cases; and allowing cases at the BEC to remain pending until the approval of the PERM case (especially since a mere typographical error could result in a PERM case being denied).

Answer. The Department is in the process of reviewing the rate at which cases have been converting from the old pre-PERM certification system to PERM. Employers currently have the option of re-filing the case if it meets the requirements of the PERM regulation. Those who wish to have the benefit of the new efficient processing system must meet the regulatory requirements of that rule. The Department does not have the resources to process identical cases under two different regulations implementing the permanent labor certification program, i.e., pre-PERM and post-PERM. Removing the "identical" standard under the PERM regulation would require a new rulemaking process and has the potential for trading backlogs between the Backlog Elimination Centers and the Department's National Processing Centers. We do not feel that this would be in the interests of employers or foreign workers. The new PERM system is much more efficient than the old system, but converting all old cases into new PERM cases would result in backlogs in PERM.

Question. What is the plan for dealing with applications for which no 45 day letter was received by June 30? Will provisions be made for reconstructing lost files? When will employers be notified of these procedures?

Answer. The BECs have taken extensive steps to ensure that all applications identified for transfer to the BECs have been shipped and received at their designated destination. However, because there may be some applications that for various reasons were never identified by the state agencies or ETA Regional Offices for shipment to the BECs, we are developing a process by which to handle those cases. Within the past two weeks, the Department posted a detailed set of Frequently Asked Questions (FAQs) on the foreign labor certification website which addresses procedures related to the 45-day letters <http://www.ows.doleta.gov/foreign/#whatsnew>.

Due to the high demand for information and time and resource constraints, we believe that posting the information on our website is the best way for the entire public to have access to the information at the same time. These FAQs will provide procedures for employers in the event they have had a case closed through the non-receipt of a 45-day letter. Additional FAQs to cover these situations may be posted if appropriate at a later date.

Question. What are the realistic expectations for adjudicating all BEC cases by September 30, 2007? How are these expectations impacted by losses of the top level people at the BEC in Pennsylvania? How has DOL factored into these expectations the lack of incentive for BEC employees to complete the cases on a timely basis since doing so will result in loss of their positions as of September 30, 2007?

Answer. The Department has plans underway to fill all vacancies, both Federal and contractor staff, at the Philadelphia Backlog Elimination Center. Since establishing the two (2) backlog centers in July 2004, we have logged in all 360,000+ cases transferred to the backlog centers from the states, sent 45-day letters to all employers, and cleared over (157,473) cases from the centers. We intend to have all backlog cases under processing by September 30, 2007.

**DEPARTMENTS OF LABOR, HEALTH AND
HUMAN SERVICES, EDUCATION, AND RE-
LATED AGENCIES APPROPRIATIONS FOR
FISCAL YEAR 2007**

U.S. SENATE,
SUBCOMMITTEE OF THE COMMITTEE ON APPROPRIATIONS,
Washington, DC.

NONDEPARTMENTAL WITNESSES

[CLERK'S NOTE.—The subcommittee was unable to hold hearings on nondepartmental witnesses. The statements and letters of those submitting written testimony are as follows:]

DEPARTMENT OF LABOR

PREPARED STATEMENT OF THE NATIONAL ASSOCIATION OF WORKFORCE BOARDS

Chairman Specter, Ranking Member Harkin, and distinguished Members of the subcommittee, my name is Stephanie Powers, Chief Executive Officer of the National Association of Workforce Boards (NAWB). I am submitting this testimony on behalf of Leonard Wilson, Chairman of the Board of Directors of NAWB, and the Nation's workforce investment boards regarding fiscal year 2007 funding for programs authorized under the Workforce Investment Act (WIA). We appreciate this opportunity.

Workforce Investment Boards (WIBs).—The Nation's 589 local, and 52 State workforce boards provide strategic guidance and leadership for the design and implementation of the Nation's workforce investment system, which includes 2,000 comprehensive One-Stop Career Centers. The boards have approximately 13,000 private sector members who volunteer their time to insure that the workforce investment programs are connected with community economic development priorities and employers' needs.

The Workforce Challenge in the United States.—More than at any time in our history, the American workplace demands a competitive and responsive workforce. The complex interplay of technology and globalization, coupled with profound demographic changes, have set in motion a set of difficult challenges to our economic prosperity. Business, political leaders, and policy experts often disagree as to the proper mix of monetary, trade, taxation, and regulatory policy to ensure prosperity in the years ahead. Nonetheless, virtually all the experts, public and private, agree that a key ingredient to our economic success lies in the capacity of the American workforce to offer knowledge, skills and innovation to the economy. Yet, the administration continues to propose potentially devastating reductions in funding, and policy changes for the Nation's workforce investment system that, if adopted, would virtually eliminate our workforce preparation infrastructure, and decimate United States efforts to maintain a skilled workforce.

As your Committee examines the President's fiscal year 2007 budget proposal, and deliberates over workforce investment and employment services funding, the National Association of Workforce Boards respectfully asks that you: (1) Weigh the potentially devastating impact of the administration's budget and policy recommendations for WIA and the Wagner-Peyser Act; (2) Decide instead to enhance and build on strengths of locally-based, private sector-led Workforce Investment system and its successes; and (3) Invest, not disinvest in the Nation's workforce devel-

opment system, funding programs authorized under WIA and the Wagner-Peyser Act at not less than the fiscal year 2005 funding levels.

In 2006, we know that it is crucial for our workers to be ready, willing, and able to respond to the pace of America's changing workplace needs. On the demand side, employers must be ready to invest in the capacity of all workers, not just those already skilled and educated. Collectively, our Nation must commit resources at all levels, to raise the performance of students and workers at the bottom, while improving the performance of those in the middle and top. We must ensure that all low wage and structurally unemployed workers have the opportunity to gain new high-value skills, maintaining important transitional income support and health insurance while upgrading skills and changing careers. Our public policy investments need to embrace the realities of a 21st Century workplace and develop a system that will help our employers and workers compete successfully. Success for the future will depend not just on educating all Americans to much higher standards, but also to different standards.

We believe that the complexity of what we are facing requires our Nation to maintain a strong Federal commitment to coherent and consistent public investment policies that address the needs of workers and employers alike. There will be a price to broad prosperity if we ignore the sum of these growing realities:

—*Broad Lack of Workforce Proficiency in Technology.*—The Global Affairs Director of the Microsoft Corporation, Pamela Passman, in a recent speech at NAWB's annual conference, expressed her company's concerns about the "readiness of the American workforce to embrace technology as an essential tool of the knowledge economy." She stressed that there is no concern with countries embracing technology, innovating, and investing in education and skills training, as long as America is doing the same. But she warned about the lack of proficiency of adults to search, comprehend, and use information (13 percent) and to perform computational tasks, despite the Nation's focus on improving math and science skills (13 percent). These deficiencies, if not quickly addressed, will hamper growth and innovation expansion for "employers who are demanding more skills that revolve around knowledge creation, collaboration and communication, and analysis."

—*A Growing Talent Shortage.*—The well-regarded staffing company manpower asserts, in a recently released white paper entitled *Confronting the Talent Crunch: What's Next States*, "There already is a talent shortage in many areas of the global labor force, a situation that will grow more widespread across more jobs over the next 10 years—and could threaten the engines of world economic growth and prosperity." The Bureau of Labor Statistics predicts a shortfall of 10 million workers in the United States by 2010, which may exert additional strain on the talent pool availability.

—*Demographic Reality #1: Aging Workforce.*—The first of the baby boomers has turned 60 this year. Older workers will be leaving the workforce much faster than new workers are entering, and as they leave the workforce they will take with them an incredible wealth of education, talent, skills, experience, and traditional work ethic. For example, more than 50 percent of the current science and engineering workforce in the United States is approaching retirement. Given this, should we be concerned that China graduates four times as many engineers as the United States? Or that out of the 1.1 million high school seniors who took a college entrance exam, just under 6 percent indicated plans to pursue a degree in engineering—nearly a 33 percent decrease in interest from the previous decade (Passman, 2/27/06).

—*Demographic Reality #2.—Immigrants and Untapped Pools of Potential Workers.* The future workforce will be far from homogeneous. The predicted growth in the American labor force will come largely from immigrants who are less likely to quickly replace the level of skills that will be departing with the boomers' exodus. If these trends continue, and they are predicted to do so, increasing workforce remedial interventions will be needed to deal with English language deficiencies and to boost basic education proficiencies. Employers will also need to be better prepared to provide various accommodations for both an aging workforce and people with disabilities who are likely to enter the workforce in greater numbers as technology and civil rights protections enable higher rates of their participation. The continued growth of working women will require more flexible working schedules and family leave policies as their child care and elder care responsibilities require them to balance work and family commitments.

So the question looms, how can workers be assisted in navigating and managing their work lives in this complex global economy? Will companies be competitive without access to a higher-skilled workforce? And importantly, how should public

policy respond to the realities of the societal changes and the vagaries of the global economy? The President acknowledged in his State of the Union message the increasing concern about national competitive challenges, but we regret that his budget proposal for workforce investment does not support his agenda in this area; in fact, it misses the mark. It is baffling why the administration would propose such deep cuts in the Nation's workforce investment programs in the face of mounting evidence, and their call for attention to American competitiveness. We should increase, not decrease these investments.

The WIA system currently provides a wide range of vital services to over 16 million U.S. jobseekers and employers through its One-Stop delivery system, including labor market information, job search assistance, guidance and counseling services to help workers find the right jobs, and employers find the right employees. The system provides essential rapid response and transition assistance to dislocated workers; support services for individuals pursuing first time employment; and assistance for low-wage workers in search of career growth opportunities leading to self-sufficiency. It is designed to help jobseekers access the education and training they need to succeed in the new knowledge economy; to meet the skill needs of employers.

According to the U.S. GAO, the WIA system spent over 40 percent of its funding in fiscal year 2003 on training for jobseekers in the United States, and this estimate did not take into account funds used to pay for computer lab workshops in software applications, basic keyboarding, computer skills training, and even certain adult basic education classes offered through the One-Stop delivery system. Nor did it take into account training arranged by the One-stops but not paid for with WIA funds.

As your Committee deliberates on funding for the U.S. workforce investment system, and considers the President's 2007 budget proposal, we respectfully ask that you:

(1) *Enhance and Build on Workforce Investment Boards' Successes*

The United States' Council on Competitiveness and the experts who participated in its National Innovation Initiative identified innovation as the single most important factor in determining America's success through the 21st Century. They identified the key ingredients for innovation as talent, investment, and infrastructure, and urged the knitting together of these strands to foster new innovation "hot spots" in regions across the United States than can sustain jobs and wage growth. It is crucial to find ways bring businesses, workers, researchers, economic developers, entrepreneurs, educational and training institutions, and governments together, at the regional level, to identify and develop their strengths and capacity for innovation.

In fact, the Workforce Investment Act is predicated on such a collaborative model. Many Workforce Boards across the country are already performing this convening/brokering role that is essential to regional economic prosperity. To eliminate funding for this work as proposed in the administration's fiscal year 2007 budget, would be to put a stop to what hundreds of local workforce investment boards from around the country have already begun—the building of collaborative regional, knowledge-based economies. Let me share some examples with you.

—*The Finger Lakes Workforce Investment Board.*—In New York identified and developed career maps for photonics and biotechnology as potential growth sectors for a region in transition. The WIB with K–12 schools, the business community, community colleges and the Syracuse University School of Education identified the foundational skill standards for these industries and recommended steps for secondary schools to realign curricula in science, math and technology, as well as ways to build awareness of the career opportunities and pathways existing in these sectors.

—*The South Florida Workforce Investment Board.*—That serves the Miami metro area served 7,648 employers and placed 69,634 clients in jobs this past year. They calculate the return on investment to the community of \$11.01 for every dollar of workforce funds invested. In an area of historically high unemployment, these results are the fruit of the partnerships that the WIB has fostered with economic development agencies, business and the community's public agencies.

—*The Brevard Workforce Development Board.*—has created an extensive menu of business services and targeted those growth industries such as healthcare, manufacturing, and Aerospace that are growing jobs in their community, which is one of the hottest job growth areas in the country. Their ability to continue this work would be diminished, if not eliminated, if the proposed budget cuts and Career Advancement Account proposals are enacted.

—*The Northwest Wisconsin Workforce Investment Board.*—Developed the "Talent Profiling System" (TPS), a soft skills matching tool, to respond to the over-

whelming requests of employers to find people that fit their jobs. Since its implementation, TPS has achieved results ranging from having the highest employer penetration rate in the State's 11 Workforce Development Areas to a decrease of \$916.88 to \$420.24 in cost-per-placement and realized \$4.22 Return On Investment (ROI) for each tax dollar invested.

—*The North Central Texas Workforce Development Board.*—Serves a fourteen county region with 1.6 million people that surrounds the Dallas/Fort Worth area. This board supports small businesses by serving as the HR department for small companies. In this vital role they provide personalized attention for recruiting and placement; applicant screening; and on-site assistance with interviewing. Services to small business such as these, the engine of economic growth, will be severely limited by 15 percent + reductions in funding and the Career Advancement Account proposal.

—*The Greater Peninsula Workforce Development Consortium.*—In Newport News, Virginia created The Manufacturing Pipeline Partnership for their local manufacturers. Participating manufacturers have been able to significantly improve their hiring practices through this collaborative effort. Northrop Grumman Newport News was able to hire 922 workers in skilled trades' positions, Siemens VDO Automotive, hired 100 plus workers for crucial positions in their advanced technology production areas. The WIB and the partnership it convened is directly contributing to the long term economic vitality of the region. This would not have been possible without the WIB's convening role, and WIBs would effectively be eliminated by the administration's budget cuts.

(2) *Weigh the Potential Impact of Cuts on the Workforce Investment System and its Customers*

The administration's fiscal year 2007 budget proposes a new 15 percent cut in funding for WIA and Wagner-Peyser. These reductions would be applied to a workforce investment system that has already sustained funding reductions over the years, and is stretched very thin. Simply put, our system cannot sustain any further cuts without having to close numerous One-Stop Centers throughout the country, and cut back on services provided to those in need (eg, dislocated workers, the structurally unemployed, low wage workers in search of self-sufficiency, at-risk youth, and employers).

These negative consequences of funding reductions do not even take into account the potential devastation that would be caused by the administration's policy recommendations contained in the fiscal year 2007 budget. In her testimony before your Committee, Secretary of Labor Elaine Chao indicated that the One-Stop delivery system would be preserved under the administration's fiscal year 2007 proposal. She stated this despite the fact that 75 percent of the funding for States under their consolidated proposal, would be required to be spent on Career Advancement Accounts—leaving less funding for all other system functions and services, than now provided for the Wagner-Peyser program alone.

The real impact of the administration's proposal (in total) would be the elimination of most of the local Workforce Investment Boards around the country, and the closure of most of the One-Stop Centers. With only 22 percent of WIA and Wagner-Peyser funding, States would be forced to provide all remaining services other than training. Funds to engage the private sector, both through the boards and through business services would be immediately impacted. The loss of the private sector engagement and focus would be diametrically opposed to the original Congressional intent of WIA and to calls from the country's leaders on U.S. competitiveness. Discussions with our colleagues around the country indicate that the impact on the workforce system infrastructure would be dramatic and would effectively dismantle much of the strategic partnership work, employer outreach, and physical One-Stop infrastructure that the WIBs have spent the last 5 years crafting. Innovative programs developed in partnership with employers and economic development, such as incumbent worker, industry sector, career ladder, and layoff aversion programs would be abruptly halted. And tragically, the private-sector leadership of the workforce boards, that has taken us so long to build, would be dismantled and swept under the rug. We believe this leadership and participation should be cultivated, not marginalized, particularly at a time when business leadership and employer engagement in the system is growing. It would be hard to find many other Federal programs where the business community has such a direct role in determining how Federal tax dollars are used in local communities.

When WIA was enacted in 1998, it was clear that Congress intended a significantly enhanced role for business vested in the Workforce Investment Boards. As WIA has matured these past 5 years, we believe that this strategic oversight has turned out to be a highly desirable value proposition and we urge Congress to con-

tinue a strong endorsement of the approach by maintaining and increasing WIA funding that insures the private sector's engagement in the public workforce system.

(3) Invest, Not Disinvest

We applaud the efforts of the subcommittee to provide funding for WIA at levels as close to constant as possible in these increasingly difficult budgetary times. NAWB knows that there are many pressures on the Federal budget and many legitimate requests for funding. However, we submit the competitive posture of the Nation needs to be placed at the top of the priority list, and urge you to fund WIA and Wagner-Peyser at the fiscal year 2005 levels.

While the Department of Labor may claim there is excess unspent money in the WIA system to justify their recommended budget cuts, they, in fact, are not presenting the facts accurately. The GAO's 2002 study clearly disputed this claim. And since the original claims of slow expenditures and excessive carryover were made, the WIA system has significantly diminished system carryover to less than 30 percent of its accrued expenditures—the standard proposed by the administration for WIA reauthorization, and included in both the House and Senate WIA reauthorization bills.

In summary, when WIA was enacted, it was intended to ensure that all Americans have access to the information, job search assistance, and training they need to qualify for good jobs, and to successfully manage their careers in the new economy of the 21st Century—we urge you not to turn your backs on America's workforce investments. . . . they are about our future prosperity, and ultimately our national security in the purest sense.

Thank you for your support in the past, and for this opportunity to submit testimony.

PREPARED STATEMENT OF THE NATIONAL JOB CORPS ASSOCIATION

JOB CORPS WORTHY INVESTMENT TO AMERICA'S YOUTH

Six Million Youth Eligible to Participate

On behalf of the National Job Corps Association (NJCA), we want to thank the Labor, Health and Human Services and Education Appropriations Subcommittee for its unwavering dedication to Job Corps and the vulnerable disadvantaged young Americans it serves. We appreciate the Committee's strong support of Job Corps in fiscal year 2006. Not only did the Committee provide a funding increase, but it established Job Corps as an office reporting directly to the U.S. Secretary of Labor. With strong bipartisan support, Congress acknowledged Job Corps' 40-year track record of success by eliminating layers of bureaucracy and ensuring department-wide attention on America's most disadvantaged youth.

Job Corps is a voluntary program that serves more than 60,000 young Americans each year, which is only about 1 percent of the nearly 6 million disadvantaged youth that are eligible for Job Corps' services. Over the last four decades, Job Corps has built its reputation as the Nation's largest and most successful residential educational and vocational training program for economically disadvantaged youth, ages 16 through 24. With millions of youth eligible and in need of Job Corps services, it is only with your help that Job Corps can remain a beacon of hope for many young Americans and an excellent example of our government's role in ensuring every American has a chance to succeed in the 21 century economy. Tony Pusateri, a Senior Vice President of Equity Residential in Plano, Texas and member of the National Apartment Association Education Institute observed: "I've been around Washington and seen a lot of government programs that I didn't support, but Job Corps is one program . that I am proud my tax dollars go to."

Unfortunately, the administration's fiscal year 2007 budget request cuts Job Corps by \$72 million from the fiscal year 2006 enacted level. We are deeply concerned that such a funding cut would force a drastic reduction in the number of youth Job Corps will be able to serve. While we encourage spending restraint by the U.S. Government, we also believe it is imperative to provide adequate funding to support the young Americans who are our Nation's future.

JOB CORPS OPERATIONS FUNDING

Administration's Fiscal Year 2007 Budget Proposal

The administration's proposal recommends funding Job Corps' operations account at \$1.401 billion, a decrease of \$64 million compared to the fiscal year 2006 appropriated levels. This level of funding amounts to a 7.8 percent decrease in Job Corps' real-dollar funding from fiscal year 2006.

If the operations account were to be cut by \$64 million, more than 3,000 economically disadvantaged young Americans would be turned away from Job Corps. These vulnerable youth, though they have the desire, would not be able to enter Job Corps to complete their high school education and place themselves on a career path. As one of the few national job training programs that has shown consistent positive results, Job Corps has the ability to preserve economic prosperity by equipping thousands of high school dropouts, foster care youth, and other vulnerable youth with job skills to enter gainful employment and become responsible, productive citizens. This cut would limit the opportunities of vulnerable youth who are seeking a way to put themselves back on track for success.

NJCA Fiscal Year 2007 Request

The NJCA requests a total of \$1.53 billion for Job Corps' fiscal year 2007 operations account to support at least 44,000 training slots and keep all Job Corps centers at full capacity. This amount is based on the Office of Management and Budget's (OMB) projected 3.3 percent rate of inflation between fiscal year 2006 and fiscal year 2007 as well as additional appropriations to support efforts to improve educational programs on Job Corps centers. The increase would (1) allow the 122 Job Corps centers across the country to operate at full capacity to ensure the programs serves as many eligible youth as possible; and (2) support the U.S. Department of Labor's efforts to ensure the program has the necessary resources to hire capable teachers and ensure the quality of its educational courses.

JOB CORPS CONSTRUCTION, REHABILITATION AND ACQUISITION (CRA) FUNDS

Administration's Fiscal Year 2007 Budget Proposal

The administration's budget proposal recommends funding Job Corps' CRA account at \$100 million, an \$8 million reduction from fiscal year 2006.

As you know, Job Corps gives young people the opportunity to focus and learn in a safe, stable, and supportive environment. However, the average building on a Job Corps center is 47 years-old—20 years older than the construction industry's recommended lifespan. While the program is committed to addressing the backlog of repairs by developing a 10-year capital improvement plan to construct and repair facilities based on priority, it needs more funding resources.

NJCA Fiscal Year 2007 Request

With respect to Job Corps' capital account, the NJCA requests \$130 million in fiscal year 2007. These funds will be used to: repair dorms, classrooms, and other student facilities on existing Job Corps centers; replace deteriorated structures, especially those that threaten the safety and health or violate minimum building codes, including mechanical systems; continue to address the \$700+ million backlog of construction and/or repair needs; and provide third year funding for incremental Job Corps expansion.

CONCLUSION

As Job Corps looks to the future to train the next generation of youth, we hope you agree that it remains a Federal program worthy of America's attention and support. Seventy-four percent of Job Corps enrollees are high school dropouts. The typical Job Corps student reads slightly less than the 8th grade level. Most youth who attend Job Corps have never held a full-time job. Thirty-two percent come from families on public assistance. However, through targeted self paced learning and dedicated counselors and teachers, these youth graduate from Job Corps with well-documented improvements in their education and skill levels and more than 90 percent transition into employment, higher education or the military. Job Corps provides thousands of youth a second chance to achieve the American dream.

The NJCA looks forward to working with the members of this Committee to ensure that thousands of disadvantaged young Americans will continue having the opportunity to lift themselves up through Job Corps. We have been encouraged by the Committee's support that have expanded and strengthened Job Corps over the years and hope that we will enjoy that support and confidence in fiscal year 2007 and into the future.

PREPARED STATEMENT OF THE NATIONAL YOUTH EMPLOYMENT COALITION

The National Youth Employment Coalition (NYEC) is a network of over 270 youth employment, education, and workforce development organizations dedicated to promoting policies and initiatives that help young people succeed in becoming lifelong learners, productive workers and self-sufficient citizens. NYEC works to improve the

effectiveness of youth-serving organizations by informing and tracking policy; setting and promoting quality standards; promoting professional development; and building organizational capacity. We thank you for your previous support of programs that provide meaningful job training and youth development opportunities for young people and for the opportunity to submit this testimony.

Youth development/employment programs must be adequately funded because our youth are facing a crisis that has profound implications for their lives, their futures, and our society at large. There are 2.4 million low-income 16 to 24 year olds who left school without a diploma or received a diploma but are unemployed.

Youth development/unemployment programs must be funded at a level commensurate with the need to develop a globally competitive and highly skilled workforce for the jobs of tomorrow and today. Youth face a crisis that has profound implications for the lives, their futures, and society at large. According to a report by Public/Private Ventures, "nationwide, 15 million people between the ages of 16 and 24 are not prepared for high-wage employment. Inadequate education or training is a major reason." A report by the National Association of Manufacturers identified three simultaneous phenomena that together are transforming the American economy and its labor force: global pressures, relentless advances in technology, and demographic shifts that will result in "a projected need for 10 million new skilled workers by 2020."

In the face of persistent youth unemployment and changes in the labor market which require more knowledge and skills, the administration's proposed 2007 budget for WIA and Employment Services programs, is a matter of serious concern. It calls for a 15 percent reduction in these important programs and perpetuates the downward trend that would leave employment and training programs \$1 billion below funding levels of 5 years ago.

Unless Congress rejects these proposals, many thousands of youth will continue to lack the opportunities and supports necessary to succeed in the 21st century workplace. NYEC urges you to increase investment in programs under the Workforce Investment Act (WIA) and to restore funds for Perkins Act programs, TRIO, and Gear-Up, and the Reintegration for Young Offenders Program.

These programs are needed because unemployment among youth is unacceptably high. While adult unemployment averaged 5 percent in the last quarter of 2005, the unemployment rate among youth 16–19 was 16.1 percent; more than three times as high. A recent study from Northeastern University's Center for Labor Market Studies found that between 2000 and 2004, the number of employed teens declined by nearly 1.3 million.

Since fiscal year 2002, our Nation has been in the process of disinvesting in youth employment and development programs. If this current round of cuts is implemented, investment in the WIA youth programs will have dropped by more than 38 percent from \$1.4 billion in fiscal year 2002 to \$841 million in fiscal year 2007. This when according to the National Center on Education and the Economy we need "to invest in training on a scale that supports the well-being of the Nation's economy and so that it is not just a privilege for the lucky few."

The administration's disinvestment runs counter to its own philosophy of investing in programs that work and divesting from programs that do not work. These programs work. According to the U.S. Department of Labor's fiscal year 2005 Performance and Accountability Report, in Program Year 2004 (July 2004-June 2005), WIA programs exceeded the Department's target for Diploma Attainment among youth 14–18 (65 percent v. 53 percent), entry to employment for youth 19–21 (72 percent v. 68 percent), and employment retention for youth 19–21 (82 percent v. 79 percent).

The only measure in which programs failed to meet or surpass the Department's target was in cost per participant. According to the Report (page 65), "Average cost per participant was slightly higher than expected—\$2,822 vs. a target of \$2,663. However, consistent with ETA's vision for youth services, the program has served a higher proportion of out-of-school youth. Out-of-school youth are a more expensive population to serve, with a cost of \$3,724 per participant, therefore the overall cost per participant increased over prior years. At the time the cost per participant target was estimated, DOL did not anticipate the full extent of increased expenditures on out-of-school youth." The Report also notes that "Results for PY 2004 continue an upward trend that began with WIA implementation in 1998. All three outcome indicators have increased from PY 2003 and exceeded performance targets. Most important is the continued increase in high school diploma attainment, given the strong statistical correlation between educational attainment and success in the labor market."

It should be noted that even at \$2,822 per participant, the cost is below the \$3,000 assumed in the administration's proposed Career Advancement Accounts (CAA).

Further, a recent study of comprehensive youth workforce development programs in 36 communities carried out by the Center for Law and Social Policy confirms that Federal investment makes a difference. It found that that between 2000 and 2005 these programs successfully connected out-of-work youth to approximately 18,456 long term unsubsidized work opportunities; 23,652 internship opportunities; 28,302 short-term unsubsidized jobs; and 23,478 training opportunities. The program reached 42 percent of the eligible target population and 62 percent of the eligible out-of-school population.

According to a 2004 report prepared by Northeastern University's Center for Labor Market Studies, there are 5.4 million 16 to 24-year-olds who left school without a diploma or received a diploma but are unemployed. About 44 percent of them are low-income. With more than 540,000 students dropping out of high school each year the implications of this phenomenon are staggering:

- The earnings gap widens with years of schooling and formal training. In 2003, earnings of male dropouts fell to \$21,447; high school graduates earned an average of \$32,266; and college graduates earned about \$63,000 or triple that of dropouts. As a result, dropouts pay less taxes, are more likely to rely on public assistance, and to be part of the criminal justice system.
- One expert estimates that the United States would save \$41.8 billion in health care costs if 2004's 600,000 dropouts were to advance an additional year in educational attainment.
- Approximately 16 percent of all young men, ages 18–24, without a high school degree or GED are either incarcerated or on parole at any one point in time.
- Three quarters of State prison inmates are high school dropouts, as are 59 percent of inmates in the Federal system.
- Increasing the high school completion rate by 1 percent for all men aged 20–60 would save the United States \$1.4 billion a year in reduced costs from crime.
- The situation is even more dire in minority communities where as few as 20 percent of black teens are employed at any time, unemployment among young black men aged 16–24 not enrolled in school is about 50 percent, and approximately one-third of all young black men are involved with the criminal justice system at any given time.

According to a paper by written by Professor Michael Wald and Tia Martinez for the Hewlett Foundation, "over the past 25 years the situation for youth who fall off the ladder as they move to adulthood has gotten considerably worse." Nevertheless, inflation-adjusted spending for programs that target at-risk youth dropped by 63 percent from 1985 to 2003.

Youth workforce development programs provide a wide range of services to improve educational achievement, prevent youth from dropping out of high school, and reengage youth who are out of school and out of work. NYEC believes that we must reverse the trend of disinvesting in youth employment and development and fund the WIA youth formula at \$1 billion. While we support new programs that help youth prepare for jobs and careers and prevent them from leaving school, funding for untested initiatives like the CAA's should not come at the expense of successful programs that are already stretched to the breaking point.

The administration's fiscal year 2007 budget also proposes to eliminate the Reintegration of Young Offenders Program. According to the Bureau of Justice Statistics, approximately 120,000 youth under the age of 18 are currently incarcerated in juvenile detention centers, State prisons, and local jails. Most will be released in the next few years.

A 1998 study by Vanderbilt Professor Mark Cohen, estimated that each teen prevented from adopting a life of crime could save the Nation between \$1.7 and \$2.3 million. A report prepared in 2002 for the California State Senate Joint Committee on Prison and Construction Operations stated, "Given the staggering cost of failure, it is hard to imagine any justifiable argument against providing education and services to this population."

Finally, the cost per participant pales in comparison with the cost of alternatives like incarceration. According to the Justice Policy Institute, for example, "incarceration, particularly for juveniles, is an expensive proposition. Each year, capital costs to build new facilities run in the range of \$100,000 per cell and operating costs typically exceed \$60,000 per cell." The return on investment in the Young Offenders program will be returned many times over.

While NYEC recognizes the administration's continuing commitment to helping prisoners successfully return to society, we are concerned that unless funds are specifically targeted to serving youth, the needs of adults will most often take prece-

dence. At a minimum, funds currently targeted at court-involved youth under the Reintegration for Young Offenders Program should be restored to fiscal year 2003 levels (\$54 million).

We support the goals of the President's "American Competitiveness Initiative" and his charge that "We must continue to lead the world in human talent and creativity. Our greatest advantage . . . has always been our educated, hardworking, ambitious people—and we're going to keep that edge." Realizing that goal, however, requires investment in all our citizens.

NYEC has many concerns about the CAA's. We are particularly concerned that the limit of \$3,000 a year for up to 2 years will function as a cap that will prevent workers from receiving the best and most appropriate training. A June 2005 GAO Report on the Workforce Investment Act (GAO-05-650) revealed that only 8 percent Workforce Investment Boards cap their Individual Training Accounts at \$3,000. Fully 63 percent impose caps of \$5,000 or more and 35 percent have caps of \$7,000 and up. Fifteen percent have no caps. While this could achieve DOL's goal of increasing the number of people trained, it would call the quality of much of that training into question.

Without Federal investment in effective programs such as those supported by WIA youth formula funds, the Responsible Reintegration of Young Offenders program, and the education programs that provide meaningful pathways from high school to higher education, millions of young people will not make the successful transition into productive employment.

We thank the Committee for its commitment to these important programs that prepare our youth to compete in the global marketplace of the 21st century. We look forward to working with you to strengthen our Nation's youth employment and youth development systems.

PREPARED STATEMENT OF THE OREGON HUMAN DEVELOPMENT CORPORATION

Honorable Chairman, Senator Arlen Specter, and Honorable Committee Members: I want to thank you for the opportunity to share information about the Workforce Investment Act, Section 167 (WIA 167) National Farmworker Jobs Program.

My name is Ronald Hauge and I am the Executive Director of Oregon Human Development Corporation (OHDC), a not-for-profit organization that has provided education, training, and workforce development services for Oregon's migrant and seasonal farmworkers for more than 27 years. Throughout this period Congress has supported focused workforce development services for migrant and seasonal farmworkers within the CETA, JTPA, and WIA Federal workforce initiatives. The underlying reason for this support has been the recognition that migrant and seasonal farmworkers have different characteristics and needs than conventional job seekers who use the Nation's workforce system, and that based on these differences specialized workforce services are necessary to effectively serve this population.

The Department of Labor's own performance reports that show the WIA 167 National Farmworker Jobs Program consistently among the higher performing workforce programs, yet the administration has tried to eliminate the WIA 167 for the last several years. It is only by congressional action that the WIA 167 program continues to exist. Each year this Committee has demonstrated its wisdom and priorities by supporting appropriations to preserve these effective workforce services. Accordingly, I want to thank the Honorable Chairman and Committee Members for your instrumental role in saving the program and maintaining these valuable investments for our Nation's agricultural workforce.

At this time I would like to point out a few features of the WIA 167 program that illustrate its importance.

PROGRAM PERFORMANCE

According the Department of Labor's performance reports the WIA 167 program has achieved entered employment rates above 80 percent, job retention rates of 75 percent, and earnings gains above \$4,000. This is unquestionably strong performance given that migrant and seasonal farmworkers are among the most difficult to serve job seekers in the workforce system, and that the program operates largely in rural areas with limited labor markets.

INTEGRATION OF THE WIA 167 PROGRAM INTO THE ONE STOP WORKFORCE SYSTEM

The WIA 167 programs in each State are integrated into the One Stop workforce system on a location-by-location basis. In Oregon, for example, OHDC has six service delivery offices and each of the offices is integrated into the local One Stop sys-

tem by virtue of co-location or other planned systemic integration. OHDC WIA 167 staff are members of local Workforce Investment Boards in each service area.

In Oregon, this integration is acknowledged at the State level and is well documented in the State of Oregon's Two-Year Plan for Title I of the Workforce Investment Act and the Wagner-Peyser Act. The plan states that "strategies in Oregon to promote equal and effective access and service delivery and to promote enhancement and integration of services to MSFWs (migrant and seasonal farm workers) include Oregon Human Development WIA 167 staff have workspace in WorkSource Oregon centers and access rights to the MSFW customer base in each workforce area they serve. With this, they are able to identify from a broader base of MSFW customers those particularly interested in the intensive and training services they can offer and where other staff are able to understand more thoroughly the value added services offered by the WIA 167 for enhanced referral of their customers; *they are seen as a critical component to delivering workforce services to MSFWs.*" (emphasis added)

FEW ALTERNATIVE OPTIONS FOR FARMWORKERS

The mainstream One Stop workforce system is geared primarily toward meeting the "demand" needs of high growth/high demand industries—as part of larger economic development strategies. This leaves lower skilled, hard working farmworkers with few or no options to improve their skills and secure stable employment in the primary labor market. Accordingly, the WIA 167 program becomes the only viable workforce development option for most farmworkers, a place with culturally sensitive, bilingual staff who are experienced in serving farmworkers and who understand the needs of local employers. It is clear that without the WIA 167 program few farmworkers would receive any developmental benefit from the Nation's workforce system.

RURAL COMMUNITY ASSET

The WIA 167 program is a real asset to rural communities. The program adds tangible service capacity and diversity to smaller rural One Stop workforce systems. The program can provide agricultural upgrade training to help agricultural employers enhance worker productivity and stability, thus extending the workforce development system's benefit into the agricultural industry. Also, the program can serve as a foundation to attract other services for farmworkers such as housing, literacy and language training, disaster services, and a variety of emergency services that help stabilize the agricultural labor force in local communities.

As you can see, the WIA 167 National Farmworker Jobs Program is an effective, valuable, coordinated resource that not only benefits farmworkers, but also strengthens the Nation's One Stop workforce system and rural communities.

Before closing I would like to share, in the words of OHDC workforce coordinators, the experience of two farmworkers who were assisted in Oregon Human Development Corporation's WIA 167 program.

*Jesus Ortiz*¹

Worked with Glen Walters Nursery for a number of years but had been unable to advance because he did not have any formal education on how to supervise a crew. Most of his knowledge came from first hand experience in the general operation of his department and observing other supervisors. In November 2004 OHDC enrolled Jesus in the WIA 167 National Farmworker Jobs Program. OHDC met with the employer and arranged to provide supervisory skills upgrade training to develop the supervisory skills of Jesus, with the understanding that Jesus would be promoted into a supervisory position following the training. Because Jesus had limited English language skills, OHDC provided the training in Spanish. Jesus completed the training, which was defined as "a success" by the employer, who promoted Jesus into a supervisory position. Jesus also received a wage increase that took his earnings from \$7.45 per hour to \$11.00 per hour. Now, Jesus not only has the knowledge foundation that makes him a more effective leader and supervisor, but he also has a better income that will dramatically improve his family's well being. It is important to note that this success story would not have been possible if OHDC's WIA 167 program had not been available to provide the training in Spanish—something not available from any other partner in the local One Stop workforce system.

¹ EDITORS NOTE.—Not real names.

*Antonio Sanchez*¹

Enrolled in the WIA 167 program in October 2005 at OHDC's Woodburn office. Antonio is a married father of three children. Antonio had worked primarily in agricultural work since he was 18 years old. He was employed with a dairy since 2003, living in employer owned housing. At the dairy Antonio worked long hours and weekends (65–75 hours per week) earning a salary of \$2,000 per month with no health or vacation benefits. Antonio was eager to start attending training classes available through the WIA 167 program—his primary goal was to obtain a Commercial Drivers License (CDL) and to secure a commercial driving job. Antonio completed job readiness, customer service, computer, CPR, and CDL trainings within a 6 month period, even though English was not his primary language. He was an active participant with a strong desire to learn as much as he could so he could secure employment that would offer him and his family health insurance benefits, a regular work schedule, and a good living wage so his family could purchase their own home. Upon obtaining his CDL, OHDC referred Antonio to a job interview with Sysco Food Service. According to the Sysco supervisor, Antonio made a great impression during his interview and was offered an entry level position starting at \$12.13 an hour—and he will be given the opportunity to transition to a Truck Driver position earning more than \$16.00 per hour. The position provides vacation and excellent health benefits, retirement and life insurance. The family is now in the process of purchasing a home of their own.

These two examples illustrate how the WIA 167 program works for both farmworkers and employers.

In closing, I want to thank you again for your ongoing concern for the Nation's agricultural workforce. Although there are many priorities the Committee must evaluate, this is not the time for the Nation to turn its back on our hard working farmworkers who produce and harvest much of the Nation's food and other agricultural products—and who contribute so much for our collective benefit. Therefore, I strongly urge the Committee to maintain or increase the appropriation for the WIA 167 National Farmworker Jobs Program in the 2007 budget.

PREPARED STATEMENT OF THE ASSOCIATION OF FARMWORKER OPPORTUNITY PROGRAMS

Good morning Chairman Specter and members of the subcommittee. My name is David Strauss and I represent the 48 nonprofit and public agencies that provide job training and related services to our Nation's migrant and seasonal farmworkers. They perform these tasks with grants from the United States Department of Labor pursuant to Section 167 of the Workforce Investment Act. As you know, the administration has tried to eliminate this program for the last 5 years. You and the members of your subcommittee have led the way in maintaining it each year, and we thank you for your leadership.

About 2.5 million people labor in the fields and farms of America, from Hawaii to Florida and Puerto Rico, from Maine to California. Estimates are that 85 percent of the fruits and vegetables we eat are hand harvested by farmworkers. The pay is extremely low: most farmworkers earn less than \$12,000 per year. Few farmworkers receive the job-related benefits, such as health insurance and sick pay, which we all take for granted. In most States, agricultural workers are not even eligible for unemployment compensation. They live a tough life. Many workers travel hundreds, sometimes thousands of miles in search of work. They get paid only when they perform the work: if the weather is bad or the crop is not as plentiful as the farmer had hoped, they simply do not receive wages. They typically cannot afford decent housing. Their children have to struggle mightily to even complete their public school education. The dropout rate for farmworker youth, especially those who migrate with their parents, is enormous.

For over 33 years the Federal Government has made and kept a commitment to these hardworking people. Special Federal programs were created to recognize the reality that farmworkers often cross State lines to work and live. Thus, we have migrant head start, migrant health, migrant education, and the job training effort called the National Farmworker Jobs Program. These all are federally funded and have guidelines that acknowledge that Governors should not be placed in a position of deciding whether or not agricultural workers qualify for these services under State residency or other localized requirements.

¹ EDITORS NOTE.—Not real names.

Today, I want to explain the way some of our program operators and staff members helped farmworkers and other rural poor people during the aftermath of the hurricanes of 2005.

When the winds and rains of Hurricanes Katrina and Rita ravaged the gulf States many impoverished groups suffered. Among the hardest hit were the area's migrant and seasonal farmworkers. Thousands lost their jobs and many saw their homes damaged or destroyed. With incomes typically far below the poverty line, most farmworkers have no safety cushion when disaster strikes. To make matters worse, language barriers and cultural isolation often prevent them from accessing emergency services delivered by mainstream providers.

It is hard to picture the severe hardships created by the hurricanes. Potable water could not be obtained, food and fuel were unavailable, and electricity and telephone services interrupted. These deprivations continued for weeks. For many, the migrant and seasonal farmworker job-training agencies provided the only relief.

It must be noted that the four agencies mentioned below can only use Federal migrant and seasonal farmworker job training and assistance funds for eligible farmworkers and their dependents. The head of household must demonstrate eligibility, which includes proof of work authorization or citizenship and evidence of a recent history of performing farmwork. For those ineligible for Federal services, the agencies found other resources. The § 167 WIA agencies in the four States are funded solely through the DOL job training grants for farmworkers. Without Congress's 2005 appropriation for migrant and seasonal farmworker job training, those agencies' doors would have been closed and none of the assistance described below would have happened.

Here is a summary of the § 167 agencies' relief activities:

LOUISIANA

Motivation, Education and Training, Inc. of Louisiana (MET) is the 167 agency in that State. MET was on the ground in the Hammond, LA area a few days after the storm hit. That area had no electric power, or telephone service, gasoline, or clean water. MET set up an intake center in a trailer, powered by a generator. Staff provided emergency services to people who could not be reached by FEMA. Red Cross trucks brought water and ice. MET provided vouchers for food, clothing, rent and other items to over 300 families (made up of over 1,200 people) who otherwise might have starved or been rendered homeless. While much of the community infrastructure, was poorly supplied, the local Wal-Mart was well prepared for the needs of people affected by the storm, and MET worked out arrangements for the vouchers to be used there. The average voucher was about \$370 per family. They continue to serve eligible families months after the storm. These vouchers are funded through the § 167 program.

Ineligible families are referred to the Quad Area Community Action Agency, which issues commodities and other goods.

MISSISSIPPI

The Mississippi Delta Council for Farmworker Opportunities (MDC) was one of the few statewide nonprofit organizations to have a nearly intact network following the hurricane. Headquartered in Clarksdale, MDC gave out vouchers and other help to hundreds of seasonal as well as migrant farmworkers. Vouchers were issued to 330 eligible farmworkers and families, and commodities and other supplies were given to 331 other people. Vouchers were provided through § 167 WIA program funds.

The commodity donations were made possible through the efforts of the § 167 WIA agency in Tucson, Arizona: Portable Practical Educational Programs (PPEP). PPEP gathered its own resources, those from the League of United Latin American Citizens, and from World Care. PPEP led two caravans consisting of a total of 14 trucks loaded with relief supplies making the 1,200-mile journey from Tucson to Clarksdale. MDC located a warehouse in Clarksdale, and the supplies continue to be distributed from there to farmworkers and other rural poor families throughout affected counties and in places where evacuees from the Gulf Coast and the New Orleans area are sited. MDC is also shipping supplies to their colleagues at Telamon Alabama for use in the Mobile area. As in Louisiana, the people they are serving are mostly outside any area of help provided by FEMA or the Red Cross.

MDC is currently assessing farmworker needs in the counties of Scott, Simpson, Smith, Forrest, Greene, and George. There appears to be a tremendous need for housing for farmworkers whose homes were devastated by the storms.

ALABAMA

Telamon Alabama is the § 167 WIA agency in that State. It has provided direct voucher services to at least 25 farmworker families dislocated by the storm, primarily in Baldwin County. They have assisted about 200 others. Very little presence of FEMA or the Red Cross is reported for the farmworker areas of that county. A particular problem is that the fishing industry on the coast was devastated. Shrimp harvesting businesses operated by Vietnamese immigrants and others were virtually wiped out by the storm. Telamon is limited by the amount of help it can provide in two ways: its § 167 WIA grant is about half that of Mississippi and considerably less than Louisiana's. In addition, there are large numbers of undocumented farmworkers, and there are few resources for referral for them. Telamon is providing as many persons as they can with commodities that have been shipped in from Arizona.

FLORIDA

The counties in which farmworkers were most affected were not declared disaster areas. That restricted FEMA's involvement. The Florida Department of Education's Adult Migrant Programs (FDOE) operates the farmworker job-training program in Florida. FDOE funds a number of sites with § 167 WIA subgrants. Those sites have assisted over 400 farmworkers and their families, primarily obtaining resources from the United Way agencies that use Community Services Block Grant funds. A number of private funds were set up in the aftermath of the 2004 hurricanes, and these funds were used to alleviate suffering from these storms. The 400 farmworkers they have already assisted were working in nurseries that were wiped out by the storm. However, the avocado orchards that were to be harvested were severely damaged, and the planting season that farmworkers rely upon in late fall were delayed because of the wet conditions.

SUMMARY

In Alabama, Louisiana, and Mississippi, the agencies that operate the programs funded under § 167 of the WIA served as primary relief sources for migrant and seasonal farmworkers and their families in the wake of Hurricanes Katrina and Rita. At least 1,800 farmworkers and family members have received emergency services to date, either in the form of vouchers or relief supplies. Hundreds of other people in those States and in Florida were referred to agencies funded to help storm victims. There are medium- and long-term problems that farmworkers will experience that are not yet fully known. Much farm labor housing in Mississippi and Alabama has been destroyed, and future prospects for employment in agriculture are unclear.

It is crucial that these four organizations were in place when the rural poor of the affected areas needed them. Had the funding for these organizations ceased in 2005 as the Department of Labor recommended, thousands of hard-working, low-paid farmworkers and their families would face life-threatening deprivations. And the growers and farmers that rely on them would be facing a much more uncertain future as they try to rebuild their agricultural enterprises. Fortunately, despite DOL's attempts to eliminate this program since 2002, Members of Congress have had the foresight to sustain the migrant and seasonal job-training program.

Without these grants, who would be there to serve the working poor in rural Louisiana, Mississippi, Alabama, and Florida during this terrible time?

PREPARED STATEMENT OF THE CENTRAL VALLEY OPPORTUNITY CENTER

Chairman Specter, and other members of the subcommittee, my name is Ernie Flores and I am the executive director of Central Valley Opportunity Center (CVOC). CVOC is the DOL WIA Title I Section 167 grantee, and also a Community Action Agency, in Madera, Merced and Stanislaus counties in the central San Joaquin Valley of California. At this time I submit my testimony for your consideration and in support of continued funding for the WIA 167 program, operated as the National Farmworker Jobs Program (NFJP) in the DOL. As you are aware, for the past 5 years, the President's budget, and the DOL, have proposed to eliminate the funding for NFJP. If this were to happen, it would effectively end vital employment and training services, job stabilization services, and various educational services that migrant and seasonal farm workers require to either continue working in agriculture, or to transition into year round employment outside of agriculture. It should also be mentioned that the funding for the entire NFJP program is approximately \$80 million. Unfortunately, this amount of funding only allows us to serve 3-5 percent of the eligible farmworkers in need of our services.

Although the U.S. DOL has testified that farm workers could be served through the local One-Stop Centers, all partners in the One Stop system, including the One Stop operators and the 167 grantee One Stop partners, are in agreement that the One Stop system is not prepared to served farmworkers. The majority of farm workers have limited English proficiency, possess very little formal education and generally have very few marketable job skills. The only jobs program that is prepared to help farm workers overcome those types of barriers, and become or continue to be gainfully employed, is the WIA 167 NFJP.

The U.S. DOL has also testified before Congress that the NFJP is ineffective and duplicates the work of other job training programs. As to effectiveness, the DOL's own internal performance reports document that the NFJP has attained the highest performance ratings, for all WIA employment programs in the areas of entered employment, wage gains, and retention in employment, during the past 4 quarters. As for duplication, the NFJP generally serves over 95 percent of all migrant and seasonal Farmworkers that are enrolled in any WIA programs during any 12 month program period. Any Farmworkers that are enrolled in other WIA programs are most likely co-enrolled into a NFJP WIA 167 program also.

For the past 27 years CVOC has provided various employment, training and social service programs to migrant and seasonal farm workers and other low income persons in our three county service area in Central California. As is the case with all NFJP grantees, our field offices are easily accessible to Farmworkers since they are located in their communities. CVOC offers the following services under the NFJP grant:

EMPLOYMENT AND TRAINING

- Outreach, assessment and enrollment
- Case management/vocational guidance
- Vocational training
 - Welding
 - Auto Mechanics
 - Cooking/Food preparation
 - General/Advance Business Occupations
 - Cashiering/Merchandising
 - Commercial Drivers License
- English As a Second Language classes
- General Equivalency Diploma classes
- Supportive Services (child care, gas, food, housing)
- Job Readiness Training
- On the Job Training
- Direct Job Placement
- Indirect Job Placement
- Active follow-up services
- Retraining services

In addition to these services, CVOC has leveraged resources with the help of the NFJP grant in order to provide farm workers with services such as energy payment assistance, emergency housing, food vouchers, medical & dental services and various other social services.

It should be understood that there are no other programs in the WIA system that are prepared to meet the employment and training needs of migrant and seasonal farmworkers except for programs like CVOC, and the other grantees of the WIA NFJP. If these programs cease to operate as a nationally administered program, and funding is seriously cut or eliminated, there will literally be no employment and training services for migrant and seasonal farm workers.

I sincerely implore you to continue the funding for the WIA 167 NFJP so that together we can continue to do for the least of our brothers. So that farmworkers can also reap the harvest of the American dream.

At this time I would like to share some of our "success stories." The stories clearly show how the lives of farmworkers, or their dependents, are forever changed for the better when they receive services from the National Farmworkers Jobs Programs grantees.

Thank You.

Isaura Gonzalez

Before coming to CVOC, Isaura Gonzalez was a seasonal cannery worker at Michael Angelo Gourmet, where she was making \$9.50/hr. This wage was not too bad considering she dropped out of school in the seventh grade. However, this was a temporary job and offered no benefits. Isaura came to CVOC with a dream. She wanted to obtain her General Education Diploma (GED) and find a year-round job

with fringe benefits. Six months later, all her dreams became true! Isaura successfully completed the CVOC 22-week General Business Occupations course a month early and obtained her GED with an amazing score of 2,910. This score is the highest ever in CVOC's history! She is now working for Hilmar Cheese Company as a Data Entry/Machine Operator Manager making \$14.95/hr. She has fringe benefits and a year-round job. Recently, during her first quarter follow-up she said she was expecting a raise soon.

Juan Hernandez

He had just graduated from high school when he came to CVOC to register for the welding program in October of 2004. He was 18 years old, the dependent of a farm worker. He was very eager to learn welding because his uncle is a welder so he wanted to follow his uncle's footsteps. While he was in training, he was very punctual and the instructor was very happy to see how well he did and how eager he was to learn. After completing training, the Job Developer placed him as a welder at Gladden Equipment Erectors. His starting pay was \$10.50 per hour and soon after, he began to travel to different States to work for the company. He sometimes spends a month traveling with the company. Today, he still works for the same company and earns \$14.00 per hour.

Hugo Sanchez

Hugo had not graduated from high school when he came to CVOC to register for the Cashiering Program in March 2004. He was hoping to obtain his GED, enroll in ESL classes, and obtain a Vocational Training Certificate. While he was attending classroom training, he found the cashiering class was too easy for him so he decided to transfer to General Business Occupations (GBO) training. While in training, he obtained his GED, improved his English skills, and completed GBO training. After completing training, he started working as a temporary data entry teller at E & J Gallo Winery in August of 2004 earning \$11.14 per hour. Since this job was temporary, he found another job. In November 2004, he started working at Foster Farms Dairy where he started earning \$12.83 per hour. He continues to work for them and now earns \$16.97 per hour. In May 2006 he will be making \$18.90 per hour as the CAT supervisor

Julian Diaz

Before Julian Diaz came to CVOC, he was working as a farm worker and at Wal-Mart. Julian was living with his parents in Modesto Housing Authority's Public Housing. He wanted to become a welder and he discovered that CVOC offered this training. He saw the CVOC ad in the Modesto Bee and he decided to call. Julian began his 22-week training in welding in September of 2005. He completed his training on February 24, 2006. Even though he finished all his exams in January, Julian decided to stay until February to gain more skills. He was a great student and attended class every day. His instructor was very pleased with his hard work. The instructor even helped him find work.

Julian is now working as a welder at West-Mark in Atwater making \$11.00 per hour. He will soon be receiving health benefits and 401k. Julian has achieved all the goals he hoped to achieve and is very happy that he chose CVOC for his training. Julian even went as far as calling the welding instructor in tears on his first day of work to express his gratitude for the training, job skills, tools, and the opportunity that was given to him.

DEPARTMENT OF HEALTH AND HUMAN SERVICES

PREPARED STATEMENT OF THE AIDS INSTITUTE

The AIDS Institute, a national public policy research, advocacy, and education organization, is pleased to submit written comments to you in support of a number of critical HIV/AIDS and Hepatitis programs as part of the fiscal year 2007 Labor, Health, and Education and Related Services appropriation measure. We thank you for your consistent support of these programs over the years, and trust you will do your best to adequately fund them in the future in order to provide for, and protect the health of, many Americans.

HIV/AIDS

HIV/AIDS remains one of the world's worst health pandemics in the history of civilization. Worldwide, some 40 million people are infected with this incurable infectious disease, and 14,000 new infections occur each passing day. Tragically, AIDS has already claimed the lives of 25 million people. Here in the United States, ac-

According to the CDC, 944,305 people have been diagnosed with AIDS, and over 529,000 people have died through 2004. It is estimated there are more than 40,000 new infections in the United States each year. At the end of 2003, an estimated 1,039,000 to 1,185,000 persons in the United States were living with HIV/AIDS.

Persons of minority races and ethnicities are disproportionately affected by HIV/AIDS. In 2003, African Americans, who make up approximately 12 percent of the U.S. population, accounted for half of the HIV/AIDS cases diagnosed. HIV/AIDS also disproportionately affects the poor, and about 70 percent of those infected rely on public health care financing.

The U.S. Government has played a leading role in fighting the AIDS epidemic, both at home and abroad. The vast majority of the discretionary programs supporting HIV/AIDS efforts domestically and a portion of our Nation's contribution to the global AIDS effort are funded through your subcommittee. The AIDS Institute, working in coalition with other AIDS organizations, have developed realistic and practical funding request numbers for each of these domestic and global AIDS programs. The AIDS Institute asks that you do your best to adequately fund these programs at the requested level.

We are keenly aware of the current budget constraints and competing interests for limited Federal dollars. Unfortunately, despite the growing need, almost all domestic HIV/AIDS programs in recent years have experienced funding decreases.

This year, the President has proposed three new domestic HIV/AIDS initiatives by providing \$70 million for getting prescription drugs to those who need them; \$90 million for testing those who do not yet know their status; and \$25 million to help raise the awareness of those who do not know they should be tested. The AIDS Institute applauds these initiatives and encourages the subcommittee to fund these increases.

RYAN WHITE CARE ACT

[In millions of dollars]

Fiscal year	Amount
2005	2,048
2006	2,038
2007 President's request	2,133
2007 community request	2,631

The centerpiece of the Federal Government's response to caring and treating low-income individuals with HIV/AIDS are those programs funded under the Ryan White CARE Act. CARE Act programs currently reach over 571,000 low-income, uninsured, and underinsured people each year, most of who are from a racial or ethnic minority group. The majority of CARE Act funds support primary medical care and essential support services.

Providing care and treatment for those who have HIV/AIDS is not only the compassionate thing to do, but it is cost-effective in the long run, and serves as a tool in prevention of HIV/AIDS.

In recent years, with the exception of minor increases for the AIDS Drug Assistance Program (ADAP), CARE Act funding has decreased. Because of across the board recessions, flat funding has actually resulted in budget cuts for the past several years. We urge you to provide these vitally important programs with the community requested level of funding. Consider the following:

(1) The caseload is increasing. People are living longer with HIV/AIDS due to life-saving medications; there are 40,000 new infections each year; and the Federal Government has initiated increased testing programs to identify positive people-all of which will necessitate the need for more medical services and medications.

(2) There is a greater financial burden on CARE Act programs. The price of healthcare, including medications, is increasing; non-profit organizations are struggling; Medicaid benefits are being scaled-back at the State level and significant Medicaid reductions recently passed the Congress.

(3) Level or decreased funding for the CARE Act is impacting State and local governments grant awards. Because of reduced funding levels, 34 out of the 51 largest cities affected by HIV/AIDS experienced cuts to their Title I awards this year. This is after 18 cities experienced cuts last year. Additionally, 41 States and territories received less money last year in their Title II base awards.

(4) ADAP funding shortfalls are causing States to place clients on waiting lists, limiting drug formularies, and increasing eligibility requirements. In February 2006, nine States reported having waiting lists, totaling 791 people. Several ADAPs re-

ported other cost containment measures, including formulary reductions (4), eligibility restrictions (2) and limiting annual client expenditures (2). Due to the small increase the ADAP program was given last year, additional severe restrictions are anticipated in many additional States across the country.

(5) Two recent reports conclude there are a staggering number of people in the United States who are not receiving life-saving AIDS medications. The Institute of Medicine report “Public Financing and Delivery of HIV/AIDS Care, Securing the Legacy of Ryan White” concluded that 233,069 people in the United States who know their HIV status do not have continuous access to Highly Active Antiretroviral Therapy (HAART). A study by the CDC titled, “Estimated number of HIV-infected persons eligible for and receiving antiretroviral therapy, 2003—United States”, reached similar conclusions. According to CDC’s estimates, 212,000, or 44 percent of eligible people living with HIV/AIDS, aged 15–49 in the United States, are not receiving antiretroviral therapy. The report concludes, “there is a substantial unmet health care need for antiretroviral therapy among HIV-infected persons in care.”

This is a travesty in our own country. As we seek to provide lifesaving medications to those abroad, we must ensure we are providing medications to our own here in the United States.

Fiscal Year 2007 Administration Initiative.—The AIDS Institute is in strong support of President Bush’s proposed increase of \$70 million for “States in need to bridge the existing gaps in coverage for Americans waiting for life-saving medications. These funds would help the States end current waiting lists and help support care for additional patients.” Since ADAP only received a funding increase of \$2 million in fiscal year 2006 and the need number for fiscal year 2007 is \$197 million, the \$70 million increase, while certainly not enough, is a welcome increase. We urge the Committee to approve this long overdue increase.

Additionally, President Bush proposed an increase of additional \$25 million Title III Ryan White CARE Act funding “to significantly strengthen outreach by local community and faith-based organizations in hardest hit areas. These grants would help raise awareness, increase early detection, combat stigma, and facilitate access to treatment, especially for African-American, Hispanic, Native American, and other minority community groups whose need is often greatest.” This additional funding is also extremely worthy of funding, and the administration should be commended for its proposal.

The AIDS Institute supports continued and increased funding for the Minority HIV/AIDS Initiative (MHAI). MHAI funds services nationwide that address the disproportionate impact that HIV has on communities of color.

CENTERS FOR DISEASE CONTROL AND PREVENTION—HIV PREVENTION AND SURVEILLANCE

[In millions of dollars]

Fiscal year	Amount
2005	662
2006	651
2007 President’s request	740
2007 community request	1,049

While the number of new HIV infections in the United States has greatly decreased since the 1980’s, there are still an estimated 40,000 new infections each year. Since AIDS is a preventable disease, these are 40,000 new infections annually that could have been prevented. Leading the Federal Government’s campaign in AIDS prevention is the CDC. As with other domestic AIDS programs, funding is severely lagging, and the CDC is being asked to do more with fewer and fewer dollars. In fact, CDC’s AIDS funding has declined in the last 4 years in a row. It is not surprising given the budget decreases, the administration’s goal of reducing the infection rate in half by 2005 did not occur.

Fiscal Year 2007 Administration Initiative.—The AIDS Institute is in strong support of President Bush’s proposed increase of \$90 million “to the purchase and distribution of rapid HIV test kits, facilitating the testing of more than 3 million additional Americans. Test kits would be distributed in areas of the country with the highest rates of newly discovered HIV cases, and the highest suspected rates of undetected cases.” A large portion of the funds would be used for the testing of prisoners and intravenous drug users, two groups with extremely high levels of infections. Knowledge of one’s HIV status, particularly for high risk individuals, is an effective prevention tool. Approximately one quarter of the over 1 million people living with HIV in the United States (252,000 to 312,000 persons) are unaware of their

HIV status. This initiative, if funded by the Congress, should help prevent future infections and bring additional people into lifesaving treatment and care. The AIDS Institute urges the Committee to fund this extremely worthy program.

While The AIDS Institute supports increased testing programs, we do not support funding those efforts at the expense of prevention intervention programs. Funding for these programs are already under funded.

We are pleased to hear that the new leadership of CDC's HIV prevention programs has pledged to make the CDC budget more transparent, and will better detail where the funds are being spent, and on what populations and programs. For far too long, this information has not been made available.

Efforts to improve prevention methods and weed out non-effective programs should be a constant undertaking and be guided by science and fact based decision-making. It is for these reasons that The AIDS Institute opposes funding of abstinence-only until marriage programs, for which the President requested a \$27 million increase. While we support abstinence-based prevention programs as part of a comprehensive prevention message, there is no scientific proof that abstinence-only programs work. On the contrary, they reject proven prevention tools, such as condoms, and fail to address the needs of homosexuals, who can not marry, and who remain greatly impacted by HIV/AIDS. Given that approximately one-half of all new infections in the United States are among those under the age of 25, it is essential that our youth be given the proper tools to prevent HIV infection.

NATIONAL INSTITUTES OF HEALTH-AIDS RESEARCH

[In million of dollars]

Fiscal year	Amount
2005	2,921
2006	2,903
2007 President's request	2,888
2007 community request	3,000

Through the NIH, research is conducted to: understand the AIDS virus and its complicated mutations; discover new drug treatments; develop a vaccine and other prevention programs such as microbicides; and ultimately, a cure. Much of this work at the NIH is done in cooperation with private funding and ingenuity. The critically important work performed by the NIH not only benefits those in the United States, but the entire world.

This research has already helped in the development of many highly effective new drug treatments, prolonging the lives of millions of people. Undoubtedly, the commitment of the Congress and the administration to double NIH funding over the past 5 years has led to great advances. As neither a cure nor a vaccine exists, and patients continue to build resistance to existing medications, additional research in cooperation with private interests must continue. We are disappointed the President's budget is proposing a decrease of \$15 million in AIDS research for fiscal year 2007. We ask the Committee to fund NIH, including critical AIDS research, at the community requested level of \$30 billion.

Substance Abuse and Mental Health Services Administration

It is widely known that many persons infected with HIV also experience drug abuse and/or mental health problems, and require the programs funded by SAMHSA. Given the growing need for services, we are disappointed that overall funding requested for SAMHSA is down by \$71 million, and the Center for Substance Abuse Treatment is being cut by \$24 million, the Center for Substance Abuse Prevention is cut by \$12 million, and the Center for Mental Health Services is cut by \$35 million. We ask the Committee to reject these cuts, and adequately fund these programs.

VIRAL HEPATITIS

Viral Hepatitis, whether A, B, or C, are infectious diseases that also deserve special attention by the Federal Government and the subcommittee. According to the CDC, there are an estimated 1.25 million Americans chronically infected with Hepatitis B, and 73,000 new infections each year. Although there is no cure, a vaccine has been available since 1982, and there are a few treatment options available. An estimated 3.9 million (1.8 percent) Americans have been infected with Hepatitis C, of whom 2.7 million are chronically infected. Currently, there is no vaccine or cure,

and very few treatment options available. It is believed that one-third of those infected with HIV are co-infected with Hepatitis C.

Given these numbers, we are disappointed that the administration is proposing to cut the 317 Immunization Grant Program funds that serve as the major source in the public sector for at-risk adult immunizations. Instead of facing cuts, since the vaccines are relatively inexpensive, this cost-effective program should be significantly enhanced in order to protect people from Hepatitis A and B. We recommend funding the 317 Program at \$800 million for fiscal year 2007 in order to fully realize the public health benefits of immunization.

The administration is also calling for decreased funding for Viral Hepatitis at the CDC. The program is currently funded at a level less than it was in fiscal year 2003, and falls way short of the \$50 million that is needed. These funds are needed to establish a program to lower the incidence of Hepatitis C through education, outreach, and surveillance, and to support such initiatives as the CDC National Hepatitis C Prevention Strategy and the 2002 NIH Consensus Statement on the Management of Hepatitis C and accompanying recommendations.

The AIDS Institute asks that you give great weight to our testimony and remember it as you deliberate over the fiscal year 2007 appropriation bill. Should you have any questions or comments, feel free to contact Carl Schmid, Director of Federal Affairs, The AIDS Institute (202) 462-3042 or cschmid@theaidsinstitute.org. Thank you very much.

PREPARED STATEMENT OF THE AMERICAN ACADEMY OF FAMILY PHYSICIANS

The 94,000-member American Academy of Family Physicians submits this statement for the record to the Senate Appropriations Subcommittee on Labor/Health and Human Services, Education and Related Agencies. Our statement is made in support of the Section 747 Primary Care Medicine and Dentistry Cluster. The Academy also supports the Agency for Healthcare Research and Quality (AHRQ) and rural health programs.

BRIEF BACKGROUND: TRAINING FAMILY PHYSICIANS

Section 747 within the Public Health Service Act is the only Federal program that funds training for family physicians. The law requires the program to meet two goals: (1) increase the number of primary care physicians (family physicians, general internists and general pediatricians) and (2) boost the number of people to provide care to the underserved. Regarding family medicine specifically, Section 747 offers competitive grants for training programs in medical school and in residency programs.

The fiscal year 2006 spending bill provided \$41 million to Section 747, a figure that was a significant cut from the \$88.8 million the cluster received in fiscal year 2005. And, unfortunately, the President's fiscal year 2007 budget proposed zero dollars for the program. We urge Congress to fund Section 747 at fiscal year 2005 levels (\$88.8 million).

WHO ARE FAMILY PHYSICIANS?

Family physicians are the specialists trained to provide comprehensive, coordinated and continuing care to patients of both genders and all ages and ethnicities, regardless of medical condition. These residency-trained, primary care physicians treat babies with ear infections, adolescents who are obese, adults with depression and seniors with multiple, chronic illnesses. And because they focus on prevention, primary care, and integrating care for their patients, they are able to treat illnesses early and cost-effectively. In addition, when necessary, family physicians help patients navigate our complex health system and find the right subspecialists. Finally, family physicians are distributed throughout the country in approximately the same proportion as the population: about one-quarter of all Americans live in rural areas and about 25 percent of family physicians practice there, as well.

COMMUNITY HEALTH CENTERS: UNDERSTAFFED WITH SHORTAGES OF FAMILY PHYSICIANS

Over the last few years, the administration has made increasing the number of Community Health Centers (CHCs) a priority within its health care budget. Specifically, the President's fiscal year 2007 blueprint recommends an increase of \$181 million for CHCs, which would increase funding to nearly \$2 billion. These dollars would complete the administration's goal to create 1,200 health center sites around the Nation. While a laudable objective, this funding does not take into account staff-

ing issues at these centers; the CHC dollars go primarily to so-called “bricks and mortar,” i.e., construction of the health care clinics.

The additional funding recommended in the President’s budget to build Community Health Centers, and the zero dollars proposed to train family physicians under Section 747, are a serious disconnect: primary care physicians make up nearly 90 percent of doctors working in CHCs—and most are family physicians. In short, without more family physicians, no one will be available to staff these new centers.

This point was brought home in a March 1, 2006 article in the *Journal of the American Medical Association* (JAMA). The authors found that in 2004, CHCs were understaffed and could not fill all clinical positions (Rosenblatt, et al.). Rural health centers had more openings that took longer to fill than those in urban areas. More alarmingly, over 13 percent of family physician positions at CHCs were vacant.

As the only Federal program that trains family physicians, funding for Section 747 is critical. Without Section 747 to train family physicians, CHCs staffing problems will get worse.

SECTION 747 PRODUCES DOCTORS WHO WORK IN CHCS AND SERVE IN THE NHSC

A second study buttresses the importance of family physicians to CHCs and to the National Health Service Corps, which is another administration priority. An unpublished 2006 study from the University of California, San Francisco and the Robert Graham Center for Policy Studies in Family Medicine and Primary Care shows that medical schools that receive Section 747 dollars produce physicians who work in CHCs and serve in the National Health Service Corps compared to schools without this funding.

The finding is particularly true for family physicians. Specifically, according to the study, nearly 4,000 family physicians and general practitioners were exposed to Title VII funding during medical school and subsequently chose to work in a CHC. Without this exposure, at least 750 fewer family physicians would have been working in a CHC in 2003. Coupled with the JAMA article, which shows that there are 600 vacancies for family physicians, without Section 747 funding, there would be twice as many vacancies in health centers.

LOWER HEALTH CARE COSTS AND IMPROVED QUALITY

Section 747 plays a role in lowering our Nation’s health care costs and increasing the quality of U.S. health care. For example, an article in *Health Affairs* (April 2004) demonstrated that States that spent more on Medicare had lower quality of care. While seemingly counterintuitive, the authors found two reasons for this result.

The first reason was that expensive health care did not improve patient satisfaction or outcomes. The second reason was that the makeup of the health care workforce made a difference: more primary care doctors in a State meant higher quality care and lower cost. In contrast, more specialists and fewer generalists led to lower quality and higher costs. And, just a small increase in the number of primary care doctors in a State was associated with a large boost in that State’s quality ranking.

The first reason was that expensive health care did not improve patient satisfaction or outcomes. The second reason was that the makeup of the health care workforce made a difference: more primary care doctors in a State meant higher quality care and lower cost. In contrast, more specialists and fewer generalists led to lower quality and higher costs. And, just a small increase in the number of primary care doctors in a State was associated with a large boost in that State’s quality ranking.

An article in a March 2005 edition of *Health Affairs*, “The Effects of Specialist Supply on Populations’ Health: Assessing the Evidence” went even further. This piece stated that there was a “negative relationship between the supply of primary care physicians and death from stroke, infant mortality and low-birthweight, and all-cause mortality.” The article went on to say that just one more primary care physician per 10,000 people was associated with a decrease of 34.6 deaths per 100,000 people.

The article also cited breast cancer research for the State of Florida, which indicated that “each tenth-percentile increase in primary care physician supply is associated with a statistically significant 4 percent increase in odds of early-stage breast cancer.” Statistics were similar for other types of cancers: there was a relationship between early identification of cancer and the supply of primary care physicians. Numerous other research was highlighted in the *Health Affairs* article that indicated a higher ratio of primary care physicians to populations led to better health outcomes. These data support the need for additional funding for Section 747, the only Federal program that produces primary care physicians.

THE OVERSPECIALIZED U.S. PHYSICIAN WORKFORCE: A WORLD ANOMALY

Unlike all other developed countries, the United States does not have a primary care-based health care system. While other developed countries have about equal numbers of primary care physicians and subspecialists, in the United States, less than one-third of the physician workforce is primary care.

More disturbingly, compared to developed countries, the United States spends the most per capita on healthcare—but has some of the worst healthcare outcomes. More than 20 years of evidence have shown that a health system based on primary care produces greater health and economic benefits. Boosting support for Section 747, which funds training for family physicians and for other primary care disciplines, could improve the health of patients in the United States.

AGENCY FOR HEALTHCARE, RESEARCH AND QUALITY

The Academy recommends \$440 million for the Agency for Healthcare, Research and Quality (AHRQ). A major purpose of AHRQ is to conduct primary care and health services research geared to physician practices, health plans and policy-makers. What this means is that the agency translates research findings from basic science entities like the National Institutes of Health (NIH) into information that doctors can use every day in their practices. Another key function of the agency is to support research on the conditions that affect most Americans.

More recently, AHRQ has become the lead Federal agency for research on comparative clinical effectiveness; information technology; and patient safety. For example, the Medicare Modernization Act asked AHRQ to study the “clinical effectiveness and appropriateness of specified health services and treatments,” and to use this information to improve the quality and effectiveness of the costly Medicare, Medicaid and SCHIP programs. In fiscal year 2006, \$15 million was appropriated by Congress for this purpose. This type of study on “what works” in clinical therapies is crucial in an era of skyrocketing health care costs and limited Federal dollars.

Historically, however, AHRQ has been the lead agency to translate research into information for physicians and patients. Over the years, Congress has provided billions of dollars to the National Institutes of Health, which has resulted in important insights in preventing and curing major diseases. However, AHRQ’s role has been to take this basic science and produce understandable, practical materials for the entire healthcare system. In short, AHRQ is the link between research and the patient care that Americans receive.

In addition, AHRQ has long-supported research on conditions that affect most people. Most Americans get their medical care in doctors’ offices and clinics. However, most medical research comes from the study of extremely ill patients in hospitals. AHRQ studies and supports research on the types of illness that trouble most people. In brief, AHRQ looks at the problems that bring people to their doctors every day—not the problems that send them to the hospital.

RURAL HEALTH PROGRAMS

Continued funding for rural programs is vital to provide adequate health care services to America’s rural citizens. We support the Federal Office of Rural Health Policy; Area Health Education Centers; the Community and Migrant Health Center Program; and the NHSC. State rural health offices, funded through the National Health Services Corps budget, help States implement these programs so that rural residents benefit as much as urban patients.

CONCLUSION

The Academy urges Congress to fund Section 747 at fiscal year 2005 levels (\$88.8 million). We believe that the two recent studies showing that Community Health Centers not only rely heavily on family physicians, but cannot fill all of their positions, and the data indicating the crucial role that primary care training plays in whether physicians practice in CHCs or serve in the NHSC, make an irrefutable case for funding Section 747. In addition, however, family physicians are critical to the health and well-being of everyone in the country. Finally, all of these studies, authored by different researchers, are consistent: Section 747 works.

The AAFP also urges Congress to fund the Agency for Healthcare Research and Quality at \$440 million; and support rural health programs. We thank you in advance for making these investments in America’s healthcare system.

PREPARED STATEMENT OF THE AMERICAN ACADEMY OF PEDIATRICS

There can be no denying that there have been numerous and significant successes in improving the health and well-being of America's children and adolescents, from even just decades ago. Infant and child mortality rates have been radically lowered. The number of 2-year-olds who have received the recommended series of immunizations is at an all-time high, while vaccine-preventable diseases such as measles, pertussis, and diphtheria have decreased by over 98 percent. Teen pregnancy rates have declined by 27 percent over the last decade. Still, despite these successes, far too many children in America continue to suffer from disease, injury, abuse, racial and ethnic health disparities, or lack of access to quality care. And more than 9 million children and adolescents through age 18 remain uninsured. Clearly there remains much work to do.

As clinicians we not only diagnose and treat our patients, we must also promote strong preventive interventions to improve the overall health and well-being of all infants, children, adolescents and young adults. Likewise, as policy-makers, you have an integral role to play in improving the health of the next generation through adequate and sustained funding of vital Federal programs.

The AAP, SAM and APA have identified three key priorities within this Committee's jurisdiction that are at the heart of improving the health and well-being of America's children and adolescents: access to health care, quality of health care, and immunizations.

ACCESS

We believe that all children and adolescents should have full access to comprehensive, age-appropriate, quality health care. From the ability to receive primary care from a pediatrician trained in the unique needs of children and adolescents, to timely access, to pediatric medical subspecialists and pediatric surgical specialists, America's children and adolescents deserve access to quality pediatric care in a medical home. Given the recent cuts to the Medicaid program and fiscal belt-tightening in the States, discretionary programs now more than ever provide a vital health care safety net for America's most vulnerable children and adolescents.

Maternal and Child Health Block Grant.—The Maternal and Child Health (MCH) Block Grant Program at the Health Resources and Services Administration (HRSA) is the only Federal program exclusively dedicated to improving the health of all mothers and children. Nationwide, the MCH Block Grant Program provides preventive and primary care services to over 32 million women, infants, children, adolescents and children with special health care needs. In addition, the MCH Block Grant Program supports community programs around the country in their efforts to reduce infant mortality, prevent injury and violence, expand access to oral health care, and address racial and ethnic health disparities. Moreover, the MCH Block Grant Program includes efforts dedicated to addressing interdisciplinary training, services and research for adolescents' physical and mental health care needs, and supports programs for vulnerable adolescent populations, including health care initiatives for incarcerated and minority adolescents, and violence and suicide prevention. It also plays an important role in the implementation of the State Children's Health Insurance Program (SCHIP), which is critically important at a time when States are struggling with ongoing deficits and shifting costs. One of the many successful MCH Block Grant programs is the Healthy Tomorrows Partnership for Children Program, a public/private collaboration between the MCH Bureau and the American Academy of Pediatrics. Established in 1989, Healthy Tomorrows has supported over 140 family-centered, community-based initiatives in 44 States, including Ohio, Wisconsin, Texas, California, Kentucky, Rhode Island, and Maryland. These initiatives have addressed issues such as access to oral and mental health care, abstinence, injury prevention, and enhanced clinical services for chronic conditions such as asthma. To continue to foster these and other community-based solutions for local health problems, in fiscal year 2007 we strongly support an increase in funding for the MCH Block Grant Program to \$724 million.

Family Planning Services.—The family planning program, Title X of the Public Health Services Act, ensures that all teens have confidential access to valuable family planning resources. For every dollar spent on family planning through Title X, \$3 is saved in pregnancy-related and newborn care costs to Medicaid. Title X—which does not provide funding for abortion services—provides critically needed preventive care services like pap tests, breast exams, and STI tests to millions of adolescents and women. But funding for Title X continues to fall well below the need. Over 9 million cases of STIs (almost half the total number) are in 15- to 24-year-olds, and over 30 percent of women will become pregnant at least once before age 20. Teen pregnancy rates continue to vary over racial and ethnic groups, and nearly

half (48 percent) of all teens say that they want more information from—and increased access to—sexual health care services. Responsible sexual decision-making, beginning with abstinence, is the surest way to protect against sexually transmitted infections and pregnancy. However, for adolescent patients who are already sexually active, confidential contraceptive services, screening and prevention strategies should be available. We therefore support a funding level in fiscal year 2007 of \$375 million for Title X of the Public Health Service Act.

Mental Health.—It is estimated that over 13 million children and adolescents have a mental health problem such as depression, ADHD, or an eating disorder, and for as many as 6 million this problem may be significant enough to disturb school attendance, interrupt social interactions, and disrupt family life. Despite these statistics, the National Institute of Mental Health (NIMH) estimates that 75–80 percent of these children fail to receive mental health specialty services, due to stigma and the lack of affordability of care and availability of specialists. Grants through the Children’s Mental Health Services program have been instrumental in achieving decreased utilization of inpatient services, improvement in school attendance and lower law enforcement contact for children and adolescents. We recommend that \$109.7 million be allocated in fiscal year 2007 for the Mental Health Services for Children program to continue these improvements for children and adolescents with mental health problems.

Child Abuse and Neglect.—Health care providers play a crucial role in the prevention, identification, and treatment of child abuse and neglect. In spite of this fact, few Federal resources are dedicated to bringing the medical profession into full partnership with law enforcement, the judiciary, and social workers. We urge the subcommittee to provide an increase of \$10 million in fiscal year 2007 for the Center for Disease Control and Prevention’s National Center for Injury Prevention and Control to establish a network of consortia to link and leverage health care professionals and resources to address—and ultimately prevent—child abuse and neglect.

Health Professions Education and Training.—Critical to building a pediatric workforce to care for tomorrow’s children and adolescents are the Training Grants in Primary Care Medicine and Dentistry, found in Title VII of the Public Health Service Act. These grants are the only Federal support targeted to the training of primary care professionals. They provide funding for innovative pediatric residency training, faculty development and post-doctoral programs throughout the country. For example, the Montefiore Medical Center in the South Bronx of New York City has used Title VII funds to support its Residency Training Program in Social Pediatrics (RPSP). Initiated in response to local needs to prepare physicians for the delivery of care to underserved populations and to practice specifically at Community Health Centers in the inner-city setting, RPSP simultaneously trains physicians in neighborhood health centers and in an academic hospital. Since its inception, RPSP has graduated over one hundred pediatricians, a large number of whom are women and minority physicians. Additionally, 79 percent of all RPSP graduates report that they currently practice in community-oriented primary care settings serving predominately poor and minority inner-city populations. Another 10 percent of RPSP graduates report that they are involved in professional activities such as health administration and policy, including directing patient care in community health centers.

Through the continuing efforts of this subcommittee, Title VII has provided a vital source of funding for critically important programs that educate and train tomorrow’s generalist pediatricians in a variety of settings to be culturally competent and to meet the special health care needs of their communities. We recommend fiscal year 2007 funding of at least \$40 million for General Internal Medicine/General Pediatrics. We also join with the Health Professions and Nursing Education Coalition in supporting an appropriation of at least \$550 million in total funding for Titles VII and VIII. We applaud the administration’s support for the National Health Service Corps and Community Health Centers, key components with Title VII to ensuring an adequate distribution of health care providers across the country; but we emphasize the need for continued support of the training and education opportunities through Title VII for health care professionals who provide care for our Nation’s communities.

Independent Children’s Teaching Hospitals.—Equally important to the future of pediatric education and research is the dilemma faced by independent children’s teaching hospitals. In addition to providing critical care to the Nation’s children, independent children’s hospitals play a significant role in training tomorrow’s pediatricians and pediatric subspecialists. Children’s hospitals train 30 percent of all pediatricians, half of all pediatric subspecialists, and the majority of pediatric researchers. However, children’s hospitals qualify for very limited Medicare support, the primary source of funding for graduate medical education in other inpatient en-

vironments. As a bipartisan Congress has recognized in the last several years, equitable funding for Children's Hospitals Graduate Medical Education (CHGME) is needed to continue the education and research programs in these child- and adolescent-centered settings. Since 2000, CHGME hospitals accounted for nearly 87 percent of the growth in pediatric subspecialty training programs and 68 percent of the growth in pediatric subspecialty fellows trained. We are extremely disappointed in the 67 percent reduction in funding for this vital program proposed by the administration, and join with the National Association of Children's Hospitals to restore funding of \$303 million for the CHGME program in fiscal year 2007. The support for independent children's hospitals should not come, however, at the expense of valuable Title VII and VIII programs, including grant support for primary care training.

QUALITY

Access to health care is only the first step in protecting the health of all children and adolescents. We must ensure that the care provided is of the highest quality. Robust Federal support for the wide array of quality improvement initiatives, including research, is needed if this goal is to be achieved.

Emergency Services for Children.—One program that assists local communities in providing quality care to children in distress is the Emergency Medical Services for Children (EMSC) grant program. There are approximately 30 million child and adolescent visits to the Nation's emergency departments every year. Children under the age of 3 years account for most of these visits. Up to 20 percent of children needing emergency care have underlying medical conditions such as asthma, diabetes, sickle-cell disease, low birthweight, and bronchopulmonary dysplasia. A CDC report issued in February of 2006 reaffirmed that more hospitals must be properly equipped and clinicians must be educated and trained to manage these special health care needs in emergency situations. In addition, emergency systems must be equipped with the resources needed to care for this especially vulnerable population. In order to assist local communities in providing the best emergency care to children, we once again reject the administration's proposed elimination of the EMSC program and strongly urge that the EMSC program be maintained and adequately funded at \$25 million in fiscal year 2007.

Agency for Healthcare Research and Quality.—Quality of care rests on quality research—for new detection methods, new treatments, new technology and new applications of science. As the lead Federal agency on quality of care research, the Agency for Healthcare Research and Quality (AHRQ) provides the scientific basis to improve the quality of care, supports emerging critical issues in health care delivery and addresses the particular needs of priority populations, such as children. Substantial gaps still remain in what we know about health care needs for children and adolescents and how we can best address those needs. Children are often excluded from research that could address these issues. The AAP and endorsing organizations strongly support AHRQ's objective to encourage researchers to include children and adolescents as part of their research populations. We also support increasing AHRQ's efforts to build pediatric health services research capacity through career and faculty development awards and strong practice-based research networks. Additionally, AHRQ is focusing on initiatives in community and rural hospitals to reduce medical errors and to improve patient safety through innovative use of information technology—an initiative that we hope would include children's hospitals as well. Through its research and quality agenda, AHRQ continues to provide policymakers, health care providers, and patients with critical information needed to improve health care; therefore, we join with the Friends of AHRQ to recommend funding of \$440 million for AHRQ in fiscal year 2007.

National Institutes of Health.—Since its inception, the National Institutes of Health (NIH) has been an integral part of the public health continuum. NIH serves as a vital component in improving the Nation's health through research, both on and off the NIH campus, and in the training of researchers, including pediatric investigators. Over the years, NIH has made dramatic strides that directly impact the quality of life for infants, children and adolescents through biomedical and behavioral research. For example, NIH research has led to successfully decreasing infant death rates by over 70 percent, increasing the survival rates from respiratory distress syndrome, and dramatically reducing the transmission of HIV from infected mother to fetus and infant from 25 percent to just 1.5 percent. NIH is engaged in a comprehensive research initiative to address and explain the reasons for a major public health dilemma—the increasing number of obese and overweight children and adults in this country. Today U.S. teenagers are more overweight than young people in many other developed countries. And the Newborn Screening Initiative is

moving forward to improve availability, accessibility, and quality of genetic tests for rare conditions that can be uncovered in newborns. The pediatric community applauds the prior commitment of Congress to maintain adequate funding for the NIH. We remain concerned, however, that the cumulative effect of several years of flat funding will stall or even set back the gains that were made under the years of the NIH's budget doubling. We urge you to sustain the momentum of scientific discovery. We support the recommendation of the Ad Hoc Group for Medical Research for a funding level in fiscal year 2007 of \$29.75 billion. In addition, to ensure ongoing and adequate child and adolescent focused research, such as the National Children's Study (NCS) led by the National Institute for Child Health and Human Development (NICHD), we join with the Friends of NICHD Coalition in requesting \$1.35 billion in fiscal year 2007. Moreover we recommend that the NCS be adequately funded in fiscal year 2007 at \$69 million to begin the implementation phase of this important study. We are greatly disappointed by and reject the administration's proposal to phase out the NCS in 2007. This large longitudinal study, authorized in the Children's Health Act of 2000, will provide critical research and information on major causes of childhood illnesses such as premature birth, asthma, obesity, preventable injury, autism, development delay, mental illness, and learning disorders.

We commend this committee's ongoing efforts to make pediatric research a priority at the highest level of the NIH. We urge continued Federal support of NIH efforts to increase pediatric biomedical and behavioral research, including such proven programs as targeted training and education opportunities and loan repayment. We recommend continued interest in and support for the Pediatric Research Initiative in the Office of the NIH Director and sufficient funding to continue the pediatric training grant and pediatric loan repayment programs both enacted in the Children's Health Act of 2000. This would ensure that we have adequately trained pediatric researchers in multiple disciplines that will not come at the expense of other important programs.

Finally, as clinicians, we know first-hand the considerable benefits for children and society in securing properly studied and dosed medications. The benefits of pediatric drug testing are undisputed. Proper pediatric safety and dosing information reduces medical errors and adverse events, ultimately improving children's health and reducing health care costs. In a very conservative estimate, the FDA projects savings from pediatric testing of over \$228 million a year in reduced hospitalization expenses for just five diseases affecting children. But until now there has been little incentive for drug companies to study off-patent drugs—older drugs that are critically needed therapies for children. The Research Fund for the Study of Drugs, created as part of the Best Pharmaceuticals for Children Act of 2002, provides support for these critical pediatric testing needs, but unfortunately is currently funded at an amount sufficient to test only a fraction of the NIH and FDA-designated "priority" drugs. Therefore, we urge the subcommittee to provide the NIH with sufficient funding to fund the study of generic (off-patent) and selected on-patent drugs for pediatric use.

We believe that these requests represent the best and most reliable estimates of the level of funding needed to sustain the high standard of scientific achievement embodied by the NIH. However, we encourage Congress to explore all possible options to identify additional sources of funding needed to support these increases if we are to reach these funding goals while not weakening any other valuable component of the Public Health Service.

IMMUNIZATION

Immunization remains one of the greatest public health achievements of the last century, saving literally millions of lives. Thanks to the widespread use of vaccines, millions of children have avoided serious and often fatal diseases that previously devastated lives. Before immunization, polio paralyzed 10,000–25,000 children and adults, rubella (German measles) caused birth defects and mental retardation in as many as 20,000 newborns, and measles infected millions of children, killing 400–500 and leaving thousands with serious brain damage each year. Immunizations have reduced by more than 95 percent the cases of vaccine-preventable infectious diseases in this country. And some, like rubella, are virtually eliminated from North America, thanks to successful immunization programs.

Pediatricians, working alongside public health professionals and other partners, have brought the United States its highest immunization coverage levels in history—over 92 percent of children received all vaccinations by school age in 2004–2005. We attribute this, in part, to the Vaccines for Children (VFC) Program, and encourage Congress to maintain its commitment to ensuring the program's viability.

The VFC program combines the efforts of public health and private pediatricians and other health care professionals to accomplish and sustain vaccine coverage goals for both today's and tomorrow's vaccines. It removes vaccine cost as a barrier to immunization for some and reinforces the concept of vaccine delivery in a "medical home." However, we are concerned that the administration's fiscal year 2007 budget once again has proposed to reduce funding for the Section 317 program by transferring funds from that program to expand VFC. This is shortsighted. Additional section 317 funding is necessary to provide the pneumococcal conjugate vaccine (PCV-7), a vaccine that prevents an infection of the brain covering, blood infections and approximately 7 million ear infections a year, to those remaining States that currently do not provide it. Increased Section 317 funding also is needed to purchase the influenza vaccine—now recommended for children between the ages of 6 months and 5 years of age. This age cohort is increasingly susceptible to serious infection and the risk of hospitalization. And an increase in funding is needed to purchase the recently recommended rotavirus vaccine, tetanus-diphtheria-pertussis (Tdap) vaccine for adolescents and the meningococcal conjugate vaccine (MCV). Meningococcal disease is a serious illness, caused by bacteria, with 10–15 percent of cases fatal and another 10–15 percent of cases resulting in permanent hearing loss, mental retardation, or loss of limbs.

The public health infrastructure that now supports our national immunization efforts must not be jeopardized with insufficient funding. One of the conclusions of the 2000 Institute of Medicine report, *Calling the Shots*, was that unstable funding for State immunization programs threatens coverage levels for specific populations and age groups and vaccine safety. This continues to be true today. A strong and sufficient infrastructure is essential. For example, adolescents continue to be adversely affected by vaccine-preventable diseases (e.g., chicken pox, hepatitis B, measles and rubella). Comprehensive adolescent immunization activities at the national, State and local levels are needed to achieve national disease elimination goals. States and communities continue to be financially strapped and therefore, many continue to divert funds and health professionals from routine immunization clinics in order to accommodate anti-bioterrorism initiatives or now pandemic influenza. Moreover, continued investment in the CDC's immunization activities must be made to avoid the reoccurrence of childhood vaccine shortages by providing and adequately funding a national 6 month stockpile for all routine childhood vaccines—stockpiles of sufficient size to insure that significant and unexpected interruptions in manufacturing do not result in shortages for children.

While the ultimate goal of immunizations clearly is eradication of disease, the immediate goal must be prevention of disease in individuals or groups. To this end, we strongly believe that CDC's efforts must be sustained. In fiscal year 2007, we recommend an overall increase in funding above fiscal year 2006 of \$282 million to ensure that the CDC's National Immunization Program has the funding necessary to accommodate vaccine price increases, new disease preventable vaccines coming on the market, global immunization initiatives—including funds for polio eradication and the elimination of measles and rubella—and to continue to implement the recommendations developed by the IOM.

CONCLUSION

We appreciate the opportunity to provide our recommendations for the coming fiscal year. As this subcommittee is once again faced with difficult choices and multiple priorities we know that as in the past years, you will not forget America's children and adolescents.

Other recommendations for fiscal year 2007:

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Agency	Amount
Centers for Disease Control and Prevention (total)	\$8,500,000,000
Polio Eradication	101,254,000
Birth Defects, Disability and Health	135,000,000
Newborn Hearing Screening Technical Assistance	9,000,000
National Violent Death Reporting System	10,000,000
Folic Acid Education Campaign	4,000,000
Health Resources and Services Administration (total)	7,500,000,000
Newborn Hearing Screening Grants to States	10,000,000
Consolidated Community Health Centers	2,038,000,000
Substance Abuse and Mental Health Services Administration (total)	3,531,000,000
Indian Health Service (total)	3,361,000,000

DEPARTMENT OF HEALTH AND HUMAN SERVICES—Continued

Agency	Amount
Food and Drug Administration (total)	1,566,000,000

PREPARED STATEMENT OF THE AMERICAN ASSOCIATION OF COLLEGES OF NURSING

The American Association of Colleges of Nursing (AACN) respectfully submits this statement highlighting funding priorities for nursing education and research programs in fiscal year 2007. AACN represents over 590 senior colleges and universities with baccalaureate and graduate nursing programs that include over 210,000 students and 11,000 faculty members. These institutions are responsible for educating almost half of our Nation's registered nurses (RNs) and all of the nurse faculty and researchers. Nursing represents the largest health profession, with approximately 2.9 million dedicated, trusted professionals delivering primary, acute, and chronic care to millions of Americans.

THE NATIONWIDE NURSING SHORTAGE

Our country continues to be challenged by a shortage of registered nurses that was first noted in 1998. This shortage is showing no signs of diminishing and demographics reveal that, unlike shortages in the past, it will affect health care delivery for the foreseeable future. In 2005, the American College of Healthcare Executives reported that 85 percent of hospitals experienced a nursing shortage. The U.S. Bureau of Labor Statistics (BLS) has projected that our country will require an additional 1.2 million new and replacement registered nurses by 2014. Nursing has been identified by BLS as the fastest growing professional occupation in the country. However, according to the Health Resources and Services Administration (HRSA), the supply of RNs will drop 29 percent below demand by 2020 unless deliberate action is taken to increase the number of nurses graduating each year and entering the workforce. Nursing vacancies exist throughout all health care sectors, including long-term care, home care, and public health. Among the Nation's 5,000 community health centers, the vacancy rate for RNs is 10 percent and 9 percent for nurse practitioners. Even the Department of Veterans Affairs, the largest sole employer of RNs in the United States, has a 10 percent RN vacancy rate.

Research clearly documents that patient safety is compromised without a sufficient number of RNs. In 2002, the Joint Commission on Accreditation of Healthcare Organizations (JCAHO) noted that the nursing shortage contributed to nearly a quarter of all unexpected incidents that adversely affect hospitalized patients. Since RNs comprise the largest component of a hospital workforce, shortages result in emergency room overcrowding and diversions, increased wait time for or cancellation of surgeries, discontinued patient care programs or reduced service hours, and delayed discharges.

The nursing shortage also threatens homeland security and disaster preparedness efforts. The Government Accountability Office reported that local and State health officials cited the nursing shortage as an impediment to their preparedness efforts in 2003.

These alarming facts are coupled with little change in contributing factors, such as the aging of America's population, the aging nurse workforce, high rates of RN retirement, and the increasing demand for high acuity health care services by chronically ill, medically complex patients. To ensure that every patient receives the safest, highest quality health care, Federal support must continue to play an integral role in our Nation's efforts to address the nursing shortage.

CURRENT STRATEGY: NURSING WORKFORCE DEVELOPMENT PROGRAMS

Acknowledging the severity of the Nation's nursing shortage, Congress passed The Nurse Reinvestment Act of 2002. This legislation created new programs and expanded existing Nursing Workforce Development authorities. Administered by HRSA under Title VIII of the Public Health Service Act, these programs focus on the supply and distribution of RNs across the country. Programs support individual students in their nursing studies through loans, scholarships, and loan repayment programs. Title VIII programs stimulate innovation in nursing practice and bolster nursing education throughout the continuum, from entry-level preparation through graduate study. They are the largest source of Federal funding for nursing education assisting students, schools of nursing, and health systems in their efforts to

educate, recruit, and retain RNs. In fiscal year 2005, these programs helped to educate 52,759 student nurses through individual and programmatic support.

Funding for these authorities is insufficient to address the severity of the nursing shortage. Currently, Nursing Workforce Development Programs receive \$149.68 million, down from \$150.67 million in fiscal year 2005. During the nursing shortage in 1974, Congress appropriated \$153 million for nursing education programs. Translated into today's dollars, that appropriation would total \$615 million, more than four times the current level. However, it will take billions of dollars to resolve today's nursing shortage.

AACN respectfully requests \$175 million for Title VIII Nursing Workforce Development in fiscal year 2007, an additional \$25.32 million over fiscal year 2006. New monies would expand nursing education, recruitment, and retention efforts to help resolve the nursing shortage.

Colleges of Nursing Respond

The approximately 1,500 schools of nursing nationwide have been working diligently to expand enrollments. AACN's 2005–2006 annual survey of 567 schools entitled, *Enrollments and Graduations in Baccalaureate and Graduate Programs in Nursing*, reveals that enrollments increased by 9.7 percent in entry-level baccalaureate nursing programs. This makes the fifth consecutive year of enrollment increases that can be attributed to a combination of Federal support through Nursing Workforce Development Programs, private sector marketing efforts, public-private partnerships providing additional resources to expand capacity of nursing programs, and State legislation targeting funds towards nursing scholarships and loan repayment.

While impressive, these increases still cannot meet the demand. In the November 2003 issue of *Health Affairs*, Dr. Peter Buerhaus reported that nursing school enrollments would have to increase by at least 40 percent annually just to replace those nurses who retire. Despite intensive efforts nationwide, AACN found that enrollments increased by a total of 57.2 percent, over the last 5 years in entry-level baccalaureate programs. Moreover, only 8.1 percent of RNs are under the age of 30, according to the 2004 National Sample Survey of Registered Nurses.

Despite increasing enrollments and the escalating demand for RNs, U.S. schools of nursing still are forced to turn away eligible students. At least 41,683 qualified applications were turned away despite the increase in enrollments. This is a 27 percent increase from the over 32,797 denied admission in 2004, according to AACN data. Reasons cited for this denial are insufficient numbers of faculty, clinical sites, classroom space, clinical preceptors, and budget constraints. Over 73 percent of the schools surveyed cited the faculty shortage as the primary barrier to increasing enrollments. Some of these qualified students are placed on waiting lists for 2 years or more, but many good students are lost to the nursing profession.

Bottleneck: The Nurse Faculty Shortage

AACN believes that the most effective strategy to resolve the nursing shortage is addressing the underlying faculty shortage. HRSA reported in 2004 that just 13 percent of the RN workforce holds either a master's or doctoral degree, credentials required to teach. In 2003, there were 10,500 full-time masters and doctorally prepared faculty in baccalaureate and graduate nursing programs. Projections through 2012 show that the faculty pool will shrink by at least 2,000 as compared to 2003, even after accounting for retirements, resignations, and additional entrants. Note that these figures do not take into account the need for faculty in new or expanded programs, but only represent present staffing requirements. If the faculty vacancy rate holds steady, the deficit of nurse faculty is expected to swell to over 2,600 unfilled positions in 2012.

This situation will only worsen with time. The number of productive years for nurse educators will decrease as faculty age continues to climb, averaging 52 years in 2004. As such, significant numbers of faculty are expected to retire in the coming years, but there are not enough candidates in the pipeline to take their places. An average of 410 individuals are awarded doctoral degrees in nursing each year, but almost a quarter (23 percent) take jobs outside of academic nursing. In 2005, AACN found a faculty vacancy rate of 8.5 percent, which translates into an average of approximately 2 faculty vacancies per school of nursing. Of those vacancies, over half (52.6 percent) required a doctoral degree. Higher compensation in clinical and private sector settings lures current and potential nurse educators away from the classroom. For example, the average salary of a nurse practitioner in an emergency department was \$84,835, according to the 2005 National Salary Survey of Nurse Practitioners. However, the average salary for a nurse practitioner in academia was

only \$66,925, 26.8 percent less. Without sufficient nurse faculty, schools of nursing cannot expand enrollments.

Reversing the Trend: Nurse Faculty Loan Program (Sec. 846A).—This trend can be reversed with additional appropriations for the Nurse Faculty Loan Program. Designed to increase the number of nurse faculty, schools of nursing receive grants to create a loan fund. To be eligible for these loans, students must pursue full-time study for a masters or doctoral degree. In exchange for teaching at a school of nursing, loan recipients will have up to 85 percent of their educational loans cancelled over a 4-year period. A student may receive a maximum loan award of \$30,000 per academic year for tuition, books, fees, laboratory expenses, and other reasonable educational costs. In fiscal year 2005, 66 new grants were made to schools of nursing, and 26 grants were continued, totaling 92. These funds will support an estimated 475 future nurse faculty members. In fiscal year 2006, \$4.77 million was appropriated. However, if the current funding was doubled to almost \$10 million, based on fiscal year 2005 projections, colleges of nursing could educate over 900 future faculty. Further, with an average faculty to student ratio of 1:10, those 900 faculty could teach an additional 9,000 nurses each year.

Advanced Education Nursing Program (Sec. 811).—These grants support the majority of schools of nursing preparing graduate-level nurses, some of whom become faculty. Receiving \$57.06 million in fiscal year 2006, this grant program helps schools of nursing, academic health centers, and other nonprofit entities improve the education and practice of nurse practitioners, nurse-midwives, nurse anesthetists, nurse educators, nurse administrators, public health nurses, and clinical nurse specialists. Out of the 88 applications reviewed for this program in fiscal year 2005, 43 new grants were awarded, and 114 were continued. In addition, 422 schools of nursing received traineeship grants, which in turn directly supported 9,000 individual student nurses.

The health system's increasing demand for primary care, increased utilization of case-management—particularly for chronic illnesses, prevention and cost-efficiency, and a shortage of physicians are driving the Nation's need for nurse practitioners, certified nurse-midwives, and other RNs with graduate education and advanced clinical skills, known as advanced practice registered nurses (APRNs). Mounting studies demonstrate the quality and cost effectiveness of APRN care. This is especially important for the 78 million aging Baby Boomers, whose demand for health care services will skyrocket in the near future. The rate of physician office visits by Medicare beneficiaries jumped 20.5 percent from 1992 to 2001, according to the Federal report *Older Americans 2004: Key Indicators of Well-Being*.

Workforce Diversity Program (Sec. 821).—These grants prepare disadvantaged students to become nurses. As the United States becomes ever more heterogeneous, it is imperative that the composition of our nursing workforce mirrors this shift. According to the U.S. Census Bureau, roughly 30 percent of the population was reported as a racial or ethnic minority in 2000, but by 2050 that percentage will jump to over 52 percent. This program awards grants to schools of nursing and other entities seeking to increase access to nursing education for disadvantaged students, including those racial and ethnic minorities under-represented among RNs. Scholarships or stipends, pre-entry preparation, and retention activities are provided to enable students to complete their nursing education. In fiscal year 2005, 171 applications were reviewed, from those 11 new grants were awarded and 48 previously awarded grants were continued. These program funds assisted at least 6,344 students. Workforce Diversity received \$16.11 million in fiscal year 2006.

At Risk: Nursing Student Loan Program (Sec. 835).—This revolving loan fund was established in 1964 to specifically target nursing workforce shortages. The Nursing Student Loan (NSL) program provides participating undergraduate or graduate nursing students with a maximum of \$13,000 in loans at 5 percent interest. Schools of nursing participating in the NSL select recipients and determine the level of assistance provided, with a preference for those with financial need. New loans are made as existing loans are repaid. This program has not received additional appropriations since 1983. However, in fiscal year 2005, the NSL provided financial assistance to 17,240 nursing students. In fiscal year 2005, Sec. 222 of the Consolidated Appropriations Act of 2005 (Public Law 108-447) included language which stated: "The unobligated balance of the Nursing Student Loan program authorized by section 835 of the Public Health Services Act is rescinded." As a result, the NSL gave back \$6.1 million to the U.S. Treasury in July 2005. In previous years, those funds were redistributed among participating institutions, increasing the amount of possible loans. A similar provision, in the fiscal year 2006 appropriations law will force the NSL to return even more funds to the Treasury that instead could have assisted nursing students in completing their education.

NATIONAL INSTITUTE OF NURSING RESEARCH

One of the 27 Institutes and Centers at the National Institutes of Health (NIH), the efforts of the National Institute of Nursing Research (NINR) improve patient care and foster advances in nursing and other health professions' practice. These practices must be constantly updated and validated based on rigorous, peer-reviewed research. The outcomes-based findings derived from NINR research are important to the future of the health care system and its ability to deliver safe, cost-effective, and high quality care. Through grants, research training, and interdisciplinary collaborations, NINR addresses care management of patients during illness and recovery, reduction of risks for disease and disability, promotion of healthy lifestyles, enhancement of quality of life in those with chronic illness, and care for individuals at the end of life. To advance this research, AACN requests a funding level of \$150 million in fiscal year 2007, an additional \$12.66 million over the \$137.34 million NINR received in fiscal year 2006.

NINR Addresses the Need for Translational and Clinical Research

NINR emphasizes translational research, the means by which basic findings relating to behavior, molecules, and genes are tested in the clinical setting and translated into innovative medical practices and improvements in public health. Under the framework of the Roadmap Initiative, NINR and nurse researchers are addressing the development of new interdisciplinary research teams and enhanced clinical research to move the overall NIH portfolio of social, behavioral, and medical research forward in this coordinated and cohesive effort.

NINR Addresses the Shortage of Nurse Researchers and Faculty

NINR allocates 8 percent of its budget, a high proportion when compared to other NIH institutes, to research training to help develop the pool of nurse researchers. In fiscal year 2005, NINR training dollars supported 80 individual researchers and provided 155 institutional awards, which in turn supported a number of nurse researchers at each site. Since nurse researchers often serve as faculty members for colleges of nursing, they are actively educating our next generation of RNs.

AGENCY FOR HEALTHCARE RESEARCH AND QUALITY

While NIH supports biomedical research that improves health care by focusing on the cause, cure, and prevention of disease, the Agency for Healthcare Research and Quality (AHRQ) supports health systems research, collecting evidence-based information on health care outcomes. AHRQ research findings are used by patients, clinicians, health system decision makers, and public policymakers to guide health care delivery systems and patient care. The research supported by AHRQ not only improves the quality of health care services, but also helps people make more informed decisions about their health care. AACN joins the Friends of AHRQ in recommending a funding level of \$440 million for fiscal year 2007, an additional \$121.3 million over the fiscal year 2006 level of \$318.7 million.

Health Systems Research at AHRQ Addresses Nurses' Role in Patient Safety

AHRQ research has demonstrated that inefficient work processes, overwhelming workloads, extended work hours, and poor workplace designs create obstacles to providing patients safe, cost-effective, and high quality health care. The New England Journal of Medicine published a study of over 6 million patients in May 2002, that found hospitalized patients had better outcomes when the majority of their nursing care was provided by RNs. Decreased hours of RN care, stemming from the nursing shortage, correlated with longer hospital stays, increased incidence of urinary tract infections and gastrointestinal bleeding, as well as higher rates of pneumonia, shock, and cardiac arrest. When patients received additional hours of RN care, the death rates dropped for pneumonia, shock or cardiac arrest, upper gastrointestinal bleeding, sepsis, and deep venous thrombosis.

CONCLUSION

AACN acknowledges the fiscal challenges that the subcommittee and the entire Congress must work within. However, the health needs of our Nation must be addressed by a dedicated, long-term vision for educating the new nursing workforce. Today, nurses must evaluate research that promotes evidence-based practice and utilize technical innovations in providing safe, high quality patient care. Research shows that patient care suffers and mortality rates increase in facilities without sufficient numbers of RNs. Without highly educated nurses, who will care for us when we must enter into our increasingly complex health care system?

PREPARED STATEMENT OF THE AMERICAN ASSOCIATION OF COLLEGES OF
OSTEOPATHIC MEDICINE

On behalf of the American Association of Colleges of Osteopathic Medicine (AACOM) which represents the administrations, faculties and students of all twenty colleges of osteopathic medicine in the United States, I am pleased to present our views on the fiscal year 2007 appropriations for health professions education programs under Title VII of the Public Health Service Act.

First, we must express our profound concern at the devastating cuts proposed by the administration for Title VII programs in its fiscal year 2007 budget. The Bureau of Health Professions received \$342 million in cuts in the President's fiscal year 2007 proposal which is fully 46 percent of its entire budget. While we support the \$181 million increase in the President's budget for Community Health Centers, the large funding decreases to the Title VII programs raises the question of whether there will be a sufficient number of health care providers to staff these clinics. The fiscal year 2007 cuts are in addition to the 12 programs that were eliminated in the fiscal year 2006 appropriations bills, as well as other programs that received significant decreases in both years. Congress must not allow these draconian slashes to cripple the programs that assist health professions schools in training the workforce needed to care for our citizens in the 21st century.

A study that recently appeared in the *Journal of the American Medical Association* recommends increased Titles VII and VIII support to alleviate provider shortages at Community Health Centers [Shortages of Medical Personnel at Community Health Centers: Implications for Planned Expansion, Roger A. Rosenblatt, C. Holly A. Andrilla, Thomas Curtin; L. Gary Hart, *Journal of the American Medical Association*, JAMA 2006;295:1042-1049]. The study found that Titles VII and VIII programs help ameliorate these shortages and maldistribution by training providers who are more likely to practice in rural and underserved communities.

Health professions education programs under Title VII and nursing education programs under Title VIII are essential components of America's health care safety net. An adequate diverse, well-distributed and culturally competent health workforce is indispensable to our national readiness efforts. Colleges of osteopathic medicine have a long tradition of training primary care physicians who practice in rural and urban underserved areas.

The health professions education programs under Title VII and the nursing education programs under Title VIII of the Public Health Service Act have been valuable in our efforts to continue to ensure this commitment. In Public Law 105-392, the Health Professions Education Partnership Act of 1998, forty-four different Federal health professions training programs were consolidated into seven clusters. These clusters provide support for training of primary care and dental providers; the establishment and operation of interdisciplinary community-based training activities; health professions workforce analysis; public health workforce development; nursing education; and student financial assistance. These programs are designed to meet the health care delivery needs of over 2,800 Health Professions Shortage Areas in the country. Many rural and disadvantaged populations depend on the health professionals trained by these programs at their only source of health care. For example, without the practicing family physicians who are currently in place, an additional 1,332 of the United States' 1,082 urban and rural counties would qualify for designation as primary care Health Professions Shortage Areas.

Title VII programs have had a significant impact in reducing the Nation's Health Professions Shortage Areas. Indeed, a 1999 study estimated that if funding for Title VII programs were doubled the effect would be to eliminate the Nation's Health Professions Shortage Areas in as little as 6 years. [Politzer, RM, Hardwick, KC, Cultice, JM, Bazell, C. "Eliminating Primary Care Health Professions Shortage Areas: The Impact of Title VII Generalist Physician Education," *The Journal of Rural Health*, 1999; 15(1): 11-19].

A study by the Robert Graham Center showed that receipt of Title VII family medicine grants by medical schools produced more family physicians and more primary care doctors serving rural areas and health professions shortage areas. Over 69 percent of Title VII funded internal medicine graduates practice primary care after graduation. This rate is nearly twice that of programs not receiving Title VII funding.

Among the programs within these clusters that have been especially important to enhancing osteopathic medical schools' ability to train the highest quality physicians are: General Internal Medicine Residencies; General Pediatric Residencies; Family Medicine Training; Preventive Medicine Residencies; Area Health Education Centers (AHECs); Health Education and Training Centers (HETCs); Health Careers Opportunities Programs (HCOP); and Centers of Excellence (COE) programs.

In addition, three Title VII programs offer interdisciplinary training for all health professions. The Geriatric Education Centers (GEC) program provides grants to support collaborative arrangements involving several health professions schools and health facilities that provide training in the diagnosis, treatment and prevention of disease and other health concerns of the elderly. The Geriatric Training program for physicians, dentists, and mental health professionals (GT) provides for these professionals who plan to become faculty members. The Geriatric Academic Career Awards (GACA) support the career development of geriatricians in junior faculty positions who are committed to an academic career of teaching clinical geriatrics in medical schools.

Accordingly, Mr. Chairman and Members of the subcommittee, AACOM recommends that the fiscal year 2007 funding levels for Titles VII Health Professions Education and VIII Nursing Education be \$299,552,000. You will note that this is the same level as the Congress approved for fiscal year 2005.

AACOM also strongly urges continuation of funding for the Council on Graduate Medical Education (COGME). Since its inception, COGME's diverse membership has given the health policy community an opportunity to discuss national workforce issues. The fifteen formal reports and multiple ancillary materials provided by COGME have offered important findings and observations in the rapidly changing health care environment and have argued for a system of graduate medical education that develops a physician workforce to meet the healthcare needs of the American people.

Some of the more significant recommendations include:

- Community-based education with an emphasis on primary care;
- Continued progress toward a more representative participation of minorities in medicine;
- The development and maintenance of a workforce planning infrastructure to improve the understanding of supply, need and demand forces;
- The development of Federal-State partnerships to further workforce planning; and
- Encouragement and support for medical education and health care delivery programs that increase the flow of physicians to rural areas, with an emphasis on the smaller, more remote communities.

In summary, Mr. Chairman and Members of the subcommittee, health profession education programs under Title VII are an essential part of the healthcare safety net for all Americans. We respectfully urge you to restore funding for these programs at the fiscal year 2005 level. Please contact me or Michael J. Dyer, AACOM's Vice President for Government Relations at (301) 968-4152 if you have any questions.

PREPARED STATEMENT OF THE AMERICAN NURSES ASSOCIATION

The American Nurses Association (ANA) appreciates this opportunity to comment on fiscal year 2007 appropriations for nursing education, workforce development, and research programs. Founded in 1896, ANA is the only full-service national association representing registered nurses (RNs). Through our 54 constituent member associations, ANA represents RNs across the Nation in all practice settings.

The ANA gratefully acknowledges this subcommittee's history of support for nursing education and research. We appreciate your continued recognition of the important role nurses play in the delivery of quality health care services. This testimony will give you an update on the status of the nursing shortage, its impact on the Nation, and the outlook for the future.

THE NURSING SHORTAGE TODAY

The nursing shortage is far from solved. Here are a few quick facts:

- According to American Hospital Association's 2005 Workforce Survey, 109,000 nurses are needed immediately to fill vacancies at our Nation's hospitals. In addition, 40 percent of the hospitals surveyed reported that RN recruitment was more difficult in 2004 than in 2003.
- The Bureau of Labor Statistics reported in February of this year that registered nursing will have remarkable job growth in the time period spanning 2004-2014. During this time decade, the health care system will require more than 1.2 million new nurses.
- The report issued by the Division of Nursing at the Health Resources and Services Administration in 2002 projects that, absent aggressive intervention, the supply of nurses in America will fall 29 percent below requirements by the year 2020.

This growing nursing shortage is having a detrimental impact on the entire health care system. Numerous studies have shown that nursing shortages contribute to medical errors, poor patient outcomes, and increased mortality rates. A study published in the January/February 2006 issue of *Health Affairs* showed that hospitals could avoid 6,700 deaths per year by increasing the amount of RN care provided to their patients. This study, "Nurse Staffing in Hospitals: Is There a Business Case for Quality?" by Jack Needleman, Peter Buerhaus, Maureen Stewart, Katya Zelevinsky and Soeren Mattke, also revealed that hospitals could avoid 4 million hours worth of inpatient care by avoiding the complications associated with a shortage of RN care.

This study built upon research published in the *New England Journal of Medicine* in May 2002. The 2002 research was based on a review of more than 6 million patients. It found that increased hours of RN care were associated with fewer "failure-to-rescue" deaths in hospitalized patients resulting from pneumonia, shock or cardiac arrest, upper gastrointestinal bleeding, sepsis and deep venous thrombosis.

Research published in the October 23, 2002 *Journal of the American Medical Association* also demonstrated that more nurses at the bedside could save thousands of patient lives each year. In reviewing more than 232,000 surgical patients at 168 hospitals, researchers from the University of Pennsylvania concluded that a patient's overall risk of death rose roughly 7 percent for each additional patient above four added to a nurse's workload.

A Joint Commission on the Accreditation of Healthcare Organizations (JCAHO) study published in 2002 shows that the shortage of nurses contributes to nearly a quarter of all unexpected incidents that kill or injure hospitalized patients.

THE IMPACT ON PREPAREDNESS AND MILITARY HEALTH CARE

This growing nursing shortage has effects well beyond traditional domestic health care. RNs are integral to everything from pandemic flu management, to terrorism preparedness, to veterans' health delivery, to disaster response. In the event of a terrorist attack or pandemic flu outbreak, nurses will be needed to evaluate patients, administer vaccines and medications, perform disease surveillance, and to train non-licensed staff. The GAO has repeatedly reported that the nursing shortage is complicating efforts at the State and local level to implement pandemic flu and bioterrorism preparedness efforts (see: GAO: 03-654T, 03-769T, 04-458T, 05-760T, 05-863T). For instance, in May 2003, the GAO testified, "Five of the [seven] States we visited reported shortages of hospital medical staff, including nurses and physicians, necessary to increase response capacity in an emergency." (GAO-03-769T).

The nursing shortage is also stressing military health care delivery. The Army, Navy, and Air Force are offering new lucrative RN recruitment packages that include large sign-on bonuses, generous scholarships, and loan forgiveness packages. Yet, neither the Army nor the Air Force has met their active service nurse recruitment goals since the 1990s. On May 10, 2005, Army leaders warned the Senate Appropriations Committee that they were experiencing a 30 percent shortage of certified registered nurse anesthetists. In 2004, the Navy Nurse Corps recruitment fell 32 percent below target. Because the military holds the vast majority of its health care assets in the reserves, the reserve activation has been particularly hard on nursing. This ongoing nurse shortage is creating real concerns about the ability to deliver needed health care to today's military.

NURSING WORKFORCE DEVELOPMENT PROGRAMS

Federal support for the Nursing Workforce Development Programs contained in Title VIII of the Public Health Service Act is unduplicated and essential. The 107th Congress recognized the detrimental impact of the developing nursing shortage and passed the Nurse Reinvestment Act (Public Law 107-205). This law improved the programs of Title VIII to meet the unique characteristics of today's shortage. This achievement holds the promise of recruiting new nurses into the profession, promoting career advancement within nursing and improving patient care delivery. This promise will not be met, however, without a significant investment.

In fiscal year 2005, this subcommittee allocated \$151 million in funding for Title VIII which supported 52,795 individual grants. In fiscal year 2006, you allocated \$150 million for Title VIII. While ANA applauds your ongoing recognition for these nursing workforce development programs, we also recognize that these funding levels fail to meet the challenges of the growing nursing shortage. For instance, in fiscal year 2005, 4,465 RNs applied for the Nurse Education Loan Repayment Program (described fully below). Due to lack of funding, a mere 803 (18 percent) were approved.

ANA strongly urges you to increase funding for Title VIII programs by at least \$25 million to a total of \$175 million in fiscal year 2007. This funding amount has been supported by a bipartisan group of 54 Senators in a Dear Colleague sent to this subcommittee. The nursing shortage and its impact on the health care of the Nation demand this continued investment.

In 1974, this subcommittee invested \$153.6 million Title VIII. Inflated to today's dollars, this appropriation would equal \$622.5 million, more than four times the current appropriation. Certainly, today's shortage is more dire and systemic than that of the 1970's; it deserves an equivalent response.

Title VIII includes the following program areas:

Nursing Education Loan Repayment Program & Scholarships.—This line item is comprised of the Nurse Education Loan Repayment Program (NELRP) and the Nursing Scholarship Program (NSP), the Secretary of HHS has the authority to allocate funds between the two areas. In fiscal year 2006, the Nurse Education Loan Repayment Program and Scholarships received \$31 million.

The NELRP repays up to 85 percent of a RN's student loans in return for full-time practice in a facility with a critical nursing shortage. The NELRP nurse is required to work for at least 2 years in a designated facility during which time the NELRP repays 60 percent of the RN's student loan balance. If the nurse applies and is accepted for a third year, an additional 25 percent of the loan is repaid.

The NELRP boasts a proven track record of delivering nurses to facilities hardest hit by the nursing shortage. HRSA has given NELRP funding preference to RNs who work in disproportionate share hospitals, skilled nursing facilities, federally-designated health centers, and departments of public health. However, lack of funding has hindered the full implementation of this program. As stated above, in fiscal year 2005, 82 percent of the nurses willing to immediately begin practicing in facilities hardest hit by the shortage were turned away from this program due to lack of funding.

The NSP offers funds to nursing students who, upon graduation, agree to work for at least 2 years in a health care facility with a critical shortage of nurses. Preference is given to students with the greatest financial need. Like the loan repayment program, the NSP has been stunted by a lack of funding. In fiscal year 2005, HRSA received 6,563 applications for the nursing scholarship. Due to lack of funding, a mere 217 scholarships were awarded. Therefore, 97 percent of nursing students willing to work in facilities with a critical shortage were denied access to this program.

Nurse Faculty Loan Program.—This program establishes a loan repayment fund within schools of nursing to increase the number of qualified nurse faculty. Nurses may use these funds to pursue a master's or doctoral degree. They must agree to teach at a school of nursing in exchange for cancellation of up to 85 percent of their educational loans, plus interest, over a 4-year period. Loans can cover the costs of tuition, fees, books, laboratory expenses, and other reasonable education expenses. In fiscal year 2006, this program received \$4.8 million.

This program is vital given the critical shortage of nursing faculty. America's schools of nursing cannot increase their capacity without an influx of new teaching staff. Last year, schools of nursing were forced to turn away tens of thousands of qualified applicants due largely to the lack of faculty. In fiscal year 2005, HRSA awarded 66 nurse faculty loan repayments.

Nurse Education, Practice, and Retention Grants.—This section is comprised of many programs designed to support entry-level nursing education and to enhance nursing practice. In fiscal year 2005, this line item supported 10,490 nursing students. All together, the Nurse Education, Practice, and Retention Grants received \$37.3 million in fiscal year 2006.

The education grants are designed to expand enrollments in baccalaureate nursing programs; develop internship and residency programs to enhance mentoring and specialty training, and; provide new technologies in education including distance learning.

Practice grants currently support 18 Nurse Managed Clinics that provide primary health care in medically underserved communities; provide nursing students the skills necessary to practice in existing and emerging health systems, and; develop cultural competencies.

Retention grant areas include career ladders and improved patient care delivery systems. The career ladders program supports education programs that assist individuals in obtaining the educational foundation required to enter the profession, and to promote career advancement within nursing. Enhancing patient care delivery system grants are designed to improve the nursing work environment. These grants help facilities to enhance collaboration and communication among nurses and other health care professionals, and to promote nurse involvement in the organizational

and clinical decision-making processes of a health care facility. These best practices for nurse administration have been identified by the American Nurse Credentialing Center's Magnet Recognition Program®. These practices have been shown to double nurse retention rates, increase nurse satisfaction, and improve patient care.

Nursing Workforce Diversity.—This program provides funds to enhance diversity in nursing education and practice. It supports projects to increase nursing education opportunities for individuals from disadvantaged backgrounds—including racial and ethnic minorities, as well as individuals who are economically disadvantaged. In fiscal year 2006, these programs received \$16 million.

Racial and ethnic minorities currently comprise more than 25 percent of the Nation's population and will comprise nearly 40 percent by the year 2020. However, only 10.6 percent of the RNs in the United States are self-identified as one or more of the racial and ethnic minority groups. Increasing cultural and ethnic diversity in nursing helps to address the prevention, treatment, and rehabilitation needs of an increasingly diverse population. For fiscal year 2005, HRSA received 191 submissions for nursing workforce diversity grants. HRSA was able to fund 97 (50 percent of applications).

Advanced Nurse Education.—Advanced practice registered nurses (APRNs) are nurses who have attained advanced expertise in the clinical management of health conditions. Typically, an APRN holds a master's degree with advanced didactic and clinical preparation beyond that of the RN. Most have practice experience as RNs prior to entering graduate school. Practice areas include, but are not limited to: anesthesiology, family medicine, gerontology, pediatrics, psychiatry, midwifery, neonatology, and women's & adult health. Title VIII grants have supported the development of virtually all initial State and regional outreach models using distance learning methodologies to provide advanced study opportunities for nurses in rural and remote areas. In fiscal year 2006, these programs received \$57 million.

These grants also provide traineeships for masters and doctoral students. Title VIII funds more than 60 percent of U.S. nurse practitioner education programs and assists 83 percent of nurse midwifery programs. Over 45 percent of the nurse anesthesia graduates supported by this program go on to practice in medically underserved communities. Many provide care to minority or disadvantaged patients. In fiscal year 2005, HRSA funded 81 advanced education nursing grants (89 percent of applications), 347 advanced education nursing traineeships (every application), and 75 nurse anesthetist traineeships (every application).

Comprehensive Geriatric Education Grants.—This authority awards grants to train and educate nurses in providing health care to the elderly. Funds are used to train individuals who provide direct care for the elderly, to develop and disseminate geriatric nursing curriculum, to train faculty members in geriatrics, and to provide continuing education to nurses who provide geriatric care. In fiscal year 2006, these grants received \$3.4 million.

The growing number of elderly Americans and the impending health care needs of the baby boom generation make this program critically important. In fiscal year 2005, HRSA received 43 applications for comprehensive geriatric education grants. HRSA continued 17 previously awarded grants and awarded 11 new ones (65 percent of applications).

NATIONAL INSTITUTE OF NURSING RESEARCH (NINR)

ANA also urges the subcommittee to increase funding for the NINR, one of the institutes at the National Institutes of Health (NIH). This research is integral to improving the effectiveness of nursing care. Advances in nursing care arising from behavioral and biomedical research have shown excellent progress in reducing health care costs. Research programs supported by NINR address a number of critical public health and patient care questions. The research is driven by real and immediate problems currently facing patients and their families.

Recent studies have illuminated the impact of placing a patient in long term care on the patient's family caregiver, the impact of maternal obesity prior to pregnancy on childhood weight problems, the difference in heart attack symptoms in women versus men, the most effective means to prevent infectious diseases in inner city households, and the incidence and risk factors for uterine rupture in pregnancies following cesarean section. NINR is leading the NIH research on end-of-life and palliative care. NINR is also the lowest funded institute at NIH. In fiscal year 2006, NINR received \$137.3 million. ANA recommends \$150 million in fiscal year 2007 NINR funding.

CONCLUSION

While ANA appreciates the continued support of this subcommittee, we are concerned that Title VIII funding levels have not been sufficient to address the growing nursing shortage. The nursing shortage will continue to worsen if significant investments are not made. Recent efforts have shown that aggressive and innovative recruitment efforts can help avert the impending nursing shortage—if they are adequately funded.

ANA asks you to meet today's shortage with a relatively modest investment of \$175 million in Title VIII programs. Additionally, an investment of \$150 million in the NINR will help assure that these nurses are equipped with the information needed to provide the best care possible.

PREPARED STATEMENT OF AMERICANS FOR NURSING SHORTAGE RELIEF

The undersigned organizations of the ANSR (Americans for Nursing Shortage Relief) Alliance greatly appreciate the opportunity to submit written testimony regarding fiscal year 2007 appropriations for Title VIII—Nursing Workforce Development Programs. The ANSR Alliance is comprised of fifty-one national nursing organizations that united in 2001 to identify and promote creative strategies for addressing the nursing and nurse faculty shortages, including passage of the Nurse Reinvestment Act of 2002—an important first step in increasing the number of qualified nurses in America.

ANSR stands ready to work with policymakers to advance programs and policies that will sustain and strengthen our Nation's nursing workforce. To ensure that our Nation has a sufficient and adequately prepared nursing workforce to provide quality care to every American well into the 21st century, ANSR advocates for the following:

- At least \$175 million in funding for Nursing Workforce Development Programs under Title VIII of the Public Health Service Act at the Health Resources and Services Administration (HRSA) in fiscal year 2007.

THE NURSING SHORTAGE

Nurses play a critical role in this Nation's health care system. With an estimated 2.9 million licensed registered and advanced practice registered nurses (RNs and APRNs), nurses represent the largest occupational group of health care workers and provide patient care in virtually all locations in which health care is delivered. This coupled by their scope of practice areas make the nursing shortage an even more interesting challenge. Some facts to consider:

- The nursing workforce is aging. In 1980, 26 percent of RNs were under the age of 30. Today, approximately 8 percent of RNs are under the age of 30 with the average nurse 46.8 years of age;
- Approximately half of the RN workforce is expected to reach retirement age within the next 10 to 15 years. The average age of new RN graduates is almost 30 years.
- The Bureau of Labor Statistics report (December, 2005) projected that registered nursing would create the second largest number of new jobs among all occupations within 9 years. In addition, employment of registered nurses is expected to grow much faster than average for all occupations through 2014. It is anticipated that approximately 703,000 additional jobs, for a total of 3,096,000, will be available for RNs by this date.
- The national nursing shortage also is affecting our Nation's 7.6 million veterans who receive care through the 1,300 Veterans Administration (VA) health care facilities;
- Nearly 1,800 faculty members leave their positions every year due to factors of retirement or higher wages earned as a staff nurse. Fewer than 400 faculty candidates receive their doctoral degrees each year; and,
- The number of full-time nurse faculty required to "fill the nursing gap" is approximately 40,000. Currently, the National League for Nursing estimates that there fewer than 10,000 full-time faculty members in the system.

THE NURSING SUPPLY IMPACTS AMERICA'S EMERGENCY PREPAREDNESS

Nurses play a critical role as front-line, first-responders. When word of the devastation caused by Hurricanes Katrina and Rita spread, nurses across the country immediately volunteered in American Red Cross shelters, medical clinics, and hospitals throughout that area. Nurse midwives delivered babies in airplane hangars, and nurses trained in geriatric care assisted in caring for those evacuated from the

comforts of their homes, assisted living facilities or nursing homes. Nurse practitioners diligently staffed temporary and permanent health care clinics to provide needed primary care to hurricane victims. In addition, many nurses realized their role in the comfort and support they offered as they listened to survivors recount their stories of pain and tragedy.

These stories seem particularly relevant in demonstrating the contributions that nurses provide during tragedies, and should illustrate the need to ensure an adequate supply of all types of nurses in all parts of the country. Unless steps are taken now, the Nation's ability to respond to disasters will be further hindered by the growing nursing shortage. An investment in the nursing workforce is a step in the right direction to bolster our public health infrastructure and increase our Nation's health care readiness and emergency response capabilities.

THE DESPERATE NEED FOR NURSE FACULTY

After years of declining interest, the nursing profession is seeing the opposite occur. Many Americans have come to find nursing an attractive career because of job security, salary levels, and the opportunity to help others. However, the common theme among prospective nursing students is that due to a lack of a sufficient number of faculty they can face waiting periods of up to 3 years before matriculating. When all nursing programs are considered, the number of qualified applications turned away during the 2004–2005 academic year was estimated to be more than 147,000 by the National League for Nursing. Without sufficient support for current nurse faculty and adequate incentives to encourage more nurses to become faculty, nursing schools will fail to have the teaching infrastructure necessary to educate and train the next generation of nurses that the Nation so desperately needs.

THE FUNDING REALITY

Enacted in 2002, the Nurse Reinvestment Act included new and expanded initiatives, including loan forgiveness, scholarships, career ladder opportunities, and public service announcements to advance nursing as a career. Despite the enactment of this critical measure, HRSA fails to have the resources necessary to meet the current and growing demands for our Nation's nursing workforce. For example, in fiscal year 2003, HRSA received 8,321 applications for the Nurse Education Loan Repayment Program but only had the funds to award 7 percent (602) of all applications. Also in fiscal year 2003, HRSA received 4,512 applications for the Nursing Scholarship Program but only had funding to support a mere 2 percent (94) of all applications.

The ANSR Alliance strongly urges this subcommittee to provide a minimum of \$17,505 million in fiscal year 2007 to fund Title VIII—Nursing Workforce Development Programs. This level of investment will help leverage the HRSA resources to fund a higher rate of Nurse Education Loan Repayment and Nursing Scholarship applications, as well as implement other essential endeavors to sustain and boost our Nation's nursing workforce.

SUMMARY

Programmatic area	Final fiscal year 2006	President's budget fiscal year 2007	ANSR's request
Title VIII: Nurse Workforce Development Programs at HRSA ..	\$149,000,000	\$150,000,000	\$175,000,000

ANSR ALLIANCE ORGANIZATIONS

Academy of Medical-Surgical Nurses; American Academy of Ambulatory Care Nursing; American Academy of Nurse Practitioners; American Association of Critical-Care Nurses; American Association of Nurse Anesthetists; American Association of Occupational Health Nurses, Inc.; American College of Nurse-Midwives; American Organization of Nurse Executives; American Society for Pain Management Nursing; American Society of PeriAnesthesia Nurses; American Society of Plastic Surgical Nurses; Association of periOperative Registered Nurses; Association of Rehabilitation Nurses; Association of State and Territorial Directors of Nursing; Association of Women's Health, Obstetric and Neonatal Nurses; Dermatology Nurses' Association; Developmental Disabilities Nurses Association; Emergency Nurses Association; Infusion Nurses Society; National Association of Clinical Nurse Specialists; National Association of Nurse Massage Therapists; National Association of Orthopaedic Nurses; National Association of Pediatric Nurse Practitioners; National Association of School Nurses; National Black Nurses Association; National Conference of Gerontological Nurse Practitioners; National Council of State Boards of Nursing; National

League for Nursing; National Student Nurses' Association; National Nursing Centers Consortium; National Organization of Nurse Practitioner Faculties; Nurses Organization of Veterans Affairs; Oncology Nursing Society; Society for Urologic Nurses and Associates; Society of Trauma Nurses; and Wound Ostomy Continence Nurses Society.

PREPARED STATEMENT OF THE AMERICAN PUBLIC POWER ASSOCIATION

The American Public Power Association (APPA) is the national service organization representing the interests of over 2,000 municipal and other State and locally owned utilities throughout the United States (all but Hawaii). Collectively, public power utilities deliver electricity to one of every seven electricity consumers (approximately 43 million people), serving some of the Nation's largest cities. However, the vast majority of APPA's members serve communities with populations of 10,000 people or less.

We appreciate the opportunity to submit this statement supporting funding for the Low-Income Home Energy Production Assistance Program (LIHEAP).

APPA has consistently supported an increase in the authorization level for LIHEAP and supports the full authorization level of \$5.1 billion for fiscal year 2007 as enacted in the Energy Policy Act of 2005.

APPA is proud of the commitment that its members have made to their low-income customers. Many public power systems have low-income energy assistance programs based on community resources and needs. Our members realize the importance of having in place a well-designed low-income customer assistance program combined with energy efficiency and weatherization programs in order to help consumers minimize their energy bills and lower their requirements for assistance. While highly successful, these local initiatives must be coupled with a strong LIHEAP program to meet the growing needs of low-income customers. In the last several years, volatile home-heating oil and natural gas prices, severe winters, high utility bills as a result of dysfunctional wholesale electricity markets and the effects of the economic downturn have all contributed to an increased reliance on LIHEAP funds.

Also when considering LIHEAP appropriations this year, we encourage the subcommittee to provide advanced funding for the program so that shortfalls do not occur in the winter months during the transition from one fiscal year to another. LIHEAP is one of the outstanding examples of a State-operated program with minimal requirements imposed by the Federal Government. Advanced funding for LIHEAP is critical to enabling States to optimally administer the program.

Thank you again for this opportunity to relay our support for increased LIHEAP funding for fiscal year 2007. We look forward to a favorable outcome.

PREPARED STATEMENT OF THE ASSOCIATION OF MATERNAL AND CHILD HEALTH PROGRAMS

The Association of Maternal and Child Health Programs (AMCHP) is a national, non-profit organization representing leaders of State public health programs for maternal and child health, including children with special health care needs, in all 50 States, the District of Columbia, and eight additional jurisdictions. Our members administer Title V Maternal and Child Health Services Block Grant funds to improve the health of mothers and children. We strongly urge you to restore funding for the MCH Block Grant to the fiscal year 2005 level of \$724 million.

First authorized in 1935, the MCH Block Grant provides for a wide range of health services and fosters prevention of disease and disabling conditions for over 32 million women and children across the country. Funds from the MCH Block Grant enable States to provide women with prenatal and postnatal care, screen newborns for genetic and hereditary conditions; support childhood immunizations; reduce infant mortality and developmentally handicapping conditions; and prevent childhood accidents and injuries. Block grant funding enables State agencies to tailor vital programs for women, children and families to the needs of each community, while ensuring that the programs meet national goals.

Since the program's inception, it has evolved into a powerful Federal-State partnership. Each year, \$600 million Federal are matched by over \$5 billion in State funds for maternal and child health programs. These funds have enabled States to reach more than 80 percent of infants, 50 percent of pregnant women and 20 percent of children in the United States. Since 2000, the number of women and children served has increased by almost 5 million, an increase of 18 percent.

In fiscal year 2006, \$693 million was appropriated for the MCH Block Grant, \$31 million below the fiscal year 2005 comparable appropriation. This loss of funds, as the number of women and children needing services continues to increase, will impact the ability of States to address areas of critical need. While President Bush recommended level funding for the MCH program in his budget request, he also recommended that Federal support for the Traumatic Brain Injury program, Universal Newborn Hearing Screening, Emergency Medical Services for Children and the Sickle Cell Anemia Demonstration Project be eliminated. If this recommendation were enacted without a commensurate increase in the block grant, States would be forced to shift MCH Block Grant funds away from other pressing health priorities to meet those addressed by these programs. We recommend that funding for these four valuable programs be restored, in addition to the restoration of the MCH Block Grant funding to the fiscal year 2005 level.

The flexibility of the block grant has allowed States to respond to emerging health issues that affect women and children, such as the rising infant mortality rates, particularly among minority populations, and the availability of newborn screening for a newly expanded range of diseases and disorders. Reducing the infant mortality rate is a goal of the MCH Block Grant program, which will be difficult to achieve if funding continues to erode. State maternal and child health programs coordinate newborn screening and follow-up services, activities to ensure that every infant born in this country receives screening tests that detect disorders that could result in death or permanent disabilities. The money spent on these screening programs saves lives, and preserves State and Federal Government dollars that would otherwise be spent on expensive, lifelong treatment and rehabilitative services for infants whose genetic disorders go undetected. Level funding of the MCH Block Grant will not allow States to meet the increasing demand for newborn screening services.

Last year's budget cut has already had a real impact on State programs, threatening the quality and quantity of care these programs provide. The MCH Block Grant can not continue to do more with less. Consider the following descriptions of the impact these cuts are having at the State level:

- In Iowa, the impact of the MCH Block Grant cut means that the State will not have the resources to address emerging public health issues, such as planning for a potential bird flu pandemic. It will, instead, be necessary to direct Title V resources toward continuing existing programs. Infant mental health, smoking cessation during pregnancy and obesity prevention programs will all be short-changed as a consequence.
- Funding has been pulled from a large Healthy Communities Access Program project in Washoe County, Nevada because of this year's cuts just as it was making great inroads in systems development for access to care for low-income families in that county. Nevada has a community-based prenatal program that reached 600 participants in its first year. Demand for services has tripled this year. Further cuts to the MCH Block Grant would necessitate cutting this program, so fewer pregnant women would be served. The MCH program has had to drop all its contracts with community coalitions to promote access to care, which has hampered the success of these activities.
- Alabama lost \$409,339 in block grant funding in fiscal year 2006. The Alabama MCH program has reduced staffing by attrition at both the central office and county office levels. Nursing and nursing assistants, administrative support, and epidemiology services and medical equipment and supplies have been affected.
- In Washington State, reductions in the MCH Block grant, impact women and children by minimizing or eliminating local community activities. Many activities will either be eliminated or drastically scaled back, including early childhood programs, adolescent health care, mental health services, the Healthy Youth Survey, newborn hearing screening, and services for children with special health care needs. Multiple Federal cuts mean that many of the MCH partners will also be reducing efforts. With this reduction, Washington State will be moving back in time, not even maintaining the status quo.
- In Michigan, cut backs in medical care and treatment for children with special health care needs will be necessary as a result of the \$656,000 reduction in its allocation.

The dramatic effects are not unique to Iowa, Nevada, Alabama, Washington State or Michigan, but affect all States and jurisdictions.

AMCHP recognizes the fiscal restraints facing this subcommittee. Nevertheless, we can not stress enough what a dire situation MCH Block Grant cuts are creating, especially given the cuts in the Medicaid program and the fact that other safety net programs also face reductions. Title V programs play a valuable, complementary role to the SCHIP and Medicaid programs. As more women and children are forced

out of the Medicaid program, they will turn to MCH programs to ensure that their health care needs are met. With increased demand for MCH Block Grant services, States will be forced to limit already stretched services to vulnerable populations.

Our children are the future. Their needs should not be short-changed by budget limitations, but addressed effectively with adequate funding. The MCH Block Grant has a proven track record of effectiveness and supports health services for over 32 million Americans. We strongly urge you to restore funding for the MCH Block Grant to the fiscal year 2005 level of \$724 million.

PREPARED STATEMENT OF THE CENTERS FOR DISEASE CONTROL AND PREVENTION
COALITION

The CDC Coalition is a nonpartisan coalition of more than 100 groups committed to strengthening our Nation's prevention programs. Our mission is to ensure that health promotion and disease prevention are given top priority in Federal funding, to support a funding level for the Centers for Disease Control and Prevention (CDC) that enables it to carry out its prevention mission, and to assure an adequate translation of new research into effective State and local programs. Coalition member groups represent millions of public health workers, researchers, educators, and citizens served by CDC programs. We are grateful to be able to present our views to the subcommittee.

The CDC Coalition continues to believe that Congress should support CDC as an agency—not just the individual programs that it funds. In the best judgment of the CDC Coalition—given the challenges and burdens of chronic disease, a potential influenza pandemic, terrorism, disaster preparedness, new and re-emerging infectious diseases and our many unmet public health needs and missed prevention opportunities—we believe the agency will require funding of at least \$8.5 billion, plus sufficient funding to prepare the Nation against a potential influenza pandemic. This request reflects the support CDC will need to fulfill its core missions for fiscal year 2007, as well as funding for the Agency for Toxic Substances and Disease Registry and the Vaccines for Children program.

The CDC Coalition appreciates the subcommittee's work over the years, including your recognition of the need to fund chronic disease prevention, infectious disease prevention and treatment, and environmental health programs at CDC. By translating research findings into effective intervention efforts, CDC has been a key source of funding for many of our State and local programs that aim to improve the health of communities. Perhaps more importantly, Federal funding through CDC provides the foundation for our State and local public health departments, supporting a trained workforce, laboratory capacity and public health education communications systems.

CDC also serves as the command center for our Nation's public health defense system against emerging and reemerging infectious diseases. With the potential onset of a worldwide influenza pandemic, in addition to the many other natural and man-made threats that exist in the modern world, the CDC has become the Nation's—and the world's—expert resource and response center, coordinating communications and action and serving as the laboratory reference center. States and communities rely on CDC for accurate information and direction in a crisis or outbreak.

Unfortunately, Congress cut overall CDC funding in fiscal year 2006 for the first time in 25 years. And in fiscal year 2007, the President has proposed cutting CDC funding even more—more than 2 percent overall, and more than 4.5 percent to CDC's core programs. We are moving in the wrong direction, especially in these challenging times when public health is being asked to do more, not less. In light of the current workload placed on the public health service—in addition to the threat of emerging diseases such as the avian flu—it simply does not make any sense to cut the budget for CDC at a time when the threats to public health are so great. Funding public health outbreak by outbreak is not an effective way to ensure either preparedness or accountability. Until we are committed to a strong public health system, every crisis will force trade offs.

CDC serves as the lead agency for bioterrorism preparedness and must receive sustained support for its preparedness programs in order for our Nation to meet future challenges. In the best judgment of CDC Coalition members, given the challenges of terrorism and disaster preparedness, and our many unmet public health needs and missed prevention opportunities, we support the proposed increase for anti-terrorism activities at CDC, including the increases for the Strategic National Stockpile and the new Botulinum Toxin Research funding. However, we strongly caution that the President's proposed level-funding of the State and local capacity grants continues to reflect a \$95 million cut from fiscal year 2005 levels. We encour-

age the subcommittee to restore these cuts to ensure that our States and local communities can be prepared in the event of an act of terrorism.

Heart disease remains the Nation's number one killer. In 2003, 684,462 people died of heart disease (51 percent of them women), accounting for 28 percent of all U.S. deaths. Stroke is the third leading cause of death after heart disease and cancer, and is a leading cause of serious, long-term disability. In 2003, stroke killed 157,800 people (61 percent of them women), accounting for about 1 of every 15 deaths. In 1998, the U.S. Congress provided funding for CDC to initiate a national, State-based heart disease and stroke prevention program with funding for eight States. Currently, 32 States and the District of Columbia are funded, 19 as capacity building programs and 14 as basic implementation programs. The CDC Coalition recommends \$55 million for the Heart Disease and Stroke Prevention Program.

The CDC funds proven programs addressing cancer prevention, early detection, and care. Cancer is the second most common cause of death in the United States. In 2006, about 1.4 million new cases of cancer will be diagnosed, and about 564,830 Americans—more than 1,500 people a day—are expected to die of the disease. The financial cost of cancer is also significant. According to the National Institutes of Health, in 2005, the overall cost for cancer in the United States was nearly \$210 billion: \$74 billion for direct medical costs, \$17.5 billion for lost worker productivity due to illness, and \$118.4 billion for lost worker productivity due to premature death.

Among the ways the CDC is fighting cancer, it funds the National Breast and Cervical Cancer Early Detection Program that helps low-income, uninsured and medically underserved women gain access to lifesaving breast and cervical cancer screenings and provides a gateway to treatment upon diagnosis. CDC also funds grants to States to develop Comprehensive Cancer Control (CCC) plans, bringing together a broad partnership of public and private stakeholders to jointly set priorities and implement specific cancer prevention and control activities customized to address each State's particular needs. CDC also funds programs to raise awareness about colorectal, prostate, lung, ovarian and skin cancers, and the National Program of Cancer Registries, a critical registry for tracking cancer trends in all 50 States. The CDC coalition recommends \$427.5 million for the Cancer Prevention and Control activities of the CDC.

Although more than 18 million Americans have diabetes, 5.2 million cases are undiagnosed. From 1980—2002, the number of people with diabetes in the United States more than doubled, from 5.8 million to 13.3 million. Each year, 12,000—24,000 people with diabetes become blind, more than 42,800 develop kidney failure, and about 82,000 have leg, foot, or toe amputations. Preventive care such as routine eye and foot examinations, self-monitoring of blood glucose, and glycemic control could reduce these numbers. Without additional funds, most States will not be able to create programs based on these new data. States also will continue to need CDC funding for diabetes control programs that seek to reduce the complications associated with diabetes.

Over the last 25 years, obesity rates have doubled among adults and children, and tripled in teens. Obesity, diet and inactivity are cross-cutting risk factors that contribute significantly to heart disease, cancer, stroke and diabetes. The CDC funds programs to encourage the consumption of fruits and vegetables, to get sufficient exercise, and to develop other habits of healthy nutrition and activity. The CDC Coalition recommends \$70 million for CDC's Division of Nutrition and Physical Activity.

Arthritis and chronic joint symptoms affect nearly 66 million Americans and they are the Nation's leading cause of disability. Early diagnosis and appropriate management of the disease can prevent much of the pain and disability associated with it. The CDC Coalition recommends \$14.4 million for the arthritis programs of the CDC.

More than 400,000 people die prematurely every year due to tobacco use. The CDC's tobacco control efforts seek to prevent tobacco addiction in the first place, as well as help those who want to quit. The CDC Coalition recommends \$145 million for the CDC's tobacco control programs.

Each day more than 4,000 young people try their first cigarette. At the same time, daily participation in high school physical education classes dropped from 42 percent in 1991 to 32 percent in 2001. Almost 80 percent of young people do not eat the recommended number of servings of fruits and vegetables, while nearly 30 percent of young people are overweight or at risk of becoming overweight. And every year, almost 800,000 adolescents become pregnant and about 3 million become infected with a sexually transmitted disease. School health programs are one of the most efficient means of correcting these problems, shaping our Nation's future health, education, and social well-being. The CDC Coalition requests \$34 million for CDC's Division of Adolescent and School Health (DASH) Coordinated School Health Program and \$41.8 million for DASH's HIV prevention education programs.

Public health programs delivered at the State and local level should be flexible to respond to State and local needs. Within an otherwise-categorical funding construct, the Preventive Health and Health Services Block Grant is the only source of flexible dollars for States and localities to address their unique public health needs. The track record of positive public health outcomes from Prevention Block Grant programs is strong, yet so many requests go unfunded. However, the President's budget proposes the elimination of the Preventive Health and Health Services Block Grant—again. We appreciate the work of the subcommittee to at least partially restore the fiscal year 2006 elimination of the Block Grant. Nevertheless, the \$20 million cut to the Block Grant in fiscal year 2006 reduces the States' ability to tailor Federal public health dollars to their specific needs. As States use their Prevention Block Grant dollars to address high priority needs such as emerging and chronic diseases, child safety seat programs, suicide prevention, smoke detector distribution and fire safety programs, adult immunization, oral health, worksite wellness, infectious disease outbreaks, food safety, emergency medical services, safe drinking water, and surveillance needs—we can scarcely understand why the Prevention Block Grant should be eliminated. We encourage the subcommittee to restore the cuts and fund the Prevention Block Grant at \$132 million.

Much of CDC's work in chronic disease prevention and health promotion is guided by its prevention research activities. Prevention research considers the factors associated with illness, disability, and injury, such as lifestyles or exposure to environmental toxins, and the best ways to address these factors and thereby promote health. By answering these questions, prevention research links biomedical research, which focuses on human physiology and disease treatment, to policies and public health interventions that promote wellness and reduce the need for treatment.

CDC provides national leadership in helping control the HIV epidemic by working with community, State, national, and international partners in surveillance, research, prevention and evaluation activities. The CDC estimates that up to 1,185,000 Americans are living with HIV, one-quarter of whom are unaware of their infection. Also, the number of people living with HIV is increasing, as new drug therapies are keeping HIV-infected persons healthy longer and dramatically reducing the death rate. Prevention of HIV transmission is our best defense against the AIDS epidemic that has already killed over 500,000 U.S. citizens and is devastating the populations of nations around the globe, and CDC's HIV prevention efforts must be expanded. The CDC Coalition recommends that a total of \$1.05 billion be appropriated to the Division of HIV Prevention.

The United States has the highest sexually transmitted diseases (STD) rates in the industrialized world. More than 18 million people contract STDs each year. In 1 year, our Nation spends over \$8.4 billion to treat the symptoms and consequences of STDs. Elimination of STDs, especially syphilis, is now within our grasp. These welcome opportunities, if adequately funded now, will save millions in annual health care costs in the future. Untreated STDs contribute to infant mortality, infertility, and cervical cancer. State and local STD control programs depend heavily on CDC funding for their operational support.

CDC conducts the National Health and Nutrition Examination Survey (NHANES), the only national source of objective health data to provide accurate estimates of diagnosed and undiagnosed medical conditions in the population. NHANES is a unique collaboration between CDC, the National Institutes of Health (NIH), and others to obtain data for biomedical research, public health, tracking of health indicators, and policy development. Through physical examinations, clinical and laboratory tests, and interviews, NHANES assesses the health status of adults and children in the United States. Mobile exam centers travel throughout the country to collect data on chronic conditions, nutritional status, medical risk factors (e.g., high cholesterol level, obesity, high blood pressure), dental health, vision, illicit drug use, blood lead levels, food safety, and other factors that are not possible to assess by use of interviews alone. Findings from this survey are essential for determining rates of major diseases and health conditions and developing public health policies and prevention interventions.

We must address the growing disparity in the health of racial and ethnic minorities. CDC's REACH 2010 Demonstration Program, Racial and Ethnic Approaches to Community Health (REACH), helps States address these serious disparities in infant mortality, breast and cervical cancer, cardiovascular disease, diabetes, HIV/AIDS and immunizations. We encourage the subcommittee to provide adequate funds for CDC's REACH program.

The CDC Coalition is requesting an appropriation of \$49.75 million for Steps to a HealthierUS (STEPS) program. Additional resources will allow for the creation of programs in more States. Furthermore, while the President's budget request in-

cludes \$1.5 million to support the YMCA Pioneering Healthier Communities initiative, \$3 million is needed to continue to expand this important effort. This would enable additional communities to participate in this initiative, to allow on-going training for communities and to support a Center for Community Health Advancement at the CDC to assist the YMCA and other communities undertaking healthy lifestyle initiatives to prevent and control obesity and chronic disease.

CDC oversees immunization programs for children, adolescents and adults, and is a global partner in the ongoing effort to eradicate polio worldwide. The value of adult immunization programs to improve length and quality of life, and to save health care costs, is realized through a number of CDC programs, but there is much work to be done and a need for sound funding to achieve our goals. Influenza vaccination levels remain low for adults. Levels are substantially lower for pneumococcal vaccination and significant racial and ethnic disparities in vaccination levels persist among the elderly. Childhood immunization programs at CDC also need a funding boost, to ensure sufficient purchase and delivery of the varicella and pneumococcal vaccines. In addition, developing functional immunization registries in all States will be less costly in the long run than maintaining the incomplete systems currently in place. The CDC Coalition requests \$802.4 million for the National Immunization Program at CDC.

Injuries are the leading cause of death in the United States for people ages 1–34. Of all injuries, those to the brain are most likely to result in death or permanent disability. Each year more than 50,000 people die as a result of a brain injury and as many as 90,000 others are left with a long-term disability. A traumatic brain injury (TBI) is defined as a blow or jolt to the head or a penetrating head injury that disrupts the function of the brain. The Traumatic Brain Injury Act is the Nation's only law that was specifically designed to respond to this public health crisis. The Institute of Medicine reported this month that this law has been effective in addressing a wide variety of gaps in service system development. The CDC Coalition requests that the subcommittee restore \$30 million in appropriations for TBI programs at CDC and at HRSA, which President Bush zeroed out. The monies would be allocated as follows: CDC—\$9 million; HRSA State Grant Program—\$15 million; and HRSA Protection and Advocacy program—\$6 million.

Injury at work remains a leading cause of death and disability among U.S. workers. During the period from 1980 through 1995, at least 93,338 workers in the United States died as a result of injuries suffered on the job, for an average of about 16 deaths per day. The Bureau of Labor Statistics (BLS) at the Department of Labor has identified 5,915 workplace deaths from acute traumatic injury in 2000. BLS also estimates that 5.7 million injuries to workers occurred in 1997 alone; while NIOSH estimates that about 3.6 million occupational injuries were serious enough to be treated in hospital emergency rooms in 1998. The injury prevention and workforce protection initiatives of NIOSH need continued support.

Of the 4 million babies born each year in the United States, 3 percent are born with one or more birth defects. Birth defects are the leading cause of infant mortality, accounting for more than 20 percent of all infant deaths. Children with birth defects who survive often experience lifelong physical and mental disabilities. An estimated 54 million people in the United States currently live with a disability, and 17 percent of children under the age of 18 have a developmental disability. Direct and indirect costs associated with disability exceed \$300 billion.

Created by the Children's Health Act of 2000 (Public Law 106–310), the National Center on Birth Defects and Developmental Disabilities (NCBDDD) at CDC conducts programs to protect and improve the health of children and adults by preventing birth defects and developmental disabilities; promoting optimal child development and health and wellness among children and adults with disabilities. We encourage the subcommittee to provide at least \$135 million in fiscal year 2007 funding for the NCBDDD. This would be a modest increase of \$10 million and would further surveillance, research and prevention activities related to birth defects and developmental disabilities and improve the lives of those living with disabilities.

We also encourage the subcommittee to provide \$10 million for CDC's Environmental Public Health Services Branch to revitalize environmental public health services at the national, State, and local level. As with the public health workforce, the environmental health workforce is declining. Furthermore, the agencies that carry out these services are fragmented and their resources are stretched. These services are the backbone of public health and are essential to protecting and ensuring the health and well being of the American public from threats associated with West Nile virus, terrorism, E. coli and lead in drinking water.

We appreciate the subcommittee's hard work in advocating for CDC programs in a climate of competing priorities. We encourage you to consider our request for \$8.5

billion, plus sufficient funding to prepare for a possible influenza pandemic, for CDC in fiscal year 2007.

PREPARED STATEMENT OF THE COLLEGE OF NEW ROCHELLE, NY

Mr. Chairman and Members of the subcommittee, on behalf of The College of New Rochelle (CNR), and the thousands of New York City metropolitan area residents impacted by our programs each year, I am grateful for the opportunity to submit testimony to your committee regarding our Center for Wellness project.

THE NATIONAL HEALTH CARE CRISIS: A NEED FOR THE PROJECT

Government sources report that one of the most important issues currently facing American society is the health care crisis. Among the reasons cited are the escalating costs of health care, an increasing lack of access to health insurance among the poor and middle class, an aging population and a growing national shortage of qualified nurses and other health care providers.

Recent data shows the following:

- Out of some 40 million Americans who are informal care givers, an estimated 72 percent are women;
- Women represent 71 percent of Americans age 85+, the fastest growing segment of the population;
- Almost two-thirds of Americans are overweight or obese;
- One in three Americans born in the year 2000 will develop Type 2 diabetes;
- Surveys indicate that 28 percent of high school girls think they are overweight; 60 percent report trying to lose weight; 8 percent suffer from anorexia or bulimia;
- More than half of all Americans get too little physical activity;
- Some 45 million Americans have no health insurance; and
- Over 1 million new and replacement nurses will be needed nationwide by 2020.

One significant health care issue is the individual's lack of attention to participation in self-care. Government experts emphasize the importance of widespread public awareness of basic health habits and preventative care, as well as support for those seeking preventative assistance in making better health and lifestyle choices. In order to keep the crisis from increasing, the U.S. Department of Health and Human Services, through the Office of Disease Prevention and Health Promotion, has launched a national initiative, Healthy People 2010. Through its School of Nursing, and programs such as Healthy Campus 2010, CNR has been participating actively in HHS initiatives for many years, developing local health education programs which benefit students and New York City metropolitan area residents, and which help address national goals.

The Office of Disease Prevention and Health Promotion has identified ten major public health issues based on their causal relationship to serious or chronic illnesses. These are: insufficient physical activity, overweight and obesity, decreasing environmental quality, tobacco use, substance abuse, irresponsible sexual behavior, mental health disorders, injury and violence, immunization deficiencies, and lack of access to health care. People of all socio-economic backgrounds are susceptible; however, the risk factors are even greater among the poor, the elderly and the uninsured.

Moreover, recent studies reveal that those most at risk for developing chronic and life-threatening conditions are African Americans, Hispanics, and Asians—populations largely represented in the New York metropolitan area where CNR has six campus locations serving 7,000 students and many local residents.

THE NATIONAL NURSING SHORTAGE: CNR'S SCHOOL OF NURSING

Compounding the health care crisis is the critical and unprecedented nationwide shortage of nurses—one that is uniquely different from previous shortages. Among the causes cited for this growing problem are an aging nursing workforce, increased job opportunities for women in other fields, and fundamental changes in how and in what setting patients are treated. A compelling statistic is the average age of nurses which is now over 45. A significant percentage of nurses currently employed will most likely retire just as the baby boom generation reaches Medicare age.

According to a recent Federal survey an estimated 1 million new and replacement nurses will be needed nationwide by 2020. Government leaders are stressing the urgency of embarking on a national agenda to encourage more students to choose nursing as a career. Among their recommendations are the creation of incentives to

recruit new candidates to the profession, and the broad-scale development of creative approaches for the continuing preparation and retention of skilled nurses.

CNR's School of Nursing (SON), founded in 1976, belongs to the National League for Nursing and is accredited by the Commission on Collegiate Nursing Education. The School is ideally poised to assume a leadership role in enacting the national recommendations cited above. In recent years, the School has been especially successful in recruiting students (including many from disadvantaged backgrounds) and in fostering a lifelong commitment to nursing careers. Enrollment in SON has increased by 25 percent over the past 2 years. At present, there are 669 students enrolled in SON: 580 in the baccalaureate program and 89 in the masters program. SON programs are addressing the shortage by creating initial student access to the nursing profession and also by providing a career ladder for nurses seeking to advance their careers. Five separate programs are offered:

- Undergraduate program leading to a Bachelor of Science Degree in Nursing (BSN);
- Programs of study for registered nurses seeking either a BSN or a Master of Science Degree;
- BSN program for those holding degrees in other fields;
- Graduate program with several tracks leading to an MS Degree in Nursing; and
- Several post-Master certificate programs.

A pivotal function of CNR's multi-faceted Center for Wellness project includes the building of a new state-of-the-art facility on the College's New Rochelle campus, providing space for nursing and health education classes and events. This will heighten the visibility of nurses as educators as a crucial part of the nursing profession throughout the New York City area and beyond. The new facility and its related health and wellness education programs also hold much promise for drawing a greater number of students to SON as well as providing expanded access and opportunity for nurses seeking to acquire additional professional skills and/or further their careers.

THE CENTER FOR WELLNESS AT THE COLLEGE OF NEW ROCHELLE

The proposed Center for Wellness will be a state-of-the-art multi-purpose facility at the College's main campus and will house Nursing programs, Physical Education, Health Education and Health Services programs. The faculty will create a comprehensive center for the development and delivery of a broad range of integrated health and wellness education programs. The program will include a variety of health and educational activities in an intergenerational fashion to involve students, employees, and members of the surrounding community. Health seminars will cover a wide variety of issues including parenting and women's issues, smoking, diabetes, heart disease, nutrition and weight issues, sex education and assault issues, drug abuse prevention and treatment, and wellness education. The School of Nursing will offer courses and workshops in wellness and disease prevention, not only through the curriculum in the School of Nursing, but also to the students, staff and faculty in Westchester and at the branch campuses. The integrated wellness program will be supplemented with fitness and education programs targeted to specific populations such as the New Rochelle School District, the Senior Center of New Rochelle and the United Hebrew Home.

The programs at the Center for Wellness will provide access to timely information and help foster lifelong healthy lifestyle choices among students, faculty and staff at the main campus and throughout the five metropolitan New York communities where CNR has city campus locations. At these city campuses, CNR will give busy low-income adult students access to wellness promotion, health maintenance and fitness programs on campus. For example, the College is working with the New York City health education program "Take Care New York" to educate all of our students on the necessity of a healthy lifestyle. CNR will also use distance learning technology so that faculty and staff at its campuses can share their own expertise, as well as that of national experts, with CNR students and community members.

The College of New Rochelle recognizes that preventative health care is vital to our Nation's future. This Center will position CNR as a model institution for the development and delivery of innovative health and wellness education. CNR believes that this holistic approach to wellness will serve as motivation for more students to enter the field of nursing and thus begin to alleviate the nursing shortage. The programs, adaptable to the needs of many different communities and populations, will be able to be replicated at other institutions regionally and nationally.

The total cost to establish the Center for Wellness is estimated at \$25 million. Through the support of the subcommittee, The College of New Rochelle received funding through the Labor, HHS and Education Appropriations Bill in the amount

of \$200,000 in 2005. CNR has utilized this funding for the development of wellness education programs that have benefited CNR students, middle school students, and senior citizens from the area surrounding the New Rochelle Campus. In fiscal year 2007, The College hopes that the subcommittee can fund our request of \$2.7 million to construct and equip the Center.

PREPARED STATEMENT OF THE DIABETES CARE COALITION

Mr. Chairman and members of the Committee, thank you for the invitation today to discuss how government, private industry and non-governmental agencies can form innovative partnerships to address the epidemic of uncontrolled diabetes in America. This raging epidemic is simply too great a challenge for any but a collective effort.

I know this subcommittee has little ability to change the fiscal reality that you must produce an appropriations bill that, for a second consecutive year, must reduce spending under your jurisdiction by multiple billions of dollars. This fiscal reality does not change the fact that one out of every three people with diabetes will suffer a heart attack by age 40, every day 144 Americans with diabetes will go blind, every hour three people with diabetes will undergo an amputation, and every minute 20 people with diabetes undergo kidney dialysis. The sad fact is most of these and other complications of diabetes are preventable through known interventions. But, not everyone living with diabetes is aware of some of the simple things they can do to monitor their disease and prevent some of these terrible consequences.

My entire career has been dedicated to improving the care of people with diabetes, through research into the causes of diabetes complications, and how to improve diabetes care. I have been President of the American Diabetes Association, a member of the Coalition I represent today, and the founding Chairman of the private-public partnership of the National Diabetes Education Program (NDEP), which was funded by the National Institutes of Health and the Centers for Disease Control and Prevention (CDC) to improve the care of Americans with diabetes. I am also the Medical Advisor to the Diabetes Care Coalition (DCC) on whose behalf I am speaking today.

As Dr. Gerberding told the House of Representatives Appropriations Subcommittee on Labor, Health and Human Services, Education, and Related Agencies in March 2006, "where we invest, we can make a difference". I am here today to tell you that the DCC is committing significant private sector resources to mount a critical public awareness campaign aimed at improving the health of individuals with diabetes. We are initiating discussions with experts at the CDC, and are excited about the potential opportunity to develop an innovative partnership with this world-renown agency to leverage scarce Federal resources, and combine our efforts with theirs, to immediately begin to reduce the burden of this rapidly growing disease.

In this difficult fiscal environment where we are seeing the CDC budget cut this year by hundreds of millions of dollars, and the President's proposal to cut it again by almost \$200 million next year, we believe it is imperative to encourage creative solutions to reach the millions of Americans living with diabetes with information that can ultimately prevent heart attacks, strokes, blindness, amputations, and other complications of this disease. The DCC represents what is truly a creative solution to combat the problem of uncontrolled diabetes.

The DCC was born out of a recognition by its various participants that Americans with diabetes lack a basic understanding of how best to control their disease to reduce their risk of complications like heart attacks and strokes. The DCC's pilot "Know Your A1C" campaign represents a novel approach to empower people with diabetes to take personal responsibility by working with their diabetes healthcare team to manage the disease.

Personally, I am concerned that the Federal Government's commitment to battling the epidemic of uncontrolled diabetes is under-funded and potentially losing ground. Since 2003, the CDC estimates that the prevalence of diabetes in America increased 14 percent. Over 20.8 million adult Americans live with diabetes today compared to 18.2 million in 2003. While I recognize the limitations on the Federal budget and the tough choices that have to be made in this Committee every day, now is not the time to approve declining budgets for our Federal programs that aim to prevent and manage diabetes.

I do not want to overwhelm you with facts and figures, but it is clear from even a brief review that diabetes is about to overwhelm America's medical system. By providing you with perspective related to the reach of diabetes, I trust you will appreciate the need to invest in battling uncontrolled diabetes before its impact dev-

astates our health system. The place our Nation needs to make this investment is here in your appropriations bill, in the CDC.

Diabetes strikes across age groups, economic status, and ethnicity. Projections for the future are even more ominous. The Yale Schools of Public Health and Medicine project the population of Americans living with diabetes will increase two and a half times by 2025. Supporting this projection, the CDC estimates that 33 percent of all children and nearly one half of minority children born in the year 2000 will develop diabetes by 2050.

The economic cost of diabetes is enormous. In 2002, the total economic impact of diabetes was \$132 billion. Put another way, 1 out of every 10 health care dollars spent in the United States is spent on diabetes care and its complications. CMS estimates that 32 percent of the Medicare budget goes towards caring for Americans with diabetes—an amazing one-third of the entire Medicare program that is struggling with long-term solvency issues far more critical and a near-term fiscal crisis than Social Security solvency.

The human costs of uncontrolled diabetes are more shocking:

—2 out of 3 people with diabetes in America will die of a heart attack or stroke.

—Diabetes is the leading cause of blindness, causing 12,000 to 24,000 new cases each year.

—Diabetes is the leading cause of kidney failure, accounting for 43 percent of new cases in 2002.

—More than 60 percent of non-traumatic lower-limb amputations occur in people with diabetes.

Unfortunately, most diabetes patients are not controlling the risk factors that can keep them healthy. A1C is a compelling example of this trend. A1C is the single most important measure of glucose control over time and a proven risk factor for all major diabetes complications. A1C is a test that shows glucose control over the previous 3 months; sort of a diabetes batting average except that lower is better.

Diabetes patients should know their A1C number and work to keep it in check—similar to blood pressure or cholesterol levels. The test is paid for by managed care, Medicare, and most private insurance plans; there are few financial barriers to being in the know.

However, a recent study by the New York State Department of Health found that 89 percent of patients with diabetes did not know their A1C. Worse, even among those who knew their A1C, 80 percent had A1C's above the value deemed acceptable by all diabetes organizations. Nationally, the CDC estimates that 65 percent of all diabetes patients are out of control, defined by the CDC as “an A1C level above 7.”

I urge this Committee to consider, based on the dire state of diabetes in America, whether we can or should continue to overlook the basic diabetes care needs of Americans. The answer to me seems obvious; we must embark on an aggressive campaign to encourage Americans to manage diabetes to control its staggering human and financial costs that encompass all sectors of the American community.

The DCC works to bridge the diabetes management knowledge gap by educating diabetes patients and their healthcare teams on ways to battle uncontrolled diabetes primarily through A1C awareness and management. Through public education in its initial test markets, the DCC aims to help diabetes patients take control of their disease and live longer, healthier lives—without the specter of heart attack, stroke, amputation, or kidney failure.

The American Diabetes Association and the Juvenile Diabetes Research Foundation International are jointly leading the DCC's “Know Your A1C” campaign to battle uncontrolled diabetes in America. Providing financial support to this novel non-branded, public-private partnership are six of the world's leading pharmaceutical and medical device companies: Abbott Diabetes Care Inc., Becton, Dickinson and Company, LifeScan, Inc., Novo Nordisk Inc., Roche Diagnostics Corporation, and sanofi-aventis U.S. Inc.

The “Know Your A1C” campaign is different from other public service campaigns. It encourages Americans and their families to control diabetes by focusing primarily on the message that patients need to know and to manage their A1C. Prior to launching its campaign, the DCC conducted research to determine the most effective way to encourage patients to manage diabetes and the findings supported a sole focus on A1C control.

The campaign utilizes television, radio and print placements to reach families affected by diabetes in the pilot markets. While these placements consist of paid advertising today, beginning in late 2006, most of the effort will rely on public service announcements generated under an agreement with the Ad Council.

The effort is enhanced by the sales teams of the corporate supporters who distribute unbranded educational materials into medical offices, clinical laboratories, pharmacies, diabetes educators' offices and any other location likely to be frequented

by a person with diabetes in the pilot markets. The campaign also provides an order fulfillment system via 800 number allowing people to request basic materials associated with the campaign, a website and direct mail to healthcare professionals to ensure campaign materials have the broadest reach possible in the test markets.

In 2006, the DCC will expand upon its 2005 “Know Your A1C” pilot program in Atlanta and Tampa. This year, the campaign will reach the television and radio markets of Atlanta, GA, Lexington, KY, Little Rock, AR and Memphis, TN.

The DCC is expanding its focused campaign simply because it is proven to work. Consider some of these compelling highlights of the campaign’s achievements in 2005 in Atlanta and Tampa.

- An improvement in the number of patients with diabetes who report obtaining an A1C test in the past 3 months from a low of 25 percent prior to campaign launch to an average of 52 percent during the campaign.
- An increase in patient with diabetes understanding of A1C awareness from a low of 38 percent among people with diabetes prior to the launch of the campaign to an average of 54 percent by the end of the campaign; and
- An increase in patient with diabetes understanding of what the A1C test measures from a low of 17 percent prior to the campaign to an average of 41 percent during the campaign.

Based upon these results, the Ad Council will join the DCC to refine the “Know Your A1C” campaign and transform it from a regional effort into a national public service campaign. This campaign is expected to launch in late 2006. Plus, the campaign hopes to reach English and Spanish speaking populations. I hope you share in my enthusiasm for this program as it could potentially transform America’s ambivalence towards the uncontrolled diabetes epidemic into a national call to action.

We would like to build on the current NIH and CDC patient awareness campaigns and will soon talk to CDC about the best ways to work with it to improve patient awareness of A1C levels. This may include CDC support for needed patient and healthcare provider components that inform Americans with diabetes how they can and should manage the disease not presently part of the campaign. Components the DCC would like to incorporate in the campaign include more aggressive healthcare provider education tools, documents informing families how to help manage a family member’s diabetes, information detailing steps patients can take for A1C control, components that speak more directly to multi-cultural audiences and a more robust order fulfillment program.

While the Diabetes Care Coalition will provide an expanded national “Know Your A1C” campaign in late 2006 and the personnel necessary to distribute the materials associated with the campaign, a partnership with the Federal Government will enable us to expand and enhance our campaign. A public-private partnership will give us the expertise and funding needed to take the battle to all Americans and their healthcare teams to eliminate uncontrolled diabetes. This makes economic and humanitarian sense.

Today, the DCC joins the American Diabetes Association in requesting an increase in the CDC diabetes prevention and control program by \$20.8 million in fiscal year 2007. Given the scope and reach of diabetes, we believe this is a modest request even in this budget climate.

We also encourage this Committee to urge the CDC to dedicate new and existing resources for its diabetes control program to battling uncontrolled diabetes. To best serve the American people, CDC must equally address both aspects of controlling this disease—primary prevention activities to stop new cases of diabetes, as well as secondary prevention activities to improve the health of the 20.8 million people living with diabetes.

Members of the Committee, the time to battle the epidemic of uncontrolled diabetes is now. If we miss this opportunity, America will lose substantial ground and run the risk of never getting the diabetes epidemic under control.

Unfortunately, the 20.8 million Americans living with diabetes today represent “the low water mark” in the reach and scope of the disease. It is time to realize that diabetes is here to stay in America and to act in a way that accepts this truth. Please help empower Americans living with diabetes, and the growing numbers who will live with it tomorrow, to “Know Your A1C” by providing the CDC with the resources needed to battle the epidemic of uncontrolled diabetes.

Thank you for your time and consideration.

PREPARED STATEMENT OF THE INTERTRIBAL BISON COOPERATIVE

INTRODUCTION AND BACKGROUND

My name is Ervin Carlson, a Tribal Council member of the Blackfeet Tribe of Montana and President of the InterTribal Bison Cooperative. Please accept my sincere appreciation for this opportunity to submit testimony to the honorable members of the Appropriations Sub-Committee on Labor, Health and Human Services and Education. The InterTribal Bison Cooperative (ITBC) is a Native American non-profit organization, headquartered in Rapid City, South Dakota, comprised of 57 federally recognized Indian Tribes located within 19 States across the United States.

Buffalo thrived in abundance on the plains of the United States for many centuries before they were hunted to near extinction in the 1800s. During this period of history, buffalo were critical to survival of the American Indian. Buffalo provided food, shelter, clothing and essential tools for Indian people and insured continuance of their subsistence way of life. Naturally, Indian people developed a strong spiritual and cultural respect for buffalo that has not diminished with the passage of time.

Numerous tribes that were committed to preserving the sacred relationship between Indian people and buffalo established the ITBC as an effort to restore buffalo to Indian lands. ITBC focused upon raising buffalo on Indian Reservation lands that did not sustain other economic or agricultural projects. Significant portions of Indian Reservations consist of poor quality lands for farming or raising livestock. However, these wholly unproductive Reservation lands were and still are suitable for buffalo. ITBC began actively restoring buffalo to Indian lands after receiving funding in 1992 as an initiative of the Bush administration.

Upon the successful restoration of buffalo to Indian lands, opportunities arose for Tribes to utilize buffalo for tribal economic development efforts. ITBC is now focused on efforts to assure that tribal buffalo projects are economically sustainable. Federal appropriations have allowed ITBC to successfully restore buffalo the tribal lands, thereby preserving the sacred relationship between Indian people and buffalo. The respect that Indian tribes have maintained for buffalo has fostered a serious commitment by ITBC member Tribes for successful buffalo herd development. The successful promotion of buffalo as a healthy food source will allow Tribes to utilize a culturally relevant resource as a means to achieve self-sufficiency.

FUNDING REQUEST FOR PREVENTATIVE HEALTH CARE INITIATIVE

The InterTribal Bison Cooperative respectfully requests an appropriation for fiscal year 2007 in the amount of \$2,000,000 in the form of an earmark to the Department of Health and Human Service Department's budget. ITBC intends to utilize the funds to conduct a national demonstration project focused on the delivery of bison meat to Native Americans suffering from diet related diseases.

The Native American population currently suffers from the highest rates of Type 2 diabetes. The Indian population further suffers from high rates of cardio vascular disease and various other diet related diseases. Studies indicate that Type 2 diabetes commonly emerges when a population undergoes radical diet changes. Native Americans have been forced to abandon traditional diets rich in wild game, buffalo and plants and now have diets similar in composition to average American diets. More studies are needed on the traditional diets of Native Americans versus their modern day diets in relation to diabetes rates. However, based upon the current data available, it is safe to assume that disease rates of Native Americans are directly impacted by a genetic inability to effectively metabolize modern foods. More specifically, it is well accepted that the changing diet of Indians is a major factor in the diabetes epidemic in Indian Country.

Approximately 65-70 percent of Indians living on Indian Reservations receive foods provided by the USDA Food Distribution Program on Indian Reservation (FDPIR) or from the USDA Food Stamp Program. The FDPIR food package is composed of approximately 58 percent carbohydrates, 14 percent proteins and 28 percent fats. Studies have shown that the FDPIR food package has not been compatible with the genetic compositions of Native Americans and has been a major factor in the high incidence of diet-related disease among Native Americans. Indians utilizing Food Stamps generally select a grain based diet and poorer quality protein sources such as high fat meats based upon economic reasons and the unavailability of higher quality protein food sources.

Buffalo meat is low in fat and cholesterol and is compatible to the genetics of Indian people. ITBC intends to develop a health care initiative that would educate Indian Reservation families of the benefits of incorporating buffalo meat into their diets. In conjunction with educating Reservation families on the benefits of buffalo meat, ITBC intends to develop methods to make buffalo meat accessible for Indian

families and to promote incorporation of buffalo into their diets. ITBC intends to coordinate with Reservation health care providers in nutritional studies of Reservation populations that incorporate buffalo meat into diet packages.

ITBC believes that incorporating buffalo meat will positively impact the diets of Indian people living on Reservations. A healthy diet for Indian people that results in a lower incidence of diabetes and other diet related illnesses will reduce Indian Reservation health care costs and result in a savings for taxpayers.

FUNDING REQUEST FOR ITBC TRAINING AND LABOR PROGRAM

The InterTribal Bison Cooperative respectfully requests an appropriation for fiscal year 2007 in the amount of \$500,000. This amount is \$400,000 above the fiscal year 2006 appropriation for ITBC and is critical to maintain last years funding level and to develop ITBC's training and labor program.

In fiscal year 2005, the ITBC and its member Tribes were funded at \$100,000, a decrease of \$200,000 from the previous year. ITBC is now requesting \$500,000 for fiscal year 2007 for job training as part of ITBC's labor initiative. To insure the success of ITBC's buffalo restoration efforts to Indian lands, training for the various jobs related to the buffalo projects is essential. Most member Tribes of ITBC have reservation unemployment rates of 72 percent. Jobs opportunities on most Indian Reservations are limited, low-paying, and often seasonal and temporary. The jobs created by buffalo restoration to Indian lands will positively impact Tribal unemployment rates and the overall Reservation poverty levels. Raising buffalo as an economic development effort requires skilled labor in permanent employment. ITBC has developed a job training program incorporating on-the-job training and work experience for youth that specifically addresses the unique needs of managing and maintaining buffalo. ITBC's training program further focuses on strengthening the economic development opportunities of buffalo restoration with training specific to meat processing, veterinary science, wildlife and biological services, infrastructure development, business and management training, and the overall development of a skilled workforce.

Sufficient funding for job training is critical to the success of the buffalo restoration projects. The increase in funding will ensure that ITBC can provide job training, job growth training to ITBC member tribes. Without funding at the requested level, the buffalo restoration projects have less assurance of success.

ITB GOALS AND INITIATIVES

In addition to developing a preventative health care initiative, ITBC intends to continue with buffalo restoration efforts and the Tribal buffalo marketing initiative.

In 1991, seven Indian Tribes had small buffalo herds, with a combined total of 1,500 animals. The herds were not utilized for economic development but were often maintained as wildlife only. During ITBC's relatively short 10-year tenure, it has been highly successful at developing existing buffalo herds and restoring buffalo to Indian lands that had no buffalo prior to 1991. Today, through the efforts of ITBC, over 35 Indian Tribes are engaged in raising over 15,000 buffalo. All buffalo operations are owned and managed by Tribes and many programs are close to achieving self-sufficiency and profit generation. ITBC's technical assistance is critical to ensure that the current Tribal buffalo projects gain self-sufficiency and become profit-generating. Further, ITBC's assistance is critical to those Tribes seeking to start a buffalo restoration effort.

Through the efforts of ITBC, a new industry has developed on Indian reservations utilizing a culturally relevant resource. Hundreds of new jobs directly and indirectly revolving around the buffalo industry have been created. Tribal economies have benefited from the thousands of dollars generated and circulated on Indian Reservations.

CONCLUSION

ITBC has proven highly successful since its establishment to restore buffalo to Indian Reservation lands to revive and protect the sacred relationship between buffalo and Indian Tribes. Further, ITBC has successfully promoted the utilization of a culturally significant resource for viable economic development.

ITBC has assisted Tribes with the creation of new jobs, on-the-job training and job growth in the buffalo industry resulting in the generation of new money for tribal economies. ITBC is also actively developing strategies for marketing Tribally owned buffalo. Finally, and most critically for Tribal populations, ITBC is developing a preventive health care initiative to utilize buffalo meat as a healthy addition to Tribal family diets to reduce the incidence of diet-related illnesses.

ITBC strongly urges you to support its request for a \$2,000,000 earmark to the Department of Health and Human Service Department's budget to develop the critically needed preventative health care initiative utilizing Tribally produced buffalo.

PREPARED STATEMENT OF THE JOHN B. AMOS CANCER CENTER

Mr. Chairman and members of the subcommittee, I appreciate the opportunity to submit testimony to the hearing record regarding the John B. Amos Cancer Center (JBACC) in Columbus, Georgia. JBACC is a comprehensive community cancer center designed to address the continuum of the disease from prevention and early detection through treatment, survivorship and palliation.

Accredited by the Commission on Cancer, American College of Surgeons, JBACC's mission is to provide exceptional quality-driven care. Accordingly, we have opened a (49,620 sq. ft.) hospital-based cancer center located on its own campus and surrounded by meditation gardens. This unique facility is designed to address cancer along a disease management approach allowing patients, families, and the community at large to enter our services at any point in the disease process whether it is for education, diagnosis, treatment, or psychosocial support. Our outreach programs are a significant component of our action plan to improve the health of the region, as well. Further development of these programs is the reason I address you today.

As you are aware, the John B. Amos Cancer Center received fiscal year 2005 Labor, HHS, and Education Appropriations. I would like to thank the subcommittee for this support and elaborate on the success of our programs thus far.

Leveraging community and government support, we have developed extensive Breast and Cervical Cancer Screening Programs that allow us to reach many underserved areas of the 14 county region encompassing our service area. Community Health Advisors (CHAs) trained and educated by JBACC in collaboration with the West Georgia Cancer Coalition to address cancer education, prevention, and diagnostic care, assist in the facilitation of community screenings to maximize the effect of the screening events. These CHAs are native to the communities they serve and therefore possess intuitive knowledge necessary for conducting successful community screenings such as appropriate venues and marketing techniques for the respective population. Other factors, such as matching a bilingual CHA with Hispanic communities to increase accessibility and comfort levels are also considered.

Screenings are conducted on a weekly basis in communities throughout the region. Rural communities are specifically targeted as screening sites at least once a month. A culturally diverse multidisciplinary team extends a comprehensive approach to providing care and access to services at these events. This is a level of service previously unattainable in some areas. The team includes a bilingual physician, a nurse practitioner, a nurse, a case manager, and clerical personnel. Additionally, volunteers are often available to set up educational materials. The CHAs often attend the events as well and may sometimes act as liaisons between patients and the JBACC staff.

By the point at which many patients walk into the Amos Cancer Center facility, the disease has advanced to a stage at which treatment and cure is exceedingly difficult. Therefore, the primary goal of community screenings is to promote and make available early detection and treatment options. To this end, initial on-site exams are performed free of charge, regardless of ability to pay, to increase service accessibility. Abnormal exams are referred to care coordinators for referral for additional screenings or diagnostic testing, as applicable. Dependent upon the patient's schedule, this can usually be achieved with the same week as the initial screening. A surgical consult is provided 2 to 4 days after testing, if necessary. If further investigation is warranted, coordinators access the system to see that the patient's needs, including financial and psychological are met. The target timeline objective is two weeks from exam to diagnosis and treatment. Identification of cervical abnormalities is slightly more involved and requires a timeline of approximately 3.5 to 4 weeks.

The outreach program is not limited to screenings. Educational programs and cancer prevention programs are provided to organizations throughout the region. These include breast health lectures provided to churches, sororities, and healthcare groups, and providing educational materials and interactive displays for cancer-themed events on local college campuses. These events reinforce the importance of early detection.

We have developed a successful early detection outreach program. The requested funding of \$2 million in fiscal year 2007 would allow us to expand the program to be even more effective within the fourteen county region in which 511,736 citizens reside. Expansion efforts would allow us to reach traditionally underserved popu-

lations by scheduling screenings in communities not yet familiar with our programs. This includes rural and urban areas in both Georgia and Alabama, some of which lie in the socio-economically deprived "Black Belt".

In addition to the community screenings, funding would provide for the development of two permanent weekly cancer screening clinics. These clinics would allow citizens the peace of mind of the availability of set screening opportunities, rather than waiting for a local opportunity to occur.

Funding from JBACC's fiscal year 2005 Labor, HHS, Education Appropriation was limited to breast and cervical cancer screening. However, we have identified a need and an opportunity within the community to focus on men's health issues as well, through prostate screenings. The requested funding would allow for the expansion of our outreach program to include this component. Incorporation of prostate screenings into our existing program could occur seamlessly. This would allow us to expand our focus to include a population previously not served in this capacity. Excluding skin cancers, prostate cancer is the most common cancer in American men. While the statistics regarding prostate cancer are staggering, early detection and more effective treatment methods have led to lower death rates in recent years. This further underscores the need for prostate screening programs in underserved areas to improve the health status of the region.

The requested funding would also provide for colorectal screenings. This year, nearly 150,000 men and women will be diagnosed with colorectal cancer while approximately 56,000 will die from it. Once again, however, early detection and treatment are essential to increased survival rates. However, studies indicate that many people are often uncomfortable talking about the disease. They are also misguided on their risk factors and chance of getting the disease. Overcoming these obstacles to diagnosis and treatment can be achieved through community educational and screening opportunities.

Mr. Chairman, John B. Amos Cancer Center is committed to improving the health of the region by addressing and embracing the Healthy People 2010 focus areas of overall cancer deaths. Recognizing that to reach our goals we must design programs that engage the region in our early detection and screening programs, we have taken great strides to do so. We believe in the documented success of our outreach programs and hope that the subcommittee will provide \$2 million toward program expansion. Through the expansion, we will reach underserved populations and reduce cancer mortality and morbidity, thereby improving the health of the region in accordance with the goals of the Department of Health and Human Services as well as this subcommittee.

PREPARED STATEMENT OF MATRIA HEALTHCARE
SUMMARY OF FISCAL YEAR 2007 RECOMMENDATIONS

- Provide full funding in fiscal year 2007 for the Health and Human Services (HHS) Health Information Technology Initiative, including funding for the Office of the National Coordinator for Health Information Technology (ONCHIT) and the Agency for Healthcare Research and Quality (AHRQ).
- Provide a 5 percent increase for fiscal year 2007 to the National Institutes of Health (NIH) budget. Within NIH, provide an increase of 5 percent to the National Library of Medicine (NLM).
- Urge the National Coordinator for the Office of the National Coordinator for Health Information Technology (ONCHIT), the National Library of Medicine (NLM) at the National Institutes of Health (NIH), the Agency for Healthcare Research and Quality (AHRQ), and the Centers for Medicare and Medicaid Services (CMS) to conduct outreach activities to all public and private sector organizations which have demonstrated capabilities in health information technology, particularly to those who have demonstrated capabilities in disease management technology as it relates to saving health care dollars, and improving care for chronically ill individuals and the workforce.

Chairman Specter and members of the subcommittee, thank you for the opportunity to present this written statement regarding the importance of health information technology, specifically as it relates to disease management technology, saving health care dollars, and improving care for chronically ill individuals and the workforce.

Matria Healthcare is a national leader in disease management. Our disease management programs have been adopted by leading corporations, health plans, and State governments as a proven solution for reducing costs and improving health and productivity. Because 15 percent of the population typically drives 85 percent of

healthcare costs, Matria believes the strongest, most effective healthcare solutions start with a strong disease management program to begin curbing costs immediately.

The disease management component of Matria's health enhancement offering provides management programs for the Nation's most costly chronic diseases, episodic conditions, and issues affecting the psychosocial well-being of patients and has produced outcomes like no other provider. Matria's industry-leading TRAX technology platform represents the state-of-the-art in healthcare data warehousing and protocol-driven healthcare delivery. This platform is driving the clinical and financial outcome success of Matria in over one hundred Fortune 1000, health plan, and State government programs. Matria's technology platform is being utilized by members of the National Coordinator for Health Information Technology's Interoperability Consortium to successfully improve clinical outcomes and reduce healthcare expenditures amongst its employees.

In April 2004, President Bush revealed his vision for the future of healthcare in the United States. The President's plan involves a health care system that puts the needs of the patient first, is more efficient, and is cost-effective. At this time, he established, within the Office of the Secretary of Health and Human Services, an Office of the National Coordinator for Health Information Technology (ONCHIT). Among other things, this office is meant to ensure that appropriate information is available to guide medical decisions, improve healthcare quality, reduce healthcare costs resulting from inefficiency, medical errors, inappropriate care, and incomplete information, promote a more efficient marketplace, greater competition, and increase in choice, and improve the coordination of care and information among hospitals, laboratories, physician offices, and other ambulatory care providers.

Matria's health enhancement offerings are consistent with these goals of the President and the ONCHIT. In the transition towards a health care system where informed consumers will own their personal health records, health savings accounts, and health insurance, it is important for the Federal Government to partner with public and private sector organizations which have demonstrated capabilities in this arena.

Health information technology will improve the practice of medicine and make it more efficient. The rapid implementation of secure and interoperable electronic health records will, for example, significantly improve the safety, quality, and cost-effectiveness of health care. To implement this vision, Matria urges the subcommittee to support the President's budget request of \$116 million for the ONCHIT to provide strategic direction for development of a national interoperable health care system. Matria also encourages the subcommittee to support the \$50 million Health Information Technology Initiative through the Agency for Healthcare Research and Quality (AHRQ) to accelerate the development, adoption, and diffusion of interoperable information technology in a range of health care settings. Additionally, Matria urges the subcommittee to provide a 5 percent increase for fiscal year 2007 to the National Institutes of Health (NIH) budget, and within NIH, provide a proportional increase of 5 percent to the National Library of Medicine (NLM).

Finally, Matria encourages the subcommittee to urge the National Coordinator for the ONCHIT, NLM, AHRQ, and the Centers for Medicare and Medicaid Services (CMS) to conduct outreach activities to all public and private sector organizations which have demonstrated capabilities in health information technology, particularly to those who have demonstrated capabilities in disease management technology as it relates to saving health care dollars, and improving care for chronically ill individuals and the workforce.

By working together, the goal of creating an efficient national healthcare system will be realized. Thank you for allowing me to submit this testimony to you today.

PREPARED STATEMENT OF THE NATIONAL ALLIANCE TO END HOMELESSNESS

The National Alliance to End Homelessness (the Alliance) is a nonpartisan, non-profit organization that has several thousand partner agencies and organizations across the country. These partners are local faith-based and community-based non-profit organizations and public sector agencies that provide homeless people with shelter, transitional and permanent housing, and services such as substance abuse treatment, job training, and health and mental health care. In addition, we have supported over 220 State and local entities as they create 10 year plans to end homelessness. The Alliance represents a united effort to address the root causes of homelessness and challenge society's acceptance of homelessness as an inevitable by-product of American life.

Overview.—Adequate social services program funding is essential to ending homelessness. Housing must be coupled with appropriate services such as health care, employment preparation, mental health and substance abuse treatment, child care, and youth directed programs to be effective. These programs were put to the test as social service agencies assisted Katrina evacuees. The Social Services Block Grant, the Community Services Block Grant, Projects for Assistance in Transition from Homelessness, Education for Homeless Children and Youth funded school liaisons and Health Care for the Homeless clinics among others were essential as the gulf coast residents overcame their housing crisis. These lessons illustrate how HHS, Labor, and Education programs can help those homeless due to other crises such as job loss or catastrophic illness.

GOALS

1. *Moving Forward to End Homelessness.*—By implementing 10 year plans to end homelessness, communities across America are ending homelessness. Communities are using Federal, State, and local funds to help homeless persons, some of whom have been homeless for years, maintain housing. It is important that this progress not be undermined. To this end, the Alliance recommends the following:

A. Allocate \$55 million for services in permanent supportive housing within SAMHSA's Center for Mental Health Services.

B. Reject cuts to the Grants for the Benefit of Homeless Individuals/Treatment for Homeless Individuals (GBHI) and insure that additional local programs can access these funds.

C. Increase funding to Projects for Assistance in Transition from Homelessness (PATH) to \$65 million.

D. Increase the Runaway and Homeless Youth Act Programs to \$140 million and reject detrimental policy recommendations.

E. Fund Education for Homeless Children and Youth services at its full authorized level of \$70 million.

F. Increase funding for the Homeless Veterans Reintegration Program to \$50 million.

2. *Connecting Homeless Families, Individuals, and Youth to Mainstream Services.*—The estimated 3.5 million people who are homeless throughout a year depend on mainstream programs such as the ones below to live day to day and once housed, remain housed. These programs help address the complex situations persons experiencing homelessness are trying to overcome. The Alliance recommends the following to meet this goal:

A. Fund the Social Services Block Grant at \$1.7 billion, the same funding level as fiscal year 2006.

B. Reject elimination of the Community Services Block Grant.

C. Appropriate \$171 million for the Health Care for the Homeless programs within the Health Resource Services Administration's Consolidated Health Centers program.

D. Appropriate \$60 million in education and training vouchers for youth exiting foster care under the Safe and Stable Families Program.

Goal #1—Moving Forward to End Homelessness

Support Services for Permanent Supportive Housing Projects

The Alliance recommends allocating \$55 million for services in permanent supportive housing within SAMHSA's Center for Mental Health Services. The administration has set a goal of ending chronic homelessness by 2012. We know this goal is attainable based on evidence based practices. For example, through the collaborative initiative grants program, HHS, the Department of Veterans Affairs, and HUD have funded programs and seen results. These eleven grants have ended homelessness for 550 people who cumulatively had over 5,000 years of homelessness. Unfortunately, funding for these grants will end in 2006. The President has proposed an increase of \$209 million for the McKinney/Vento homelessness programs as part of the proposed fiscal year 2007 HUD budget to primarily pay for housing for those who are chronically homeless. No such investment has been included for HHS.

Treatment for Homeless Individuals

The Alliance recommends that Congress fully reject cuts in Grants for the Benefit of Homeless Individuals (GBHI) funding and work to strengthen the program for additional grantees. Maintaining programs such as GBHI is essential to achieving the President's goal of ending chronic homelessness by 2012. Mainstream health, welfare, addiction, and mental health programs often do not adequately serve homeless

people. In 2003, the U.S. Department of Health and Human Services studied mainstream programs and their ability to serve chronically homeless populations. The report, entitled *Ending Chronic Homelessness: Strategies for Action*, explained that no mainstream program is comprehensive enough to adequately serve chronically homeless people. Thus, HHS included in the recommendations that future program budgets should focus on funding programs directed for chronic homelessness.

There are a variety of reasons mainstream programs fail to adequately service people who are chronically homeless. Many programs simply lack the ability to fund or coordinate the full range of health, housing, and support services required to adequately help homeless people. Grants through the Treatment for Homeless Individuals/Grants for the Benefit of Homeless Individuals (GBHI) program help homeless service providers assemble services that meet the complex needs of their clients and maintain their housing.

Projects for Transition Assistance from Homelessness (PATH)

The Alliance recommends that Congress increase PATH funding to \$65 million. The PATH program provides homeless people with serious mental illnesses access to mental health services. PATH focuses on outreach to eligible consumers, followed by help in ensuring that those consumers are connected with mainstream services. Under the PATH formula grant, approximately 30 States share in the program's annual appropriations increases. The remaining States and territories receive the minimum grant of \$300,000 for States and \$50,000 for territories. These amounts have not been raised since the program was authorized in 1991. To account for inflation, the minimum allocation should be raised to \$600,000 for States and \$100,000 for territories. Amending the minimum allocation requires a legislative change. If the authorizing committees do not have sufficient time to address this issue, we hope that appropriators will explore ways to make the amendment through appropriations bill language.

Runaway and Homeless Youth Programs

The Alliance recommends funding the Runaway and Homeless Youth Act (RHYA) programs at \$140 million. RHYA programs support cost-effective, community and faith-based organizations that protect youth from the harms of life on the streets. The problems of homeless and runaway youth are addressed by the Administration for Children and Families within HHS, which operates coordinated competitive grant programs like RHYA. The RHYA programs can either reunify youth safely with family or find alternative living arrangements. RHYA programs end homelessness by: engaging youth living on the street with Street Outreach Programs, quickly providing emergency shelter and family crisis counseling through the Basic Centers, or providing supportive housing that helps young people develop lifelong independent living skills through Transitional Living Programs.

Education for Homeless Children and Youth

The Alliance recommends funding Education for Homeless Children and Youth (EHCY) at its full authorized level of \$70 million. The most important potential source of stability for these children is school. The mission of the Education for Homeless Children and Youth program is to ensure that homeless children can continue to attend school and thrive. A struggle for homeless service providers who serve families with children is to maintain the children's stability during a time when their lives are turned upside down. Even if new housing can be found in a short time, the lasting effects of a spell of homelessness can be devastating.

The Education for Homeless Children and Youth program, within the Department of Education's Office of Elementary and Secondary Education, removes obstacles to enrollment and retention by establishing liaisons between schools and shelters and providing funding for transportation, tutoring, school supplies, and the coordination of statewide efforts to remove barriers.

Homeless Veterans Reintegration Program (HVRP)

The Alliance recommends that Congress increase HVRP funding to \$50 million. HVRP, within the Department of Labor's Veterans Employment and Training Service (VETS), provides competitive grants to community-based, faith-based, and public organizations to offer outreach, job placement, and supportive services to homeless veterans. HVRP is the primary employment services program accessible by homeless veterans and the only targeted employment program for any homeless subpopulation. The Department of Labor estimates that 8,750 homeless veterans will be served through HVRP at the fiscal year 2006 appropriation level of \$22 million. This figure represents just 2 percent of the overall homeless veteran population, which the Department of Veterans Affairs estimates numbers more than 400,000 over the course of a year. An appropriation at the authorized level of \$50

million would enable HVRP grantees to reach approximately 19,866 homeless veterans.

Goal #2—Connecting Homeless Families, Individuals and Youth to Mainstream Services

Social Services Block Grant (SSBG)

The Alliance recommends that Congress fully restore SSBG funding to its fiscal year 2006 level of \$1.7 billion. Cuts to programs like the SSBG will create additional barriers for communities trying to achieve the President's goal of ending chronic homelessness by 2012. SSBG funds are essential for programs dedicated to ending homelessness. In particular, youth housing programs and permanent supportive housing providers often receive State, county, and local funds which originate from the SSBG. As the U.S. Department of Housing and Urban Development has focused its funding on housing, programs that provide both housing and social services have struggled to fund the service component of their programs. This gap is often closed using Federal programs such as SSBG.

Community Services Block Grant (CSBG)

The Alliance recommends that Congress fully restore CSBG funding to its fiscal year 2006 level of \$630 million. Eliminating funding for the CSBG will destabilize the progress communities have made toward ending homelessness by not only ending services directly provided by CSBG funds but limiting a community's ability to access other Federal dollars such as those provided by HUD. This runs contrary to the President's stated goal of ending chronic homelessness by 2012. Community Action Agencies (CAAs) are directly involved in housing and homelessness services. In several communities, CAAs lead the Continuum of Care (CoC). CoCs coordinate local homeless service providers and the community's McKinney-Vento Homeless Assistance Grant application process with the Department of Housing and Urban Development.

In the fiscal year 2004 Community Services Block Grant Information Systems report published by the U.S. Department of Health and Human Services, CAAs reported administering \$207.4 million in Section 8 vouchers, \$30 million in Section 202 services¹ and \$271.1 million in other Department of Housing and Urban Development (HUD) programs which includes homeless program funding.²

Health Care for the Homeless (HCH)

The Alliance recommends \$171 million, the amount recommended by the President, for HCH (8.7 percent of the \$1.963 billion requested for the Consolidated Health Centers account). Persons living on the streets suffer from health problems resulting from or exacerbated by the conditions of being homeless, such as hypothermia, frostbite, and heatstroke. In addition, they often have infections of the respiratory and gastrointestinal systems, tuberculosis, vascular diseases such as leg ulcers, and hypertension.³ Health care for the homeless programs are vital to prevent these conditions from becoming fatal. Congress allocates 8.7 percent of the Consolidated Health Centers account for Health Care for the Homeless (HCH) projects. The HCH program has achieved significant success since its inception in 1987, but the health care needs Americans experiencing homelessness each year far exceed the service capacity of Health Care for the Homeless grantees. The President's fiscal year 2007 budget would create 15 to 20 new projects, serving an additional 25,000 to 30,000 people experiencing homelessness.

Foster Youth Education and Training Vouchers

The Alliance recommends that Congress appropriate \$60 million in education and training vouchers for youth exiting foster care under the Safe and Stable Families Program. The Education and Training Voucher Program offers funds to foster youth and former foster youth to enable them to attend colleges, universities and vocational training institutions. Students may receive up to \$5,000 a year for college or vocational training education. The funds may be used for tuition, books, housing, or other qualified living expenses. Given the large number of people experiencing homelessness who have a foster care history, it is important to provide assistance such as these education and training vouchers to stabilize youth, prevent economic crisis, and prevent possible homelessness.

¹Section 202 is dedicated to housing from elderly and disabled individuals and families.

²U.S. Department of Health and Human Services, Administration of Children and Families. The Community Services Block Grant Fiscal Year 2004 Statistical Report. Prepared by the National Association for State Community Services Programs.

³Harris, Shirley N, Carol T. Mowbray and Andrea Solarz. Physical Health, Mental Health and Substance Abuse Problems of Shelter Users. Health and Social Work, Vol. 19, 1994.

CONCLUSION

Homelessness is not inevitable. As communities implement plans to end homelessness, they are struggling to find funding for the services homeless and formerly homeless clients need to maintain housing. The Federal investments in mental health services, substance abuse treatment, employment training, youth housing, and case management discussed above will help communities create stable housing programs and change social systems which will end homelessness for millions of Americans.

PREPARED STATEMENT OF THE NATIONAL ASSOCIATION OF COMMUNITY HEALTH CENTERS

On behalf of more than 1,000 health center grantees across the country serving more than 15 million patients, the National Association of Community Health Centers (NACHC) is pleased to submit this statement for the record, and thank the subcommittee for its continued support and investment in the Health Centers program.

ABOUT HEALTH CENTERS

Over more than 40 years, the Health Centers program has grown from a small demonstration project providing desperately needed primary care services in underserved communities to one of the fundamental elements of our Nation's health care safety net. Funding was approved in 1965 for the first two neighborhood health center demonstration projects, one in Boston, Massachusetts, and the other in Mound Bayou, Mississippi.

Today, America's health centers are helping communities meet escalating health needs and address costly and devastating health problems, from prenatal and infant health development to chronic illness (like diabetes and asthma), to mental health, substance addiction, domestic violence and HIV/AIDS. Health centers are the family doctor for 1 in 8 uninsured individuals, and 1 in every 5 low-income children. Health centers serve as the primary health care safety net for many communities across the country and the Federal grant program enables more low-income and uninsured patients to receive care each year.

Every Federally Qualified Health Center (FQHC) is governed by a community board with a patient majority—a true patient democracy. Health centers are required to be located in a federally designated Medically Underserved Area (or MUA), and must provide a package of comprehensive primary care services to anyone who comes in the door, regardless of their ability to pay. At the typical health center, roughly one-quarter of the operating revenues are from the Federal grant; and just over 40 percent are from reimbursement through Federal insurance programs, principally Medicare and Medicaid. The balance of the revenues are from State and community partnerships, privately insured individuals, and patients ability to pay.

The Health Centers program is administered by the Bureau of Primary Health Care (BPHC) at the Health Resources and Services Administration (HRSA), within the U.S. Department of Health and Human Services (HHS).

FUNDING BACKGROUND

The subcommittee has approved substantial funding increases for the Consolidated Health Centers program over the past several years resulting in a broad expansion effort to serve many of those that remain underserved in our country. Most recently, the increase in funding approved for fiscal year 2006 will help more than 600,000 additional Americans gain access to effective, affordable primary and preventive care services offered by our Nation's Health Centers.

Since 2001, the subcommittee has increased funding for Health Centers in order to stabilize existing centers and meet the goals of the President's initiative—1,200 new or expanded centers and an additional 6.1 million patients served by 2006. To date, the expansion has brought high-quality services to an additional 4 million Americans and has produced new or expanded facilities in over 800 communities nationwide. Even with the increases provided over the past several years, hundreds of communities submitted applications that received high ratings but could not be funded, due to lack of funds. There is clearly a tremendous need and a tremendous desire to expand health center services to new communities.

The health centers program has succeeded in expanding access to primary and preventive care services in underserved communities across the country. The Office of Management and Budget rated the Health Centers program as one of the top 10 Federal programs, and the best competitive grant program within all of HHS. With

additional resources, health centers stand ready to provide low-cost, highly effective care to millions more uninsured and underserved individuals and families.

FISCAL YEAR 2007

In his fiscal year 2007 budget proposal, President Bush requested an increase for the Health Centers program of \$181 million, for a total funding level of \$1.963 billion in fiscal year 2007. NACHC strongly supports the President's requested increase for the program, which will continue the historic expansion of the Health Centers program into hundreds of additional communities nationwide.

In 2005, President Bush called for "a community health center in every poor county" in America. NACHC strongly supports this goal and urges Congress to provide funds to begin this critical expansion effort. NACHC was encouraged that the administration did not recommend waiving the statutorily designated proportionality requirements for Migrant, Public Housing and Homeless Health Centers in order to implement this second expansion initiative.

In addition to the expansion efforts, it is critical that Federal funding for health centers keep pace with the growing cost of delivering care. NACHC requests that the subcommittee designate \$50 million of any increase in funding to be used to make base grant adjustments for existing centers, allowing an average increase of 2.8 percent in current health center grants, equal to the Medicare Economic Index. Under the subcommittee's leadership, Congress has provided base grant adjustments for existing centers in 5 out of the 7 previous fiscal years. A recent study by NACHC found that in the 2 years that these adjustments were not included in the Health Centers appropriation, the number of patient visits per grantee actually decreased.

NACHC appreciates the subcommittee's leadership in stabilizing the Federal Tort Claims Act (FTCA) judgment fund for health centers in past years. For fiscal year 2007, the President has requested that \$44,500,000 be appropriated for this purpose. This is the same funding level as last year, and NACHC expects it will be sufficient to cover FTCA claims in 2007.

In 1997, Congress authorized and began funding the HRSA Loan Guarantee Program (LGP) for the construction, renovation, and modernization of health centers. Demand for this guarantee program has accelerated significantly in the last year. NACHC expects that at the current rate of usage, the remaining \$5 million in credit subsidy will be entirely used during fiscal year 2006. In response that the success of this program, NACHC is requesting an additional \$5 million be provided until expended for additional loan guarantees. The LGP has proven to be a vital resource for health centers across the country as they seek financing to fund the facilities necessary to accommodate the growth in patient visits resulting from recent expansion efforts.

Finally, Health Centers support funding for other Federal programs that are integral to the continued expansion and strength of community health centers. These include:

- \$150 million for the National Health Service Corps, which is the largest source of health professionals for health centers;
- \$250 million for Title III of the Ryan White CARE Act, which provides grants to health centers and other safety net providers for outpatient early intervention services;
- \$550 million for Title VII and Title VIII Health Professions programs, particularly Area Health Education Centers, which bring together academic and community partners to improve the supply and distribution of health professionals in underserved communities.
- \$170 million for health information technology (HIT) resources through various programs at the Department of Health and Human Services. Health centers must have adequate resources through HHS to facilitate the utilization of electronic health records and other important HIT tools to promote health disparities reduction.

CONCLUSION

America's health centers are grateful to the subcommittee for its ongoing efforts to support and stabilize the Health Centers program and to expand health centers' reach into more than 5,000 communities nationwide. As a result of those efforts, more than 15 million people have access to the affordable, effective primary care services that our Nation's health centers provide.

We respectfully ask that the subcommittee continue that investment, as the work of caring for our uninsured and medically underserved is far from complete. Some 36 million Americans are still without regular access to medical services. America's

health centers look forward to meeting that need and rising to the challenge of providing a health care system that works for all Americans. We look forward to working with you over the coming year to move toward that goal.

If you need any additional information or have any questions related to health centers or NACHC, please do not hesitate to contact me or John Sawyer, Assistant Director of Federal Affairs, at (202) 331-4603, or via email at jsawyer@nachc.com.

PREPARED STATEMENT OF THE NATIONAL ASSOCIATION FOR STATE COMMUNITY SERVICES PROGRAMS

The National Association for State Community Services Programs (NASCSPP) thanks this committee for its continued support of the Community Services Block Grant (CSBG), and seeks an appropriation of \$650 million for the State grant portion of the CSBG, the same as its fiscal year 2004 appropriation. We are requesting that the CSBG funding be restored to the fiscal year 2004 level this year in order for the CSBG Network to continue addressing the long-term needs of those families affected by Hurricanes Katrina and Rita, those families transitioning from welfare to work, and to assist low-income workers in remaining at work through supportive services such as transportation and child care. It is essential that the CSBG funding be restored in full for fiscal year 2007. The across the board cuts the CSBG has experienced the past several years have decreased the ability of the CSBG Network to provide essential services to low-income Americans.

In addition, NASCSPP urges this Committee to eliminate all authorization language regarding the management of the CSBG from the fiscal year 2007 appropriation bill. In fiscal year 2006, the appropriations bill included authorization language regarding the use of the block grant at the State level. Specifically, the fiscal year 2006 appropriations report included the following authorization language which conflicted with "SEC. 675C. USES OF FUNDS (A)(3) of the Public Law 105-285: The Community Opportunities, Accountability, and Training and Educational Services Act of 1998 (the CSBG authorization law): "That to the extent Community Services Block Grant funds are distributed as grant funds by a State to an eligible entity as provided under the Act, and have not been expended by such entity, they shall remain with such entity for carryover into the next fiscal year for expenditure by such entity consistent with program purposes."

The 1998 CSBG Authorization allows CSBG eligible entities to carry over up to 20 percent of funds but requires the State to recapture or redistribute any funds that exceed 20 percent. According to the 1998 CSBG Authorization, once these funds are recaptured the State is to redistribute the excess funds to other low-income communities in dire need of additional funds. When language such as the above is placed in the Appropriations document, it overrides the Authorization language. The inclusion of such language in the appropriations report caused a hardship on States as they managed the block grant. Passing national legislation which contradicts the authorization language regarding the distribution of funds preempts the prerogative of States. NASCSPP urges the committee to discourage the incorporation of authorization language in the appropriations act.

NASCSPP is the national association that represents State administrators of the Community Services Block Grant (CSBG), and State directors of the Department of Energy's Low-Income Weatherization Assistance Program.

BACKGROUND

The States believe the Community Services Block Grant (CSBG) is a unique block grant that has successfully devolved decision making to the local level. Federally funded with oversight at the State level, the CSBG has maintained a local network of nearly 1,100 agencies which coordinate nearly \$9.7 billion in Federal, State, local, and private resources each year. Operating in 99 percent of counties in the Nation and serving nearly 15.2 million low-income persons, local agencies, known as Community Action Agencies (CAAs), provide services based on the characteristics of poverty in their communities. For one town, this might mean providing job placement and retention services; for another, developing affordable housing; in rural areas it might mean providing access to health services or developing a rural transportation system.

Since its inception, the CSBG has shown how partnerships between States and local agencies benefit citizens in each State. We believe it should be looked to as a model of how the Federal Government can best promote self-sufficiency for low-income persons in a flexible, decentralized, non-bureaucratic and accountable way.

Long before the creation of the Temporary Assistance for Needy Families (TANF) block grant, the CSBG was setting the standard for private-public partnerships that

work to the betterment of local communities and low-income residents. Family oriented, while promoting economic development and individual self-sufficiency, the CSBG relies on an existing and experienced community-based service delivery system of CAAs and other non-profit organizations to produce results for its clients.

MAJOR CHARACTERISTICS OF THE COMMUNITY SERVICES NETWORK

Emergency Response.—CAAs are utilized by Federal and State emergency personnel as a frontline resource to deal with emergency situations such as floods, hurricanes and economic downturns. They are also relied on by citizens in their community to deal with individual family hardships, such as house fires or other emergencies.

In fact, during and after Hurricane Katrina and Rita the State CSBG offices and local CAAs quickly mobilized to provide immediate and long-term assistance to over 355,000 evacuees. This immediate assistance included, but was not limited to, transportation, food, medical check-ups, housing, utility deposits, job placement, and clothing. State CSBG offices and CAAs across the country coordinated their relief efforts with other agencies providing disaster relief assistance such as FEMA, Red Cross, and other faith-based and community-based organizations.

State CSBG offices through their local network of CAAs continue to provide the long-term assistance evacuees will need as they relocate and re-establish themselves through self-sufficiency and family development programs. These programs offer comprehensive approaches to selecting and offering supportive services that promote, empower and nurture the individuals and families seeking economic self-sufficiency. At a minimum, these approaches include:

- A comprehensive assessment of the issues facing the family or family members and of the resources the family brings to address these issues;
- A written plan for becoming more financially independent and self-supporting;
- A comprehensive mix of services that are selected to help the participant implement the plan;
- Professional staff members who are flexible and can establish trusting, long-term relationships with program participants; and
- A formal methodology used to track and evaluate progress as well as to adjust the plan as needed.

Additional information on the CSBG Network's Hurricane Katrina relief efforts may be found in the attached issue brief.

Accountable.—The Federal Office of Community Services, State CSBG offices and CAAs have worked closely to develop a results-oriented management and accountability (ROMA) system. Through this system, individual agencies determine local priorities within six common national goals for CSBG and report on the outcomes that they achieved in their communities.

Leveraging Capacity.—For every CSBG dollar they receive, CAAs leverage \$4.87 in non-federal resources (State, local, and private) to coordinate efforts that improve the self-sufficiency of low-income persons and lead to the development of thriving communities.

Volunteer Mobilization.—CAAs mobilize volunteers in large numbers. In fiscal year 2004, the most recent year for which data are available, the CAAs elicited more than 44 million hours of volunteer efforts, the equivalent of almost 21,182 full-time employees. Using just the minimum wage, these volunteer hours are valued at nearly \$227 million.

Locally Directed.—Tri-partite boards of directors guide CAAs. These boards consist of one-third elected officials, one-third low-income persons and one-third representatives from the private sector. The boards are responsible for establishing policy and approving business plans of the local agencies. Since these boards represent a cross-section of the local community, they guarantee that CAAs will be responsive to the needs of their community.

Adaptability.—CAAs provide a flexible local presence that governors have mobilized to deal with emerging poverty issues.

The statutory goal of the CSBG is to ameliorate the effects of poverty while at the same time working within the community to eliminate the causes of poverty. The primary goal of every CAA is self-sufficiency for its clients. Helping families become self-sufficient is a long-term process that requires multiple resources. This is why the partnership of Federal, State, local, and private enterprise has been so vital to the successes of the CAAs.

WHO DOES THE CSBG SERVE?

National data compiled by NASCSP show that the CSBG serves a broad segment of low-income persons, particularly those who are not being reached by other pro-

grams and are not being served by welfare programs. Based on the most recently reported data, from fiscal year 2004:

- More than 2.7 million customer families have incomes at or below the poverty level; 1.1 million customer families have incomes at or below 50 percent of the poverty guidelines. In 2004, the poverty level for a family of three was \$15,670.
- 58 percent of adults have a high school diploma or equivalency certificate.
- 44 percent of all customer families are “working poor” and have wages or unemployment benefits as income.
- 23 percent depend on pensions and Social Security and are therefore poor, former workers.
- Almost 430,000 families are TANF participants, 22 percent of the average monthly TANF caseload.
- Nearly 60 percent of families assisted have children under 18 years of age.

WHAT DO LOCAL CSBG AGENCIES DO?

Since Community Action Agencies operate in rural areas as well as in urban areas, it is difficult to describe a typical Community Action Agency. However, one thing that is common to all is the goal of self-sufficiency for all of their clients. Reaching this goal may mean providing day care for a struggling single mother as she completes her General Equivalency Diploma (GED) certificate, moves through a community college course and finally is on her own supporting her family without Federal assistance. It may mean assisting a recovering substance abuser as he seeks employment. Many of the Community Action Agencies’ clients are persons who are experiencing a one-time emergency. Others have lives of chaos brought about by many overlapping forces—a divorce, sudden death of a wage earner, illness, lack of a high school education, closing of a local factory or the loss of family farms.

CAAs provide access to a variety of opportunities for their clients. Although they are not identical, most will provide some if not all of the services listed below:

- a variety of crisis and emergency safety net services;
- employment and training programs;
- transportation and child care for low-income workers;
- individual development accounts;
- micro business development help for low-income entrepreneurs;
- local community and economic development projects;
- housing and weatherization services;
- Head Start;
- energy assistance programs;
- nutrition programs;
- family development programs; and
- senior services.

CSBG funds many of these services directly. Even more importantly, CSBG is the core funding which holds together a local delivery system able to respond effectively and efficiently, without a lot of red tape, to the needs of individual low-income households as well as to broader community needs. Without the CSBG, local agencies would not have the capacity to work in their communities developing local funding, private donations and volunteer services and running programs of far greater size and value than the actual CSBG dollars they receive.

CAAs manage a host of other Federal, State and local programs which makes it possible to provide a one-stop location for persons whose problems are usually multifaceted. Over half (52 percent) of the CAAs manage the Head Start program in their community. Using their unique position in the community, CAAs recruit additional volunteers, bring in local school department personnel, tap into religious groups for additional help, coordinate child care and bring needed health care services to Head Start centers. In many States they also manage the Low Income Home Energy Assistance Program (LIHEAP), raising additional funds from utilities for this vital program. CAAs may also administer the Weatherization Assistance Program and are able to mobilize funds for additional work on residences not directly related to energy savings that, for example, may keep a low-income elderly couple in their home. CAAs also coordinate the Weatherization Assistance Program with the Community Development Block Grant program to stretch Federal dollars and provide a greater return for tax dollars invested. They also administer the Women, Infants and Children (WIC) nutrition program as well as job training programs, substance abuse programs, transportation programs, domestic violence and homeless shelters, as well as food pantries.

EXAMPLES OF CSBG AT WORK

Since 1994, CSBG has implemented Results-Oriented Management and Accountability practices whereby the effectiveness of programs is captured through the use of goals and outcomes measures. Below you will find the network's first nationally aggregated outcomes achieved by individuals, families and communities as a result of their participation in innovative CSBG programs during fiscal year 2004:

- 103,057 participants gained employment with the help of community action (49 States reporting);
- 13,313 participants obtained “living wage” employment with benefits (35 States reporting);
- 88,187 low-income participants obtained safe and affordable housing in support of employment stability (43 States reporting);
- 510,322 low-income households achieved an increase in non-employment financial assets, including tax credits, child support payments, and utility savings, as a result of community action (\$133.5 million in aggregated savings);
- 5,645 families achieved home ownership as a result of community action assistance (41 States reporting);
- 56,283 low-income people obtained pre-employment skills and received training program certificates or diplomas (47 States reporting);
- 30,776 low-income people completed Adult Basic Education or GED coursework and received certificates or diplomas (40 States reporting);
- 9,647 low-income people completed post-secondary education and obtained a certificate or diploma (41 States reporting); and
- 2,284,577 new community opportunities and resources were created for low-income families as a result of community action work or advocacy, including “living wage” jobs, affordable and expanded public and private transportation, medical care, child care and development, new community centers, youth programs, increased business opportunity, food, and retail shopping in low-income neighborhoods (46 States reporting).

All the above considered, NASCSP urges this committee to fund the CSBG grant to the States at \$650 million.

PREPARED STATEMENT OF THE NATIONAL CONSUMER LAW CENTER

The National Consumer Law Center (NCLC),¹ on behalf of our low-income clients,² respectfully submits this testimony regarding the appropriation of funds for the Low Income Home Energy Assistance Program (LIHEAP)³ for fiscal year 2007. NCLC and our clients are strong supporters of LIHEAP, the primary safety net between low-income consumers and the disconnection of vital utility service. The high energy prices that squeeze the budgets of low-income households to the breaking point show no sign of abating. The recent National Energy Assistance Directors' Association (NEADA) national study on LIHEAP recipients documents the tremendous value of LIHEAP to low-income families as well as the severe sacrifices made by the poor to pay their home energy bills.⁴ Low-income families and fixed-income elderly clients continue to fall further behind as energy prices have reached a new, higher baseline. LIHEAP is essential for their safety and well being. We thank the subcommittee for its strong support of the LIHEAP program in the fiscal year 2006 appropriations process and, in light of the forecasted continued high energy prices, urge the subcommittee to consider fully appropriating LIHEAP at \$5.1 billion in regular LIHEAP funds for fiscal year 2007, the amount authorized under the Energy Policy Act of 2005, with advance appropriations of the same amount for fiscal year 2008.

Home Energy Prices Are At An All-Time High.—Residential energy prices were expected to continue to rise this year, but the disruption in the Gulf fuel refineries by the hurricanes sent them skyrocketing. Consequently, paying home energy bills has been all the more difficult for fixed income seniors and low-income households and has made LIHEAP all the more important for these vulnerable families. The

¹The National Consumer Law Center (NCLC) is a nonprofit organization that represents the interests of low-income consumers on a broad range of issues, including access to adequate and affordable supplies of utility service for home heating and cooling. This testimony was prepared by Olivia Wein, staff attorney in NCLC's Washington, DC office.

²The Appalachian People's Action Coalition (Ohio); Texas Legal Services Center; Action, Inc. (Gloucester, MA); Action for Boston Community Development, Inc.

³42 U.S.C. § 8621 et seq.

⁴National Energy Assistance Directors Association, National Energy Assistance Survey (April 2004) (NEADA survey) available at www.neada.org.

Center on Budget and Policy Priorities has acknowledged that this year marks the “largest 1-year jump in home heating prices in three decades.”⁵ According to Guy Caruso, Administrator of the Energy Information Administration at the U.S. Department of Energy, “several factors are driving up winter prices and expenditures: first, international factors such as low spare crude oil capacity and political tensions contribute to uncertainty and low supply growth for crude oil and high crude prices; second, recent hurricanes and associated disruptions exacerbate already tight markets in oil, petroleum products, and natural gas; and, finally, winter weather affects consumption and consequently household expenditures.”⁶ The summer heat is also dangerous, especially for the elderly, the very young and those with chronic diseases. Unfortunately, the vast majority of newer electric generation plants rely on natural gas, thus tying electricity prices to the volatile natural gas prices. Taking all of these factors into account, it is obvious how critical LIHEAP’s heating and cooling assistance is to the livelihood of so many families. The mounting increases in essential residential energy prices as illustrated in the chart below are putting more and more families’ health and safety at risk.

More Households Than Ever Cannot Keep Up With Costs Of Home Energy.—Although the costs of home energy have been a burden to most Americans, those with low incomes have been hurt the most. The salary for low-income Americans has stayed relatively flat while the cost of living has gone up, resulting in even more challenging struggles just to make ends meet for many families. According to Dr. Meg Power of Economic Opportunity Studies, families below 150 percent of the Federal poverty guideline spend on average about \$1,470 on energy costs, about 19 percent of their total yearly income. In 2005, however, low income families were expected to pay more than \$1,650.⁷ Those prices will only go up for 2006. Having their heat switched off is a real possibility for numerous low-income households, and although there are winter utility shut-off moratoria in place for many States, not every home is protected against energy shut-offs in the middle of winter. As we approach the lifting of winter shut-off moratoria, we expect to see a wave of disconnections as households are unable to afford the cost of the energy bills. In the summer, the inability to keep the home cool can be lethal, especially to seniors. According to the CDC, in 2001 300 deaths were caused by excessive heat exposure and seniors and young children are particularly vulnerable to heat stress.⁸ The CDC also notes that air-conditioning is the number one protective factor against heat-related illness and death.⁹

Iowa.—Despite milder winter temperatures this winter, the sharp rise in natural gas prices has set back a record number of low-income households in Iowa. The number of low-income households with past due energy accounts as of January 2006 is 14.7 percent higher than the same time last year and 162 percent higher than the number in January 1999. The total amount of arrearages of LIHEAP households has also grown sharply due to the increase in prices. By January 2006, the total amount of LIHEAP household arrearages had increased 32 percent from the same period in 2005 and 169 percent compared to the same period in 1999. The total number of LIHEAP households increased 8 percent from this same period last year.¹⁰

Ohio.—In Ohio, the number of households entering into the State’s low-income energy affordability program, the Percentage of Income Payment Program (PIPP), increased 23 percent from January 2005 to January 2006. The increase is even more dramatic at 84 percent, when comparing PIPP enrollment from January 2002 to January 2006. The total dollar arrearage amounts for PIPP customers also increased 27 percent from January 2005 to January 2006. Likewise, the total PIPP arrearages have increased dramatically, 84 percent, from January 2002 to January 2006. Ohio’s LIHEAP program expects to provide heating assistance to almost 5 percent more households in fiscal year 2006 than in fiscal year 2005 (and almost 30

⁵ Center on Budget and Policy Priorities. “Steep Spike in Energy Costs Increases Low-Income Households’ Need For Help Paying Heating Bills This Winter” (Oct. 6, 2005).

⁶ Statement of Guy Caruso, Administrator for the Energy Information Administration, U.S. Department of Energy before the Committee on Energy and Natural Resources, United States Senate. Full Committee Hearing—Winter Fuels Outlook (Oct. 18, 2005).

⁷ Meg Power, PhD. Economic Opportunity Studies. “Energy Bills of Low-Income Consumers in Fiscal Year 2005, The Resources Available to Help Them Pay, and the Impact on Their Household Budgets” (Nov. 23, 2004).

⁸ CDC, “Extreme Heat: A Prevention Guide to Promote Your Personal Health and Safety” available at www.bt.cdc.gov/disasters/extremeheat/heat_guide.asp.

⁹ Id.

¹⁰ National Energy Assistance Directors, “Est. Total Households Receiving LIHEAP Heating Assistance by State—Projected Applications for Fiscal Year 2006” (2/13/06).

percent more households when compared to Ohio households that received heating assistance in fiscal year 2002).¹¹

Pennsylvania.—Utilities in Pennsylvania that are regulated by the Pennsylvania Public Utility Commission (PA PUC) have established universal service programs that assist utility customers in paying bills and reducing energy usage. Even with these programs, electric and natural gas utility customers find it difficult to keep pace with their energy burdens. The PA PUC estimates that approximately 21,000 households entered the current heating season without heat-related utility service—this number includes about 4,000 households who are heating with potentially unsafe heating sources such as kerosene space heaters. This is an increase of 68 percent when compared to the average number entering the heating season without heat for the years 2000–2003. An additional 17,500 residences where service was previously terminated are now vacant.¹² In 2005, the number of terminations increased 52 percent compared with terminations in 2004.¹³ As of January 2006, 17.48 percent of residential electric customers and 18.19 percent of natural gas customers are overdue on their energy bills. As of February 2006, Pennsylvania projected serving 354,065 LIHEAP applicants in fiscal year 2005, an 8.2 percent increase over the prior year.¹⁴

LIHEAP Helps These Vulnerable Households.—Growing utility arrearages for low-income households will only place these fragile households on a downward spiral towards disconnections. Adequate LIHEAP assistance can help families facing terminations, but, even more importantly, adequate LIHEAP appropriations can help struggling families maintain vital energy services and protect the health and safety of vulnerable seniors, families with young children or disabled family members. The recent NEADA national energy assistance survey found that 48 percent of LIHEAP recipients would have had their electricity or home heating fuel discontinued if LIHEAP had not been available.¹⁵

The Need For LIHEAP Is Greater Than Ever.—The continued sharp rise in residential energy prices is expected for the near future. The data from Iowa, Ohio and Pennsylvania, which are amongst the few States that collect residential utility customer payment data, show that even in a milder than normal winter, the prices have risen to such a degree that an increasing number of low-income households is falling behind. This year's dramatic rise in residential energy prices has yielded the greatest number of LIHEAP applications in 12 years.¹⁶ Last year, the number of eligible recipients for LIHEAP climbed to 32 million; however, only around 5 million were able to benefit from it.

The Consequences Of Unaffordable Energy Bills Are Dire.—When people are unable to afford paying their home energy bills, many dangerous and unhealthy actions are often taken. Common practices include resorting to alternative heating sources, such as space heaters, ovens and burners, all of which are huge fire hazards; numerous deaths due to fires started by space heaters have already occurred this year and are a recurring problem every year. According to the U.S. Consumer Product Safety Commission, about 25,000 fires in homes are caused by space heaters and 300 people are killed because of them every year in the United States.¹⁷ Other dangerous practices include illegal gas hookups that create dangerous gas leaks, keeping the thermostat at unhealthy and sometimes hypothermic temperatures (and hyperthermic temperatures in the summer). Those who cannot afford their winter heating bill often face dire choices such as sacrificing food, medical care or prescription medicine.¹⁸ In the summer, the inability to afford cooling bills can result in heat-related deaths and illness. The loss of essential utility services can be devastating, especially for poor families that can find themselves facing the pros-

¹¹ Based on data from the National Energy Assistance Directors, "Est. Total Households Receiving LIHEAP Heating Assistance by State—Projected Applications for Fiscal Year 2006 (2/13/06)" and "Estimated Total Households Receiving LIHEAP Heating Assistance by State Actuals in 2002, 2003; Projected in 2004." Available at www.neada.org.

¹² http://www.puc.state.pa.us/general/press_releases/press_releases.aspx?ShowPR=1435.

¹³ http://www.puc.state.pa.us/general/pdf/Terminations_Table_Jan-Dec04-05.pdf

¹⁴ http://www.neada.org/news/news060213_liheap06projections.pdf

¹⁵ NEADA Survey, Table 47.

¹⁶ http://www.neada.org/news/news060213_liheap06projections.pdf.

¹⁷ U.S. Department of Energy: A Consumer's Guide to Energy Efficiency and Renewable Energy. http://www.eere.energy.gov/consumer/your_home/space_heating_cooling/index.cfm/mytopic=12600.

¹⁸ NEADA Survey, Table 39. To pay their energy bills, 22 percent of LIHEAP recipients went without food, 38 percent went without medical or dental care, 30 percent did not fill or took less than the full dose of a prescribed medicine.

pects of hypothermia in the winter, hyperthermia in the summer,¹⁹ eviction, property damage from frozen pipes, the use of dangerous alternative sources of heat,²⁰ and the potential threat of the intervention of child welfare agencies.²¹ Studies have also demonstrated the clear links between homelessness and utility disconnections, as well as the connections between unaffordable utility service and the disruption to families and children's education. LIHEAP works to bring fuel costs within a manageable range for low-income households. There are other societal benefits to a strong LIHEAP. A recent study documents an association between receipt of LIHEAP assistance and a reduced incidence of undernutrition in young children.²²

People are putting themselves at risk when they do not have sufficient funds to pay their home energy bills, but LIHEAP can and does come to their aid and does greatly alleviate some of the hardship caused by high energy bills. With the assistance of LIHEAP, households will not have to make such unconscionable, dangerous sacrifices.

The Need for Advance Appropriations is Critical.—The timing of the release of the LIHEAP block grant to the States is critical for the effective and efficient operation of the State programs. The normal appropriations process leaves very little time between enactment of the Labor-HHS-Education spending bill and the start of most States' heating programs. An advance appropriation is essential for States to determine income guidelines and benefit levels well ahead of time and for properly planning the components of their program year (e.g., amounts set aside for heating, cooling and emergency assistance, weatherization, self sufficiency and leveraging activities). Without advance appropriations, delayed passage of the spending bill can force States to open their winter heating program without knowledge of their final grant amount. Advance appropriations shield States from disruption of the start-up of their winter heating programs if there is a delay in the passage of the Labor-HHS-Education spending bill.

LIHEAP Works.—LIHEAP is a targeted block grant that assists vulnerable low-income households with the costs of home energy. According to the U.S. Department of Health and Human Services, one-third of households receiving LIHEAP heating and cooling assistance had an elderly member; over 30 percent of households receiving heating and cooling assistance had a member with a disability; and almost one third of households receiving heating assistance and around a fifth of households receiving cooling assistance had young children. In fiscal year 2001, LIHEAP recipient households had a mean individual energy burden almost five times the energy burden for non-low income households.²³ While there are broad Federal guidelines for LIHEAP, States have the flexibility to tailor their programs to best meet their needs. Administrative costs are minimal—capped at 10 percent. This ensures that the vast majority of LIHEAP dollars are directed to energy assistance for low-income families.

The National Association of Regulatory Utility Commissioners (NARUC), the National Energy Assistance Directors Association and the National Fuel Funds Network also support fully funding the regular block grant LIHEAP program at \$5.1 billion.

Conclusion.—In light of the continued projected increase in residential energy costs and LIHEAP's continued demonstrated success in helping low-income families maintain access to vital energy service, we urge the subcommittee to appropriate \$5.1 billion for the regular LIHEAP program in fiscal year 2007 as well as advance appropriations for fiscal year 2008 of \$5.1 billion for the regular program. Thank you for consideration of our testimony.

¹⁹ From 2000 to 2003, approximately 50 percent-68 percent of heat-related deaths were 60 years old or older. Office of Climate, Water and Weather Services, Heat Related Fatalities by Age and Gender, reports for 2000–2003.

²⁰ In 1998 there were over 49,000 heating-equipment related home fires resulting in 388 deaths and 1,445 injuries and \$515 million in property damage. National Fire Protection Association Fact Sheets on Home Heating, in United States Home Heating Fire Patterns and Trends, John H. Hall, Jr., NFPA, June 2001.

²¹ Robert B. Swift, Rising Costs for Home Heating Fuel Could Spawn More Problems, Sunbury (PA) Item, Jan. 29, 2000.

²² Pediatric Academic Societies, Publication #921, Platform Presentation, Epidemiology Session, May 6, 2003, Seattle, WA: Children's Sentinel Nutrition Assessment Program: Heat or Eat: Low Income Home Energy Assistance Program and Nutritional Risk Among Children < 3.

²³ U.S. Department of Health and Human Services, Administration for Children and Families, Office of Community Services, Division of Family Assistance, LIHEAP Home Energy Notebook for Fiscal Year 2001 (February 2003), Table A–2b, p. 49.

PREPARED STATEMENT OF THE NATIONAL KIDNEY FOUNDATION

The National Kidney Foundation (NKF), a voluntary health organization whose membership includes patients and families; organ transplant recipients; families who have donated the organs of loved ones for transplantation and living organ donors; and health care professionals, is pleased to submit public witness testimony for the written record in support of fiscal year 2007 Appropriations.

We are very appreciative of the \$1,800,000 in funding that Congress provided in fiscal year 2006 to establish a Chronic Kidney Disease (CKD) program within the Centers for Disease Control and Prevention (CDC). As the subcommittee drafts the fiscal year 2007 Labor, Health and Human Services, and Education Appropriations Bill, we respectfully request your continued support for funding to expand these activities, as outlined below. Unfortunately, the administration did not request continued funding for this program in its 2007 Budget Request.

IMPACT OF CHRONIC KIDNEY DISEASE

The implications of kidney disease for the public are considerable, yet the average American is relatively unaware of its consequences. Twenty million Americans have CKD, and another 20 million are at risk of developing the disease, but most people with kidney disease do not know they have it and will not be diagnosed until it has threatened their health and even their lives. Individuals with diabetes or hypertension are especially vulnerable.

Kidney disease is the 9th leading cause of death in the United States, and death by cardiovascular disease is 10 to 30 times higher in kidney dialysis patients than in the general population. Kidney disease is associated with 25 percent of the Medicare budget and 7 percent of the Medicare population has a diagnosis of kidney disease. Further, the number of individuals with end stage renal disease (ESRD), irreversible kidney failure requiring either dialysis or a transplant to remain alive, is expected to increase from 382,000 patients in 2000 to 712,000 by 2015. Effective treatments are available to reduce morbidity and mortality resulting from kidney disease and its complications and to retard progression to kidney failure. However, CKD is not being detected sufficiently early to initiate treatment regimens and reduce death and disability. NKF believes a public health approach would contribute toward early detection and treatment, thereby reducing hardship and saving money and lives.

2006 CDC ACTIVITIES

NKF is working closely with CDC to implement this program and we are very pleased with the progress to date. CDC intends to use the current-year appropriation to identify and coordinate sources for CKD data; propose solutions to fill data deficiencies; undertake a surveillance system feasibility study; fund pilot projects in selected States; and, organize an expert consensus conference to lay the groundwork for a Public Health Kidney Disease Strategic Plan. Earlier this year, CDC requested proposals to support the development of a comprehensive CKD surveillance system. The agency expects to award two grants in 2006 designed to identify sources of CKD data, as well as gaps and deficiencies in existing data. The program will also propose solutions to remedy deficiencies, including the execution of a feasibility study and pilot test for a surveillance system. Additional activities in 2006 will include studies of the economic benefit of CKD intervention.

FISCAL YEAR 2007 REQUEST

A restoration of funding to the 2006 level would enable CDC to continue planning for capacity and infrastructure for a kidney disease epidemiology, research and health outcomes program and to institute a CKD surveillance system. We are hopeful for a funding increase over fiscal year 2006, which would enable the agency to expand the number and scope of grants to support State-based community demonstration projects for CKD detection and treatment, a core component of this CKD initiative. We envision this would include tracking the progression of CKD in patients who have been diagnosed, as well as identify the onset of kidney disease among individuals who are members of high risk groups.

We thank you for your past support of this initiative and respectfully request your continued support, to enable CDC and the public health community to move forward to address the growing concern of Chronic Kidney Disease.

PREPARED STATEMENT OF THE NATIONAL LEAGUE FOR NURSING

The National League for Nursing (NLN)—representing more than 1,100 nursing schools and health care agencies, some 17,000 individual members comprised of nurses, educators, administrators, public members, and 18 constituent leagues—appreciates the subcommittee's past support for nursing education and your continued recognition of the important role nurses play in the delivery of health care services.

We, however, are concerned. Unless additional resources are expended, the advancements made by Congress to help alleviate the nursing shortage will be impeded owing to the currently proposed fiscal year 2007 appropriations level. The NLN advocates your continued support for Title VIII—Nursing Workforce Development Programs (Public Health Services Act), housed in the Health Resources and Services Administration (HRSA) with the congressionally prescribed mission of ensuring a sufficient supply of nurses. We urge you to fund the Title VIII programs at a minimum level of \$175 million for fiscal year 2007. Placing this minimal funding request in perspective, note that during the last serious nursing shortage in 1974, Congress appropriated \$153 million for nurse education programs. In today's dollars that appropriation would equate to approximately \$592 million, nearly four times the amount the Federal Government is spending on nurse education now.

Today's nursing shortage is very real and very different from any experienced in the past. The existing shortage is evidenced by an aging workforce and too few people entering the profession. A critical factor exacerbating the national nurse-workforce deficiency is the declining number of qualified nurses available to teach future generations of registered nurses. The NLN's Faculty Survey conducted in 2002 concludes that not enough qualified nurse educators exist to teach the number of nurses necessary to ameliorate the nursing shortage.

The NLN Survey found three trends influencing the future of nursing education over the next decade:

The aging of the nurse faculty population

An average of 1.3 full-time faculty members per program left their positions in nursing education in 2002. About half the survey respondents had at least one unfilled budgeted full-time faculty position and some had as many as 15 such positions. 36.5 percent of faculty who left their positions in the preceding year did so because of retirement; 8.6 percent of faculty were 61 years of age or older; and 75 percent of the current faculty population is expected to retire by 2019.

Approximately 1,800 full-time faculty members leave their positions each year. About 10,000 master's level nurses graduate per year, 15 percent of whom would have to enter teaching in order to maintain today's production level for generating the Nation's nurse workforce. Since this is highly unlikely, the gap between unfilled positions and the candidate pool is widening significantly.

The increasing number of part-time faculty

The number of part-time faculty has increased notably since 1996—nearly 17 percent in baccalaureate programs and 14 percent in associate degree programs. Part-time faculty now provides approximately 23 percent of the estimated number of faculty FTEs.

Part-time employees often are not an integral part of the design, implementation, and evaluation of the overall nursing education program. Many may hold other positions that often limit their availability to students. Further, many part-time faculty have not been prepared for the faculty role.

The large number of nursing faculty who are not prepared at the doctoral level

Approximately half the full-time faculties in baccalaureate and higher-degree programs hold a doctoral degree. In associate degree programs, doctorally-prepared faculty account for only 6.6 percent of the total faculty and the number is slightly more than 5 percent in diploma programs. Only 350 to 400 nursing students receive doctoral degrees each year and the pool of doctorally-prepared candidates for full-time nursing professorships is very limited.

Educators without doctoral degrees may lack credibility within a university setting and have limited opportunities to assume leadership positions. Institutions with low numbers of doctorally-prepared educators may be less likely to obtain funds to support research or educational innovations. As important as educational incentives are for future practicing nurses, the scholarships for doctoral students who will instruct the next generation of nurses are even more critical.

Since less than an adequate number of nurse educators currently teach in the education pipeline, the situation appears to be growing acute and is not expected to improve in the near future absent adequate intervention. In a survey of the 2004–2005 academic year conducted by the NLN, an estimated 147,000 qualified ap-

plications were turned away from nursing programs at all degree levels owing in large part to the lack of faculty necessary to teach this number of additional students. This number represents a 17.6 percent increase from the 2003–2004 academic year. With an increasing application pool, a key priority in tackling the nurse shortage has to be scaling up the capacity to accept qualified applicants. Today's undersized supply of appropriately prepared nurses and nurse faculty does not bode well for meeting the needs of a diverse, aging population.

Congress made an important step in passing the Nurse Reinvestment Act in 2002. The new monies used to fund loans and scholarships are appreciated. Yet, it has become abundantly clear that significantly more funding is required to even minimally meet the HRSA charge to support nursing students and schools of nursing so as to meet the existing and rising national needs for nurses. In fiscal year 2005, HRSA was forced to turn away 82 percent of the applicants for the Nurse Education Loan Repayment Program and more than 98 percent of the applicants for the Nursing Scholarship Program due to lack of adequate funding.

Please do not allow the Nation to lose ground in the effort to remedy the nursing shortage. Fund Title VIII—Nursing Workforce Development Programs at a level commensurate with the severity of the health care crisis facing the Nation today. Your support will help ensure that nurses exist in the future who are prepared and qualified to take care of you, your family, and all those in this country who will need our care.

PREPARED STATEMENT OF THE ONCOLOGY NURSING SOCIETY

The Oncology Nursing Society (ONS) appreciates the opportunity to submit written comments for the record regarding fiscal year 2007 funding for cancer and nursing related programs. ONS, the largest professional oncology group in the United States composed of more than 33,000 nurses and other health professionals, exists to promote excellence in oncology nursing and the provision of quality care to those individuals affected by cancer. As part of its mission, the Society honors and maintains nursing's historical and essential commitment to advocacy for the public good.

This year more than 1.4 million Americans will be diagnosed with cancer and more than 565,000 will lose their battle with this terrible disease. Despite these grim statistics, significant gains in the War Against Cancer have been made through our Nation's investment in cancer research and its application. Research holds the key to improved cancer prevention, early detection, diagnosis, and treatment, but such breakthroughs are meaningless unless we can deliver them to all Americans in need. Recent studies have reported 126,000 registered nurse vacancies in hospitals and 13,900 registered nurse vacancies in nursing homes. Moreover, a recent survey of ONS members found that the nursing shortage is having an adverse impact in oncology physician offices and hospital outpatient departments. Some respondents indicated that when a nurse leaves their practice that they are unable to hire a replacement due to the shortage—leaving them short-staffed and posing scheduling challenges for the practice and the patients. These vacancies in all care settings create significant barriers to ensuring access to quality care.

To ensure that all people with cancer have access to the comprehensive, quality care they need and deserve, ONS advocates on-going and significant Federal funding for cancer research and application, as well as funding for programs that help ensure an adequate oncology nursing workforce to care for people with cancer. The Society stands ready to work with policymakers at the local, State, and Federal levels to advance policies and programs that will reduce and prevent suffering from cancer and sustain and strengthen the Nation's nursing workforce.

SECURING AND MAINTAINING AN ADEQUATE ONCOLOGY NURSING WORKFORCE

Oncology nurses are on the front lines in the provision of quality cancer care for individuals with cancer—administering chemotherapy, managing patient therapies and side-effects, working with insurance companies to ensure that patients receive the appropriate treatment, providing counseling to patients and family members, and engaging in myriad other activities on behalf of people with cancer and their families. Cancer is a complex, multifaceted chronic disease, and people with cancer require specialty-nursing interventions at every step of the cancer experience. People with cancer are best served by nurses specialized in oncology care, who are certified in that specialty. Overall, age is the number one risk factor for developing cancer. Approximately 77 percent of all cancers are diagnosed at age 55 and older. Currently, Medicare beneficiaries account for more than 50 percent of all cancer diagnoses and 64 percent of cancer deaths. Over the next 10 to 15 years the number of Medicare beneficiaries with cancer is estimated to double while, according to U.S.

Department of Labor estimates, more than 1.1 million registered nursing vacancies will need to be filled by 2012 to meet growing patient demand and replace retiring nurses.

As the overall number of nurses will drop precipitously in the coming years, we likely will experience a commensurate decrease in number of nurses trained in the specialty of oncology. With an increasing number of people with cancer needing high quality health care, coupled with an inadequate nursing workforce, our Nation could quickly face a cancer care crisis of serious proportion with limited access to quality cancer care, particularly in traditionally underserved areas. A study in the *New England Journal of Medicine* found that nursing shortages in hospitals are associated with a higher risk of complications—such as urinary tract infections and pneumonia, longer hospital stays, and even patient death. Without an adequate supply of nurses, there will not be enough qualified oncology nurses to provide the quality cancer care to a growing population of people in need and patient health and well-being could suffer.

Further, of additional concern is that our Nation also will face a shortage of nurses available and able to conduct cancer research and clinical trials. With a shortage of cancer research nurses, progress against cancer will take longer because of scarce human resources coupled with the reality that some practices and cancer centers resources could be funneled away from cancer research to pay for the hiring and retention of oncology nurses to provide direct patient care. Without a sufficient supply of trained, educated, and experienced oncology nurses, our Nation may falter in its delivery and application of the benefits from our Federal investment in research.

ONS has joined with others in the nursing community in advocating \$175 million as the fiscal year 2007 funding level necessary to support implementation of the Nurse Reinvestment Act and the range of nursing workforce programs housed at the U.S. Health Resources and Services Administration (HRSA). Enacted in 2002, the Nurse Reinvestment Act included new and expanded initiatives, including loan forgiveness, scholarships, career ladder opportunities, and public service announcements to advance nursing as a career. Despite the enactment of this critical measure, HRSA fails to have the resources necessary to meet the current and growing demands for our Nation's nursing workforce. For example, in fiscal year 2005, HRSA was forced to turn away 82 percent of the applicants for the Nurse Education Loan Repayment Program and over 98 percent of the applicants for the Nursing Scholarship Program due to lack of adequate funding.

While a number of years ago one of the biggest factors associated with the shortage was a lack of interested and qualified applicants, due to the efforts of the nursing community and other interested stakeholders, the number of applicants is growing. As such, now one of the greatest factors contributing to the shortage is that nursing programs are turning away qualified applicants to entry-level baccalaureate programs due to a shortage of nursing faculty. According to the American Association of Colleges of Nursing (AACN), at least 32,617 of such qualified applicants were turned away in 2004 alone. Many of these qualified students are being placed on waiting lists that may be as long as 2 years or more. The National League for Nursing (NLN) released a preliminary report in December 2005 that showed that due to faculty shortages, in total schools of nursing were forced to reject more than 147,000 qualified applications for 2005, an 18 percent increase over 2004 figures. The number of full-time nursing faculty required to "fill the nursing gap" is approximately 40,000 and currently there are less than 20,000 full-time nursing faculty in the system. The nurse faculty shortage is only expected to worsen with time as faculty age continues to climb, averaging 52 years in 2004. Significant numbers of faculty are expected to retire in the coming years with insufficient numbers of candidates in the pipeline to take their places. If funded sufficiently, the components and programs of the Nurse Reinvestment Act will help address the multiple factors contributing to the nursing shortage.

ONS strongly urges Congress to provide HRSA with a minimum of \$175 million in fiscal year 2007 to ensure that the agency has the resources necessary to fund a higher rate of nursing scholarships and loan repayment applications and support other essential endeavors to sustain and boost our Nation's nursing workforce. Nurses—along with patients, family members, hospitals, and others—have joined together in calling upon Congress to provide this essential level of funding. One Voice Against Cancer (OVAC), a collaboration of more than 45 national nonprofit organizations representing millions of Americans, also advocates \$175 million for the Nurse Reinvestment Act in fiscal year 2007. ONS and its allies have serious concerns that without full funding, the Nurse Reinvestment Act will prove an empty promise and the current and expected nursing shortage will worsen, and people will not have access to the quality care they need and deserve.

BOOST OUR NATION'S INVESTMENT IN CANCER PREVENTION, EARLY DETECTION, AND
AWARENESS

Approximately two-thirds of cancer cases are preventable through lifestyle and behavioral factors and improved practice of cancer screening. Although the potential for reducing the human, economic, and social costs of cancer by focusing on prevention and early detection efforts remains great, our Nation does not invest sufficiently in these strategies. While as a Nation we spend almost a trillion dollars a year on our health care system, we only allocate approximately 1 percent of that amount for population-based prevention efforts. By 2020, cancer and other chronic disease expenditures will reach \$1 trillion or 80 percent of health care costs. The Nation must make significant and unprecedented Federal investments today to address the burden of cancer and other chronic diseases, and to reduce the demand on the healthcare system and diminish suffering in our Nation both for today and tomorrow.

As the Nation's leading prevention agency, the Centers for Disease Control and Prevention (CDC) plays an important role in translating and delivering at the community level what is learned from research. Therefore, ONS joins with our partners in the cancer community—including OVAC—in calling on Congress to provide additional resources for the CDC to support and expand much-needed and proven effective cancer prevention, early detection, and risk reduction efforts. Specifically, ONS advocates the appropriation of \$427.5 million in fiscal year 2007 for the CDC's comprehensive cancer, ovarian cancer, breast and cervical cancer early detection, cancer registries, prostate cancer, colorectal cancer, and skin cancer programs. ONS also urges a funding increase for the CDC's physical activity, nutrition, and tobacco-control programs to help reduce risk factors for developing cancer and other chronic diseases. ONS advocates the following fiscal year 2007 funding levels:

- \$250 million for the National Breast and Cervical Cancer Early Detection Program;
- \$65 million for the National Cancer Registries Program;
- \$25 million for the Colorectal Cancer Prevention and Control Initiative;
- \$50 million for the Comprehensive Cancer Control Initiative;
- \$20 million for the Prostate Cancer Control Initiative;
- \$5 million for the National Skin Cancer Prevention Education Program;
- \$7.5 million for the Ovarian Cancer Control Initiative;
- \$5 million for the Geraldine Ferraro Blood Cancer Program;
- \$145 million for the National Tobacco Control Program; and
- \$70 million for the Nutrition, Physical Activity, and Obesity Program.

SUSTAIN AND SEIZE CANCER RESEARCH OPPORTUNITIES

Our Nation has benefited immensely from past Federal investment in biomedical research at the National Institutes of Health (NIH). ONS has joined with the broader health community in advocating \$29.7 billion for NIH in fiscal year 2007. This will allow NIH to sustain and build on its research progress resulting from the recent doubling of its budget while avoiding the severe disruption to that progress that would result from a minimal increase. Cancer research is producing extraordinary breakthroughs—leading to new therapies that translate into longer survival and improved quality of life for cancer patients. We have seen extraordinary advances in cancer research resulting from our national investment that have produced effective prevention, early detection and treatment methods for many cancers. To that end, ONS calls upon Congress to allocate \$5.034 billion to the National Cancer Institute (NCI) in fiscal year 2007 to continue our battle against cancer.

The National Institute of Nursing Research (NINR) supports basic and clinical research to establish a scientific basis for the care of individuals across the life span—from management of patients during illness and recovery to the reduction of risks for disease and disability and the promotion of healthy lifestyles. These efforts are crucial in translating scientific advances into cost-effective health care that does not compromise quality of care for patients. Additionally, NINR fosters collaborations with many other disciplines in areas of mutual interest such as long-term care for older people, the special needs of women across the life span, bioethical issues associated with genetic testing and counseling, and the impact of environmental influences on risk factors for chronic illnesses such as cancer. ONS joins with the nursing community in advocating an allocation of \$150 million for NINR in fiscal year 2007.

CONCLUSION

ONS stands ready to work with policymakers to advance policies and support programs that will reduce and prevent suffering from cancer and sustain and strengthen our Nation's nursing workforce. Moreover, ONS maintains a strong commitment to working with Members of Congress, other nursing societies, patient organizations, and other stakeholders to ensure that the oncology nurses of today continue to practice tomorrow and that we recruit and retain new oncology nurses to meet the unfortunate growing demand that we will face in the coming years. Thank you for this opportunity to discuss the fiscal year 2007 funding levels necessary to ensure that our Nation has a sufficient nursing workforce to care for the patients of today and tomorrow and that our Nation continues to make gains in our fight against cancer.

PREPARED STATEMENT OF THE PANCREATIC CANCER ACTION NETWORK

On behalf of The Pancreatic Cancer Action Network (PanCAN), I thank you for this opportunity to present written testimony to the Labor, Health and Human Services, and Education subcommittee of the House Appropriations Committee.

PanCAN was founded in 1999 to focus national attention on the need to find the cure for pancreatic cancer. We provide public and professional education that embraces the urgent need for more research, effective treatments, prevention programs, and early detection methods. PanCAN is the first and only national patient based advocacy organization specifically focused on pancreatic cancer. We now have a full time staff of 30 individuals, and 90 "Team Hope" affiliates in communities across the country, comprised of thousands of volunteers who seek to increase awareness about this disease, raise funds, and voice their concern that there is a desperate need to find a cure for pancreatic cancer.

BACKGROUND ON PANCREATIC CANCER

Every 17 minutes, someone in the United States dies from pancreatic cancer. It is the 4th leading cause of cancer death in the United States. The facts on pancreatic cancer are striking:

- Over 33,730 Americans will be diagnosed with pancreatic cancer in 2006, and 32,300 will die from this disease.
- The 99 percent mortality rate is the highest of any cancer.
- There are no early detection methods.
- The average life expectancy after diagnosis with metastatic disease is just 3 to 6 months.

Yet, despite these statistics, pancreatic cancer receives the least amount of research funding from the Federal Government of all major cancers. Federal funding for pancreatic cancer research totaled roughly \$66 million in fiscal year 2005, a mere 1 percent of the National Cancer Institute's (NCI's) \$4.825 billion research budget. While good progress is being made in early detection, research and treatment programs for some cancers, this is clearly not the case for pancreatic cancer.

Pancreatic cancer is the deadliest cancer for one reason: limited Federal funding opportunities discourage researchers from pursuing pancreatic cancer as a focus. There are less than 15 fully-funded researchers nationwide who are specifically dedicated to this disease. The combination of few dollars and few researchers means there has been very little scientific progress.

PanCAN has outlined opportunities below for the Federal Government to take specific actions to facilitate progress in combating this disease.

Provide Adequate Funding Increases for Cancer Research, Prevention, and Treatment Programs

Pancreatic cancer is the country's fourth leading cause of cancer death, killing over 33,730 people annually, yet it remains severely under-funded when comparing NCI funding levels for the top five cancers based on mortality. The NCI spent a reported \$66 million on pancreatic cancer research in fiscal year 2005, yet the other four top cancers (in mortality) are funded at levels at least four times this amount. Further, the discrepancy in funding has existed for many years, only compounding this inconsistency.

PanCAN supports the highest possible funding increase that Congress can provide for the National Institute of Health (NIH) and the NCI in fiscal year 2007. With additional funding for both the NIH and the NCI, new research grants can be awarded to fulfill the research goals identified by the NCI as essential to combating this disease. PanCAN is a member of the "One Voice Against Cancer" (OVAC) coali-

tion which is comprised of more than 50 cancer advocacy organizations that have come together to support our common goal: increased Federal funding for cancer research, prevention and training programs that are funded through the NIH, NCI and Centers for Disease Control and Prevention (CDC).

PanCAN wholeheartedly endorses OVAC's proposed fiscal year 2007 funding requests that seek a 5 percent increase for both the NIH and NCI. We urge you to provide a minimum of \$29.7 billion for the NIH in fiscal year 2007. Separate testimony submitted to the Committee by OVAC reiterates the need for additional Federal funding for biomedical research: "The tremendous investment our Nation has made in the NIH has reaped remarkable returns and set the table for a period of unparalleled innovation in the fight against cancer and other diseases. For fiscal year 2007, OVAC joins with the broader public health community and urges Congress to provide \$29.7 billion for the NIH. This is the minimal level of funding that will allow the NIH to maintain the current pace of discovery and innovation."

PanCAN also supports the NCI Director's Professional Judgment Budget, which calls for a total of \$5.9 billion for the NCI in fiscal year 2007. Those within the agency and very knowledgeable of the research being conducted by the NCI have developed this plan and accompanying budget that seeks to investigate the most promising research available to the community at this time. We urge the Committee to do all that it can to support investments in biomedical research that will save lives. At a minimum, we urge the Committee to support a funding increase of 5 percent above last year's level for the NCI, which would bring the agency's fiscal year 2007 funding level to \$5.034 billion. This funding level would provide an additional \$240 million to at least keep the existing level of research at the NCI moving forward at a stable pace and thus protect the current number of investigator grant awards from significant cuts.

Ensure that Pancreatic Cancer Research is Not Compromised as the NCI Shifts its Focus from Disease Specific Research to More Global Science Initiatives

Last year, PanCAN requested that the Committee oversee implementation of the short, medium, and long-term strategies as identified in the Pancreatic Cancer Progress Review (PRG). The PRG has been in place since September 2002 and yet, 4 years later, few of these strategies have been implemented. For this reason, PanCAN urges the Committee to require the NCI to implement, in fiscal year 2007, all of the outstanding strategies as identified in the NCI implementation plan for pancreatic cancer PRG recommendations.

Through conversations and meetings with NCI leadership, we've learned about the shift in the NCI's focus on research. Disease specific science is being shelved in favor of sexier initiatives in the areas of nanotechnology, genomics, and the development of a biospecimen repository.

As the NCI moves its scientific agenda forward in these three areas, PanCAN is concerned that critical resources will be taken away from the significant investments that have been made in research related to early detection, diagnosis and treatment protocols for specific cancers. Other cancers have achieved significant declines in their respective mortality rates after early detection protocols have been developed. Since there is no such tool for diagnosing pancreatic cancer early in its development, the mortality rates remain high, and tens of thousands of patients are lost each year. As the advocacy community for pancreatic cancer patients, we feel that the NCI cannot justify any reductions in funding for pancreatic cancer research until significant reductions are achieved in the mortality rate for this cancer.

PanCAN urges the Committee to obtain assurance from the NCI that the cornerstone research of the agency will not be diminished as these new scientific initiatives are pursued. Further, PanCAN urges the Committee to direct the NCI to develop a written report that specifically details how these three major scientific initiatives will specifically advance pancreatic cancer research and submit this report to the Committee by April 1, 2007.

Support Selected Opportunities for Advancement of Pancreatic Cancer Research to Capitalize on the Initial Investment of Disease Specific Research

Identify genetic factors, environmental factors, and gene-environment interactions that contribute to pancreatic cancer development.

Achieve a more complete understanding of the biology of the normal pancreas and the development of pancreatic adenocarcinoma and use this knowledge to improve prevention, early detection, and treatment interventions.

Develop nationwide tissue and data repositories, molecular profiling resources, and bioinformatics tools for pancreatic cancer research. Use these resources to develop prevention and early detection interventions that are based on molecular features of pancreatic cancer.

Establish models for the study of environmental factors, gene-environment interactions, chemoprevention, chemotherapy, radiation therapy, vaccines, and imaging to improve understanding of pancreatic cancer risk, prevention, diagnosis, and treatment.

Identify and develop surveillance and diagnosis methods for early detection of pancreatic cancer and its precursors.

Develop and establish sustained, expanded training and career development efforts in pancreatic cancer research and care to build a comprehensive, multidisciplinary research community focused on this disease.

Mr. Chairman, the scientific community—through research—is making great progress in combating cancer. More people are surviving cancer today than any other time in history. Unfortunately, these achievements are not extended to the vast majority of pancreatic cancer patients. We urge you to provide America's world-renowned research enterprise with the funding levels necessary for investigators to continue to work their magic and develop screening protocols, effective treatments and therapies that will one day lead to the eradication of all cancers—including pancreatic. To quote Congressman Clay Shaw (R-FL), a cancer patient, "When you approach the finish line, you don't walk . . . you run!" If the United States truly seeks to move forward with its ambitious goal to stop pain and death from cancer by 2015, it is imperative that Federal research programs be adequately funded to achieve this goal. On behalf of the 33,730 patients diagnosed with pancreatic cancer in 2006, I urge you to support increased funding for cancer research, treatment and prevention programs in your fiscal year 2007 bill.

PREPARED STATEMENT OF PEOPLE FOR THE ETHICAL TREATMENT OF ANIMALS

People for the Ethical Treatment of Animals (PETA) represents more than 1.3 million Americans who support the Federal Government's ongoing commitment to develop scientifically valid safety tests to protect human health and the environment from chemical hazards while reducing, and ultimately replacing, the use of animals. Thank you for the opportunity to present testimony relevant to the fiscal year 2007 budget request for the National Institute of Environmental Health Sciences in relation to the National Toxicology Program (NTP).

HISTORY OF THE NTP

The NTP was established in 1978 to provide information about potentially toxic chemicals and to coordinate toxicity testing programs within the Federal Government, strengthen the science of toxicology, and develop and validate improved testing methods. Three agencies form the core of the NTP: the National Institute of Environmental Health Sciences of the National Institutes of Health (NIEHS/NIH), the National Institute of Occupational Safety and Health of the Centers for Disease Control and Prevention (NIOSH/CDC), and the National Center for Toxicological Research of the Food and Drug Administration (NCTR/FDA). The NTP's activities are funded through the NIEHS at an annual level of approximately \$500 to \$600 million.¹

NTP RODENT CANCER TESTING PROGRAM

During the 1960s and 70s, as vast numbers of new chemicals were being produced and used in agriculture, manufacturing, food preparation, and virtually every other aspect of modern life, the public became increasingly concerned that these chemicals were finding their way into the environment and food supply. Since much of the public anxiety regarding chemicals related to their potential to cause cancer, the Federal Government instituted a program to assess the cancer-causing potential of chemicals using rats and mice—on the assumption that rodent carcinogens could also present a cancer risk to humans. This rodent cancer-testing program began under the auspices of the National Cancer Institute, but has been managed by the NTP since its inception in 1968.

A conventionally NTP rodent cancer study takes approximately 5 years to design, conduct and interpret, consuming at least 860 animals and up to \$4 million per chemical tested.² The study exposes three groups of animals to three different doses

¹White House Office of Technology Assessment. Researching health risks. Washington, DC: EOP (1993).

²NIEHS Fact Sheet: The National Toxicology Program. Research Triangle Park, NC: NIEHS (1996).

of a test chemical, while a fourth group (known as the “control” group) receives no chemical exposure. The chemically exposed animals receive daily doses of a test substance for their entire 18- to 24-month life span. If these animals develop more tumors than the non-chemically exposed controls, this is taken as evidence that a chemical causes cancer. To date, the NTP has tested hundreds of substances in rodent cancer studies—including pharmaceuticals, pesticides, plastics, industrial chemicals, and even plant extracts—at a projected cost of more than 1 billion U.S. taxpayer dollars.³

A HISTORY OF CONTROVERSY

The NTP recently celebrated the publication of its 500th rodent cancer study as “the gold standard in animal toxicology.”⁴ However, in contrast to the fanfare with which this announcement was made, the history of NTP rodent cancer studies is one of controversy spanning several decades, with top Federal officials admitting:

“The current 2-year rodent carcinogenicity study was never validated and there is little evidence supporting the repeatability and reproducibility of the current rodent carcinogenicity study.”⁵

—Drs. Joseph Contrera, Abigail Jacobs, and Joseph DeGeorge

Food and Drug Administration, Center for Drug Evaluation and Research

“We have been concerned about the predictivity of 2-[year] [rodent cancer studies] for the past 10 [years], as our experience and knowledge have expanded.”⁶

—Drs. Bernard Schwetz and David Gaylor

Food and Drug Administration, Office of the Director/National Center for Toxicological Research

“The problem is we don’t know what the findings really mean.”⁷

—Dr. Robert Maronpot, chief, Laboratory of Experimental Pathology,

National Institute of Environmental Health Sciences (NIEHS)

“Even if a chemical is found to be nontoxic in animal studies, the safety of the chemical cannot be assured.”⁸

—Dr. Barbara Shane, NTP executive secretary

“I have to say we don’t serve the American people very well right now.”⁶

—Dr. Kenneth Olden, director, NTP & NIEHS (1991–2005)

PETA’S ANALYSIS

PETA recently conducted an in-depth analysis of all 502 federally funded and conducted lifetime rodent cancer studies published on the NTP website as of January 2006.⁹ On the basis of this analysis, together with more than 25 years of published scientific literature on this subject, we have determined that:

—The great majority of the U.S. Government’s more than \$1 billion investment in the NTP rodent cancer-testing program has produced little or no actual benefit, having been used to underwrite studies that:

—Have been judged by the NTP itself to be “inadequate” or to produce “equivocal” (ambiguous) results, which are of no use to health authorities (\$121 million).

—Have produced such dubious and conflicting results that more than 75 percent of tested chemicals remain either unclassified as to their cancer risk to humans, or are lumped into such meaningless categories as “possible” human carcinogens or “unclassifiable” as to human cancer risk—designations that do nothing to enhance public health or worker protection (\$460–720 million).

—Have been shown by other scientists to produce consistent and reproducible results only 57 percent of the time when the same chemicals are tested more

³ 502 lifetime cancer studies in rats and mice × \$2–4 million/study = \$1–2 billion.

⁴ NIEHS News Release: NTP completes 500th two-year rodent study and report; series is the gold standard of animal toxicology. 25 Jan 2001. <<http://www.niehs.nih.gov/oc/news/ntp500.htm>>.

⁵ Contrera JF, Jacobs AC, DeGeorge JJ. Carcinogenicity testing and the evaluation of regulatory requirements for pharmaceuticals. *Regulatory Toxicology and Pharmacology* 25, 130–145 (1997).

⁷ Brinkley J. Many say lab-animal tests fail to measure human risk. *The New York Times* 1993 Mar 23;Sect A:1.

⁸ Shane BS. Human reproductive hazards. *Environmental Science and Technology* 30, 1193 (1989).

⁶ Schwetz B, Gaylor D. New directions for predicting carcinogenesis. *Molecular Carcinogenesis* 20, 275–279 (1997).

⁹ PETA’s full report is available upon request or may be downloaded from <http://www.stopanimaltests.com/u-ntp.asp>.

than once using the same method—a result that could be achieved by simply tossing a coin.

- Critical public health and worker protection measures related to cigarette smoke, asbestos, benzene, and other cancer-causing substances were delayed for many years because of misplaced trust in animal tests, which for years could not replicate cancerous effects that had already been documented in people.¹⁰
¹¹ ¹² ¹³ If standard animal tests failed to readily identify these well-known human carcinogens, how many other dangerous chemicals are Americans being exposed to today as a result of misleading animal data?
- Conversely, substances such as saccharin and ethyl acrylate (used in the manufacturing of latex paints and textiles) have been branded as “probable” human carcinogens and stigmatized on the basis of animal data later dismissed as irrelevant or otherwise inapplicable to humans.¹⁴ False alarms such as these can cost society billions in terms of loss of viable products in commerce, decreased international competitiveness, job loss, litigation, and unnecessary public anxiety.
- Lifetime cancer studies in rats and mice are so costly and inefficient that the NTP has only been able to conduct an average of 12 such studies per year over the past several decades. At this rate, it would take the NTP more than 32,000 years, 68 million animals, and \$160 billion to test the more than 80,000 environmental chemicals whose cancer-causing potential has not yet been specifically assessed.¹⁵

These findings call into question the wisdom of continued Federal appropriations to the NTP rodent cancer-testing program. Taxpayer dollars would be better spent developing more reliable, relevant, and cost-effective methods for assessing chemical safety.

NTP VISION AND ROADMAP FOR THE 21ST CENTURY

The NTP itself appears to recognize the limitations of relying upon decades old and never validated toxicity studies. In 2003, the NTP articulated its “vision” to move toxicology from an observational to a predictive science with markedly reduced reliance on animal testing.¹⁶ Among the methods that the NTP has identified for further development are “high throughput” screens, which combine robotics and in vitro (cell-based) toxicology to create a system capable of rapidly and inexpensively screening tens of thousands of substances per year at multiple concentrations relevant to real-world human exposure levels. PETA believes that a “battery” of several in vitro tests—based on human tissues and mechanisms of cancer induction that are relevant to people (e.g., genetic damage, cell transformation, depression of the immune system, hormone imbalance, etc.) represents the most credible and viable approach to accurately identifying chemicals that pose a cancer risk to humans.

REQUEST FOR APPROPRIATIONS

In order to more rapidly and effectively screen chemicals to detect those that present a cancer risk to humans, we respectfully urge the subcommittee to support increasing appropriations from within the existing NIEHS budget for the development and validation of efficient and economical non-animal test methods under the NTP’s “21st Century Vision” program.¹⁶ Given the dubious value of the NTP rodent cancer-testing program, we respectfully recommend that funding of this program be discontinued and redirected instead to the NTP Vision program.

¹⁰ Laskin S, Sellakumar AR. Models in chemical respiratory carcinogenesis. In: Karbe E, Park JF, eds. *Experimental lung cancer: carcinogenesis and bioassays*. New York: Springer-Verlag (1974).

¹¹ Rodelsperger K, Weitowitz H-J. Airborne fiber concentrations and lung burden compared to the tumor response in rats and humans exposed to asbestos. *Annals of Occupational Hygiene* 39, 715–725 (1995).

¹² DeLore P, Borgomono C. Acute leukemia following benzene poisoning. *Journal de MAE1decin de Lyon* 9, 227–236 (1928).

¹³ De Marini DM and others. *Benchmarks: alternative methods in toxicology*. MA Mehlman, ed. Princeton, NJ: Princeton Scientific Publishing (1989).

¹⁴ NIEHS Fact Sheet: The Report on Carcinogens—9th edition. 15 May 2000. <<http://www.niehs.nih.gov/oc/news/9thROC.htm>>.

¹⁵ Ward EM, Schulte PA, Bayard S, et al. Priorities for development of research methods in occupational cancer. *Environmental Health Perspectives* 111, 1–12 (2003).

¹⁶ Toxicology in the 21st Century: The Role of the National Toxicology Program. 24 Feb 2004. <<http://ntp-server.niehs.nih.gov/index.cfm?objectid=EE4AED80-F1F6-975E-7317D7CB17625A15>>.

REQUEST FOR COMMITTEE REPORT LANGUAGE

We also respectfully request that the subcommittee consider the following report language for the Senate Labor, Health and Human Services, Education and Related Agencies Appropriations bill:

“Not later than March 30, 2007, the Director of the NTP/NIEHS shall provide Congress with a report detailing the number of rodent lifetime cancer studies funded to date by the NTP/NCI which (i) produced results deemed to be equivocal and/or inadequate for classification as to human cancer risk, or (ii) have failed to provide a clear answer as to whether the substance tested presents a cancer risk to humans. The Director’s report should detail the costs associated with such studies, and explain the NTP’s continued reliance on rodent lifetime cancer studies in light of criticisms from senior Federal officials regarding their dubious validity and utility.”

Thank you for the opportunity to submit this request on behalf of our more than 1.3 million members and supporters.

PREPARED STATEMENT OF PROJECT R&R

Project R&R: Release and Restitution for Chimpanzees in U.S. Laboratories, whose advisory board of chimpanzee experts includes 12 organizations with a combined membership of 500,000, respectfully submits testimony on our funding priority.

We request that Federal funding for breeding chimpanzees for research, or for projects that require breeding, be terminated. We do so for the following reasons:

- A “surplus” of chimpanzees has resulted from over-breeding in the 1980s for HIV/AIDS research and later findings that they are a poor HIV/AIDS model.¹
- There are enough chimpanzees to address existing federally funded research.²
- As a result of the “surplus,” the government funds a national sanctuary system.³
- The current population costs about \$11 million Federal per year.
- Breeding more chimpanzees increases taxpayers’ financial burden.
- Expansion of the population compounds existing concerns about their quality of care.
- While there is a breeding moratorium, NIH still funds research projects requiring breeding.⁴
- The public is concerned about the use of chimpanzees in research.

Background.—Of an estimated 1,300 chimpanzees in laboratories in the United States today, approximately 850 are federally owned or supported. In the mid-1990s, the National Research Council (NRC) made recommendations to address the “surplus” that included a moratorium on breeding federally-owned or supported chimpanzees for at least 5 years⁵ (implemented in 1995). The National Advisory Research Resources Council, which advises NCRR on funding activities, policies, and program, met on 09/15/05 and recommended that NCRR extend the moratorium to 12/07. The recommendation was accepted⁶—reasons included the high costs associated with care and the fact that chimpanzees are a poor model for human HIV research.^{7 8}

Circumventing the moratorium.—Despite the moratorium, NIH funds research projects requiring breeding. For example, the National Institute of Allergy and Infectious Diseases (NIAID) maintains a contract with the New Iberia Research Center (NIRC) to provide 10 to 12 infants annually for research. The 10 year contract entitled “Leasing of chimpanzees for the conduct of research’ was allotted over \$22 million (\$3.9 million has been spent since 2002).⁹

¹ National Research Council (1997) Chimpanzees in research: strategies for their ethical care, management and use. National Academies Press: Washington, D.C.

² Report of the Chimpanzee Management Plan Working Group to the National Advisory Research Resources Council; May 18, 2005.

³ http://www.ncrr.nih.gov/compmed/cm_chimp.asp.

⁴ Ibid.

⁵ National Research Council (1997) Chimpanzees in research: strategies for their ethical care, management and use. National Academies Press: Washington, D.C.

⁶ http://www.ncrr.nih.gov/compmed/cm_chimp.asp

⁷ Muchmore, E., (2001) Chimpanzee models for human disease and immunobiology, Immunological Reviews, 183, 86–93.

⁸ Reynolds, V., (1995) Moral issues in relation to chimpanzee field studies and experiments, Alternatives to Laboratory Animals, 23, 621–625.

⁹ Source: http://dcis.hhs.gov/nih/nih_daily_active_web.html (See contract No. 272022754).

NIRC has also received \$5.47 million from 09/00 to 08/05 for a grant from NCRR to maintain 138 chimpanzees for breeding. NIH/NCRR spends more than \$1 million annually to maintain the NIRC breeding colony.¹⁰ These grants result in \$9 million going to breeding-related activities at NIRC alone since 2000.

Such expenditures circumvent the intent of the breeding moratorium, compelling the need to prevent the growing financial burden of increasing numbers of chimpanzees, particularly since, by the government's own admission, a "surplus" already exists.

Costs for Chimpanzee Maintenance.—The cost of care for chimpanzees is a major concern, particularly with NIH's tightening budget. In 1995, the Institute for Laboratory Animal Research (ILAR) published a study that projected the future costs of maintaining chimpanzees in U.S. research.¹¹ ILAR, a division of the National Academies of Science, functions as "an advisor to the Federal Government, the biomedical research community, and the public."¹²

The ILAR study examined the per diem costs of the existing population of chimpanzees at six facilities. Taking into account a variety of factors such as longevity, distribution of sex, and complexity of care, it projected costs of maintaining the present colony over the next 60 years. To account for inflation, an annual 4 percent increase was incorporated, corresponding approximately to the Biomedical Research and Development Price Index.

The results of the study indicated that the lifetime cost of maintaining chimpanzees over the next 60 years—the approximate lifespan of chimpanzees in captivity—will exceed \$3.14 billion. The 1995 projection, however, was based on a population of 1,447 chimpanzees. The present population of federally owned or supported chimpanzees in 2006, due to implementation of the partial breeding moratorium in 1995 and the close of the Coulston Foundation in 2002, stands closer to 850. This represents approximately 59 percent of the 1,447 number used in ILAR's projection. Thus we can estimate the cost of the existing colony to be \$1.85 billion.

The ILAR projection also concluded that the current 2006 annual costs would be approximately \$18.8 million. Adjusting this number by 59 percent results in \$11 million spent in 2006 alone to maintain chimpanzees for research.

It is important to note that \$11 million represents only a partial estimate of the entire Federal expenditure for chimpanzee research. The total population of U.S. chimpanzees available for research is estimated at 1,300. Approximately 500 of these chimpanzees are privately owned. Privately owned chimpanzees are also partially funded by Federal research dollars. Therefore, the 2006 estimate of annual expenditure actually exceeds \$11 million by an undetermined amount.

Delivery of care.—USDA inspection reports indicate that facilities housing chimpanzees for research are not adequately meeting basic housing needs. Inspection reports for the NIRC 2004 showed some chimpanzees being housed in less than the minimal space requirements. The facility was given one year to correct the non-compliance, which needed to be further extended as construction of new housing facilities was still not completed. NIRC was also cited 7 times during its 12/04 inspection for improperly sanitizing cages and living quarters, as well as for failing to provide adequate environment enhancement.

Inspection reports filed on the Southwest Foundation for Biomedical Research and the Yerkes Primate Facility, both National Primate Research Centers, also demonstrate multiple non-compliant items for failing to keep chimpanzee areas in well-maintained condition, and failing to maintain safe facilities free of dangers due to disrepair.

A poor model.—It is widely agreed within the scientific community that chimpanzees are a poor model for HIV. Years of research demonstrated that HIV-infected chimpanzees do not develop AIDS. Similarly, while chimpanzees are used in current hepatitis C research, they do not model the course of the human disease. The decoding of the chimpanzee genome pointed out similarities as well as differences between humans and chimpanzees. Some of those greatest differences relate to the immune system.¹³ Such differences question the validity of using chimpanzees in infectious disease research, further arguing the need to curb populations and costs.

¹⁰ <http://nirc.louisiana.edu/divisions/nihgrants.html>

¹¹ Dyke, B., Williams-Blangero, S. et al, 1995 "Future costs of chimpanzees in U.S. research institutions," ILAR Journal V37(4) http://dels.nas.edu/ilar/ilarjournal/37_4/37_Future.shtml

¹² Institute for Laboratory Animal Research, website at http://dels.nas.edu/ilar_n/ilarhome/about.shtml

¹³ The Chimpanzee Sequencing and Analysis Consortium/Mikkelsen, TS, et al., (1 September 2005) Initial sequence of the chimpanzee genome and comparison with the human genome, Nature 437, 69–87.

Ethical concerns.—The U.S. public is concerned about the use of chimpanzees in research because of their intellectual, emotional and social similarities to humans. A 2005 poll conducted by the Humane Research Council revealed that 4 out of 5 (83 percent) of the U.S. public recognize chimpanzees as highly intelligent, social individuals who have an extensive capacity to communicate. A full 71 percent of Americans support the release of chimpanzees if they have been used in research for more than 10 years.¹⁴ A 2001 poll conducted by Zogby International showed that 90 percent of Americans believe it is unacceptable to confine chimpanzees in government-approved cages.¹⁵

Conclusion.—We respectfully request that the following language appear in the House Labor, Health and Human Services, Education and Related Agencies Appropriations Subcommittee Report for Fiscal Year 2007:

“None of these funds shall be used for the breeding of chimpanzees or research projects that require the breeding of chimpanzees.”

We hope the committee will accommodate this modest request that will save the government substantial money, benefit chimpanzees, and allay some concerns of the public at large. Thank you for your consideration.

LETTER FROM SENATOR PAT ROBERTS, ET AL.

WASHINGTON, DC, April 5, 2006.

Hon. ARLEN SPECTER, *Chair*,
 Hon. TOM HARKIN, *Ranking Member*,
Subcommittee on Labor, HHS, and Education, Senate Committee on Appropriations,
Washington, DC

DEAR CHAIRMAN SPECTER AND RANKING MEMBER HARKIN: As you begin your work on the fiscal year 2007 Labor, Health and Human Services, and Education Appropriations bill, we urge you to provide the same level of funding for Title VII health professional as was appropriated in fiscal year 2005 (\$299,552,000). These programs provide direct financial support for health care workforce development and education. In addition, they are the only Federal programs designed to train providers in interdisciplinary setting to respond to the needs of special and underserved populations. They also work to increase minority representation in the health care workforce.

The fiscal year 2006 Labor, Health and Human Services, Education Appropriations bill dramatically reduced funding for Title VII health professions programs, resulting in a 51 percent overall cut below fiscal year 2005. At a time of serious health professions shortages, this reduction has already had devastating effects on the country's neediest communities. By restoring funding to these programs to fiscal year 2005 levels, you will enable them to continue to improve the distribution, quality, and diversity of the health professions workforce.

We respectfully urge you to restore funding to the Title VII programs in the fiscal year 2007 Labor, Health and Human Services, and Education appropriations bill. We greatly appreciate your consideration of the request.

Sincerely,

Senators Pat Roberts, Jack Reed, Elizabeth Dole, Daniel K. Akaka, Susan M. Collins, Lamar Alexander, Richard Durbin, Sam Brownback, Blanche L. Lincoln, Richard G. Lugar, James M. Jeffords, Paul S. Sarbanes, Norm Coleman, Charles E. Schumer, Byron L. Dorgan, Frank R. Lautenberg, Dianne Feinstein, Mark L. Pryor, Hillary Rodham Clinton, Evan Bayh, Christopher J. Dodd, Patrick J. Leahy, John F. Kerry, Tim Johnson, Debbie Stabenow, Jon Kyl, Ken Salazar, Bill Nelson, Benjamin E. Nelson, Edward M. Kennedy, Robert Menendez, Barbara A. Mikulski, Russell D. Feingold, George V. Voinovich, Mary L. Lanorieu, Maria Cantwell, Barack Obama, Joseph I. Lieberman, Jeff Bingaman, Harry Reid, John D. Rockefeller, IV, Conrad Burns, Barbara Boxer, Mark Dayton, Lincoln Chafee, Patty Murray, Christopher S. Bond, Carl Levin, Mike DeWine, Chuck Hagel, John Warner, Lindsey Graham, Richard M. Burr, James M. Talent, Jeff Sessions, and Ron Wyden.

¹⁴U.S. Public Opinion of Chimpanzee Research, Support for a Ban, and Related Issues, Prepared for the New England Anti-Vivisection Society, by the Humane Research Council, 2005.

¹⁵Public Opinion Poll, Prepared for the Chimpanzee Collaboratory, by Zogby International, 2001.

PREPARED STATEMENT OF THE SPINA BIFIDA ASSOCIATION

On behalf of the more than 70,000 individuals and their families who are affected by Spina Bifida, the Spina Bifida Association (SBA) appreciates the opportunity to submit written testimony for the record regarding fiscal year 2007 funding for the National Spina Bifida Program and other related Spina Bifida initiatives. SBA is the national voluntary health agency working on behalf of people with Spina Bifida and their families through education, advocacy, research and service. The Association was founded in 1973 to address the needs of the Spina Bifida community and today serves as the representative of 56 chapters serving more than 125 communities nationwide. SBA stands ready to work with Members of Congress and other stakeholders to ensure our Nation takes all the steps necessary to reduce and prevent suffering from Spina Bifida.

BACKGROUND ON SPINA BIFIDA

Spina Bifida, a neural tube defect (NTD), occurs when the spinal cord fails to close properly during the early stages of pregnancy, typically within the first few weeks of pregnancy and most often before the mother knows that she is pregnant. Over the course of the pregnancy—as the fetus grows—the spinal cord is exposed to the amniotic fluid which increasingly becomes toxic. It is believed that the exposure of the spinal cord to the toxic amniotic fluid erodes the spine and results in Spina Bifida. There are varying forms of Spina Bifida occurring from mild—with little or no noticeable disability—to severe—with limited movement and function. In addition, within each different form of Spina Bifida the effects can vary widely. Unfortunately, the most severe form of Spina Bifida occurs in 96 percent of children born with this birth defect.

The result of this neural tube defect is that most children with it suffer from a host of physical, psychological, and educational challenges—including paralysis, developmental delay, numerous surgeries, and living with a shunt in their skulls which seeks to ameliorate their condition by helping to relieve cranial pressure associated with spinal fluid that does not flow properly. As we have testified previously, the good news is that after decades of poor prognoses and short life expectancy, children with Spina Bifida are now living long enough to become adults with Spina Bifida. These gains in longevity principally are due to breakthroughs in research, combined with improvements generally in health care and treatment. However, with this extended life expectancy, our Nation and people with Spina Bifida now face new challenges—education, job training, independent living, health care for secondary conditions, aging concerns, among others. Despite these gains, individuals and families affected by Spina Bifida face many challenges—physical, emotional, and financial. Fortunately, with the advent of the National Spina Bifida Program 4 years ago, individuals and families affected by Spina Bifida now have a national resource to provide them with the support, information, and assistance they need and deserve.

While the consumption of 400 micrograms of folic acid daily prior to becoming pregnant and throughout the first trimester of pregnancy, can help reduce the incidence of Spina Bifida by up to 75 percent, cases of Spina Bifida still occur and our Nation still must take steps to ensure that the tens of thousands of individuals living with Spina Bifida can live full, healthy, and productive lives. To ensure the highest quality-of-life possible, prevention interventions and treatment therapies must be identified, developed, and delivered to those in need.

COST OF SPINA BIFIDA

It is important to note that the lifetime costs associated with a typical case of Spina Bifida—including medical care, special education, therapy services, and loss of earnings—are as much as \$1 million. The total societal cost of Spina Bifida is estimated to exceed \$750 million per year, with just the Social Security Administration payments to individuals with Spina Bifida exceeding \$82 million per year. Moreover, tens of millions of dollars are spent on medical care paid for by the Medicaid and Medicare Programs. Our Nation must do more to help reduce the emotional, financial, and physical toll of Spina Bifida on the individuals and families affected. Efforts to reduce and prevent suffering from Spina Bifida help to save money and save lives.

IMPROVING QUALITY-OF-LIFE THROUGH THE NATIONAL SPINA BIFIDA PROGRAM

SBA has worked with Members of Congress to ensure that our Nation is taking all the steps possible to prevent Spina Bifida and diminish suffering for those currently living with this condition. With appropriate, affordable, and high-quality medical, physical, and emotional care, most people born with Spina Bifida likely will

have a normal or near normal life expectancy. Ensuring access to these services is essential to improving the quality-of-life for those born with this birth defect.

The National Spina Bifida Program at the National Center for Birth Defects and Developmental Disabilities (NCBDDD) at the Centers for Disease Control and Prevention (CDC) works on two critical levels—to reduce and prevent Spina Bifida incidence and morbidity and to improve quality-of-life for those living with Spina Bifida. The program seeks to ensure that what is known by scientists is practiced and experienced by the 70,000 individuals and families affected by Spina Bifida. Moreover, the National Spina Bifida Program works to improve the outlook for a life challenged by this complicated birth defect—principally identifying valuable therapies from in-utero throughout the lifespan and making them available and accessible to those in need.

The National Spina Bifida Program serves as a national center for information and support to help ensure that individuals, families, and other caregivers, such as health professionals, have the most up-to-date information about effective interventions for the myriad primary and secondary conditions associated with Spina Bifida. Among many other activities, the program helps individuals with Spina Bifida and their families learn how to treat and prevent secondary health problems, such as bladder and bowel control difficulties, learning disabilities, depression, latex allergy, obesity, skin breakdown and social and sexual issues. Children with Spina Bifida often have learning disabilities and may have difficulty with paying attention, expressing or understanding language, and grasping reading and math. All of these problems can be treated or prevented, but only if those affected by Spina Bifida—and their caregivers—are properly educated and taught what they need to know to maintain the highest level of health and well-being possible. The National Spina Bifida Program's secondary prevention activities represent a tangible quality-of-life difference to the 70,000 individuals living with Spina Bifida with the goal being living well with Spina Bifida.

In fiscal year 2006, Congress folded funding for a study on folic acid (also known as the "China Study") into the National Spina Bifida Program and provided \$5.1 million in fiscal year 2006 (a final allocation of \$5 million after the one percent across-the-board cut) for this new joint program. SBA appreciates Congressional interest and intent in ensuring that the CDC's folic acid and Spina Bifida activities are coordinated. SBA maintains a strong interest in working with NCBDDD and Members of the subcommittee to ensure that this new joint program fulfills Congressional intent and that the quality-of-life components of the National Spina Bifida Program receive adequate funding to support ongoing and expanded endeavors.

SBA advocates that the National Spina Bifida Program receive \$6 million in fiscal year 2007 and that that sum be used to expand and continue to promote quality-of-life programs that support people with Spina Bifida so they can live fulfilling and productive lives. In its first 3 years, this program already has made a difference for our community and with additional resources it can expand its reach and provide additional assistance and hope to those with an affected loved one. Increasing funding for the National Spina Bifida Program will help ensure that our Nation continues to mount a comprehensive effort to prevent and reduce suffering from Spina Bifida.

PREVENTING SPINA BIFIDA

While the exact cause of Spina Bifida is unknown, over the last decade, medical research has confirmed a link between a woman's folate level before pregnancy and the occurrence of Spina Bifida. Sixty million women are at-risk of having a child born with Spina Bifida and each year approximately 3,000 pregnancies in this country are affected by Spina Bifida, resulting in 1,500 births. As mentioned above, the consumption of 400 micrograms of folic acid daily prior to becoming pregnant and throughout the first trimester of pregnancy can help reduce incidence of Spina Bifida up to 75 percent. There are few public health challenges that our Nation can tackle and conquer by three-fourths in such a straightforward fashion. However, we must still be concerned with addressing the 25 percent of Spina Bifida cases that cannot be prevented by folic acid consumption, as well as ensuring that all women of childbearing age—particularly those most at-risk for a Spina Bifida pregnancy—consume adequate amounts of folic acid.

The good news is that progress has been made in convincing women of the importance of folic acid consumption and the need to maintain diet rich in folic acid. Since 1968, the CDC has led the Nation in monitoring birth defects and developmental disabilities, linking these health outcomes with maternal and/or environmental factors that increase risk, and identifying effective means of reducing such risks.

Former CDC Director Jeff Koplan has stated that the agency's folic acid prevention campaign has reduced neural tube defect births by 20 percent. This public health success should be celebrated, but it is only half of the equation as approximately 3,000 pregnancies still are affected by this devastating birth defect. The Nation's public education campaign around folic acid consumption must be enhanced and broadened to reach segments of the population that have yet to heed this call—such an investment will help ensure that as many cases of Spina Bifida can be prevented as possible.

SBA works collaboratively with CDC and the March of Dimes to increase awareness of the benefits of folic acid, particular for those at elevated risk of having a baby with neural tube defects (those who have Spina Bifida themselves or those who have already conceived a baby with Spina Bifida). With additional funding in fiscal year 2007 these activities could be expanded to reach the broader population in need of these public health education, health promotion, and disease prevention messages. SBA advocates that Congress provide additional funding to CDC to allow for a particular public health education and awareness focus on at-risk populations (e.g. Hispanic-Latino communities) and health professionals who can help disseminate information about the importance of folic acid consumption among women of child-bearing age.

In addition to a \$6 million fiscal year 2007 allocation for the National Spina Bifida Program, SBA supports a fiscal year 2007 allocation of \$135 million for the NCBDDD so the agency can enhance its programs and initiatives to prevent birth defects and developmental disabilities and promote health and wellness among people with disabilities.

IMPROVING HEALTH CARE FOR INDIVIDUALS WITH SPINA BIFIDA

The mission of the Agency for Healthcare Research and Quality (AHRQ) is to improve the outcomes and quality of health care; reduce its costs; improve patient safety; decrease medical errors; and broaden access to essential health services. The work conducted by the agency is vital to the evaluation of new treatments in order to ensure that individuals and their families living with Spina Bifida continue to receive the high quality health care that they need and deserve—SBA recommends that AHRQ receive \$443 million in fiscal year 2007 so that it can continue to conduct follow-up efforts to evaluate Spina Bifida treatments, promulgate associated standards of care, and further the provision of evidence-based care stemming from the outcomes of the 2003 Spina Bifida Research Conference.

SUSTAIN AND SEIZE SPINA BIFIDA RESEARCH OPPORTUNITIES

SBA seeks to support individuals and families affected by Spina Bifida, maximize the prevention of Spina Bifida, and ensure that all babies born with Spina Bifida have the greatest chance of survival and the highest quality-of-life—through the lifespan. When families recently diagnosed with a Spina Bifida pregnancy contact SBA, the organization puts them in touch with another family who has a child with the condition so they can learn of the joys and challenges of having a child with the birth defect. Unfortunately, traditionally when families have faced a Spina Bifida diagnosis they have had two difficult options. The first is to continue the pregnancy with the expectation of multiple surgeries for the child after birth, uncertain life expectancy, and many physical and developmental challenges and complications. The second, unfortunately, is to terminate the pregnancy. Fortunately, now there may be an important and effective third option.

Since the late 1990s, doctors at three U.S. hospitals—Children's Hospital of Philadelphia, Vanderbilt University Medical Center in Nashville, and the University of California at San Francisco—have been operating before birth on fetuses diagnosed with Spina Bifida. In 2004, the University of North Carolina became the fourth hospital in the Nation to perform the in-utero operations. By closing the spinal lesion early in pregnancy, physicians believe they can minimize the damage created by fluid leaking from the spine, as well as limit by the harm done due to the spinal cord's contact with the amniotic fluid. Surgeons have found that closing the hole in the spine in this fashion before birth may correct breathing problems in 15 percent of the children receiving the procedure and may reduce the need for a shunt to drain fluid from the brain by between 33 percent and 50 percent.

To determine whether or not this new procedure is safer and more effective than the traditional post-birth surgery to address the condition, the National Institute of Child Health and Human Development (NICHD) is conducting a large study involving the Children's Hospital of Philadelphia, Vanderbilt University Medical Center, and the University of California at San Francisco. While these three institutions have undertaken preliminary studies of the in-utero surgery technique, the overall

and long-term effectiveness of this approach as compared to traditional therapy remains unknown. Given the potential for this surgery to ameliorate many of the conditions associated with Spina Bifida, we must do a better job of studying and evaluating this procedure, educating health care providers about this surgery as a potential option, and making information about it available to more families facing a Spina Bifida pregnancy.

Additionally, the National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK) is scheduled to host an interagency meeting in spring 2006 on urological complications. We are also excited to report that the National Institute of Neurological Disorders and Stroke (NINDS) has formed a trans-agency Spina Bifida Working Group. SBA looks forward to working with both agencies on these and other important Spina Bifida related initiatives.

Our Nation has benefited immensely from our past Federal investment in biomedical research at the National Institutes of Health (NIH). SBA joins with the rest of the public health community in advocating that NIH receive \$29.7 billion in fiscal year 2007. This funding will support applied and basic biomedical, psychosocial, educational, and rehabilitative research to improve the understanding of the etiology, prevention, cure and treatment of Spina Bifida and its related conditions. In addition, SBA urges the NIH to explore the following as they relate to individuals with Spina Bifida: assistive technology, in utero surgery, cost of care, women's and men's health, tethered spinal cord, hydrocephalus, latex allergies, and other related factors.

CONCLUSION

SBA stands ready to work with policymakers to advance policies that will reduce and prevent suffering from Spina Bifida. Again, we thank you for the opportunity to present our views on funding for programs that will improve the quality-of-life for the 70,000 Americans and their families living with Spina Bifida and stand ready to answer any questions you may have.

PREPARED STATEMENT OF THE TUOMEY HEALTHCARE SYSTEM

Mr. Chairman, and Members of the subcommittee, thank you for the opportunity to submit testimony regarding the need for a Bedside Medication Verification System and subsequently a Computerized Practitioner Order Entry and Clinical Decision Support System at Tuomey Healthcare System.

For more than 90 years, Tuomey's growth and advancement have been guided by professionals who care deeply about the Sumter community and the individual healthcare needs of every person in it. From the small 20-bed Sumter Hospital born out of Timothy Tuomey's gift in 1913 to a healthcare system of more than 1,600 employees and 266 beds, Tuomey's history has been one of compassion and resolve. It is propelled by a long-term vision for healthcare that's second to none and is enhanced by a deeply philanthropic mission.

Since 2000, Tuomey has provided tens of millions of dollars in community services. And each year, we absorb almost \$20 million in indigent care. Our employee base is tremendously dedicated to Sumter's health as well, as evidenced by their gift of close to \$1 million since 2000. Through all of this, Tuomey is committed to Sumter, and it shows in everything we do. In the last year, Tuomey has ranked in the 97th and 98th percentiles nationally in the Press Ganey customer satisfaction scores in the inpatient and ambulatory surgery center categories.

The demand for Tuomey services will be further increased with the upcoming addition of approximately 850 service men and women to Shaw Air Force Base and the closing of the base's inpatient hospital. This equates to an approximate 3,000 person increase in total population to the Sumter community. To handle Tuomey's additional patient volume and to continue providing the quality care for which we are known, it is imperative we increase our inpatient capacity. Likewise, we must expand our women's and obstetrics service areas and our Emergency Department to meet the growing needs of this community. It is an expensive proposition, but one to which we are committed. It's the next step in our path to safeguarding this community's health.

Plans are currently underway for the construction of a new 24-bed women's complex called The Tuomey Women's Center, expansion and enhancement of our nurseries, the addition of 22 general medical inpatient rooms, and the expansion of the Emergency Department. The total combined cost of these expansions and enhancements is \$31.5 million.

High quality care and patient safety are the core elements of everything we do at Tuomey, utilizing technology where appropriate and cost effective. We have been

a Meditech Information Systems customer since 1988, with virtually every department in our facility computerized, to include nursing documentation, radiology results, laboratory results and all financials. In July 2005, we went live with the McKesson Electronic Medical Record, which allows physicians to access patient information from anywhere with an internet connection, enhancing the timely delivery and continuity of care. However, even with the benefits gained from our technology, we still deal with the challenges of caring for sicker patients in a shorter period of time with limited financial resources and shortages of skilled labor. Like many other hospitals, a completely safe and accurate medication management process remains one of our most difficult challenges. In addition, the medication management process is one of the areas where technology can offer the greatest number of improvements in terms of patient safety and quality of care.

In its 1999 report, "To Err is Human: Building a Safer Health System," The Institute of Medicine (IOM) estimated that 44,000 to 98,000 patients die each year from medical errors, of which the largest portion, up to one-third, has been linked to medication errors or adverse drug events (ADEs). A medication error can lead to increased charges and longer patient stays while adverse drug events can lead to patient injury and death. While there is a difference between medication errors and adverse drug events, Tuomey's goal is to avoid both and to consistently offer the highest quality care in the safest patient care environment possible.

Medication administration safety is dependent on five basic safety checks: the correct patient, the correct drug, the correct dose, the correct route of administration and the correct time of administration. Any deviation from these five standards of medication administration practice can lead to medication errors and Adverse Drug Events. Given that there are now more than 17,000 brand and generic names for pharmaceuticals in North America and nurses are caring for sicker patients on shorter hospital stays, the implementation of automated systems to safeguard against human errors in all aspects of the medication administration process has reached a state of critical need at Tuomey.

Currently, Tuomey is using an antiquated, yet not uncommon, system of medication ordering in which providers handwrite orders that are sent via pneumatic tube to a pharmacy location. The pharmacy staff deciphers the handwritten orders to the best of their human ability and sends the medications to the nursing staff that then rely on handwritten orders and the five rights of medication administration. In addition, the pharmacy charges the patient's account for the medications at the point the medications are dispensed from the pharmacy. The pharmacy is then responsible for crediting the patient's account if the medications are never taken.

The failure rate for this type of system is staggering throughout the healthcare community. Physicians, pharmacists, nurses and support staff work long hours with fluctuating levels of stress. Experts have estimated that at least 38 percent of all medication errors take place at the bedside using manual handwritten systems like the one currently in use at Tuomey. There are simply too many distractions and too many chances for something to go wrong when completely relying on protocols and procedures to assure safe and accurate medication administration. It is important to note, though, that Tuomey has never been complacent with a system that puts any patient at risk. Tuomey has remained vigilant to the risks associated with its current medication administration process and has made many improvements and changes to the manual system to promote patient safety and accuracy.

Unfortunately, for many years, there has not been a feasible alternative to the manual system. Technology and system availability have only recently reached a State worth investigating for true process improvement. Tuomey has investigated the currently available technologies and has identified viable solutions to improve the medication administration process. Bedside Medication Administration systems using barcode verification (BMV) and Computerized Physician Order Entry with Clinical Decision Support (CPOE/CDSS) have been identified as two systems that can greatly minimize the chance of errors and promote the highest quality care in the medication administration process.

Bedside Medication Administration using barcode identification systems have consistently been shown to improve patient safety and patient billing in hospital sites throughout the country. The basic process for bar code medication administration systems begins with an initial positive identification of a patient by the nursing staff. After the initial identification, the patient is given a wristband with an identifying bar code. From that point forward, the patient will be identified via a scan of the wristband's bar code. Before administering any medication or performing a treatment, the patient must be identified to the system via the scan. By first correctly identifying the patient to the system, the nurse then allows the system to double check the other four rights before the actual administration.

If a medication order has expired or been changed, the nurse is immediately alerted to avoid a possible medication error or Adverse Drug Event. The basic setup for the bar code medication administration system involves a laptop computer with a scanner linked to a hospital wireless network that runs the medication verification and patient billing systems. Accurate identification and correct order association assure patient safety and patient billing is accurately updated at the point of administration.

Computerized Practitioner Order Entry (CPOE) and Clinical Decision Support System (CDSS) implementation at Tuomey will virtually eliminate the chance of error in the deciphering of handwritten orders and eliminate any need for transcription all together since providers will be entering all medication and treatment orders directly into the information system with alerts and warnings regarding allergies, duplications and dangerous interactions readily available. If the orders are accurately entered and double checked for safety, then the bedside point of administration system will accurately ensure the correctly entered orders are carried out safely and accurately as intended by the ordering clinicians. Nurses will ensure that all five standards of medication administration are correct and accurate using barcodes identifying both the medication and the patient.

While Bedside Medication Verification and Computerized Practitioner Order Entry/Clinical Decision Support Systems are highly interdependent, staging of the implementations are vital to success. CPOE/CDSS cannot receive real-time feedback regarding medication administration without a Bedside Medication Verification system implemented and functioning. Likewise, Computerized Practitioner Order Entry (CPOE) and Clinical Decision Support System (CDSS) maturity lags behind Bedside Medication Verification due to the level of sophistication and logic design required. Any implementation strategy for Bedside Medication Verification and CPOE/CDSS at Tuomey Healthcare System must include plans to implement Bedside Medication Verification before moving to the other systems.

In fiscal year 2007, we hope that the subcommittee will support our request for funding of \$1.5 million in order to implement a Bedside Medication Verification system that will be Phase I of this entire project. It is our belief that we will be highly successful in this project and could serve as a resource and site for other health care organizations to learn from in enhancing the safety of all patients.

As healthcare continues to evolve, so does Tuomey Healthcare System. We're here to anticipate the needs of the communities we serve, responding with proactive healthcare initiatives, such as the systems noted above. Our stable but consistent growth positions Tuomey as one of South Carolina's largest healthcare systems. Tuomey is committed to Sumter, and it shows in everything we do.

NATIONAL INSTITUTES OF HEALTH

PREPARED STATEMENT OF THE AMERICAN ASSOCIATION FOR CANCER RESEARCH (AACR)

The number of cancer deaths is falling and the number of cancer survivors is increasing each year. This remarkable progress has occurred because of the advances in cancer research, discovery, detection, prevention, and treatment made possible, in part, by a strong and steady level of funding and commitment by the Federal Government.

The National Cancer Program supports an incredible array of cancer research programs that shows great promise for benefit to patients with cancer. To sustain the research momentum that has been so carefully built up over the past decade—and to continue to give hope to those with cancer—the Congress must provide sufficient resources to preserve the scientific infrastructure and foster new discoveries.

The American Association for Cancer Research (AACR) stands ready to contribute its share to accelerate our progress against this devastating disease. The AACR joins with other leaders in the cancer community to call upon the Congress to take the following actions to enable these invaluable programs to continue their contributions to improving the lives of patients with cancer and other life-threatening diseases:

- (1) Provide a 5 percent increase in funding for the National Institutes of Health to \$29.75 billion for fiscal year 2007; and
- (2) Provide a 5 percent increase in funding for the National Cancer Institute to \$5.03 billion for fiscal year 2007.

Early this year, it was reported that the number of cancer deaths every year in the United States fell for the first time in more than 70 years. Coupled with the fact that observed cancer death rates from all cancers combined dropped 1.1 percent

each year from 1993 to 2002, these persistent declines in cancer mortality rates are evidence of the success of the National Cancer Program and its research, prevention, and treatment advances.

Among these advances are a series of new targeted cancer therapies that have evolved from a process of rational drug design based upon our expanded understanding of the genetic basis of disease. For example, Herceptin became the first targeted therapy for breast cancer in 1997—it is an injectable antibody that targets and blocks the function of HER2 protein when it is overproduced in the body, which leads to cancer. In 2001, Gleevec became the first approved kinase inhibitor for cancer, shutting down the BCR-ABL kinase that causes chronic myeloid leukemia. These discoveries have led to a half-dozen other more recent drug approvals that are based upon these and other novel mechanisms of action.

Exciting, life-saving scientific progress such as this will only continue if it is nurtured and sustained by an adequate level of Federal research investment. The American Association for Cancer Research (AACR) calls upon the President and the United States Congress to make the commitment to sustain this research momentum by increasing the appropriations for the National Institutes of Health (NIH) to \$29.75 billion and the National Cancer Institute (NCI) to \$5.03 billion for fiscal year 2007. Without such a commitment, promising research will be abandoned, new treatments may never come to fruition, and patients with cancer will lose the hope of enjoying a life beyond cancer.

The AACR stands ready to contribute its share to accelerate our progress against this devastating disease. As AACR approaches its Centennial Year in 2007, with more than 24,000 members, it is well positioned to foster and facilitate the scientific developments that will underpin our forward movement in basic, translational, and clinical cancer research. Through its five prestigious scientific journals—including *Cancer Research*, the most frequently cited cancer journal in the world—AACR rapidly disseminates cutting-edge, peer-reviewed findings throughout the medical research community. AACR's Annual Meeting attracts more than 16,000 scientists worldwide to cross-disciplinary sessions led by the world's leading experts. The AACR has been at the forefront of the art of anticancer drug development and the science of cancer prevention, and originated the annual International Conference on Cancer Prevention Research. Through these high quality scientific meetings, along with prestigious awards and research training programs and grants, the AACR utilizes a multilayered approach to stimulate and foster the best science that will lead to the conquest of cancer.

No single sector or entity alone can successfully tackle the complex set of diseases known as cancer. Academic scientists and clinicians have a large role to play in discovery and the translation of discoveries into standard clinical care. Biotechnology and pharmaceutical companies, with their vast research and development and manufacturing and distribution capabilities, are also essential for the smooth, efficient, and effective delivery of cancer medicines to hospitals and patients. Barriers or roadblocks in any aspect of the research, discovery, development, or delivery path will have an adverse impact on achieving the goal of conquering cancer and saving lives.

Central to this multisector effort is the National Cancer Program and the fundamental and foundational work of the National Cancer Institute. For 35 years, because of the National Cancer Act, the NCI has spearheaded the research efforts that have led to the declining mortality rates we are experiencing today. The strategies underlying the National Cancer Program have been developed by the NCI in close collaboration with the cancer community. Each year the Director of the NCI engages in an open and transparent priority-setting process to develop a plan and budget proposal for the following year. It is reviewed by the cancer community and published each fall as *The Nation's Investment in Cancer Research: A Plan and Budget Proposal*. It is the definitive guide to how the NCI is using its funds and how it plans to spend additional funds should they become available.

The scope and breadth of the activities in which the National Cancer Institute is engaged are truly remarkable. As the leader of the Nation's grand plan to attack cancer, the NCI must be provided with the resources necessary to carry out its mission on many different fronts and in many different ways. The five-year doubling of the budget of the NIH enabled the National Cancer Institute to begin to expand its activities into promising new areas that had been beyond its reach. However, since the completion of the budget doubling in 2003, negligible NCI budget increases (in the .5 to 2.6 percent range) and an actual hard budget cut in fiscal year 2006, have forced retrenchment and curtailing of some research.

Our Nation's current investment in the National Cancer Institute supports a broad range of scientific research, infrastructure, communications structure, and technological advances. The AACR strongly supports continued and increased in-

vestments in these key areas as the surest way to guarantee progress against cancer. In particular, the AACR urges that the NCI maintain its focus on:

- Research to understand the causes and mechanisms of cancer, including continued studies into the genetic, environmental, and lifestyle factors that contribute to cancer causation. This research includes population studies that identify cancer risks, studies of normal as well as abnormal biological functioning, and research on cellular and molecular mechanisms of cancer initiation, progression, and metastasis.
- Research on new approaches to prevent or delay the onset of cancer, including nutrition, vaccination, and chemoprevention. This research should continue its emphasis on behavioral factors that affect cancer risk—poor diet, lack of physical activity, sun exposure, and tobacco use—and strategies to change these behaviors.
- Research to improve early detection and diagnosis of cancer through the discovery and development of biomarkers and imaging techniques. This research includes using proteomic technologies to develop biomarker panels and anatomical and molecular imaging techniques to detect tumors and identify metastasis, as well as studying how patients accept and comply with cancer screening methods.
- Research to discover, develop, and evaluate therapeutics for destroying or controlling cancer cells and metastasis. These include localized therapies—such as surgery or radiotherapy; systemic therapies—such as chemotherapy or vaccines; molecularly targeted therapies (such as Herceptin and Gleevec) directed at specific tumors or tissues; and combinations which are often more effective than either therapy alone.
- Research to improve the quality of cancer care and the quality of life of cancer patients, including the development of ways to measure quality, the impact of aging on quality of care, health and lifestyle issues of cancer survivors, and the development and application of interventions to overcome cancer health disparities.

The National Cancer Institute carries out this vast research portfolio through a wide variety of different vehicles and mechanisms in its research infrastructure. The AACR strongly favors continued and increased support for these areas to optimize the return on research dollars. In particular, the AACR recommends that the National Cancer Institute continue to utilize the following successful multisector approaches to implementing the National Cancer Program:

- Extramural program supports independent scientists conducting research in universities, teaching hospitals, and other organizations outside the NIH. The largest portion of NCI research funds is devoted to this program. It supports a balanced portfolio of more than 7,000 research and training awards, as well as grants, cooperative agreements, and contracts with individual investigators, professional societies, and research institutions. Peer-reviewed research under this program includes genetic, epidemiological, behavioral, social, applied, and surveillance research, basic prevention science, cancer biomarkers, chemopreventive agent development, community oncology and prevention trials, early detection, nutrition science, organ system research, cancer diagnostics, imaging, drug development, and biometrics, among others.

Thousands of AACR member scientists participate in and depend upon support from the extramural program to advance their research goals. Investigator-initiated scientific research is the engine driving new discoveries and advances in cancer research and it must remain at the forefront of efforts to conquer this disease. Funding for this aspect of the National Cancer Program must be maintained at a sufficiently high level to promote and advance research progress.

- Training and Career Development to increase the number of scientists who specialize in the basic or clinical biomedical fields is a critical NCI function. Such investments foster the development of interdisciplinary teams and ensure a growing core of well trained investigators to focus on cancer.
- Partnerships, including with other agencies, pharmaceutical companies, academia, and a wide variety of other organizations, are essential to leverage the limited resources of the NCI. Interagency agreements with the Food and Drug Administration and the Centers for Medicare and Medicaid Services have been highly successful in expediting new drug development and coverage for new treatments. The Academic Public Private Partnership Program (AP⁴) supports a new way of accelerating drug discovery and development through multiple partnerships.
- Additional important means used by the National Cancer Institute to advance its cancer research agenda include Cancer Centers and Centers of Research Excellence at major academic and research institutions across the country; Net-

works and Consortia, such as the Early Detection Research Network; NCI-Supported Clinical Trials that involve more than 12,000 investigators; Cancer Surveillance through the voluminous data collected by the NCI Surveillance, Epidemiology, and End Results (SEER) program; Technology Development, including the cancer Biomedical Informatics Grid (caBIG) platform for sharing research data; and Communication, Education, and Dissemination of research progress directly to and for the benefit of the public and public health professionals.

Through this wide array of effective mechanisms, the National Cancer Institute seeks to implement the ambitious research goals of the National Cancer Program. Each facet of the strategy is important and generates synergies with other facets to accomplish more than the apparent sum of the parts. Cuts to cancer research funding jeopardize multiple facets of the strategy and have a direct adverse impact on patients by delaying or halting development of promising treatments.

To sustain the research momentum that has been so painstakingly built up over the past decade, the Congress must provide sufficient resources to preserve the current infrastructure and prevent its diminishment through inflation or other means. The American Association for Cancer Research and the cancer community, recognizing the many competing demands on the Federal budget, believe that, at a minimum, a 5 percent increase for the NIH and the NCI, to \$29.75 billion and \$5.03 billion respectively, will enable these valuable programs to continue in a strong, if not robust, way.

To make a quantum push forward with our efforts against cancer, the Director of the National Cancer Institute has identified, with significant communitywide input, at least five additional areas and opportunities that the NCI is poised to exploit if the resources become available. By investing in these new strategic initiatives (at an additional cost of less than \$800 million) the Congress will clearly demonstrate its strong commitment to making the conquest of cancer a national priority and a goal that is within our reach. Several of these areas for strategic new investments to accelerate our progress against cancer include:

- Expand the Number of Cancer Centers to improve access for underserved populations and extend their outreach and collaboration capabilities.
- Reengineer Cancer Clinical Trials through implementation of the recommendations of the Clinical Trials Working Group.
- Link Science and Technology using a variety of new mechanisms and resources.
- Integrate Cancer Science and encourage interdisciplinary team science across the biomedical research community.

This Nation has the most sophisticated and highly developed biomedical research infrastructure in the world in the National Institutes of Health. A significant portion of that research investment is directed squarely at the cancer problem. Incredible progress has been made in understanding this disease and in devising cutting-edge approaches to preventing, controlling, and eliminating it. The pace of this research must be maintained to continue our record of advances that is leading to decreased mortality and improved patient care and outcomes.

The American Association for Cancer Research respectfully requests the Congress to support, at a minimum, a 5 percent funding increase for the National Institutes of Health (to \$29.75 billion) and the National Cancer Institute (to \$5.03 billion) to preserve the ability of these successful institutions to continue their groundbreaking work toward the conquest of cancer for the benefit of all of our citizens.

PREPARED STATEMENT OF THE AMERICAN ASSOCIATION FOR GERIATRIC PSYCHIATRY

The American Association for Geriatric Psychiatry (AAGP) appreciates this opportunity to present its recommendations on issues related to fiscal year 2007 appropriations for mental health research and services. AAGP is a professional membership organization dedicated to promoting the mental health and well being of older Americans and improving the care of those with late-life mental disorders. AAGP's membership consists of approximately 2,000 geriatric psychiatrists as well as other health professionals who focus on the mental health problems faced by senior citizens.

AAGP appreciates the work this subcommittee has done in recent years in support of funding for research and services in the area of mental health and aging through the National Institutes of Health (NIH) and the Substance Abuse and Mental Health Services Administration (SAMHSA). Although we generally agree with others in the mental health community about the importance of sustained and adequate Federal funding for mental health research and treatment, AAGP brings a unique perspective to these issues because of the elderly patient population served by our members.

AAGP recognizes the Federal budget constraints that the subcommittee must consider in making allocations. At the same time, it is important to note that research dollars and better trained professionals can help avert a crisis in the delivery of mental health care to the elderly in future generations when more efficient and effective therapies are identified through research. In fact, the *New England Journal of Medicine* has just published an important study, funded by NIMH, that suggests we can significantly decrease relapse rates in depression—which lead to more physician visits and hospitalizations—by continuing these patients for longer periods on antidepressant medication. In addition, studies of the IMPACT model for treating late-life depression suggest that effective treatment of depression in primary care reduces the cost of general health care in those settings.

Even as we note the important research being doing in the field, there are serious concerns, shared by AAGP and researchers, clinicians, and consumers that there exists a critical disparity between appropriations for research, training, and health services and the projected mental health needs of older Americans. This disparity is evident in the convergence of several key factors:

- demographic projections inform us that, with the aging of the U.S. population, there will be an unprecedented increase in the burden of mental illness among aging persons, especially among the baby boom generation;
- this growth in the proportion of older adults and the prevalence of mental illness is expected to have a major direct and indirect impact on general health service use and costs;
- despite the fact that effective treatment exists, the current mental health needs of many older adults remain unmet;
- the number of physicians being trained in geriatric mental health research and clinical care is insufficient to meet current needs, and this workforce shortfall is projected to become a crisis as the U.S. population ages over the next decade;
- a major gap exists between research, mental health care policy, and service delivery; and
- as funding for Federal health research has slowed across disciplines, the allocation of funds for research that focuses specifically on aging and mental health is disproportionately low, and woefully inadequate to deal with the impending crisis of mental health in older Americans.

In this context, it is important to note actions relating to late life mental health addressed by the White House Conference on Aging, which was convened by President Bush in December 2005. Recognizing the current health and mental health needs of older Americans and the challenges awaiting as the Baby Boom generation ages, delegates placed mental health and geriatric health professional training issues at the forefront by voting them among their top 10 resolutions.

DEMOGRAPHIC PROJECTIONS AND THE MENTAL DISORDERS OF AGING

With the baby boom generation nearing retirement, the number of older Americans with mental disorders is certain to increase in the future. By the year 2010, there will be approximately 40 million people in the United States over the age of 65. Over 20 percent of those people will experience mental health problems. A national crisis in geriatric mental health care is emerging and has received recent attention in the medical literature. Action must be taken now to avert serious problems in the near future. While many different types of mental and behavioral disorders can occur late in life, they are not an inevitable part of the aging process, and continued research holds the promise of improving the mental health and quality of life for older Americans.

The current number of health care practitioners, including physicians, who have training in geriatrics is inadequate. As the population ages, the number of older Americans experiencing mental problems will almost certainly increase. Since geriatric specialists are already in short supply, these demographic trends portend an intensifying shortage in the future. There must be a substantial public and private sector investment in geriatric education and training, with attention given to the importance of geriatric mental health needs. We will never have, nor will we need, a geriatric specialist for every older adult. However, without mainstreaming geriatrics into every aspect of medical school education and residency training, broad-based competence in geriatrics will never be achieved. There must be adequate funding to provide incentives to increase the number of academic geriatricians to train health professionals from a variety of disciplines, including geriatric medicine and geriatric psychiatry. This year's loss of all funding for geriatric health professions programs under Title VII of the Public Health Service Act is a stunning blow to this critical need, and AAGP urges the subcommittee to restore these programs.

Current and projected economic costs of mental disorders alone are staggering. It is estimated that total costs associated with the care of patients with Alzheimer's disease is over \$100 billion per year in the United States. Psychiatric symptoms (including depression, agitation, and psychotic symptoms) affect 30 to 40 percent of people with Alzheimer's and are associated with increased hospitalization, nursing home placement, and family burden. These psychiatric symptoms, associated with Alzheimer's disease, can increase the cost of treating these patients by more than 20 percent. Although NIA has supported extensive research on the cause and treatment of Alzheimer's, treatment of these behavioral and psychiatric symptoms has been neglected and should be supported through NIMH.

Depression is another example of a common problem among older persons. Of the approximately 32 million Americans who have attained age 65, about 5 million suffer from depression, resulting in increased disability, general health care utilization, and increased risk of suicide. Depression is associated with poorer health outcomes and higher health care costs. Co-morbid depression with other medical conditions affects a greater use and cost of medications as well as increased use of health services (e.g., medical outpatient visits, emergency visits, and hospitalizations). For example, individuals with depression are admitted to the emergency room for hypertension, arthritis, and ulcers at nearly twice the rate of those without depression. Those individuals with depression are more likely to be hospitalized for hypertension, arthritis, and ulcers than those without depression. And, those with depression experience almost twice the number of medical visits for hypertension, arthritis and ulcers than those without depression. Finally, the cost of prescriptions and number of prescriptions for hypertension, arthritis, and ulcers were more than twice than those without depression.

Older adults have the highest rate of suicide rate compared to any other age group. Comprising only 13 percent of the U.S. population, individuals age 65 and older account for 19 percent of all suicides. The suicide rate for those 85 and older is twice the national average. More than half of older persons who commit suicide visited their primary care physician in the prior month—a truly stunning statistic.

NATIONAL INSTITUTE OF MENTAL HEALTH

In his fiscal year 2007 budget, the President proposed a decrease in funding for the National Institutes of Health (NIH), for the first time in 30 years. This decline in funding is likely to have a devastating impact on the ability of NIH to sustain the ongoing, multi-year research grants that have been initiated in recent years.

AAGP would like to call to the subcommittee's attention the fact that, even in the years in which funding was increased for NIH and NIMH, these increases did not always translate into comparable increases in funding that specifically address problems of older adults. Data supplied to AAGP by NIMH indicates that while extramural research grants by NIMH increased 59 percent during the five-year period from fiscal year 1995 through fiscal year 2000 (from \$485,140,000 in fiscal year 1995 to \$771,765,000 in fiscal year 2000), NIMH grants for aging research increased at less than half that rate: only 27.2 percent during the same period (from \$46,989,000 to \$59,771,000). Furthermore, despite the fact that over the past 5 years, Congress, through committee report language, has specifically urged NIMH to increase research grant funding devoted to older adults, this has not occurred.

AAGP is pleased that NIMH has recently renewed its emphasis on mental disorders among the elderly, and commends the recent creation of a new Aging Treatment and Prevention Intervention Research Branch at NIMH. AAGP would like the scope of this Branch increased into a comprehensive aging Branch that is responsible for all facets of clinical research, including translational, interventions, and disease-based psychopathology. The Branch should also be given adequate resources to fulfill its primary mission within NIMH.

In addition to supporting research activities at NIMH, AAGP supports increased funding for research related to geriatric mental health at the other institutes of NIH that address issues relevant to mental health and aging, including the National Institute of Aging (NIA), the National Institute on Alcohol Abuse and Alcoholism (NIAAA), the National Institute on Drug Abuse (NIDA), and the National Institute of Neurological Disorders and Stroke.

CENTER FOR MENTAL HEALTH SERVICES

It is also critical that there be adequate funding for the mental health initiatives under the jurisdiction of the Center for Mental Health Services (CMHS) within SAMHSA. While research is of critical importance to a better future, the patients of today must also receive appropriate treatment for their mental health problems. SAMHSA provides funding to State and local mental health departments, which in

turn provide community-based mental health services to Americans of all ages, without regard to the ability to pay. AAGP was pleased that the final budgets for the last 5 years have included \$5 million for evidence-based mental health outreach and treatment to the elderly. AAGP worked with members of this subcommittee and its House counterpart on this initiative, which is a very important program for addressing the mental health needs of the Nation's senior citizens. Increasing this mental health outreach and treatment program must be a top priority, as it is the only Federally funded services program dedicated specifically to the mental health care of older adults.

The greatest challenge for the future of mental health care for older Americans is to bridge the gap between scientific knowledge and clinical practice in the community, and to translate research into patient care. Adequate funding for this geriatric mental health services initiative is essential to disseminate and implement evidence-based practices in routine clinical settings across the States. Consequently, we would urge that the \$5 million for mental health outreach and treatment for the elderly included in the CMHS budget for fiscal year 2005 be increased to \$20 million for fiscal year 2006. Of that \$20 million appropriation, AAGP believes that \$10 million should be allocated to a National Evidence-Based Practices Program, which will disseminate and implement evidence-based mental health practices for older persons in usual care settings in the community. This program will provide the foundation for a longer-term national effort that will have a direct effect on the well-being and mental health of older Americans.

The Community Mental Health Services Block Grant Program requires States and territories to include an annual plan for providing comprehensive community mental health services to adults with a serious mental illness and children with a serious emotional disturbance. Experience has demonstrated that States do not make adequate provisions for older adults. AAGP recommends that SAMHSA require these plans to include specific provisions for mental health services for older adults.

HEALTH RESOURCES AND SERVICES ADMINISTRATION

Despite growing evidence of the need for more geriatric specialists to care for the nation's elderly population, a critical shortage persists. For fiscal year 2006, the Congress inexplicably eliminated all funding for the geriatric health professions program under Title VII of the Public Health Service Act. The loss of these programs could have a disastrous impact on physician workforce development over the next decade, with dangerous consequences for the growing population of older adults who will not have access to appropriate specialized care. The geriatric health professions program supports three important initiatives. The Geriatric Faculty Fellowship trains faculty in geriatric medicine, dentistry, and psychiatry. The Geriatric Academic Career Award program encourages newly trained geriatric specialists to move into academic medicine. The Geriatric Education Center (GEC) program provides grants to support collaborative arrangements that provide training in the diagnosis, treatment, and prevention of disease. In fiscal year 2005, these programs were funded at \$31.5 million, but, while they were funded in the Senate Appropriations bill for fiscal year 2006, the final legislation followed the House version, which eliminated funding for them. AAGP urges the subcommittee to restore funding to this program at fiscal year 2005 levels.

The loss of these programs, just as the massive Baby Boomer generation are entering late life, will have a devastating effect on the Nation's ability to provide the kind of health care that will allow these seniors to be independent and productive as they age.

CONCLUSION

Based on AAGP's assessment of the current need and future challenges of late life mental disorders, we submit the following fiscal year 2007 funding recommendations:

1. The current rate of funding for aging grants at NIMH and CMHS is inadequate and should be increased to at least three times their current funding levels. In addition, the substantial projected increase in mental disorders in our aging population should be reflected in the budget process in terms of dollar amount of grants and absolute number of new grants.
2. To help the country's elderly access necessary mental health care, previous years' funding of \$5 million for evidence-based mental health outreach and treatment for the elderly within CMHS must be increased to \$20 million.
3. Funding for the geriatric health professions program under Title VII of the Public Health Service Act should be restored to fiscal year 2005 levels.

4. Both NIMH and CMHS must support adequate infrastructure and funding within both NIMH and CMHS to develop initiatives in aging research, to monitor the number and quality of applicants for aging research grants, to promote funding of meritorious projects, and to manage those grant portfolios.

5. The scope of the recently formed Aging Treatment and Prevention Intervention Research Branch at NIMH should be increased to include all relevant clinical research, including translational, interventions, and disease-based psychopathology, and must receive NIMH's full support so it may fulfill its primary mission.

AAGP looks forward to working with the members of this subcommittee and others in Congress to establish geriatric mental health research and services as a priority at appropriate agencies within the Department of Health and Human Services.

PREPARED STATEMENT OF THE AMERICAN ASSOCIATION OF IMMUNOLOGISTS

The American Association of Immunologists ("AAI") is pleased to have this opportunity to submit its views on fiscal year 2007 funding for the National Institutes of Health (NIH). AAI would like to thank the members of the subcommittee for their strong support for biomedical research, and in particular, express our great appreciation to the chairman, Senator Specter, and Ranking Member, Senator Harkin, for their extraordinary leadership and dedication to advancing biomedical research.

The AAI is a not-for profit professional society representing more than 6,500 research scientists and physicians who are the world's leading experts on the immune system. While our members work in academia, government, and industry, most are among the more than 200,000 research personnel affiliated with more than 3,000 institutions who depend on NIH funding to support their work.¹ With approximately 84 percent of NIH funds awarded to these individuals and institutions, NIH's funding level has a huge impact both on the advancement of biomedical research and on the local, State, and national economies.

THE IMPORTANCE OF IMMUNOLOGY

Immunological research is crucial in a world increasingly at risk from infectious agents and chronic diseases.² Basic research on the immune system provides a foundation for the development of diagnostics, vaccines, and therapeutics. Current efforts are focused on preventing and treating diseases caused by natural infectious agents, including influenza and avian flu, SARS, West Nile Virus, tuberculosis, and AIDS, as well as those that may be modified for use as agents of bioterrorism, including plague, smallpox, and anthrax. In addition, basic immunological research continues to be crucial in the development of increasingly effective approaches for treating chronic diseases, including cancer, autoimmune diseases, inflammatory disorders, and immunodeficiencies.

The immune system works by recognizing and attacking "foreign invaders" (i.e., bacteria and viruses) inside the body. It also plays an important role in controlling the growth of tumor cells. The immune system can protect its host (human or animal) from illness or disease either entirely—by attacking and destroying the virus, bacterium, or tumor cell—or partially, resulting in a less serious illness. But even a healthy immune system cannot completely protect us from all threats that might cause disease. Moreover, the immune system also has a "dark side": it can lead to the rejection of transplanted organs or bone marrow and—if it is working improperly—can allow the body to attack itself instead of an invader, resulting in an "auto-immune" disease (e.g., Type 1 diabetes, multiple sclerosis, rheumatoid arthritis).

Recent advances in immunology have allowed for revolutionary treatments. For example, therapeutic substances called "biologics" have provided new, effective treatments for painful, debilitating and life-threatening diseases such as rheumatoid

¹National Institutes of Health Fiscal Year 2007 Performance Budget Overview, pp.1–2. Many AAI members are medical school professors and researchers who receive grants from NIH, and in particular from the National Institute of Allergy and Infectious Diseases (NIAID) and the National Cancer Institute (NCI) (as well as other NIH Institutes and Centers), to support their research endeavors.

²Immunologists depend heavily on the use of animal models in their research. Without animal experimentation, theories about immune system function and treatments that might cure or prevent disease would have to be tested first on human subjects, something our society—and our scientists—would never countenance. Despite the clear necessity for animal research, we are experiencing both increasing regulatory burden in animal experimentation (eroding the return on NIH's investment), and threats from people and organizations that oppose such research. The legal and illegal methods used by some groups to further an animal-rights/anti-medical research agenda are diverting precious resources from our work, threatening the personal safety and security of scientists, and delaying the progress of important research now underway.

arthritis, inflammatory diseases, and cancer. Biologics that use modified human antibodies and cell receptors specifically target the substance (TNF) that causes joint destruction in rheumatoid arthritis, and the painful symptoms of psoriasis, and ankylosing spondylitis. An engineered antibody (herceptin) is being used to control the reoccurrence of breast cancer; resulting in a two-fold reduction in reoccurrence. Another monoclonal antibody and human protein—CTLA4Ig—has been dramatically effective in clinical trials treating prostate cancer and melanoma as well as showing promise as a treatment for lupus, arthritis, multiple sclerosis, and organ transplant rejection.

Immunologists have also focused on improved approaches to vaccine development, including a vaccine for *Hemophilus influenzae* type b. This vaccine has reduced the incidence of pediatric meningitis in the United States from approximately 20,000 to 200 cases per year. Our understanding of what makes an efficacious vaccine will be critical as we face future pandemics, be they natural, like avian flu, or altered pathogens that could be used for bioterrorism, like missilized anthrax.

None of these advances could have been made without substantial public investment in basic immunological research. But even as we make huge strides, new threats emerge: immunologists are working feverishly to defend against bird flu and potential bioterrorism pathogens.

THE NIH BUDGET: TROUBLE IN THE POST-DOUBLING YEARS

AAI is very grateful to this subcommittee and the Congress for doubling the NIH budget from fiscal year 1998 to fiscal year 2003. This “doubling” represented an unprecedented commitment by the Federal Government to preventing, treating, and curing disease, and has allowed scientists to begin new, cutting edge research made possible by recent advances in sequencing the genomes of humans, model organisms, and microbial pathogens that cause human and animal diseases.

But scientific research takes time, and the doubling of the NIH budget will have been for naught if we are unable to complete ongoing studies or retain trained personnel. Indeed, the doubling has already been eroded. Since 2003, the annual increases in the NIH budget have not kept pace with biomedical research inflation.³ Moreover, the President’s fiscal year 2007 “flat” budget would result in an effective decrease in the NIH budget, only the second time in 36 years that the NIH budget has been reduced. This would have a devastating effect:

1. Key NIH Institutes could be forced to drop paylines even lower than the current, far too low 10–14 percent (significantly below the approximately 22 percent funded during the doubling);⁴

2. There would be no inflationary increases for direct, recurring costs in non-competing Research Project Grants (RPGs), undermining NIH’s fiscal year 2007 goal to “preserve to the greatest extent possible the ability of scientists to obtain individual support for their research ideas.” National Institutes of Health Summary of the Fiscal Year 2007 President’s Budget February 6, 2006, p.3;

3. It would have rapid, adverse repercussions on the future of the research enterprise. Our brightest young people will be deterred from pursuing biomedical research careers if their chances of receiving an NIH grant become even lower. If we cannot attract and retain the best young minds, the United States will lose its pre-eminence in science and technology to nations—including India, Singapore, China, and Korea—that are investing aggressively to compete.

4. It would not permit increases in already inadequate stipends to pre- and post-doctoral fellows, and will undermine efforts to attract excellent scientists to NIH and to academia.

PANDEMIC INFLUENZA/INFLUENZA

Influenza leads to more than 200,000 hospitalizations and about 36,000 deaths nationwide in an average year. Pandemic influenza could cause millions of deaths and hospitalizations. Despite these very real threats, the President’s fiscal year 2007 NIH Budget includes an increase of only \$17 million to support specific re-

³NIH funding increases/decreases since the doubling period ended [fiscal year 2004 (3.03 percent), fiscal year 2005 (2.18 percent) and fiscal year 2006 (-.12 percent)] have all been below the Biomedical Research and Development Price Index (“BRDPI”), a U.S. Department of Commerce (“DOC”) estimate of the cost of inflation for biomedical research. The BRDPI was developed by the DOC’s Bureau of Economic Analysis under an agreement with NIH and is updated annually. It indicates how much the NIH budget must increase to maintain purchasing power. Projections for future years are prepared by the NIH Office of Science Policy.

⁴AAI analyzed paylines of key NIH Institutes from fiscal year 2000-fiscal year 2002; see www.nih.gov.

search initiatives focused on pandemic influenza, bringing total NIH spending on influenza to approximately \$199 million (about \$35 million over fiscal year 2006).

The vast majority of funds (more than \$3 billion) appropriated to date under the Department of Health and Human Services Pandemic Influenza Preparedness Plan have been devoted to other pandemic influenza related activities (including production/procurement of vaccines/antivirals). While these public health efforts are extremely important, it is essential to realize that any existing pathogen that could cause influenza or pandemic influenza (e.g., bird flu) can mutate, rendering existing countermeasures ineffective. Since new influenza strains can quickly emerge, research to identify new pathogens, understand the immune response, and develop tools for protecting against the pathogen should never take a back seat to other pandemic influenza-related activities. The need for this research supports AAI's request for an increased budget for NIH.

BIODEFENSE RESEARCH

AAI supports the President's request for \$1.891 billion for biodefense research, an increase of 6.2 percent over fiscal year 2006. NIH's fiscal year 2007 biodefense research priorities include continuing work on developing vaccines and treatments for anthrax, smallpox, plague, tularemia, hemorrhagic fevers, and botulinum toxin.

NIH plans to direct \$160 million to an Advanced Development Fund ("ADF") within the Office of the NIH Director to "support efforts to work with academia and industry to develop candidate countermeasures from the point of Investigation New Drug Application (INDA) to the level that these candidate countermeasures could be eligible for acquisition by Project Bioshield." AAI urges that the NIH Director work closely with the NIAID Director to ensure that the ADF focuses on NIH's traditional expertise in basic and translational research and not on activities relevant to commercial development or the manufacturing of a product.

NIH also plans to spend \$25 million to construct additional high containment laboratories at biosafety level (BSL) 3 and to renovate existing labs to meet current BSL-3 standards. (BSL-3 labs are necessary for the safe conduct of research on dangerous and infectious pathogens.) AAI recommends that these funds be used first for the renovation of existing labs; the construction of new labs may not be necessary with the limited research funding that may be available this year.

ADMINISTRATIVE ISSUES

1. Office of Portfolio Analysis and Strategic Initiatives

AAI supports the newly formed Office of Portfolio Analysis and Strategic Initiatives (OPASI) as a way of better managing and analyzing NIH's portfolio. While we understand the need for a "Common Fund" to support OPASI, we believe that, in this difficult fiscal climate, such a fund should be limited and should grow no faster than the overall NIH budget.

2. Research, Management and Support (RM&S)

The President's fiscal year 2007 budget proposal for Research, Management and Services (RM&S), which supports the management, monitoring, and oversight of intramural and extramural research activities (including NIH's highly regarded peer review process), includes an increase of \$14 million, or 1.3 percent. AAI supports an appropriate increase in the RM&S budget to ensure that it is sufficient (1) to enable NIH to supervise a portfolio of increasing size and complexity and (2) to ensure that NIH funds are well and properly spent.

3. Outsourcing

AAI continues to be concerned about the "outsourcing" of NIH jobs. While certain NIH jobs may be appropriate for such an approach, it should not be applied to program administration staff, many of whom are highly experienced and have historical knowledge and understanding of NIH programs and policies. Such outsourcing would result in the loss of a dedicated and capable workforce and reduce efficiency in the long run.

AAI'S RECOMMENDED BUDGET INCREASE FOR FISCAL YEAR 2007: 5 PERCENT (1.2 PERCENT ABOVE PROJECTED INFLATION)

AAI strongly believes that we must increase the NIH budget now in order to capitalize on important advances that have resulted from the doubling. We urge this subcommittee to increase the NIH budget by 5 percent (\$1.4 billion) in fiscal year 2007, for a total budget of \$29.75 billion. This increase, which is only 1.2 percent above the projected rate of biomedical research inflation, would enable researchers to capitalize on important advances that have resulted from the doubling, leading

to increased translational and clinical applications. It would also assist efforts to attract and retain bright young American scientists to research careers.

THE EFFECTIVE USE OF NIH FUNDS

While AAI advocates a 5 percent increase in NIH funding, we agree that NIH should use its existing funds as effectively as possible. To that end, we recommend the following:

(1) *The “NIH Roadmap for Biomedical Research” (“NIH Roadmap”)*

AAI notes that the President’s fiscal year 2007 budget request for the NIH Roadmap has grown to \$443 million, an increase of \$113 million over fiscal year 2006. While AAI supports this effort to fund multidisciplinary, interdisciplinary research and agrees that such research is an important part of biomedical research in the 21st century, we recommend that funds allocated to the NIH Roadmap not grow faster than the overall NIH budget and that all Roadmap funds, including the Director’s Pioneer Awards, be awarded through a rigorous peer review process.

(2) *NIH “Enhanced Access to Scientific Publications” Policy*

AAI recommends that NIH partner with not-for-profit scientific publishers to provide enhanced public access to NIH-funded research results, rather than continuing an expensive effort to publish manuscripts itself. In this era of limited funds, NIH should work with these willing partners to ensure that its budget is used to support and advance research and not to duplicate services already provided by the private sector. AAI urges the subcommittee to support efforts underway between NIH and the not-for-profit scientific publishing community to develop a policy that will enhance public access while addressing the concerns of publishers.

(3) *Peer review and the independence of science*

Millions of lives—as well as the prudent use of taxpayer dollars—depend on government officials receiving—and taking—the very best and most independent scientific advice available. We urge this subcommittee to provide oversight which ensures that funds expended enhance the ability of scientists to provide independent scientific advice (particularly on government scientific advisory panels) and preserve independent peer review (including ensuring the review of scientific research results by peers through robust, independent scientific journals).

CONCLUSION

AAI greatly appreciates this opportunity to testify and thanks the members of this subcommittee for your strong support for biomedical research, the NIH, and the scientists who devote their lives to preventing, treating, and curing disease. We look forward to working with you and hope that you will contact me or AAI if you have any questions or if we can be of assistance.

PREPARED STATEMENT OF THE AMERICAN ASSOCIATION OF NURSE ANESTHETISTS

FISCAL YEAR 2007 APPROPRIATIONS REQUEST SUMMARY

	Fiscal year 2006 actual	Fiscal year 2007 budget	AANA fiscal year 2007 request
HHS/HRSA/BHPr Title VIII Advanced Education Nursing, Nurse Anesthetist Education Reserve.	Awaiting grant allocations. \$3.5 million fiscal year 2005.	Grant allocations not specified.	\$4 million for nurse anesthesia education \$65 million for advanced education nursing
Title VIII HRSA BHPr Nursing Education Programs	\$151,191,000	\$150,000,000	\$175,000,000

The AANA is the professional association for more than 34,000 Certified Registered Nurse Anesthetists (CRNAs) and student nurse anesthetists representing over 90 percent of the nurse anesthetists in the United States. Today, CRNAs are directly involved in approximately 65 percent of all anesthetics given to patients each year in the United States. CRNA services include administering the anesthetic, monitoring the patient’s vital signs, staying with the patient throughout the surgery, as well as providing acute and chronic pain management services. CRNAs provide anesthesia for a wide variety of surgical cases and are the sole anesthesia providers in almost 70 percent of rural hospitals, affording these medical facilities ob-

stretical, surgical, and trauma stabilization, and pain management capabilities. CRNAs work in every setting in which anesthesia is delivered including hospital surgical suites and obstetrical delivery rooms, ambulatory surgical centers (ASCs), pain management units and the offices of dentists, podiatrists and plastic surgeons.

Nurse anesthetists are experienced and highly trained anesthesia professionals whose record of patient safety in the field of anesthesia was bolstered by the Institute of Medicine report that found in 2000, that anesthesia is 50 times safer than 20 years previous. (Kohn L., Corrigan J., Donaldson M., ed. *To Err is Human*. Institute of Medicine, National Academy Press, Washington DC, 2000.) Nurse anesthetists continue to set for themselves the most rigorous continuing education and re-certification requirements in the field of anesthesia. Relative anesthesia patient safety outcomes are comparable among nurse anesthetists and anesthesiologists, with Pine having recently concluded, “the type of anesthesia provider does not affect inpatient surgical mortality.” (Pine, Michael MD et al. *Surgical mortality and type of anesthesia provider*. *Journal of American Association of Nurse Anesthetists*. Vol. 71, No. 2, p. 109–116. April 2003.) In addition, a recent AANA workforce study’s data showed that CRNAs and anesthesiologists are substitutes in the production of surgeries. Through continual improvements in research, education, and practice, nurse anesthetists are vigilant in their efforts to ensure patient safety.

CRNAs provide the lion’s share of the anesthesia care required by our U.S. Armed Forces through active duty and the reserves, from here at home to the leading edge of the field of battle. In May 2003, at the beginning of “Operation Iraqi Freedom” 364 CRNAs were deployed to the Middle East to ensure military medical readiness capabilities. For decades, CRNAs have staffed ships, remote U.S. military bases, and forward surgical teams without physician anesthesiologist support.

IMPORTANCE OF TITLE VIII NURSE ANESTHESIA EDUCATION FUNDING

The nurse anesthesia profession’s chief request of the subcommittee is for \$4 million to be reserved for nurse anesthesia education and \$65 million for advanced education nursing from the Title VIII program. This sustained funding is justified by two facts. First, there is a 12 percent vacancy rate of nurse anesthetists in the United States impacting people’s healthcare. And second, the Title VIII program, which has been strongly supported by members of this subcommittee in the past, is an effective means to help address the nurse anesthesia workforce demand. This demand for CRNAs is something that the nurse anesthesia profession addresses every day with success, and with the critical assistance of Federal funding through HHS’ Title VIII appropriation.

The increase in funding for advanced education nursing from \$58 million to \$65 million is necessary to meet the continuing demand for nursing faculty and other advanced education nursing services throughout the United States. Only a limited number of new programs and traineeships can be funded each year at the current funding levels. The program provides for competitive grants and contracts to meet the costs of projects that support the enhancement of advanced nursing education and practice and traineeships for individuals in advanced nursing education programs. This funding is critical to the efforts to meet the nursing workforce needs of Americans who need healthcare.

In 2003, the AANA conducted a nurse anesthesia workforce study that concluded a 12 percent vacancy rate in hospitals for CRNAs, and a lower vacancy rate in ambulatory surgical centers. The supply has increased in recent years, stimulated by increases in the number of CRNAs trained. However, these increases had not been enough to offset the number of retiring CRNAs. This trend, established in 2003, requires a continuous growth in the number of nurse anesthesia graduates to fill the vacancy rate. This is compounded by the rising number of Medicare-eligible Americans, from about 34 million today to more than 40 million in 2010, who will require the care that CRNAs provide.

The problem is not that our 99 accredited programs of nurse anesthesia are failing to attract qualified applicants; it is that the programs are full. Each CRNA program continues to turn away qualified applicants—bachelor’s educated registered nurses who had spent at least 1 year serving in an acute care environment. These CRNA schools are located all across the country including the following:

State	Number of accredited nurse anesthesia programs
PA	12
FL	6
OH	5

State	Number of accredited nurse anesthesia programs
TX	5
IL	4
NY	4
CA	3
CT	3
MD	3
RI	2
WI	1

Recognizing the importance of nurse anesthetists to quality healthcare, the AANA has been working with the 99 accredited programs of nurse anesthesia to increase the number of qualified graduates. In addition, the AANA has worked with nursing and allied health deans to develop new CRNA programs.

The Council on Certification of Nurse Anesthetists (CCNA) reports that in 1999, our schools produced 948 new graduates. In 2005, that number had increased to 1,790, an 89 percent increase in just 5 years. This growth is expected to continue. The CCNA projects CRNA programs to produce over 1,900 graduates in 2006.

To truly meet the nurse anesthesia workforce challenge, the capacity and number of CRNA schools must continue to expand. With the help of competitively awarded grants supported by Title VIII funding, the nurse anesthesia profession is making significant progress, expanding both the number of clinical practice sites and the number of graduates.

The AANA is pleased to report that this progress is extremely cost-effective from the standpoint of Federal funding. Anesthesia can be provided by nurse anesthetists, physician anesthesiologists, or by CRNAs and anesthesiologists working together. As mentioned earlier, it has been confirmed, "the type of anesthesia provider does not affect inpatient surgical mortality." Yet, for what it costs to train just one anesthesiologist, several CRNAs may be educated to provide the same service with the same optimum level of safety. This represents a significant educational cost/benefit for supporting CRNA educational programs with Federal dollars vs. supporting other models of anesthesia education.

To further demonstrate the effectiveness of the \$3 million Title VIII investment in nurse anesthesia education, the AANA surveyed its CRNA program directors in 2003 to gauge the impact of the Title VIII funding. Of the eleven schools that had reported receiving competitive Title VIII Nurse Education and Practice Grants funding from 1998 to 2003, the programs indicated an average increase of at least 15 CRNAs graduated per year. They also reported on average more than doubling their number of graduates, who provide care to patients during and following their education. Moreover, they reported producing additional CRNAs that went to serve in rural or medically underserved areas. Under both of these circumstances, an increased number of student nurse anesthetists and CRNAs are providing healthcare to the people of medically underserved America.

We believe it is important for the subcommittee to allocate \$4 million for nurse anesthesia education for several reasons. First, as this testimony has documented, the funding is cost-effective and well needed. Second, the Title VIII authorization previously providing such a reserve expired in September 2002. Third, this particular funding is important because nurse anesthesia for rural and medically underserved America is not affected by increases in the budget for the National Health Service Corps and community health centers, since those initiatives are for delivering primary and not surgical healthcare. Lastly, this funding meets an overall objective to increase access to quality healthcare in medically underserved America.

TITLE VIII FUNDING FOR STRENGTHENING THE NURSING WORKFORCE

The AANA joins a growing coalition of nursing organizations and others in support of the subcommittee providing a total of \$175 million in fiscal year 2007 for nursing shortage relief through Title VIII. This amount is approximately \$25 million over the fiscal year 2005 level and over the President's fiscal year 2007 budget.

Every district in America is familiar with the importance of nursing. The AANA is appreciative of the leadership of the subcommittee and the congressional support for the \$5 million year 2005 increase over the President's request in fiscal year 2005 for nurse education funding.

America spends more than \$2 trillion on healthcare this year, paid by private and public sources. About \$298 billion accounted for Medicare outlays in 2005. Medicare directs about \$8.7 billion of that to fund direct and indirect GME, with some 99 per-

cent of that funding helping to educate physicians and allied health professionals, and about 1 percent to help educate nurses. For every present and future healthcare patient, Congress must put some focus on nurses and nurse anesthesia care.

To ensure that America has access to nurse anesthesia care when needed, a sustained investment from Congress is necessary especially for the provision of services in rural and medically underserved America. Quality anesthesia care provided by CRNAs saves lives, promotes quality of life, and makes fiscal sense. This Federal support for nurse education will improve patient access to quality services and strengthen the Nation's healthcare delivery system.

Thank you.

PREPARED STATEMENT OF THE AMERICAN COLLEGE OF CARDIOLOGY

The American College of Cardiology appreciates the opportunity to provide the subcommittee with recommendations for fiscal year 2007 funding for life-saving cardiovascular research and education.

The ACC is a 33,000 member non-profit professional medical society and teaching institution whose purpose is to foster optimal cardiovascular care and disease prevention through professional education, promotion of research, and leadership in the development of standards and formulation of health care policy.

Heart disease is the leading cause of death for both women and men in the United States, killing more than 900,000 Americans each year. More than 70 million Americans live with some form of heart disease. The economic impact of cardiovascular disease on the U.S. health care system continues to grow as the population ages. In 2005, heart disease and stroke were projected to cost the Nation \$393 billion, including health care services, medications, and lost productivity.

As the premier cardiovascular society, the ACC supports a strong Federal investment in research and public education that addresses the prevention, detection and treatment of cardiovascular disease. Current Federal research is providing breakthrough advances that fundamentally change our understanding of cardiovascular disease, leading to more effective treatments, decreased costs and increased quality of life for patients.

For instance, a study published in the February 2006 issue of the *Journal of the American College of Cardiology* yielded important findings for women with coronary heart disease. Part of the National Heart, Lung, and Blood Institute (NHLBI)'s Women's Ischemia Syndrome Evaluation (WISE) study, researchers found that women with a condition called coronary microvascular syndrome often go undiagnosed for heart disease because dysfunction occurs in very small arteries of the heart and does not show up when physicians use standard tests. As a result of the missed diagnosis, women are not treated for angina and high cholesterol and remain at high risk for a heart attack. National Institutes of Health (NIH) studies like WISE are helping to unravel the mystery of cardiovascular disease in women and hold immediate implications for the treatment of women at risk for heart disease.

The ACC is extremely concerned that the administration's budget request proposes no increase in funding for the NIH and cuts funding for many critical health programs. If instituted, the administration's budget would force the research community to scale back and even halt valuable initiatives. The ACC is encouraged that the Senate recently approved an amendment to its budget resolution that provides an extra \$7 billion for key health and education programs.

FUNDING RECOMMENDATIONS

The ACC urges Congress to support the following fiscal year 2007 funding recommendations.

National Institutes of Health: \$29.849 billion.—Research conducted through the NIH has resulted in better diagnosis and treatment of cardiovascular disease, improving the quality of life for those living with the disease and lowering the number of deaths attributed to it.

National Heart Lung and Blood Institute: \$3.068 billion.—The NIH is doing critical research into the causes, treatment and prevention of cardiovascular disease through the NHLBI.

Agency for Healthcare Research and Quality: \$440 million.—The Agency for Healthcare Research and Quality (AHRQ)'s health services research complements the research of the NIH by helping cardiologists make choices about what treatments work best, for whom and when.

CDC State Heart Disease and Stroke Prevention Program: \$55 million.—The Centers for Disease Control and Prevention (CDC) State Heart Disease and Stroke Pre-

vention program's public education efforts is making strides in the prevention and early intervention of cardiovascular disease.

HRSA Rural and Community AED Program: \$9 million.—The Health Resources and Services Administration (HRSA) Rural and Community Access to Emergency Defibrillation program is saving lives by placing external defibrillators in public facilities.

SUMMARY

The ACC appreciates the subcommittee's past support for these important programs. The ACC urges Congress to provide a strong fiscal year 2007 investment in the cardiovascular research and education programs described above to continue the great strides being made in fighting cardiovascular disease. Should you have any questions, please contact Jennifer Brunelle at jbrunell@acc.org or (301) 581-3477.

PREPARED STATEMENT OF THE AMERICAN COLLEGE OF OBSTETRICIANS AND GYNECOLOGISTS

The American College of Obstetricians and Gynecologists (ACOG), representing 49,000 physicians and partners in women's health care, is pleased to offer this statement to the House Committee on Appropriations, Subcommittee on Labor, Health and Human Services, and Education. We thank Chairman Regula, Ranking Member Obey, and the entire subcommittee for their leadership to continually address maternal and child health care services.

The Nation has made important strides to improve women and children's health over the past several years, and ACOG is grateful to this Committee for its commitment to research. We look forward to working with the Members of this Committee to ensure that vital research continues to eliminate disease and to ensure valuable new treatment discoveries are implemented. The National Institutes of Health (NIH) has examined and determined many disease pathways, while the Health Resources and Services Administration (HRSA) and the Centers for Disease Control and Prevention (CDC) have been successful in translating research findings into valuable public health policy solutions. This dedicated commitment to elevate, promote and implement medical research faces an uncertain future at a time when scientists are on the cusp of new cures.

It is essential that the Committee provide strong support for current studies, and for future advances, as well. We urge the Committee to support a an fiscal year 2007 appropriation of \$29.75 billion for the NIH, and \$1.328 billion for the National Institute of Child Health and Human Development (NICHD), both a 5 percent increase over fiscal year 2006 levels. We also continue to support efforts to secure adequate funds for important public health programs at HRSA (\$7.5 billion) and the CDC (\$8.5 billion plus funding for pandemic influenza preparedness). Continued appropriations to these agencies will ensure ongoing and new research initiatives continue to yield positive results for women and children's health.

NATIONAL INSTITUTES OF HEALTH—RESEARCH LEADING THE WAY

Research at the NICHD

The NICHD conducts research that holds great promise to improve maternal and fetal health and safety. With the support of Congress, the Institute has initiated research addressing the causes of cerebral palsy, gestational diabetes and pre-term birth. However, much more needs to be done to reduce the rates of maternal mortality and morbidity in the United States. More research is needed on such pregnancy-related issues as the impact of chronic conditions during pregnancy, racial and ethnic disparities in maternal mortality and morbidity, and drug safety with respect to pregnancy.

A commitment to research in maternal health sheds light on a breadth of issues that save women's lives. Important research examining the following issues must continue:

Reducing High Risk Pregnancies

NICHD's Maternal Fetal Medicine Unit Network, working at 14 sites across the United States (University of Alabama, University of Texas-Houston, University of Texas-Southwestern, Wake Forest University, University of North Carolina, Brown University-Women and Infant's Hospital, Columbia University, Drexel University, University of Pittsburgh-Magee Women's Hospital, University of Utah, Northwestern University, Wayne State University, Case Western University, and Ohio State University), will help reduce the risks of cerebral palsy, caesarean deliveries,

and gestational diabetes. This Network discovered that progesterone reduces preterm birth by one-third.

Reducing the Risk of Perinatal HIV Transmission

In the last 10 years, NICHD research has helped decrease the rate of perinatal HIV transmission from 27 percent to 1.2 percent. This advancement signals the near end to mother-to-child transmission of this deadly disease.

Reducing the Effects of Pelvic Floor Disorders

The Institute has made recent advancements in the area of pelvic floor disorders. The NICHD is investigating whether women that have undergone cesarean sections have fewer incidences of pelvic floor disorder than women who have delivered vaginally.

Reducing the Prevalence of Premature Births

NICHD is helping our Nation understand how adverse conditions and health disparities increase the risks of premature birth in high-risk racial groups.

Drug Safety During Pregnancy

The NICHD recently created the Obstetric and Pediatric Pharmacology Branch to measure drug metabolism during pregnancy.

The Challenge of the Future: Attracting New Researchers

Despite the NICHD's critical advancements, reduced funding has made it difficult for this research to continue, largely due to the lack of new investigators. Congressional programs such as the loan repayment program, the NIH Mentored Research Scientist Development Program for reproductive health, and a small grant program, all attract new researchers, but low pay lines make it difficult for the NICHD to maintain them. Due to the structure of the peer review system, previous grant recipients have an advantage because their grants require fewer funds. This makes it more difficult for new investigators to get into the system, jeopardizing the future of women's health research. We urge the Committee to significantly increase funding at the NICHD to maintain a high level of research innovation and excellence, in turn reducing the incidence of maternal morbidity and mortality and discovering cures for other chronic conditions.

HRSA AND CDC: TURNING RESEARCH INTO PUBLIC HEALTH SOLUTIONS

It is essential that we rapidly transform women's health research findings into public health solutions. HRSA and the CDC have created women and children's health outreach programs based on research conducted on infant mortality, birth defects, gynecological cancers, and a variety of other health issues.

For example, research shows tobacco abuse and health disparities are risk factors for infant mortality. Healthy Start offers programs for States, which fund provider and community education programs that improve maternal health through tobacco cessation programs, and finds ways to decrease the infant mortality rate by investigating cultural and institutional health disparities. Research also shows that early screening and detection of certain strands of the human papilloma virus (HPV) may progress into cervical cancer. By screening thousands of low-income women who would not otherwise receive access to care; this CDC program has saved hundreds of lives.

National Fetal Infant Mortality Review

The Fetal and Infant Mortality Review (FIMR) is a cooperative Federal agreement between ACOG and the Maternal Child Health Bureau at HRSA. FIMR uses the expertise of ob-gyns and local health departments to find solutions to problems related to infant mortality. In light of the increase in the infant mortality rate for 2002, the FIMR program is vital to develop community-specific, culturally appropriate interventions. Today 220+ local programs in 42 States are implementing FIMR and finding it is a powerful tool to bring communities together to address the underlying problems that negatively affect the infant mortality rate.

In order to meet the demand of the increasing number of FIMR programs, NFIMR must be able to continue its activities at an adequate funding level. A rigorous national evaluation of FIMR conducted by Johns Hopkins University has concluded that the FIMR methodology is an effective perinatal initiative. Based on that new research, FIMR can now be called an evidence based MCH intervention. All Healthy Start programs and every locality with disparities in infant outcomes should be actively encouraged to implement this FIMR process. We urge this Committee to recognize the many positive contributions of the FIMR program and ensure it remains a fully funded program within HRSA.

Provider's Partnership

Through May 2003, HRSA funded the Provider's Partnership, a cooperative agreement between the Federal Maternal and Child Health Bureau and ACOG. This Partnership includes a series of State-level projects initiated to address key women's health issues, while simultaneously building partnerships between ACOG Members and public health leadership.

The Partnership works specifically with psychosocial issues that greatly impact the health and well-being of women. The morbidity and mortality attributed to issues such as a woman's depression, tobacco use, substance abuse and domestic violence are becoming increasingly apparent as they weigh on both the woman and her entire family. Without treatment, these psychosocial issues place a heavy financial burden on State and Federal resources. Obstetrician-gynecologists play a critical role in addressing these problems within their current practice; however because of the complexity and the importance of promptly linking at-risk women with appropriate services, responsibility for full psychosocial assessment and treatment cannot fall solely on obstetrician-gynecologists. Partnerships between women's health care physicians and State and community programs are needed that allow for integration of medical care with psychosocial services. Partnerships increase coordination thereby minimizing demands on both the behavioral health care system and individual providers. Provider's Partnership enables stakeholders to improve prevention interventions, so that later complications can be avoided.

There are currently 30 State-level Partnership teams focused on depression in women, tobacco use, perinatal HIV transmission and oral health. These teams have been successful at surveying obstetric providers on their screening; counseling and referral practices for perinatal depression and tobacco use, the results of which have been the basis for the development of statewide legislative and practice policy guidelines; establishing pilot screening and intervention initiatives for depression in women; and instituting provider training and technical assistance for depression and tobacco use screening and intervention. Despite their successes, these teams still struggle for funds to offset administrative and program costs. Representatives from additional States have expressed an interest in developing an ACOG Provider's Partnership; however, any new efforts are being postponed until additional funding can be identified. We urge the committee to restore funding for the Partnership to fiscal year 2003 levels.

The National Breast and Cervical Cancer Early Detection Program (NBCCEDP)

The National Breast and Cervical Cancer Early Detection Program (NBCCEDP) administered by the CDC is an indispensable health program in helping underserved women gain access to screening programs for early detection of breast and cervical cancers. The NBCCEDP has served over 2.5 million women and provided 5.8 million screening examinations. Early detection and treatment of breast and cervical cancers greatly increase a woman's odds of conquering these diseases. The President's fiscal year 2007 Budget recommends decreasing funding by \$1.4 million, preventing access to these services for an estimated 4,000 women per year. We strongly urge the Committee to continue saving women's lives and prevent cuts to this vital program.

National Center on Birth Defects and Developmental Disabilities (NCBDDD)

Birth defects affect about one in every 33 babies born in the United States each year. Babies born with birth defects have a greater chance of illness and long term disability than babies without birth defects. According to the CDC, a great opportunity for further improvement lies in prevention strategies that, if implemented prior to conception, would result in additional improvement of pregnancy outcomes. A cooperative agreement between the NCBDDD and ACOG has resulted in increased provider knowledge of genetic screening and diagnostic tests, technical guidance on routine preconception care and prenatal genetic screening, and improved access to care for women with disabilities.

Again, we would like to thank the Committee for its continued support in addressing the multiple factors that affect maternal and child health. We strongly urge this subcommittee to support increased funding for the NICHD, and renewed appropriations for the maternal child health programs at the CDC and HRSA. By continuing to translate research done at the NICHD into positive outreach programs such as the Provider's Partnership and the NBCCEDP, we can further improve our Nation's overall health.

PREPARED STATEMENT OF THE AMERICAN DIABETES ASSOCIATION

Thank you for the opportunity to submit testimony on the importance of Federal funding for diabetes programs at the Centers for Disease Control and Prevention (CDC) and diabetes research at the National Institutes of Health (NIH).

As the Nation's leading nonprofit health organization providing diabetes research, information and advocacy, the American Diabetes Association feels strongly that Federal funding for diabetes prevention and research efforts is critical not only for the 20.8 million Americans who currently have diabetes, but also for the more than 40 million who have a condition known as "pre-diabetes."

Diabetes is a serious disease, and is a contributing and underlying cause of many of the diseases on which the Federal Government spends the most health care dollars. In addition to the \$132 billion in 2002 dollars in direct and indirect costs spent solely on diabetes each year, diabetes is a significant cause of heart disease (which costs our Nation \$258.5 billion each year), a significant cause of stroke (\$57.9 billion each year), and the leading cause of kidney disease (\$40.3 billion). Diabetes is also the leading cause of adult-onset blindness and lower limb amputations.

Approximately 48,000 people suffering from diabetes live in each congressional district and the number of people living with diabetes in this country is growing at a shocking rate. In the last 2 years alone, diabetes prevalence in the United States has increased by 14 percent. The number of Americans with diabetes is now growing at a rate of 8 percent per year and is the single most prevalent chronic illness among children. Because of the systemic havoc that diabetes wreaks throughout the body, it is no surprise that the life expectancy of a person with the disease averages 10–15 years less than that of the general population.

As the statistics listed above illustrate, we are facing an epidemic of diabetes in this country, which if left unchecked could have significant implications for many future generations. A recent study of the diabetes epidemic in New York City warns that diabetes-caused heart attacks threatens to reverse the tremendous gains made in preventing deaths from heart disease. One of the authors of the study termed it "a public health catastrophe." We know, for example, that in every 24 hour period, there will be 4,100 people diagnosed with diabetes, 230 amputations in people with diabetes, 120 people who enter end-stage kidney disease programs and 55 people who go blind. All told, there will be nearly 225,000 deaths from diabetes each year. That is the ultimate cost of underfunding research and prevention programs.

While science continues to work towards finding a cure, we must first adequately fund the diabetes prevention and outreach work being done at the Centers for Disease Control and Prevention. Therefore, we are requesting:

- At least a 10 percent increase over fiscal year 2006 levels for the CDC's Center on Chronic Disease Prevention and Health, including an additional \$20.8 million increase for the CDC's Division of Diabetes Translation (DDT), only \$1 for each American suffering from diabetes; and

- Restoration of the Preventive Health & Health Services Block Grant.

The CDC's Division of Diabetes Translation is critical to our national efforts to prevent and manage diabetes because they translate the research that has already been done to real programs at the community level. Currently, for every \$1 that diabetes costs this country, the Federal Government invests less than \$.01 to help Americans prevent and manage this deadly disease. This dynamic must be changed. While the Association strongly believes that significant funding is needed to fully fund programs in all 50 States, our request of \$20.8 million will allow these critical programs to expand to an additional 10 States.

In 2005 DDT provided support for more than 50 State- and territorial-based Diabetes Prevention and Control Programs (DPCPs) to increase outreach and education, and reduce the complications associated with diabetes. However, funding constraints required DDT to provide severely limited support to 22 States, 8 territories, and D.C. This level of funding, referred to as "capacity building," allows a State to do surveillance, but is not enough for the State to do much—or anything—in the way of intervention.

DDT was able to provide the higher level of support, "basic implementation," to the other 28 States. At the basic implementation level, States are able to devise and execute community-level programs. With an additional \$20.8 million over fiscal year 2006 funding levels, an additional 10 States could start to receive the substantial benefits of basic implementation programs.

The basic implementation programs undoubtedly make a major impact on local communities. For example, the West Virginia DPCP has developed a model education training program in state-of-the-art diabetes care, and has established a work-site health promotion program for State employees. At the same time, by collaborating with the West Virginia Association of Diabetes Educators, the State has

almost doubled the number of certified diabetes educators, and plans to expand that success to underserved rural areas through satellite training programs. Our goal is to make this a reality for the rest of the country, so that communities have the ability to invest in their future by investing in diabetes prevention and education.

Without fully-funded diabetes programs and projects in all parts of the country, it will be exceedingly difficult—if not impossible—to control the escalating costs associated with diabetic complications and to stem the epidemic rise in diabetes rates. State DPCPs, when provided with enough funding, are proven programs that have been extremely successful in helping Americans prevent and manage their diabetes. In the Division of Diabetes Translation Program Review fiscal year 2004, the CDC stated, “The Basic Implementation DPCPs serve as the backbone for our growing primary prevention efforts. These State programs are the key elements to our success in meeting the challenges of controlling and preventing diabetes.” For example, the Texas DPCP contracts with local health departments, community health centers, and local non-profits to serve counties throughout the State. These programs have demonstrated success in promoting physical activity, weight and blood pressure control, and smoking cessation for those with diabetes. One of their programs, Coordinated Approach to Child Health (CATCH), is an elementary school program to increase activity levels, improve diets and reduce children’s risk for obesity, a leading factor in the development of diabetes in children. Americans in every State should have access to such quality programs. Unfortunately, the Division’s fiscal year 2006 budget of just over \$63 million, and the President’s request for a cut in fiscal year 2007 to \$62.42 million, will prevent more counties and States from implementing programs such as the one described above.

In addition to DPCP, the CDC’s Division of Diabetes Translation also conducts other activities to help people currently living with diabetes. To put research into action, CDC works with NIH to jointly sponsor the National Diabetes Education Program (NDEP), which seeks to improve the treatment and outcomes of people with diabetes, promote early detection, and prevent the onset of diabetes. The CDC is also currently working to develop a National Public Health Vision Loss Prevention Program that will investigate the economic burden and strengthen the surveillance and research of this all-to-common complication of diabetes. In addition, CDC funds work at the National Diabetes Laboratory to support scientific studies that will improve the lives of people with diabetes. In fiscal year 2005, the Division of Diabetes Translation alone published 53 manuscripts on the care, prevention, and science of diabetes, including 17 abstracts.

The Association appreciates the increased attention by Congress to diabetes research at the National Institutes of Health (NIH) in recent years. While there is not yet a cure for diabetes, researchers at NIH are working on a variety of projects that represent hope for the millions of individuals with Type 1 and Type 2 diabetes. The Association strongly encourages you to provide at least a 5 percent increase to the NIH to fulfill this promise. Unfortunately, while the death rate due to diabetes has increased by more than 40 percent in recent years, diabetes research funding has not kept pace. Indeed, from 1987–2001, appropriated diabetes funding as a share of the overall NIH budget has dropped by more than 20 percent (from 3.9 percent to 2.9 percent). While Congress had initially begun to address this discrepancy, the fiscal year 2006 budget reduced funding at the National Institutes of Diabetes, Digestive and Kidney Diseases (NIDDK) by \$9 million. This is unconscionable when diabetes deaths continue to increase at such a rate. The Association believes that NIH research and CDC translational programs go hand in hand in the effort to combat the diabetes epidemic.

The Association is also supportive of restoration of the CDC’s Preventive Health & Health Services Block Grant (PBG). The PBG, which allows States to develop innovative health programs at the community level, received \$99 million in fiscal year 2006, but is currently slated for no funding for fiscal year 2007. These programs have been very successful. In the State of Louisiana, the grants are used to train school based health personnel on the diagnosis and management of type 2 diabetes, and also to screen adolescents at significant risk for type 2 diabetes. There are 53 school based health centers in Louisiana that are directly assisted by this program. As the State continues to rebuild following Hurricane Katrina, it would be tragic to remove this small but critical piece of health infrastructure funding.

The Association, and the millions of individuals with diabetes we represent, firmly believes that we could rapidly move toward curing, preventing, and managing this disease by increasing funding for diabetes programs and research both at CDC and NIH. Your leadership is essential to accomplishing this goal. As you are considering fiscal year 2007 funding, we ask you to remember that chronic diseases, including diabetes, account for nearly 70 percent of all health care costs as well as 70 percent of all deaths annually. Unfortunately, less than \$1.25 per person is directed toward

public health interventions focused on preventing the debilitating effects associated with chronic diseases, demonstrating that Federal investment in chronic disease prevention remains grossly inadequate. We cannot ignore those Americans who are currently living with diabetes and other diseases.

In closing, the American Diabetes Association strongly urges the subcommittee and Congress to provide a 10 percent increase for the CDC's Center on Chronic Disease Prevention and Health, including a \$20.8 million increase for the CDC's Division of Diabetes Translation, and to restore the Preventive Health & Health Services Block Grant. Providing this funding would be an important step towards empowering States to fight diabetes at the community level. Additionally, we urge the subcommittee to increase NIH funding by 5 percent to allow for an increased commitment to diabetes research.

On behalf of the 20.8 million Americans with diabetes—a disease that crosses gender, race, ethnicity and political party; a disease that is among the most costly, debilitating, deadly and prevalent in our Nation; and a disease that is exploding throughout our Nation—thank you for the opportunity to submit this testimony. The American Diabetes Association is prepared to answer any questions you might have on these important issues.

PREPARED STATEMENT OF THE AMERICAN FOUNDATION FOR THE BLIND

Mr. Chairman and members of the subcommittee, my name is Paul Schroeder and I am the Vice President for Programs and Policy at the American Foundation for the Blind. Thank you for giving the American Foundation for the Blind (AFB) the opportunity to submit testimony to the subcommittee as you begin to consider funding priorities for fiscal year 2007. The AFB is a national non-profit organization with a commitment to enhancing and promoting the health, education, employment, and overall quality of life for people with vision loss.

For nearly a century AFB has been expanding possibilities for people with vision loss by setting trends and devising innovative programs. For example, AFB works with the corporate sector to get the latest technologies that promote equal access into the hands of people who have vision loss. AFB also promotes the development and dissemination of new ideas and resources for service professionals, and AFB assists consumers with vision loss to maintain independent and healthy lives by providing them and their families with information about services and advice on purchasing decisions. In these and many other ways AFB continues to respond to the current needs of the vision loss community.

The AFB, with headquarters in New York City, and a Public Policy Center in Washington, DC, also operates the National Center on Vision Loss in Dallas, TX, to help ensure that Americans with vision loss have information and access to all technologies needed to maintain their independence. This innovative resource center offers information, education, technology, and training—all under one roof and through the Internet—to create accessible living and work environments for people who are visually impaired. The AFB has launched a \$2.4 million campaign—Project Independence—to expand and enhance the Dallas center and ensure it has national reach through web-based and other information dissemination programs. Also this year, the AFB has enhanced its efforts to promote health maintenance and prevention of secondary health conditions among those with vision loss. The testimony that follows will speak in more detail to this issue.

RECOGNIZING THE LEADERSHIP OF THE SUBCOMMITTEE IN SUPPORT OF AMERICANS WITH DISABILITIES

According to the Institute of Medicine's 1991 report *Disability in America: Toward a National Agenda for Prevention*, "disability is an issue that affects every individual, community, neighborhood and family in the United States." This statement remains equally true today. An estimated 54 million people in the United States currently live with a disability, including severe vision loss. There are approximately 10 million Americans that are blind or have vision impairment, 6.5 million of whom are elderly. With the continued aging of the population, the number of elderly Americans affected by vision loss will only increase.

Mr. Chairman, AFB commends the subcommittee's leadership and commitment to programs of interest and benefit to citizens with disabilities. Within the jurisdiction of the Labor, Health and Human Services, and Education Subcommittee are the vast majority of the Federal programs that support services to people with disabilities. The main focus of our testimony, however, is to highlight for the subcommittee the critically important work of the CDC's National Center on Birth Defects and Developmental Disabilities.

THE CDC'S NATIONAL CENTER ON BIRTH DEFECTS AND DEVELOPMENTAL DISABILITIES

Mr. Chairman, on behalf of the American Foundation for the Blind, I would like to commend the leadership of the CDC's National Center on Birth Defects and Developmental Disabilities (NCBDDD) for their hard work and dedication to their mission to promote the health and wellness of children and adults living with disabilities. We are particularly pleased and supportive of the Center's new focused initiatives to address the secondary health effects of people with vision loss and other disabilities.

It has been widely documented that individuals with disabilities experience negative health, social, emotional, family, and community outcomes at higher rates than others. Sadly, 20.1 percent of people with disabilities lack health insurance, as compared to 17.8 percent of the general population. Moreover, secondary conditions such as heart disease, diabetes and stroke, all of which are modifiable and preventable, are also particularly acute among Americans with vision loss. For example, elderly Americans with vision loss have higher rates of depression, hypertension, heart disease, stroke, and physical injuries than people without these sensory impairments. Unique to individuals with vision loss is the risk of prescription errors stemming from inaccessible print labeling and/or instructions about safe administration of the drugs.

These disparities in health have multiple consequences including the decreased ability to perform valued activities, participate in social roles including employment, and ever-escalating costs associated with deteriorating health conditions.

Many Americans with vision impairment, however, could substantially improve their every day lives and prevent the onset of secondary conditions with appropriate health interventions and information. To ensure that this help is available, additional research to strengthen the evidence base for effective public health interventions needs to be conducted. In addition, substantially enhanced dissemination programs of these interventions through a website and other means accessible to people with vision loss is a vital component of such a program. Such a dedicated program would be of significant benefit to those facing vision loss and their families. The initiation of such a program at the National Center on Birth Defects and Developmental Disabilities would reduce health disparities and push forward the public health frontier in assisting people with blindness and vision loss.

RECOMMENDATIONS

Mr. Chairman, the administration's request for the National Center on Birth Defects and Developmental Disabilities is \$110,481,000, a decrease of \$14.28 million below fiscal year 2006 levels. If enacted, this would be the second year in a row that the incredibly important programs funded in this national Center received cuts. AFB strongly encourages the subcommittee to reverse these reductions and to specifically add \$950,000 for a dedicated program to ameliorate and prevent secondary health conditions that affect individuals with vision loss. AFB would also encourage the subcommittee to support an expansion of the proposed Center on Vision Loss in Dallas, Texas.

SUMMARY AND CONCLUSIONS

Mr. Chairman, again we wish to thank the subcommittee for its past leadership and commitment to disability issues. With your leadership much additional progress can be made to improve the lives and health of Americans with vision loss.

Thank you for this opportunity to testify.

PREPARED STATEMENT OF THE AMERICAN PHYSIOLOGICAL SOCIETY

The American Physiological Society (APS) thanks the subcommittee for its sustained support for the National Institutes of Health (NIH). The doubling of the agency budget that took place between fiscal years 1996 and 2002 allowed the NIH to expand its efforts to address old and new challenges in biomedical science. Our Nation's investment in basic, translational, and clinical research plays an important role in the continued health and prosperity of our people. Increases in NIH funding have allowed researchers to explore scientific opportunities on an unprecedented scale. However, to build on existing knowledge and explore new areas, NIH must be able to provide research support for innovative ideas. In fiscal year 2006 the NIH budget was cut for the first time since 1970, and the administration's fiscal year 2007 budget proposal would keep the agency at the same level. Taking inflation into account, the President's budget plan represents another budget cut that will reduce the number of research grants funded. As funding falters, the best and brightest

minds will turn away from careers in medical science. If NIH cannot fund new ideas, this will not only hamper efforts to find cures, it will also discourage up and coming researchers who could become the next generation of basic and clinical scientists. The APS urges you to make every effort to provide the NIH with a 5 percent funding increase so we can take advantage of more scientific opportunities that will lead to ways to alleviate the suffering and burdens of disease and strengthen the Nation's scientific workforce to face future challenges.

The APS is a professional society dedicated to fostering research and education as well as the dissemination of scientific knowledge concerning how the organs and systems of the body work. The Society was founded in 1887 and now has more than 10,000 member physiologists across the United States. The APS offers these comments on the budget recognizing both the enormous financial challenges facing our Nation and the enormous opportunities before us to make progress against disease.

NIH's task is both to cure specific diseases and to look broadly at scientific opportunities that may help us expand our understanding of biological problems that affect health. Basic research contributes to a body of knowledge whose importance will only be determined over time. Physiology, which is the study of biological function, provides the foundation for much of the translational research that turns discoveries into therapies and prevention strategies.

One example of this is the lung disease cystic fibrosis. Over the last 20 years, the scientific community has made great leaps in understanding the role that genes play in the development of various diseases. The CFTR gene responsible for cystic fibrosis was identified in 1989. Since then, researchers have worked to gain a better understanding of what happens in the disease at the molecular level with the hope of developing a gene therapy that would prolong and improve patients' lives. One critical question was how much of the normal gene is necessary to improve lung function. In late 2005, NIH supported researchers at the University of Iowa published the results of experiments in which they delivered healthy copies of the CFTR gene to cultured lung cells taken from cystic fibrosis patients.¹ They were then able to measure whether function improved with increasing amounts of gene product. Unexpectedly, delivery of low levels of the CFTR gene was more effective than very high doses. This type of experiment provides the foundation for designing safe and effective clinical treatments.

In addition to supporting research, the NIH must also address workforce issues to be sure our Nation's researchers are ready to meet the challenges they will face in the future. Last year the NIH announced a new program to encourage clinical and translational research at universities. The new Clinical and Translational Service Awards (CTSAs) will provide a total of \$30 million in fiscal year 2006 to develop new research and training programs at academic institutions around the country. This will allow researchers to capitalize on knowledge generated from basic research through the development of clinical applications and treatments.

The NIH plays many critical roles in advancing biomedical research. It provides opportunities for individual researchers at universities and medical schools throughout the country to compete for research funds based upon the scientific merit of their ideas. NIH also carries out other functions including:

- Sponsoring research training opportunities for young scientists and physicians;
- Funding major collaborative initiatives that bring together multiple institutions with diverse resources;
- Providing the public with up-to-date information about the latest research on various diseases and health conditions through individual institutes and online resources such as "MedLine Plus" and ClinicalTrials.gov;
- Supporting unique science education programs, particularly for underserved minority students; and
- Funding innovative research through the NIH Roadmap initiative.

These activities are critical to moving science forward, and they are unique to the NIH. Another example is the newly developed Genes and Environment Initiative (GEI). The GEI is a multi-institute effort to identify genetic and environmental risk factors that contribute to common diseases such as asthma, diabetes, heart disease, cancer and Alzheimer's disease. The planned research will build on the Human Genome Project and take advantage of new technologies developed in the pursuit of basic research. With its wide range of expertise, the NIH is uniquely suited to undertake broad projects such as this.

The examples listed above represent a select few examples from the NIH's extensive and outstanding portfolio. The APS joins the Federation of American Societies for Experimental Biology (FASEB) and the Ad Hoc Group for Medical Research Funding in urging that NIH be provided with a 5 percent funding increase in fiscal

¹S. L. Farnen et al., *Am J Physiol Lung Cell Mol Physiol* 289, L1123–30 (Dec. 2005).

year 2007 to permit the agency to maintain its current wide-ranging and important research efforts. This forward-looking approach to our Nation's biomedical research efforts is much to be preferred over the administration's proposal to fund the agency at last year's level, which would force the NIH to contract its research portfolio, thus leaving many important projects unfunded.

PREPARED STATEMENT OF THE COALITION OF NORTHEASTERN GOVERNORS

The Coalition of Northeastern Governors (CONEG) is pleased to provide this testimony for the record to the Senate Subcommittee on Labor, Health and Human Services, Education, and Related Agencies regarding fiscal year 2007 appropriations for the Low Income Home Energy Assistance Program (LIHEAP). The Governors appreciate the subcommittee's consistent support for the LIHEAP program. We also welcome the additional fiscal year 2006 funds recently provided by the Congress, even as we recognize the difficult challenges facing the subcommittee in this time of severe fiscal constraints. However, in light of sharply higher home energy prices, we request the subcommittee to provide the full authorized amount of \$5.1 billion in regular fiscal year 2007 LIHEAP funding—to restore the purchasing power of the LIHEAP program. In addition, we request that the subcommittee provide contingency funds to address energy emergency situations.

The continuing trend in rising prices for natural gas and home heating fuels is creating a growing home energy crisis for low-income citizens across the Nation. Low-income households, whose percentage of income spent on energy may be four times that of average households, can amass significant home energy debt that makes it difficult to purchase heating fuels or pay outstanding utility bills. High levels of accumulated arrearages owed by low-income households raise the prospect of hundreds of thousands of households cut off from utility service this spring.

Particularly in the Northeast, which is heavily dependent on deliverable home heating fuels such as home heating oil, kerosene, and propane, price volatility has an especially perverse impact. These low-income households, without the disposable income to purchase fuels off-season, typically enter the market when both the demand for and price of fuels are high. Without access to LIHEAP assistance during the heating season, they may not be able to obtain any fuel at all, due to the collect-on-delivery business policy commonly used by fuel dealers. If LIHEAP benefit levels are too low, these households may not be able to afford the cost of the required minimum delivery.

LIHEAP is a vital tool in making home energy more affordable for almost 5 million of the Nation's very low-income households faced with high energy burden—the elderly and disabled on fixed incomes and families with young children. Over the past 5 years, as the average price of home heating oil and natural gas more than doubled, the purchasing power of the LIHEAP grant has plummeted—undercutting the ability of the program to serve adequately these vulnerable households. States across the country in recent years have seen significant increases in their regular LIHEAP caseloads, as well as in requests for emergency crisis from those households in imminent danger of a utility or fuel service cut-off. The number of requests for LIHEAP assistance has reached its highest level in more than a decade. In response to the continually rising home energy costs and the growing crisis in this recent heating season, States across the country have stepped in to provide more than \$450 million for low-income energy programs. In addition to regulatory actions, such as extending shut-off moratoria periods and limiting deposit and reconnection fees, many State public utility commissions have provided more than \$100 million in assistance from funding sources such as public benefit funds or universal service funds.

The LIHEAP program delivers maximum program dollars to households in need—the consequence of its administrative costs being among the lowest of human service programs. In the Northeast, States have incorporated various administrative strategies designed to minimize the amount of program funds used to operate the program. Innovative administrative strategies include the use of uniform application forms to determine program eligibility, establishment of a one-stop shopping approach for the delivery of LIHEAP and related programs, sharing administrative costs with other programs, and the use of mail recertification.

The recent action by Congress to increase LIHEAP funding in fiscal year 2006 is a welcome and important step to begin restoring some of the lost LIHEAP purchasing power. However, the prospect of continued high and potentially volatile prices for home energy means that the projected need continues to outweigh available Federal and State funding. Even with these additional Federal and State funds, the value of the LIHEAP grant has been significantly reduced, defraying only

a modest amount of a low-income household's total heating bill; and it reaches only a small percentage of the households that need assistance.

Increased Federal funding is vital for LIHEAP to assist the Nation's vulnerable, low-income households faced with unaffordable home energy bills. An increase in the regular LIHEAP appropriation to the full authorized level of \$5.1 billion for fiscal year 2007 in addition to contingency funds, will enable our States to help mitigate the potential life-threatening emergencies and economic hardship that confront the Nation's most vulnerable citizens. With these additional funds, States can provide assistance to more households in need, offer benefit levels that can make a meaningful reduction in their home energy burden, lessen the need for emergency crisis, plan and operate a more efficient program, and again make optimal use of leveraging and other cost-effective programs.

We thank the subcommittee for this opportunity to share the views of the Coalition of Northeastern Governors, and we stand ready to provide you with any additional information on the importance of the Low Income Home Energy Assistance Program to the Northeast.

PREPARED STATEMENT OF THE AMERICAN LUNG ASSOCIATION

SUMMARY: FUNDING RECOMMENDATIONS

[In millions of dollars]

Agency	Amount
National Institutes of Health	30,205
National Heart, Lung, and Blood Institute	3,099
National Cancer Institute	5,030
National Institute of Allergy and Infectious Disease	4,682
National Institute of Environmental Health Sciences	680
National Institute of Nursing Research	146
Fogarty International Center	70
Centers for Disease Control and Prevention	8,500
National Institute for Occupational Safety and Health	285
Office on Smoking and Health	145
Environmental Health: Asthma Activities	70
Tuberculosis Control Programs	252
Influenza Pandemic	2,652

The American Lung Association is pleased to present our recommendations for programs in the Labor Health and Human Services and Education Appropriations Subcommittee purview. These appropriations will make a difference in the lives of millions of Americans who suffer from lung disease.

The American Lung Association is one of the oldest voluntary health organizations in the United States, with a National Office and constituent associations around the country. Founded in 1904 to fight tuberculosis, the American Lung Association today fights lung disease in all its forms, with special emphasis on funding research for cures, promoting cleaner air and helping prevent kids from smoking. The Lung Association is funded by contributions from the public, along with gifts and grants from corporations, foundations and government agencies, and achieves its many successes through the work of thousands of committed volunteers and staff.

THE TOLL OF LUNG DISEASE

Each year, an estimated 349,000 Americans die of lung disease. Lung disease is America's number three killer, responsible for one in every seven deaths. More than 35 million Americans suffer from a chronic lung disease. Each year lung disease costs the economy an estimated \$157.8 billion. Lung diseases represent a spectrum of chronic and acute conditions that interfere with the lung's ability to extract oxygen from the atmosphere, protect against environmental or biological challenges and regulate a number of metabolic processes. Lung diseases include: asthma, chronic obstructive pulmonary disease, lung cancer, tuberculosis, pneumonia, influenza, sleep disordered breathing, pediatric lung disorders, occupational lung disease and sarcoidosis.

CHRONIC OBSTRUCTIVE PULMONARY DISEASE

Chronic Obstructive Pulmonary Disease, or COPD, is a growing health problem. Yet it remains relatively unknown to most Americans and much of the research community. COPD refers to a group of largely preventable diseases, including emphysema and chronic bronchitis, that generally gradually limit the flow of air in the body. COPD is the fourth leading cause of death in the United States and worldwide.

In 2004, the annual cost to the Nation for COPD was \$37.2 billion. This includes \$20.9 billion in direct health care expenditures, \$8.9 billion in indirect morbidity costs and \$7.4 billion in indirect mortality costs. Medicare expenses for COPD beneficiaries were nearly 2.5 times that of the expenditures for all other patients.

It has been estimated that 11.4 million patients have been diagnosed with some form of COPD and as many as 24 million adults may suffer from its consequences. In 2004, an estimated 9 million Americans were diagnosed with chronic bronchitis by a health professional. Further, an estimated 3.6 million Americans have been diagnosed with emphysema in their lifetime. In 2002, 120,555 people in the United States died of COPD. Women have exceeded men in the number of deaths attributable to COPD since 2000. Over the past 30 years, the death rate due to COPD has doubled while the death rates for heart disease, cancer and stroke have decreased by over 50 percent.

Today, COPD is treatable but not curable. Fortunately, promising research is on the horizon for COPD patients. Research on the genetic susceptibility underlying COPD is making progress. Research is also showing promise for reversing the damage to lung tissue caused by COPD.

Despite these promising research leads, the American Lung Association believes that research resources committed to COPD are not commensurate with the impact COPD has on the United States and the world.

The American Lung Association strongly recommends that the NIH and other Federal research programs commit additional resources to COPD research programs. In addition, there is a need for improved surveillance data on the disease. The Lung Association supports the CDC in gathering more information about COPD as part of the National Health and Nutrition Examination Survey, the Behavioral Risk Factor Surveillance System and other health surveys. This information will help public health professionals and researchers understand the disease better and lead to possible control of the disease.

TOBACCO USE

Tobacco use is the leading preventable cause of death in the United States, killing more than 438,000 people every year. Smoking is responsible for one in five U.S. deaths. The direct health care and lost productivity costs of tobacco-caused disease and disability are also staggering, an estimated \$167 billion each year. Taxpayers pay billions of dollars each year to treat tobacco-caused disease through federally funded health programs including Medicare and Medicaid.

The CDC's Office on Smoking and Health provides significant technical assistance to States that are using tobacco settlement dollars to develop comprehensive and effective tobacco prevention programs, in addition to providing a small, yet essential, amount of Federal assistance directly to State tobacco control and prevention programs. States that currently fund comprehensive programs, as well as those seeking to develop programs, rely on CDC's expertise. Funds for tobacco prevention at CDC also are used to maintain comprehensive information on smoking and health and to support ongoing research on tobacco-related issues.

We believe Congress should fund the type of youth tobacco prevention programs that science tells us are essential to counter the impact of tobacco company marketing to our kids. The American Lung Association strongly supports a minimum level of \$145 million in fiscal year 2007 funding for the CDC's Office on Smoking and Health.

ASTHMA

Asthma is a chronic lung disease in which the bronchial tubes become swollen and narrowed, preventing air from getting into or out of the lung. An estimated 30.2 million Americans have ever been diagnosed with asthma by a health professional. Approximately 20.5 million Americans currently have asthma, of which 11.7 million had an asthma attack in 2004. Asthma prevalence rates are 39 percent higher among African Americans than whites. Studies also suggest that Puerto Ricans have higher asthma prevalence rates and age-adjusted death rates than all other Hispanic subgroups.

Asthma is expensive. The growth in the prevalence of asthma will have a significant impact on our Nation's health expenditures, especially Medicaid. Asthma incurs an estimated annual economic cost of \$16.1 billion to our Nation. Asthma is the third leading cause of hospitalization among children under the age of 15. It is also the number one cause of school absences attributed to chronic conditions. The Federal response to asthma has three components: research, programs and planning. We are making progress on all three fronts but more must be done:

Asthma Research

Researchers are developing better ways to treat and manage chronic asthma. Two examples show why this should continue. Research supported by National Heart, Lung and Blood Institute (NHLBI) has shown that using corticosteroids to treat children with mild to moderate asthma is safe and effective, answering a parent's question about whether these effective drugs would stunt the growth of children who used them.

Genetic research is also providing insights into asthma. Researchers in the NHLBI-supported Asthma Clinical Research Network have discovered that a genetic variation determines how well asthma patients will respond to the most common asthma medication, inhaled beta-agonists. This discovery will help physicians better target the drugs they prescribe.

Asthma Programs

Last year, Congress provided approximately \$31.9 million for the Centers for Disease Control and Prevention (CDC) to conduct asthma programs. The American Lung Association recommends that CDC be provided \$70 million in fiscal year 2007 to expand its asthma programs. This funding includes State asthma planning grants, which leverage small amounts of funding into more comprehensive State programs.

Asthma Surveillance

In addition to public education programs, the CDC has been piloting programs to determine how to establish a nationwide health-tracking system. The pilots have shown how to integrate different data to determine how pervasive asthma is in these communities. Congress needs to increase funding to create a nationwide health-tracking system, based on the localized pilots that are underway now.

LUNG CANCER

An estimated 350,679 Americans are living with lung cancer. During 2005, an estimated 172,570 new cases of lung cancer will be diagnosed. This year 163,510 Americans will die from lung cancer. Survival rates for lung cancer tend to be much lower than those of most other cancers. Men have higher rates of lung cancer than women. However, over the past 30 years, the lung cancer age-adjusted incidence rate has decreased 9 percent in males compared to an increase of 143 percent in females. Further, African Americans are more likely to develop and die from lung cancer than persons of any other racial group.

Given the magnitude of lung cancer and the enormity of the death toll, the American Lung Association strongly recommends that the NIH and other Federal research programs commit additional resources to lung cancer research programs. We support increasing the National Cancer Institute budget to \$5.003 billion.

INFLUENZA

Influenza is a highly contagious viral infection and one of the most severe illnesses of the winter season. It is responsible for an average of 200,000 hospitalizations and 36,000 deaths each year. Further, the emerging threat of a pandemic influenza is looming. Public health experts warn that over half a million Americans could die and over 2.3 million could be hospitalized if a moderately severe strain of a pandemic flu virus hits the United States. To prepare for a potential pandemic, the American Lung Association supports funding the Federal Pandemic Influenza Plan at the recommended level of \$2.652 billion.

TUBERCULOSIS

Tuberculosis is an airborne infection caused by a bacterium, *Mycobacterium tuberculosis* (TB). TB primarily affects the lungs but can also affect other parts of the body, such as the brain, kidneys or spine. There are an estimated 10 million to 15 million Americans who carry latent TB infection. Each has the potential to develop active TB in the future. About 10 percent of these individuals will develop active

TB disease at some point in their lives. In 2005, there were 14,093 cases of active TB reported in the United States.

The American Lung Association has endorsed the Institute of Medicine (IOM) report, *Ending Neglect: The Elimination of Tuberculosis in the United States*, IOM report and its recommendations on how to eliminate TB in the United States. While declining overall TB rates are good news, the emergence and spread of multi-drug resistant TB pose a significant threat to the public health of our Nation. Continued support is needed if the United States is going to continue progress toward the elimination of TB. We estimate it will cost \$528 million for the CDC Tuberculosis Elimination Program to implement the report recommendations. We request that Congress increase funding for tuberculosis programs to \$252 million for fiscal year 2007.

The NIH also has a prominent role to play in the elimination of TB. Currently there is no highly effective vaccine to prevent TB transmission. However, the recent sequencing of the TB genome and other research advances has put the goal of an effective TB vaccine within reach. In addition, the American Lung Association encourages the subcommittee to fully fund the TB vaccine blueprint development effort at the National Institutes of Allergy and Infectious Disease (NIAID).

Fogarty International Center TB Training Programs

The Fogarty International Center (FIC) at NIH provides training grants to U.S. universities to teach AIDS treatment and research techniques to international physicians and researchers. Because of the link between AIDS and TB infection, FIC has created supplemental TB training grants for these institutions to train international health care professionals in the area of TB treatment and research. However, we believe TB training grants should not be offered exclusively to institutions that have received AIDS training grants. The TB grants program should be expanded and open to competition from all institutions. The American Lung Association recommends Congress provide \$70 million for FIC to expand the TB training grant program from a supplemental grant to an open competition grant.

ENVIRONMENTAL HEALTH

The National Institute of Environmental Health Sciences funds vital research on the impact of environmental influence on disease. The American Lung Association supports increasing the appropriation from this subcommittee to \$680 million.

RESEARCHING AND PREVENTING OCCUPATIONAL LUNG DISEASE

The American Lung Association recommends that the subcommittee provide \$285 million for the National Institute for Occupational Safety and Health (NIOSH) at the CDC.

CONCLUSION

In conclusion, Mr. Chairman, lung disease is a continuing, growing problem in the United States. It is America's number three killer, responsible for one in seven deaths. The lung disease death rate continues to climb. Mr. Chairman, the level of support this committee approves for lung disease programs should reflect the urgency illustrated by these numbers.

PREPARED STATEMENT OF THE AMERICAN NEPHROLOGY NURSES' ASSOCIATION

The American Nephrology Nurses' Association (ANNA) appreciates the opportunity to submit written comments for the record regarding fiscal year 2007 funding to address the challenges that kidney disease and the nursing shortage are posing to the Nation. ANNA exists to advance nephrology nursing practice and positively influence outcomes for patients with kidney or other disease processes requiring replacement therapies through advocacy, scholarship, and excellence. ANNA consists of more than 12,000 registered nurses and other health care professionals with varying experience and expertise in such areas as hemodialysis, peritoneal dialysis, conservative management, continuous renal replacement therapies, chronic kidney disease, and renal transplantation.

As part of our mission, we educate health professionals, the public, and policymakers to increase public awareness and understanding of the unique health care needs and challenges people with kidney disease face. Moreover, ANNA maintains a strong commitment to securing public policies and programs that help secure better treatments and care for individuals with kidney disease. ANNA specifically seeks to advance public and private efforts to improve treatment of kidney disease,

reduce and prevent the onset of end stage renal disease (ESRD), and ensure that all people with kidney disease have access to the medical care and treatment options they need to live the highest quality of life possible.

To that end, ANNA respectfully requests that Congress reject the President's proposed \$11 million cut in funding for the National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK) and instead support increased funding for diabetes and kidney disease research to find better treatments, preventive interventions, and develop a cure. NIDDK conducts and supports research on most of the more serious diseases affecting public health. The Institute supports much of the clinical research on the diseases of internal medicine and related subspecialty fields, as well as many basic science disciplines. Additional fiscal year 2007 funding for NIDDK will help advance our Nation's understanding of the risk factors associated with kidney disease, boost efforts to identify ways in which kidney disease can be reduced and prevented, and increase initiatives to improve care and treatment of individuals with chronic kidney disease as well as those with ESRD.

The National Institute of Nursing Research (NINR) supports clinical and basic research to establish a scientific basis for the care of individuals across the life span—from management of patients during illness and recovery to the reduction of risks for disease and disability, the promotion of healthy lifestyles, promoting quality of life in those with chronic illness, and care for individuals at the end of life. NINR seeks to understand and ease the symptoms of acute and chronic illness, to prevent or delay the onset of disease or disability or slow its progression, to find effective approaches to achieving and sustaining good health, and to improve the clinical settings in which care is provided. Importantly, NINR research also focuses on the special needs of at-risk and under-served populations, with an emphasis on health disparities, such as those seen among the ESRD population. These efforts are crucial in the creation of scientific advances and their translation into cost-effective health care that does not compromise quality. ANNA is pleased to join with others in the nursing community in advocating a fiscal year 2007 allocation of \$150 million for NINR.

As you know, the Nation is facing a nursing shortage of unprecedented proportion. At the same time the nursing shortage is expected to worsen, the number of people with ESRD needing access to state-of-the-art treatment and care is estimated to increase significantly. More than 350,000 Americans have ESRD which gives the United States the highest incidence rate. As the population continues to grow and age and medical services advance, the need for nurses will continue to increase. A report issued by the U.S. Health Resources and Services Administration (HRSA), *Projected Supply, Demand, and Shortages of Registered Nurses: 2000–2020*, predicted that the nursing shortage is expected to grow to 29 percent by 2020, compared to a seven percent shortage in 2005. Nurses are crucial to the health of our Nation and those with ESRD.

According to the U.S. Department of Health and Human Services (HHS), the nursing workforce programs housed at HRSA will support the recruitment, education, and retention of an estimated 36,750 nurses and nursing students and approximately 956 new loan repayments and scholarships among other activities. With additional funding in fiscal year 2007, the HRSA nursing workforce programs would have more sufficient resources to bolster the Nation's nursing workforce at a rate necessary to help stem the nursing shortage tide. To address this current and growing challenge in the health care delivery system, ANNA urges Congress to support the nursing community's request of \$175 million for the HRSA nursing workforce programs. Moreover, please note that ANNA supports the written testimony submitted by the Americans for Nursing Shortage Relief (ANSR) Alliance and respectfully requests your full and fair consideration of the funding allocations and issues outlined by ANSR.

Please know that we understand that Congress has limited resources to allocate. However, we are concerned that without adequate funding for research and the Nation's nursing workforce, the Nation will falter in its efforts to diminish suffering from kidney disease and to provide quality nursing care to all in need. On behalf of ANNA's Board of Directors and the hundreds of thousands of individuals with kidney disease to whom we provide care, thank you for this opportunity to submit written testimony regarding the fiscal year 2007 funding levels necessary to ensure that our Nation adequately supports kidney disease research and the Nation's nursing workforce. Please feel free to contact us at any time; we are happy to be a resource to subcommittee members and your staff.

PREPARED STATEMENT OF THE AMERICAN PUBLIC HEALTH ASSOCIATION

The American Public Health Association (APHA) is the Nation's oldest, largest and most diverse organization of public health professionals in the world, dedicated to protecting all Americans and their communities from preventable, serious health threats and assuring community-based health promotion and disease prevention activities and preventive health services are universally accessible in the United States. We are pleased to submit our views on Federal funding for public health activities in fiscal year 2007.

RECOMMENDATIONS FOR FUNDING THE PUBLIC HEALTH SERVICE

The APHA's budget recommendation for overall funding for the Public Health Service includes funding for the Centers for Disease Control and Prevention (CDC), the Health Resources and Services Administration (HRSA), the Substance Abuse and Mental Health Services Administration (SAMHSA), the Agency for Healthcare Research and Quality (AHRQ), and the National Institutes of Health (NIH), as well as agencies outside the subcommittee's jurisdiction—the Food and Drug Administration (FDA) and the Indian Health Service (IHS). We encourage the subcommittee to restore \$1 billion in funding cuts that occurred in fiscal year 2006, and reject the President's proposal to cut an additional \$600 million from the Public Health Service.

CENTERS FOR DISEASE CONTROL AND PREVENTION (CDC)

The APHA believes that Congress should support CDC as an agency—not just the individual programs that it funds. We support a funding level for CDC that enables it to carry out its mission to protect and promote good health and to assure that research findings are translated into effective State and local programs.

In the best professional judgment of the APHA, in conjunction with the CDC Coalition—given the challenges of terrorism and disaster preparedness, new and re-emerging infectious diseases, the epidemic of obesity, particularly among children, and our many unmet public health needs and missed prevention opportunities—we believe the agency will require funding of at least \$8.5 billion, plus sufficient funding to prepare the Nation against a potential influenza pandemic. This request reflects the support CDC will need to fulfill its core missions for fiscal year 2007, as well as funding for the Agency for Toxic Substances and Disease Registry and the Vaccines for Children program.

The APHA appreciates the subcommittee's work over the years, including your recognition of the need to fund chronic disease prevention, infectious disease prevention and treatment, and environmental health programs at CDC. By translating research findings into effective intervention efforts, CDC has been a key source of funding for many of our State and local programs that aim to improve the health of communities. Perhaps more importantly, Federal funding through CDC provides the foundation for our State and local public health departments, supporting a trained workforce, laboratory capacity and public health education communications systems.

CDC also serves as the command center for our Nation's public health defense system against emerging and reemerging infectious diseases. With the potential onset of an influenza pandemic, in addition to the many other natural and man-made threats that exist in the modern world, the CDC has become the Nation's—and the world's—expert resource and response center, coordinating communications and action and serving as the laboratory reference center. States and communities rely on CDC for accurate information and direction in a crisis or outbreak.

Unfortunately, Congress cut overall CDC funding in fiscal year 2006 for the first time in 25 years. And in fiscal year 2007, the President has proposed cutting CDC funding even more—more than 2 percent overall, and more than 4.5 percent to CDC's core programs. We are moving in the wrong direction, especially in these challenging times when public health is being asked to do more, not less. In light of the current workload placed on the public health service—in addition to the threat of emerging diseases such as the avian flu—it simply does not make any sense to cut the budget for CDC at a time when the threats to public health are so great. Funding public health outbreak by outbreak is not an effective way to ensure either preparedness or accountability. Until we are committed to a strong public health system, every crisis will force trade offs.

CDC serves as the lead agency for bioterrorism preparedness and must receive sustained support for its preparedness programs in order for our Nation to meet future challenges. APHA supports the proposed increase for anti-terrorism activities at CDC, including the increases for the Strategic National Stockpile and the new

Botulinum Toxin Research funding. However, we strongly caution that the President's proposed level-funding of the State and local capacity grants continues to reflect a \$95 million cut from fiscal year 2005 levels. We encourage the subcommittee to restore these cuts to ensure that our States and local communities can be prepared in the event of an act of terrorism.

Unfortunately, the President's budget proposes the elimination of some very important CDC programs, like the Preventive Health and Health Services Block Grant. Within an otherwise-categorical funding construct, the Preventive Health and Health Services Block Grant is the only source of flexible dollars for States and localities to address their unique public health needs. The track record of positive public health outcomes from Prevention Block Grant programs is strong, yet so many requests go unfunded. However, the President's budget proposes the elimination of the Preventive Health and Health Services Block Grant—again. We appreciate the work of the subcommittee to at least partially restore the fiscal year 2006 elimination of the Block Grant. Nevertheless, the \$20 million cut to the Block Grant in fiscal year 2006 reduces the States' ability to tailor Federal public health dollars to their specific needs. As States use their Prevention Block Grant dollars to address high priority needs such as emerging and chronic diseases, child safety seat programs, suicide prevention, smoke detector distribution and fire safety programs, adult immunization, oral health, worksite wellness, infectious disease outbreaks, food safety, emergency medical services, safe drinking water, and surveillance needs—we can scarcely understand why the Prevention Block Grant should be eliminated. We encourage the subcommittee to restore the cuts and fund the Prevention Block Grant at \$132 million.

We also encourage the subcommittee to provide \$10 million for CDC's Environmental Public Health Services Branch to revitalize environmental public health services at the national, State, and local level. As with the public health workforce, the environmental health workforce is declining. Furthermore, the agencies that carry out these services are fragmented and their resources are stretched. These services are the backbone of public health and are essential to protecting and ensuring the health and well being of the American public from threats associated with West Nile virus, terrorism, E. coli and lead in drinking water.

We appreciate the subcommittee's hard work in advocating for CDC programs in a climate of competing priorities.

HEALTH RESOURCES AND SERVICES ADMINISTRATION (HRSA)

HRSA programs are designed to give all Americans access to the best available health care services. Through its programs in thousands of communities across the country, HRSA provides a health safety net for medically underserved individuals and families, including more than 45 million Americans who lack health insurance; 50 million Americans who live in neighborhoods where primary health care services are scarce; African American infants, whose infant mortality rate is more than double that of whites; and the estimated 1 to 1.2 million people living with HIV/AIDS. Programs to support the underserved place HRSA on the front lines in erasing our Nation's racial/ethnic and rural/urban disparities in health status. HRSA funding goes where the need exists, in communities all over America. We support a growing trend in HRSA programs to increase flexibility of service delivery at the local level, necessary to tailor programs to the unique needs of America's many varied communities. The agency's overriding goal is to achieve 100 percent access to health care, with zero disparities. In the best professional judgment of the APHA, to respond to this challenge, the agency will require an overall funding level of at least \$7.5 billion for fiscal year 2007.

The APHA is gravely concerned about a number of programs that are slated for deep cuts or elimination under the administration's budget proposal. Building on the HRSA programs that were cut or eliminated in the fiscal year 2006 appropriations bill, we strongly suggest that this trend is moving our Nation in the wrong direction. We urge the subcommittee to restore funding to HRSA programs that were cut last year, as well as ensure adequate funding for fiscal year 2007 by rejecting the proposed cuts contained in the President's budget.

We express our dismay at the eroding support from the subcommittee for some of HRSA's programs over the last few years, including Health Professions programs, Area Health Education Centers, and the Maternal and Child Health block grant, among others. On top of the \$250 million cut to the agency for fiscal year 2006, the President has proposed another \$321 million overall cut from last year's appropriated level. Under the President's proposal, total cuts to HRSA since fiscal year 2005 would reach more than \$570 million, a devastating 8 percent cut in 2 years.

We urge the subcommittee to restore the fiscal year 2006 cuts, and reject the President's proposed cuts for fiscal year 2007.

One program that has received consistent support from the subcommittee is the community-based health centers and National Health Service Corps-supported clinics, which form the backbone of the Nation's health safety net. More than 4,000 of these sites across the Nation provide needed primary and preventive care to 15 million poor and near-poor Americans. HRSA primary care centers include community health centers, migrant health centers, health care for the homeless programs, public housing primary care programs and school-based health centers. Health centers provide access to high-quality, family-oriented, culturally and linguistically competent primary care and preventive services, including mental and behavioral health, dental and support services. Nearly three-fourths of health center patients are uninsured or on Medicaid, two-thirds are people of color, and more than 90 percent live below 200 percent of the poverty level. Additional primary care is provided by 2,700 clinicians in the National Health Service Corps. Corps members work in communities with a shortage of health professionals in exchange for scholarships and loan repayments. The APHA is pleased that the President has requested a significant increase for Community Health Centers for a total of \$1.918 billion.

Nevertheless, in the context of corresponding cuts to the Health Professions programs, we are left with some doubt about who, exactly, is going to staff all these new Community Health Centers. We are once again very concerned that the HRSA health professions programs under Title VII and VIII of the Public Health Service Act have landed on the chopping block. Today our Nation faces a widening gap between challenges to improve the health of Americans and the capacity of the public health workforce to meet those challenges. An adequate, diverse, well-distributed and culturally competent health workforce is indispensable to our national readiness efforts and to address critical health care needs. These programs help meet the health care delivery needs of the areas in this country with severe health professions shortages, at times serving as the only source of health care in many rural and disadvantaged communities. Therefore, the elimination of most funding for the Title VII health professions training programs and flat funding for Title VIII nurse training will only make certain that the needs of these medically underserved populations will not be met.

Furthermore, we believe the elimination of the Healthy Community Access Program, universal newborn hearing screening programs, and the Emergency Medical Services for Children Program, will further undermine the availability of basic health services for some that are most in need—especially children. The Healthy Community Access Program is an example in which communities build partnerships among health care providers to deliver a broader range of health services to their neediest residents. This program of coordinated service delivery is innovative, not duplicative of other available programs, and therefore its elimination is of grave concern. Also, the proposed zero funding of universal newborn hearing screening programs in the administration's budget will likely cause many hearing impairments in infants to go undetected, which can negatively impact speech and language acquisition, academic achievement, and social and emotional development. The proposed elimination of the Emergency Medical Services for Children Program will likely halt the improvements made in recent years to pediatric emergency care, which will disproportionately affect children who are eligible for Medicaid and SCHIP, but not enrolled due to State enrollment limits and budgetary pressures, and therefore frequently use emergency health services.

The Maternal and Child Health (MCH) Block Grant is operating for a second year with less funds than in fiscal year 2005, yet with greater needs among more pregnant women, infants, and children, particularly those with special health care needs. Furthermore, if programs like the Traumatic Brain Injury program, Universal Newborn Hearing Screening, and Emergency Medical Services for Children program are eliminated, those costs will be borne by the MCH Block Grant.

We are pleased with the increases proposed by the President for programs under the Ryan White CARE Act, administered by HRSA's HIV/AIDS Bureau. The CARE Act programs are an important safety net, providing an estimated 571,000 people access to services and treatments each year. At a time when HIV/AIDS is the sixth leading cause of death for people who are 25 to 44 years old in the United States, and the number of new domestic HIV/AIDS cases is increasing, we support increased funding for Ryan White Act programs.

Through its many programs and initiatives, HRSA helps countless individuals live healthier, more productive lives. As leaders of our Nation, this subcommittee decides what direction we will go in terms of delivering health care to those who need it most. The APHA believes that with adequate resources, HRSA is well positioned to meet these challenges as it continues to provide needed health care to the Na-

tion's most vulnerable citizens. We encourage the subcommittee to restore the funds to these important public health programs and reject the proposed cuts in the President's budget.

AGENCY FOR HEALTHCARE RESEARCH AND QUALITY (AHRQ)

We request a funding level of \$440 million for the AHRQ for fiscal year 2007, an increase of \$121 million over the enacted fiscal year 2006 level. This level of funding is needed for the agency to fully carry out its congressional mandate to improve health care quality, including eliminating racial and ethnic disparities in health, reducing medical errors, and improving access and quality of care for children and persons with disabilities. The cuts proposed in the administration budget will severely hamper these efforts.

SUBSTANCE ABUSE AND MENTAL HEALTH SERVICES ADMINISTRATION (SAMHSA)

The APHA supports a funding level of \$3.466 billion for SAMHSA for fiscal year 2007, an increase of \$107 million over the enacted fiscal year 2006 level. This funding level would provide support for substance abuse prevention and treatment programs, as well as continued efforts to address emerging substance abuse problems in adolescents, the nexus of substance abuse and mental health, and other serious threats to the mental health of Americans.

NATIONAL INSTITUTES OF HEALTH (NIH)

The APHA supports a funding level of \$29.75 billion for the NIH for fiscal year 2007, an increase of \$1.1 billion over the enacted fiscal year 2006 level. The translation of fundamental research conducted at NIH provides the basis for community based public health programs that help to prevent and treat disease.

DEPARTMENT OF HEALTH AND HUMAN SERVICES

The budget of the Office of Minority Health faced several years of decreasing budgets prior to last year. In fiscal year 2006, OMH received \$56 million; and the proposed budget in fiscal year 2007 is \$46 million. APHA is concerned that at a time when we have increasing evidence of disparities in health care delivery, access and health outcomes, the budget of OMH is getting cut. We support maintaining OMH funding at the fiscal year 2006 level.

CONCLUSION

In closing, we emphasize that the public health system requires financial investments at every stage. Successes in biomedical research must be translated into tangible prevention opportunities, screening programs, lifestyle and behavior changes, and other interventions that are effective and available for everyone. While we have said this before, in the post-September 11th era, we need to apply this to our spending growth in terrorism and influenza preparedness as well. We must think in a broad and balanced way, leveraging homeland security programs and funding whenever possible to provide public health benefits as a matter of routine, rather than emergency.

We thank the subcommittee for the opportunity to present our views on the fiscal year 2007 appropriations for public health service programs.

PREPARED STATEMENT OF THE AMERICAN SOCIETY FOR CLINICAL PATHOLOGY

DEMAND FOR QUALIFIED LABORATORY PERSONNEL OUTSTRIPS SUPPLY

On behalf of the American Society for Clinical Pathology (ASCP), a non-profit organization representing 140,000 pathologists, medical technologists, cytotechnologists and other medical laboratory professionals, we are submitting this written testimony regarding the Title VII Allied Health Professions program that is administered by the Health Resources and Services Administration (HRSA).

Last year, funding for the Title VII Allied Health Professions program was cut by 68 percent. Funding for these programs, which provide seed money for the establishment and expansion of medical laboratory education training programs, was reduced from \$300 million in fiscal 2005 to \$94 million for the 2006 fiscal year. Funding for the allied health and other disciplines program was reduced from \$11.8 million to \$4 million. Congress eliminated funding for the allied health special project grants that fund medical laboratory education programs under the Title VII of the Public Health Service Act. These programs represent a small portion of the funding provided by the Labor, Health and Human Services, and Education Appropriations

bill, but their importance to developing the next cadre of laboratory professionals can not be overstated.

Because few patients have direct contact with the people who work in our Nation's medical laboratories, the important role these health care practitioners play in patient care often goes unnoticed. Not only is laboratory testing key to diagnosing patient health, but laboratories also help identify appropriate patient treatments. In fact, the results of diagnostic laboratory testing impact over 70 percent of all healthcare treatment decisions. So, ensuring that our Nation's laboratories possess the laboratory professionals needed to accurately process laboratory testing demands is critical to patient health.

Unfortunately, the United States continues to face a severe shortage of qualified laboratory personnel. The U.S. Department of Labor projects that approximately 15,000 medical laboratory professionals will be needed each year through 2014. Unfortunately, fewer than 5,000 individuals are graduating each year from accredited or approved educational training programs.

Hardest hit by the shortage are rural areas and areas served by smaller hospitals. These areas are finding it increasingly difficult to recruit and retain qualified laboratory personnel. According to data gathered by the American Society for Clinical Pathology, half of all medical laboratories are reporting substantial difficulties hiring new testing personnel. It can often take a laboratory 6 to 12 months to hire an employee.

Another cause for concern is the average age of the laboratory workforce, which has been increasing steadily over the past few years, reflecting the fact that the pace with which younger, newly trained laboratorians have entered the laboratory workforce has not kept pace with retirements. At 43.7, the average age of medical technologists is essentially the same as that of nurses (43.3). An aging workforce can be more vulnerable to the adverse health and safety risks associated with shift work. Moreover, as our Nation ages, estimates project that the demand for laboratory testing services may increase.

Personnel turnover is also an increasing problem. With competition for laboratory personnel intensifying over the last year, turnover rates for some categories of laboratory personnel exceed 20 percent. Because of the difficulty in finding qualified staff, medical laboratories are increasingly turning to temporary staff (many of whom may already be working full- or part-time at another medical laboratory) to handle the patient testing workload.

To make matters worse, our Nation's capacity to train new laboratory personnel has declined substantially over the past 10 years. According to the National Accrediting Agency for Clinical Laboratory Sciences, school closings in the last 5 years have reduced the number of medical technologists and medical laboratory technicians being trained annually. The number of individuals graduating from these educational programs has declined approximately 35 percent over the last 10 years, from 6,783 graduates in 1994 to 4,390 in 2004. Over the last 10 years, the number of educational programs for laboratory professionals has declined more than 30 percent, from 637 programs in 1994 to 435 programs in 2004. For cytotechnologists, the number of educational programs has been reduced 25 percent over the last 10 years, from 65 programs in 1994 to 49 programs in 2004. Only 260 cytotechnologists graduate from these educational programs each year. Now with the devastating cuts to the Title VII programs, more programs may close.

Besides reducing our ability to train new laboratorians quickly, these losses have an especially profound impact on rural areas, where prospective laboratory practitioners often seek training close to home. Wyoming, for example, has no accredited or approved medical laboratory educational programs. Not surprisingly, data provided by HRSA indicates Wyoming has one of the lowest concentrations of laboratory professionals per resident (66 per 100,000 residents) in the United States.

ASCP believes that the Title VII Allied Health Education Programs have helped make a difference. For example, the University of Nebraska has for several years now offered a medical laboratory education program that has received funding under the allied health and other disciplines program. The University's program includes an effective distance training program that has served other nearby States as well. HRSA data indicates Nebraska has more than 128 laboratory professionals per 100,000 residents—almost twice the number of Wyoming and one of the highest concentrations of laboratory personnel in the United States. Because of cuts to the Title VII programs, Federal funding for the University of Nebraska's medical laboratory education program has been eliminated.

Given that medical technologist and medical laboratory technician jobs have often been ranked among the best jobs by the Jobs Rated Almanac, we hope increasing funding for laboratory professionals education programs will help encourage more individuals to pursue rewarding careers in the medical laboratory. Your help in re-

storing funding for these important educational programs will make our shared goal of reversing the laboratory personnel shortage much more obtainable. ASCP joins with our colleagues in the Health Professions and Nursing Education Coalition to request that Congress appropriate \$550 million for the Title VII programs.

PREPARED STATEMENT OF THE AMERICAN SOCIETY FOR MICROBIOLOGY

The American Society for Microbiology (ASM) is pleased to submit the following statement on the fiscal year 2007 appropriation for the National Institutes of Health (NIH). The ASM is the largest single life science Society with over 42,000 members who are involved in basic biomedical research, research and development activities, and diagnostic testing in university, industry, government and clinical laboratories.

The ASM is deeply concerned that the President's proposed fiscal year 2007 budget falls far short of adequately funding biomedical research supported by the NIH. Under the President's fiscal year 2007 budget request, 18 of the 19 Institute budgets are reduced in real dollars. These proposed reductions come at a time when more, not less, research is needed to address pressing health problems. Funding for the NIH in recent years has fallen substantially in constant dollars, foreshadowing a troubling future for biomedical research and for progress against health challenges from emerging and entrenched infectious diseases and chronic diseases. The continued toll on human life from chronic diseases, new threats from pandemic diseases and the potential dangers from bioterrorism make the ASM firmly believe that now is not the time to perpetuate the decline in funding of the past three fiscal years for the NIH. Biomedical research supported by the NIH is critical to the discovery of new knowledge and understanding which underpins development of medical treatments and vaccines. As the U.S. population ages and as global stability is threatened by pandemics, basic research which can only be supported by the NIH is essential to the well being of the world. However, basic biomedical research and the recruitment and training of the next generation of researchers will be weakened if funding for the NIH stagnates and does not keep pace with inflation for a fourth year.

The ASM commends Congress for the past decades of substantial and sustained funding for the NIH, an investment which is key to global health and benefits all Americans medically and economically. The ASM is pleased that the Senate recently has taken steps to increase the NIH budget for fiscal year 2007. The ASM urges Congress to continue to recognize the medical, economic, and strategic importance of adequately funding the NIH and recommends at least a 5 percent increase for the NIH in fiscal year 2007, an appropriation of \$29.75 billion. This level of funding is the minimum amount necessary to sustain the current rate of research progress and offset biomedical research inflation.

BIOMEDICAL RESEARCH BENEFITS PUBLIC HEALTH PREPAREDNESS AND THE ECONOMY

In the past year, there have been tragic reminders that being unprepared protects neither the public health nor the economic and strategic interests of the United States. Increased support for biomedical research is needed because new knowledge and technology are the pillars of preparedness against biological threats. Each day we face local, national, and global threats to health, safety, and well-being. To counter these threats, the NIH's resources are focused on preserving and improving health in this country and elsewhere through innovative, cutting-edge research. Declining cancer, heart disease and stroke mortality, extended HIV/AIDS life expectancies, and massive genome databanks are evidence of the power of biomedical research. Research supported by the NIH is responding to the realities of 21st century medicine, developing predictive and preemptive medical capabilities to overcome expected health resource shortages and unforeseen dangers like newly identified microbial pathogens.

Research funded by the NIH also contributes to the Nation's competitiveness and economic strength, which is clearly rooted in basic science that generates commercially viable products and technologies. Biomedical research advances scientific knowledge, expands the high-technology workforce of the Nation, and enhances innovation among the country's private sector companies. Roughly 84 percent of the proposed fiscal year 2007 NIH budget will support the extramural science community through research grants and contracts. This funding will sustain work by more than 200,000 research personnel affiliated with approximately 3,000 hospitals, universities, private companies, and other research facilities.

INFECTIOUS DISEASE RESEARCH NEEDS INCREASED SUPPORT

Inadequate increases in funding for biomedical research weakens our national defenses against infectious diseases, which despite some medical victories persist as the second leading cause of death worldwide, accounting for 26 percent of all deaths. Infectious diseases particularly affect years of healthy life lost because they cause approximately two-thirds of deaths among children less than 5 years of age. Our ability to combat infectious diseases depends on basic research of how microbes spread, how they are harbored in the environment, and how they cause disease. The National Institute of Allergy and Infectious Diseases (NIAID) supports research that is essential to developing strategies to prevent, diagnose and treat infectious diseases here and abroad. NIAID funding supports both intramural and extramural researchers in academia and the private sector searching for new therapies, diagnostics, vaccines, and other technologies that improve health care for infectious diseases. This critical work also focuses on high-priority homeland security initiatives, includes influenza preparedness and counter-bioterrorism. Unfortunately, the proposed fiscal year 2007 budget leaves funding for the NIAID flat, about \$4.4 billion or 0.3 percent over the fiscal year 2006 appropriation. With additional resources the NIAID could fund more promising initiatives and restore funding for research projects.

THE THREAT OF PANDEMIC INFLUENZA

Biomedical research and preparedness save lives and, in the case of pandemic influenza, the number of lives saved could be significant. Anticipating dire possibilities if the H5N1 avian influenza virus mutates sufficiently to move easily from human to human, the Department of Health and Human Services (DHHS) and other Federal agencies recently introduced the National Strategy for Pandemic Influenza. The ASM commends this plan as a prudent response to what could become a lethal global event. Fearsome pandemics have ravaged human populations three times in the past century: the 1918–1919 Spanish influenza that took more than 40 million lives worldwide, the 1957 Asian influenza, and the 1968 Hong Kong influenza. Those unusually virulent viral strains contained genetic material from avian influenza viruses like the current H5N1 virus. Confirmed reports of H5N1 related deaths in birds and mammals are coming from an expanding list of nations, where millions of domestic and wild fowl have died or been destroyed. In just the 4 months since the introduction of the National Strategy for Pandemic Influenza, H5N1 has spread to 37 nations. At present about 186 humans have contracted the disease, more than half of whom have died. Feared for their facile ability to infect and kill, influenza viruses are always with us. Every year, seasonal influenza causes 250,000 to 500,000 deaths worldwide. In the United States, this highly communicable disease annually causes an average 36,000 deaths, more than 200,000 hospitalizations, and, when calculated with pneumonia, an estimated \$37.5 billion in direct and indirect costs. Together influenza and pneumonia are the leading infectious cause of deaths in the United States, ranked seventh among all causes of death. The Centers for Disease Control and Prevention has estimated that if pandemic flu arrives in the United States, 90 million people will become ill and almost 2 million people could die. The global potential for profound loss, millions of human lives and billions in financial costs, clearly demands that our public health institutions be ready with the most effective preventive and therapeutic measures against influenza.

The ASM strongly supports the critically important NIH influenza initiatives. Researchers sponsored by the NIAID are focusing on effective vaccines and antivirals as prioritized in the national strategic plan, which calls for pandemic vaccine within 6 months of detection, as well as enough antiviral treatment. Scientists supported by the NIAID have completed a successful clinical trial of an experimental inactivated H5N1 influenza vaccine. Research efforts in the DHHS Plan also include the development of new vaccine delivery systems and higher capacity cell-based production methods. Recent advances supported by the NIAID include the institute's Influenza Genome Project, collecting to date the full genomic sequences of more than 830 influenza viral isolates from human patients and building a repository databank for use by other scientists.

PROGRESS AGAINST INFECTIOUS DISEASES

There are numerous research programs at the NIH that battle a long and growing list of infectious diseases which deserve increased support. Biomedical research consistently yields new ways to treat or prevent diseases. The following are just a few examples of new science advances:

Scientists supported by the NIAID have collaborated to develop a tissue culture cell system in which the whole hepatitis C virus can be grown, which will allow researchers to better understand how Hepatitis C Virus (HCV) replicates and causes infection. HCV is a major cause of chronic liver disease with over 170 million infected people worldwide and can progress to cirrhosis of the liver, leading to liver cancer and failure. Two studies by the NIAID have shown that anti-cancer drugs show promise as potential antiviral drugs and merit further exploration. A vaccine to protect adults and adolescents against illness due to *Bordetella pertussis* infection, or whooping cough, has proved more than 90 percent effective in a large-scale clinical trial, which could help stem the increase in pertussis cases in the United States. The NIAID has supported a clinical trial of a vaccine against pneumococcal disease, which is a major cause of illness and death in children worldwide.

Biomedical research must remain focused on major killers like HIV/AIDS, tuberculosis and malaria, which together are responsible for more than 5 million deaths each year. Despite extensive prevention programs, an estimated 14,000 people are newly infected with HIV daily. Twenty-five years after physicians first described AIDS as a new disease, more than 40 million people are living with HIV. The bacterium that causes TB currently infects about one-third of the world's population. Multi-drug resistant (MDR) TB increased 13.3 percent in the United States from 2003 to 2004, the largest single year increase in MDR TB since 1993, presenting significant challenges to treatment and control of TB in the United States and abroad. Extensively drug-resistant (XDR) TB has increased in the industrialized nations from 3 percent of MDR TB cases in 2000 to 11 percent in 2004. Two new engineered TB vaccines developed with support of the NIAID have entered clinical trials and a number of TB drug candidates are ready for clinical testing. Scientists continue to pursue a wealth of genomic data to understand malaria pathogenesis and to uncover new molecular targets for both drugs and vaccines for malaria which has an incidence of 300 to 500 million cases a year.

The NIAID funds extensive, multifaceted programs focused on these devastating diseases. In the past year, advances include: the new Center for HIV/AIDS Vaccine Immunology to address what is proving to be the very difficult task of finding HIV vaccines, with clinical sites in England, Africa, and three U.S. States; a clinical trial of two topical microbicides to assess effectiveness in stopping HIV transmission; and detection of a cellular protein that helps the tuberculosis microbe resist standard antimicrobials.

EMERGING DISEASES AND BIODEFENSE RESEARCH

A world influenced by rapid transit and global markets challenges not just U.S. competitiveness, but also our public health networks and our national sense of security. We no longer can view far-flung disease outbreaks as remote or theoretical threats to our well-being. The administration has requested \$1.9 billion in fiscal year 2007 funding for the NIH's biodefense efforts in recognition that the ability to counter bioterrorism depends on progress in biomedical research and the support of scientific capacity to respond to new biological threats. In 2005, the NIAID awarded two additional grants to research consortia aimed at new vaccines, therapies, and diagnostics, completing a national network of 10 Regional Centers of Excellence for the NIAID Biodefense and Emerging Infectious Diseases Research program. Research targets include anthrax, plague, smallpox, West Nile fever, botulism, hantaviruses, viral hemorrhagic fevers and many other less-common diseases. The NIAID also began clinical trials of an experimental DNA vaccine against the West Nile virus, which first appeared in the United States in 1999; two NIAID-supported teams identified how Nipah and Hendra viruses attack human and animal cells, both emerging viruses that cause serious respiratory and neurological disease; and NIAID researchers and their university partners determined which host-cell enzymes Ebola viruses can hijack to infect humans.

CONCLUSION

To sustain the pace of research discovery, we must continue to enhance the research capacity and productivity of the Nation's biomedical research enterprise. We must be prepared for the predictable diseases and build sufficient research capacity to detect and respond quickly to unexpected health threats. The 2002–2003 outbreak of Severe Acute Respiratory Syndrome (SARS) is a prime example of this balance, a rapid international response occurred to the sudden reality of a novel pathogen, which spread to more than two dozen countries. Biomedical scientists drew upon vast reserves of earlier viral research and quickly developed three distinct SARS vaccines now being evaluated, with the first human clinical trial opening just 21 months after SARS appeared as a new disease. Increased funding for biomedical

research will strengthen our public health preparedness, our technological competitive edge and our ability to improve the quality and length of life for people. We urge Congress to provide at least a 5 percent increase for the NIH budget for fiscal year 2007 to help accomplish these goals.

PREPARED STATEMENT OF THE AMERICAN SOCIETY FOR MICROBIOLOGY

The American Society for Microbiology (ASM) is submitting the following statement in support of increased funding for the Centers for Disease Control and Prevention (CDC) in fiscal year 2007. The ASM is the largest single life science society with over 42,000 members who are involved in research and diagnostic testing in university, industry, government and clinical laboratories.

The fiscal year 2007 budget request would reduce funding for the CDC for the second year in a row. Excluding one-time emergency funding items, CDC core programs would be cut over 4 percent below the fiscal year 2006 level of funding, which was 4 percent below the fiscal year 2005 budget. In view of the CDC's critical role in protecting the health and safety of the public, the cumulative two year reduction of funding of over 8 percent is cause for serious concern. The ASM recommends that Congress provide \$8.5 billion plus sufficient funding for pandemic influenza preparedness for the CDC in fiscal year 2007. This level of funding will sustain core programs crucial to improving public health in the United States and overseas.

The CDC works with partners in the United States and across the globe to monitor health status and trends, detect and investigate health problems, conduct research to enhance prevention, develop and advocate sound health policies, and foster safe and healthy environments. CDC capabilities must expand, not contract, as increasing worldwide connectivity brings global health concerns to the United States. Among the CDC's health protection goals are "people prepared for emerging health threats" and "healthy people in a healthy world." Both will require continued, extensive efforts here and abroad and clearly need sustained funding to assure success.

CDC PREPAREDNESS

CDC leadership in public health requires readiness to respond to unexpected health crises, above and beyond the Agency's ability to guard day-to-day wellness of people. In fiscal year 2005, the CDC's Epidemic Intelligence Service (EIS) officers responded to 66 health outbreaks, eight of them in other countries, and personnel from the CDC assigned to State or local health departments conducted 367 field investigations. After Hurricane Katrina struck the Gulf Coast, the CDC quickly provided information critical to preserving health and created the Katrina Information Network, later called the Emergency Response Information Network. Within two weeks, the CDC posted nearly 200 pertinent documents on its website (on infection control, first responder and volunteer safety, environmental issues and more). A commercial test kit for mold contamination, developed in 2003 by scientists of the CDC and a private biotech company, became a valuable assessment tool post-Katrina. Calls to the agency for rapid response generally involve infectious diseases, which persist as a principal concern of the CDC.

PANDEMIC INFLUENZA

Within the proposed fiscal year 2007 budget, pandemic influenza is a top-priority for funding for the CDC. The requested \$188 million for pandemic preparedness would expand the CDC's participation in the Federal interagency National Strategy for Pandemic Influenza, the Federal agency plan to prevent, detect, and treat outbreaks of influenza. Since mid-2005, a virulent avian influenza virus (strain H5N1) has been moving more rapidly from nation to nation, killing millions of wild and domestic birds and causing concern that viral mutations might cause human-to-human transmission. Scientists recently found that the human virus strains responsible for three major pandemics in the 20th century contained genetic material derived from avian viruses. Thus far, human deaths from H5N1 have been relatively few, but those known to be infected suffer a high mortality rate. Globally, traditional seasonal influenza already kills 250,000 to 500,000 each year; pandemic influenza could kill many millions. Although the H5N1 virus has not reached the United States, many health officials consider future outbreaks in this country to be inevitable. If viral mutations provoke a human pandemic, 15–35 percent of the U.S. population could be affected, exacting a large number of influenza deaths and economic losses of \$71.3–\$166.5 billion, according to the CDC's estimates.

The proposed fiscal year 2007 funding for pandemic preparedness will continue fiscal year 2006 improvements in domestic disease surveillance, upgrades of quar-

antine stations at major ports of entry, and support of global surveillance and detection activities in endemic, epidemic, and other high-risk countries. The proposed budget would fund new resources to increase stocks of diagnostic reagents; establish laboratory facilities with appropriate biocontainment capabilities; develop models and risk-assessment tools to predict disease spread; increase seasonal flu vaccine production; establish a viral-genome reference library; and create an electronic registry to more effectively track, distribute and administer vaccines to the public. The CDC would conduct studies that examine human infections of animal influenza A viruses; an additional \$2.8 million would streamline outbreak response in countries identified as needing special assistance; and nearly \$20 million would help States administer more seasonal influenza vaccines and thus stimulate greater vaccine production by manufacturers.

In the past year, Federal support for the CDC's influenza preparedness activities yielded promising testing and vaccine development innovations. Researchers developed a laboratory test to diagnose currently circulating A/H5 (Asian lineage) strains of influenza in patients, which was approved this February by the Food and Drug Administration. Using advanced molecular technology, the test gives preliminary results within four hours, compared to two to three days with previous testing. To more rapidly detect U.S. influenza outbreaks, the test is being distributed to laboratories within the national Laboratory Response Network (LRN), facilities in all 50 States with special training in molecular testing, biosafety, and containment procedures. The CDC also shared the new testing technology with the World Health Organization (WHO); the CDC is one of four WHO Collaborating Centers worldwide providing technical and logistical expertise on pandemic influenza. Using new genetic sequence information, scientists from the CDC also collaborated last year with Federal and academic researchers to reconstruct the virus responsible for an estimated 20 to 50 million people during the 1918–19 pandemic. The virus particles are being stored at the CDC, for use in expedited vaccine and antiviral drug development.

INFECTIOUS DISEASES

To protect public health, the CDC has a major responsibility for preventing and controlling infectious diseases, still a leading cause of death and disability in this country and worldwide. The ASM is particularly aware of the important role of the CDC in protecting against infectious diseases. The fiscal year 2007 budget request includes \$245 million for infectious disease programs, from laboratory research and epidemic investigations to surveillance networks, public education programs and specialized training. Increased funding for infectious diseases is needed not only to maintain and expand funding for existing infectious disease problems, but also to respond to new infectious disease threats and emergencies. The CDC must be able and ready to respond to shifting challenges, as it has done in the past for emerging disease outbreaks. The public clearly expects and relies on the CDC for rapid response to disease threats and for accurate, science-based advice on health issues. After the agency consolidated all of its more than 40 health information hotlines and clearinghouses into one toll-free service last March, the consumer center handled nearly 500,000 calls during its first 9 months and continues to expand.

Preventing and controlling serious infectious diseases in the United States depends on the CDC's scientific expertise and education outreach tailored for specific diseases. An example is the CDC program to prevent HIV/AIDS, sexually transmitted diseases, and tuberculosis, an ongoing multi-faceted effort that is allotted \$1.0 billion in the administration's fiscal year 2007 request (\$86 million more than fiscal year 2006). Tuberculosis continues to be a serious threat in the United States and worldwide, with a 13.3 percent increase in multi-drug resistant (MDR) TB in the United States from 2003 to 2004, the largest single year increase in MDR TB since 1993. An estimated 40,000 individuals newly acquire HIV in the United States each year and far more effort to prevent new infections is needed. The prevalence of anti-retroviral resistance to therapy at the time of HIV diagnosis is also increasing rapidly and will result in dramatically increased morbidity and health care costs if more effective efforts at prevention are not implemented. In contrast, new pediatric HIV infections are decreasing in number and routine prenatal HIV testing planned by the CDC for fiscal year 2007 should decrease pediatric cases even further. The CDC's National Plan to Eliminate Syphilis, started in 1999, requires further support with syphilis rates among U.S. men unfortunately increasing in the United States.

Preventive health in the United States met a major milestone last year, when government efforts finally eliminated rubella virus, the highly contagious agent of childhood measles. The ASM agrees with the CDC's fiscal year 2007 budgetary em-

phasis on vaccination, certainly one of the most efficient and effective methods to fight infectious diseases. The fiscal year 2007 \$2.6 billion immunization program continues two established components to protect the Nation's children, the Vaccines for Children program that provides vaccines free to children in financial need (40 percent of all childhood vaccines purchased in the United States), and the Section 317 program, supporting State-managed immunization programs. Researchers from the CDC recently used computer modeling to evaluate economic benefits from this country's standard childhood immunization schedule, comprising seven vaccines for illnesses like diphtheria, mumps, and polio. They concluded that collectively the immunizations not only save thousands of lives each year, but also \$10 billion in direct medical costs plus more than \$40 billion in indirect costs.

The CDC's protection of American health and safety reaches beyond national borders, facing infections that can migrate from one afflicted population to the next through global travel and commerce. International collaboration against pandemic influenza is a large-scale example, but one among many such responses. Last year, experts from the CDC worked with officials from the WHO and the Angola government to control an outbreak of Marburg hemorrhagic fever in that African nation, posting traveler alerts on its website and providing on-site laboratory and field investigative services.

The proposed fiscal year 2007 budget requests \$381 million for the CDC's global health activities, to improve detection and control of diseases such as HIV/AIDS, malaria, polio, and measles. In fiscal year 2005, the CDC program Preventing Mother-and-Child HIV Transmission collaborated with other nations to screen 2 million pregnant women in 15 countries, giving short-course antiretroviral prophylaxis to 125,000 who tested HIV-positive. The fiscal year 2007 budget includes \$122 million in direct AIDS-related funding for ongoing prevention, treatment, and surveillance in 25 countries. From 1988 to 2004, global polio incidence declined by more than 99 percent, saving about 250,000 lives and avoiding 5 million cases of childhood paralysis. Global deaths due to measles fell by 48 percent between 1999 and 2004.

The National Laboratory Training Network (NLTN) is a unique training system sponsored by the CDC and the Association of Public Health Laboratories. The NLTN is solely dedicated to ensuring quality laboratory practice for testing of public health significance through relevant and timely continuing education offered in a variety of educational venues at a reasonable cost, often at no charge. The NLTN Continuing Education programs offer laboratories critical insights into public health needs while also ensuring high quality, cost-effective, and clinically relevant direct patient testing needs are met. The ASM strongly supports the continuation of the NLTN programs through the CDC.

BIOTERRORISM

The possibility of bioterrorism persists as a principal focus for the CDC, and the fiscal year 2007 budget requests \$1.7 billion to support ongoing programs, the Strategic National Stockpile (SNS), surveillance and quarantine efforts, laboratory research on high-risk pathogens like anthrax, and assistance to State and local governments. Since its creation in 1999, the SNS has expanded its inventory of vaccines, drugs, and other countermeasures, preparing for health crises like influenza pandemics, natural catastrophes like Hurricane Katrina, and biological, chemical, radiological, or nuclear terrorist attacks. Supplies can be delivered anywhere in the United States within 12 hours of an event. The SNS fiscal year 2007 request of \$593 million increases the fiscal year 2006 appropriation by \$70 million, nearly \$50 million of which will finance portable hospital units under the Mass Casualty Initiative, for rapid deployment to expand local hospital capacity. The CDC's fiscal year 2007 bioterrorism strategy also includes funding to utilize a recent invention, a new mass spectrometry method from the CDC's Environmental Health Laboratory for detecting botulinum toxin in people and the Nation's milk supply within 15 seconds. The additional funds will improve the method to more rapidly detect anthrax lethal factor, ricin and other toxins that can be used as bioweapons, as well as fully exploit the method's "fingerprinting" of suspect toxins to determine their source.

The ASM asks Congress to recognize and support the CDC's crucial activities by providing increased support for the CDC's core programs and pandemic influenza preparedness.

PREPARED STATEMENT OF THE AMERICAN SOCIETY OF NEPHROLOGY

INTRODUCTION

The American Society of Nephrology (ASN) is pleased to submit this statement for the record to the Senate Appropriations Subcommittee on Labor, Health and Human Services, and Education in support of the ASN's top funding and research priorities for fiscal year 2007.

The ASN is a professional society of more than 10,000 researchers, physicians, and practitioners who are committed to the treatment, prevention, and cure of kidney disease. Specifically, the ASN is committed to enhance and assist the study and practice of nephrology, to provide a forum for the promulgation of research, and to meet the professional and continuing education needs of its members.

The ASN statement focuses on those issues and programs that most immediately fall under the committee's jurisdiction and assist our members to fulfill their missions. We want to express our strong support for advancing programs supported by the National Institutes of Health (NIH) and Agency for Healthcare Research and Quality (AHRQ). The ASN thanks the subcommittee for its commitment and steadfast support of these programs.

THE FACE OF KIDNEY DISEASE

Kidney disease is a major health problem in the United States, and along with Alzheimer's disease, the fastest growing cause of death in the United States. (CDC data). It is estimated that at least 15 million people have lost 50 percent of their kidney function without even knowing it and suffer from Chronic Kidney Disease (CKD). Another 20 million more Americans are at increased risk of developing kidney disease. Sub clinical kidney disease has emerged recently as a major risk factor for CVD. The culmination of unimpeded progression is end stage renal disease (ESRD), a condition in which patients have permanent kidney failure, affects almost 400,000 Americans, and directly causes 50,000 deaths annually. In the past 10 years, the number of patients in the United States with ESRD has almost doubled. Although the largest age group having ESRD ranges from 45-64 years old, rates increase steadily for those between the ages of 65-74 and are disproportionately high in African-Americans. African-Americans represent about 32.4 percent of all patients treated for kidney failure in the United States and the risk of ESRD for middle-age African-American males with high blood pressure is six times that of their Caucasian counterparts.

ECONOMIC COSTS

Although no dollar amount can be affixed to human suffering or the loss of human life, economic data can help to identify and quantify the current and projected future financial costs associated with ESRD. The 2000 report of the United States Renal Data System indicates that the total Medicare ESRD program cost will more than double, surpassing \$28 billion, by 2010, as the prevalence of kidney failure is projected to double. The annual average cost per ESRD patient is approximately \$55,000. These escalating costs serve to magnify the need to investigate new, and better apply, recently proven strategies for preventing progressive kidney disease.

In short, we can treat and maintain patients who have lost their kidney function but the critical need is to prevent the loss of kidney function and its complications in the first place. Meeting this vital goal can only be accomplished through more concerted research and education.

MAJOR CAUSES OF END STAGE RENAL DISEASE

Diabetes, a disease that affects 17 million Americans, is the most common cause of ESRD in the United States. Nearly 34 percent of all Americans being treated for kidney failure have diabetes. Moreover, only 18 percent of people with diabetes survive 5 years after beginning treatment for kidney failure. With current projections that the epidemic of obesity-related diabetes mellitus will continue to soar, a dramatic increase in kidney disease is anticipated in the next 10 years.

Hypertension, or high blood pressure, is the next leading cause of ESRD, accounting for 23.6 percent of ESRD patients. Similar to diabetes, higher rates of hypertension can be found among certain age and ethnic groups. For example, hypertension is common among African-Americans (35 percent). It is also a disease of the aged and accounts for 37 percent of new ESRD cases in those 65 years old and above.

Despite recent progress and discoveries regarding the major causes of ESRD, it is among many areas of disease research that remain under-investigated. Research-

ers agree that significant inroads in previously understudied sub-fields need to be made. Significant among them, more focus and direction need to be introduced into the general field of renal research and patient and physician education. These pressing factors provided the impetus for an informal dialogue on the resulting calls to action.

LACK OF PUBLIC AWARENESS

A major problem with kidney disease is that it is largely a "Silent Disease". In fact, of the 15 million Americans who have lost at least half of their kidney function, the vast majority have no knowledge of their condition. While people with chronic kidney disease may not show any symptoms, this does not mean that they are not going to have long-term damage to their kidney function, requiring dialysis or a transplant. These people may also be especially vulnerable to cardiovascular disease. If these 15 million people were identified early, there are new therapies, particularly special blood pressure drugs known as ACE inhibitors, which could be prescribed with potentially significant benefits. In addition, vigorous treatment of hypertension and other complications that cause illnesses and loss of productivity could be administered to the patients.

Given the cost to human life and to the Federal Government caused by ESRD specifically, as well as other forms of kidney disease, we urge this subcommittee to provide funding increases for kidney disease research.

KIDNEY DISEASE RESEARCH

National Institutes of Health (NIH)

The ASN applauds Congress and members of the subcommittee for leading the bipartisan effort to double our investment in promising biomedical research supported and conducted by the NIH. NIH has served as a vital component in improving the Nation's health through research, both on and off the NIH campus, and in the training of research investigators, including nephrology researchers. Strides in biomedical discovery have had an impact on the quality of life for people with kidney disease. If we are to sustain this momentum and translate the promise of biomedical research into the reality of better health, this Nation must maintain its commitment to medical research. We support the recommendation of the Ad-Hoc Group for Medical Research Funding to add 5 percent in fiscal year 2007 to the NIH budget for a total of \$29.750 billion.

In fiscal year 2007, the NIH budget must grow by 3.5 percent, or nearly \$1 billion, just to keep pace with inflation. Further, the NIH has ambitious plans for new initiatives to combat the health challenges of the future. To ensure that NIH's momentum is not further eroded, and to continue the fight against the diseases and disabilities that affect millions of Americans, the ASN will work with the administration and the Congress to seek an NIH budget of at least \$30 billion for fiscal year 2007.

National Institute of Diabetes, Digestive, and Kidney Diseases (NIDDK)

Many recent advances have been made in our understanding into the causes and progression of renal failure, such as: how diabetes and hypertension affect the kidney and the mechanisms responsible for acute renal failure.

Despite these advances, the number of people with renal failure and the numbers who die of renal failure continue to increase each year. Most alarming is the significant increase in diabetes, the most common cause of chronic kidney failure, and its relationship to kidney disease. The ASN believes the rising incidence and prevalence of diabetes-related kidney disease warrants additional recourses to improve our understanding of the relationship between kidney disease and diabetes.

The NIDDK sponsors a number of activities that researchers hope will lead to improved detection, treatment and prevention of kidney disease and chronic kidney failure. To ensure ongoing kidney disease and kidney disease related research and important clinical trials infrastructure development we recommend a 5 percent increase for the NIDDK over fiscal year 2006 levels.

ASN RESEARCH GOALS & RECOMMENDATIONS FOR KIDNEY DISEASE

In the fall of 2004, the ASN conducted a series of research retreats to develop priorities to combat the growing prevalence of kidney disease in the United States. The ASN joined experts, both within and outside the renal community, and identified five areas requiring attention: acute renal failure, diabetic nephropathy, hypertension, transplantation, and kidney-associated cardiovascular disease.

The final research retreat report(s) highlighted priorities and contained three overriding recommendations. These include:

1. *Development of Core Centers for kidney disease research*

Expansion of the kidney research infrastructure in the United States can be achieved by vigorous funding of a program of kidney research core centers. Specifically, we propose that the number of kidney centers be increased with the goal of providing core facilities to support collaborative research on a local, regional and national level. It should be emphasized that such a program of competitively reviewed kidney core centers would facilitate investigator-initiated research in both laboratory and patient-oriented investigation. This approach is highly compatible with the collaborative research enterprise conceived in the NIH Road Map Initiative.

2. *Support programs/research initiatives that impact the understanding of the relationship between renal and cardiovascular disease*

It is now well recognized that chronic kidney dysfunction is an important risk factor for the development of cardiovascular disease. It is recommended that the NIDDK and NHLBI work cooperatively to support both basic and clinical science projects that will shed light on the pathogenesis of this relationship and to support the exploration of interventions that can decrease cardiovascular events in patients with CKD. Thus, we specifically propose that NHLBI should support investigator-initiated research grants in areas of kidney research with a direct relationship to cardiovascular disease. Similarly, NHLBI should work collaboratively with NIDDK to support the proposed program of kidney core research centers.

3. *Continued support and expansion of investigator initiated research projects*

In each of the five subjects there are areas of fundamental investigation that require the support of investigator initiated projects, if ultimately progress is to be made in the understanding of the basic mechanisms that underlie the diseases processes. It is recommended that there should be an expansion of support for research in the areas that lend themselves to this mechanism of funding, by encouraging applications with appropriate program announcements and requests for proposals. In addition to vigorous support for RO1 grants, continued funding of Concept Development and R21/R33 grants is essential to support development of investigator-initiated clinical studies in these areas of high priority. Such funding is critical to accelerate the transfer of new knowledge from the bench to the bedside.

In summary, the ASN foresees the following important directions in the future of kidney disease research:

- Continued research in acute renal failure, diabetic nephropathy, hypertension, transplantation, and kidney-associated cardiovascular disease;
- The establishment of core centers for kidney disease research;
- Persistent attention to the relationship between kidney disease and hypertension and collaboration between NIDDK and NHLBI;
- Expansion of investigator initiated research projects.

The ASN will strive to fulfill its mission statement and research recommendations (agenda). The ASN will remain active on Capitol Hill and assist members of Congress and the administration in their understanding of kidney disease and problems facing CKD and ESRD patients and the health care providers who serve them.

Agency for Health Care Research and Quality (AHRQ)

Complementing the medical research conducted at NIH, the AHRQ sponsors health services research designed to improve the quality of health care, decrease health care costs, and provide access to essential health care services by translating research into measurable improvements in the health care system. The AHRQ supports emerging critical issues in health care delivery and addresses the particular needs of priority populations, such as people with chronic diseases. The ASN firmly believes in the value of AHRQ's research and quality agenda, which continues to provide health care providers, policymakers, and patients with critical information needed to improve health care and treatment of chronic conditions such as kidney disease. The ASN supports the Friends of AHRQ recommendation of \$440 million for AHRQ in fiscal year 2007.

CONCLUSION

Currently, there is no cure for kidney disease. The progression of chronic renal failure can be slowed, but never reversed. Meanwhile, millions of Americans face a gradual decline in their quality of life because of kidney disease. In many cases, abnormalities associated with early stage chronic renal failure remain undetected and are not diagnosed until the late stages. In sum, chronic renal failure requires our serious and immediate attention.

As practicing nephrologists, ASN members know firsthand the devastating effects of renal disease. ASN respectfully requests the subcommittees' continued support to

enable the nephrology community to continue with its efforts to find better ways to treat and prevent kidney disease.

Thank you for your continued support for medical research and kidney disease research. To obtain further information about ASN, please go to <http://www.asn-online.org> or contact Paul Smedberg, ASN Director of Policy & Public Affairs at 202-416-0646.

PREPARED STATEMENT OF THE ASSOCIATION OF ACADEMIC HEALTH CENTERS

The Association of Academic Health Centers (AAHC) is pleased to submit this statement for the record with its fiscal year 2007 appropriations recommendations for a number of essential programs that are critical to improving health and health care delivery in our Nation.

The AAHC, the national organization representing almost 100 academic health centers, is dedicated to improving the Nation's health care system by mobilizing and enhancing the strengths and resources of the academic health center enterprise in health professions education, patient care, and research. An academic health center consists of an allopathic or osteopathic medical school, one or more other health professions schools or programs, and one or more owned or affiliated teaching hospitals, health systems, or other organized health care services. Our member institutions have enormous impact on their regions, the Nation, and the global economy.

THE RESEARCH ENTERPRISE

AAHC member institutions are the infrastructure of the Nation's research enterprise. Academic health center researchers in both the basic and clinical sciences are pushing the bounds of science to advance progress in the diagnosis and treatment of myriad diseases and chronic illnesses. In addition, our institutions are engaged in a broad range of health services research contributing to improvements in the organization, financing, and delivery of health services.

Our key partner in the nation's research achievements is the National Institutes of Health (NIH), which throughout its history has provided the necessary funding for basic science research and a wide array of projects to test clinical applications. Maintaining NIH's capabilities to carry out investigator-initiated research is absolutely critical to ensure that the Nation advances in health care, sustains the education and advancement of highly trained scientists, and builds the infrastructure for the conduct of research across the country. We believe that America's preeminence in science and its leading position in our global economy are tied closely to the Nation's investment in its research enterprise through the NIH.

Over the past 3 years, increases in appropriations for the NIH have not kept pace with inflation. In fact, the administration's current proposal to freeze the NIH budget at a level that is more than 11 percent below the 2003 funding level in constant dollars can only be viewed as threatening to the Nation. The practical effect of such funding is that NIH cannot sustain its ongoing efforts and at the same time support promising new research. The opportunity costs in terms of our capacity to reduce the burden of illness and improve patient outcomes are enormous. Disrupting ongoing research projects or failing to support promising new proposals is, in the long run, more costly than any short-term budget savings. The cost will be counted by the missed opportunities to mitigate or cure many conditions, reducing the quality of life for people throughout the world.

We believe that the Congress must renew its commitment to the research enterprise, even in these times of budgetary restraint. Failure to do so means that with each passing year the NIH will support less internal and extramural research. We are very pleased that the Senate Budget Resolution for fiscal year 2007 provides for a \$7 billion increase in overall discretionary dollars for health and education programs, including an assumption of at least \$1 billion for the NIH. We are very grateful for the leadership of Senators Specter and Harkin who proposed an amendment to increase funding and argued persuasively for making this investment in the future of biomedical research. We strongly recommend that funding for the NIH in fiscal year 2007 be increased at least 5 percent or no less than the funding provided in fiscal year 2005 to prevent further erosion of its purchasing power.

THE HEALTH PROFESSIONS WORKFORCE

The health workforce must be viewed as a cornerstone of our Nation's well being. The health professions not only treat and care for patients but also represent an economic engine for the country. Unfortunately, the supply of health professionals is threatened. By most estimates, there are an insufficient number of health profes-

sionals to meet current and future demands. It has been estimated that the Nation will need approximately 3.5 million health care workers in addition to the 2 million workers to replace those who leave the workforce.

Further, the geographic maldistribution of health professionals—especially primary care physicians and other non-physician practitioners—leaves large numbers of Americans without access to care with as many as 50 million people living in communities officially designated as health professions shortage areas. Of particular concern are estimated shortages in dentistry, medicine, nursing, pharmacy, and an array of allied health professionals that will likely increase with an aging population and potentially less migration of health professionals throughout the world.

The health and economic prosperity of the Nation depend on an effective and well-trained health workforce. Key to ensuring an adequate supply is investment in the educational programs and the students who are pursuing careers in the health professions. Moreover, these educational programs need to increasingly attract students who will practice in underserved areas—both during their training and afterward. At the same time, continuing education and distance learning programs must be maintained to connect practitioners with advances in care and provide opportunities for consultation and referral. Strengthening the health care delivery system in underserved areas is key to our efforts to improve the health of the Nation and eliminate the disparities in health outcomes that result from inadequate access to care.

The cornerstone of efforts to address the maldistribution of health professionals, to train a diverse health professions workforce, and to promote access for elderly and other vulnerable populations has been the programs authorized under Title VII of the Public Health Service Act. These programs include targeted scholarships for disadvantaged students; initiatives at the secondary school level to prepare students for college-level programs in the allied health professions; direct support for programs in pharmacy, dentistry, geriatrics, pediatrics, and other primary care disciplines; and Area Health Education Centers and Health Education and Training Centers. In addition, Title VIII funds for nursing have been especially important in helping to address widespread and persistent shortages and to develop programs for much needed advanced practice nurses, including the faculty to direct these programs. Support for health professions programs has been unstable and, in the case of Title VII, was cut more than half this year—from \$252 million in fiscal year 2005 to \$99 million in fiscal year 2006.

It is also important to note that cutting support for health professions education is likely to undermine current efforts to significantly expand community health centers. Staffing for these centers relies on primary care practitioners in the disciplines that are the focus of many of the programs in Titles VII and VIII. A recent study published in *The Journal of the American Medical Association* (March 1, 2006; Vol. 295, No. 9) found that workforce shortages “may impede the expansion of the U.S. community health center safety net, particularly in rural areas.” The study also recommends that funding for Title VII be bolstered as this is “the only Federal program that exists to encourage the production of primary care clinicians likely to practice in underserved areas . . .”

Reports from the member institutions of the AAHC confirm the adverse impact of further reductions in funding for Title VII. For example, at the University of Nebraska Medical Center, Title VII grants totaling \$3.2 million were received in fiscal year 2005. These grants support the placement of behavioral health professionals in more than 140 rural and other underserved settings providing over 5,000 annual behavioral health visits.

In addition, the Nebraska Geriatric Education Center, supported by a Title VII grant, plays a key role in training professionals to meet the needs of older patients while at the same time expanding access to care for this population. Finally, the School of Allied Health and the primary care medicine programs at the University of Nebraska Medical Center depend on Title VII grants to increase the diversity of their student population and to provide teaching opportunities in sites serving rural and other underserved communities.

Without continuing support from Title VII grants, California health professions training programs could lose approximately \$18 million annually. Statewide programs in California train physicians to work in underserved areas such as rural and inner city clinics, teach medical Spanish and cultural awareness skills to health professionals, and work with community health workers in low-income neighborhoods to teach self-help skills to patients with diabetes and asthma.

In North Carolina more than \$12.5 million in Title VII grants were distributed to the University of North Carolina at Chapel Hill, Duke University, and Wake Forest University. These funds are used to train primary care physicians, dentists, geriatric specialists, physician assistants, and others. These programs have helped to recruit a diverse cadre of students as well as support the work of Area Health Edu-

cation Centers which are linked to the universities and provide essential access to care in underserved areas.

These are just a few examples of the valuable work that results from the Federal funding of Title VII. The administration's recommendations would virtually eliminate funding for these programs.

Leaders of academic health centers nationwide confirm that these programs have made a difference in the nation's health. The Nation's return on its investment is clear. Title VII has succeeded in (1) supplying a workforce to serve populations in need, (2) enabling institutions and communities to recruit a diverse workforce, and (3) expanding access to care for many of the Nation's most vulnerable individuals.

We strongly recommend that funding for Titles VII and VIII total \$550 million for fiscal year 2007. This would help to off-set the \$155 million cut in place for this year and ensure that these critical programs can continue to address the urgent need to improve the health of our Nation.

HOSPITAL PREPAREDNESS PROGRAM

The continuing threats from natural and/or terrorist events require our health system to be prepared to treat mass casualty events. Critical emergency care and inpatient surge capacity must be available across the country. Because of the financial condition of many public and non-profit hospitals, the cost of capital to undertake the necessary preparations for the treatment of large numbers of patients is beyond their reach. These funds make it possible for hospitals to build the infrastructure and surge capacity that is necessary to meet unknown, but potentially large, public health emergencies.

We strongly support the administration's budget request for \$474 million for the hospital preparedness program to continue progress toward a more rapid and coherent response to these unpredictable circumstances.

STATE HIGH-RISK INSURANCE POOLS

The number of uninsured in America continues to grow as employers curtail or drop group coverage and many workers are forced to forego coverage. The AAHC has been at the forefront of efforts to address the crisis of the Nation's uninsured. This is an urgent problem and we are committed to supporting a range of approaches to make health coverage more accessible and affordable.

One subset of the uninsured population involves individuals at risk for health care coverage because of one or more pre-existing health conditions. Some of these individuals have only been able to purchase coverage under the auspices of State high-risk health insurance pools because no other insurance product is available to them. State high-risk insurance pools are a vital pathway for those who have been excluded from the health insurance market because of their health status.

Section 2745 of the Public Health Service Act authorizes a program of grants to the States for the establishment and operation of qualified high-risk health insurance pools. In the recently enacted Deficit Reduction Act, Congress extended this program and authorized \$75 million for fiscal year 2007. Unfortunately, the President's budget does not recommend any funding for this important program. We urge the subcommittee to fund this grant program at the fully authorized amount of \$75 million.

We thank you for the opportunity to present our views and recommendations regarding funding for discretionary health programs in fiscal year 2007. Our member institutions are committed to improving the Nation's health and well-being, and we look forward to working with Chairman Specter and all members of the subcommittee. We are pleased to be available to provide information and answer questions at any time.

PREPARED STATEMENT OF THE ASSOCIATION OF AMERICAN CANCER INSTITUTES

The Association of American Cancer Institutes (AACI), representing 86 of the Nation's premier academic and free-standing cancer centers, appreciates the opportunity to submit this statement for consideration as the Labor-Health and Human Services Appropriations Subcommittee plans the fiscal year 2007 appropriations for the National Institutes of Health (NIH) and the National Cancer Institute (NCI).

AMERICA'S INVESTMENT IN CANCER RESEARCH

Thirty-five years ago, a diagnosis of cancer was largely a death sentence. Since then, our national investment in cancer research has reaped remarkable returns, including potential cancer vaccines, improved detection strategies, and targeted, less

difficult therapies. The last several years have been particularly exciting for science and specifically for cancer research. Advances such as the sequencing of the human genome and improved insights about the genetics of cancer have led to promising new approaches to the prevention and treatment of cancer. Today, many patients are benefiting from targeted drug therapies, like Gleevec, Tarceva and Avastin that are more specific, less toxic and more effective. It is the support of the Nation's cancer research enterprise by the NCI, 80 percent¹ of whose funds are spent at academic research institutions across the country, that has led to these discoveries.

The President's 2007 budget proposal provides only level funding for the NIH and a \$40 million cut for the NCI. This is of great concern to the Nation's cancer centers, which play a critical role in the progress against cancer, and are major hubs of State of the art cancer research, drug development, treatment, prevention and control. A depleted budget for NCI directly impacts the pace of scientific discovery and may mean that new ideas to combat cancer will go unexplored, and the development of novel cancer therapies will be seriously compromised. Reduced funding will also discourage the next generation of cancer researchers leading some to choose other fields. We are at a time of unprecedented opportunity to make a dramatic assault on cancer, and the hard-won momentum that has been achieved in recent years must be sustained. Otherwise, America risks losing an entire generation of ideas that could produce possible cures for the diseases we know as cancer.

CANCER RESEARCH: SAVING LIVES AND MONEY

At the Nation's cancer institutes, we have demonstrated that cancer research saves lives. Cancer mortality rates decreased by 10 percent between 1991 and 2001, translating to as many as 321,000 lives saved² and in 2003, the number of cancer deaths dropped for the first time since the war on cancer began. The death rate for all cancers combined is dropping about 1.1 percent per year, while the rate of new cancers is holding steady.² The five-year relative survival rate for all cancers diagnosed between 1995 and 2000 is 64 percent, an increase from just 50 percent in the mid-1970s. Thanks to prevention research and the development of early detection technologies and new treatments, today, nearly 10 million Americans are cancer survivors.²

The financial cost of cancer is rising, but research advances help to mitigate cancer's annual price tag, which in 2005 was estimated at \$210 billion, including \$136 billion in lost productivity and over \$70 billion in direct medical costs.³ Tamoxifen, used to treat breast cancer, is saving \$41,372 for each year of life gained in women 35 to 49 years old; \$68,349 for women 50 to 59 years old; and \$74,981 for women 60 to 69 years old.⁴ The drug Cisplatin has translated to an increase in the survival rate for testicular cancer patients. The drug cost an estimated \$56 million to develop and has already produced an annual return of \$166 million in treatment savings.⁵ That research saves money is evident.

THE NATION'S CANCER CENTERS: ECONOMIC ENGINES IN THEIR COMMUNITIES

In addition to training the future workforce for cancer care and research, America's cancer centers themselves have direct economic impact, both locally and nationally. It is estimated that every dollar spent on research funding and patient activities at cancer centers translates to \$2.50 to \$3 invested in the local economy.⁶ In addition, the amount of research support and operating budgets that are leveraged through NCI-designated cancer centers support grant (CCSG) funding alone is striking. The total amount of research support is more than ten times the amount generated by the CCSG grants themselves.⁷ By attracting patients from outside the community, constructing new laboratories and clinical facilities, recruiting new faculty and staff from outside the region who bring cutting-edge scientific, clinical and public health expertise to work in communities, and developing entrepreneurial op-

¹ United States. Department of Health and Human Services. The Nation's Investment in Cancer Research. 2006. (http://plan.cancer.gov/pdf/nci_2007_plan.pdf)

² Statistics from the American Cancer Society.

³ Estimates from the National Heart, Lung and Blood Institute.

⁴ United States Senate. Joint Economic Committee, Office of the Chairman, Connie Mack. The Benefits of Medical Research and the Role of NIH. 2000. (<http://jec.senate.gov>)

⁵ Estimates from Lasker/Funding First. (www.fundingfirst.org)

⁶ United States. Department of Commerce, Bureau of Economic Analysis. Regional Multipliers: A User Handbook for the Regional Input-Output Modeling System (RIMS II). 3rd ed. 1997.

⁷ United States. National Cancer Institute. Advancing Translational Cancer Research: A Vision of the Cancer Center and SPORE Programs of the Future. 2003. (<http://deainfo.nci.nih.gov/advisory/ncab/p30-p50/P30-P50final12feb03.pdf>)

portunities in the biotech and pharmaceutical industries, cancer research centers serve as an economic stimulus and generate commerce in their communities.

UNITED STATES: GLOBAL LEADER IN CANCER RESEARCH

The United States is a world leader in the battle against cancer because of the Nation's past investment in cancer research, but our competitive edge will quickly erode without continued commitment. Sustained inquiry and scientific advancement are critical to maintaining our competitive stature. Failure to appropriate new funds for biomedical innovation and discovery threatens America's capacity to compete with emerging global economies and other countries are eager to take our place as the world's leader in biomedical research. The United States must significantly enhance its research and technical capacity to maintain our preeminent position.

CONCLUSION

In summary, cancer research saves lives, saves money, stimulates economic growth at home and enhances U.S. competitiveness abroad. Federal investment in cancer research must remain a national priority. America must commit to sustaining the pace of cancer-related science so that new discoveries are translated into clinical benefit for all. Congress has the opportunity now to take an important leadership role in assuring that the NIH budget is increased in fiscal year 2007. We urge your support to increase this critically important funding.

PREPARED STATEMENT OF THE ASSOCIATION OF INDEPENDENT RESEARCH INSTITUTES

The Association of Independent Research Institutes (AIRI) respectfully submits this written statement for the record of the U.S. Senate Appropriations Subcommittee on Labor, Health and Human Services, and Education. AIRI appreciates the commitment that the members of this Subcommittee have made to biomedical research through support for the National Institutes of Health (NIH).

AIRI is a national organization of 86 independent, not-for-profit research institutes that perform basic and clinical research in the biological and behavioral sciences in 28 States. Our member institutes are private, stand-alone research centers that set their sights on the vast frontiers of medical science. AIRI institutes—many of which were originally established by generous philanthropists or from spin-offs of unique university research areas—tend to be relatively small in size, with budgets ranging from a few million to hundreds of millions of dollars. In addition, each AIRI institution is governed by its own independent Board of Directors, which allows our members to be structurally nimble and capable of adjusting their research programs to emerging areas of inquiry. While the primary function of AIRI institutes is research, most are also strongly involved in training the next generation of biomedical researchers. In a testament to the quality of research and innovative ideas that AIRI institutes bring to the national biomedical enterprise—our institutions consistently exceed the success rates of the overall NIH grantee pool, and receive about 11 percent of NIH's peer reviewed, competitively awarded extramural grants.

The doubling of the NIH budget allowed the biomedical research community to accelerate solutions to human disease and disability. We have blazed new trails for medical research, diving into the intricacies of how the human body musters its defenses, and how those responses can be evaluated, enhanced, and modified. In addition, it helped us to realize new scientific management strategies such as fostering interdisciplinary research and creating new robust teams of scientists that, before the doubling, did not have scientific common ground. These research teams navigate the fast progressing research environment where there is an increasing need to integrate and aggregate basic research, computational capabilities, and clinical evidence into new cures more quickly. Further, the doubling has helped us to redefine health and healthcare goals based on scientific discoveries that were out of reach prior to the doubling. We now talk about disease and health care in terms of predictive, preventative and pre-emptive tactics.

With flexible structures that are friendly to change, AIRI institutes are able to move amongst the new science partnerships that will transform America's health and health care in the 21st century. NIH has responded to the rapidly changing world by strategically framing the next generation of biomedical research through cross-cutting, interdisciplinary initiatives such as those supported in the NIH Roadmap, the NIH Neuroscience Blueprint, the new Clinical and Translational Science Award program and the new Genes, Environment and Health Initiative. AIRI institutes are innovators poised to foster partnerships that will nurture the collaborative

environment necessary to successfully and efficiently conduct research within these evolving NIH frameworks.

AIRI endorses the fiscal year 2007 Ad Hoc Group for Medical Research proposal to increase the NIH budget by five percent over the fiscal year 2006 level. We recognize that the current budget environment puts pressure on Congress to face difficult funding trade-offs; however, as this subcommittee works to define priorities for the year and set goals for the future, AIRI asks that you maintain your long-term commitment of support for NIH and its mission. The President's fiscal year 2007 budget would flat-fund NIH. The 5 percent increase for NIH supported by AIRI would not only allow the agency to sustain current programs but also invest in critical new initiatives. This would prevent NIH from falling behind the "Innovation Index"—the rate of biomedical inflation as calculated in the Biomedical Research and Development Price Index (BRDPI) plus a modest investment in new initiatives.

Using the fiscal year 2007 BRDPI projection as a base, NIH would require an increase of at least 3.8 percent over fiscal year 2006. AIRI strongly believes that an increase for NIH above BRDPI is justified by the health needs as well as current and burgeoning research capabilities of the Nation. An increase above BRDPI would allow new innovative ideas to be funded and would infuse existing programs to evolve as their research findings push them to higher levels of basic understanding, translation and clinical functionality.

AIRI also hopes that the subcommittee will support programs and policies that foster a sustainable, biomedical research workforce. The biomedical research community is dependent upon a knowledgeable and skilled workforce to address current and future critical health research challenges. The cultivation and preservation of this workforce is dependent upon several factors, including the ability to: recruit scientists and students globally; train researchers both in basic and clinical biomedical research; focus on career development initiatives to recruit and retain researchers at critical stages; support new and young investigators; and maintain the NIH extramural investigator salary cap at Executive Level I. By again maintaining the NIH extramural investigator salary cap (the salary level that extramural researchers may apply toward their NIH grants) at Executive Level I in the fiscal year 2007 Appropriations bill, Congress will ensure that extramural investigators' salaries are competitive with the salary level for intramural researchers at NIH. As we work to enhance biomedical research capabilities, we should not impose barriers that would discourage talented people from committing to careers in research.

In addition, AIRI urges Congress to support NIH-funded equipment and infrastructure programs. As the investment in medical research and the national biomedical research agenda have expanded, the need for acquisition and modernization of laboratory equipment and infrastructure has become critical. NIH equipment grants meet the specific infrastructure needs of research institutions to maximize productivity of their research grants.

Medical research is a long-term process and, in order to meet the challenges of improving human health, we must not diminish our Federal commitment and investment. It is essential to sustain the momentum of NIH-funded research so that it continues to meet the goal of improving the health of all Americans. AIRI would like to thank the subcommittee for its important work to ensure the health of the Nation, and we appreciate this opportunity to present recommendations concerning the fiscal year 2007 Appropriations bill.

PREPARED STATEMENT OF THE ASSOCIATION OF WOMEN'S HEALTH, OBSTETRIC AND NEONATAL NURSES (AWHONN)

The Association of Women's Health, Obstetric and Neonatal Nurses (AWHONN) appreciates the opportunity to provide comment on the fiscal year 2007 appropriations for nursing education, research, and workforce development programs as well as programs designed to improve maternal and child health. AWHONN is a membership organization of 22,000 nurses, and it is our mission to promote the health and well-being of all women and newborns. AWHONN members are registered nurses, nurse practitioners, certified nurse-midwives, and clinical nurse specialists who work in hospitals, physicians' offices, universities, and community clinics throughout the United States.

HEALTH RESOURCES AND SERVICES ADMINISTRATION (HRSA)

AWHONN recommends a minimum of \$7.5 billion in funding for HRSA

AWHONN is deeply concerned by the President's budget request of a \$255 million cut in fiscal year 2007 to HRSA. Through its many programs and new initiatives, HRSA helps countless individuals live healthier, more productive lives. In this day

and age, rapid advances in research and technology promise unparalleled change in the Nation's health care delivery system. HRSA could be well positioned to meet these new challenges as it continues to provide for the Nation's most vulnerable citizens. In order to respond to these challenges, AWHONN asserts that HRSA will require an overall funding level of at least \$7.5 billion for fiscal year 2007.

TITLE VIII—NURSING WORKFORCE DEVELOPMENT PROGRAMS UNDER HRSA

AWHONN recommends a minimum of \$175 million in funding for Title VIII

Nursing workforce development programs are authorized under Title VIII of the Public Health Service Act. These programs are essential components of the American health care safety net, which brings critical services to our entire Nation. In addition, Title VIII programs are the only comprehensive Federal programs that provide annual funds for nursing education that help nursing schools and nursing students prepare to meet patient needs in a changing healthcare delivery system. These programs are also in institutions that train nurses for practice in medically underserved communities and Health Professional Shortage Areas. While the President's budget recommends level funding of Title VIII at \$150 million for fiscal year 2007, AWHONN supports a minimum of \$175 million in funding for Title VIII Nursing Workforce Development programs.

In 2002, Congress enacted the Nurse Reinvestment Act that provides funding for new and expanded programs such as scholarship and repayment programs like the Nurse Education Loan Repayment Program (NELRP), career ladders, internships and residencies, retention programs, and faculty loans designed to encourage students to consider nursing, keep nurses in the field, and ensure that nurse educators are plentiful enough to educate future nurses that we desperately need. These new programs received an initial appropriation of \$20 million in fiscal year 2003, which was in addition to \$93 million in funding provided for existing Title VIII programming. Unfortunately, due to limited funding in the first 2 years of the new authorization, the loan and scholarship programs have not been as successful as they could be in providing support to students in nursing schools. For example, NELRP is a competitive program that repays 60 percent of the qualifying loan balance of registered nurses selected for funding in exchange for 2 years of service at a critical shortage facility. In fiscal year 2005, HRSA made a total of 599 awards of this nature with an obligation of \$19 million. These loans are imperative for continuing to bring nurses into underserved communities in addition to bringing nurses through their education and training years.

Nurses are essential health care providers, and the nursing community seeks the support of this subcommittee for bolstering existing nursing programs and creating new ones for recruiting students into the nursing profession. In addition, AWHONN seeks development of qualified faculty members for educating new nurses, and we need to create career opportunities for retaining nurses as faculty. The entire nursing workforce needs strengthening. As a result, it will take long-term planning and innovative initiatives at the local, State, and Federal level to assure an adequate supply of a qualified nurse workforce for the Nation. Federal investment in nursing education and retention programs is critical for meeting the health care needs of our Nation.

Increased funding for Title VIII will make a positive impact on the nursing shortage

Recent data from the Bureau of Health Professions, Division of Nursing's National Sample Survey of Registered Nurses—February 2002, confirm that of the approximately 2.9 million registered nurses in the Nation only 82 percent of these nurses work full-time or part-time in nursing. A dominant factor in this shortage is the impending retirement of up to 40 percent of the workforce by 2010. This surge in retirement will occur at the same time as the surging baby boomer population retires, which will noticeably cause an increase in demand for health care services and the services of registered nurses. In addition, the U.S. Bureau of Labor and Statistics detailed in February 2004 that registered nurses will have the largest projected 10-year job growth in the United States, with about 1 million new job openings by 2010.

The shortage of registered nurses and the effect of this shortage on staffing levels, patient safety and quality care demands attention and a significant increase in funding to bolster and improve these programs. Nursing is the largest health profession, yet only one-fifth of one percent of Federal health funding is directed to nursing education. A significant increase in funding for these programs can help lay the groundwork for expanding the nursing workforce, through education and clinical training and retention programs.

Increased funding for Title VIII will help fill the nursing gap

The nursing shortage is not confined solely to care providers, and this demand for providers is hindered by the growing shortage of nursing faculties. Nursing faculty continues to decrease in number. According to a 2005 survey on faculty vacancies from the American Association College of Nursing, the number of full-time nursing faculty required to “fill the nursing gap” is approximately 40,000. Currently, there are less than 20,000 full-time nursing faculty in the system. In 2004, nursing schools turned away more than 32,000 qualified applicants to entry-level baccalaureate and graduate nursing programs due to insufficient faculty, clinical sites, classroom space, clinical preceptors, and budget constraints, including almost 3,000 students who could potentially fill faculty roles. When all nursing programs are considered, the number turned away during the 2003–2004 academic year grows to more than 125,000 qualified applicants. Without sufficient support for current nursing faculty and adequate incentives to encourage more nurses to become faculty, nursing schools will fail to have the teaching infrastructure necessary to educate and train our next generation of nurses that we so desperately need.

While the capacity to implement faculty development is currently available through Section 811 and Section 831, adequate funding and direction is needed to ensure that these programs are fully operational. Options to provide support for full-time doctoral study are essential to rapidly prepare the nurse educators of the future. AWHONN recommends that a portion of the funds be allocated for faculty development and mentoring.

Increase funding for Title VIII will encourage advance practice nursing.

AWHONN recognizes the importance of the investment in advanced practice nursing programs. As in other professions, the advanced degree has become a necessary achievement for career advancement, and registered nurses who pursue the MSN degree are part of the cadre of nurses who go on to become faculty. Our Nation needs more nurses with basic training to enter the field, but focusing only on these nurses addresses only half the problem. The nursing shortage encompasses nursing faculty; both advanced practice nursing and basic nursing must receive additional funding but not one at the expense of the other.

TITLE V—MATERNAL AND CHILD HEALTH BUREAU (MCHB) UNDER HRSA

AWHONN recommends \$850 million in funding for MCHB

The Maternal and Child Health Bureau incorporates valuable programs like the Traumatic Brain Injury program, Universal Newborn Hearing Screening, Emergency Medical Services for Children and Healthy Start, which were zeroed out, and the Maternal and Child Health Block Grant (MCH) that was level funded. These programs provide comprehensive, preventive care for mothers and young children, as well as an array of coordinated services for children with special needs. In fact, MCH serves over 80 percent of all infants in the United States, half of all pregnant women, and 20 percent of all children.

Restore Funding to the Universal Newborn Hearing Screening

The Children’s Health Act of 2000 authorized funding for grants and programs to improve State-based newborn screening. Newborn screening is a public health activity used for early identification of infants affected by certain genetic, metabolic, hormonal or functional conditions for which there are effective treatment or intervention. Screening detects disorders in newborns that, left untreated, can cause death, disability, mental retardation and other serious illnesses.

Screening programs coordinated through MCHB help to ensure that every baby born in the United States receives, at a minimum, a universal core group of screening tests regardless of the State in which he or she is born. However, the administration again proposes eliminating universal newborn screening programs. It goes without saying that more disorders will go unnoticed if the affected newborns are not screened. AWHONN encourages the subcommittee to restore funding to the fiscal year 2006 level plus inflation for the newborn hearing screening program.

NATIONAL INSTITUTES OF HEALTH (NIH)

AWHONN recommends \$29.75 billion in funding for the NIH

Multiple institutes housed under the National Institutes of Health (NIH) serve valuable roles in helping promote the importance of nursing in the health care industry along with the health and well-being of women and newborns. While AWHONN applauds the doubling of NIH’s budget over the years, the President’s Budget signals a level funding of NIH programs for fiscal year 2007. By allowing level funding, America will most certainly lose its edge in biomedical research.

NATIONAL INSTITUTE OF NURSING RESEARCH (NINR) UNDER NIH

AWHONN recommends \$160 million in funding for NINR

The National Institute of Nursing Research (NINR) engages in significant research affecting areas such as health disparities among ethnic groups, training opportunities for management of patient care and recovery, and telehealth interventions in rural/underserved populations. This research allows nurses to continually refine their practice and provide quality patient care.

For example, NINR research is invaluable in contributing to improved health outcomes for women. Recent public awareness campaigns target differences in the manifestation of cardiovascular disease between men and women. The differing symptoms are the source of many missed diagnostic opportunities among women suffering from the disease, which is the primary killer of American women. Because of the emphasis on biomedical research in this country, there are few sources of funds for high-quality behavioral research for nursing other than NINR. It is critical that we increase funding in this area in an effort to optimize patient outcomes and decrease the need for extended hospitalization. While the President's budget recommended level funding for NINR at \$137 million, AWHONN requests \$160 million for fiscal year 2007.

NATIONAL INSTITUTE OF CHILD HEALTH AND HUMAN DEVELOPMENT (NICHD) UNDER NIH

AWHONN recommends \$1.328 billion in funding for NICHD

The National Institute of Child Health and Human Development (NICHD) seeks to ensure that every baby is born healthy, that women suffer no adverse consequences from pregnancy, and that all children have the opportunity for a healthy and productive life unhampered by disease or disability. For example, with increased funding, NICHD could expand its use of the NICHD Maternal-Fetal Medicine Network to study ways to reduce the incidence of low birth weight. Prematurity/low birth weight is the second leading cause of infant mortality in the United States and the leading cause of death among African American infants. AWHONN, like many organizations directly involved in programs to improve the health of women and newborns, looks to NICHD to provide national initiatives, such as the Maternal-Fetal Medicine Network that assists with the care of pregnant women and babies.

NATIONAL INSTITUTE OF ENVIRONMENTAL HEALTH SCIENCES (NIEHS) UNDER NIH

AWHONN recommends \$680 million for NIEHS

Research conducted by the National Institute of Environmental Health Sciences (NIEHS) plays a critical role in what we know about the relationship between environmental exposures and the onset of diseases. Through the research sponsored by this Institute, we know that Parkinson's disease, breast cancer, birth defects, miscarriage, delayed or diminished cognitive function, infertility, asthma and many other diseases and ailments have confirmed environmental triggers. Our expanded knowledge, as a result, allows both policymakers and the general public to make important decisions about how to reduce toxin exposure and reduce the risk of disease and other negative health outcomes.

INDIAN HEALTH SERVICE (IHS) UNDER THE DEPARTMENT OF HEALTH AND HUMAN SERVICES (HHS)

AWHONN recommends \$5.54 billion in funding for IHS

The Indian Health Service (IHS) is the principal Federal health care provider and health advocate for the American Indian and Alaska Native populations. The President's budget recognizes this importance by requesting an increase to the IHS budget of \$124 million over the fiscal year 2006 level, bringing the total to \$4 billion for fiscal year 2007. While AWHONN applauds this increase, we recommend further increased funding for IHS to fully achieve its goals.

A recent study of Federal health care spending per capita found that the United States spends \$3,803 per year per Federal prisoner, while spending about half that amount for a Native American: \$1,914. Per capita health care spending for the U.S. general population is \$5,065 per year. A significant increase in funding over fiscal year 2006 spending levels is necessary for the Federal government to fulfill its responsibility to Indian Country and achieve its stated goals.

While the nursing shortage continues nationwide, IHS has been disproportionately affected by the lack of RNs. IHS nurses are older, with an average age of 48, and nearly 80 percent of RNs are over the age of 40. Further, the average vacancy rate for RNs is 14 percent. IHS administers three interrelated scholarship programs

designed to meet the health professional staffing needs of IHS and other health programs serving Indian people. These programs are severely under-funded. Targeted resources need to be invested in the IHS health professions programs in order to recruit and retain registered nurses in Indian Country.

CENTERS FOR DISEASE CONTROL AND PREVENTION (CDC) UNDER HHS

AWHONN recommends \$8.65 billion in funding for CDC

The President's budget request funds the CDC at \$8.2 billion for fiscal year 2007, a \$179 million decrease over fiscal year 2006. It is critically important to increase funding for CDC. For example, CDC has been deeply involved in the prevention of birth defects through programs like the Folic Acid Education Campaign and the National Center on Birth Defects and Developmental Disabilities (NCBDDD) for over 30 years. The public health impact of birth defects is tremendous. Of the four million babies born each year in the United States, approximately 120,000 are born with a serious birth defect. CDC funds several programs critical to reducing the number of children born with birth defects, including funding to States for birth defects tracking systems. Due to lack of funds, in fiscal year 2005 CDC was only able to fund 15 States, which were down from 28 States in fiscal year 2004. Additional funding for these grants is needed to fund all of the States seeking CDC assistance for these critical surveillance programs.

Overall, AWHONN urges the Subcommittee to at a minimum restore all cuts to programs from fiscal year 2006 and adjust for inflation. Funding the aforementioned agencies and their programs at this minimum level will at least allow them to effectively operate and achieve their stated mission. AWHONN thanks you for your time, and we greatly appreciate this opportunity submit testimony on these critical areas of funding.

PREPARED STATEMENT OF THE CHARLES R. DREW UNIVERSITY OF MEDICINE AND SCIENCE

SUMMARY OF RECOMMENDATIONS FOR FISCAL YEAR 2007

- Provide a 5 percent increase for fiscal year 2007 to the National Institutes of Health (NIH) and a proportional increase of 5 percent to the individual institutes and centers, specifically, the National Cancer Institute (NCI), the National Center for Research Resources (NCRR), and the National Center on Minority Health and Health Disparities (NCMHD).
- Continue to urge NCI to support the establishment of a collaborative minority health comprehensive research center at a historically minority institution in collaboration with the existing NCI Cancer Centers. Continue to urge NCRR and NCMHD to collaborate on the establishment of a minority health comprehensive research center.
- Urge the Department of Health and Human Service, particularly the Office of Minority Health (OMH), to support a Health Professions Leadership Development and Support Program at Charles R. Drew University of Medicine and Science.

Mr. Chairman and members of the subcommittee, thank you for the opportunity to present you with testimony. Charles R. Drew University of Medicine and Science is one of four predominantly minority medical schools in the country, and the only one located west of the Mississippi River. It is also one of the Hispanic serving institutions in California.

Charles R. Drew University of Medicine and Science is located in the Watts-section of South Central Los Angeles, and has a mission of rendering quality medical education to underrepresented minority students, and, through its affiliation with the University of California Los Angeles (UCLA) at the co-located King-Drew Medical Center, Drew provides valuable health care services to the medically underserved community. Through innovative basic science, clinical, and health services research programs, Charles R. Drew University works to address the health and social issues that strike hardest and deepest among inner city and minority populations.

The population of this medically underserved community is predominately African American and Hispanic. Many of these people would be without health care if not for the services provided by Charles R. Drew University of Medicine and Science. This record of service has led Charles R. Drew University (in partnership with UCLA School of Medicine) to be designated as a Health Resources and Services Administration Minority Center of Excellence.

RESEARCH: A RESPONSE TO HEALTH DISPARITIES

Racial and ethnic disparities in health outcomes for a multitude of major diseases in minority and underserved communities continue to plague this Nation that was built on a premise of equality. As articulated in the Institute of Medicine report entitled "Unequal Treatment: Confronting Racial and Ethnic Disparities in Health Care", this problem is not getting better on its own. For example, African American males develop cancer 15 percent more frequently than white males. Similarly, African American women are not as likely as white women to develop breast cancer, but are much more likely to die from the disease once it is detected. In fact, according to the American Cancer Society, those who are poor, lack health insurance, or otherwise have inadequate access to high-quality cancer care, typically experience high cancer incidence and mortality rates. Despite these devastating statistics, we still do not have the resources to try to combat cancer in our communities.

In response to these findings and the high cancer rate in our own community, Charles R. Drew University of Medicine and Science has been working to build a Life Sciences Research Facility on its campus. The Center would specialize in providing not only medical treatment services for the community, but would also serve as a research facility, focusing on prevention and the development of new strategies in the fight against cancer. These strategies will be disseminated locally and nationally to communities at risk, as well as to others engaged in comprehensive cancer prevention programs.

The Life Sciences Research Building will provide the additional laboratory and support space necessary for further progress and development of innovative research in the clinical, biological, and life sciences. The new, three story building will provide Drew with state-of-the-art, flexible, modern biomedical and bio-behavioral research space. The proposed structure will provide 40,000 gross square feet, which is a significant increase over existing facilities at the University. Current research activities will be enhanced by additional laboratory and support space. The facility will house the Life Sciences Institute, building upon Drew's demonstrated strengths in clinical research, health services research, and basic science research. The Life Sciences Research Building will allow researchers in the College of Medicine and in the College of Allied Health to capitalize on the explosion of knowledge in genetics and biology, epidemiology, and health care delivery while exploring the interface between health, social, and economic infrastructure, cultural attitudes, and legislative policy. The Institute will play a unifying role for the life sciences across the University by bringing researchers from a wide array of disciplines together under one roof to collaborate in forward-looking research aimed at improving the health and quality of life of medically underserved and low-income communities.

Mr. Chairman, the support that this subcommittee has given to the National Institutes of Health (NIH) and its various institutes and centers has and continues to be invaluable to our university and our community. The dream of a state-of-the-art facility to aid in the fight against cancer and other diseases in our underserved community would be impossible without the resources of NIH.

To help facilitate the establishment of the Life Sciences Research Building at Charles R. Drew University of Medicine and Science, the University is seeking support from the National Institutes of Health's National Center for Research Resources (NCRR), the National Center for Minority Health and Health Disparities (NCMHD), and the National Cancer Institute (NCI).

HEALTH PROFESSIONS LEADERSHIP DEVELOPMENT AND SUPPORT PROGRAM

A Health Professions Leadership Development & Support Program is designed to: (1) enhance faculty recruitment and retention support for academicians providing for the supervision, instruction, and guidance of resident physicians-in-training in underserved communities; and (2) provide financial stability for the Office of Graduate Medical Education (GME) to ensure the sustainability of this national priority area.

This is a critical program for improving the minority pipeline as outlined in the recent report by a committee chaired by former Secretary of DHHS, Dr. Louis Sullivan titled "Missing Persons: Minorities in the Health Professions September 20, 2004". This report highlights the critical role played by institutions such as Drew University as a major training site for minority health care professionals and biomedical scientists. Specifically, this program will help to support the Drew University Graduate Medical Education program.

The Program will be used by the University to augment and/or recruit physician leaders in Family Medicine, Pediatrics, Psychiatry, Surgery, Internal Medicine, and Obstetrics/Gynecology in response to the need to develop external, non-County residency rotations. The Surgery residency program was not renewed as of 2005, how-

ever, the University plans to reapply for a new program as part of its faculty recruitment plans. These actions coincide with the affiliated medical center's anticipated efforts to secure institutional approval from the Centers for Medicare and Medicaid Services (CMS) as well as the Joint Commission on the Accreditation of Healthcare Organizations (JCAHO).

CONCLUSION

Despite our knowledge about racial/ethnic, socio-cultural and gender-based disparities in health outcomes, the "gap" continues to widen in most instances. Not only are minority and underserved communities burdened by higher disease rates, they are less likely to have access to quality care upon diagnosis. As you are aware, in many minority and underserved communities preventive care and/or research is completely inaccessible either due to distance or lack of facilities and expertise. This is a critical loss of untapped potential in both physical and intellectual contributions to the entire society.

Even though institutions like Charles R. Drew are ideally situated (by location, population, and institutional commitment) for the study of conditions in which health disparities have been well documented, research is limited by the paucity of appropriate research facilities. With your help, the Life Sciences Research Facility will facilitate translation of insights gained through research into greater understanding of disparities.

We look forward to working with you to lessen the burden of health disparities and working with the Department of Health and Human Services to address the residency training program issues at Charles R. Drew University.

Mr. Chairman, thank you for the opportunity to present testimony on behalf of Charles R. Drew University of Medicine and Science.

PREPARED STATEMENT OF THE COOLEY'S ANEMIA FOUNDATION

SUBJECT

Mr. Somma's testimony thanks the subcommittee for the past support it has shown to the Cooley's Anemia Foundation and to the patients who are afflicted with this fatal genetic blood disease, also known as thalassemia. He urges the Committee to restore the funding cut in the President's budget from the Thalassemia Blood Safety Surveillance program at CDC. He discusses the importance of funding NIH research into this disease, particularly through NHLBI and NIDDK. He challenges the subcommittee to challenge the NIH to find the cure for thalassemia and, with it, for other similar diseases through a strong commitment to gene therapy. He urges continued support for the Thalassemia Clinical Research Network.

Mr. Chairman and Members of the Subcommittee: Thank you for the opportunity to present this testimony to the subcommittee today. My name is Frank Somma. I live in Holmdel, New Jersey and I am honored to serve as the National President of the Cooley's Anemia Foundation. I speak to you in my capacity as a volunteer. As many members of this subcommittee know, Cooley's anemia, or thalassemia, is a fatal genetic blood disease.

I could bog you down in a detailed scientific explanation of what happens physiologically when the human body cannot produce red blood cells in adequate numbers and of adequate quality to sustain life. I am not going to do that. The important thing for members of this subcommittee to remember about Cooley's anemia is that it is an incurable and fatal genetic blood disease. Period.

I also understand that I can present you with five pages of single-spaced testimony. I am not going to do that either. Instead, I am respectfully going to address the following three issues in a clear and succinct manner.

- The first is the immediate need to restore \$2.0 million to the CDC to fund the thalassemia blood safety surveillance network.
- The second issue is the equally critical need for this subcommittee to commit our government to the development of a focused gene therapy program that is designed to cure something.
- The third issue is the urgent need to restore funding to NIH to assure the continuation of desperately needed research at NIDDK and for the Thalassemia Clinical Research Network at NHLBI.

Blood Safety Surveillance

Mr. Chairman, when a baby is diagnosed with Cooley's anemia, or thalassemia major, the standard of treatment is to begin that child on blood transfusions. I want to be very clear here that the treatment is not to give the child a blood transfusion;

it is to begin a lifetime treatment regimen of such invasive and dangerous intervention. Our patients receive a blood transfusion every two weeks for the rest of their lives.

Because Cooley's anemia patients are transfused so regularly, they are the early warning system for problems in the blood supply. If there is an emerging infection or other problem with the blood supply, it is our patients that will get it first.

Please understand that nearly every patient over the age of 18 today who has thalassemia major also has HIV or hepatitis C as a result of their transfusions—or did have it while they were still alive.

Blood safety is a major national issue. Surgical and trauma patients often have no choice but to be transfused. And, it is done on an emergency basis many times. Nothing is more important to the patient at the time of transfusion than that they can be confident that the blood being pumped into their veins is free from infectious agents.

Utilizing the status of our patient population, the CDC has been monitoring the overall safety of the blood supply to this Nation and is prepared to issue an alert if a new virus or threat emerges. The blood safety surveillance program is currently operating very effectively through the Office of Hereditary Blood Diseases in the National Center for Birth Defects and Developmental Disability (NCBDDD) with about \$2.0 million in funding. Inexplicably, the President's budget eliminates the program, leaving the blood supply vulnerable to contamination by new viruses or mutated versions of old viruses, putting all Americans not just those with Cooley's Anemia at risk.

We are respectfully requesting that the subcommittee restore this funding to the \$2.0 million level that currently exists in order to continue to protect Americans from unnecessary infections and diseases that may occur in the blood supply.

Gene Therapy

Mr. Chairman, it has been a long time coming, but we are here to bring you some very good news about gene therapy. After a lot of false starts, we can now see a pathway for scientists to follow to help turn the promise of gene therapy into cures for single gene disorders. The problem to this point has not been one of science; it has been one of expectations. As a society, we forgot that science requires trial and error and that experiments are just that—experiments.

Today, gene therapy is advancing at a rapid pace in the rest of the world. Exciting work is being undertaken in Japan and China, in the UK and in France. Unfortunately, it is showing less progress in the United States of America . . . and that is not right. We are the international leaders in scientific research and, in a field like this—fraught with financial, scientific and ethical minefields—it is essential that America be the world leaders. We set the highest ethical and moral standards on every one of these issues. We protect human subjects best. It is simply too important to leave it to anyone else.

For persons with a single cell mutation disorder like thalassemia or sickle cell disease or severe combined immune deficiency (SCID), gene therapy holds out great promise for a cure. In fact, the CAF has recently launched the CURE Campaign: Citizens United for Research Excellence. The theme of the campaign is "It is Time to Cure Something." We are now learning so much about how to deliver healthy genes to unhealthy cells that we cannot turn back—nor can we as a Nation afford to let our friends in Europe and Asia race ahead of us in the areas of biomedical research and gene therapy.

We hope that this Congress—speaking through this subcommittee—will do what we have done and dare the NIH and its grantees to "cure something." You are investing nearly \$29 billion of taxpayer money in this agency that houses the "best and the brightest" and that funds "the best and the brightest." We as Americans must never stop striving to reach previously unimaginable heights. If that means that we have to shake up the status quo and create a new funding mechanism, let's do it. But let's not continue to follow the slow going incremental path of the past.

We need to spend our tax dollars in a coordinated and focused manner that will maximize the chances that we will unlock the secrets of how to correct single gene defects. We are very close now, with an experiment currently being conducted—in France—that may be a breakthrough. It is time for the United States to step up and lead the world in this life-saving area of research.

NIH and the Thalassemia Clinical Research Network

Mr. Chairman, about 5 years ago, working closely with members of this subcommittee, the CAF convinced the NHLBI of the need to create a clinical research network that would allow the top researchers in the field to collaborate on desperately needed research projects using common protocols. Today, that network is

up and running and is the focal point for thalassemia research, most of which takes place in academic medical centers throughout the country.

However, there is a cloud hanging over this, and all other, research at NIH. As the Biomedical Research and Development Price Index continues to escalate, the buying power of a flat-funded NIH continues to decrease. There would be nothing wrong with this if we had cured thalassemia, and hemophilia, and cystic fibrosis, and all other genetic and non-genetic diseases. But that is not the case.

There is an enormous amount of work to be done. And there is no one else to do it but our National Institutes of Health, with the support of our Congress and President.

I urge the subcommittee to settle for nothing less than a 5 percent increase in funding for NIH so that the critical life saving research that is occurring there can continue. Some of our fellow citizens don't have another year to wait.

CONCLUSION

As I indicated at the outset, Mr. Chairman, I am not interested in filling the air with words. Unfortunately, I don't have the luxury of time to do that. The Cooley's Anemia Foundation has three priorities this year:

- Funding the blood safety surveillance program at CDC at \$2.0 million;
- An enhanced focus on gene therapy designed to cure something; and,
- A five percent increase in NIH funding to continue current vital research programs.

Mr. Chairman, every night when I watch my beautiful, smart, talented 21 year old daughter Alicia put a needle under her skin to infuse a drug for 8–10 hours to remove the excess iron in her system from her bi-weekly blood transfusions, I know we can do better.

Please excuse my passion, but this is the United States of America. I know we can prevent this disease from happening in newborns. I know we can improve the lives of those who currently have it. And, most importantly, I am absolutely certain we can cure it once and for all.

You don't need five pages of testimony from me to do that. You just need to demand the very best from the very best—our scientists, our government, the patient advocacy community and ourselves.

Thank you for your very kind attention and for all the support this committee has shown to our patients and their families over the years.

PREPARED STATEMENT OF THE CROHN'S AND COLITIS FOUNDATION OF AMERICA

SUMMARY OF FISCAL YEAR 2007 RECOMMENDATIONS

(1) A 5 percent increase for the National Institute of Diabetes, and Digestive and Kidney Diseases, and the National Institute of Allergy and Infectious Diseases.

(2) \$700,000 for the National Inflammatory Bowel Disease Epidemiological Program at the Centers for Disease Control and Prevention.

Mr. Chairman, thank you for the opportunity to submit testimony on behalf of the Crohn's and Colitis Foundation of America (CCFA). We greatly appreciate your leadership and the opportunity to work with you to improve the quality of life for our patients and families.

My name is Kenneth Edmonds and I serve on the National Board of Trustees for the CCFA, the Nation's oldest and largest voluntary organization dedicated to finding a cure for and to seeking to prevent Crohn's disease and ulcerative colitis.

Through research, education and support, CCFA is committed to improving the quality of life of children and adults affected by these diseases, collectively known as inflammatory bowel disease (IBD). I am one of them.

IBD is a chronic disorder that causes inflammation of the digestive tract. It affects approximately 1.4 million Americans, 30 percent of whom are diagnosed in their childhood. IBD can cause persistent diarrhea, severe abdominal pain, fever, and, at times, rectal bleeding. If complications develop, it also can lead to, among other conditions, anemia, liver disease and colorectal cancer.

Indeed, inflammatory bowel disease can be painful and debilitating. And, its impact is perhaps most devastating for children and adolescents, whose diagnoses often make them stand out at a time when they most want to fit in. Their disease can make them not only feel different, but look different as some adolescents with IBD may have delays in physical growth and puberty, causing them to appear younger and smaller than their peers. But, at any age, being diagnosed with IBD can bring change and challenge.

The news of my diagnosis came not in one, sudden rush, but rather in a long, gradual backslide—and into a hospital bed. In retrospect, I exhibited typical signs of IBD as early as 1993 while a student in college. But, unfortunately, I responded to those signals like too many adolescents and young adults—I overlooked them.

At the time, I experienced acute abdominal pain so sharp and sudden that I would double over. These cramps often came without warning, creating an intense urge to use the nearest bathroom. On these occasions and others, my stools had traces of blood.

But, because I was young and active, I didn't think that much about it. And, I certainly didn't talk about it, to anyone. I chalked these brief episodes up to my regimen, rather than my abdomen. I figured that I just needed to add more greens to my diet and add more hours to my sleep.

But, by 1996, after moving to Chicago, my symptoms had become too persistent, too serious and too severe to ignore. By the summer of that year, I had developed sores or ulcers on my tongue, making it difficult and painful to eat. I lost appetite and lost weight.

In addition to the persistent diarrhea and acute cramps, I also had developed a tear (a fissure) in the lining of my anus, which caused excruciating pain and bleeding during bowel movements. I also suffered from severe exhaustion.

As you can imagine, this was an agonizing predicament: I was losing weight, but could not eat. I was fatigued, but could not sleep. I had frequent, sudden bowel movements, but they caused sharp, piercing pain. Indeed, I had deteriorated dramatically; my condition relegating me to somewhere between bedridden and bathroom-bound.

A misdiagnosis, three, long, withering weeks, and a plane ride later, I found myself in the Washington Hospital Center under the care of my uncle, a gastroenterologist here in the District. After a series of tests, x-rays and examinations, I was diagnosed with Crohn's colitis and prescribed medications for my symptoms. Since my hospitalization 10 years ago, I am pleased to report that the disease has been in remission and I have enjoyed relatively good health.

But, Mr. Chairman, IBD is a life-long disease. While there are drug therapies to treat symptoms, there is no medical cure. And, its cause is unknown.

That's why CCFA's work has been so critical and groundbreaking.

RECOMMENDATIONS FOR FISCAL YEAR 2007

(1) National Institutes of Health

In fact, CCFA has developed incredibly successful research partnerships with the NIH, forging longstanding collaborations with the National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK), which sponsors the majority of IBD research, and the National Institute of Allergy and Infectious Diseases (NIAID). CCFA provides crucial "seed-funding" to researchers, helping investigators gather preliminary findings, which in turn enables them to pursue advanced IBD research projects through the NIH. This approach led to the identification of the first gene associated with Crohn's—a landmark breakthrough in understanding this disease.

Mr. Chairman, CCFA's scientific leaders, with significant involvement from NIDDK, have developed an ambitious research agenda, titled "Challenges in Inflammatory Bowel Disease" that outlines and seeks to address the many opportunities that currently exist. Fortunately, the field of IBD is widely viewed within the scientific community as one of tremendous potential. To help capitalize on these opportunities, CCFA recommends that the subcommittee provide a 5 percent increase in funding for NIDDK and NIAID in fiscal year 2007. Moreover, CCFA requests that the subcommittee encourage these two institutes to expand their IBD research portfolios at a similar rate.

(2) Centers for Disease Control and Prevention

IBD Epidemiology Program

Mr. Chairman, CCFA estimates that 1.4 million people in the United States suffer from IBD, but there could be many more. We do not have an exact number due to these diseases' complexity and the difficulty in identifying them.

We are extremely grateful for your leadership in providing funding over the past 2 years for an epidemiology program on IBD at the Centers for Disease Control and Prevention. This program is yielding valuable information about the prevalence of IBD in the United States and increasing our knowledge of the demographic characteristics of the IBD patient population. If we are able to generate an accurate analysis of the geographic makeup of the IBD patient population, it will provide us with invaluable clues about the potential causes of IBD.

Unfortunately Mr. Chairman, the President has eliminated funding for this important program in his fiscal year 2007 budget for the CDC. CCFa encourages the subcommittee to restore support for the IBD Epidemiology Program at last year's level of \$700,000.

Once again Mr. Chairman, thank you for the opportunity to submit written testimony

PREPARED STATEMENT OF THE DIGESTIVE DISEASE NATIONAL COALITION

SUMMARY OF FISCAL YEAR 2007 RECOMMENDATIONS

- Provide increased funding for the National Institutes of Health (NIH) at an increase of 5 percent over fiscal year 2006. Increase funding for the National Cancer Institute (NCI), the National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK) and the National Institute of Allergy and Infectious Diseases (NIAID) by 5 percent.
- Continue focus on digestive disease research and education at NIH, including the areas of Inflammatory Bowel Disease (IBD), Hepatitis and other liver diseases, Irritable Bowel Syndrome (IBS), Colorectal Cancer, Endoscopic Research, Pancreatic Cancer, Celiac Disease, and Hemochromatosis.
- \$30 million for the Centers for Disease Control and Prevention's (CDC) Hepatitis Prevention and Control activities.
- \$25 million for the Center for Disease Control and Prevention's (CDC) Colorectal Cancer Screening and Prevention Program.

Chairman Specter, thank you for the opportunity to again submit testimony to the subcommittee. Founded in 1978, the Digestive Disease National Coalition (DDNC) is a voluntary health organization comprised of 23 professional societies and patient organizations concerned with the many diseases of the digestive tract. The Coalition has as its goal a desire to improve the health and the quality of life of the millions of Americans suffering from both acute and chronic digestive diseases.

The DDNC promotes a strong Federal investment in digestive disease research, patient care, disease prevention, and public awareness. The DDNC is a broad coalition of groups representing disorders such as Inflammatory Bowel Disease (IBD), Hepatitis and other liver diseases, Irritable Bowel Syndrome (IBS), Pancreatic Cancer, Ulcers, Pediatric and Adult Gastroesophageal Reflux Disease, Colorectal Cancer, Celiac Disease, and Hemochromatosis.

Mr. Chairman, the social and economic impact of digestive disease is enormous and difficult to grasp. Digestive disorders afflict approximately 65 million Americans. This results in 50 million visits to physicians, over 10 million hospitalizations, collectively 230 million days of restricted activity. The total cost associated with digestive diseases has been conservatively estimated at \$60 billion a year.

The DDNC would like to thank the subcommittee for its past support of digestive disease research and prevention programs at the National Institutes of Health (NIH) and the Centers for Disease Control and Prevention (CDC). With respect to the coming fiscal year, the DDNC is recommending an increase of 5 percent to \$30.1 billion for the National Institutes of Health (NIH) and all of its Institutes.

Specifically the DDNC recommends

- \$5.35 billion for the National Cancer Institute (NCI).
- \$2 billion for the National Institute of Diabetes and Digestive and Kidney Disease (NIDDK).
- \$4.89 billion for the National Institute of Allergy and Infectious Diseases (NIAID).

We at the DDNC respectfully request that any increase for NIH does not come at the expense of other Public Health Service agencies.

With the competing and the challenging budgetary constraints the subcommittee currently operates under, the DDNC would like to highlight the research being accomplished by NIDDK which warrants the increase for NIH.

INFLAMMATORY BOWEL DISEASE

In the United States today about 1 million people suffer from Crohn's disease and ulcerative colitis, collectively known as Inflammatory Bowel Disease (IBD). These are serious diseases that affect the gastrointestinal tract causing bleeding, diarrhea, abdominal pain, and fever. Complications arising from IBD can include anemia, ulcers of the skin, eye disease, colon cancer, liver disease, arthritis, and osteoporosis. Crohn's disease and ulcerative colitis are not usually fatal but can be devastating.

The cause of IBD is still unknown, but research has led to great breakthroughs in therapy.

In recent years researchers have made significant progress in the fight against IBD. In 1998, the FDA approved the first drug ever specifically to fight Crohn's disease, a remarkable milestone. The DDNC encourages the subcommittee to continue its support of IBD research at NIDDK and NIAID at a level commensurate with the overall increase for each institute. The DDNC would like to applaud the NIDDK for its strong commitment to IBD research through the Inflammatory Bowel Disease Genetics Research Consortium. The DDNC urges the Consortium to continue its work in IBD research. Given the recent advancements in treatment for these diseases and the increased risk that IBD patients have for developing colorectal cancer, the DDNC strongly believes that generating improved epidemiological information on the IBD population is essential if we are to provide patients with the best possible care. Therefore the DDNC and its member organization the Crohn's and Colitis Foundation of America encourage the CDC to initiate a nationwide IBD surveillance and epidemiological program in fiscal year 2007.

HEPATITIS C: A LOOMING THREAT TO HEALTH

It is estimated that there are over 4 million Americans who have been infected with Hepatitis C of which over 2.7 million remain chronically infected. About 10,000 die each year and the Centers for Disease Control and Prevention (CDC) estimates that the death rate will more than triple by 2010 unless there is additional research, education, and more effective treatments and public health interventions. Hepatitis C infection is the largest single cause for liver transplantation and one of the principal causes of liver cancer and cirrhosis. There is currently no vaccine for hepatitis C, and treatment has limited success, making the infection among the most costly diseases in terms of health care costs, lost wages, and reduced productivity. Patients who are older at the time of infection, those who continually ingest alcohol, and those co-infected with HIV demonstrate accelerated progression to more advanced liver disease.

The DDNC applauds all the work NIH and CDC have accomplished over the past year in the areas of hepatitis and liver disease. The DDNC urges that funding be focused on expanding the capability of State health departments, particularly to enhance resources available to the hepatitis C State coordinators. The DDNC also urges that CDC increase the number of cooperative agreements with coalition partners to develop and distribute health education, communication, and training materials about prevention, diagnosis and medical management for hepatitis A, B, and C.

The DDNC supports \$30 million for the CDC's Hepatitis Prevention and Control activities. The hepatitis division at CDC supports the hepatitis C prevention strategy and other cooperative nationwide activities aimed at prevention and awareness of hepatitis A, B, and C. The DDNC also urges the CDC's leadership and support for the National Viral Hepatitis Roundtable to establish a comprehensive approach among all stakeholders for viral hepatitis prevention, education, strategic coordination, and advocacy.

COLORECTAL CANCER PREVENTION

Colorectal cancer is the third most commonly diagnosed cancer for both men and woman in the United States and the second leading cause of cancer-related deaths. Colorectal cancer affects men and women equally. According to the American Cancer Society, this year alone about 135,400 individuals will be diagnosed with colorectal cancer, and of those diagnosed 56,700 patients will die. Although colorectal cancer is preventable and curable when polyps are detected early, a General Accounting Office report issued in March 2000 documented that less than 10 percent of Medicare beneficiaries have been screened for colorectal cancer. This report revealed a tremendous need to inform the public about the availability of screening and educate health care providers about colorectal cancer screening guidelines. In 2003, the New York City Department of Health has recommended colonoscopy for everyone over age 50 to prevent colorectal cancer.

The DDNC recommends a funding level of \$25 million for the CDC's Colorectal Cancer Screening and Prevention Program. This important program supports enhanced colorectal screening and public awareness activities throughout the United States. The DDNC also supports the continued development of the CDC-supported National Colorectal Cancer Roundtable, which provides a forum among organizations concerned with colorectal cancer to develop and implement consistent prevention, screening, and awareness strategies.

PANCREATIC CANCER

In 2006, an estimated 33,730 people in the United States will be found to have pancreatic cancer and approximately 32,300 will die from the disease. Pancreatic cancer is the fifth leading cause of cancer death in men and women. Only 1 out of 4 patients will live 1 year after the cancer is found and only 1 out of 25 will survive 5 or more years. Although we do not know exactly what causes pancreatic cancer, several risk factors linked to the disease have been identified:

- (1) Age: Most people are over 60 years old when the cancer is found;
- (2) Sex: Men have pancreatic cancer more often than women;
- (3) Race: African Americans are more likely to develop pancreatic cancer than are white or Asian Americans;
- (4) Smoking;
- (5) Diet: Increased red meats and fats; and
- (6) Diabetes.

The National Cancer Institute (NCI) has established a Pancreatic Cancer Progress Review Group charged with developing a detailed research agenda for the disease. The DDNC encourages the subcommittee to provide an increase for pancreatic cancer research at a level commensurate with the overall percentage increase for NCI and NIDDK.

IRRITABLE BOWEL SYNDROME (IBS)

IBS is a disorder that affects an estimated 35 million Americans. The medical community has been slow in recognizing IBS as a legitimate disease and the burden of illness associated with it. Patients often see several doctors before they are given an accurate diagnosis. Once a diagnosis of IBS is made, medical treatment is limited because the medical community still does not understand the pathophysiology of the underlying conditions.

Living with IBS is a challenge, patients face a life of learning to manage a chronic illness that is accompanied by pain and unrelenting gastrointestinal symptoms. Trying to learn how to manage the symptoms is not easy. There is a loss of spontaneity when symptoms may intrude at any time. IBS is an unpredictable disease. A patient can wake up in the morning feeling fine and within a short time encounter abdominal cramping to the point of being doubled over in pain and unable to function.

The unpredictable bowel symptoms may make it next to impossible to leave your home. It is difficult to ease the pain that may repeatedly occur periodically throughout the day. A patient can become reluctant to eat for fear that just eating a meal will trigger symptoms all over again. IBS has a broad and significant impact on a person's quality of life. It strikes individuals from all walks of life and results in a significant toll of human suffering and disability.

While there is much we don't understand about the causes and treatment of IBS, we do know that IBS is a chronic complex of systems affecting as many as one in five adults. In addition:

- (1) It is reported more by women than men;
- (2) It is the most common gastrointestinal diagnosis among gastroenterology practices in the United States;
- (3) It is a leading cause of worker absenteeism in the United States; and
- (4) It costs the U.S. Health Care System an estimated \$8 billion annually.

Mr. Chairman, much more can still be done to address the needs of the nearly 35 million Americans suffering from irritable bowel syndrome and other functional gastrointestinal disorders. The DDNC recommends that NIDDK increase its research portfolio on Functional Gastrointestinal Disorders and Motility Disorders.

GASTROPARESIS

Gastroparesis, or paralysis of the stomach, refers to a stomach that empties slowly. Gastroparesis is characterized by symptoms from the delayed emptying of food, namely: bloating, nausea, vomiting or feeling full after eating only a small amount of food. Gastroparesis can occur as a result of several conditions; it can occur in up to 30 percent to 50 percent of patients with diabetes mellitus. A person with diabetic gastroparesis may have episodes of high and low blood sugar levels due to the unpredictable emptying of food from the stomach, leading to diabetic complications. Other causes of gastroparesis include Parkinson's disease and some medications, especially narcotic pain medications. In many patients a cause of the gastroparesis cannot be found and the disorder is termed idiopathic gastroparesis. Over the last several years, as more is being found out about gastroparesis, it has become clear this condition affects many people and the condition can cause a wide range of symptoms of differing severity.

CELIAC DISEASE

Celiac Disease is a life-long condition in which the body develops an allergy to gluten, a protein found in wheat, barley, and rye, which can result in damage to the small intestine. Celiac disease affects as many as 2 million Americans. Onset of the disease can occur at any age. The common symptoms of Celiac Disease include fatigue, anemia, chronic diarrhea or constipation, weight loss, and bone pain. The only treatment for celiac disease is strict adherence to a gluten-free diet. Undiagnosed and untreated celiac disease can lead to other disorders such as osteoporosis, infertility, neurological conditions, and in rare cases cancer. Persons with Celiac Disease often have other associated autoimmune disorders as well.

DIGESTIVE DISEASE COMMISSION

In 1976, Congress enacted Public Law 94-562, which created a National Commission on Digestive Diseases. The Commission was charged with assessing the State of digestive diseases in the United States, identifying areas in which improvement in the management of digestive diseases can be accomplished and to create a long-range plan to recommend resources to effectively deal with such diseases. The Commission's subsequent report in 1979 laid the groundwork for significant progress in the area of digestive disease research. After almost 25 years, however, the burden of digestive diseases among the U.S. population remains substantial.

The DDNC recognizes the creation of the National Commission on Digestive Diseases, and looks forward to working with the National Commission to address the numerous digestive disorders that remain in today's diverse population.

CONCLUSION

The DDNC understands the challenging budgetary constraints and times we live in that this subcommittee is operating under, yet we hope you will carefully consider the tremendous benefits to be gained by supporting a strong research and education program at NIH and CDC. Millions of Americans are pinning their hopes for a better life, or even life itself, on digestive disease research conducted through the National Institutes of Health.

Mr. Chairman, on behalf of the millions of digestive disease sufferers, we appreciate your consideration of the views of the Digestive Disease National Coalition. We look forward to working with you and your staff.

DIGESTIVE DISEASE NATIONAL COALITION

The Digestive Disease National Coalition was founded 25 years ago. Since its inception, the goals of the coalition have remained the same: to work cooperatively to improve access to and the quality of digestive disease health care in order to promote the best possible medical outcome and quality of life for current and future patients with digestive diseases.

PREPARED STATEMENT OF THE DORIS DAY ANIMAL LEAGUE

The Doris Day Animal League represents 350,000 members and supporters nationwide who support a strong commitment by the Federal Government to research, development, standardization, validation and acceptance of non-animal and other alternative test methods. We are also submitting our testimony on behalf of the Humane Society of the United States and The Procter & Gamble Company. Thank you for the opportunity to present testimony relevant for the fiscal year 2007 budget request for the National Institute of Environmental Health Sciences (NIEHS) for the fiscal year 2007 activities of the National Toxicology Program Center for the Evaluation of Alternative Toxicological Test Methods (NICEATM), the support center for the Interagency Coordinating Committee for the Validation of Alternative Test Methods (ICCVAM).

In 2000, the passage of the ICCVAM Authorization Act into Public Law 106-545, created a new paradigm for the field of toxicology. It requires Federal regulatory agencies to ensure that new and revised animal and alternative test methods be scientifically validated prior to recommending or requiring use by industry. An internationally agreed upon definition of validation is supported by the 15 Federal regulatory and research agencies that compose the ICCVAM, including the EPA. The definition is: "the process by which the reliability and relevance of a procedure are established for a specific use."

FUNCTION OF THE ICCVAM

The ICCVAM performs an invaluable function for regulatory agencies, industry, public health and animal protection organizations by assessing the validation of new, revised and alternative toxicological test methods that have interagency application. After appropriate independent peer review of the test method, the ICCVAM recommends the test to the Federal regulatory agencies that regulate the particular endpoint the test measures. In turn, the Federal agencies maintain their authority to incorporate the validated test methods as appropriate for the agencies' regulatory mandates. This streamlined approach to assessment of validation of new, revised and alternative test methods has reduced the regulator burden of individual agencies, provided a "one-stop shop" for industry, animal protection, public health and environmental advocates for consideration of methods and set uniform criteria for what constitutes a validated test methods. In addition, from the perspective of animal protection advocates, ICCVAM can serve to appropriately assess test methods that can refine, reduce and replace the use of animals in toxicological testing. This function will provide credibility to the argument that scientifically validated alternative test methods, which refine, reduce or replace animals, should be expeditiously integrated into Federal toxicological regulations, requirements and recommendations.

HISTORY OF THE ICCVAM

The ICCVAM is currently composed of representatives from the relevant Federal regulatory and research agencies. It was created from an initial mandate in the NIH Revitalization Act of 1993 for NIEHS to "(a) establish criteria for the validation and regulatory acceptance of alternative testing methods, and (b) recommend a process through which scientifically validated alternative methods can be accepted for regulatory use." In 1994, NIEHS established the ad hoc ICCVAM to write a report that would recommend criteria and processes for validation and regulatory acceptance of toxicological testing methods that would be useful to Federal agencies and the scientific community. Through a series of public meetings, interested stakeholders and agency representatives from all 14 regulatory and research agencies, developed the NIH Publication No. 97-3981, "Validation and Regulatory Acceptance of Toxicological Test Methods." This report, and subsequent revisions, has become the sound science guide for consideration of new, revised and alternative test methods by the Federal agencies and interested stakeholders.

After publication of the report, the ad hoc ICCVAM moved to standing status under the NIEHS' NICEATM. Representatives from Federal regulatory and research agencies and their programs have continued to meet, with advice from the NICEATM's Advisory Committee and independent peer review committees, to assess the validation of new, revised and alternative toxicological methods. Since then, several methods have undergone rigorous assessment and are deemed scientifically valid and acceptable. In addition, the ICCVAM is working to streamline assessment of methods from the European Union (EU) that have already been validated for use within the EU. The open public comment process, input by interested stakeholders and the continued commitment by the Federal agencies has led to ICCVAM's success. It has resulted in a more coordinated review process for rigorous scientific assessment of the validation of new, revised and alternative test methods.

REQUEST FOR APPROPRIATIONS

On December 19, 2000, the "ICCVAM Authorization Act" which makes the entity a permanent standing committee, was signed into Public Law No. 106-545. For several years, the NIEHS has provided financial resources to the NICEATM for ICCVAM's activities. In order to ensure that Federal regulatory agencies and their stakeholders benefit from the work of the ICCVAM, it is important for NIEHS to provide funding at an appropriate level. We respectfully request a fiscal year funding level of \$4 million.

REQUEST FOR COMMITTEE REPORT LANGUAGE

The NIEHS should support the NICEATM/ICCVAM in creating a five-year road-map for assertively setting goals to prioritize ending the use of antiquated animal tests for specific endpoints. While the stream of methods forwarded to the ICCVAM for assessment has remained relatively steady, it is imperative that the ICCVAM take a more proactive role in isolating areas where new methods development is on the verge of replacing animal tests. These areas should form a collective call by the Federal agencies that compose ICCVAM to fund any necessary additional research, development, validation and validation assessment that is required to eliminate the

animal methods. We also strongly urge the NICEATM/ICCVAM to closely coordinate research, development and validation efforts with its European counterpart, the European Centre for the Validation of Alternative Methods (ECVAM) to ensure the best use of available funds and sound science. This coordination should also reflect a willingness by the Federal agencies comprising ICCVAM to more readily accept validated test methods proposed by the ECVAM to ensure industry has a uniform approach to worldwide chemical safety evaluation.

We also respectfully request the subcommittee consider the following report language for the Senate Labor, Health and Human Services, Education and Related Agencies Appropriations bill:

“The Committee commends the National Interagency Center for the Evaluation of Alternative Methods/Interagency Coordinating Committee on the Validation of Alternative Methods (NICEATM/ICCVAM) for its leadership role in the assessment of new, revised and alternative scientifically validated methods for the Federal government. The Committee also commends the National Toxicology Program (NTP) for finalizing its ‘Roadmap to Achieve the NTP Vision, A Toxicology Program for the 21st Century’, which commits to ‘develop and validate improved testing methods and, where feasible, ensure that they reduce, refine or replace the use of animals’ as one of its top four goals.

“The Committee directs the NICEATM/ICCVAM, in partnership with the relevant Federal agency program offices and the NTP, to build on the NTP Roadmap to create a 5-year plan to research, develop, translate and validate new and revised non-animal and other alternative assays for integration of relevant and reliable methods into the Federal agency testing programs. In this 5-year plan the Federal agency program offices shall be directed to identify areas of high priority for new and revised non-animal and alternative assays or batteries of those assays to create a path forward for the replacement, reduction and refinement of animal tests, when this is scientifically valid and appropriate. The Committee directs a transparent, public process for developing this plan and recommends the plan be presented to the Committee by November 15, 2007. Funding for developing the plan shall be from the NIEHS and the NTP, and shall not reduce the NICEATM/ICCVAM funding base.”

PREPARED STATEMENT OF THE DYSTONIA MEDICAL RESEARCH FOUNDATION

SUMMARY OF FISCAL YEAR 2007 RECOMMENDATIONS

- Provide increased funding for the National Institute of Health at an increase of 5 percent over fiscal year 2006. Increase funding for the National Institute of Neurological Disorders and Stroke (NINDS), the National Institute of Deafness and other Communication Disorders (NIDCD), and the National Eye Institute (NEI) by 5 percent.
- Fiscal Year 2007 Recommendations for NIH
 - NIH: \$30 billion
 - NINDS: \$1.61 billion
 - NEI: \$700.4 million
 - NIDCD: \$412.7 million
- Continue to accelerate funding for intramural and extramural dystonia research at NINDS.
- Continue to expand NIDCD’s intramural and extramural research on dysphonia.
- Continue to expand NEI’s intramural and extramural research on dystonia.

Chairman Specter, thank you for the opportunity to submit testimony to the subcommittee on behalf of the Dystonia Medical Research Foundation (DMRF). Dystonia has affected the lives of many Americans and we are thankful to be able to provide for you our recommendations for fiscal year 2007 Federal funding with regards to dystonia research.

Dystonia is a neurological disorder characterized by powerful and painful involuntary muscle spasms that causes the body to twist, repetitive jerking movements, and sustained postural deformities. There are several different variations of dystonia, including: focal dystonias which affect specific parts of the body, such as the arms, legs, neck, jaw, eyes, vocal cords; and generalized dystonia, affecting many parts of the body at the same time. Some forms of dystonia are genetic and others are caused by injury or illness. Dystonia does not affect a person’s consciousness or intellect, but is a chronic and progressive movement disorder for which, at this time, there is no known cure. The Foundation estimates that some form of dystonia affects about 300,000 people in North America.

Even though there is no known cure for dystonia, there are treatments to lessen the severity of the symptoms of the disease such as oral medications, botulinum toxin injections, and in some cases surgery. Having increased access to these medical therapies is becoming an increasing larger issue for the community as a whole.

In the past few decades, dystonia researchers have made several exciting scientific advancements and have been able to rapidly turn laboratory and clinical research into diagnostic examinations and treatment procedures, directly benefiting those affected. Genetics, in particular, is opening up a new understanding into the cause and pathophysiology of the disorder. Thus far, 13 dystonia related genes or gene loci have been identified. In 1997, the DYT1 gene for childhood early onset dystonia was identified, and we now have a genetic test available to confirm diagnosis of this particular type of dystonia. Most recently, in 2002, the gene for myoclonus dystonia was identified. However the community is still without a diagnostic test and misdiagnosis still occurs too frequently.

Deep brain stimulation is a surgical procedure that was originally developed to treat Parkinson's disease but is now being applied to severe cases of dystonia. Deep brain stimulation has drastically improved the lives of dozens of dystonia patients during the past few years. Individuals who were previously bedridden by muscle spasms and pain are able to walk without assistance, to speak clearly, to dress themselves, to get a driver's license, to date, to travel, and to live the life of an able-bodied person. Deep brain stimulation is currently used primarily to treat severe cases of generalized dystonia but its promising role in treating focal dystonias is being explored. Surgical interventions are a crucial and active area of dystonia research.

RESEARCH, AWARENESS, AND SUPPORT

Now is an exciting time to be involved in dystonia research and awareness. Researchers are becoming more interested in movement disorders and dystonia at the National Institutes of Health (NIH), and research is yielding promising clues for better understanding and management of this disorder.

One way the Dystonia Medical Research Foundation has advocated for more research on dystonia, is by funding "seed" grants to researchers. Thus far the Dystonia Foundation has funded over 415 grants and fellowships totaling more than \$21 million. Due to our advocacy there are a growing number of talented researchers dedicated to understanding the biochemistry of dystonia, genetic causes, new therapeutics and the necessity of an epidemiology study.

Another primary goal of the Dystonia Foundation is education of both lay and medical audiences. The Foundation conducts regular medical workshops and patient symposiums to present, discuss, and disseminate comprehensive medical and research data on dystonia. In January 2001, NINDS co-sponsored a genetics and animal models meeting, designed to involve not only prominent researchers but inviting junior investigators to participate in the discussions. In September, 2005 NIH funded a workshop on "Rehabilitation in Dystonia" at which leading experts from neurosurgeons and neurologists to physical therapists, psychologists, and biomedical engineers argued for more aggressive research and the use of new concepts and tools in the treatment of dystonia and in 2006 NIH is funding a science workshop on the dystonia protein torsinA/Nuclear envelope. On June 6 & 7 a NINDS Research Agenda Workshop will take place.

The Young Investigators Award Program and the Residency Program are in place to entice emerging medical professionals into the field of dystonia research and cultivate future dystonia experts.

Since 1995, over 10,000 educational medical videos have been distributed to hospitals, medical and nursing schools, and at medical conventions. In addition to medical and coping publications, we have a children's video to educate families and increase public awareness of this devastating disorder in younger populations. Media awareness is conducted throughout the year, and especially during Dystonia Awareness Week, observed nationwide from June 4 through 11. Local volunteers have been successful in securing news stories on dystonia in local venues as well as national media shows such as Good Morning America, The Oprah Winfrey Show, and Maury Povich. Through his friendship with the mother of a dystonia patient, screen star Kirk Cameron has taken an interest in promoting dystonia awareness, and the Dystonia Foundation is in the process of investigating the possibility of a public service announcement and several appearances at fundraising events. In the Fall of 2006 the new dystonia documentary entitled TWISTED will be premiered on PBS.

The Dystonia Foundation has over 100 chapters, support groups, and area contacts across North America. In addition, there are chairpersons whose mission is to

promote awareness, children's advocacy, development, extension, Internet resources, leadership, medical education, and symposiums. Furthermore, patient symposiums are held internationally and regionally to provide the latest medical and coping information to dystonia patients and others interested in the disorder.

DYSTONIA AND THE NATIONAL INSTITUTES OF HEALTH

The Dystonia Medical Research Foundation recommends an increase to \$31.6 billion or 5 percent for NIH overall, and a 5 percent increase for NINDS, and NIDCD. We at DMRF request that this increase for NIH does not come at the expense of other Public Health Service agencies.

We also urge the subcommittee to recommend that NINDS provide the necessary funding for additional extramural research. There is also an imperative need for NINDS to increase its efforts to educate the public and medical community about dystonia through co-sponsorship of workshops and seminars. We also encourage the subcommittee to support NIDCD in its efforts to revamp its strategic planning process by implementing a Strategic Planning Group which will help NIDCD as they: consider applications for high program priority; develop program announcements and requests for applications; and develop new research areas in the Intramural Research Program.

The National Institute of Neurological Disorders and Stroke (NINDS) awarded eleven grants for dystonia research in response to the Program Announcement, "Studies into the Causes and Mechanisms of Dystonia" (August 2002). These awards covered a wide range of research areas, which included gene discovery, the genetics and genomics of dystonia, the development of animal models of primary and secondary dystonia, molecular and cellular studies inherited forms of dystonia, epidemiology studies, and brain imaging. In addition, the National Institute on Deafness and Other Communication Disorders (NIDCD) funded an eighth study on brainstem systems and their role in spasmodic dysphonia.

DMRF also supports the many intramural researchers studying dystonia. Research includes: exploring improved clinical rating scales for dystonia, elevations of sensory motor training, utilizing Botox as a possible treatment for focal hand dystonia, characterization of abnormalities in sensory regions of the brain, treatments for spasmodic dysphonia, deep brain stimulation (the direct electrical stimulation of specific brain targets), non-invasive transcranial brain stimulation, anatomy imaging of the affect of dystonia on brain activity, and exploring the link between laryngitis and spasmodic dysphonia. The public awareness impact of pianist Leon Fleisher's treatment through the NIH intramural research program has had a tremendously positive impact.

NINDS continues to work with dystonia research and voluntary disease groups in the community. In June 2005, NINDS sponsored a workshop on spasmodic dysphonia, which was held at the NIH and was supported by the NINDS and the NIH Office of Rare Diseases. NIH staff are currently drafting a white paper on the results of the meeting and future research opportunities for improving the diagnosis, understanding the pathogenesis, developing new treatments, and preventing spasmodic dysphonia. Another NINDS laboratory is investigating several neurodegenerative disorders, including a form of hereditary dystonia known as the Mohr-Tranebjaerg deafness-dystonia syndrome. This form of dystonia is inherited through the X chromosome. The NINDS laboratory is investigating how abnormalities in a specific protein lead to the death of affected cells.

Dystonia is the third most common movement disorder after Parkinson's Disease and tremor, and affects many times more people than better known disorders such as Huntington's Disease, muscular dystrophy and ALS or Lou Gehrig's Disease. We ask that NINDS fund dystonia-specific extramural research at the same level that it supports research for other neurological movement disorders.

CONCLUSION

The ultimate goal of the Dystonia Foundation is a cure for dystonia. Until that goal is realized, we are hungry for knowledge about the nature of dystonia and for more effective treatments with fewer side effects. We have amassed many exceptional and diligent researchers; who are committed to our goal, and our top priority is funding their very important research. But the Foundation cannot do it alone. We need Federal support through NIH to continue to fund quality scientific research and eliminate this debilitating disease.

Combine the thwarting of scientific progress with the decreased access to therapies and all the progress of the last few years could be wiped away. We ask that you aggressively support medical research, specifically for movement disorders and

brain research. By doing so, you are doing a tremendous service for my family and myself and to the hundreds of thousands of people and families affected by dystonia. Thank you very much.

PREPARED STATEMENT OF THE FSH SOCIETY

Chairman Specter, Senator Harkin and members of the subcommittee, I am Daniel Perez, President & CEO of the FSH Society. The FSH Society is a non-profit volunteer health agency organized by patients for patients with facioscapulohumeral muscular dystrophy (FSHD). Our purpose is to be a resource for individuals and families with FSH muscular dystrophy (FSHD), represent them and advocate on their behalf. On behalf of the FSH Society and its members, thank you for this opportunity to testify.

FSHD is the third most prevalent form of muscle disease and the second most prevalent adult muscular dystrophy. It affects 1/20,000 people. For men, women, and children the major consequence of inheriting FSHD is a lifelong progressive and severe loss of all skeletal muscles. The FSH Society was created because of a need for a comprehensive resource for FSHD individuals and families. A world leader in combating muscular dystrophy it has provided well over a million dollars in seed grants to pioneering researchers worldwide and created an international collaborative network of patients and researchers. The Society relies entirely on private grants, donations and philanthropy. Since our establishment in 1991, our major focus has been to help facilitate Federal research agencies such as the National Institutes of Health (NIH) grow funding and programs for FSHD research. The Society has submitted 28 written and five oral testimonies to Senate and House Appropriations Subcommittees on Labor, Health, Human Services and Education on the need for more NIH funding on FSHD.

The NIH often applauds the effort and dedication of the Society in expanding research efforts in FSHD and bringing additional attention to this dystrophy. We commend the Director of the NIH, Dr. Elias Zerhouni, for the significant efforts made by his agency in muscular dystrophy. Between 1987 and 2005, the overall NIH funding for dystrophy increased from \$4.6 million to \$39.3 million. Since 2000, the FSHD budget has increased from \$400,000 to \$2.1 million (fiscal year 2006 estimated). We applaud Dr. Stephen I. Katz, Director, National Institute of Arthritis and Musculoskeletal Disorders (NIAMS) and Chairman of the Muscular Dystrophy Coordinating Committee (MDCC), and John D. Porter, Program Director Muscular Dystrophy, National Institute of Neurological Disorders and Stroke (NINDS) and Executive Secretary MDCC, for their extraordinary comprehension, accuracy and for the speed in which the NIH Action Plan for Muscular Dystrophy was researched, compiled, written, and approved. The NIH is making significant investments to understand muscular dystrophy research needs and has made excellent choices in recruiting program staff with the ability to understand the extremely complex nature of muscular dystrophy. However, to this day, the NIH reports difficulty in growing and expanding its FSH muscular dystrophy research portfolio and in receiving sufficient numbers of investigator-submitted applications of high quality.

THE MD-CARE ACT, PUBLIC LAW 107-84

Congress enacted The Muscular Dystrophy Community Assistance, Research and Education Amendments of 2001 (the MD-CARE Act, Public Law 107-84) that was signed into law on December 18, 2001. Both the Senate and House acted with force and clarity to mandate the NIH and other applicable Federal agencies, to immediately expand and intensify research on all forms of muscular dystrophy. The MD-CARE Act declared that: (1) the Director of the NIH work with the Directors of NIAMS, NINDS and NIH National Institute of Child Health and Human Development (NICHD) to expand and intensify research on all nine types of dystrophy described in the Act; (2) Centers of excellence for research should be established for all nine types of dystrophy; (3) a MDCC with two-thirds government and one-third public members be established to coordinate activities across NIH and other national research agencies on all forms of dystrophy; and; (4) the MDCC to submit a research action plan for conducting, and supporting research and education for all nine types of dystrophy. The MD-CARE Act also requires annual updates on research funding amounts by the Department of Health and Human Services (DHHS) for Duchenne, Myotonic, FSHD and other muscular dystrophies.

In August 2004, the MDCC submitted an initial report for the NIH Muscular Dystrophy Research and Education Plan to Congress which was put through a more intensive planning process that involved external scientific experts in the field of mus-

cular dystrophy and muscle disease. This detailed version of the MDCC "Action Plan for the Muscular Dystrophies" was submitted to Congress in December 2005.

FSHD is prominently and well represented in the five sections of the NIH "Action Plan for the Muscular Dystrophies." Three key sections for FSHD research are: Mechanisms Section, Research Objective 3, "Define the molecular pathogenetic mechanisms that lead to facioscapulohumeral muscular dystrophy"; Mechanisms Section, Research Objective 4, "Establish mouse (and cellular) models for facioscapulohumeral muscular dystrophy, specific to emerging candidate genes and/or disease genomics, to understand the epigenetic mechanisms and for the development of novel intervention strategies"; and, the Infrastructure Section, Research Objective 13, "Stimulate international collaborations and infrastructure sharing to ensure that opportunities are exploited and resources are used to maximum advantage, particularly in cases of novel opportunity or for the rare and/or understudied muscular dystrophies." The full description and text of research objective three in the mechanisms section illustrates that the NIH fully comprehends what needs to be done to achieve progress in FSHD.¹

It is absolutely clear that muscular dystrophy is a high priority for the NIH and it understands the research that needs be developed, funded and contracted. However, the dystrophies such as FSHD with complex etiology, low prevalence or that present unique scientific opportunity are getting far less funding than they deserve. FSHD is clearly deficient in projects and funding caused by it being a complicated disease with complex etiology that requires mastery to review grants or to undertake research. In the dystrophy area, the NIH believes that insight gained from studying a specific type of dystrophy will provide benefit for all of the muscular dystrophies. Sadly, that is not the case for FSHD.

NIH EFFORTS ON FSH MUSCULAR DYSTROPHY (2000-PRESENT)

NIH has supported several initiatives in recent years in dystrophy research and training. In response to the fiscal year 2000 report language, the NINDS, NIAMS and the NIH Office of Rare Diseases (ORD) held a research symposium in May 2000, in Bethesda, on the cause and treatment of FSH muscular dystrophy. The international team of researchers and NIH staff assembled research recommendations and directions that called for enhancing the understanding of the mechanism and molecular process associated with FSHD, strategies for exploring potential treatments and therapies, strategies to promote establishment of biomaterials registries and longitudinal and population based studies of FSHD, and a listing of required infrastructure and research resources.

The findings of the conference on FSHD were used to create NIH solicitations. One request focused on exploratory and high risk research applications on FSH muscular dystrophy, and several other announcements were made for grant applications on therapeutic and pathogenic approaches for muscular dystrophy in which FSHD was mentioned.

In September 2000, the NINDS and NIAMS issued a contract to establish and fund a National Registry for Myotonic and FSH Muscular Dystrophy based at the University of Rochester. Patients join the registry voluntarily by providing medical and family history data. The registry brings together FSHD patients and families seeking to participate in research with researchers seeking patients for research on the disorder.

¹NIH Action Plan for the Muscular Dystrophies, Mechanisms Section, Research Objective 3: "Define the molecular pathogenetic mechanisms that lead to facioscapulohumeral muscular dystrophy," December 2005.

"Defining the molecular mechanisms by which a reduction in repeats at the D4Z4 translates into the multi-system symptoms seen in facioscapulohumeral muscular dystrophy has been difficult. Elucidation of the function of the allelic variants (A and B) at D4Z4 may help advance understanding of disease mechanisms. If perturbations of chromatin structure and/or derepression of gene expression ultimately figure into pathogenesis, there are some other diseases that could help inform researchers in this field. A potentially important avenue of research is the analysis of the chromatin structure at the D4Z4 locus, including methylation and/or binding of specific repressors or activators. Such chromatin conformational changes have been suggested as a possible disease mechanism, presumably affecting the regulation of expression of other genes. Since the issue of altered regulation of genes in the vicinity of D4Z4 remains controversial, there is a need for careful studies using microarrays or other techniques, to determine if genes near the D4Z4 repeat units on chromosome 4q, or at more distant locations on this chromosome, are up-regulated or down-regulated in facioscapulohumeral muscular dystrophy. The expression and function of the D4Z4 gene, DUX4, should be analyzed. The association of 4qter with the nuclear lamina and the potential role of this association upon gene expression profiles should be explored. Genetic causes for facioscapulohumeral muscular dystrophy, other than the D4Z4 contraction (such as non-chromosome 4 linked cases), should be investigated in available patients."

Several program announcements were issued to promote large scale clinical and translational research in muscular dystrophy, as called for in the MD-CARE Act, called the Senator Paul D. Wellstone Muscular Dystrophy Research Centers. One of these centers, at the University of Rochester, focuses on myotonic and FSH muscular dystrophy. One-quarter of this Wellstone MD CRC center focuses on the molecular pathology of FSHD and serves as a resource for cell lines, tissue biopsies, antibodies and data about gene expression. This Wellstone MD CRC core at Rochester is the only funding specific for FSHD in the six Wellstone MD CRCs.

The MD-CARE Act provides that the Wellstone MD CRC centers are not to replace funding and projects in existing basic research portfolios. In addition to building national infrastructure for dystrophy research, the NIH is expanding research resources for FSHD by funding several basic research grants related to understanding the mechanism and pathology of FSH muscular dystrophy.

One of these grantees, Rossella Tupler, supported by the FSH Society, helped bring about a momentous breakthrough in FSHD research. The prestigious scientific journal Nature made an advance online publication of "Facioscapulohumeral muscular dystrophy in mice over-expressing FRG1", by Davide Gabellini and Rossella Tupler, et al., on December 11, 2005. The Nature paper is a breakthrough on multiple levels, it: (1) creates an animal model for FSHD; (2) points to a gene, called FRG1, that causes FSHD; (3) identifies other genetic processes impacted by FRG1 over-expression involved in other major adult dystrophies; (4) shows that both the FRG1 gene and mis-expressed pre-mRNA intermediary products can be targeted and regulated by new and novel gene therapy techniques to correct expression levels; and (5) gives FSHD the hard target needed in order have better success in securing major funding from large agencies. They have demonstrated that transcriptional modulation of a gene from the region can produce an interesting, potentially relevant phenotype. This model can now be used to create conditional variants and ultimately move on to look for transcriptional suppressors of the phenotype.

The NINDS, NIAMS and NICHD support career development and training awards for muscle biology and neuroscience through three program announcements for domestic and foreign investigators to help create a cadre of new scientists and researchers working on muscular dystrophy. The NINDS, NIAMS program officers in dystrophy are working diligently trying to help extramural researchers submit the highest quality applications.

The NIH assisted Dr. Melanie Ehrlich of Tulane University, who was displaced by hurricane Katrina by offering a position in the NIAMS intramural research laboratory of Dr. Kuan Wang and granting supplemental relief funds to salvage her FSHD research.

NIH MUSCULAR DYSTROPHY FUNDING

However, in the 6 years since the MD-CARE Act was signed the NIH (NIAMS, NINDS, NICHD, NHGRI) funding for FSHD remains very small. Since 2000, the overall NIH wide muscular dystrophy budget has increased from \$12.6 million to \$39.0 million in fiscal year 2007 estimated. Since 2000, the FSHD budget has increased from \$400,000 to \$2.1 million in fiscal year 2007 estimated. In the past year, at least five basic research grant applications (R01s) were submitted on FSHD and none were chosen for funding! Though the international field of FSHD researcher is small, the researchers are absolutely top-rate, world class and certainly competitive with other NIH grant applicants. Five applications represents about 25-30 percent of the entire field of FSHD researchers with the standing and experience to submit a basic research grant. A significant amount of FSHD researchers are submitting grant applications!

NATIONAL INSTITUTES OF HEALTH (NIH) APPROPRIATIONS HISTORY

[Dollars in millions]

Fiscal year	NIH overall	MD research	MD percent of NIH	FSHD research	FSHD percent of MD	FSHD percent of NIH
2000	\$17,821	\$12.60	0.071	\$0.40	3.18	0.0022
2001	20,458	21.00	0.103	0.50	2.38	0.0024
2002	23,296	27.60	0.118	1.30	4.71	0.0056
2003	27,067	39.10	0.144	1.50	3.83	0.0055
2004	27,887	38.70	0.139	2.20	5.67	0.0079
2005	28,494	39.50	0.139	2.00	5.06	0.0070
2006	28,428	39.3E	0.138	2.1E	5.31	0.0074

NATIONAL INSTITUTES OF HEALTH (NIH) APPROPRIATIONS HISTORY—Continued

[Dollars in millions]

Fiscal year	NIH overall	MD research	MD percent of NIH	FSHD research	FSHD percent of MD	FSHD percent of NIH
2007E	28,428	39.0E	0.137	2.1E	5.38	0.0074

Source: NIH/OD Budget Office & NIH OCPL.

NIAMS has one research contract for FSHD, the National Registry for Myotonic and FSH muscular dystrophy for \$295,888 (fiscal year 2005). Its total muscular dystrophy portfolio for fiscal year 2005 was 57 projects, including two Wellstone MD CRC components for a total of \$17,136,343. FSHD was only 1.7 percent of NIAMS fiscal year 2005 muscular dystrophy funding.

NINDS reports three research grants, one intramural grant, one research contract, and one-quarter of a Wellstone CRC for FSHD for a total of \$1,359,930 in fiscal year 2005. The total muscular dystrophy fiscal year 2005 portfolio reported for fiscal year 2005 was 33 projects, including two Wellstone CRCs for a total of \$11,987,219. FSHD was only 11.4 percent of NINDS fiscal year 2005 muscular dystrophy funding.

NICHD reports that approximately ten percent of its \$4,762,321 fiscal year muscular dystrophy portfolio has some broad or general application to FSHD, but does not identify specific projects. The NICHD reports that \$400,000 was spent on FSHD. The total muscular dystrophy fiscal year 2005 portfolio reported was 17 projects, including three Wellstone MD CRC components for a total of \$4,762,321. FSHD was only 8.4 percent of NICHD fiscal year 2005 dystrophy funding.

The NIAMS, NINDS, NICHD, and NHGRI—the four lead institutes on muscular dystrophy—reported a combined total of 108 projects on muscular dystrophy totaling \$34,285,883 in fiscal year 2005. Of that total amount facioscapulohumeral muscular dystrophy (FSHD) received \$1,440,555 in directly titled funds for three grants, one contract and one-quarter of a Wellstone MD CRC.

The NIH now has six Wellstone MD CRCs, which are approximately equivalent to 27 basic research grants (R01). One-quarter of one Wellstone, or one R01 equivalent, has direct relevance to FSHD. Only 3.7 percent of the total Wellstone MD CRC expenditure is being spent on the second most prevalent adult muscular dystrophy or the third most prevalent form of muscular dystrophy affecting men, women and children.

REQUEST

Mr. Chairman and Members of the Committee, we request an appropriation of \$10 million–\$12.5 million to accomplish the FSH muscular dystrophy research plan as outlined by the NIH and submitted to the Congress. As a start, simply examining the scope of the work outlined in the NIH Action Plan for Muscular Dystrophy “Mechanisms Section, Research Objective 3: Define the molecular pathogenetic mechanisms that lead to FSH muscular dystrophy,” illustrates a requirement of at least 12 to 15 basic research grants (R01s) and/or high risk innovative research grants (R21s) that require \$5 million–\$6 million to adequately fund them.

We also request that the umbrella area of muscular dystrophy receive an appropriation commensurate with similar disease areas, and we request equity by starting with a doubling of the current \$39 million to \$80 million to adequately fund the NIH research plan for dystrophy. NIH Disease Funding, Special Areas of Interest table shows that similar umbrella areas of health burden, scope, and impact such as Multiple Sclerosis (\$109 million), Motor Neuron Disease (\$57 million), Cystic Fibrosis (\$89 million), Parkinson’s (\$223 million), and Huntington’s (\$48 million) receiving average funding levels of \$105 million. Muscular dystrophy affects hundreds of thousands of individuals, including family and friends.

We understand that the NIH overall budget went down in fiscal year 2006 to \$28,428M from \$28,494M and that Congress is strapped with other priorities. Chairman Specter, thank you for the constant and consistent support of biomedical research and for the NIH programs that offer hope for millions of sick and dying people. Mr. Chairman, members of the committee and members of Congress, the opportunities for FSHD research are greater than ever. The past year brought with it several major breakthroughs and discoveries and we are on the cusp of understanding FSHD and a never before seen class of disease. Now that we have a very refined plan of attack and research direction by the NIH, the need for funding is even greater. FSHD research needs to continue unabated and we remind you that there is no treatment or therapy for this devastating and crippling disease.

We ask the subcommittee to appropriate in fiscal year 2007 \$12.5 million for FSH Muscular Dystrophy and \$80 million for Muscular Dystrophy either as new money towards the overall NIH budget or as a requested allocation/re-allocation of resources internally within the NIH, to support the NIH stated plan of action to work on dystrophy. We thank the subcommittee for this opportunity to present our views.

PREPARED STATEMENT OF THE FOSTER GRANDPARENT PROGRAM

Mr. Chairman and members of the subcommittee, thank you for the opportunity to submit this testimony in support of fiscal year 2007 funding for the Foster Grandparent Program (FGP), the oldest and largest of the three programs known collectively as the National Senior Volunteer Corps, which are authorized by Title II of the Domestic Volunteer Service Act (DVSA) of 1973, as amended and administered by the Corporation for National and Community Service (CNS). NAFGPD is a membership-supported professional organization whose roster includes the majority of more than 350 directors, who administer Foster Grandparent Programs nationwide, as well as local sponsoring agencies and others who value and support the work of FGP.

Mr. Chairman, I would like to begin by thanking you and the distinguished members of the subcommittee for your steadfast support of the Foster Grandparent Program. No matter what the circumstances, this subcommittee has always been there to protect the integrity and mission of our programs. Our volunteers and the children they serve across the country are the beneficiaries of your commitment to FGP, and for that we thank you. I also want to acknowledge your outstanding staff for their tireless work and very difficult job they have to “make the numbers fit.”—an increasingly difficult task in this budget environment.

NAFGPD remains concerned that the Corporation’s fiscal year 2007 request does not provide any new funding where it is needed most—in the field. All of us recognize the spending constraints placed on the President and, most importantly on you and the Appropriations Committee. However, in a time of such scarce Federal resources, NAFGPD believes strongly that any new funding should flow to our programs in the field where it is most urgently needed, not CNCS headquarters.

This fiscal year 2007 budget request follows fiscal year 2006 in which FGP experienced a nearly \$500,000 funding cut. The last time FGPs in the field realized any increases at all to cover the increased costs of doing business—especially in the area of transportation costs—was in fiscal year 2005; that increase amounted to a very small .84 percent, when inflationary price increases have been averaging 2–3 percent every year. FGP programs continue to face considerable stress in covering the rising costs of administering programs and maintaining program quality.

NAFGPD respectfully requests two things of the subcommittee:

(1) To provide \$115.929 million for the Foster Grandparent Program in fiscal year 2007, an increase of \$4.992 million over the fiscal year 2006 level. This critical funding will ensure the continued viability of the Foster Grandparent Program, and allow for important expansion of this unique program. Specifically, this proposal would fund a 3 percent cost of living increase for every Foster Grandparent Program and expansion grants to existing programs that would add 370 new low-income senior volunteers to serve children;

(2) To maintain current appropriations statutory language that prohibits CNCS from using funds in the bill to pay non-taxable stipend to volunteers whose incomes exceed 125 percent of the national poverty level. In its budget narrative, CNCS has again requested that this language be eliminated because it stifles innovation. In fact, CNCS has the ability to test any innovations they wish through demonstration activities—they just cannot pay a non-taxable stipend to volunteers whose incomes exceed 125 percent of the national poverty level. Congress has repeatedly over the last six years disavowed this practice and re-affirmed that the non-taxable stipend must be reserved for low-income volunteers. We ask that you again protect the mission of the Foster Grandparent and Senior Companion Programs—to enable low-income older people—to serve their communities by maintaining this important statutory language.

FGP: AN OVERVIEW

Established in 1965, the Foster Grandparent Program was the first federally funded, organized program to engage older volunteers in significant service to others. From the 20 original programs based totally in institutions for children with severe mental and physical disabilities, FGP now comprises nearly 350 programs in every State and the District of Columbia, Puerto Rico, and the Virgin Islands. These programs are now primarily in community-based child caring agencies or organiza-

tions—where most special needs children can be found today—and are administered locally through a non-profit organization or agency and Advisory Council comprised of community citizens dedicated to FGP and its mission. FGP represents the best in the Federal partnership with local communities, with Federal dollars flowing directly to local sponsoring agencies, which in turn determine how the funds are used. Through this partnership and the flexibility of the program, FGP is able to meet the immediate needs of the local communities. This was demonstrated by Foster Grandparent Programs in communities that were impacted by the influx of Hurricane Katrina evacuees. Foster Grandparents rallied to provide services to children in shelters, child care centers, and schools.

There are currently 38,700 Foster Grandparent volunteers who give over 36 million hours annually to more than 277,000 children. The Foster Grandparent Program is unique for several reasons. The program is one of only two volunteer programs in existence that enable seniors living on very limited incomes to serve their communities as volunteers by providing a small non-taxable stipend and other support which allow volunteers to serve at little or no cost to themselves. FGP volunteers provide intensive, consistent service—15 to 40 hours every week, usually four hours every day. FGP provides intensive pre-service orientation and at least 48 hours of ongoing training every year to keep volunteers current and informed on how to work with children who have special needs. And our volunteers provide one-to-one service to their assigned children, exactly what is required to help prepare our Nation's neediest children to become self-sufficient adults.

FGP: THE VOLUNTEERS

The Foster Grandparent Program is a versatile, dynamic, and uniquely multi-purpose program. First, the program gives Americans 60 years of age or older who are living on incomes at or less than 125 percent of the poverty level the opportunity to serve 15 to 40 hours every week and use the talents, skills and wisdom they have accumulated over a lifetime to give back to the communities which nurtured them throughout their lives. Seniors in general are not valued or respected in today's society, and low-income seniors are particularly devalued because of their economic status. They are rarely asked by their communities to contribute through volunteering, because they are not traditionally those who participate in community activities.

FGP actively seeks out these low-income seniors. We dare to ask them to serve, to give something back. And we help them to develop the additional skills they may need to function effectively in settings unfamiliar to them, like public schools, hospitals, childcare centers, and juvenile detention facilities. We also provide them with ongoing training and support throughout their tenure as Foster Grandparents. Through their service, our older volunteers say they feel and stay healthier, that they feel needed and productive. Most importantly, they leave to the next generation a legacy of skills, perspective and knowledge that has been learned the hard way—through experience.

Within budgetary constraints, FGP is engaging older people who are not usually asked to serve and those usually considered as needing services rather than being able to serve: 86 percent are 65 or older and 45 percent come from various ethnic groups.

FGP: THE CHILDREN

Through our volunteers, the Foster Grandparent Program also provides person-to-person service to children and youth under the age of 21 who have special or exceptional needs, many of whom face serious, often life-threatening challenges. With the changing dynamics in family life today, many children with disabilities and special needs lack a consistent, stable adult role model in their lives. The Foster Grandparent is very often the only person in a child's life who is there every day, who accepts the child, encourages him no matter how many mistakes the child makes, and focuses on the child's successes.

Special needs of children served by Foster Grandparents include AIDS or addiction to crack or other drugs; abuse or neglect; physical, mental, or learning disabilities; speech, or other sensory disabilities; incarceration and terminal illness. Of the children served, 7 percent are abused or neglected, 26 percent have learning disabilities, and 11 percent have developmental delays. FGP focuses its resources in areas where they will have the most impact: early intervention services and literacy activities. Nationally, 85 percent of the children served by Foster Grandparents are under the age of 12, with 39 percent of these children age 5 or under. Foster Grandparents work intensively with these very young children to address their problems at as early an age as possible, before they enter school. Nearly one-half of FGP vol-

unteers serve nearly 12 million hours annually addressing literacy and emergent-literacy problems with special needs children.

Activities of the FGP volunteers with their assigned children include teaching parenting skills to teen parents; providing physical and emotional support to babies abandoned in hospitals; helping children with developmental, speech, or physical disabilities develop self-help skills; reinforcing reading and mathematics skills; and giving guidance and serving as mentors to incarcerated or other youth.

FGP: THE VOLUNTEER SITES

The Foster Grandparent Program provides child-caring agencies and organizations offering services to special-needs children with a consistent, reliable, invaluable extra pair of hands 15 to 40 hours every week to assist in providing these services. Seventy-one percent of FGP volunteers serve in public and private schools as well as sites that provide early childhood pre-literacy services to very young children, including Head Start.

FGP: COST-EFFECTIVE SERVICE

The Foster Grandparent Program serves local communities in a high quality, efficient and cost-effective manner, saving local communities money by helping our older volunteers stay independent and healthy and out of expensive in-home or institutional care. Using the Independent Sector's 2003 valuation for one hour of volunteer service (\$17.19/hour), the value of the service given by Foster Grandparents annually is over \$618 million, and represents a 5-fold return on the Federal dollars invested in FGP. The annual Federal cost for one Foster Grandparent is \$3,800—less than \$4 per hour.

The value local communities place on FGP and its multifaceted services is evidenced by the large amount of cash and in-kind donations contributed by communities to support FGP. For example, FGP's fiscal year 2001 Federal allocation was matched with \$40 million in non-Federal donations from States and local communities in which Foster Grandparents volunteer. This represents a non-Federal match of 42 percent, or \$.42 for every \$1 in Federal funds invested—well over the 10 percent local match required by law.

NAFGPD'S FISCAL YEAR 2007 BUDGET REQUEST

Given the dramatically expanding number of low-income seniors eligible to serve and the staggering number of troubled and challenged children in America today, we respectfully request that the subcommittee provide \$115.929 million for the Foster Grandparent Program in fiscal year 2007, an increase of \$4.992 million over fiscal year 2006. This critical funding will ensure the continued viability of the Foster Grandparent program, and allow for an expansion of this important program.

The requested increase would be allocated for the following purposes, in order of priority:

1. in accordance with the Domestic Volunteer Service Act (DVSA), designate one-third of the increase over the fiscal year 2006 level to fund Program of National Significance (PNS) expansion grants to allow existing FGP programs to expand the number of volunteers serving in areas of critical need as identified by Congress in the DVSA. This expansion of FGP was overwhelmingly supported and endorsed by White House Conference in Aging delegates at the recent 2005 Conference convened by the President.

2. use all remaining funds to award an administrative cost increase of at least 3 percent to each existing Foster Grandparent Program in order to maintain quality, enable recruitment and sustain the work already being done by programs.

This funding proposal will generate opportunities for approximately 370 new low-income senior volunteers to contribute 390,000 hours of service annually to nearly 2,000 additional children with special needs through PNS grants to existing FGPs.

We request that no funds be provided for Senior Demonstration. Language in the Corporation for National and Community Service's Budget Justification indicate that any demonstration funds awarded will again be used for programming that allows the payment of a stipend to individuals whose incomes exceed 125 percent of the national poverty level. In recognition of the fact that this practice has nothing to do with the true spirit of volunteerism, Congress has expressly prohibited this practice for the last 6 years in appropriations language; we request that this important language be maintained to protect the purpose of FGP and SCP: to enable low-income elders to serve their communities.

The message is clear: (1) the population of low-income seniors available to volunteer 15 to 40 hours every week is increasing; (2) communities need and want more Foster Grandparent volunteers and more Foster Grandparent Programs. The sub-

committee's continued investment in FGP now will pay off in savings realized later, as more seniors stay healthy and independent through volunteer service, as communities save tax dollars, and as children with special needs are helped to become contributing members of society.

Mr. Chairman, in closing I would like to again thank you for the subcommittee's support and leadership for FGP over the years. NAFGPD takes great comfort in knowing you and your colleagues in Congress appreciate what our low-income senior volunteers accomplish every day in communities across the country.

PREPARED STATEMENT OF FRIENDS OF THE NATIONAL INSTITUTE ON AGING

Chairman Specter and members of the subcommittee, thank you for this opportunity to testify in support of increasing funding within the National Institutes of Health (NIH), and in particular within the National Institute on Aging (NIA).

The Friends of the NIA is a relatively new coalition comprised of some 50 organizations from academia and the non-profit community. All of the groups comprising the Friends of the NIA conduct, fund or advocate for scientific efforts to improve the health and quality of life for Americans as they grow older. All of our groups support the continuation and expansion of biomedical, behavioral, and social science research within the NIA. The Friends of the NIA seeks to raise awareness about aging research and the important scientific progress supported and guided by the NIA. Our testimony not only addresses recent research advances funded by the NIA, but also points to missed opportunities if there is not growth in the NIA appropriation from Congress in fiscal year 2007.

The NIA is dedicated to conducting biomedical, behavioral, and social science research in order to prevent disease and other problems of the aged, and to maintain the health and independence of older Americans. This research is all the more urgent because of the explosive growth of the older population in the United States. This year, the first wave of our largest generation—some 77 million members of the postwar Baby Boom generation—began turning aging 60. Currently there are some 36 million Americans aged 65 and older. That population is expected to double in size within the next 25 years, at which time nearly 20 percent of the American population will be older than age 65 and eligible for old age assistance for health care under the Federal Medicare program (Federal Interagency Forum on Aging-Related Statistics 2004, Older Americans). Of particular interest is the dramatic growth that is anticipated among those most at risk for disease and disability, people age 85 and over whose numbers are expected to grow from 4.3 million in 2000 to at least 19.4 million in 2050 (65+ in the United States: 2005, U.S. Census, 2006).

This growing population presents many social and economic challenges as increasing numbers of Americans reach retirement age. This rapidly expanding population, many of whom will have multiple medical needs, will require substantial changes in health care delivery. Aging itself is not the cause of disease, disability, and frailty, but these conditions are influenced by age-related changes, lifestyle choices and rising risk factors. We also know that outside influences, such as economic, physical, environmental, and caregiving stresses increase vulnerability to disease, especially amongst the elderly. NIA has a broad research portfolio and is the only Institute that studies the normal changes associated with aging as well as pathological conditions from an interdisciplinary perspective. Understanding when and how changes occur as we age provides important clues for developing interventions that will prevent and treat diseases, and improve quality of life.

In addition to participating in NIH-wide initiatives, NIA has made and supported many significant contributions of its own to the biomedical and psycho-social understanding of the aging processes and, through ongoing clinical trials, to the testing of promising interventions for the detection, treatment and prevention of many age-related conditions.

The NIA is the lead Federal research agency for Alzheimer's disease (AD). AD is the most common cause of dementia and a serious threat to the Nation's health and economic well-being. Today, an estimated 4.5 million Americans, 1 in 10 persons over age 65 and nearly one-half of those over 85, suffer from this debilitating disease. That toll is projected to increase to 5.1 million people by 2010 and 16 million by 2050 (Hebert et al. 2003, Alzheimer's Disease in the U.S. Population). Over the next decade, Medicare spending on beneficiaries with AD will more than triple to \$189 billion. Our concern is that flattened budgets for the NIH institutes are threatening major AD research initiatives. One example is the Alzheimer's Disease Neuroimaging Initiative (ADNI), launched in 2004 as a public/private partnership: the most comprehensive effort to date to identify neuroimaging strategies and biomarkers to identify the onset of mild cognitive impairment and early AD with great-

er sensitivity. The project currently involves approximately 50 sites across the United States and Canada and holds the promise of early diagnosis and subsequent interventions that could postpone or more effectively treat AD. The Genetics Initiative is another multi-site collaboration that is collecting, sharing, and analyzing data to complete the picture of genetic risk factors for AD. These programs offer enormous potential to identify AD and intervene early, but lack of adequate funding will prevent or slow realization of the full potential of these programs. With aging baby boomers on the horizon, we cannot afford this delay.

Great strides have been made in AD. Only a few years ago, this disease could not be positively confirmed until autopsy. Now we can diagnose the disease in life with a high degree of certainty; we understand some of the basic mechanisms of the disease; and five approved drugs for treating symptoms are now approved with many new compounds being tested in publicly and industry-supported clinical trials.

This is a critical time for investment not retrenchment. Scientists are poised to find effective ways to prevent, delay onset, and even treat this disease. If the onset of AD could be delayed by just two years, the AD afflicted population would remain at current size, even with the expected increases in senior population; a five-year delay of onset would cut the projected AD population in half.

Other promising NIA biomedical research efforts into prominent diseases include research programs to discover new Parkinson's susceptibility genes; studies of age-related bone loss and osteoporosis; development of programs to assess genetic and environmental factors in racial and ethnic health differences simultaneously; and bone marrow failure diseases, all of which occur in higher incidence in people over 60.

NIA's behavioral and social science research programs have been instrumental in providing crucial economic and demographic population information. NIA's Centers on the Demography of Aging, particularly their Health and Retirement Survey (HRS) and the National Long-Term Care Survey (NLTC), provide critical data on the health and economic status of the older population. These data have been used by Congress to better understand the budgetary impact of population aging, as potential changes to public programs such as Social Security, Medicare, and Medicaid are deliberated. By using NLTC data, investigators identified the declining rate of disability in older Americans first observed in the mid-1990s—a trend that has continued. This trend, if continued, could have momentous impact on reducing the need for costly long-term care. The Social Security Administration recognizes and cofunds the HRS as a "Research Partner" and posts the study on its home page to improve its availability to the public and to policymakers. In 2005, the Center for Medicare and Medicaid Services (CMS) funded a supplemental survey using the HRS to provide timely information on who is likely to enroll in the new Medicare Part D prescription drug program and how those decisions are related to knowledge of the program, drug use and costs.

There is building evidence that continued engagement in productive activities has a positive impact on health and life satisfaction. The experience and expertise of the new 65+ population offers great potential to help address workforce shortages as well as some of the critical social needs of our country. The NIA is working to build a research agenda that focuses on maximizing older workers' safety, health, productivity and life satisfaction—knowledge that this will be critical to developing sound national policies.

NIA provides critical support for the training of new investigators. The reduction in funded proposals as a result of limited NIA budget will impact the ability to recruit and sustain an appropriate pool of qualified researchers in gerontology and geriatrics. Numerous reports have cited the need for more geriatricians and geriatric-trained professionals for our aging society. By 2030, the United States will need up to 36,000 geriatricians and will fall far short of that figure by as many as 25,000 unless effective steps are taken to train new providers (Medical Never-Never Land, Alliance for Aging Research, 2002). Further budget cuts will reduce funding available for training, and may force some leading researchers and practitioners to abandon gerontology as well as the mentoring of new professionals in the field.

With bipartisan leadership in Congress, the NIH budget doubled between 1998 and 2003 (\$13.6 to \$27.3 billion). However, since 2003, funding for the NIH in real dollars has been on a downward trajectory. Under the President's proposed fiscal year 2007 budget, the NIA is slated to be decreased in real terms by \$10 million. Further, in order to preserve clinical trials already underway, NIA will fund only 18 percent of new grant proposals. This is down substantially from 28.5 percent in 2003, and will not come close to supporting the more than 50 percent of submitted applications that the NIA has determined to be highly promising. At the same time that the acceptance rate of new proposals is down, the funding levels of new grants has also dropped from years past. Moreover, even those grantees receiving funding

face an average reduction from requested budgets by 18 percent across the board. (Fiscal Year 2007, National Institutes on Aging, Justification of Estimates for Appropriations Committees). Investigator-initiated research projects provide new breakthroughs in knowledge and treatment to benefit older Americans and their families. Declining budgets slow momentum and impact future research programs. For example, continued cuts will impact projects such as, the start up of new clinical trials in caloric restriction, testosterone supplementation in men, and lifestyle interventions and independence for elders, all of which have shown great potential for significant public health outcomes.

The Friends of the National Institute on Aging recommend the following directives:

(1) The time for research on aging is now if we are to achieve a healthier and more productive aging America. To further this goal, the Friends of the NIA endorse the recommendation issued by the Ad Hoc Group for Medical Research in calling for a 5 percent overall increase for the National Institutes of Health in fiscal year 2007.

(2) NIA needs additional resources to support individual investigator awards, to avoid an 18 percent cut in its existing grants, and to sustain training and research opportunities for new investigators.

Mr. Chairman, the Friends of the NIA thank you for this opportunity to outline the challenges, threats, and opportunities that lie ahead as you consider appropriate funding for the NIH and the National Institute on Aging.

PREPARED STATEMENT OF FRIENDS OF NIDA COALITION

The Friends of the National Institute on Drug Abuse (FoN), a burgeoning coalition of scientific and professional societies, patient groups, and other organizations committed to preventing and treating substance use disorders as well as understanding the causes and public health consequences of addiction, is pleased to provide testimony in support of the NIDA's extraordinary work. Pursuant to clause 2(g)4 of House Rule XI, the Coalition does not receive any Federal funds.

Drug abuse is costly—to individuals and to our society as a whole. Smoking, alcohol abuse and illegal drugs cost this country more than \$500 billion a year, with illicit drug use alone accounting for about \$180 billion in health care, crime, productivity loss, incarceration, and drug enforcement. Beyond its monetary impact, drug and alcohol abuse tear at the very fabric of our society, often spreading infectious diseases and bringing about family disintegration, loss of employment, failure in school, domestic violence, child abuse, and other crimes. The good news is that treatment for drug abuse is effective and recovery from addiction is real for millions of Americans across the country. Preventing drug abuse and addiction and reducing these myriad adverse consequences is the ultimate aim of our Nation's investment in drug abuse research. Over the past three decades, scientific advances resulting from research have revolutionized our understanding of and approach to drug abuse and addiction.

NIDA supports a comprehensive research portfolio that spans the continuum of basic neuroscience, behavior and genetics research through applied health services research and epidemiology. While supporting research on the positive effects of evidence-based prevention and treatment efforts, NIDA also recognizes the need to keep pace with emergent problems. Research shows encouraging trends that NIDA's public education and awareness efforts are having an impact: For example, the 2005 Monitoring the Future Survey of 8th, 10th, and 12th graders shows a dramatic 19 percent reduction in use since 2001. However, areas of significant concern remain. Some of NIDA's current research priorities include understanding more about methamphetamine and the brain, addressing the growing problem of prescription drug abuse, using drug abuse treatment to curtail the spread of HIV/AIDS, and encouraging collaborations that address comorbidity.

Because of the critical importance of drug abuse research for the health and economy of our Nation, we write to you today to request your support for a 5 percent increase for NIDA in the fiscal 2007 Labor, Health and Human Services, Education and Related Agencies Appropriations bill. That would bring total funding for NIDA in fiscal 2007 to \$1,050,030,450. Recognizing that so many health research issues are inter-related, we also support a 5 percent increase for the National Institutes of Health overall, which would bring its total to \$30 billion for fiscal 2007. This work deserves continuing, strong support from Congress. Below is a short list of significant NIDA accomplishments, challenges, and successes.

Adolescent Brain Development—How Understanding the Brain Can Impact Prevention Efforts.—NIDA maintains a vigorous developmental research portfolio fo-

cused on adolescent populations. NIDA working collaboratively with other NIH Institutes has shown that the human brain does not fully develop until about age 25. This adds to the rationale for referring to addiction as a “developmental disease;” it often starts during the early developmental stages in adolescence and sometimes as early as childhood, a time when we know the brain is still developing. Having insight into how the human brain works, and understanding the biological underpinnings of risk taking among young people will help in developing more effective prevention programs. FoN believes NIDA should continue its emphasis on studying adolescent brain development to better understand how developmental processes and outcomes are affected by drug exposure, the environment and genetics.

Medications Development.—NIDA has demonstrated leadership in the field of medications development by partnering with private industry to develop anti-addiction medications resulting in a new medication, buprenorphine, for opiate addiction. FoN recommends that NIDA continue its work with the private sector to develop much needed anti-addiction medications, for cocaine, methamphetamine, and marijuana dependence.

Co-Occurring Disorders.—NIDA recognizes the need to adequately address research questions related to co-occurring substance abuse and mental health problems. In particular, NIDA has developed robust collaborations with other agencies (such as NIAAA, NIMH and SAMHSA) to stimulate new research to develop effective strategies and to ensure the timely adoption and implementation of evidence-based practices for the prevention and treatment of co-occurring disorders. Through these initiatives, NIDA is supporting research to determine the most effective models of clinically appropriate treatment and how to bring them to communities with limited resources. FoN recognizes the imperative for continued funding of essential research into the nature of and improved treatment for these complex disorders and endorses these efforts.

Drug Abuse and HIV/AIDS.—One of the most significant causes of HIV virus acquisition and transmission involves drug taking practices and related risk factors in different populations (e.g. criminal justice, pregnant women, minorities, and youth). Drug abuse prevention and treatment interventions have been shown to be effective in reducing HIV risk. FoN congratulates NIDA on its “Drug Abuse and HIV—Learn the Link” public awareness campaign, targeting young people, and believes NIDA should continue to support research that focuses on developing and testing drug-abuse related interventions designed to reduce the spread of HIV/AIDS.

Emerging Drug Problems.—NIDA recognizes that drug use patterns are constantly changing and expends considerable effort to monitor drug use trends and to rapidly inform the public of emerging drug problems. FoN believes NIDA should continue supporting research that provides reliable data on emerging drug trends, particularly among youth and in major cities across the country and will continue its leadership role in alerting communities to new trends and creating awareness about these drugs.

Reducing Prescription Drug Abuse.—NIDA research has documented continued increases in the numbers of people, especially young people, who use prescription drugs for non-medical purposes. Particular concern revolves around the inappropriate use of opiod analgesics—very powerful pain medications. FoN commends NIDA for its research focus in this area, and for the new Prescription Opioid Use and Abuse in the Treatment of Pain initiative. Research targeting a reduction in prescription drug abuse, particularly among our Nation’s youth, will continue to be a priority for NIDA. Finally, FoN endorses NIDA’s programmatic research designed to further the development of medications that are less likely to have abuse/addiction liability, and to develop prevention and treatment interventions for adolescents and adults who are abusing prescription drugs.

Reducing Methamphetamine Abuse.—NIDA continues to recognize the epidemic abuse of methamphetamine across the United States. Methamphetamine abuse not only affects the users, but also the communities in which they live, especially due to the dangers associated with its production. FoN believes NIDA should continue to support research to address the broad medical consequences of methamphetamine abuse, and is encouraged by the evidence of treatment effectiveness in these populations. Topics of particular concern include: understanding the effects of prenatal exposure to methamphetamine, developing pharmacotherapies and behavioral therapies to treat methamphetamine addiction and information dissemination strategies to inform the public that treatment for methamphetamine addiction is effective.

Reducing Inhalant Abuse.—FoN recognizes that inhalant use continues to be a significant problem among our youth. Inhalants pose a particularly significant problem since they are readily accessible, legal, and inexpensive. They also tend to be abused by younger teens and can be highly toxic and even lethal. FoN applauds

NIDA's inhalant research portfolio and believes NIDA should continue its support of research on prevention and treatment of inhalant abuse, and to enhance public awareness on this issue.

Long-Term Consequences of Marijuana Use.—NIDA research shows that marijuana can be detrimental to educational attainment, work performance, and cognitive function. However, more information is needed in order to assess the full impact of long-term marijuana use. Therefore, FoN recommends that NIDA continue to support efforts to assess the long-term consequences of marijuana use on cognitive abilities, achievement, and mental and physical health, as well as work with the private sector to develop medications focusing on marijuana addiction.

Translating Research Into Practice.—FoN commends NIDA for its outreach and work with State substance abuse authorities to reduce the current 15- to 20-year lag between the discovery of an effective treatment intervention and its availability at the community level. In particular, FoN applauds NIDA for continuing its work with SAMHSA to strengthen State substance abuse agencies' capacity to support and engage in research that will foster statewide adoption of meritorious science-based policies and practices. FoN encourages NIDA to continue collaborative work with State substance abuse agencies to ensure that research findings are relevant and adaptable by State substance abuse systems. NIDA is also to be congratulated for its broad and varied information dissemination programs as part of an effort to ensure drug abuse research is used in everyday practice. The Institute is focused on stimulating and supporting innovative research to determine the components necessary for adopting, adapting, delivering, and maintaining effective research-supported policies, programs, and practices. As evidence-based strategies are developed, FoN urges NIDA to support research to determine how these practices can be best implemented at the community level.

Primary Care Settings and Youth.—NIDA recognizes that primary care settings, such as offices of pediatricians and general practitioners, are potential key points of access to prevent and treat problem drug use among young people; yet primary care and drug abuse services are commonly delivered through separate systems. FoN encourages NIDA to continue to support health services research on effective ways to educate primary care providers about drug abuse; develop brief behavioral interventions for preventing and treating drug use and related health problems, particularly among adolescents; and develop methods to integrate drug abuse screening, assessment, prevention and treatment into primary health care settings.

Utilizing Knowledge of Genetics and New Technological Advances to Curtail Addiction.—NIDA recognizes that not everyone who takes drugs becomes addicted and that this is an important phenomenon worthy of further exploration. Research has shown that genetics plays a critical role in addiction, and that the interplay between genetics and environment is crucial. The science of genetics is at a crucial phase—technological advances are providing the tools to make significant breakthroughs in disease research. For example, FoN believes NIDA should take advantage of new high-resolution genetic technologies which may help to develop new tailored treatments for smoking.

Reducing Health Disparities.—NIDA research demonstrates that the consequences of drug abuse disproportionately impacts minorities, especially African American populations. FoN believes that researchers should be encouraged to conduct more studies in this population and to target their studies in geographic areas where HIV/AIDS is high and or growing among African Americans, including in criminal justice settings.

The Clinical Trials Network—Using Infrastructure to Improve Health.—FoN applauds the continued success of NIDA's National Drug Abuse Treatment Clinical Trials Network (CTN), which was established in 1999 and has grown to include over 17 research centers or nodes spread across the country. The CTN provides an infrastructure to test the effectiveness of new and improved interventions in real-life community settings with diverse populations, enabling an expansion of treatment options for providers and patients. FoN suggests NIDA continue to develop ways to use the CTN as a vehicle to address emerging public health needs.

Behavioral Science.—NIDA has long demonstrated a strong commitment to supporting behavioral science research. FoN encourages NIDA to continue to determine the interplay of behavioral, biological, and social factors that affect development and the onset of diseases like drug addiction to understand common pathways that may underlie other compulsive behaviors such as gambling and eating disorders.

Drug Treatment in Criminal Justice Settings.—NIDA is very concerned about the well-known connections between drug use and crime. Research continues to demonstrate that providing treatment to individuals involved in the criminal justice system decreases future drug use and criminal behavior, while improving social functioning. Blending the functions of criminal justice supervision and drug abuse treat-

ment and support services create an opportunity to have an optimal impact on behavior by addressing public health concerns while maintaining public safety. FoN strongly supports NIDA's efforts in this area, particularly the Criminal Justice Drug Abuse Treatment Studies (CJ-DATS), a multi-site set of research studies designed to improve outcomes for offenders with substance use disorders by improving the integration of drug abuse treatment with other public health and public safety systems.

Social Neuroscience.—Research-based knowledge about the dynamic interactions of genes with environment confirm addiction as a complex and chronic disease of the brain with many contributors to its expression in individuals. FoN applauds NIDA's involvement in the recently released "social neuroscience" request for applications, and encourages the Institute to continue its focus on the interplay between genes, environment, and social factors and their relevance to drug abuse and addiction.

Translational Research: Ensuring Research is Adaptable and Useable.—FoN commends NIDA for its broad and varied information dissemination programs. FoN also understands that the Institute is focused on stimulating and supporting innovative research to determine the components necessary for adopting, adapting, delivering, and maintaining effective research-supported policies, programs, and practices. As evidence-based strategies are developed, FoN urges NIDA to support research to determine how these practices can be best implemented at the State and community level.

Blending Research and Practice.—FoN notes that it takes far too long for clinical research results to be implemented as part of routine patient care, and that this lag in diffusion of innovation is costly for society, devastating for individuals and families, and wasteful of knowledge and investments made to improve the health and quality of people's lives. FoN applauds NIDA's collaborative approach aimed at proactively involving all entities invested in changing the system and making it work better. NIDA is leading efforts to make the best substance abuse treatments available to those who need them, and this effort requires working with many different contributors to assimilate their feedback and create change at multiple levels.

CONCLUSION

The Nation's investment in scientific research has changed the way people view drug abuse and addiction in this country. We now know how drugs work in the brain, their health consequences, how to treat people already addicted, and what constitutes effective prevention strategies. FoN asks you to provide an appropriation of \$1,050,030,450 for NIDA, so that it may continue to serve the public health of all Americans and capitalize on new opportunities as science advances.

We understand that the fiscal year 2007 budget cycle will involve setting priorities and accepting compromise. However, in the current climate, we believe a focus on substance abuse and addiction, which according to the World Health Organization account for nearly 20 percent of disabilities among 15–44 year olds, deserve to be prioritized accordingly. We look forward to working with you to make this a reality.

Thank you, Mr. Chairman, and the subcommittee, for your support for the National Institute on Drug Abuse.

PREPARED STATEMENT OF THE HEART RHYTHM SOCIETY

The Heart Rhythm Society (HRS) thanks you and the Subcommittee on Labor, Health and Human Services and Education for your past and continued support of the National Institute of Health, and specifically the National Heart, Lung and Blood Institute (NHLBI).

The Heart Rhythm Society, founded in 1979 to address the scarcity of information about the diagnosis and treatment of cardiac arrhythmias, is the international leader in science, education and advocacy for cardiac arrhythmia professionals and patients, and the primary information resource on heart rhythm disorders. The Heart Rhythm Society serves as an advocate for millions of American citizens from all 50 States, since arrhythmias are the leading cause of heart-disease related deaths. Other, less lethal forms of arrhythmias are even more prevalent, account for 14 percent of all hospitalizations of Medicare beneficiaries.¹ Our mission is to improve the care of patients by promoting research, education and optimal health care policies

¹Heart Rhythm Foundation, Arrhythmia Key Facts, 2004 <http://www.heartrhythmfoundation.org/facts/arrhythmia.asp>.

and standards. We are the preeminent professional group, representing more than 4,200 specialists in cardiac pacing and electrophysiology.

The Heart Rhythm Society recommends the subcommittee renew its commitment to supporting biomedical research in the United States and recommends Congress provide NIH with a 5 percent increase for fiscal year 2007. This translates into an appropriation of \$29.849 billion for NIH, with \$3.068 billion designated to the National Heart, Lung, and Blood Institute (NHLBI). This increase will enable NIH and NHLBI to sustain the level of research that leads to research breakthroughs and improved health outcomes. In particular, the Heart Rhythm Society recommends Congress support research into abnormal rhythms of the heart.

HRS appreciates the actions of Congress to double the budget of the NIH in recent years. The doubling has directly promoted innovations that have improved treatments and cures for a myriad of medical problems facing our Nation. Medical research is a long-term process and in order to continue to meet the evolving challenges of improving human health we must not let our commitment wane. Furthermore, NIH research fuels innovation that generates economic growth and preserves our Nation's role as a world leader in the biomedical and biotech industries. Healthier citizens are the key to robust economic growth and greater productivity. Economists estimate that improvements in health from 1970 to 2000 were worth \$95 trillion. During the same time period, the United States invested \$200 billion in the NIH. If only 10 percent of the overall health savings resulted from NIH-funded research, our investment in medical research has provided a 50-fold return to the economy.²

RESEARCH ACCOMPLISHMENTS

In the field of cardiac arrhythmias, NIH-funded research has advanced our ability to treat atrial fibrillation and thus prevent the devastating complications of stroke. Atrial fibrillation is found in about 2.2 million Americans and increases the risk for stroke about 5-fold. About 15–20 percent of strokes occur in people with atrial fibrillation. Stroke is a leading cause of serious, long-term disability in the United States and people who have strokes caused by AF have been reported as 2–3 times more likely to be bedridden compared to those who have strokes from other causes. Each year about 700,000 people experience a new or recurrent stroke and in 2002 stroke accounted for more than 1 of every 15 deaths in the United States. Ablation therapy however is providing a cure for individuals whose rapid heart rates had previously incapacitated them, giving them a new lease on life.³

Important advances have also been made in identifying patients with heart failure and those who have suffered a heart attack and are at risk for sudden death. The development, through initial NIH-sponsored research, and implantation of sophisticated internal cardioverter defibrillators (ICD's) in such patients has saved the lives of hundreds of thousands and provides peace of mind for families everywhere, including that of Vice-President Cheney's. A new generation of pacemakers and ICDs is restoring the beat of the heart as we grow older, permitting us to lead more normal and productive lives, reducing the burden on our families, communities and the healthcare system. Arrhythmias and sudden death affect all age groups and are not solely diseases of the elderly.

Research advances in molecular genetics have provided us the root basis for life-threatening abnormal rhythms of the heart associated with a wide range of inherited syndromes including long and short QT, Brugada syndromes, and hypertrophic cardiomyopathies. This knowledge has provided guidance to physicians for better detection and treatment of these sudden death syndromes reducing mortality and disability of infants, children and young adults. Individuals who survive an instance of sudden death often remain in vegetative states, resulting in a devastating burden on their families and an enormous economic burden on society. These advances have translated into sizeable savings to the health care system in the United States. Researchers are also developing a noninvasive imaging modality for cardiac arrhythmias. Despite the fact that more than 325,000 Americans die every year from heart rhythm disorders, a noninvasive imaging approach to diagnosis and guided therapy of arrhythmias, the equivalent of CT or MRI, has previously not been available.

The NIH-funded Public Access Defibrillation (PAD) Trial was also able to determine that trained community volunteers increase survival for victims of cardiac arrest. It had already been known that defibrillation, utilizing an automated external

²Murphy, KM and Topel, RH, The Value of Health and Longevity, National Bureau of Economic Research Working Paper Series, Working Paper 11405, June 2005.

³American Stroke Association and American Heart Association, Heart Disease and Stroke Statistics 2005 Update, 2005 <http://www.americanheart.org/downloadable/heart/1105390918119HDSStats2005Update.pdf>.

defibrillator (AED), by trained public safety and emergency medical services personnel is a highly effective live-saving treatment for cardiac arrest. A NIH-funded trial however was able to conclude that placing AED's in public places and training lay persons to use them can prevent additional deaths and disabilities.⁴

Without NIH support, these life-saving findings may have taken a decade to unravel. The highly focused approach utilizing basic and clinical expertise, funded through Federal programs made these advances a reality in a much shorter time-period.

BUDGET JUSTIFICATION

These impressive strides notwithstanding, cardiac arrhythmias continue to plague our society and take the lives of loved ones at all ages, nearly one every minute of every day, as well as straining an already burdened health system. Sudden Cardiac Arrest is a leading cause of death in the United States, claiming an estimated 325,000 lives every year, or one life every two minutes.⁵ The burden of morbidity and mortality due to cardiac arrhythmias is predicted to grow dramatically as the baby boomers age. Atrial fibrillation strikes 3–5 percent of people over the age of 65,⁶ presenting a skyrocketing economic burden to our society in the form of healthcare treatment and delivery. It is estimated in 2005 that the direct and indirect cost of stroke will be \$56.8 billion.⁷ Cardiac diseases of all forms increase with advancing age, ultimately leading to the development of arrhythmias. NIH research provides the basis for the medical advances that hold the key to lowering health care costs.

The above progress we have witnessed in recent years will provide treatments for this illness, only if the resources continue to be available to the academic scientific and medical community. However, the budgets appropriated by Congress to the NIH in the past three years were far below the level of scientific inflation. These vacillations in funding cycles threaten the continuity of the research and the momentum that has been gained over the years. While HRS recognizes that Congress must balance other priorities, sustaining multi-year growth for the biomedical research enterprise is critical. A central objective of the doubling of the NIH budget was to accelerate solutions to human disease and disability. NIH is now engaging in the next generation of biomedical research to translate basic research and clinical evidence into new cures. Our ability to bring together uniquely qualified and devoted investigators and collaborators both at the basic science level and in the clinical arena is a vital key to our success. Funding models however show that a threshold exists, below which NIH will not be able to maintain its current scope and number of grants, let alone expand its programs to address new concerns and emerging opportunities. Furthermore, the United States is in danger of losing its leadership role in science and technology. The United States faces growing competition from other nations, such as China and India, which are working to invest more of their GDP's into building state-of-the-art research institutes and universities to foster innovation and compete directly for the world's top students and researchers.⁸

It is for this reason that we are asking for your support to increase NIH appropriations by 5 percent for a fiscal year 2007 budget of \$29.849 billion for NIH and \$3.068 billion for NHLBI. The Heart Rhythm Society recommends Congress specifically acknowledge the need for cardiac arrhythmia research to prevent sudden cardiac arrest and other life threatening conditions such as sudden infant death syndrome, definitive therapeutic approaches for atrial fibrillation and the prevention of stroke, and other genetic arrhythmia conditions. Thank you very much for your consideration of our request.

If you have any questions or need additional information, please contact Nevena Minor, Coordinator, Health Policy at the Heart Rhythm Society (amelnick@hrsonline.org or 202-464-3434).

Thank you again for the opportunity to submit testimony.

⁴National Heart Lung and Blood Institute, NIH, Public Access Defibrillation by Trained Community Volunteers Increases Survival for Victims of Cardiac Arrest, November 2003 http://www.nhlbi.nih.gov/new/press/03_11_11.htm.

⁵Heart Rhythm Foundation, The Facts on Sudden Cardiac Arrest, 2004 http://www.heartrhythmfoundation.org/its_about_time/pdf/provider_fact_sheet.pdf.

⁶Heart Rhythm Society, Atrial Fibrillation & Flutter, 2005 http://www.hrspatients.org/patients/heart_disorders/atrial_fibrillation/default.asp.

⁷American Stroke Association, Impact of Stroke, 2005 <http://www.strokeassociation.org/presenter.jhtml?identifier=1033>.

⁸Task Force on the Future of American Innovation, The Knowledge Economy: Is the United States Losing its Competitive Edge?, February 16, 2005.

PREPARED STATEMENT OF THE HEMOPHILIA FEDERATION OF AMERICA

SUMMARY OF FISCAL YEAR 2007 RECOMMENDATIONS

- Continued support for Hemophilia Treatment Centers through the Health Resources and Services Administration Maternal and Child Health Block Grant.
- \$10 million for hemophilia programs at the Centers for Disease Control and Prevention and expansion of the program to allow partnerships with additional patient-based organizations within the hemophilia community.
- A 5 percent increase overall for the National Institutes of Health, including a 5 percent increase for the National Heart, Lung, and Blood Institute, and the National Institute for Allergy and Infectious Diseases.

INTRODUCTION

The Hemophilia Federation of America (HFA) is a national nonprofit organization that assists and advocates for the blood clotting disorders community. The vision of the HFA is that the blood clotting disorders community will face no barriers to choice of treatment and quality of life.

The programming of HFA is designed to be of assistance to the consumer and their families and is structured to follow our mission and vision. We at HFA consider ourselves the “consumer organization.” That was the purpose of our organization when we were established a decade ago and it has remained constant in the structure and activities of the organization. The following is a summary of some of the programs that HFA offers to the hemophilia community:

“Helping Hands”

Helping Hands is a program that offers financial assistance to patients and families in a crisis. The grant applicant requests funds for emergency assistance with various needs such as: rent, utilities, car repair, and quality of life issues. Over one half of the requests funded in recent years were first time applicants. The requests are comprised of referrals from member organizations and industry.

“Dads in Action”

Dads in Action is a new program launched in the fall of 2003 that is designed to encourage dads to take a more active role in their children’s lives, to be more involved in the care of their child with hemophilia and to strengthen communication throughout the family. Participants return to their home chapters to start a “Dads in Action” program where they carry the lessons learned to fellow Dads at their local chapter. The program receives high reviews from participants and is an integral part of our vision for the community.

The Annual HFA Symposium

HFA’s annual Symposium is one of the brightest stars in our programmatic agenda. This event has grown from a small gathering of 100 people in 1996 to over 500 in 2006. The sole focus at this annual event is the consumer. Our patients view that annual symposium as a big family reunion where they learn how to cope with everyday situations. There are also free programs for teens and children. The goal of the Symposium is to address issues that impact the entire community. Presenters are experts in their field and share their expertise with the community.

FISCAL YEAR 2007 APPROPRIATIONS RECOMMENDATIONS

Hemophilia Treatment Centers/Health Resources and Services Administration

In 1974, Congress created a network of Hemophilia Treatment Centers (HTCs) throughout the United States. These treatment centers remain essential to ensuring that comprehensive and specialized care is available for persons with bleeding disorders. There are currently over 140 HTCs in the United States. These centers abide by Federal guidelines for the delivery of comprehensive hemophilia services as developed by the Health Resources and Services Administration and the Centers for Disease Control and Prevention.

HTC’s provide family centered, state-of-the-art medical and psychosocial services, as well as education and research to persons with inherited bleeding disorders. The bleeding disorder community utilizes many services through the Hemophilia Treatment Centers. These services include diagnostic evaluations for hemophilia, von Willebrand disease and other bleeding disorders. They also include annual comprehensive evaluations, clinical trials on new blood clotting therapies, coordination with the individual’s primary care physician, emergency consultations, hematological management for surgeries, dental procedures and childbirth. HTC’s educate patients and family members on infusion training, encourage collaboration

with clinicians throughout the United States, participate in CDC research, and collaborate with the hemophilia community.

At the Health Resources and Services Administration, funding is provided to HTC's through the Maternal and Child Health Block Grant program. For fiscal year 2007, HFA encourages the subcommittee to reject the president's proposed \$36 million cut to MCHBG, and restore funding to the fiscal year 2006 level of \$816 million.

Hemophilia Program at the Centers for Disease Control and Prevention

Mr. Chairman, HFA strongly supports the expansion of hemophilia related programs within CDC's National Center on Birth Defects and Developmental Disabilities' Hereditary Blood Disorders program. In partnership with HRSA, this program provides vital support to Hemophilia Treatment Centers, particularly in the areas of research, education, disease management, blood safety and surveillance. For fiscal year 2007, HFA encourages the subcommittee to provide an increase of \$3 million for hemophilia related activities at CDC. This proposed increase would bring the total level of CDC funding for the hemophilia treatment center network to \$10 million. This increase is important given the fact the program has been level funded for over 10 years.

HFA was very pleased that the fiscal year 2006 Senate Labor-HHS-Education committee report encouraged CDC to expand opportunities for additional patient-based organizations to participate in the agency's hemophilia program. Under the current structure of the program, only one hemophilia organization is eligible to receive support for the purpose of providing much needed services to patients. In order to maximize the effectiveness of the CDC program, we believe that additional patient based organizations should be empowered to receive funding on an annual basis. As referenced earlier, HFA offers a wide variety of high quality, consumer focused, programs that no other organization provides. If the CDC program were opened-up to allow additional organizations to participate, we would be able to help a much larger number of patients and families throughout the country. We encourage the subcommittee to support our efforts in this regard in the fiscal year 2007 bill.

Research at the National Institutes of Health

HFA applauds the National Heart, Lung and Blood Institute, the National Institute of Diabetes and Digestive and Kidney Diseases, and the National Institute of Allergy and Infectious Diseases for their strong support of hemophilia related research. We are grateful to the subcommittee for recognizing the growing problem of bleeding disorders in women, which if untreated, can lead to serious medical conditions including anemia, unnecessary hysterectomies, and menstrual complications.

Patients and families in the hemophilia community are placing their hopes for a better quality of life on treatment advances made through biomedical research. For fiscal year 2007, we encourage the subcommittee to provide a 5 percent increase overall for each institute and center at the NIH.

Mr. Chairman, thank you for the opportunity to present the views of the Hemophilia Federation of America.

PREPARED STATEMENT OF HEPATITIS FOUNDATION INTERNATIONAL

SUMMARY OF FISCAL YEAR 2007 RECOMMENDATIONS

- Continue the great strides in research at the National Institutes of Health (NIH) by providing a 5 percent budget increase for fiscal year 2007. Increase funding for the National Institute for Allergy and Infectious Diseases (NIAID), the National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK), the National Institute on Alcohol Abuse and Alcoholism (NIAAA), and the National Institute on Drug Abuse (NIDA) by 5 percent.
- Continued support for the hepatitis B vaccination program for adults at the Centers for Disease Control and Prevention (CDC) as well as CDC's Prevention Research Centers by providing an 8 percent increase for CDC.
- Support for the Substance Abuse and Mental Health Services Administration (SAMHSA) by providing an 8 percent increase in fiscal year 2007.
- Urge CDC, NIAID, NIDDK, NIAAA, NIDA, and SAMHSA to work with voluntary health organizations to promote liver wellness, education, and prevention of both hepatitis and substance abuse.

Mr. Chairman and members of the subcommittee, thank you for your continued leadership in promoting better research, prevention, education, and control of diseases affecting the health of our Nation. I am Thelma King Thiel, Chairman and Chief Executive Officer of the Hepatitis Foundation International (HFI).

Currently, five types of viral hepatitis have been identified, ranging from type A to type E. All of these viruses cause acute, or short-term, viral hepatitis. Hepatitis B, C, and D viruses can also cause chronic hepatitis, in which the infection is prolonged, sometimes lifelong. While treatment options are available for many patients, individuals with chronic viral hepatitis B and C represent a significant number of patients requiring a liver transplant. Current treatments have limited success and there is no vaccine available for hepatitis C, the most prevalent of these diseases.

HEPATITIS A

The hepatitis A virus (HAV) is contracted through fecal/oral contact (i.e. fecal contamination of food, water, and diaper changing tables if not cleaned properly), and sexual contact. In addition, eating raw or partially cooked shellfish contaminated with HAV can spread the virus. Children with HAV usually have no symptoms; however, adults may become quite ill suddenly experiencing jaundice, fatigue, nausea, vomiting, abdominal pain, dark urine/light stool, and fever. There is no treatment for HAV; however, recovery occurs spontaneously over a 3 to 6 month period. About 1 in 1,000 with HAV suffer from a sudden and severe infection that may require a liver transplant. A highly effective vaccine can prevent HAV. This vaccination is recommended for all children and individuals who have chronic liver disease or clotting factor disorders, in addition to those who travel or work in developing countries.

HEPATITIS B

Hepatitis B (HBV) claims an estimated 5,000 lives every year in the United States, even though therapies exist that slow the progression of liver damage. Vaccines are available to prevent hepatitis B. This disease is spread through contact with the blood and body fluids of an infected individual and from an HBV infected mother to child at birth. Unfortunately, due to both a lack in funding to vaccinate adults and the absence of an integrated preventive education strategy, transmission of hepatitis B continues to be problematic. Additionally, there are significant disparities in the occurrence of chronic HBV-infections. Asian Americans represent four percent of the population; however, they account for over half of the 1.3 million chronic hepatitis B cases in the United States. Current treatments do not cure hepatitis B, but appropriate treatment can help to reduce the progression to liver cancer and liver failure. Yet, many are not treated. Preventive education and universal vaccination are the best defenses against hepatitis B.

HEPATITIS C

Infection rates for hepatitis C (HCV) are at epidemic proportions. Unfortunately, many individuals are not aware of their infection until many years after they are infected. This creates a vicious cycle, as individuals who are infected continue to spread the disease, unknowingly. The Center for Disease Control and Prevention estimates that there are over 4 million Americans who have been infected with hepatitis C, of which over 2.7 million remain chronically infected, with 8,000–10,000 deaths each year. Additionally, the death rate is expected to triple by 2010 unless additional steps are taken to improve outreach and education on the prevention of hepatitis C and scientists identify more effective treatments and cures. As there is no vaccine for HCV, prevention education and treatment of those who are infected serve as the most effective approach in halting the spread of this disease.

PREVENTION IS THE KEY

The absence of information about the liver and hepatitis in education programs over the years has been a major factor in the spread of viral hepatitis through unknowing participation in liver damaging activities. Adults and children need to understand the importance of the liver and how viruses and drugs can damage its ability to keep them alive and healthy. Many who are currently infected are unaware of the risks they are taking that expose them to viral infections and ultimate liver damage.

Knowledge is the key to prevention. Preventive education is essential to motivate individuals to protect themselves and avoid behaviors that can cause life-threatening diseases. Primary prevention that encourages individuals to adopt healthful lifestyle behaviors must begin in elementary schools when children are receptive to learning about their bodies. Schools provide access to one-fifth of the American population.

Individuals need to be motivated to assess their own risk behaviors, to seek testing, to accept vaccination, to avoid spreading their disease to others, and to under-

stand the importance of participating in their own health care and disease management. The NIH needs to support education programs to train teachers and healthcare providers in effective communication techniques, and to evaluate the impact preventive education has on reducing the incidence of hepatitis and substance abuse.

Therefore, HFI recommends that CDC, NIAID, NIDDK, NIAAA, NIDA, and SAMHSA be urged to work with voluntary health organizations to promote liver wellness, education, and prevention of viral hepatitis, sexually transmitted diseases and substance abuse.

Only a major investment in immunization and preventive education will bring these diseases under control. All newborns, young children, young adults, and especially those who participate in high-risk behaviors must be a priority for immunization, outreach initiatives, and preventive education. We recommend that the following activities be undertaken to prevent the further spread of all types of hepatitis:

- Provide effective preventive education in our elementary and secondary schools so children can avoid the serious health consequences of risky behaviors that can lead to viral hepatitis.
- Train educators, health care professionals, and substance abuse counselors in effective communication and counseling techniques.
- Promote public awareness campaigns to alert individuals to assess their own risk behaviors, motivate them to seek medical advice, encourage immunization against hepatitis A and B, and to stop the consumption of any alcohol if they have participated in risky behaviors that may have exposed them to hepatitis C.
- Expand screening, referral services, medical management, counseling, and prevention education for individuals who have HCV, many of whom may be co-infected with HIV and Hepatitis C and/or Hepatitis B.

CENTERS FOR DISEASE CONTROL AND PREVENTION (CDC)

HFI recommends an 8 percent increase in fiscal year 2007 for further implementation of CDC's Hepatitis C Prevention Strategy. This increase will support and expand the development of State-based prevention programs by increasing the number of State health departments with CDC funded hepatitis coordinators. The Strategy will use the most cost-effective way to implement demonstration projects evaluating how to integrate hepatitis C and hepatitis B prevention efforts into existing public health programs.

CDC's Prevention Research Centers, an extramural research program, plays a critical role in reducing the human and economic costs of disease. Currently, CDC funds 26 prevention research centers at schools of public health and schools of medicine across the country. HFI encourages the subcommittee to increase core funding for these prevention centers, as it has been decreasing since this program was first funded in 1986. We recommend the subcommittee provide an 8 percent increase for the Prevention Research Centers program in fiscal year 2007.

Also, HFI recommends that the CDC, particularly the Division of Adolescent and School Health (DASH), work with voluntary health organizations to promote liver wellness with increased attention toward childhood education and prevention.

INVESTMENTS IN RESEARCH

Investment in the NIH has led to an explosion of knowledge that has advanced understanding of the biological basis of disease and development of strategies for disease prevention, diagnosis, treatment, and cures. Countless medical advances have directly benefited the lives of all Americans. NIH-supported scientists remain our best hope for sustaining momentum in pursuit of scientific opportunities and new health challenges. For example, research into why some HCV infected individuals resolve their infection spontaneously may prove to be life saving information for others currently infected. Other areas that need to be addressed are:

- Reasons why African Americans do not respond as well as Caucasians and Hispanics to antiviral agents in the treatment of chronic hepatitis C.
- Pediatric liver diseases, including viral hepatitis.
- The outcomes and treatment of renal dialysis patients who are infected with HCV and HBV.
- Co-infections of HIV/HCV and HIV/HBV positive patients.
- Hemophilia patients who are co-infected with HIV/HCV and HIV/HBV.
- The development of effective treatment programs to prevent recurrence of HCV infection following liver transplantation.
- The development of effective vaccines to prevent HCV infection.

HFI supports a 5 percent increase for NIH in fiscal year 2007. HFI also recommends a comparable increase of 5 percent in hepatitis research funding at NIAID, NIDDK, NIAAA, and NIDA.

HFI is dedicated to the eradication of viral hepatitis, which affects over 500 million people around the world. We seek to raise awareness of this enormous worldwide problem and to motivate people to support this important—and winnable—battle. Thank you for providing this opportunity to present testimony.

PREPARED STATEMENT OF IN DEFENSE OF ANIMALS

Six years ago, In Defense of Animals (IDA) testified before Congress about the NIH's egregious oversight failures and illegal funding of the New Mexico-based Coulston Foundation, at the time the world's largest chimpanzee lab. IDA testified about Coulston's abysmal animal care record and unprecedented violations, dating back to 1993, of Federal animal welfare laws. IDA recommended, among other things, a Congressional investigation.

Within weeks of IDA's March 2000 testimony, the NIH took ownership of 288 chimpanzees from Coulston, citing concerns about the lab's resources and ability to properly care for the animals, which IDA had raised in our testimony. The NIH left the chimpanzees in Coulston's "care" and continued to illegally fund the lab despite its continued animal welfare violations.

The NIH's Coulston oversight debacle resulted in international media coverage, public outrage and intense Congressional scrutiny. As a result, the NIH was finally forced to end its illegal funding of Coulston in June 2001. The agency took over ownership of the lab where the 288 chimpanzees were housed, renamed it the "Alamogordo Primate Facility" (APF), and awarded a ten-year, \$42 million taxpayer-funded contract to Charles River Laboratories (CRL) to operate it. However, the APF was now NIH-owned and part of the agency's Intramural Research Program; the contract between the NIH and CRL explicitly states that the NIH is responsible for "day-to-day management" of the lab, including its "associated animal activities."

Subsequently, the House Committee on Energy and Commerce conducted an investigation, and found that the NIH had indeed continued to fund Coulston despite its violation of Federal administrative laws. This prompted the Investigations subcommittee to question the NIH's oversight and management of billions of dollars in taxpayer-funded grants; this subcommittee consequently launched a broad investigation of the NIH in March 2003.

Amazingly, six years after IDA's March 2000 testimony, the NIH oversight debacle that launched a prior Congressional investigation is actually worse, and cries out for Congressional action. That is because in September 2004, New Mexico District Attorney Scot Key filed multiple counts of criminal animal cruelty against CRL. After an independent investigation that lasted almost one year, the D.A. found that it was "standard practice" for CRL to have trained animal care staff leave at the end of the workday, and leave the "care" of critically ill or injured chimpanzees to once-per-hour monitoring by untrained security guards. This "standard practice"—instituted in August 2002 as an apparent cost-saving measure—resulted in the suffering and deaths of two chimpanzees, Rex and Ashley, and the near-death of a third, Topsy. The D.A. charged CRL and APF Director Rick Lee with three counts of criminal cruelty alleging abandonment and failure to provide necessary sustenance. This understaffed small-town D.A. with a caseload of murders had stepped in to enforce the law and protect the chimpanzees from a multi-billion dollar public company and a \$28 billion Federal agency. It should be noted that because the APF is now a Federal research lab, the USDA has no jurisdiction under the Animal Welfare Act. This was the first time in U.S. history that an entire lab had been charged with criminal animal cruelty. This case, the culmination of 10 years of NIH-funded abuse of these New Mexico chimpanzees, contains shocking facts that cry out for further Congressional action.

Despite initial promises of cooperation, CRL instead hired a high-powered criminal law firm perhaps best known for obtaining an acquittal of a two-time husband killer after she had shot husband number two in New Mexico. CRL refused to cooperate with the D.A.'s criminal investigation. CRL refused to comply with the D.A.'s subpoena demanding records relating to the three chimpanzees. The D.A. then obtained a grand jury subpoena, but CRL still refused to supply the records to the D.A. The NIH did nothing to force CRL to cooperate.

Tellingly, however, CRL did supply these records to an ad-hoc NIH consultant with no law enforcement authority. During only a portion of his one-day site visit, this veterinarian simply reviewed the records, without interviewing a single witness, and, predictably, found no problems. Neither the NIH nor CRL wanted an

independent, legitimate law enforcement officer, such as the D.A., to get within a mile of these records, and did everything possible to prevent his obtaining them. The NIH did not want any independent, legitimate investigation, since any problems found would be an indictment of the agency's own management of the lab. The NIH's responsibility for "oversight" at its own lab constitutes an unmitigated conflict of interest. Had the NIH found a chimpanzee shot in the head, the agency would no doubt have ruled it a suicide.

Like CRL, the NIH has also refused to supply these records to the public, even after IDA filed a Federal FOIA lawsuit in September 2004. In its briefs, the NIH has actually claimed that it does not possess these clinical records—for NIH-owned chimpanzees at an NIH-owned facility that is part of the NIH's Intramural Research Program. This laughable assertion is belied by the NIH's own contract with CRL, which explicitly states that the NIH does indeed possess these records.

CRL submitted only one of two reports generated by the one-day NIH site visit to the New Mexico court trying the criminal case—predictably, the one praising CRL's veterinary care, which was based on only a review of records, not any witness interviews nor an actual investigation. However, the criminal charges had nothing to do with CRL's veterinary care, but instead CRL's alleged "standard practice" of abandoning critically ill or injured chimpanzees to once-per-hour monitoring by untrained security guards. The second report, written by the NIH Project Officer for the CRL contract and obtained by IDA through FOIA, clearly shows that the NIH was completely and totally unaware of the abandonment alleged by the D.A.

During the time period covered by the multiple counts of criminal animal cruelty, the NIH actually awarded CRL bonuses totalling \$175,000 paid for with taxpayer funds. CRL received the maximum bonuses; the major criterion for these bonuses was "no animal care deficiencies."

While the D.A.'s independent investigation—run by a 24-year police veteran—took almost a year and interviewed six witnesses, including eyewitnesses, the NIH interviewed no witnesses regarding Rex, Ashley and Topsy and allowed the so-called "investigation" to be conducted by CRL—another blatant conflict of interest. Because CRL refused to cooperate—despite its initial promises—the D.A. could only interview ex-CRL employees. But those ex-employees painted a devastating portrait of the alleged acts of cruelty and CRL's operation of this NIH lab.

Dr. Kelly Avila started work at the APF only 58 days after she graduated from veterinary school. She told the D.A.'s investigator that she had been promised training, but instead found herself the main clinician for over 250 chimpanzees. She confirmed that in August 2002, APF Director Rick Lee instituted the policy where security guards would take over for animal care at quitting time, 4:00 p.m. She repeatedly stated that Ashley, the first chimpanzee mentioned in the criminal charges, had shock. Avila had "serious problems" with APF practices, and discussed problems associated with having security/maintenance personnel perform animal care. She started a system of writing daily reports of what she found on exams and also which chimpanzees were sick and needed monitoring; apparently no such systemic surveillance existed before her arrival. Being fresh out of vet school, she also said she felt she had to defer to the more-experienced vets Lee and Langner. She stated that financial considerations played a role in the standard of care; if she wanted an animal care staffer to stay past quitting time she would have to go through Andrea Lee, the APF's Program Administrator and wife of Director Rick Lee. That would have "meant that Dr. Lee's wife would have gotten all over my case for overtime." Avila said that it was "always a fight" with Andrea Lee—who had no veterinary training whatsoever—and that the "veterinary staff . . . either cowed down to this lady or you had to leave." Avila also stated that Rick Lee, instead of training her as promised, "spent his time in the office doing director kind of activities," and that she hardly ever saw him. Instead, she said her mentors included an online message board, the Veterinary Information Network (VIN).

Dr. Avila posted dozens of messages to the VIN during her year working at the APF. Perhaps the most devastating was posted on September 16, 2002, only hours before Ashley died. Avila explains Ashley's condition, that she was bleeding from a fight and suffered from a condition that makes blood clotting more difficult. After describing how she had treated Ashley to that point, she then asks the chilling, all-revealing question: "Does anyone have other ideas on how to treat?" Many of these messages demonstrate a facility in disarray, and a veterinarian fresh out of vet school who was trying to do the right thing but was clearly in over her head. Avila asked for advice on almost every conceivable subject relating to chimpanzee care: reference texts for chimpanzee nutrition (she noticed what she thought were signs of malnutrition); how to conduct biopsies and take bone marrow samples; how to treat hypertension; how to interpret ultrasounds and x-rays. She repeatedly stated that she conducted her own medical literature searches in attempts to find treat-

ments. She tells of her APF colleagues' ignorance of specific treatments and dangerous side effects of drugs. In a May 23, 2003 post, she states "I recently lost my fifth chimp," then describes how a chimp died after a tooth extraction. Importantly, she states that this chimp had a history of suffering from grand mal seizures when given ketamine, which is one of the only two sedatives allowed at the APF (the other is pharmacologically similar to ketamine), and says that she had just been lucky prior to that because she had given him only very small doses as supplements. She states this is one of the reasons she is resigning. She tells VIN that respiratory diseases, measles and chicken pox have been passed to the chimps from human employees over the past year. She asks about vaccinations, questioning why the APF only vaccinates against tetanus, and is told that there is a standard series of vaccinations recommended for chimpanzees, which includes tetanus, measles, mumps and rubella. She describes her fight against a drug company trying to test a drug for hepatitis C on chimpanzees, since the side effects in humans are so severe and she is concerned that the chimpanzees would suffer, while relating that she "dislike[s] the pressure greatly" that she is getting from the drug company to perform the study. For one chimpanzee, she is "at her wits end" in trying to find a treatment; one she had previously used "led to more edema so I won't be doing that again. Oh well I guess I am learning here," and then asks for suggestions on how to treat. She asks if anyone knows of a procedure for tapping the heart (fluid) of a chimpanzee, and asks "Do I proceed as I would with a dog?" In another revealing post, she asks if anyone has experience with using steroids as an appetite stimulant in chimpanzees, for a 40-year-old. Other vets chime in, saying that old age is not a disease, and that this and some of her other posts indicate that she is treating symptoms, not trying to get diagnosis so she can treat an underlying disease. Avila responds with a devastating indictment of the APF operation: "I am working at getting actual diagnosis before I continue treatments. There is great resistance to this as the old adage 'if it ain't broke don't fix it' applies here on a regular basis! However, it is against my nature to give up and allow people to act foolishly while I clean up the mess they leave behind so I will continue to try to find specific diagnosis and treat those whenever I can." A similar post concerns a self-mutilating chimpanzee; Avila is concerned about the long-term effects of Prozac. Vets chime in again that she should try to determine the underlying cause of the self-mutilation; one vet relates that's what she did, and was able to stop the mutilation and wean a baboon off of Prozac. Avila states that the APF behaviorist pretty much wants to keep the chimpanzee on Prozac forever, and agrees that she should try to find the underlying cause of the self-mutilation.

Maintenance man Ernest Farwell went into great detail about the cases of Rex and Ashley to the D.A.'s investigator. He confirms Dr. Avila's recollection that August 2002 is when CRL instituted the policy of having maintenance/security, such as Farwell, take over from animal care after quitting time. Like the other maintenance man interviewed, Benjamin Thompson, Farwell confirmed that he received no special training in chimpanzee care. He saw Rex unconscious, lying on his side with his mouth open, vomiting, and an animal care staffer suctioning out the vomit with an evacuation wand. He witnessed Dr. Avila say to the animal care staffer "We have to go, he won't let us stay." The animal care staffer then actually removed Rex's life support, and he and Avila left while Rex was still unconscious and vomiting. Farwell later witnessed Rex on his side, but with the vomit coming out of his mouth (since no one was there to suction it out). Rex was found dead later that night; the pathology report showed vomit in his mouth and trachea. Farwell also witnessed Ashley; when he first saw her, he was shocked at the amount of blood in her cage, and she was still bleeding. He then witnessed her shake violently; this was the symptom of shock mentioned by Dr. Avila in her witness statement. Later he found her dead. Farwell also states that APF employees were threatened with polygraph tests when Rick Lee was trying to find out who gave information to the D.A. about the alleged cruelty, and were ordered not to speak with anyone, including the D.A., about the allegations. Such threats violate the 1988 Federal Employee Polygraph Protection Act. This climate of intimidation was also apparent when Farwell complained about having to give medicine to chimpanzees, protesting that he wasn't qualified, explaining "If animal care found a problem with the boilers you wouldn't expect them to fix it." He was then written up and felt threatened, and signed an agreement that he would perform these duties (i.e., care of chimpanzees) and anything else CRL told him to, for apparent fear of losing his job.

The APF had problems from day one; for the first 6 months, the facility did not have requirements for care as basic as euthanasia drugs. This resulted in chimpanzees suffering; CRL actually had to borrow euthanasia drugs from the Coulston Foundation, which was offsite, miles away, and almost bankrupt. Although the chimpanzees lacked for drugs, APF Program Administrator Andrea Lee—who made

decisions on animal care overtime—had plenty; in 2004, she was criminally charged with 15 counts of fraudulently obtaining a controlled substance (Vicodin). She had been illegally using the DEA licenses of two APF veterinarians—at a taxpayer-funded facility—and pled guilty to one count. APF veterinarian Cynthia Doane—not the NIH or CRL management—became suspicious and began to investigate. Further buttressing the existence of a climate of intimidation and fear at the APF, Doane wrote a letter to the New Mexico Board of Pharmacy in April 2004, stating her willingness to help in the investigation, but that “I emphasize, however, that I cannot trust anyone at my place of work at this time.”

Instead of proclaiming its innocence by demanding its day in court, CRL, presumably with the NIH’s blessing, threw up one legal technicality after another in a prolonged effort to hide from the evidence accumulated by the D.A. and to prevent a jury, and the public, from ever seeing it argued in open court. CRL claimed that the State of New Mexico had no jurisdiction to prosecute its own animal cruelty statute because the APF was located on a Federal Air Force Base, despite the fact that the New Mexico legislature had specifically amended its cruelty statute in 2001 because of the chimpanzee abuses at this very same facility. This amendment gave the D.A. the legal authority to prosecute CRL. The company claimed that because the New Mexico cruelty statute did not require qualified personnel, there was no abandonment because untrained security guards were in the vicinity of the critically ill or injured chimpanzees (once per hour). And in the most egregious of all the technicalities, CRL actually claimed that it was engaged in the practice of veterinary medicine in the cases of Rex, Ashley and Topsy, and because the cruelty statute exempts the practice of veterinary medicine, the case should be dismissed. In other words, according to CRL and the NIH, the deliberate policy of denying veterinary care constitutes the practice of veterinary care. Incredibly, the judge agreed with that technicality, and dismissed the case—a dismissal having nothing to do with the merits of the D.A.’s investigation or case. The D.A. appealed, and the case is currently being adjudicated at the New Mexico Court of Appeals, the State’s second-highest court.

RECOMMENDATIONS

IDA believes that given the NIH’s egregious record, Congress should both investigate and hold hearings, not only into the NIH/Coulston/Charles River debacle, but the larger oversight issues raised by the NIH’s actions. One would have thought that, given the years of Coulston Foundation administrative animal welfare violations, the NIH would have been that much more careful in choosing and overseeing a successor. Instead, the facility—now directly owned and managed by the NIH—descended into alleged criminal animal cruelty. Given the NIH’s ten-year record of funding abuse against these chimpanzees, we respectfully request that the NIH be barred from any responsibility whatsoever for them. These chimpanzees have endured enough; the survivors should be placed at a reputable private sanctuary for permanent retirement, with the remainder of the \$42 million contract going to the sanctuary. This would be the morally and ethically correct course of action that is so greatly overdue for these long-suffering chimpanzees.

PREPARED STATEMENT OF INDEPENDENCE TECHNOLOGY

Mr. Chairman and members of the subcommittee, my name is Gregg Howard and I am the Vice President for Sales and Reimbursement for Independence Technology, LLC, a Johnson & Johnson company. I appreciate the opportunity to provide comments in support of the many programs within the jurisdiction of the subcommittee that are important to citizens with disabilities.

The Institute of Medicine report, “Disability in America: Toward a National Agenda,” began with the words “Disability is an issue that affects every individual, community, neighborhood, and family in the United States.” These words are as true today as when the IOM published its report.

The demographic imperative resulting from the aging of the baby boom generation will soon substantially increase the proportion and numbers of Americans in the older age groups that are most at risk of physical and mental impairments, limitations, and disabilities. At the same time, certain trends in other age groups—for example, the increased rates of survival of extremely premature infants, increases in the prevalence of obesity in younger populations and a growing number of disabled Iraq era veterans—are putting more children and younger adults at risk of disabling conditions. Thus, the promotion of good health, independence, and social integration for people with disabilities and the prevention of disabling injuries, diseases, and disorders are more important objectives than ever.

Mr. Chairman, the Labor, Health and Human Services, and Education subcommittee funds the significant majority of Federal programs of interest and benefit to citizens with disabilities. These programs are in the Department of Labor, the Department of Health and Human Services, and the Department of Education. At the end of this statement, we list these many programs in tabular form and include a fiscal year 2007 funding recommendation for each of these programs. We join with the 100 plus organizations of Consortium for Citizens with Disabilities in making these recommendations and would urge the subcommittee's efforts to address these funding needs.

Mr. Chairman, also very importantly, the Social Security Administration, Medicare and Medicaid programs are of significant importance for citizens with disabilities. While these programs are mostly viewed as entitlements and therefore fall in the jurisdiction of the Senate Finance Committee and House Ways and Means Committee, your subcommittee appropriates administrative funds that permit the operations of these programs. On behalf of Independence Technology, LLC, I would like to highlight a matter currently under consideration by administrative personnel at Medicare that will have an important impact on the lives of many disabled Americans.

Independence Technology, LLC, has invested over \$100 million over the last decade to develop a revolutionary new mobility system that allows individuals with disabilities to achieve extensive function and the physical mobility necessary in order to live independently. This innovative technology is the first of its kind to largely eliminate barriers by climbing stairs, improving reach, transversing various surfaces, and balancing the seated user at standing eye level. For many this technology can take the place of more costly and/or drastic alternatives such as moving from one's home, extensive home modifications, use of home health aides, and unnecessary institutionalization or bed confinement.

While this new technology is clearly not appropriate for all individuals with mobility impairments, for the subset disabled of individuals for whom it is appropriate, it is a life changing device which improves health, functional status, independent living, and quality of life. In 2002 and 2003 the Veterans Health Administration evaluated these devices and made a determination as to which subset of disabled veterans could appropriately benefit from the device. Based on this review and policy determination, the Veterans Health Administration now prescribes and provides financial support for the procurement of these devices.

Currently underway at CMS is a similar review process. On January 26, 2006 CMS posted for public comment the application by Independence Technology, LLC, for the development of a National Coverage Determination for an interactive balancing mobility system such as the iBOT. A total of 151 comments were presented to CMS by patients, disability groups, health care providers, and others affected by disabilities. Letters were also sent in support of the application by 10 U.S. Senators and approximately 20 House Members. Overall, 97 percent of the comments provided to CMS on this matter were positive.

The comment period for establishing a National Coverage Determination for "interactive balancing mobility systems" closed on March 5, 2006. CMS now has up to 6 months to announce a decision on the question of proceeding to the development of a National Coverage Determination. It is our view that the establishment of coverage criteria for this new state-of-the-art interactive balancing mobility systems sends an important message that when research and development results in technological advancements improving the health, functional status, independent living, and quality of life, these advances will be made accessible to those who will benefit.

Mr. Chairman, in summary we appreciate the leadership of you and your subcommittee in championing so many important programs of benefit to disabled Americans. While we recognize the limitations placed on the subcommittee by spending ceilings, we would urge your careful review and considerations of the funding recommendations found at the end of this statement. We would also request the subcommittee's support and direct guidance to CMS to support reimbursement policies that will help bring new technological advances such as the iBOT to disabled Americans who stand to benefit from their use.

Thank you for the opportunity to testify.

APPROPRIATIONS RECOMMENDATIONS FOR FISCAL YEAR 2007

[In millions of dollars]

	Fiscal year 2006 final	Fiscal year 2007 President	Fiscal year 2007 CCD
DEPARTMENT OF LABOR			
Workforce Investment Act (selected programs):			
Adult Employment	857.0	712.0	987.9
Pilots, Demonstrations, Research	29.7	17.7	151.0
Youth Activities	940.5	840.5	1,093.4
Office of Disability Employment Policy	27.7	20.0	47.5
Work Incentives Grants	19.5	20.7
DEPARTMENT OF HEALTH AND HUMAN SERVICES			
Health Services Resources Administration:			
Maternal & Child Health Block Grant	693.0	693.0	724.0
Developmental Disabilities Act Programs:			
Basic State Grants—Councils on DD	71.8	72.0	84.5
Protection & Advocacy Systems—DD	38.7	39.0	45.0
University Centers for Excellence in DD	33.2	33.0	37.0
Projects of Nat'l Sig. & Family Support	11.4	11.0	22.6
TBI State Grants	9.0	15.0
TBI Protection & Advocacy Grants	3.1	6.0
Universal Newborn Hearing Screening	10.0	10.0
Centers for Disease Control and Prevention:			
Birth Defects, Developmental Disabilities, & Health	124.7	110.5	137.6
Chronic Disease Prevention	836.6	818.7	417.4
Environmental Health	149.9	141.0	153.0
Preventive Health Block Grant	99.0	133.6
Injury Prevention and Control	139.0	138.2	142.8
Epilepsy Program	7.7	8.0
TBI Registries and Surveillance	5.3	5.3	9.0
National Institutes of Health	28,578.0	28,578.0	29,750.0
Natl. Institute of Child Health and Hum. Dev.	1,264.7	1,257.0	1,327.9
Natl. Institute on Deafness & Other Communication Disorders	393.0	392.0	412.7
Natl. Inst. of Neurological Disorders & Stroke	1,534.8	1,525.0	1,611.5
Natl. Institute on Mental Health	1,403.8	1,395.0	1,474.0
Natl. Institute on Drug Abuse	1,000.0	995.0	1,050.0
Natl. Institute on Alcohol Abuse	435.9	433.0	457.7
Social Services Block Grant	1,683.0	1,200.4	2,380.0
Child Care & Development Block Grant	2,062.1	2,062.0	2,588.0
Head Start	6,876.0	6,786.0	7,300.0
Child Abuse Prevention and Treatment Act	95.2	101.0	142.0
Nat'l Family Caregiver Support Program	162.0	160.0	162.0
Grants to States to Remove Barriers to Voting	10.9	10.9	25.0
Protection & Advocacy for Voting Access	4.9	4.8	10.0
SAMHSA:			
Children's Mental Health Services	104.1	104.1	109.7
PATH Homeless Program	54.3	54.3	57.1
Protection & Advocacy for Indivs. with MI	34.0	34.0	40.0
Mental Health Block Grant	428.5	428.5	451.2
Projects of Regional and Nat'l Significance	263.2	228.1	285.9
DEPARTMENT OF EDUCATION			
Individuals with Disabilities Education Act:			
State and Local Grants Part B	10,582.8	10,682.9	16,938.9
Preschool Grants	380.8	380.8	841.0
Early Intervention Part C	436.4	436.4	680.0
Part D National Programs:			
State Personnel Development	50.1	55.7
Technical Assistance and Dissemination	48.9	48.9	57.6
Personnel Preparation	89.7	89.7	108.7
Parent Information Centers	25.7	25.7	28.6
Technology and Media	38.4	31.1	42.6
Transition Initiative	2.0	5.5
Research and Innovation (Inst. Ed. Sciences)	81.7	81.7	92.4

APPROPRIATIONS RECOMMENDATIONS FOR FISCAL YEAR 2007—Continued

[In millions of dollars]

	Fiscal year 2006 final	Fiscal year 2007 President	Fiscal year 2007 CCD
Rehabilitation Services Administration:			
Rehabilitation State Grant	2,693.0	2,837.2	3,120.0
Client Assistance Programs	11.8	11.8	13.0
Rehabilitation Training	38.4	38.4	42.7
Special Demonstrations	6.5	6.5	28.1
Recreation	3.0	3.0
Protection & Advocacy for Individual Rights	16.5	16.5	22.0
Projects with Industry	20.0	50.0
Supported Employment State Grant	29.7	50.0
Migrant & Seasonal Farm workers	2.0	2.3
Independent Living State Grant	22.6	22.6	25.0
Centers for Independent Living	74.6	74.6	82.9
Independent Living Serv. for Older Blind Ind.	32.9	32.9	36.5
State Assistive Technology Programs and TA	22.4	22.4	29.0
Protection & Advocacy for Assistive Tech.	4.4	6.0
National Institute for Disability & Rehabilitation Research	106.7	106.7	120.0
Demonstration Projects-Disability (Higher Ed.)	6.9	10.0
National Council on Disability	3.1	2.8	3.7
Helen Keller National Center	8.5	8.5	11.7
American Printing House for the Blind	17.6	17.6	20.0

PREPARED STATEMENT OF THE INTERNATIONAL FOUNDATION FOR FUNCTIONAL
GASTROINTESTINAL DISORDERS

SUMMARY OF FISCAL YEAR 2007 RECOMMENDATIONS

- Provide a 5 percent increase for fiscal year 2007 to the National Institutes of Health (NIH) budget. Within NIH, provide proportional increases of 5 percent to the various institutes and centers, specifically, the National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK).
- Accelerate funding for extramural clinical and basic functional gastrointestinal disorders (FGID) and motility disorders research at NIDDK.
- Continue to urge NIDDK to develop a strategic plan on irritable bowel syndrome (IBS) with the purpose of setting research goals, determining improved treatment options for IBS sufferers, and assisting in recruitment of new investigators to conduct IBS research.
- Urge the National Institute of Child Health and Human Development (NICHD) and NIDDK to continue to support research into fecal and urinary incontinence, including the development of a standardization of scales to measure incontinence severity and quality of life and to develop strategies for primary prevention of fecal incontinence associated with childbirth.
- Provide funding to NIDDK and the National Cancer Institute (NCI) for more research on the causes of esophageal cancer.

Chairman Specter and members of the subcommittee, thank you for the opportunity to present this written statement regarding the importance of functional gastrointestinal and motility disorders research. IFFGD has been serving the digestive disease community for fifteen years. We work to broaden the understanding about functional gastrointestinal and motility disorders in adults and children. IFFGD speaks about and raises awareness on disorders and diseases that many people are uncomfortable and embarrassed to talk about. The prevalence of fecal incontinence and irritable bowel syndrome or IBS, as well as a host of other gastrointestinal disorders affecting both adults and children, is underestimated in the United States. These conditions are truly hidden in our society. Not only are they misunderstood, but also the burden of illness and human toll has not been fully recognized.

Since its establishment, the IFFGD has been dedicated to increasing awareness of functional gastrointestinal and motility disorders, among the public, health professionals, and researchers. While maintaining a high level of public education efforts, the IFFGD has also become recognized for our professional symposia. We consistently bring together a unique group of international multidisciplinary investigators to communicate new knowledge in the field of gastroenterology. In the spring

of 2007, IFFGD will be hosting our Seventh International Symposium on Functional Gastrointestinal Disorders, bringing scientists, researchers, and clinicians from across the world together to discuss the current science and opportunities on IBS and other functional gastrointestinal and motility disorders. Also, in November of 2002, we hosted a conference on fecal and urinary incontinence, the proceedings of which were published in *Gastroenterology*, the official journal of the American Gastroenterological Association (AGA). The IFFGD has also been working with the National Institute of Child Health and Human Development (NICHD), the National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK), and the Office of Medical Applications of Research (OMAR) in the NIH Office of the Director on the State of the Science Conference on Fecal and Urinary Incontinence.

The majority of the diseases and disorders we address have no cure. We have yet to completely understand the pathophysiology of the underlying conditions. Patients face a life of learning to manage chronic illness that is accompanied by pain and an unrelenting myriad of gastrointestinal symptoms. The costs associated with these diseases are enormous; estimates range from between \$25–\$30 billion annually. The human toll is not only on the individual but also on the family. Economic costs spill over into the workplace. In essence, these diseases reflect lost potential for the individual and society. The IFFGD is a resource and provides hope for hundreds of thousands of people as they try to regain as normal a life as possible.

IRRITABLE BOWEL SYNDROME (IBS)

IBS strikes people from all walks of life affecting between 25 to 45 million Americans and results in significant human suffering and disability. This chronic disease is characterized by a group of symptoms, which include abdominal pain or discomfort associated with a change in bowel pattern, such as loose or more frequent bowel movements, diarrhea, and/or constipation. Although the cause of IBS is unknown, we do know that this disease needs a multidisciplinary approach in research and often treatment.

IBS can be emotionally and physically debilitating. Because of persistent bowel irregularity, individuals who suffer from this disorder may distance themselves from social events, work, and even may fear leaving their home.

In the House and Senate fiscal years 2004, 2005, and 2006 Labor, Health and Human Services, and Education Appropriations bills, Congress recommended that NIDDK develop an IBS strategic plan. The development of a strategic plan on IBS would greatly increase the institute's progress toward the needed research on this functional gastrointestinal disorder, as well as serve to advance our understanding of this disease, determine improved treatment options for IBS sufferers, and assist in recruiting new investigators to conduct IBS research. NIDDK is formulating an action plan for digestive diseases through the National Commission on Digestive Diseases and has indicated that IBS will be included as a component of this overall plan. IBS must be given sufficient attention, however, in order to increase the FGID and motility disorders research portfolio at NIDDK.

FECAL INCONTINENCE

At least 6.5 million Americans suffer from fecal incontinence. Incontinence is neither part of the aging process nor is it something that affects only the elderly. Incontinence crosses all age groups from children to older adults, but is more common among women and in the elderly of both sexes. Often it is a symptom associated with various neurological diseases and many cancer treatments. Yet, as a society, we rarely hear or talk about the bowel disorders associated with multiple sclerosis, diabetes, colon cancer, uterine cancer, and a host of other diseases.

Damage to the anal sphincter muscles; damage to the nerves of the anal sphincter muscles or the rectum; loss of storage capacity in the rectum; diarrhea; or pelvic floor dysfunction can cause fecal incontinence. People who have fecal incontinence may feel ashamed, embarrassed, or humiliated. Some don't want to leave the house out of fear they might have an accident in public. Most try to hide the problem as long as possible. They withdraw from friends and family, and often limit work or education efforts. Incontinence in the elderly burdens families and is a major reason for nursing home admissions, an already huge social and economic burden in our increasingly aging population.

In November 2002, the IFFGD sponsored a consensus conference—"Advancing the Treatment of Fecal and Urinary Incontinence Through Research: Trial Design, Outcome Measures, and Research Priorities." Among other outcomes, the conference resulted in six key research recommendations:

1. More comprehensive identification of quality of life issues associated with fecal incontinence and improved assessment and communication of treatment outcomes related to quality of life.
2. Standardization of scales to measure incontinence severity and quality of life.
3. Assessment of the utility of diagnostic tests for affecting management strategies and treatment outcomes.
4. Development of new drug compounds offering new treatment approaches to fecal incontinence.
5. Development and testing of strategies for primary prevention of fecal incontinence associated with childbirth.
6. Further understanding of the process of stigmatization as it applies to the experience of individuals with fecal incontinence.

The IFFGD has been working with the NICHD, NIDDK, and OMAR on a State of the Science Conference on Fecal and Urinary Incontinence. The goal of this conference will be to assess the state of the science and outline future priorities for research on both fecal and urinary incontinence; including, the prevalence and incidence of fecal and urinary incontinence, risk factors and potential prevention, pathophysiology, economic and quality of life impact, current tools available to measure symptom severity and burden, and the effectiveness of both short and long term treatment. Once the conference is completed, the NIH must prioritize implementation of the recommendations of this important conference.

GASTROESOPHAGEAL REFLUX DISEASE (GERD)

Gastroesophageal reflux disease, or GERD, is a common disorder affecting both adults and children, which results from the back-flow of acidic stomach contents into the esophagus. GERD is often accompanied by persistent symptoms, such as chronic heartburn and regurgitation of acid. But sometimes there are no apparent symptoms, and the presence of GERD is revealed when complications become evident. One uncommon complication is Barrett's esophagus, a potentially pre-cancerous condition associated with esophageal cancer. Symptoms of GERD vary from person to person. The majority of people with GERD have mild symptoms, with no visible evidence of tissue damage and little risk of developing complications. There are several treatment options available for individuals suffering from GERD.

Gastroesophageal reflux (GER) affects as many as one-third of all full term infants born in America each year. GER results from an immature upper gastrointestinal motor development. The prevalence of GER is increased in premature infants. Many infants require medical therapy in order for their symptoms to be controlled. Up to 25 percent of older children and adolescents will have GER or GERD due to lower esophageal sphincter dysfunction. In this population, the natural history of GER is similar to that of adult patients, in whom GER tends to be persistent and may require long-term treatment.

GASTROPARESIS

Gastroparesis, or paralysis of the stomach, refers to a stomach that empties slowly. Gastroparesis is characterized by symptoms from the delayed emptying of food, namely: bloating, nausea, vomiting or feeling full after eating only a small amount of food. Gastroparesis can occur as a result of several conditions; it can occur in up to 30 percent to 50 percent of patients with diabetes mellitus. A person with diabetic gastroparesis may have episodes of high and low blood sugar levels due to the unpredictable emptying of food from the stomach, leading to diabetic complications. Other causes of gastroparesis include Parkinson's disease and some medications, especially narcotic pain medications. In many patients a cause of the gastroparesis cannot be found and the disorder is termed idiopathic gastroparesis. Over the last several years, as more is being found out about gastroparesis, it has become clear this condition affects many people and the condition can cause a wide range of symptoms of differing severity.

ESOPHAGEAL CANCER

Approximately 13,000 new cases of esophageal cancer are diagnosed every year in this country. Although the causes of this cancer are unknown, it is thought that this cancer may be more prevalent in individuals who develop Barrett's esophagus. Diagnosis usually occurs when the disease is in an advanced stage; early screening tools are currently unavailable.

CHILDHOOD DEFECACTION DISORDERS AND DISEASES

Chronic Intestinal Pseudo-Obstruction (CIP).—About 200 new cases of CIP are diagnosed in American Children each year. Often life threatening, the future for children severely affected with CIP is brightened by the evolving promise of cure with intestinal or multi-organ transplantation.

Hirschsprung's Disease.—A serious childhood and sometimes life-threatening condition that can cause constipation, occurs once in every 5,000 American children born each year. Approximately 20 percent of children with HD will continue to have complications following surgery. These complications include infection and/or fecal incontinence.

Functional Constipation.—Millions of children (1 in every 10) each year will be diagnosed with functional constipation. In fact, it is the chief complaint of 3 percent of pediatric outpatient visits and 10–25 percent of pediatric gastroenterology visits.

FUNCTIONAL GASTROINTESTINAL AND MOTILITY DISORDERS AND THE NATIONAL INSTITUTES OF HEALTH

The International Foundation for Functional Gastrointestinal Disorders recommends an increase of 5 percent for NIH overall, and a 5 percent increase for NIDDK and NICHD. However, we request that this increase for NIH does not come at the expense of other Public Health Service agencies.

We urge the subcommittee to provide the necessary funding for the expansion of the NIDDK's research program on functional gastrointestinal disorders (FGID) and motility disorders. This increased funding will allow for the growth of new research on FGID and motility disorders at NIDDK, a strategic plan on IBS, and increased public and professional awareness of FGID and motility disorders. In addition, we urge the subcommittee to continue to support and provide adequate funding to the Office of Research on Women's Health (ORWH) under the NIH Office of the Director, particularly for their Specialized Centers of Research on Sex and Gender Factors Affecting Women's Health (SCORs) program and the Building Interdisciplinary Research Careers in Women's Health (BIRCWH) program. The ORWH supports important research into IBS.

A primary tenant of IFFGD's mission is to ensure that clinical advancements concerning GI disorders result in improvements in the quality of life of those affected. By working together, this goal will be realized and the suffering and pain millions of people face daily will end.

Thank you.

PREPARED STATEMENT OF THE INDUSTRIAL MINERALS ASSOCIATION—NORTH AMERICA

It appears that the President's 2007 Budget for the Centers for Disease Control (CDC) includes a proposed reduction from \$255.2 million to \$250.2 million in funding for the National Institute for Occupational Safety and Health (NIOSH). IMA-NA notes that the fiscal year 2007 estimate carries forward fiscal year 2006 Conference language to move management and administrative costs (\$34.8 million) from Occupational Safety and Health to Business Services Support. However, please note that the portion of the NIOSH budget to cover CDC overhead apparently has increased from 4.3 percent of NIOSH's budget in 2001 to nearing 14 percent in fiscal year 2007. This fee appears to be taking an increasingly larger share of NIOSH funds that otherwise would be dedicated to occupational safety and health research. IMA-NA encourages you to fund NIOSH as a stand-alone agency within the HHS organizational structure.

IMA-NA also favors increasing the fiscal year 2007 budget to expand the NIOSH in-house mining research program. Recent mining fatalities in the underground coal-mining sector have highlighted the need for a forward-looking initiative to improve mine emergency communications and to develop reliable technologies for tracking the location of underground miners. While IMA-NA supports these research initiatives, there is concern that other critical mine safety and health-related research important to the industrial minerals sector could be affected adversely. IMA-NA encourages you to fund NIOSH mining-related occupational safety and health research programs above current funding levels to address such critical issues as cumulative musculoskeletal trauma, dust control, and noise-induced hearing loss.

The Industrial Minerals Association—North America (IMA-NA) is a trade association organized to advance the interests of North American companies that mine or process industrial minerals. These minerals are used as feedstocks for the manufacturing and agricultural industries and are used to produce such essential products

are glass, paints and coatings, ceramics, detergents and fertilizers. The IMA-NA membership includes producers of ball clay, bentonite, borates, feldspar, industrial sand, mica, soda ash (trona), sodium silicate, talc and wollastonite. IMA-NA's membership also includes many of the suppliers to the industrial minerals industry, including equipment manufacturers, railroads and trucking companies, and consultants.

IMA-NA respectfully requests your support in opposing reductions in funding for occupational safety and health research, particularly as they affect mine safety and health. In the latter regard, we respectfully request additional funding above current levels.

PREPARED STATEMENT OF THE HHT FOUNDATION INTERNATIONAL

Mr. Chairman and honorable members of the committee, thank you for the opportunity to present my family's story in this testimony in support of the HHT Foundation's legislative initiative. I would like express my appreciation to Congresswoman DeLauro for all of her assistance to make this testimony possible.

My name is Jane Ribicoff Silk, I was fortunate to be the daughter of the former Senator Abraham & Mrs. Ruth Ribicoff, but I was unfortunate to have inherited Hereditary Hemorrhagic Telangiectasia (HHT). I am also the past president of the HHT Foundation, International.

HHT is a hidden killer: 20 percent of people with HHT die early or are disabled due to lung or brain involvement.

It is estimated that 70,000–100,000, or 1 in 3,000–5,000 Americans, are affected with Hereditary Hemorrhagic Telangiectasia (HHT). HHT is a genetic disorder, which affects blood vessels of the brain, spinal cord, lung, liver, gastrointestinal tract and most commonly, the nose. The affected blood vessels of the brain, spinal cord, and lung are prone to rupture and may result in stroke, hemorrhage or death. Bleeding from the nose and gastrointestinal tract can cause transfusion dependency and anemia, which can lead to heart failure. HHT can be treated successfully if correctly diagnosed. Children of an affected parent have a 50 percent chance of inheriting HHT.

DISABILITY AND DEATH CAN BE PREVENTED WITH PROPER DIAGNOSIS, SCREENING AND TREATMENT.

Nine of 10 people with HHT are not yet diagnosed due to widespread lack of knowledge by medical professionals.

HHT is a national health problem associated with high health care costs that has long been neglected.

From the time I was a very young child, I experienced the trauma of my grandmother's severe hemorrhages of the nose. The bleeding would not stop. The ambulance came. My grandmother went to the hospital where she received multiple transfusions of blood and came back home, her nose packed with gauze—and still bleeding. This was not an infrequent occurrence. In between her severe nosebleeds, there would be daily nosebleeds lasting for more than an hour. My grandmother died at the age of 67 from a transfusion tainted with hepatitis. The severity of my grandmother's bleeding, and the number of transfusions she needed to keep her alive, can now be prevented with modern therapy.

I realized at an early age that my mother, Ruth Ribicoff, also had a bleeding problem. She bled from her nose multiple times a week and every few months was hospitalized for transfusions due to blood loss. In her mid forties, it was discovered that she was also bleeding from her intestines. Additionally, she had HHT in her liver which caused her heart to pump harder and to enlarge. This eventually led to heart failure. She was often weak and never robustly energetic. Being the wife of a busy congressman, governor, cabinet member and senator put an additional social strain on my mother as she never knew at what inopportune moment she might get a bad nosebleed. Every purse she owned was stocked with a good supply of cotton.

In 1972, my mother died at the age of 64 of complications of the liver, intestinal bleeding and nosebleeds that are treatable today. Even today, it is still not recognized that 9 out of 10 people with HHT are not diagnosed.

My older brother, Peter, has carried the family burden of HHT almost his whole life and is the most impaired of all of us. His quality of life has been greatly diminished and he suffers every day. As a young boy he had occasional nosebleeds. When he was in his 20's he started getting backaches. He went to several doctors who could not help him, including Dr. Janet Travell, President Kennedy's personal back specialist. When he was in his 30's he began to lose sensation in the tops of his legs. An astute physician took some x-rays and noticed some dark spots around his spine.

The only doctor in the world at that time, who used dye to see the blood vessels in the spinal cord, was in Paris. So, my brother took his young family and went to Paris. During his hospitalization, he was told to go home and have exploratory surgery on his spine as there were malformations there that were most likely life threatening. Indeed, they were life threatening. During a 9-hour surgery, it was discovered that his HHT had affected the arteries of his spinal cord. He had had multiple hemorrhages over the years, which had caused his mysterious backaches, and if he had waited much longer, a massive hemorrhage of the malformed blood vessels of the spinal cord would have occurred—which would have either paralyzed him or killed him. So with meticulous care, each tangled and malformed artery snaking through his whole spinal column was tied off. It was not known if he would ever walk again. With extensive rehabilitation he did walk. But the loss of sensation caused by nerve damage was never regained. This has led to a continuously deteriorating condition for my brother. With a loss of sensation in his legs, he has become stooped over, uses a cane for balance and walks with a limp. Also due to his nerve damage, he has multiple complications with his bladder. For years he has had daily nosebleeds. He is in a weakened state all the time and his life has been permanently affected. If recognized early, his spinal cord malformation could have been treated and much suffering prevented.

Adding further insult to injury, my brother's daughter, Judith, a successful young woman, has a liver abnormality associated with HHT. When it was first discovered, doctors thought it was a tumor and almost did a biopsy which could have led to her loss of life. The doctors had no awareness of HHT. Fortunately, because of our experience with the Yale University HHT Center of Excellence and Dr. Robert I. White, Jr., she was taken care of and is now leading a normal life.

Last, but not least is myself. My nosebleeds started in adolescence and in my late teens and early 20's I had nosebleeds that could last 2 hours—and with HHT—you never have advance warning about when they are coming! I have led a pretty normal life, but have never had a lot of stamina.

When I was about 55, I went through a period of time of feeling completely exhausted. A check up at the doctor showed that my liver enzymes were unusually high. In the search for the cause, a CAT scan of my liver was done. What was discovered was something that the doctors in my community had never seen. They were ready to do a liver biopsy. I insisted that the lead doctor speak to the Yale HHT Center of Excellence. They explained that what they were looking at was not uncommon for people with HHT and should not be touched at that time. I am monitored regularly and as I get older, it is clear that of all of those in my family I am the most fortunate.

I have a daughter with HHT and granddaughter with HHT who may one day have children with HHT. I ask for funding so that not only my family, but all future generations will not have to live with HHT themselves or watch a family member slowly deteriorate or die a sudden preventable death.

HOW THE FEDERAL GOVERNMENT CAN HELP

Stroke, lung and brain hemorrhages can be prevented through early diagnosis, screening and treatment. Severe hemorrhages in the nose and gastrointestinal tract can be controlled through intervention and heart failure can be managed through proper diagnosis of HHT and treatments. Access to effective evidence-based interventions and treatment should be established through a joint legislative initiative between the 8 established National HHT Treatment Centers of Excellence and the National Center on Birth Defects and Disabilities Hereditary Blood Disorders Group with a legislative initiative of a \$10 million set aside at the CDC through the HHS Appropriations bill in support of the 8 U.S. HHT Centers. These funds will be used to provide surveillance; create a multi-center clinical database to collect and analyze data; support epidemiological studies; document effectiveness or patient interventions, develop educational programs for health care programs and ultimately improve the quality of life for people living with HHT and future generations.

An additional \$0.75 million is requested for the establishment of an HHT National Resource Center through a partnership between the CDC and the national voluntary agency representing HHT Families. These funds would be used to provide family support, education targeted to families and medical professionals, annual patient conferences, national and international scientific meetings and an aggressive research program. The CDC is ready and willing to work in partnership with the HHT Foundation to accomplish this mission.

Mr. Chairman, again, thank you for the opportunity to testify. On behalf of the HHT Foundation and all of its members I personally appeal to the committee for funding for the 8 HHT Centers of Excellence. We believe this will benefit those with

HHT and also reduce health care costs by the prevention of complications and the development of new therapies for this condition.

PREPARED STATEMENT OF THE LUPUS FOUNDATION OF AMERICA, INC.

As President and CEO of the Lupus Foundation of America, Inc. (LFA) I appreciate the opportunity to submit written comments for the record regarding funding for lupus related programs for fiscal year 2007. The LFA is the Nation's leading non-profit voluntary health organization dedicated to improving the diagnosis and treatment of lupus, supporting individuals and families affected by the disease, increasing awareness of lupus among health professionals and the public, and finding the causes and cure. As you may know, lupus is a debilitating, chronic autoimmune disease that causes inflammation and tissue damage to virtually any organ system; it can cause significant disability or even death. Lupus is the prototypical autoimmune disease; therefore, finding answers to questions about lupus may also provide understanding about other autoimmune diseases that affect 22 million Americans. The leaders and members of the LFA and the 1.5 to 2 million people suffering from lupus respectfully request the following for fiscal year 2007 to reduce and treat suffering from lupus:

- \$29.7 billion for the National Institutes of Health (NIH) to support lupus research. Specifically, we urge Congress to direct NIH to support and bolster lupus research across all relevant institutes, centers, and offices.
- \$1 million in new funding for The Office of Women's Health at the Department of Health and Human Services (HHS) to support a sustained national lupus education campaign. This campaign is directed towards the general public and healthcare professionals who diagnose and treat people with lupus, with emphasis on reaching those individuals at highest risk—women of color—a health disparity that remains unexplained.
- \$1.5 million for the National Lupus Patient Registry (NLPR) at the National Center for Chronic Disease Prevention and Health Promotion within the Center for Disease Control and Prevention (CDC) to sustain current epidemiological efforts, and expand the CDC's work to include all forms of lupus and all affected populations, particularly African Americans, Hispanics, and Asian Americans who are disproportionately at-risk for—and have worse outcomes associated with—lupus.

The purpose of the CDC lupus registry is to collect data and conduct lupus epidemiological studies to better understand and measure the burden of the illness, the social and economic impact of the disease, and stimulate additional private investment by industry in the development of new, safe and effective therapies for lupus. Existing epidemiological data on lupus is decades old and no longer reliable. Population-based epidemiological studies of lupus must be conducted at strategically-located sites throughout the Nation that will provide accurate data on all forms of lupus (i.e. systemic lupus, primary discoid lupus, drug-induced lupus, neonatal lupus, antiphospholipid antibodies) and the disparity among the various racial and ethnic populations.

To ensure that we begin to comprehensively study and understand the dramatic health disparities associated with lupus, the NLPR and associated epidemiological studies must be expanded to include additional sites that constitute a mix of urban and rural areas and contain academic centers with a track record and some existing infrastructure for performing epidemiological studies. Thank you.

I am Dr. Michael Madaio, Professor of Medicine at the University of Pennsylvania School of Medicine, and a lupus researcher. I have been funded for lupus research for over twenty years. I am proud to be affiliated with the Lupus Foundation of America as a member of the Medical Scientific Advisory Board and Chairman of the Medical Advisory Board for the Southeastern Pennsylvania Chapter of the LFA. While I am a nephrologist, since my research and clinical practice is focused on lupus, I really work day-to-day within the realms of nephrology and rheumatology as well as other medical specialties and subspecialty areas. I understand the importance of biomedical research funding and the impact that Federal research funding has had, does have, and can have on the lives of the 1.5 million people living with lupus and the 22 million Americans with other autoimmune diseases.

After a tragic 40 year dearth of new treatments to manage this often debilitating and devastating disease, the good news is that we finally are on the brink of major breakthroughs, thanks to research sponsored by the National Institutes of Health. Exciting research and strides in treatments for people with lupus are on the horizon and a sustained investment now in lupus research will speed the day to better treatments and a cure. Specifically, I am conducting extensive research on lupus nephri-

tis, which is kidney involvement in lupus disease. My field is advancing rapidly, due in large part to factors directly dependent on NIH funding:

- the burgeoning growth in the number of new animal models, including a wealth of informative transgenic and gene-targeted mutants;
- increased access to improved powerful technologies such as gene and protein arrays, now available at many institutions and to many investigators through NIH core facilities;
- new technologies that permit successful query of the very small amounts of human tissue typically available from patients and, collaboration across disciplines and across institutions to bring crucial expertise together;
- new insights into underlying biology and pathophysiology in immunity and lupus are constantly emerging;
- technologies to identify biomarkers are improved and accessible; and
- new approaches to therapy are being explored.

These endeavors are bearing fruit but they are highly dependent on NIH funding. If funding for the NIH is cut or level funded, it could cripple or paralyze current lupus research efforts.

As lupus is a systemic disease that can affect any organ or tissue elucidating pathogenesis (or cause) and treatments of lupus will have direct impact on many other autoimmune diseases (e.g. results and treatments translating to other diseases). Providing adequate resources to support lupus research will help the Nation turn the corner on finding better treatments or a cure for lupus while also supporting breakthroughs and progress for other disease states. It is important to note that the corollary is true: cuts in lupus research funding also will have an adverse effect on progress for lupus and for progress in related diseases. Cuts in NIH funding could bring to a standstill support of clinical trials and large observational studies, and could curtail research on those at highest risk for lupus, women of color; it also could negatively impact pediatric research at a time when researchers have just begun to undertake studies in important new areas. Furthermore, insufficient Federal funding also could slow much-needed genetic research when we are just discovering the critical components that may contribute to lupus and its effects. Therefore, it is critical that biomedical researchers be provided the necessary resources to continue seeking answers to the questions that will lead to better lupus treatments. Increased research funding will help deliver much-needed breakthroughs from the laboratory to patients in need.

The National Institute of Arthritis and Musculoskeletal and Skin Diseases (NIAMS), the institute most involved in lupus research, is one of the smallest institutes at NIH. In the past two years there has been a decrease in research funding for NIAMS overall, with a ten percent decrease in new research grants. Currently, only 12–15 percent of the grant applications submitted to NIAMS receives funding. Further cuts will cause this rate to drop precipitously to below 10 percent next year. Just two or three years ago, funding levels were at 25–30 percent. Cuts in research funding, coupled with the rate of biomedical research inflation (3–4 percent per year), further erode NIAMS' ability to fund lupus research grant applications at the rate necessary to begin making real progress. As such, an increase above the rate of biomedical research inflation is necessary to allow NIH to sustain and build on its research progress resulting from the recent budget doubling while avoiding the severe disruption to that progress that would result from a lesser increase or cut.

Furthermore, in the proposed budget for NIAMS for 2007 there will be a loss of 10 training grants; each grant funds training for four physicians, mostly rheumatologists. Young and senior investigators alike are moving into other fields because of the lost of funding. Exacerbating the situation, medical schools are struggling financially due to public funding cuts thus eliminating any safety net for researchers that may have previously existed. As a result, young investigators are not attracted to lupus research which means there will be not be a future generation of lupus scientists and clinicians to do research. Moreover, after having attracted scientists to translational immunology in the last five to ten years, when funding was increasing, there is now a possibility we could lose both the current and next generation of young investigators. Increased funding is necessary to support an adequate number of training grants. Without research and training funds lupus researchers might be forced to become private practice physicians instead, leading to an imbalance in the health care system: sufficient numbers of physicians to treat lupus patients, but no new treatments with which to care for them, and no researchers to develop the cures of tomorrow.

We recognize and appreciate that Congress and the Nation face unprecedented fiscal challenges; however, we cannot afford to lose ground in biomedical research at such a promising time. The LFA looks forward to working with the subcommittee and others in Congress to reduce and prevent the suffering caused by lupus. We

stand ready to serve as a resource for any information you may need in this regard and thank you for this opportunity to submit written testimony for the record concerning fiscal year 2007 lupus related funding.

PREPARED STATEMENT OF THE MARCH OF DIMES BIRTH DEFECTS FOUNDATION

The 3 million volunteers and 1,400 staff members of the March of Dimes appreciate the opportunity to submit the Foundation's Federal funding recommendations for fiscal year 2007. The March of Dimes is a national voluntary health agency founded in 1938 by President Franklin D. Roosevelt to prevent polio. Today, the Foundation works to improve the health of mothers, infants and children by preventing birth defects, premature birth and infant mortality through research, community services, education, and advocacy. The March of Dimes is a unique partnership of scientists, clinicians, parents, members of the business community, and other volunteers affiliated with 52 chapters in every State, the District of Columbia, and Puerto Rico.

The volunteers and staff of the March of Dimes are deeply concerned that the funding recommendations in the President's Budget are not sufficient to meet the challenge of improving the health of women and children across the Nation. Continued under-funding of critical research and public health programs imperils the health of mothers and children today and in the future. In our judgment, the funding increases recommended below would lead to an immediate positive impact on reducing the incidence of preterm birth and birth defects, as well as making newborn screening for treatable metabolic and functional disorders more widely available.

NATIONAL INSTITUTES OF HEALTH

The March of Dimes joins the larger research community in recommending a 5 percent increase in funding for the National Institutes of Health (NIH), bringing total Federal support to just under \$30 billion. The administration's fiscal year 2007 budget recommendation would necessitate absolute reductions in research investments as the levels of funding proposed are insufficient even to keep up with inflation and certainly will not sustain the necessary investment in medical research.

National Institute of Child Health and Human Development

The March of Dimes recommends a 5 percent increase for NICHD in fiscal year 2007 and an increase of at least \$100 million over the next five years to boost prematurity-related research. Additional resources are needed to support research on the causes of preterm labor and delivery and on strategies for improving the care and treatment of infants born prematurely or at low birth weight. In addition, funding should be provided to enable the Institute to work with the Office of the Director of NIH to create a comprehensive strategic plan for this research that includes coordination of strategies and studies across multiple Institutes.

Since 1981, the preterm birth rate has increased 33 percent resulting in more than 500,000 premature births in 2004—that is 1 in 8 births. Preterm birth is the leading cause of death in the first month of life and, for those babies who do survive, one in 5 experiences multiple health problems including cerebral palsy, mental retardation, chronic lung disease, and vision and hearing loss. Preterm labor can happen to any pregnant woman, and the causes of nearly half of all premature births are unknown. This growing problem is a tragedy for families and expensive for the Nation. In 2003, the national hospital bill for the care of babies with a primary or secondary diagnosis of prematurity exceeded \$18 billion, half of which was borne by Medicaid and other public programs and the remainder was charged to employers and families. Until we know how to prevent preterm labor, the worsening incidence of prematurity means that overall hospital charges will also spiral upward.

In recent years, the NICHD has made a major commitment to increasing our understanding of the factors that result in premature birth and to developing strategies to prolong pregnancy. But additional work is needed and adequate funding is key.

An area deserving more support is the collaborative Maternal-Fetal Medicine Units (MFMU) and Neonatal Research (NR) collaboratives. One clinical trial funded through the MFMU network reported a promising preventive intervention that relies on a derivative of the hormone progesterone. The incidence of preterm delivery was reduced by up to 30 percent in women who received weekly injections of the compound compared to the women who were given a placebo. The results of this intervention are impressive and additional funding is needed to support further clinical trials of this promising intervention.

Finally, the March of Dimes urges the subcommittee to include in its bill an increase of \$57 million for the National Children's Study (NCS). While the amount may seem substantial, it is dwarfed by the cost of treating the diseases and conditions the study is designed to address. If allowed to go forward, the NCS will generate groundbreaking research that greatly increases our knowledge of the role family genetics and the environment play in the health and development of children. Planning for this study has been completed; the Vanguard sites have been designated. The project is poised to start implementation which will yield critical information for research on preterm birth. The NCS will prove a rich and ongoing information resource for use by scientists and clinicians to develop treatments and preventive measures tailored for the pediatric population. Failure to provide the resources needed for this study would be extremely shortsighted.

CENTERS FOR DISEASE CONTROL AND PREVENTION (CDC)

Safe Motherhood/Infant Health

The National Center for Chronic Disease Prevention and Health Promotion, Division of Reproductive Health works to promote optimal reproductive and infant health. The March of Dimes recommends a \$20 million increase in fiscal year 2007 to support expansion of research to identify risk factors and to develop strategies for preventing preterm birth. This can be accomplished with increased funding for the two programs described below:

1. The Pregnancy Risk Assessment Monitoring System (PRAMS) is a state-specific, population-based surveillance system designed to identify and monitor selected maternal behaviors and experiences before, during, and after pregnancy. Data collected through PRAMS is used to increase understanding of maternal behaviors and experiences and their relationship to adverse pregnancy outcomes, to improve maternal and child health programs, and to facilitate the dissemination of the latest research findings and clinical practice standards. The March of Dimes recommends an increase of \$5 million to improve PRAMS so that CDC can develop national estimates on behavioral and demographic risk factors for preterm birth.

2. Epidemiological research conducted at CDC is vital to the prevention of preterm labor and delivery. The March of Dimes recommends an increase of \$15 million for the expansion of basic etiologic research, research on women at risk for preterm delivery and the social and environmental factors contributing to higher rates of preterm delivery in African-American women. Increasing CDC's research activities related to preterm birth will lead to improvements in screening and early detection and new interventions for women at risk for preterm labor.

National Center on Birth Defects and Developmental Disabilities

The March of Dimes recommends a minimum of \$135 million in fiscal year 2007 funding for the National Center on Birth Defects and Developmental Disabilities (NCBDDD). NCBDDD conducts programs to protect and improve the health of children by: (1) preventing birth defects and developmental disabilities; and (2) promoting optimal development and wellness among children with disabilities. Of particular interest to the March of Dimes is NCBDDD's birth defects program that includes surveillance, research and prevention activities. For fiscal year 2007, the March of Dimes requests an increase of \$6 million to support surveillance and research and an additional \$2 million for folic acid education. These modest increases are vital to making progress in reducing the incidence of birth defects.

In the United States, about 3 percent of all babies are born with a major birth defect. Birth defects are the leading cause of infant mortality accounting for more than 20 percent of all infant deaths every year. Children with birth defects who survive often experience long term physical and mental disabilities, and are at increased risk for developing other significant health problems. In fact, birth defects contribute substantially to the Nation's health care costs. According to CDC, the lifetime cost of caring for infants born with one of the 18 most common birth defects exceeds \$8 billion annually.

NCBDDD provides funding to assist States with community-based birth defects tracking systems, programs to prevent birth defects and improve access to health services for children with birth defects. In 2006, CDC has been able to support only 15 States in their efforts to improve surveillance programs, down from 28 States in fiscal year 2004. Additional resources are sorely needed to help States seeking assistance.

The causes of nearly 70 percent of birth defects are unknown and it is therefore critical that the Committee increase funding for the National Birth Defects Prevention Study. This groundbreaking CDC initiative is being carried out by 9 regional Centers for Birth Defects Research and Prevention located in Arkansas, California,

Georgia, Iowa, Massachusetts, New York, North Carolina, Texas, and Utah. Each of these centers obtains data on infants with major birth defects through interviews with their mothers and biological samples that provide information about medical history, environmental exposures, and lifestyle before and during pregnancy. The study focuses on both genetic and environmental causes, including medication use during pregnancy, maternal diet and vitamin use. This study is an ongoing source of information for use in research on the causes of birth defects. With adequate funding this study has the potential to dramatically increase our understanding of the causes of birth defects and will provide information for developing effective preventive measures.

NCBDDD is conducting a national public and health professions education campaign designed to increase the number of women taking folic acid. CDC estimates that up to 70 percent of neural tube defects (NTDs), serious birth defects of the brain and spinal cord including anencephaly and spina bifida could be prevented if all women of childbearing age consume 400 micrograms of folic acid daily, beginning before pregnancy. Since fortification of grain products with folic acid in 1996, the rate of NTDs in the United States has decreased by 26 percent, but more must be done to educate every woman of childbearing age and the health professionals who treat them about the importance of taking folic acid daily.

Finally, the March of Dimes recommends that additional funds be provided to conduct surveillance and epidemiological research on cerebral palsy through the network already in place for autism (Centers of Excellence for Autism and Developmental Disabilities Research and Epidemiology). Cerebral palsy is one of the most common developmental disabilities and there is currently very limited surveillance and research being conducted.

National Immunization Program

If the Nation is to meet the Healthy People 2010 goals of vaccinating 90 percent of children and adults, CDC, States, and localities will need the resources required to reach those in need of immunizations. According to the CDC, nearly 25 percent of two-year-olds have not received all of the recommended vaccine doses. CDC's National Immunization Program provides grants to 64 State, local, and territorial public health agencies to reduce the incidence of disability and death resulting from 12 vaccine preventable diseases. The March of Dimes urges the subcommittee to continue its longstanding policy of ensuring that Federal vaccine programs are well funded. For fiscal year 2007, the March of Dimes recommends \$802.4 million to ensure that the National Immunization Program has the resources it needs to account for vaccine price increases, introduction of new vaccines, and to implement recommendations by the Institute of Medicine.

Polio Eradication

The March of Dimes supports a funding level of \$101.254 million for CDC's fiscal year 2007 global polio eradication activities. Level with fiscal year 2006, this funding would allow CDC to continue its supplementary immunization activities in the remaining endemic and high-risk countries in Africa and Asia and to move quickly to interrupt polio transmission in these regions. The U.S. Government must maintain its commitment to the worldwide eradication initiative that promises to save lives and reduce unnecessary health-related costs globally.

National Center for Health Statistics

The National Center for Health Statistics (NCHS) provides data essential for both public and private research and programmatic initiatives. The National Vital Statistics System and the National Survey on Family Growth, for example, are major sources of information on the utilization of prenatal care and on birth outcomes, including preterm delivery, low birthweight and infant mortality. Increased funding would enable CDC to introduce web-based technology to facilitate more rapid and accurate compilation of data obtained from health professionals and facilities. This information is used to track trends in birth outcomes and to support State birth defects registries. Data from NCHS surveys are also used to identify emerging trends and to optimize use of existing program resources.

HEALTH RESOURCES AND SERVICES ADMINISTRATION (HRSA)

Newborn Screening

Newborn screening is a vital public health activity used to identify genetic, metabolic, hormonal and/or functional conditions in newborns that if left untreated can cause disability, mental retardation, and even death. Although nearly all babies born in the United States are screened for some genetic birth defects, the number of these tests varies from State to State. The March of Dimes recommends that

every baby born in the United States receive, at a minimum, screening for a core set of 28 metabolic disorders plus hearing deficiencies.

In fiscal year 2005 and fiscal year 2006, Congress provided funding for implementation of Title XXVI of the Children's Health Act of 2000; specifically, to fund the Regional Genetic Service and Newborn Screening Collaboratives that work to address the maldistribution of genetic services and resources and bring services closer to local communities. The March of Dimes supports an appropriation of \$25 million to enable HRSA to improve the capacity of States to: (1) provide screening, counseling, testing, and special services for newborns and children at risk for heritable disorders; (2) educate health professionals and parents on the availability and importance of newborn screening; and (3) support States with technical assistance on the acquisition and use of new technologies and newborn screening services.

Healthy Start

The Healthy Start Initiative is a collection of community based projects focused on reducing infant mortality, low birthweight and racial disparities in perinatal outcomes. The March of Dimes strongly supports Healthy Start and urges continued funding for this important program to decrease this Nation's tragically high rate of infant mortality.

Maternal and Child Health Block Grant

In recent years, Federal funding for Title V of the Social Security Act, the Maternal and Child Health (MCH) Block Grant, has not kept pace with increased demand for services. Although the MCH Block Grant provides assistance for a growing number of community-based programs (such as home visiting, respite care for children with special health care needs and "wrap around" services for pregnant women and children enrolled in Medicaid and SCHIP), the funding level was reduced by \$24 million in fiscal year 2006. In order for maternal and child health programs to shoulder responsibility for additional beneficiaries and services, funding must be increased. The March of Dimes recommends full funding of the MCH Block Grant at the authorized level of \$850 million.

Consolidated Health Centers

Consolidated (Community) Health Centers are an important source of obstetric and pediatric care for more than 15 million individuals, approximately 40 percent of whom are uninsured. The Foundation recommends new funding sufficient to increase the number of centers and to improve the scope of perinatal services provided. Adding funds to this program would be consistent with the President's five-year plan to create and expand health center sites in 1,200 communities and to increase the number of patients served annually to more than 16 million.

Thank you for the opportunity to testify on the federally supported programs of highest priority to the March of Dimes. The Foundation's volunteers and staff in every State, the District of Columbia, and Puerto Rico look forward to working with members of the subcommittee to improve the health of the Nation's mothers, infants and children.

PREPARED STATEMENT OF THE MEDICAL LIBRARY ASSOCIATION AND THE ASSOCIATION OF ACADEMIC HEALTH SCIENCES LIBRARIES

Mr. Chairman, thank you for the opportunity to testify today on behalf of the Medical Library Association (MLA) and the Association of Academic Health Sciences Libraries (AAHSL) regarding the fiscal year 2007 budget for the National Library of Medicine (NLM). I am Marianne Comegys, Director of the Louisiana State University Health Sciences Center Library, Shreveport, Louisiana.

MLA, a nonprofit educational organization established in 1898, comprises health sciences information professionals with more than 4,500 members worldwide. Through its programs and services, MLA provides lifelong educational opportunities, supports a knowledgebase of health information research, and works with a global network of partners to promote the importance of quality information for improved health to the health care community and the public.

AAHSL is comprised of the directors of the libraries of 142 accredited United States and Canadian medical schools belonging to the Association of American Medical Colleges (AAMC). Together, MLA and AAHSL address health information issues and legislative matters of importance through a joint task force.

Mr. Chairman, the National Library of Medicine (NLM), on the campus of the National Institutes of Health (NIH) in Bethesda, Maryland, is the world's largest medical library. NLM collects material in all areas of biomedicine and health care, as

well as works on biomedical aspects of technology, the humanities, and the physical, life, and social sciences.

With respect to the Library's budget for the coming year, I would like to touch briefly on six issues: (1) the growing demand for NLM's basic services; (2) NLM's outreach and education services; (3) Emergency preparedness and response; (4) NLM's health information technology activities; (5) NLM's facility needs; and (6) NLM's infrastructure that supports the NIH Public Access Policy.

THE GROWING DEMAND FOR NLM'S BASIC SERVICES

Mr. Chairman, it is a tribute to NLM that the demand for its collections continues to steadily increase each year. These collections stand at 8.5 million items-books, journals, technical reports, manuscripts, microfilms, photographs, and images. Housed within the library is one of the world's finest collections of old and rare medical works. NLM is a national resource for all U.S. health science libraries through the National Network of Libraries of Medicine. Increasingly, it is also becoming an international resource for world-wide research collaboration.

Our Nation's healthcare providers, researchers, and consumers all use the library's collections, through the reading rooms or through interlibrary loan, and on the World Wide Web. Increasingly, NLM's collection is also available in digital form. NLM is developing a strategy for selecting, organizing, and ensuring permanent access to digital information. By doing so they are ensuring their availability for future generations. This availability of health information remains the highest priority for the Library.

Mr. Chairman, simply stated, NLM is a national treasure. I can tell you that without NLM our Nation's medical libraries would be unable to provide the quality information services that our Nation's healthcare providers, educators, researchers, and patients, have all come to expect.

Recognizing the invaluable role that NLM plays in our healthcare delivery system, the Medical Library Association and the Association of Academic Health Sciences Libraries join with the Ad Hoc Group for Medical Research Funding in recommending a 5 percent increase for NLM and NIH overall in fiscal year 2007.

OUTREACH AND EDUCATION

NLM's outreach programs are of particular interest to both MLA and AAHSL. These activities, designed to educate medical librarians, healthcare professionals and the general public about NLM's services, are an essential part of the Library's mission.

The Library has taken a leadership role in promoting educational outreach aimed at public libraries, secondary schools, senior centers, and other consumer-based settings. NLM's emphasis on outreach to underserved populations assists the effort to reduce health disparities among large sections of the American public.

NLM's "Partners in Information Access" program is designed to improve the access of local public health officials to health information. The establishment of additional programs across the country will go a long way towards ensuring that healthcare workers across America are familiar with NLM and the National Network of Libraries of Medicine. My own facility, the LSU Health Sciences Center in Shreveport, Louisiana, participates in this program. Through it, we are able to train public health workers on how to access health information online.

We ask the Committee to encourage NLM to coordinate its outreach activities with the medical library community.

PubMed Central

The medical library community also applauds NLM for its leadership in establishing PubMed Central, an online repository for life science articles. Introduced in 2000, PubMed Central was created by NLM's National Center for Biotechnology Information and evolved from an electronic archiving concept proposed by former NIH director Dr. Harold Varmus. The site houses 615,000 articles from 232 journals including the Proceedings of the National Academy of Sciences and Molecular Biology of the Cell.

The medical library community believes that medical librarians should continue to play a key role in the further development of PubMed Central and we are pleased that medical librarians are members of the PubMed Central Advisory Committee. Because of the high level of expertise health information specialists have in the organization, collection, and dissemination of medical literature, we believe that our community can assist NLM with issues related to copyright, fair use, and information classification. We look forward to continuing our collaboration with the Library as this exciting project continues to evolve.

MEDLINEplus

MEDLINEplus [<http://www.nlm.nih.gov/medlineplus>], a source of authoritative, full-text, health information resources from the NIH institutes and a variety of non-Federal sources, has grown tremendously in its coverage and its usage by the public. In January of 2006, MEDLINEplus had 8.6 million unique visitors research 67 million pages of health information (including information from over 1,250 organizations). MEDLINEplus's features include illustrated interactive patient tutorials, a daily news feed from the public media on health-related topics, and the NIH SeniorHealth website [<http://www.nihseniorhealth.gov>], a collaborative project between NLM and the National Institute on Aging.

"Go Local" is another new and exciting feature of MEDLINEplus. Go Local enables local and State agencies and others to participate by creating sites that connect the MEDLINEplus information seeker to local hospitals, pharmacies, doctors, and other health services. These agencies use the infrastructure created by NLM that makes this possible. Using Go Local, a search by topic on MEDLINEplus will lead the consumer to local services connected to that topic. Currently, there are fourteen localities participating in the Go Local service, and many more will be added in the near future. Through this service, NLM and MEDLINE are becoming increasingly valuable tools, not just for medical librarians and other health professionals but also for the health consumer.

Clinical Trials

Mr. Chairman, I also want to address another frequently used service offered by NLM—its clinical trials database [<http://www.clinicaltrials.gov>]. This listing of more than 27,000 Federal and privately funded trials for serious or life-threatening diseases was launched in February 2000 and currently logs more than 8 million page views per month and 25,000 visitors daily. The clinical trials database is a free and invaluable resource to patients and families interested in participating in cutting edge treatments for serious illnesses. The medical library community congratulates NLM for its leadership in creating ClinicalTrials.gov and looks forward to assisting the Library in advancing this important initiative.

EMERGENCY PREPAREDNESS AND RESPONSE

Since the late 1960s, NLM has been actively involved in disaster response and management. As a Louisiana resident, I am pleased to report about NLM's relief work in response to Hurricane Katrina. NLM's Specialized Information Services (SIS) Division compiled a Hurricane Katrina Web page on toxic chemical and environmental health information resources. The Web page provided links to information on chemicals that may have been released and on environmental concerns following the wind and flood damage. The page also linked to the Wireless Information System for Emergency Responders (WISER). WISER provides information on 400 of the most hazardous chemicals in NLM's Hazardous Substances Databank. It can be downloaded to a Personal Digital Assistant (PDA) or field laptop, providing first responders with ready access to basic emergency haz-mat information. At the request of the Environmental Protection Agency, NLM provided 15 PDAs loaded with WISER for the EPA National Decontamination Team to take with them when they were deployed to New Orleans. In addition, NLM's National Center for Biotechnology Information (NCBI) has provided assistance to the State of Louisiana in identifying Katrina victims with software tools that improve speed and accuracy of DNA identification.

In addition to NLM's efforts on the national level, the South Central Regional office of the NLM-supported National Network of Libraries of Medicine provided specific help to the libraries in its territory that were impacted by Katrina. When librarians were dispersed to remote sites, the Regional office purchased laptops and printers for them to use. Arrangements were also made for Katrina-area libraries to have free interlibrary loans. The South Central Regional office also created a blog, "Hurricane Katrina in the SCR," for librarians to post information regarding colleagues and building conditions. During the first few weeks after Katrina, when we were unsure of where our friends had relocated and how to contact them, the blog was an invaluable resource for helping us to find them and for suggesting ways to assist them.

Mr. Chairman, we applaud the success of NLM's outreach initiatives, particularly those initiatives that reach out to medical libraries and healthcare consumers. We look forward to continuing our work with the Library in fiscal year 2007 on these important programs.

HEALTH INFORMATION TECHNOLOGY AND BIOINFORMATICS

Mr. Chairman, NLM played a major role in creating and nurturing the field of medical informatics. For nearly 35 years, the Library has supported informatics research and training and the application of advanced computing and communications to biomedical research and health care delivery. Many of today's informatics leaders are graduates of NLM-funded informatics research programs at universities across the country. Many of the country's exemplary electronic health record systems (e.g., in Indianapolis, Vanderbilt, and Pittsburgh) benefited from NLM grant support. The Library began supporting informatics research that addresses information management problems relevant to disaster management several years ago. It has also funded innovative telemedicine projects in various rural and urban medically underserved communities, as models for evaluating the impact of telemedicine on cost, quality, and care. A leader in supporting, licensing, developing, and disseminating standard clinical terminologies for free nationwide use, NLM works closely with the National Coordinator of Health Information technology to promote adoption of interoperable electronic records. Through its National Center for Biotechnology Information, NLM creates and provides access to GenBank, the genetic sequence repository, and a wide array of related scientific data and analysis tools. These publicly accessible resources are speeding the pace of scientific discovery around the world, including important insights into the evolution of the flu. Building on this success, NLM will develop databases to manage the vast amount of genetic, medical and environmental information that will emanate from new HHS and NIH efforts to analyze genetic variation in groups of patients with specific illnesses and to devise new ways of monitoring personal environmental exposures that interact with genetic variations and result in human diseases.

We are pleased that NLM is supporting informatics research that addresses information management problems relevant to disaster management. Medical librarians and health information specialists have an important role to play in supporting these cutting edge technologies and in serving as important sources of health information for those displaced by disasters. We encourage Congress and NLM to continue their strong support of NLM's medical informatics and genomic science initiatives, at a point when the linking of clinical and genetic data holds increasing promise for enhancing the diagnosis and treatment of disease. MLA and AAHSL also support Health Information Technology initiatives in the Office of the National Coordinator for Health Information Technology (ONCHIT) and the Agency for Healthcare Research and Quality (AHRQ) that build upon initiatives housed at NLM.

NLM'S FACILITIES NEEDS

Mr. Chairman, over the past two decades NLM has assumed several new responsibilities, particularly in the areas of biotechnology, health services research, high performance computing, and consumer health. As a result, the Library has had tremendous growth in its basic functions related to the acquisition, organization, and preservation of an ever-expanding collection of biomedical literature. In order to complete these functions, NLM has had to expand its staff. NLM now houses 1,100 staff in a facility built to accommodate only 650. This increase in the volume of biomedical information and in the number of personnel has led to a serious shortage of space at the Library.

In order for NLM to continue its mission as the world's premier biomedical library, a new facility is urgently needed. The NLM Board of Regents has assigned the highest priority to supporting the acquisition of a new facility. The medical library community is pleased that Congress appropriated the necessary architectural and engineering funds for the design of the facility expansion at NLM in 2003. The community is also pleased that the American Center for Cures Act, (S. 2104) introduced in the Senate by Senator Lieberman, asks Congress to make a special effort to fund the expansion of NLM's facilities.

We encourage the subcommittee to provide the resources necessary to construct a new facility and to support the Library's health information programs.

NIH PUBLIC ACCESS POLICY

MLA and AAHSL support the goals of the NIH public access policy to create a central archive of NIH-funded research publications to advance science and enable NIH to better manage its research portfolio, and to provide electronic access to the public to NIH-funded research publications. We are concerned, however, that the current rate of participation in the voluntary policy is low—less than 4 percent. Information provided by the NIH Public Access Working Group indicates that the sub-

mission system is not difficult to use and that the majority of NIH-funded researchers appear to know about the policy. For these reasons, we concur with the conclusion of NLM's Board of Regents, that the NIH Policy cannot achieve its stated goals unless deposit of manuscripts becomes mandatory. We also support the Board of Regents' recommendation that NIH and NLM develop a careful plan for transitioning to a mandatory policy, and to provide clear guidance and a reasonable timetable to minimize burden on NIH-funded researchers and grantee institutions, and also to work with publishers to make it easy for them to submit articles on behalf of their NIH-supported authors.

We encourage Congress to continue to ask for periodic evaluation of the plan as it is implemented in the coming months and years.

Mr. Chairman, thank you again for the opportunity to present the views of the medical library community.

PREPARED STATEMENT OF THE MENDED HEARTS, INC.

The Mended Hearts, Inc. (MHI) is a national nonprofit organization that offers the gift of hope to heart patients, their families and caregivers for more than 50 years. Mended Hearts has 21,000 members operating through 280 community-based chapters across the country, with two in Canada. Chapters partner with more than 450 hospitals and cardiac care facilities in providing patient-to-patient support services. I have been appointed by the group as their legal representative—a volunteer position. I am a heart disease survivor.

About 30 years ago, I was diagnosed with a rare heart disease. After having chest discomfort and trouble breathing for more than two years, I was diagnosed with hypertrophic cardiomyopathy (HCM), a disease in which the heart enlarges. The heart muscle gradually thickens so much that heart cannot pump blood out effectively. The new heart muscle replacing the old heart tissue does not grow in the normal parallel pattern. Instead, it grows in a helter-skelter pattern. Studies show that 36 percent of young athletes who die suddenly have probable or definite hypertrophic cardiomyopathy, but it also affects men and women of all ages. HCM is one of the major causes of sudden death due to cardiac arrhythmias. There is no cure for HCM. However, medication may work, and there is surgery, which may alleviate the pain and discomfort, prolonging the patient's life. If surgery does not work, the alternative is a heart transplant, but donor organs are scarce. The doctor who made my diagnosis was trained at the National Institutes of Health's (NIH) National Heart, Lung, and Blood Institute (NHLBI).

Initially, I received several medications, which enabled me to engage in most activities. However, some activities, such as walking up hills, caused shortness of breath and severe chest pains. But, generally I could function normally. After about 10 years, the discomfort was increasing, and it became apparent that I was in serious trouble. I could not walk sixty feet without having to stop to catch my breath. Sometimes the pain was so severe that I would almost double over in the middle of the street. My wife told me later that my face would become gray. And the perspiration would pour off my body. The quality of my life had deteriorated so drastically that I knew I needed some treatment.

In 1988, I went to Georgetown Hospital for an angiogram—the gold standard for diagnosing heart problems. After the test, the cardiologist told me that he had bad news and worse news. The bad news was that I had a 95 percent blockage in my left anterior descending heart artery at the location known as the “widow-makers spot.” The worse news was that I had a major chance of suffering a severe heart attack, with less than a 5 percent chance of survival because of the HCM. At this point, my wife was quietly crying and I was perspiring profusely.

Because Georgetown Hospital did not have the expertise to operate on my condition, they called the NIH to see if they would accept me as a patient. I was sent home pending notice from NIH. I knew that I had run out of alternatives. No matter what the results, I needed treatment and I needed it immediately.

Subsequently, the NIH accepted me. After entering the NHLBI on February 9, my surgery occurred on February 11, 1998. No matter how trite the expression, it is very true—the day after surgery was the first day of the rest of my life. The surgery, a left ventricular myotomy and myectomy, was considered drastic. I was later told that the mortality rate was as high as 10 percent. That surgery is still done in only a few hospitals. It is considered the gold standard for the treatment of HCM. This Murrow Procedure, in honor of the innovator, was developed and improved at the NIH.

Currently, there is a new experimental protocol in which the same effect is now being attempted by using alcohol to deaden the excessive heart tissue, instead of

removing a piece of heart muscle from the heart's main pumping chamber, as was done in my case.

Now, I am on medication for the rest of my life. My condition is progressive. More than 10 years ago, I was fitted with a pacemaker to ensure that my heart beats at the correct rate. I am 100 percent dependent upon my pacemaker. Without the pacemaker, there are times when my normal heart beat is so slow that I could die.

I am eternally grateful to the physicians funded by the NHLBI, particularly to Dr. Charles MacIntosh and his staff, for the gift of life. Because of this marvelous doctor and research, I have lived eighteen years free of pain. I have seen two children graduate from college, witnessed the birth of three grandchildren, and shared these years with a wonderful wife. And, I have been able to work at my profession—attorney at law.

I have had the gift of life restored to me. To express my gratitude for that gift, under the aegis of the Mended Hearts, Inc., I visit patients recovering from heart episodes at two hospitals: Washington Hospital Center and Washington Adventist Hospital. Last year MHI visited more than 228,000 patients and their families in our mission of support. We have also made 6,700 visits over the telephone to give succor to these patients.

If this tale of woe is not enough, about 3.5 years ago, I suddenly began to have mini-strokes. I experienced five episodes within 13 months. The last episode was just a year ago. Medication, including coumadin, now seems to have the incidents under control. Coumadin is a blood thinning drug that requires constant monitoring. At least once a month, I have to go to the hospital to get blood drawn from my arm to check the level of the drug.

To advance the fight against heart disease and stroke, I respectfully ask for the fiscal year 2007 appropriations in the following amounts:

- National Institutes of Health—\$29.8 billion
- National Heart, Lung, and Blood Institute—\$3.1 billion
- National Institute of Neurological Disorders and Stroke—\$1.6 billion.

My experience and my continued life is proof that the research supported by the NIH benefits not just the patients at the Clinical Center, but throughout the United States. The benefits go worldwide too.

Cardiovascular diseases remain the major killer of men and women in the United States. Nearly 40 percent of people who die in the United States, die from cardiovascular diseases. From 1979 through 2003, cardiovascular operations and procedures increased 470 percent.

PREPARED STATEMENT OF THE MONTGOMERY COUNTY (MARYLAND) STROKE
ASSOCIATION

My name is Susan Emery. I am the President of the Montgomery County Stroke Association and I am a stroke survivor.

Our Association conducts education and supports activities for stroke survivors, their family members, and caregivers. We serve people in the Maryland suburbs of Washington, D.C., and are fortunate to be in the same county as the National Institutes of Health. We have benefited on many occasions by the participation of NIH staff members in our membership meetings. They have been generous in sharing information with us about their research on stroke prevention and treatment.

On December 26, 1965, at the age of nine, I was playing a new game with my brother and a few friends at the kitchen table. That is the last thing that I remember. I was unconscious for the next two days. My mother first learned, incorrectly, that I had spinal meningitis. I was transferred to another hospital where my mother was told that I had little chance of survival. Yet, I am here, more than 40 years later, and I have survived a stroke.

People seldom associate strokes with children. These strokes are rare, but they do happen. There are about three cases of stroke per year in every 100,000 children aged 14 and under. One of the difficulties in dealing with strokes in children is getting the right diagnosis quickly. There are often delays in diagnosis of childhood stroke.

I spent two weeks in the hospital and the subsequent 4 months in intensive physical therapy. My 10th birthday was spent in the hospital, and I have a picture in my photo album of myself with my mother and a new friend. My right eye is turned down, my mouth is turned down, but I am still smiling. During the 4 months in therapy at Holy Cross in Detroit, I learned the basics: how to walk, how to talk, and how to move the fingers on my right hand. My mother followed the doctor's instructions and sent me back to school very quickly, where classmates helped me button and unbutton my coat and carry my books, and teachers taped papers to the

desk so I could learn to write again. I survived that 4 months, and would never wish to repeat it.

I have been in therapy six times in my life. I need to tell you about the one time that was the most important to my family. I was 26 years old and had just had my first child. I kept her safe, for I knew my limitations. I always used my left hand to support her. But when she was 6 months old, she got to be a little heavy, and twice, as I was putting her on the floor to change her diaper, my right hand slipped from under her buttocks. She fell only inches in both cases and did not even notice. But I noticed. I went in for 2 or 3 months of therapy close to Denver, Colorado, where I was living at the time. Here, for the first time, they helped my right hand and arm dexterity through occupational therapy. I also learned that I had aphasia—the inability to speak, write or understand spoken or written language because of brain injury—because I called things like fruit baskets “unicorns” instead of cornucopias. Instead of the word being the same, I picked a word that sounded the same. The therapists in Colorado worked with my mind and my body and I will forever be in their debt.

Close to 15 years ago, I made a new life for myself in Maryland. Here, I have been an outpatient at the National Rehabilitation Hospital three times: once for my right foot, once for my Achilles tendon, and once for my right knee. I have seen numerous physiatrists, all of whom are excellent in their field. I have also seen my fair share of therapists. Since I have had therapy on and off for most of my life, I can honestly say that the first few times you go in to see a therapist, you will come out hurting more than when you went in. But in the long run, they help tremendously.

On a work related note, I received a Bachelor of Science in 1978 from Michigan State University in Computer Science and worked for 12 years in the field. I started working in the telecommunications industry in 1990, and got a Master of Science from the University of Maryland, University College in Telecommunications Management. I now work for ITT Industries as a senior engineer on a contract supporting the Federal Aviation Administration’s leased telecommunications activities, and have worked with the FAA for more than 10 years. I have done more than survive. I have become a productive member of society.

Stroke research has changed my life. Without the research carried out 40 to 50 years ago, I would not have benefited from electric shock therapy that made me understand the muscles that move my fingers. Without research done 30 years ago, I may not have been able to understand how to exercise my hand for dexterity. Without research performed 10 years ago, the people around me would not understand that they need to get me to the hospital quickly if ever I have another stroke. Without current support, researchers may never understand how to stop strokes before they happen or how to make current stroke survivors live healthier lives.

Stroke remains America’s No. 3 killer and a major cause of permanent disability. An estimated 5.5 million Americans live with the consequences of stroke and about 1 in 4 is permanently disabled. Yet, stroke research continues to receive a mere 1 percent of the National Institutes of Health budget. I strongly urge you to significantly increase funding for the National Institutes of Health-supported stroke research, particularly for National Institute of Neurological Disorders and Stroke-supported stroke research. NIH stroke research is essential to prevent strokes from happening to children and adults in the first place, and to advance recovery and rehabilitation of those who survive this potentially devastating illness.

PREPARED STATEMENT OF THE NATIONAL ASSOCIATION OF CHILDREN’S HOSPITALS

The National Association of Children’s Hospitals (N.A.C.H.) is pleased to submit a statement for the record in support of the Children’s Hospitals’ Graduate Medical Education (CHGME) Program in the Health Resources and Services Administration. On behalf of the Nation’s 60 independent children’s teaching hospitals, N.A.C.H. very much appreciates Chairman Specter’s and the subcommittee’s early and continuing commitment over many years to provide full, equitable GME funding for these hospitals. CHGME seeks to give them a level of Federal support for their teaching comparable to what all other teaching hospitals receive from Medicare.

N.A.C.H. also appreciates the subcommittee’s support for \$300 million for fiscal year 2006. Ultimately this was reduced to \$297 million, or less than level funding, due to a 1 percent across-the-board cut in discretionary spending. This marked the third consecutive year CHGME was reduced due to across-the-board cuts since Congress first agreed to appropriate \$305 million for fiscal year 2004.

CHGME has been a success. Thanks to the program, Federal GME support to children’s hospitals now approaches equity with Medicare GME support to adult

hospitals. CHGME has made it possible for children's hospitals to strengthen their training of pediatric providers at a time of national shortages, without having to sacrifice clinical or research programs. It has enabled them to have strong financial positions, which are essential for their capital intensive missions.

For fiscal year 2007, N.A.C.H. respectfully requests \$330 million for CHGME funding. This amount would make up for erosion in funding over the last three years and address the cost of inflation, a critical factor in a program associated with both wage-related and medical teaching costs. Full funding would ensure the hospitals will have the resources necessary to train and educate the Nation's pediatric workforce. Given the challenges the subcommittee faces, we hope, at a minimum, CHGME can be maintained at level funding and not lose further ground in fiscal year 2007.

N.A.C.H. AND CHILDREN'S HOSPITALS

N.A.C.H. represents more than 130 children's hospitals. They include independent acute care children's hospitals, children's hospitals within larger medical centers, and independent children's specialty and rehabilitation hospitals. N.A.C.H. helps its members fulfill their missions of clinical care, education, research and advocacy for the health and well-being of all children.

Children's hospitals are regional and national centers of excellence for children with serious and complex conditions. They are centers of biomedical and health services research for children and serve as the major training centers for pediatric researchers, as well as a significant number of children's doctors. They also are major safety net providers, serving a disproportionate share of children from low-income families, and they are advocates for the public health of all children.

Although they represent less than 5 percent of all hospitals in the United States, the three major types of children's hospitals provide 41 percent of the inpatient care for all children, 42 percent of the inpatient care for children assisted by Medicaid, and the vast majority of hospital care for children with serious conditions such as cancer or heart defects.

BACKGROUND: THE NEED FOR CHGME

While they account for less than 1 percent of all hospitals, independent children's teaching hospitals train nearly 30 percent of all pediatricians, half of all pediatric specialists and the majority of pediatric researchers. These hospitals provide required pediatric rotations for many other residents and train more than 4,800 resident full time equivalents annually. Shortages of pediatric specialists across the Nation only heighten the importance of these hospitals.

Prior to initial funding of the CHGME program for fiscal year 2000, the eligible hospitals faced enormous challenges in maintaining their training programs. The increasingly price competitive medical marketplace was resulting in more and more payers failing to cover the costs of care, including the costs associated with teaching.

Because they see few—if any—Medicare patients, independent children's hospitals were essentially left out of Medicare GME funding, which had become the one major source of GME financing for other teaching hospitals. Independent children's hospitals received only 1/200th (or less than 0.5 percent) of the Federal GME support that all other teaching hospitals received under Medicare. This lack of GME financing, combined with financial challenges stemming from other missions, threatened the hospitals' teaching programs, as well as other services.

Safety Net Institutions.—Independent children's hospitals are a significant part of the health care safety net for low-income children. This critical mission puts the hospitals at financial risk. In fiscal year 2005, children assisted by Medicaid were, on average, more than 50 percent of all discharges from independent acute care children's hospitals. Yet, Medicaid, on average, paid only 79 percent of costs. Without disproportionate share hospital payments, Medicaid would cover, on average, only 73 percent of costs. Medicaid payment shortfalls for outpatient and physician care are even greater.

Independent children's hospitals also are essential providers of care for seriously and chronically ill children. The hospitals devote more than 75 percent of their care to children with one or more chronic or congenital conditions. They provide the majority of inpatient care to children with many serious illnesses—from children with cancer or cerebral palsy, for example, to children needing heart surgery or organ transplants. In some regions, these children's hospitals are the only source of pediatric specialty care. The services they must maintain to assure access to high quality, complex care for all children are often inadequately reimbursed.

Many of the independent children's hospitals also are a vital part of the emergency and critical care services in their regions. They are part of the emergency re-

sponse system that must be in place for public health emergencies. Expenses associated with preparedness add to their continuing costs in meeting children's needs.

Mounting Financial Pressures.—The CHGME program, and its relatively quick progress to full funding in fiscal year 2002, came at a critical time. In 1997, when Congress first considered establishing CHGME, a growing number of independent children's hospitals had financial losses; many more faced mounting financial pressures. More than 10 percent had negative total margins, more than 20 percent had negative operating margins and nearly 60 percent had negative patient care margins. Some of the Nation's most prominent children's hospitals were at financial risk. Thanks to CHGME, these hospitals have been able to maintain and strengthen their training programs.

Pediatric Workforce Development.—The important role CHGME plays in the continual development of our Nation's pediatric workforce is not lost on the larger pediatric community, including the American Academy of Pediatrics and Association of Medical School Pediatric Department Chairs. They support CHGME and recognize it is critical not only to the future of the individual hospitals but also to provision of children's health care and advancements in pediatric medicine overall.

CONGRESSIONAL RESPONSE

In the absence of movement to broader GME financing reform, Congress authorized the CHGME discretionary grant program in 1999 to address the existing inequity in GME financing for the independent children's hospitals. The legislation was reauthorized in 2000, through fiscal year 2005, and provided \$285 million for fiscal year 2001 and "such sums as necessary" in the years beyond. Congress passed the initial authorization as part of the "Healthcare Research and Quality Act of 1999" and the reauthorization as part of the "Children's Health Act of 2000."

With this subcommittee's support, Congress appropriated initial funding for CHGME in fiscal year 2000, before the enactment of the program's authorization. Following enactment, Congress moved substantially toward full funding for the program in fiscal year 2001 and completed that goal, providing \$285 million in fiscal year 2002. Subsequently, Congress appropriated \$290 million in fiscal year 2003, \$303 million in fiscal year 2004, \$301 million in fiscal year 2005, and \$297 million in fiscal year 2006. (In the last three years, the funding levels are net of across-the-board cuts in discretionary funding.)

Health Resources and Services Administration (HRSA).—CHGME funding is distributed through HRSA to 60 children's hospitals according to a formula based on the number and type of full-time equivalent residents trained, in accordance with Medicare rules, as well as the complexity of care and intensity of teaching the hospitals provide. Consistent with the authorizing legislation, HRSA allocates the annual appropriation in biweekly periodic payments to eligible independent children's hospitals.

"Adequate" Rating from Administration.—The Office of Management and Budget gave CHGME an "adequate" rating in 2003, using its Program Assessment Rating Tool (PART). The PART review found CHGME has a "clear purpose," is "effectively targeted," has specific "long-term performance measures" that focus on outcomes, and holds grantees "accountable for cost, schedule, and performance results."

CHGME SUCCESS

The annual CHGME appropriation represents an extraordinary achievement for the future of children's health and the Nation's independent children's teaching hospitals:

- Thanks to CHGME, the Federal Government has made substantial progress in providing more equitable Federal GME support to independent children's hospitals. The hospitals now receive about 80 percent of the level of Federal GME support that Medicare provides to other teaching hospitals. This is still not true equity, but it is dramatic improvement from the 0.5 percent of 1998.
- As a result of CHGME, children's hospitals have been able to make a substantial improvement in their contribution to the Nation's pediatric workforce, without having to sacrifice their clinical or research missions. From 2000 to 2004, without the CHGME hospitals being able to increase the numbers of general pediatric residents they trained, the Nation would have experienced a net decline in number of new pediatricians. During the same time, CHGME hospitals accounted for more than 80 percent of new pediatric subspecialty programs and more than 60 percent of the new pediatric subspecialists trained.
- CHGME has allowed children's hospitals to achieve strong financial positions. According to Moody's, before 2000, children's hospitals tended to have negative

to break-even financial margins. Since then, their margins have improved. CHGME is a major reason.

FISCAL YEAR 2007 REQUEST

N.A.C.H. respectfully requests that the subcommittee provide equitable GME funding for independent children's hospitals by providing \$330 million in fiscal year 2007. Such funding is particularly important for a program that has wage-related and medical teaching costs and has experienced three years of successive reductions due to across-the-board cuts. Given the challenges the subcommittee faces, we hope CHGME at least can be maintained at level funding and not lose further ground in fiscal year 2007.

Adequate, equitable funding for CHGME is an ongoing need. Children's hospitals continue to train new pediatric residents and researchers every year. Children's hospitals have appreciated very much the support they have received, including the attainment of the program's authorized full funding level in fiscal year 2002 and continuation of full funding with an inflation adjustment in fiscal year 2003 and fiscal year 2004. Congress can regain this progress by providing \$330 million in fiscal year 2007.

Continuing equitable CHGME funding is more important than ever in light of budget shortfalls in many States and pressures for significant reductions in State Medicaid spending. Because children's hospitals devote such a substantial portion of their care to children from low-income families, they are especially affected by cutbacks in State Medicaid programs.

Support for a strong investment in GME at independent children's teaching hospitals is also consistent with the repeated concern the subcommittee has expressed for the health and well-being of our Nation's children, through education, health and social welfare programs. And it is consistent with the subcommittee's repeated emphasis on the importance of enhanced investment in the National Institutes of Health (NIH) and in NIH support for pediatric research in particular, for which N.A.C.H. is grateful.

CHGME funding is essential to the ability of the independent children's hospitals to sustain their GME programs. At the same time, the program enables them to do so without sacrificing support for other critically important services that also rely on hospital subsidy, such as specialty and critical care services, child abuse prevention and treatment services, poison control centers, services to low-income children with inadequate or no coverage, mental health and dental services, and community advocacy, such as immunization and motor vehicle safety campaigns.

CONCLUSION

In conclusion, CHGME is a success. The program is an invaluable investment in children's health. The future of the pediatric workforce and children's access to quality pediatric care, including specialty and critical care services, depend upon CHGME. N.A.C.H. and the independent children's teaching hospitals are deeply grateful to the Chairman and subcommittee for your continuing leadership on behalf of children's hospitals.

PREPARED STATEMENT OF THE NATIONAL ASSOCIATION OF COUNTY AND CITY HEALTH OFFICIALS

SUMMARY

The proposed cuts in the fiscal year 2007 budget for the Centers for Disease Control and Prevention (CDC) continue a pattern of reduced funding for public health that gravely worries the Nation's local health departments. The National Association of County and City Health Officials (NACCHO) is particularly concerned about two funding streams that directly benefit local health departments, although the range of reductions in CDC's budget threaten overall work in prevention that we fully support.

Last year, funding for State and local bioterrorism and public health preparedness was cut by \$95 million, more than 10 percent. NACCHO understands that this will result in a cut of about 12 percent in the cooperative agreement funding that goes directly to States and four large cities. The Preventive Health and Health Services block grant program, the other major source of CDC funding to local health departments, was cut by \$19 million, which was 16 percent below the actual fiscal year 2005 funding made available to grantees, and almost 25 percent below the fiscal year 2005 appropriated amount. The fiscal year 2007 budget freezes preparedness funds and eliminates the block grant. Taken together, these reductions will seri-

ously compromise the ability of the Nation's governmental public health system to fulfill its mission of protecting and promoting health.

Local public health departments work every day on the front lines to combat threats to the health of their communities. They can ill afford substantial reductions in Federal support for their roles as first responders to bioterrorism and other public health emergencies. Moreover, local public health departments receive about 40 percent of the Preventive Health and Health Services block grant (PHHS) funds. These enable them to carry out programs ranging from prevention of heart attack and stroke to combating West Nile virus. In States where local health departments rely exclusively on these funds to run prevention programs activities to reduce the burdens of preventable disease will cease.

At a time when the Nation is engaged in urgent work to protect the homeland from terrorists and natural disasters, as well as to stop an epidemic of obesity, it is profoundly counterproductive and irrational to reduce support for local programs that are the first line of defense against the greatest threats to the health of communities. NACCHO urges Congress to continue funding these two CDC programs at levels no less than those in fiscal year 2005. Those levels are \$927 million for State and local bioterrorism preparedness and \$131 million for the Preventive Health and Health Services block grant.

STRENGTHENING THE GOVERNMENTAL PUBLIC HEALTH SYSTEM TO IMPROVE HOMELAND SECURITY REQUIRES SUSTAINED FUNDING

Congress recognized in 1997 an unmet need to strengthen the Nation's capacity to respond to an act of bioterrorism and initiated funding for bioterrorism preparedness in fiscal year 1999. The initial funding of about \$121 million (which included \$51 million solely for stockpiling medications) assisted CDC and State and local health departments to begin examining what plans and resources were necessary. After 9/11 and the anthrax outbreaks in the fall of 2001, Congress increased bioterrorism funding markedly and included \$940 million for building State and local capacities, of which about \$870 million was actually made available to States and localities. The Department of Health and Human Services got these funds out to States and three large cities via cooperative agreements very promptly, far ahead of other homeland security funds for States and localities.

Substantial bioterrorism preparedness funds for improving all aspects of preparedness have actually been in the hands of State health departments since August 2002. Local public health departments, many of which have been funded for less time, are justifiably proud of the progress they have made.

Extensive response plans, developed in collaboration with local emergency management systems, have been made. Numerous "tabletop" and real field exercises have tested local capabilities. Mass vaccination clinics have taken place, some as part of a real response to flu vaccine shortages. Communications systems and equipment that enable rapid electronic information exchange among and by health departments to their communities are operational. Improved systems for disease detection are in place.

Local health departments have engaged hospitals, physicians, and others in the private sector to develop further their roles in responding to a serious disease outbreak. Complex logistical arrangements needed to distribute medications or equipment from the Strategic National Stockpile to stricken populations have been developed.

In some locations, genuine public health crises, such as flu vaccine shortages or an influx of evacuees from the Gulf Coast in the wake of Katrina, have demanded a response. In the act of responding, local health departments and their community partners continually identify new challenges and new ways to improve their ability to respond. Improving a locality's ability to detect a disease outbreak promptly and to contain it swiftly is a continuous process of training, exercising, and improving plans based on these exercises. Interrupting that process through funding cuts would take the Nation's public health preparedness backwards, not forward. New capacities that are now in place cannot be sustained without sustained funding.

Congress appropriated supplemental funding of \$350 million to assist States and localities in pandemic influenza preparedness. These funds are greatly appreciated, but they cannot fill the gaps left by other funding cuts. The narrow range of activities permitted by CDC's grant guidance for the first \$100 million now available to States adds to the tasks required of health departments, but the sums available are insufficient to enable hiring new personnel to carry them out. Moreover, the production and exercise of plans for any biological event, including pandemic influenza, is never a one-time activity. Meaningful progress requires a continuous process of training, exercising and improvement that involves not merely public health re-

sponders, but all community partners that are part of any response, including law enforcement, emergency management, hospitals, schools, and a host of private sector partners.

The Nation has a long way to go before every citizen enjoys the best possible protection by disease detection and response systems that work as quickly as humanly possible. Providing this protection is the job of the governmental public health system. No other entity can do it. NACCHO urges Congress to reverse the cuts in funds available to local public health departments, the Nation's first responders to bioterrorism.

THE PHHS BLOCK GRANT IS A LINCHPIN FOR PREVENTION

Local public health departments receive approximately 40 percent of the Preventive Health and Health Services block grants nationally. The proportion varies among States from less than 5 percent to almost 100 percent. The block grant funds fulfill three critical purposes. First, they enable States to address critical unmet public health needs. The coexistence of other Federal categorical public health funds does not mean that sufficient funds are available to address all public health needs. They are not. Improving chronic disease prevention through screening programs and programs that promote healthy nutrition and physical activity are prime examples of activities to which many jurisdictions devote PHHS funds. Forty percent of fiscal year 2004 block grant funds were spent on chronic disease prevention, including prevention of obesity, stroke, heart disease, cancer, diabetes, and dental caries.

Second, PHHS funds provide some flexible funding to address unexpected problems or problems unique to a particular geographic area. West Nile virus, a fully preventable disease spread to humans by mosquitoes, is one good example. Third, PHHS fund provide leverage for more funds and in-kind resources from non-Federal sources. In one southern State, local health departments collectively used \$2.77 million in block grant funds to establish new prevention programs and generate \$5 million in additional resources for those programs.

States are fully accountable to the Department of Health and Human Services for their expenditures of block grant funds and must report how much money they spend by specific program area. In those States where local health departments receive a significant amount of PHHS funds from the State, local prevention efforts will diminish. Local and State health departments are key leaders and providers of population-based prevention programs. They work to keep prevention in the public eye and build on programs that have been proven effective in reducing disease and preventing premature death. As health care costs escalate, reducing the Nation's commitment to prevention by eliminating the PHHS block grant, weakening state and local public health departments, is unwise and uneconomic.

The National Association of County and City Health Officials (NACCHO) is the organization representing the almost 3,000 local public health departments in the United States.

PREPARED STATEMENT OF THE NATIONAL COALITION FOR OSTEOPOROSIS AND RELATED BONE DISEASES

The National Coalition for Osteoporosis and Related Bone Diseases (Bone Coalition) is pleased to comment on the fiscal year 2007 budget for the National Institutes of Health (NIH) as it relates to bone research. The Federal investment made to date goes a long way towards improving the bone health of our citizens and we are appreciative of the Committee's leadership over the years. We also congratulate the Committee for recognizing the complexities of the issues in the bone field and including language in the fiscal year 2006 committee report directing the NIH to establish a "Bone Health Research Blueprint."

The recent Surgeon General's Report on bone health and osteoporosis illustrates the large burden that bone disease places on our Nation and its citizens. The Bone Coalition is committed to reducing the impact of bone diseases through expanded basic, clinical, epidemiological and behavioral research and through education leading to improvement in patient care. The Coalition participants are leading national bone disease organizations—the American Society for Bone and Mineral Research, the National Osteoporosis Foundation, the Osteogenesis Imperfecta Foundation, and the Paget Foundation for Paget's Disease of Bone.

Bone diseases such as osteoporosis, osteogenesis imperfecta, and Paget's disease of bone pose a significant public health and economic challenge.

—*Osteoporosis*.—Is a disease characterized by low bone mass and structural deterioration of bone tissue, leading to bone fragility and an increased susceptibility to fractures of the hip, spine, and wrist. It remains widespread across all popu-

lations. This is due to several factors, such as the aging of our population, the prevalence of secondary osteoporosis, and low bone mass that is common in immobilized patients and nursing home populations. Secondary osteoporosis, resulting from numerous chronic medical conditions and the long-term use of many medications, causes osteoporosis and related fractures in children, adolescents, and young adults. Over 10 million Americans have osteoporosis, the majority of whom (80 percent) are women, and 34 million more have low bone mass, placing them at increased risk for this disease. One out of every two women and one in four men over 50 will have an osteoporosis-related fracture in her/his lifetime. Osteoporosis is responsible for more than 1.5 million fractures annually, and mortality and morbidity following both spine and hip fractures is high when compared to unaffected peers. The estimated national direct expenditures for osteoporosis and related fractures total \$18 billion (2002 dollars) each year.

—*Paget's Disease of Bone*.—The second most prevalent bone disease after osteoporosis—is a chronic skeletal disorder that may result in enlarged or deformed bones in one or more regions of the skeleton. Excessive bone breakdown and formation can result in bone that is dense, but fragile. Complications may include arthritis, fractures, bowing of limbs, neurological complications, and hearing loss if the disease affects the skull. Prevalence in the population ranges from 1.5 percent to 8 percent depending on the person's age and geographical location. Paget's disease primarily affects people over 50.

—*Osteogenesis Imperfecta (OI)*.—Causes brittle bones that break easily due to a problem with collagen production. For example, a cough or sneeze can break a rib, rolling over can break a leg. Besides fragile bones, people with OI may have hearing loss, brittle teeth, short stature, skeletal deformities, and respiratory difficulties. OI affects between 20,000 to 50,000 Americans. In severe cases fractures occur before and during birth. In some cases, an affected child can suffer repeated fractures before a diagnosis can be made. Undiagnosed OI may result in accusations of child abuse.

—*Cancer Metastasis to Bone*.—A frequent complication of cancer is its spread to bone (bone metastasis) that occurs in up to 80 percent of patients with myeloma, 70 percent of patients with either breast or prostate cancer, and 15 to 30 percent of patients with lung, colon, stomach, bladder, uterine, rectal, and renal cancer causing severe bone pain and pathologic fractures. Only 20 percent of breast cancer patients and 5 percent of lung cancer patients survive more than 5 years after discovery of bone metastasis.

According to Dr. Zerhouni, “. . . we are facing great challenges in [the area of bone research]: an aging population at increasing risk for bone problems; the attendant costs of bone disease, both in human and financial terms; and the need for more physician-scientists to continue the important work of discovery, treatment, and prevention.”

Bone diseases take many forms and cause complications such as fractures, chronic pain, hearing loss, brittle teeth, respiratory difficulties, bone metastasis from cancer, and neurological complications that reduce people's quality of life and cost society billions of dollars. These challenges in bone research cut across numerous institutes/centers at the National Institutes of Health. They traverse the focus of individual Institutes and require an interdisciplinary scientific approach.

At the NIH, as part of the Roadmap Initiative, a series of awards have been established that will make it easier for scientists to conduct interdisciplinary research and an Office of Portfolio Analysis and Strategic Initiatives has been established to coordinate trans-NIH initiatives. The health problems in the bone field require new approaches. We believe these new efforts will remove obstacles to scientific progress and better coordinate the discoveries of tomorrow.

NIH-supported research in bone health has led to important discoveries and has generated new treatments and pharmaceutical products. It must be recognized that new discoveries and breakthroughs could come from any areas of biomedical research and could result in new treatments and eventually a cure for bone diseases.

—Research has taught us that those with low bone mass are at risk for osteoporosis. These individuals can then address their risk with exercise, diet, other behavioral and lifestyle changes, and medication.

—Research has decreased fracture risk and extended the lifespan to normal for people with OI.

—Research has identified drugs which improve the quality of life of people whose cancer has metastasized to bone.

—Research has led us to develop simple, non-invasive and accurate tests that can determine bone mass and help predict fracture risk.

- Research has identified and demonstrated a variety of drugs that can reduce bone loss and fractures, and even build new bone. Thirty years ago, there was no treatment for osteoporosis.
 - Research has helped us to understand the need for weight-bearing exercise to build and maintain bone in order to reduce fracture risk. Falling can be reduced by strength-building exercise that increases balance and flexibility.
- But much remains to be done. A concentrated effort is required to address bone health. The Coalition is particularly interested in NIH support for the following in fiscal year 2007:
- Research is needed into the pathophysiology of bone loss in varied populations and in targeted therapies to improve bone density and bone quality according to the etiology of osteoporosis. In addition research is needed to identify patients at risk for fracture who do not meet current criteria for osteoporosis, as well as to study the effects of available and developing osteoporosis treatments on the reduction of fracture risk in these patients.
 - NCI, NIAMS, NIA and NIDDK must support research to determine mechanisms and to identify, block and treat cancer metastasis to bone. Furthermore, NCI must expand research on osteosarcoma to improve survival and quality of life and to prevent metastatic osteosarcoma in children and teenagers who develop this cancer.
 - Although bone mineral density has been a useful predictor of susceptibility to fracture, other properties of the skeleton contribute to bone strength, including mechanical loading (exercise) and mechanisms of biomineralization. However, at this time little is understood as to how these properties assist in the maintenance of bone strength. Support of this research by NIA, NIAMS, NIBIB, NICHD, NIDDK, and NHLB will achieve identification of these parameters and lead to better prediction for prevention and treatment of bone diseases such as osteoporosis, osteogenesis imperfecta, bone loss due to kidney disease, and heart attacks due to hardening of the arteries.
 - Thousands of children and adolescents nationwide suffer from musculoskeletal disorders and malformations, many of which have devastating effects on mortality and disability. NIAMS and NICHD must support research focusing on mechanisms of preventing fractures and improving bone quality and correcting malformations, on innovations in surgical and non-surgical approaches to treatment, and on physical factors that affect growth.
 - Diseases such as osteogenesis imperfecta, fibrous dysplasia, osteopetrosis, and Paget's disease are caused by poorly understood genetic mutations. In Paget's disease, underlying genetic defects can also be exacerbated by environmental factors. NIAMS, NICHD, NIDCR, and NIDDK must support research on genetic defects that cause bone disease.
 - 57.9 million Americans are injured annually, more than one-half incur injuries to the musculoskeletal system. In the United States, back pain is a major reason listed for lost time from work and sports injuries are increasing in "weekend warriors" of both sexes. NIAMS, NIA, and NCCAM must study ways to better understand the epidemiology of back pain, improve on existing diagnostic techniques for back pain, as well as to develop new ones. NIAMS, NIBIB, NIDDK and NIA must expand research to improve diagnostic and therapeutic approaches to significantly lower the impact of musculoskeletal traumas, and on research on accelerated fracture healing, the use of biochemical or physical bone stimulation, and bone substitutes such as hydroxyapatite and allogeneic tissues.
- To move this research forward, Congress must provide sufficient funding to the National Institutes of Health to sustain the robust research atmosphere in which to address the challenges in the bone field. The revolution in genetics/genomics that has provided new tools and databases and the powerful new imaging devices must not be hindered. Research must continue to be accelerated in order to improve the health of the Nation.

RECOMMENDATIONS

The National Coalition for Osteoporosis and Related Bone Diseases supports a 5 percent increase for the National Institutes of Health (above the fiscal year 2006 funding level), as recommended by the Ad Hoc Group for Medical Research, along with the National Health Council, the Campaign for Medical Research and Research!America.

The recent Surgeon General's Report on bone health and osteoporosis illustrates the large burden that bone disease places on our Nation and its citizens. We support the establishment of a "Bone Health Research Blueprint" to address the need for interdisciplinary approaches to research and increased coordination of research ef-

forts. We believe that more deliberately integrated activities in the areas of bone research at NIH and at extramural institutions will move our science more rapidly to discoveries that will preserve health and cure disease.

Thank you for the opportunity to submit our statement regarding the fiscal year 2007 budget for the National Institutes of Health.

PREPARED STATEMENT OF THE NATIONAL COMMUNITY ACTION FOUNDATION
REQUESTING LEVEL FUNDING FOR THE FISCAL YEAR 2007 COMMUNITY SERVICES BLOCK
GRANT, LIHEAP, AND HEAD START PROGRAMS

I first want to convey the deep gratitude of every one of the Nation's 1,100 Community Action Agencies to Chairman Specter and Senator Harkin for their leadership in amending the Budget Resolution to preserve critical domestic programs.

We are requesting that the subcommittee go forward with the Chairman's original intent of restoring all the programs that are reduced or eliminated by the President's 2007 budget request. This remains the correct priority in light of the extreme and, in our opinion, destructive constraints placed on all domestic discretionary spending. Of course, this one-year policy is no substitute for a renaissance of investment in healthy children, in the workforce of tomorrow, in the health of the public, and in the science that will sharpen America's competitive edge in 21st century trade.

The following facts on the threat to Community Action's top priority programs—CSBG, Head Start and LIHEAP—will indicate how important to Community Action are the strategic decisions facing the subcommittee.

The Community Service Block Grant (CSBG) is the funding that underwrites the unique assignment of CAAs: their responsibility to convene local leadership to make a plan with the low-income community that implements a mix of strategies to bring in new investment and social resources. CAAs sustain their communities' long-term commitment to expand access to new opportunities for their residents who need to become more productive and more self-sufficient. Fifty two Senators have written the subcommittee opposing the President's request.

If CSBG is reduced or eliminated, important community institutions will be lost. In Pennsylvania:

- Mercer County's Weed & Seed Community Revitalization effort, Micro-enterprise Development project that makes small business owners out of former low-income workers and the Elm Street revitalization project will cease.
- That CAA would also end its sponsorship of three HUD projects (22 units) which are home to special needs populations; those precious subsidized apartments will be rented out at "fair market value".
- In Venango and Crawford Counties services in the areas of youth development, supportive housing services, and education would be eliminated.
- The Pittsburgh and Philadelphia CAAs would close, their services absorbed into a variety of city government departments;
- Outreach Centers across the State's rural areas would be shuttered.

In Iowa, eliminating CSBG means:

- 91 outreach centers will close; these are the local offices where programs operate, meet both those in need and offer the entire community space for groups working on local betterment.
- The same will befall dozens of food pantries supported by CAA warehouses, storage and trucking in which Churches and other volunteers participate.
- 633 homeless children in the Hawkeye area will have no preventive screenings.
- 117 elderly individuals around Davenport will lose the chore assistance services that have allowed them to remain in their own homes.
- In Des Moines the vast community gardens project will shut down and three thrift stores the low-income community depends on will close;
- In Dubuque, the financial literacy education initiative will end.

Even more ominous is the prospect that no future partnerships or new initiatives will be imagined and developed; in the past two years, CAAs across America have used their CSBG as the flexible "venture capital" that supports the efforts to develop partnerships, plan projects, and raise and package resources. Among the results that are permanently changing their communities are: numerous dental clinics, housing developments, job creation projects, energy services for all the community, and clean water supply facilities. CAAs have developed and improved communities with permanent investments such as these for four decades. Ending CSBG dams up the stream of emerging community infrastructure and services and cuts

the ties that keep public-private local partnerships that coordinate their resources to change local conditions.

CAAs serve one-third of the Head Start and Early Head Start participants.—The requirements for program quality have increased as science's knowledge of early childhood; the expectations for the depth and number of services and professional care are high. The staff cannot receive cost of living increases, much less the salaries their skills merit, without reductions in enrollment. The threat to children's hard won gains grows with each reduction. CAAs will be forced to deny places to 6,300 of the 19,000 qualified children that are anticipated to go unserved under a freeze in fiscal year 2007 Head Start funding.

Finally, LIHEAP must be maintained at least at its current level.—This year the Congress, led by the Senate with many Members of this subcommittee in the vanguard, at last got LIHEAP right.

The \$3.1 billion the Chairman and Ranking Member supported for the fiscal year 2006 program is desperately needed. We have surveyed our member agencies who, collectively, deliver more than a third of the LIHEAP program nationwide. They are confident that, in spite of the late start, all the new resources will be distributed either to consumers who were shut out of the first round of assistance or to participants whose initial benefits were too low to buy them more than a few short weeks worth of fuel.

The "Sunbelt" programs that nearly doubled their initial grants when the supplemental funds were appropriated are making especially speedy and good use of the resources they have long needed. It is surprising, but true, that low-income consumers in Florida, the Gulf Coast States and the Southwest spend nearly as high a percentage of their income on energy bills as do Midwesterners. That is just one reason it is essential that most of 2007 LIHEAP funds be distributed according to the statutory formula, as is the case with the fiscal year 2006 funding.

Further, the only good reason for a large contingency fund is to correct for the extreme effects of the formula factors that deny the cold States a fair share of appropriations above \$2 billion. A presidential contingency reserve for crises should only be an amount sufficient to meet an unpredicted need—such as a major natural disaster—during the period of awaiting major supplemental emergency legislation. Winter and Summer do not qualify as unexpected events; neither do high prices. The level and timing of program funding cannot be abandoned to Presidential politics.

The Department of Energy predicted on April 11 that 2007 home fuel prices will essentially remain at this year's record levels. (EIA Short-term Energy Outlook) Last year, its April prediction for prices in normal 2005–06 winter weather turned out to be about 10 percent under the prices we faced in this unusually mild winter. Next winter, the energy markets will afford no relief for struggling LIHEAP-eligible customers. LIHEAP must, at least, be sustained.

Community Action will be beside and behind this subcommittee's fight for a fair budget for America's priorities in every way possible in every part of this Nation. Thank you for considering these views and for your strategic and moral leadership.

PREPARED STATEMENT OF THE NATIONAL AHEC ORGANIZATION

SUMMARY OF FISCAL YEAR 2007 RECOMMENDATIONS:

1. Increase funding for the Health Professions and Nursing Education programs under Title VII and Title VIII of the Public Health Service Act to at least \$550 million for fiscal year 2007.
2. Restore funding for area Health Education Centers (AHECs) to the fiscal year 2003 level of \$33.141 million.
3. Restore funding for the Health Education Training Centers to the fiscal year 2003 level of \$4.371 million.

Mr. Chairman, and members of the subcommittee, I am pleased to present testimony on behalf of the National Area Health Education Centers Organization (NAO). NAO is the professional organization representing the Area Health Education Centers (AHECs) and the Health Education Training Centers (HETCs).

I am Kathleen Vasquez, director of the Ohio Statewide AHEC program, director of the Medical University of Ohio's AHEC program, and the co-chair of the National AHEC Organization (NAO)'s Public Policy Committee.

AHECs develop and support the community based training of health professions students, particularly in underserved rural and urban areas. They also provide continuing education and other services that improve the quality of community-based health care. HETCs use the infrastructure of the AHECs to address the needs of

diverse populations with persistent and severe unmet health needs. In 5 border and 6 non-border States, HETCs train and support Community Health Workers to provide health information and services in their communities. Last year alone HETCs provided the initial training and continuing education for over 5,000 Community Health Workers.

Since 1980, the Ohio AHEC program has played a vital part in training the State's healthcare workforce. Through a community-based education infrastructure, the delivery of direct patient care is expanded and a pipeline of professionals is maintained to provide future care. That pipeline of future professionals who will go on to practice in rural and underserved areas is maintained through collaborative partnerships with community health centers (CHCs) and the National Health Service Corps (NHSC). These partnerships allow the AHECs to help the Nation's health professions workforce to address timely issues such as bioterrorism, flu prevention and the nursing shortage.

COMMUNITY HEALTH CENTERS AND THE NATIONAL HEALTH SERVICE CORPS

Community Health Centers are dedicated to providing preventive and ambulatory health care to the most uninsured and underinsured populations by placing point-of-service facilities in these areas. A March 2006 study published in the *Journal of the American Medical Association (JAMA)* found that community health centers report high percentages of provider vacancies, including an insufficient supply of dentists, pharmacists, pediatricians, family physicians, and registered nurses. These shortages are especially pronounced in rural community health centers. Because Title VII programs (including AHECs and HETCs) have a successful record of training providers who work in underserved areas, the study recommends increased support for Title VII as the primary means of alleviating the health professions shortage in rural areas. The article serves as an important reminder that the success of CHCs is highly dependent upon a well-trained clinical staff to provide care.

The Ohio AHEC program has worked closely with Community Health Centers to promote and support their complementary missions through the co-sponsorship of educational programs, the development of clinical training sites, and the recruitment of talented students. The Ohio AHEC program places students in rotations at Community Health Centers all over the State. For example, the Northeast Ohio AHEC places nursing, nutrition, and health education students in rotations at the Health and Dental Centers of Community Action Agency of Columbiana County. The Summit Portage AHEC places third year medical students in an "exploratory experience" elective with the Akron Community Health Resources. Other medical students are placed at the Ohio North East System, which has three Community Health Centers in Youngstown, Warren, and Alliance. The AHECs affiliated with the Medical University of Ohio place students at the expansion community health center in Lima as well as at the only designated migrant health center in Ohio, Community Health Services in rural Fremont. A network of over 500 physicians volunteer their time to teach the students at these Community Health Centers along with students placed in other underserved and rural areas of the State.

Through another partnership with the Ohio Primary Care Association (OPCA), Ohio AHECs organized a statewide health literacy and diabetes conference, with accompanying health literacy train-the-trainer components. Through this type of train-the-trainer education, Ohio AHECs have maximized limited resources to build capacity to continue providing education beyond the initial offering. Many of the participants in this health literacy and diabetes conference worked at a Community Health Center.

The leadership of the Community Health Centers and the AHECs in Ohio often work closely together. I, as the Director of the Ohio Statewide AHEC program, serve on the board of a Community Health Center. The Executive Director of that same Community Health Center serves on the board of the Sandusky AHEC. And the Executive Director of the Health and Dental Centers of Community Action Agency of Columbiana County is a member of the Eastern Ohio AHEC Board. These partnerships allow the AHEC program to help Community Health Centers in Ohio to recruit, train, and retain well-qualified health professionals who are passionate about serving in a rural or otherwise underserved area.

AHECs also undertake a variety of programs related to the placement and support of National Health Service Corps (NHSC) scholars and loan repayment recipients. The Ohio AHEC is a contractor of the NHSC "SEARCH" program. The AHECs, in collaboration with the Ohio Academy of Family Practice and the Ohio Department of Health, annually recruit 70 students, develop training sites, monitor placements and advise on individual community projects. These students will gain

experience and exposure to practice in rural, underserved and especially community health center sites throughout the State.

BIOTERRORISM AND FLU PREVENTION

Ohio AHECs provide nearly 400 continuing education programs, which are attended by 11,000 practicing professionals. These providers do not have to leave their communities or arrange coverage in order to attend these programs, because the programs are brought to them in their local communities. The topics of continuing education programs are determined by the needs of the practitioners in the community, so timely topics such as avian flu and bioterrorism have been recently provided.

Ohio AHECs have stepped in to provide health professionals with the latest updates on surveillance, reporting, risk communication, treatment, and other responses to the threat of bioterrorism. In rural areas of the State, AHECs bring in downlinks and sponsor bioterrorism preparedness programs. Ohio AHECs have provided preparedness training for clinicians at the Community Health Centers, and also provided train-the-trainer education programs at 4 regional locations. In addition, some of our sister AHEC programs are already heavily involved in public education for flu prevention.

NURSING SHORTAGE

Contrary to what may be commonly understood, persistent and severe shortages exist in a number of health professions. Chronic shortages exist for all health professions in many of our Nation's underserved communities, and substantial shortages exist in all communities for some high-need professions such as nursing.

Historically, the supply of and demand for health care professionals has waxed and waned in a manner that produced cycles of shortage and excess. However, it is reasonable to believe that the current shortages are of a different and more persistent nature. First, the breadth and depth of shortages are greater than at any time in the past. More disciplines are in short supply, more sites of care (hospitals, nursing homes, home care agencies, and clinics) are experiencing shortages, and the duration of vacancies is longer. Second, the demand for health care services is steadily and inexorably increasing due to the aging population and the advances in medical technology. Third, the health care provider population is aging itself. Fourth, the resources with which the health care industry might respond to shortages are inadequate. Due to the squeeze of managed care, provider institutions are unable to increase salaries, and due to cuts in government funding, educational institutions are unable to expand class sizes. Finally, the career opportunities available to women, who historically have dominated the nursing profession, have expanded greatly.

Currently, AHECs and HETCs are working with schools of nursing, State nursing associations, Community Health Centers, and the National Health Service Corps, to increase the number of qualified applicants to nursing schools, increase minority enrollment in nursing schools, expand the number of community-based nursing training sites, and retrain nurses who wish to re-enter the profession.

JUSTIFICATION FOR FUNDING RECOMMENDATIONS

Mr. Chairman, I respectfully ask the subcommittee to support our recommendations to increase funding for the health professions and nursing education programs under Title VII and Title VIII of the Public Health Act to at least \$550 million for fiscal year 2007. Our recommendations are consistent with those of the Health Professions and Nursing Education Coalition (HPNEC). 56 of your colleagues (led by Senators Reed and Roberts), signed a letter to the subcommittee, stating that restoring funding to Title VII health professions programs is vital to reversing health professions shortages in the Nation's neediest communities.

Two of the Title VII programs, AHECs and HETCs, improve access to primary and preventive care through community partnerships, linking the resources of academic health centers with local communities. AHECs and HETCs have proven to be responsive and efficient models for addressing an ever-changing variety of community health issues, including bioterrorism, flu prevention, and the nursing shortage. In order to continue this potential, additional Federal investment is required. We request that in fiscal year 2007 you restore funding to the fiscal year 2003 levels of \$33.141 million for AHECs, and \$4.371 million for HETCs.

PREPARED STATEMENT OF THE NATIONAL COALITION FOR HEART AND STROKE
RESEARCH

My name is Jack Owen Wood. I solicit your support for more aggressive Federal funding for research into prevention and treatment of the sister diseases, stroke and heart disease. Strokes and heart attacks are occurring at an alarming rate.

I am representing the National Coalition for Heart and Stroke Research. The coalition consists of 18 national organizations representing more than 5 million volunteers and members united in support for increased funding for heart and stroke research. Members of the Coalition include: American Academy of Neurology; American Academy of Physical Medicine and Rehabilitation; American Association of Neurological Surgeons; American College of Cardiology; American College of Chest Physicians; American Heart Association; American Neurological Association; American Stroke Association; American Vascular Association Foundation; Association of Black Cardiologists; Child Neurology Society; Children's Cardiomyopathy Foundation, Inc.; Congress of Neurological Surgeons; Heart Rhythm Society; Mended Hearts, Inc.; National Stroke Association; Society of Interventional Radiology; and Society for Vascular Surgery.

I will deal primarily with one man's personal experience with stroke and its functional and financial costs—my own. I have only the use of my right arm.

I was born in 1937, raised in Vicksburg, Mississippi, earned an engineering degree at Mississippi State University and currently reside in Port Orchard, Washington. I worked for the Boeing Company in Seattle, am a former Director of the Washington State Energy Office, served as Director of Cost and Revenue Analysis and as the Forecasting Manager for a major Northwest Area Natural Gas Utility until May 1, 1995.

On May 1, 1995, at the age of 57, I was stricken and severely disabled by my stroke. Two years later I experienced a triple bypass heart operation. You might say I've "been there and done that" for both major cardiovascular diseases. So you see, I am an expert.

Years ago I was offered an exciting and rewarding volunteer opportunity. I was asked to lead the "JACK WOOD STROKE VICTOR TOUR" for the American Heart Association.

The JACK WOOD STROKE VICTOR TOUR was a 5-State lobbying tour. Through it I tried to meet personally with every Northwest Congressional representative on his or her home turf (in Alaska, Idaho, Montana, Oregon and Washington). In each meeting I was joined by local people, stroke survivors and their families and medical professionals. I told my story and asked them to join the Congressional Heart and Stroke Coalition and to support increased Federal funding for heart and stroke research.

I am proud to say I traveled to 18 communities and met personally with 28 members of our delegation or their staff.

One of the most powerful memories for me was the frequency in which Members of Congress or staff members related their personal experience with stroke. One member I spoke to lost both parents to stroke. I suspect many of you have stories too.

I realize your interest is greater than the physical impact of my stroke. Your concern must include the financial impact, not only to me, but also on our country from increased health care costs and lost productivity and its many implications.

I have confronted the difficult and painful task of calculating that cost to me. Besides being a man whose stroke took his ability to pick up and play with his grandchildren and his livelihood, I remain a statistician at heart. I could not resist calculating and telling that part of my story. But please remember my story is not dissimilar to that of many of the 5.5 million stroke survivors in the United States. Many of whom were stricken in their prime earning years. Who in a matter of moments, seemingly without warning, are transformed from a contributor and provider to a receiver and patient.

Allow me to highlight three figures that I feel sum up my data and should be important to you. I estimate that my stroke at age 57:

—Reduced my earnings before retirement age 65 by more than \$600,000.

—Subsequently, the cost to the Federal Government in lost income and other taxes, early Medicare payments and Social Security disability payments is more than \$320,000.

—My HMO spent approximately \$150,000 to respond to and treat my stroke.

—One man, over \$1 million.

About 700,000 Americans will suffer a stroke this year costing this Nation an estimated \$58 billion in medical expenses and lost productivity.

Earlier I described a stroke as occurring seemingly without warning. All too often as in my case, people either don't know or ignore the signs of a stroke, even one in progress. When my stroke hit I denied it. It took me two days after my stroke to acknowledge it and seek help. Because of research into new treatments, we now have tPA, a clot-busting drug, which if administered within 3 hours of the onset of stroke symptoms, can dramatically reduce the damage of clot-based strokes. Had I recognized and acknowledged my stroke, gone to a hospital with a neurologist on staff and had there been tPA, the impact of my stroke most certainly would have been lessened.

What is even more painful to me is that my impending stroke could have been detected. Unfortunately, we need to create easier and less expensive diagnostic techniques so that effective diagnostics can be given routinely as part of regular health exams. And they must be covered through insurance.

I am not asking for your sympathy. Instead, please think of me as two of the ghosts in the famous Dickens' story. Please don't misunderstand, I am not casting you as Scrooge. See me as both the ghosts of things past and things yet to be. I too am here to tell you, the future, which I represent, needs not be. It is largely up to you.

I hope my story and estimate of the cost of my stroke convinces you that taking on stroke and heart disease through increased research, leading to better prevention, diagnosis and treatment is fiscally responsible. The human and financial costs are astronomical.

Thank you for your past support of research.

PREPARED STATEMENT OF THE NATIONAL MULTIPLE SCLEROSIS SOCIETY

Mr. Chairman and distinguished members of the subcommittee, we appreciate the opportunity to submit written testimony on behalf of the National Multiple Sclerosis Society. Multiple sclerosis (MS) is a chronic, unpredictable and often disabling disease of the central nervous system. Symptoms range from numbness in the limbs, to loss of vision, memory deficits, and in some instances partial or total paralysis. The progress, severity and specific symptoms of MS in any one person can vary and cannot yet be predicted, but advances in research and treatment are giving hope to those affected by the disease.

Since its inception in 1946, the Society's highest priority has been to end the devastating effects of MS by supporting research aimed at finding the cause of MS, providing better treatments, and ultimately discovering a cure. In 2006, the National MS Society will spend over \$40 million on MS research supporting over 350 MS investigations. By the end of 2006, the Society cumulatively will have expended some \$500 million since awarding its first three grants in 1947. This represents the largest privately funded program of basic, clinical, and applied research and training related to MS in the world.

Any effort to conquer MS will require the collective efforts of many individuals as well as private and public organizations. The Federal Government is a critical partner in the fight against MS and must continue its vital role in furthering the scientific understanding of MS. To this end, the Society supports the following proposals related to Federal efforts:

- There is a great need to determine how many Americans have MS. We therefore ask that the National Institutes of Health (NIH) collaborate with the Centers for Disease Control/Agency for Toxic Substances and Disease Registry (CDC/ASTDR), the Society and other MS organizations to begin the task of establishing the incidence and prevalence of MS.
- There is a great need to find treatments for the primary-progressive form of MS (PPMS). We therefore ask that NIH bring additional research focus to the primary-progressive form of MS.
- There is a great need to develop laboratory tests to help physicians easily diagnose and monitor MS. We therefore ask that NIH expand its efforts to identify biomarkers for MS.
- There is a great need provide effective rehabilitation services to Americans with MS. We therefore urge that the National Institute on Disability and Rehabilitation Research (NIDRR) in the Department of Education fund one additional Medical Rehabilitation Research and Training Center for MS and take steps to stimulate individual research projects in MS.
- There is a great need to sustain the country's research enterprise and to accelerate the discovery of life-changing treatments for MS. We therefore ask that Congress increase fiscal year 2007 NIH funding by 5 percent.

The National MS Society has had a long and productive relationship with the NIH, particularly with National Institute of Neurological Disorders and Stroke (NINDS). Our founder, Sylvia Lawry, helped spearhead the legislation that established NINDS in 1950 and the Society has been pleased to work with the NINDS on many areas of mutual interest. Indeed, we extend our thanks to NINDS Director, Dr. Story Landis, and key members of her staff, for meeting the Society's senior leadership to explore collaborative opportunities. We look forward to continued discussions with Dr. Landis and are eager to initiate similar discussions with the leadership of other NIH institutes.

The Federal investment in the NIH and the NIDRR plays a major role in MS research. At the NIH, there are two other institutes that conduct or fund the majority of MS research: the NINDS, which funds 75 percent, and the National Institute of Allergy and Infectious Diseases (NIAID), which funds about 20 percent. The National Center for Medical Rehabilitation Research (NCMRR—a unit of the National Institute of Child Health and Human Development) also funds a small amount of MS research specifically targeting rehabilitation issues. In addition to the NIH, the NIDRR through the Department of Education invests in MS research.

For fiscal year 2006 and fiscal year 2007, it is estimated that NIH expenditures on MS research will be approximately \$109 and 108 million, respectively. For fiscal year 2006 and fiscal year 2007 NIDRR expenditures on MS research will be approximately \$1.6 million per year out of a total budget of \$107 million per year.

—While this demonstrates one measure of the Federal investment in MS research, this amount pales in comparison with the annual direct and indirect disease cost—approximately \$23 billion for all people with MS in the United States.¹

INVESTING IN RESEARCH PRIORITIES RELEVANT TO MS

The National MS Society recognizes that new discoveries and breakthrough findings could come from almost any area of biomedical research and could apply to the primary concern of our members: finding a cure for MS. NIH plays THE major role in maintaining our country's preeminence in the biotechnology industry and provides world-wide leadership in health research and discovery. We thus encourage Congress to focus on NIH as a whole, and on agencies of particular relevance to our concern, knowing that a well-funded Federal research enterprise will benefit all of us.

Determining how many Americans are affected by MS.—An area in critical need of attention is determining the incidence, prevalence, and distribution of MS. The last national study of incidence and prevalence of MS in the United States took place more than 30 years ago. Since that time the population of the United States has changed dramatically in size, composition, and distribution. Moreover, numerous questions have arisen concerning possible ethnic, geographic, and local variations in the distribution of MS. Knowledge concerning these distributions and possible causal factors may provide important information concerning the nature of MS and its triggers. Rational policy formulation for MS health care requires up-to-date information concerning numbers and characteristics of persons with MS down to the State level.

We are pleased to note that CDC/ASTDR has taken an important step in addressing this issue by convening a workshop to discuss a proposal for setting up national surveillance systems for MS and amyotrophic lateral sclerosis (ALS). The Society was pleased to participate in this meeting and looks forward to collaborating with CDC/ASTDR in planning of regional pilot studies of methods to establish incidence and prevalence of MS, and ultimately the design and deployment of a national or multi-regional surveillance system for MS. Establishment of such systems, however, is beyond the resources of the Society. We therefore urge NINDS and other appropriate NIH institutes to collaborate with the CDC/ATSDR and to allocate funds for the conduct of the critical pilot studies and to support a national effort to accurately measure incidence and prevalence of MS.

Finding new treatments for primary-progressive MS.—Advances in immunology have provided clinicians with powerful tools to better understand the underlying causes of MS, leading to new therapeutic advances. Although there are FDA-approved treatments for relapsing MS, there are still no approved treatments for progressive MS. The primary-progressive form of MS (PPMS) is characterized from the

¹Based on a 1994 Duke University study, indexed for 2004 by the National MS Society, the average annual cost of MS is estimated at \$57,500 per person due to lost wages, increased medical care and other expenses. Nationwide, there are an estimated 400,000 people with MS.

onset by the absence of acute attacks and instead involves a continuous and gradual clinical decline.

Approximately 10 percent of individuals are diagnosed with PPMS from the onset. Clinically, this form of the disease is associated with a lack of response to any form of the approved MS therapies. This leads to the concept that PPMS may in fact be a very different disease as compared to relapsing-remitting MS. The Society identifies the study of primary-progressive MS as an area that merits greater attention by the research community in order to increase our understanding of PPMS and to have effective therapies for this progressive form of the disease. In the upcoming year, the Society encourages NIH to help the Society address this underserved area of MS research.

Helping physicians with diagnosis and treatment.—The complexity of MS poses many challenges for both diagnosis and treatment of the disease. Biomarkers, substances that are detectable in blood or other body fluids by laboratory testing, are a promising tool for physicians since they could aid in diagnosis, treatment selection, and prediction of disease course. In addition, valid biomarkers will be very useful in evaluating the effectiveness of new drugs.

The fundamental importance of biomarkers for MS has been recognized by the NIH Autoimmune Disease Coordinating Committee and NINDS, which sponsored a workshop on this topic in 2004. Moreover we are pleased to note that NINDS has provided \$4 million for a major biomarker discovery effort as part of a large-scale clinical trial, CombiRx. The CombiRx trial is evaluating whether or not a combination of approved MS therapies is more effective in treating MS than individual therapies. We applaud NINDS for its efforts to-date and urge that NINDS and other NIH institutes work with the Society to expand their efforts to support research directed at the discovery and validation of biomarkers for MS.

EXPANDING THE SCOPE OF FEDERAL SUPPORT FOR MS RESEARCH

In addition to efforts at the NIH, the Society is pleased to note that for more than 20 years, NIDRR has funded a Medical Rehabilitation Research and Training Center (MRRTC) for MS. However, the institute's overall investment in MS research remains limited, \$1.6 million in fiscal year 2006 and fiscal year 2007. It is dismaying that the current NIDRR portfolio includes only 4 projects related to MS whereas spinal cord injury, with a prevalence less than that of MS, has 39 active projects in the NIDRR portfolio.

Since the advent of FDA-approved MS disease-modifying treatments in 1993, persons with MS have had access to therapeutics which can slow the progression of disability. However, in order to maintain maximum levels of independence, persons with MS need rehabilitation to address residual deficits. Unfortunately, due to the limited support for MS rehabilitation research, we know relatively little about the efficacy of rehabilitative interventions in MS. We therefore urge the NIDRR to increase its support for MS rehabilitation research through the funding of at least one additional MRRTC along with initiatives to stimulate individual research projects.

OVERALL NIH FUNDING INCREASE FOR FISCAL YEAR 2007

The Society is deeply concerned that NIH may face a fourth year of overall low funding increases. This low funding level endangers the potential breakthroughs and discoveries that motivated Congress to complete a five-year campaign to double NIH's budget in 2003. In fact, the trend toward flat or slightly decreased NIH funding could put NIH on a trajectory to un-double its budget because the annual cost of inflation cannot be covered.

Furthermore, we are gravely concerned that the current annual NIH investment in MS research of \$110 million is projected to drop by \$1 million in 2007 and another \$1 million in 2008. This trend jeopardizes progress toward a cure and new treatments for MS. Indeed, we remind the committee that in the 1990's, it was the NIH's basic and clinical research that contributed greatly to the development of the first disease modifying drugs for MS. Now there are 6 such drugs approved for MS therapy, and the NIH is funding a major trial to test whether combining drugs can enhance their benefit.

Moreover, NIH-funded research catalyzes industry efforts to develop drugs in many ways. Industry tells us that developing biomarkers that can measure the progression of MS could dramatically enhance their efforts to develop drugs. Over the last several years, advances in brain imaging for MS have taken a major step towards the goal of MS biomarkers. The NIH has a major effort underway to identify additional methods to measure the progression of MS, this is another step toward increased understanding of MS. Moreover, because of these advances in understanding of MS, biotech and pharmaceutical companies currently have more than

a dozen drugs for MS in various stages of clinical testing. Despite these significant efforts, the number of new drug applications to the Food and Drug Administration continues to decline. The Society fears that this negative trend will be accelerated by continued reductions in NIH-funded research.

A lack of Federal funds for biomedical research and MS research, in particular, will also force junior and senior researchers to leave the scientific workforce, further slowing the pace of research. Such an outcome would mean that substantial investments biomedical research would have been squandered, and replenishing this workforce would take a generation. We therefore urge Congress to:

- Appropriate a 5 percent fiscal year 2007 funding increase for NIH.
- Balance the fiscal year 2007 NIH appropriation to allow growth across all NIH institutes and all areas of disease research.

We ask the subcommittee to be mindful of the thousands of Americans, and particularly those with MS, who will be affected if the pace of research is slowed by reductions in NIH funding. While treatments are available for MS, these are expensive and only partially effective for some patients. Until a cure is found, people affected by MS want more effective and more economical treatments.

The surest path to discovering treatments for MS, and for human diseases in general, is by sustaining the country's investment in innovative biomedical research at universities and small businesses. Funding cuts threaten these efforts, and will invariably harm the country's research infrastructure. Correcting such damage may take a generation, and Americans with MS cannot afford to wait that long. Moreover, the country cannot afford the economic consequences of delaying the discovery of treatments that could change the lives of those impacted by MS.

We thank the subcommittee for this opportunity to comment and applaud your commitment to advancing the health and well-being of all Americans through investment in biomedical research.

PREPARED STATEMENT OF THE NIH TASK FORCE OF THE BIOENGINEERING DIVISION
OF THE BASIC ENGINEERING GROUP OF THE COUNCIL ON ENGINEERING OF ASME

The NIH Task Force of the Bioengineering Division of the Basic Engineering Group of the Council on Engineering of ASME, is pleased to provide comments on the bioengineering-related programs in the National Institutes of Health (NIH) fiscal year 2007 budget request. The ASME Bioengineering Division is focused on the application of mechanical engineering knowledge, skills and principles from conception to the design, development, analysis and operation of biomechanical systems.

THE IMPORTANCE OF BIOENGINEERING

Bioengineering is an interdisciplinary field that applies physical, chemical and mathematical sciences and engineering principles to the study of biology, medicine, behavior, and health. It advances knowledge from the molecular to the organ systems level, and develops new and novel biologics, materials processes, implants, devices, and informatics approaches for the prevention, diagnosis, and treatment of disease, for patient rehabilitation, and for improving health. Bioengineers have employed mechanical engineering principles in the development of many life-saving technologies, such as the artificial heart, prosthetic joints and numerous rehabilitation technologies.

BACKGROUND

NIH is the world's largest and most eminent organization dedicated to improving health through medical science. During the last 50 years, NIH has played a pre-eminent role in the major breakthroughs that have increased average life expectancy by 15 to 20 years.

NIH is comprised of different Institutes and Centers that support a wide spectrum of research activities including basic research, disease and treatments related studies, and epidemiological analyses. The missions of individual Institutes and Centers focus on a particular organ (e.g. heart, kidney, eye), on a given disease (e.g. cancer, infectious diseases, mental illness), on a stage of development (e.g. childhood, old age), or, may encompass crosscutting needs (e.g., sequencing of the human genome and the National Institute of Biomedical Imaging and Bioengineering (NIBIB).

The total fiscal year 2007 NIH budget request is \$28.6 billion, which represents approximately the same level as the fiscal year 2006 appropriation. Some \$50 million of this increase is for radiological/nuclear countermeasures development. NIH R&D, 97 percent of the total NIH budget, would also remain flat at \$27.8 billion

next year. The largest increases would go to the Office of Director and towards bio-defense R&D.

According to the President's fiscal year 2007 budget request, "NIH's highest priority is the funding of medical research through research project grants (RPGs). Support for RPGs allows NIH to sustain the scientific momentum of investigator-initiated research while pursuing new research opportunities." The administration estimates that the fiscal year 2007 budget would support an estimated 9,337 new research project grants (RPGs), an increase of about 275 new competing RPGs from fiscal year 2006. Nevertheless, NIH projects a decline in the total number of RPGs for the third year in a row, no inflation adjustment for most new or continuing grants, and a decline in the RPG success rate for the sixth year in a row down to 19 percent. RPGs account for 52 percent of the 2007 NIH Budget Request.

The largest percentage increase would go to the Office of the Director (OD; up 25.1 percent) to boost OD funding for clinical research, high-risk basic research, and collaborative research in the NIH Roadmap for Biomedical Research. The Roadmap would receive \$443 million in fiscal year 2006 (up 34 percent), with \$332 million coming from institute budgets. Currently, the Roadmap Initiatives provides \$80 million annually, or roughly 24 percent of the total roadmap budget, for bioengineering-related project.

Other initiatives funded by the fiscal year 2007 budget request are 5 awards for the new K/R "Pathway to Independence" program and the Genes, Environmental, and Health Initiative (GEHI) that will study genetic factors associated with disease and accelerate technological development that can measure human responses to environmental influences on health.

The President's fiscal year 2007 budget requests \$294.5 million for the NIBIB, a reduction of \$1.96 million (0.7 percent) below the fiscal year 2006 enacted level. Most NIH institutes are also slated for reductions in funding in the President's budget request.

Below are some highlights from the fiscal year 2007 budget request for NIBIB. Further details can be found at <http://www.nibib.nih.gov/publicPage.cfm?pageID=263#FY2007>.

NIBIB Extramural Research would decline 1.3 percent, to \$268 million.

The number of research project applications to NIBIB continues to grow, with the number doubling from fiscal year 2003 to fiscal year 2004 and then increasing by 20 percent from fiscal year 2004 to fiscal year 2005. The research budget, however, has remained flat. Consequently, the success rate for investigators applying for extramural research grants from the NIBIB is the second lowest among the NIH institutes and centers. It is estimated that the success rate for these applications was 16.8 percent in fiscal year 2004, decreasing to approximately 15 percent in fiscal year 2005. The projected success rate for fiscal year 2006 is only between 10 and 15 percent.

NIBIB Intramural Research would grow 6.3 percent, to \$7.7 million.

In September 2004, the NIBIB Special Advisory Panel for Intramural Programs met to develop recommendations for the National Advisory Council on Biomedical Imaging and Bioengineering concerning an intramural research program within the NIBIB. Intramural research accounts for approximately 10 percent of the total NIH budget. The NIBIB currently is at the low end in terms of funds it commits to intramural research among all of the NIH institutes, both in terms of dollars expended and percentage of its total budget. The Panel recommended that NIBIB not pursue the near-term expansion of its Intramural Research Program beyond the available funding in the current budget and the fiscal year 2005 President's Budget proposal. The Panel further recommended that NIBIB use its limited intramural funds primarily to expand interdisciplinary training opportunities at the postdoctoral level. In addition to the already established training grants offered by the NIBIB, there is a new initiative co-sponsored by the NSF Engineering Directorate to offer summer institute training for undergraduate students. It is hoped that such programs can be offered regularly now and/or expanded. More information can be found at <http://bbsi.eicom.com/>.

The estimate for NIH-wide bioengineering research was \$1.291 billion in fiscal year 2006, and \$1.32 billion in fiscal year 2005. The proposed 2007 amount is \$1.296 billion, a 0.4 percent increase over 2006. These numbers reflect bioengineering funding by any of the 27 NIH institutes or Office of the Director.

RECOMMENDATIONS

The Task Force is concerned that funding for bioengineering has continued to lag compared to many areas of NIH, and will continue to do so, especially now that the

doubling of the NIH budget is complete and the total funding for NIH remains flat. While a strong supporter of the NIBIB, the Task Force is also concerned that bioengineering continues to constitute less than half the budget for the NIBIB. There is a need for advanced engineering concepts to be applied to basic and translational biomedical problems for the potential of recent biological advances to be realized. The request for more bioengineering funding addresses a critical need for developing and applying more complex engineering principles to biomedical problems. In many cases, such engineered solutions to health care problems will result in a reduction in health care costs. Therefore, the Task Force strongly urges Congress to provide increased funding for bioengineering within the NIBIB and across NIH. The NIBIB requires exceptional consideration for funding increases in the coming years. It is notable that the success rate for funding applications to the NIBIB is currently between 10–15 percent, even lower than the declining average NIH-wide success rate of 19 percent. This is a direct manifestation of the continued growth of the field outpacing funding increases to the NIBIB.

While the Task Force supports new Federal proposals that seek to double Federal research and development in the physical sciences over the next decade, the Task Force believes that strong Federal support for bioengineering and the life sciences is essential to the health and competitiveness of the Nation. Increased funding for the NIH has put the United States in a leading position in pharmaceuticals, bioengineering, and medical sciences. Long-term lack of funding for NIH programs would harm the tremendous gains the United States has made over the last decade.

ASME International is a non-profit technical and educational organization with 125,000 members worldwide. The Society's members work in all sectors of the economy, including industry, academic, and government. This statement represents the views of the ASME NIH Task Force of the Bioengineering Division and is not necessarily a position of ASME as a whole.

PREPARED STATEMENT OF THE NATIONAL PRIMATE RESEARCH CENTERS

The Directors of the National Primate Research Centers (NPRCs) respectfully submit this written testimony for the record of the U.S. Senate Appropriations Subcommittee on Labor, Health and Human Services, and Education. The NPRCs appreciate the commitment that the members of this subcommittee have made to biomedical research through strong support for the National Institutes of Health (NIH). Given your leadership on this issue, the NPRCs urge Congress to direct resources to NIH to ensure that the Federal investment in vital biomedical research will not be compromised.

The NPRCs are a national network of eight primate research centers supported by the NIH National Center for Research Resources (NCRR). The centers comprise the National Primate Research Program (NPRP), which was developed by Congress in 1960. The program seeks to address human health problems through scientific research using the animal models that most closely resemble humans in their genetics, physiology, and disease processes—primates. NPRCs support research that is sponsored by nearly every institute of NIH. For example, NPRCs conduct research to help understand and treat diseases such as heart disease, hypertension, cancer, diabetes, hepatitis, AIDS, kidney disease, Alzheimer's disease, and Parkinson's disease. They also conduct research on emerging infectious diseases and many aspects of biodefense. Each NPRC makes its facilities available to investigators from around the country. Our centers create collaborative research environments that allow scientists to combine their individual expertise beyond the scope of established disciplinary research projects.

NPRCs endorse the fiscal year 2007 Ad Hoc Group for Medical Research proposal to increase the NIH budget by five percent over the fiscal year 2006 level. We recognize that the current budget environment puts pressure on Congress to face difficult funding trade-offs; however, as this subcommittee works to define priorities for the year and set goals for the future, we ask that you maintain your long-term commitment of support for NIH and its mission. The President's fiscal year 2007 budget would flat-fund NIH. The five percent increase for NIH supported by NPRCs would not only allow the agency to sustain current programs but also invest in critical new initiatives. This would prevent NIH from falling behind the "Innovation Index"—the rate of biomedical inflation as calculated in the Biomedical Research and Development Price Index (BRDPI) plus a modest investment in new initiatives. Using the fiscal year 2007 BRDPI projection as a base, NIH would require an increase of at least 3.8 percent over fiscal year 2006 to maintain current programs. However, we strongly believe that an increase for NIH above BRDPI is justified by the health needs as well as current and burgeoning research capabilities of the Nation. An in-

crease above BRDPI would allow new innovative ideas to be funded and would infuse existing programs to evolve as their research findings push them to higher levels of basic understanding, translation and clinical functionality.

As a result of years of expanded investment in biomedical research, the demand for the NPRCs' resources has increased significantly. The ability of NIH-funded researchers to conduct future projects with primate models will depend on the enhancement of three key areas: (1) the nationwide availability of primates; (2) the quality and capacity of primate housing and breeding facilities, as well as the availability of related state-of-the-art diagnostic and clinical support equipment at NPRCs; and (3) the number of personnel trained in primate care and management at NPRCs. These areas can be enhanced by an NIH/NCRR commitment to increase the NPRCs P51 base grants (the mechanism that funds each NPRC). Biomedical researchers across the Nation are experiencing shortages in the availability of primates for essential research. Increases to the P51 base grants would allow NPRCs to: expand existing breeding colonies and develop bridging programs to use effectively the under-utilized species of primates in research; invest in repairs, renovation, and construction of research facilities, as well as the purchase of modern laboratory equipment; and ensure that adequate numbers of experts are trained in laboratory animal medicine and research, because NPRCs must maintain primate management teams comprised of behavioral specialists, veterinarians, and primate research experts to ensure excellent primate care, health, and research success.

Increases from NIH/NCRR to the NPRCs P51 base grant are necessary to meet the needs discussed above and are critical to the ability of NPRCs to supply adequate primate resources for scientists across the Nation to carry out important research projects. As mentioned previously, these research projects span the disease foci at NIH institutes and centers, and also play important roles in the NIH Roadmap, the NCRR Strategic Plan, and grand challenges facing the scientific community. In the 1950's, primate research produced the first vaccine for one of the world's worst childhood killers, the Polio virus, reducing the number of cases in the United States from 58,000 to one or two per year. Primates have also served as the best model for various types of HIV research, and their availability for use has resulted in at least 14 licensed anti-viral drugs for treatment of HIV infection. Primate models will continue to be necessary to defend the world against possible future epidemics such as SARS, West Nile Virus, and avian flu. In addition to deadly viral epidemics, primate research has enabled the discovery of better treatments and therapies for diseases and occurrences such as stroke, cataracts, depression and other psychiatric illnesses. Significant advances in prenatal and postnatal care have also resulted from primate research.

Further, not only do primates have the potential to provide answers for long-standing research questions, primate research provides an unparalleled opportunity to address more recently defined research priorities, such as those relating to genomics and bioterrorism. The specific availability of information in the primate genome, which is quite similar to the human genome, makes primates essential in studies that require an integrated understanding of a whole biological system. Recent reports suggest that extensive analysis of genome structure and function in nonhuman primates could make immediate and significant contributions to the overall mission of NIH by accelerating progress in understanding many human diseases. Also, primates serve as critical animal models in biodefense research projects for which, in some cases, it would be inappropriate to conduct early clinical trials in humans. Primates are recognized as vital research resources within Federal strategic plans regarding biodefense research, including: the National Institute of Allergy and Infectious Diseases (NIAID) Strategic Plan for Biodefense Research; the NIAID Research Agenda for Category A Agents; and the NIAID Research Agenda for Category B and C Priority Pathogens. Also, NPRCs are partners in NIAID-funded Regional Centers of Excellence for Biodefense and Emerging Infectious Diseases as well as with NIAID-funded National and Regional Biocontainment Laboratories.

As NIH and the national biomedical research agenda evolve, NPRCs adjust to meet the resource needs of the research community but also to maintain research programs that are on the cutting-edge of science. The reservoirs of knowledge residing within the NPRCs create new opportunities for research partnerships with investigators at host academic institutions and in the biomedical research community at large. Never have the research questions been so profound, or the implications for human health so critical. NPRCs are poised to bridge the gap between knowledge already gleaned from simple cellular and animal models and knowledge that is needed to promote human health and cure human disease. Past accomplishments demonstrate, and current and future research directions will rely on, the roles of robust primate research programs in addressing critical research questions. The

breadth and success of primate research programs confirm the vital role that the eight NPRCs play in biomedical research nationwide.

Thank you for the opportunity to submit this written testimony and for your attention to the critical need for primate research and enhancement of the NPRCs P51 base grant, as well as our recommendations concerning funding for NIH in the fiscal year 2007 Appropriations Bill.

PREPARED STATEMENT OF THE NATIONAL PROSTATE CANCER COALITION

On behalf of the National Prostate Cancer Coalition, I appreciate the opportunity to submit written comments regarding funding to Prostate Cancer programs. I would also like to offer our best estimates on the resources necessary to continue to fight the war on prostate cancer in fiscal year 2007, most specifically funding for prostate cancer research, prevention, detection and treatment programs funded by the Labor, Health and Human Services and Education Appropriations Bill.

HISTORY OF PROSTATE CANCER FUNDING

For the past ten years, the NPCC has worked to reduce the burden of prostate cancer through awareness, outreach, and advocacy. As you may know Prostate cancer is the most common cancer (next to skin cancer) and the second leading cause of cancer-related death in men in the United States. It is estimated this year over 234,000 men will be diagnosed with prostate cancer, and more than 27,000 will die as a result of the disease. Of the 10 million Americans living with cancer today, two million of these have prostate cancer.

This past decade has been an exciting and important one for prostate cancer research. Congress and the administration have taken notice of the impact prostate cancer has on our Nation. In 1998, Congress promised to double the budget of the NIH within 5 years, and triple the amount of Federal funding for prostate cancer research. By keeping that promise, prostate cancer research funding has increased and expanded to record levels. As a result, more men are screened and diagnosed with this disease and prostate cancer survivorship rates have increased. Also for the first time since 1930, the number of cancer deaths has decreased in 2003. These exciting results cannot continue without a stable and reasonable level of funding to the NIH. Unfortunately in fiscal year 2003, NIH funding did not keep up with the increase of inflation. Last year in fiscal year 2006 the NIH and prostate cancer research programs received a hard cut to programs at the Center for Disease Control and the National Cancer Institute.

With less funding, researches cannot continue to discover ways to combat prostate cancer. New drugs and treatment options are harder to translate from the lab to the patients. We cannot fight the war on prostate cancer without the proper tools. The National Prostate Cancer Coalition understands the limited resources our Nation faces. However, when research continues to show the eradication of cancer is within research, we must continue to fund these programs which will save millions of lives, reduce untold suffering and save the Nation billions of dollars in healthcare costs.

It is important to note that Americans spend over \$4.6 billion per year for treatment of this disease (this does not include the burden of lost productivity and wages). Statistics show that as baby boomers continue to age, the number of Americans impacted by cancer will increase. These statistics show the far reaching effects prostate cancer can have, not only on individuals and their families, but the Nation's economy as well.

FUNDING REQUESTS

This year we have joined with the Cancer and Public Health Communities to urge this committee and Congress to provide \$29.7 billion for the NIH, a \$1.4 billion increase of fiscal year 2006. We request funding that will maintain current programs and progress at the NIH. We would also request that Congress appropriate \$5.034 billion for the National Cancer Institute, a \$240 million increase over fiscal year 2006. Again, this funding would only maintain the current discovery pace. Additionally we ask for Congress to appropriate \$20 million (+6.07 million) for the Prostate Cancer Control Initiatives at the Centers for Disease Control. With this program, the public receives information about prostate screening and early detection. With increased funding, this program can expand and improve outreach efforts.

The NPCC urges these changes to the fiscal year 2007 Appropriations bill to ensure funding to cancer research and related programs are a top priority in fiscal year 2007 and in the future. We thank you for the opportunity to discuss the need

for these tools to fight the war on prostate cancer. Again, we need to continue to fund these programs to ensure that our Nation continues to make advances in cancer eradication.

PREPARED STATEMENT OF THE NATIONAL SLEEP FOUNDATION

SUMMARY OF FISCAL YEAR 2007 RECOMMENDATIONS

- Provide a 5 percent increase for fiscal year 2007 to the National Institutes of Health (NIH) and a proportional increase of 5 percent to the individual institutes and centers, specifically, the National Heart, Lung, and Blood Institute (NHLBI).
- Continue to urge the National Center on Sleep Disorders Research (NCSDR) of the NHLBI and the Centers for Disease Control and Prevention (CDC) to partner with voluntary health organizations, such as the National Sleep Foundation (NSF), to develop a collaborative sleep education and public awareness initiative based on the roundtable model that other public health-related agencies have used with success. In view of the success of the CDC with similar initiatives, encourage and support the CDC in taking a leadership role with the roundtable initiative.
- Encourage the Director of the NIH and the Director of the National Heart, Lung, and Blood Institute to name a permanent Director to the National Center on Sleep Disorders Research.
- Encourage CDC to increase support for initiatives connecting sleep to overall health and safety. Provide \$6.321 billion for fiscal year 2007 to the CDC, the same amount Congress provided to the agency in fiscal year 2005.
- Continue to urge the United States Surgeon General to develop and implement a report on sleep and sleep disorders in order to call attention to the importance of sleep and develop strategies to protect and advance the health and safety of the Nation.

Mr. Chairman and members of the subcommittee, thank you for allowing me to submit testimony on behalf of the National Sleep Foundation (NSF). I am Dr. Barbara Phillips, Chairman of the NSF Board of Directors and professor at the University Of Kentucky College Of Health in the Department of Preventive Medicine. The NSF is an independent, non-profit organization that is dedicated to improving public health and safety by achieving understanding of sleep and sleep disorders, and by supporting sleep-related education, research, and advocacy. We work with sleep medicine and other health care professionals, researchers, patients and drowsy driving victims throughout the country as well as collaborate with many government and public and private organizations with the goal of preventing health and safety problems related to sleep deprivation and untreated sleep disorders.

Sleep problems, whether in the form of medical disorders, or related to work schedules and a 24/7 lifestyle, are ubiquitous in our society. At least 50 million Americans suffer from sleep disorders and millions of others experience sleep problems related to other medical conditions; yet more than 60 percent of adults have never been asked about the quality of their sleep by a physician, and fewer than 20 percent have ever initiated such a discussion. Millions of individuals struggle to stay alert at school, on the job, and on the road. According to the National Highway Traffic Safety Administration's 2002 National Survey of Distracted and Drowsy Driving Attitudes and Behaviors, an estimated 1.35 million drivers have been involved in a drowsy driving related crash in the past five years. A large number of academic studies have linked work accidents, absenteeism, and school performance to sleep deprivation and circadian effects.

Sleep apnea, a sleep-related breathing disorder which affects at least 5 percent of adult Americans and is closely related to some of America's most pressing health problems, such as obesity, hypertension, heart failure, and diabetes. Chronic insomnia, experienced by at least 10 percent of our population is a strong risk factor for depression and other widespread mental health conditions. The direct and indirect costs associated with sleep disorders and sleep deprivation total an estimated \$100 billion annually.

Sleep science has clearly demonstrated the importance of sleep to health and well-being, yet research studies continue to show that millions of Americans are at risk for the serious health and safety consequences of untreated sleep disorders and inadequate sleep. Moreover their quality of life suffers and the personal and national economic impact is staggering. The severity of the public health burden represented by sleep issues are compellingly detailed in a groundbreaking new report, Sleep Dis-

orders and Sleep Deprivation: An Unmet Public Health Problem by the Institute of Medicine.

NSF believes that every American needs to understand that good health includes healthy sleep, just as it includes regular exercise and balanced nutrition. We must elevate sleep to the top of the national health agenda. We need your help to make this happen.

Our biggest challenge is bridging the gap between the outstanding scientific advances we have seen in recent years and the level of knowledge about sleep held by health care practitioners, educators, employers, and the general public. Consequently, the NSF is spearheading two important initiatives to raise public and physician awareness of the importance of sleep to the health, safety and well-being of the Nation.

First, because resources are limited and the challenges great, we think creative and new partnerships need to be developed to address sleep awareness. Therefore, the NSF has been working with the National Center on Sleep Disorders Research (NCSDR) and the Centers for Disease Control and Prevention (CDC), to develop an ongoing, inclusive mechanism for public and professional awareness on sleep, sleep disorders and the consequences of fatigue. Such collaboration between Federal agencies and voluntary health organizations would create an opportunity for dramatically improving public health and safety as well as the quality of life for millions, if not all, Americans. Since November of 2004, NIH, CDC, and NSF have been meeting with other interested and diverse voluntary and professional groups and Federal agencies to discuss the formation of a broad coalition dedicated to raising public awareness of sleep. This effort should continue to receive the support of Congress in order to encourage the participation of relevant Federal agencies.

In relation to this effort, the National Center on Sleep Disorders Research within the National Heart, Lung and Blood Institute (NHLBI) currently has an acting director as the result of the recent promotion of Dr. Carl Hunt. NCSDR was created in 1993 by the National Institutes of Health Revitalization Act (Public Law 103-43) and has served an important role in furthering the scientific and public health knowledge related to sleep deprivation and sleep disorders. NSF requests that you encourage both Drs. Elias Zerhouni, the Director of NIH, and Elizabeth Nabel, the Director of the NHLBI to name a permanent director to this vitally important Center as soon as possible, so that the mission of the NCSDR is not significantly impacted. Additionally, given the significant and unique mission of the Center, NIH should consider the following characteristics for the NCSDR director position: history of collaborative efforts among sleep investigators and educators; recognition and stature in the field of sleep medicine; and familiarity with the research needs and gaps in the field of sleep medicine.

Secondly, at the National Institutes of Health's Frontiers of Knowledge in Sleep and Sleep Disorders conference, the U.S. Surgeon General acknowledged widespread illiteracy in our country regarding sleep loss and untreated sleep disorders. He emphasized that sleep problems are easily related to the three top areas of the national health agenda: prevention, preparedness, and health disparities. Prevention of some of our Nation's most pressing health problems would be fostered by attending to sleep disorders. Sleep deprivation is a major barrier to maximizing preparedness and response in times of crisis. Finally, like many health concerns, access to knowledge and medical care for sleep problems is less accessible to some of our citizens.

Conferences and workshops held by the Surgeon General involve educating the public, advocating for effective disease prevention and health promotion programs and activities, and providing a highly recognized symbol of national commitment to protecting and improving the public's health. The NSF believes it is time that the Federal Government helps promote sleep as a public health concern through the development of a Surgeon General's Report on Sleep and Sleep Disorders in order to call attention to the importance of sleep and develop strategies to protect and advance the health and safety of the Nation. Therefore, the NSF is advocating for the development and dissemination of a Surgeon General's Report on Sleep and Sleep Disorders.

The new report by the Institute of Medicine includes important recommendations that support the spirit of these efforts and other specific actions to be taken by the CDC, NIH and other Federal agencies and private foundations to increase surveillance of and education on sleep health and sleep disorders. CDC, NIH and the Surgeon General must partner with voluntary health organizations and increase support for initiatives that help ensure the health and safety of all Americans.

Thank you again for the opportunity to present you with this testimony.

PREPARED STATEMENT OF THE NEPHCURE FOUNDATION

SUMMARY OF RECOMMENDATIONS FOR FISCAL YEAR 2007

(1) A 5 percent increase for the National Institutes of Health (NIH) and the National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK).

(2) Continue to expand the NIH's Nephrotic Syndrome (NS) and Focal Segmental Glomerular Sclerosis (FSGS) research portfolios by aggressively supporting NIDDK grant proposals in this area and by encouraging the National Center for Minority Health and Health Disparities (NCMHD) to initiate studies into the incidence and cause of NS and FSGS in minority populations.

Mr. Chairman and members of the subcommittee, I am pleased to present testimony on behalf of the NephCure Foundation (NCF), a non-profit organization driven by a panel of respected medical experts and a dedicated band of patients and families working together towards a common goal-to save kidneys and to save lives. NCF is the only non-profit organization exclusively devoted to fighting idiopathic nephrotic syndrome (NS) and focal segmental glomerulosclerosis (FSGS). Now in its sixth year, the NephCure Foundation continues to work tirelessly to support glomerular disease research.

FSGS: One Family's Story

My son, Bradley Grizzard, was diagnosed with focal segmental glomerulosclerosis (FSGS) in 2002. In May of 2005, I donated one of my kidneys to him.

FSGS is one of a cluster of glomerular diseases that attack the one million tiny filtering units (nephrons) contained in each human kidney. Glomerular disease attacks the portion of the nephron called the glomerulus, scarring and often destroying these filters. Scientists do not know why glomerular injury occurs, and there is no known cure for these diseases.

FSGS patients, upon diagnosis, often take a downward plunge at a rapid rate and it is extremely difficult to make a comeback. My son was a star football player at his high school and was being recruited by college football coaches before FSGS attacked his body. When his kidneys failed, he was forced to give up football, and he had to try and juggle college classes along with several hours of dialysis a day. We were lucky that my kidney was a match for him, but even so the first few hospitals that we approached refused to perform the transplant. We were eventually able to find a doctor and a hospital that was willing to perform the operation, and the transplanted kidney is now working well. But Bradley must remain on costly immunosuppressant drugs for the rest of his life. These drugs cause many unpleasant side effects and medical complications.

My son's story is not unique. There are thousands of other people in this country who have had their lives disrupted due to the sudden onset of FSGS or NS. And although kidney transplants have been very successful for thousands of patients, many patients end up rejecting the transplanted kidney. Other times, the disease comes back and attacks the transplanted kidney. In either case, the patient must then again rely on daily dialysis as a means of survival. There are thousands of young people who are in a race against time, hoping for a treatment that will save their lives. The NephCure Foundation today raises its voice to speak for them all, asking you to take specific actions that will aid our quest to find the cause and cure of FSGS and NS.

First and foremost, we join the Ad Hoc Group for Medical Research Funding in asking for a 5 percent increase for the National Institutes of Health (NIH) and the National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK).

More Research is Needed

We are no closer to finding the cause or the cure of FSGS. Scientists tell us that much more research needs to be done on the basic science behind the disease.

We are thankful that the NIDDK continues to work with the NephCure Foundation on the FSGS clinical trial. Currently 150-175 patients nationwide are enrolled in the trial. Recently, the steering committee charged with providing programmatic direction to the trial decided on several changes which would accelerate progress. NCF is also working with the NIDDK to cosponsor ancillary basic biological material studies of the enrolled patients.

The NephCure Foundation is also grateful to the NIDDK for issuing two program announcements (PAs) that serve to initiate grant proposals on glomerular disease. The first program announcement, issued in December of 2005, includes glomerular disease as one of several kidney or urologic diseases for which the PA will fund grant proposals. The second PA, issued in March of 2006, is glomerular-disease specific. Both of these announcements will utilize the R21 mechanism to award researchers \$275,000 over two years.

We ask the Committee to encourage the NIDDK to help find the cause and the cure for glomerular disease by continuing its support for the FSGS clinical trial and the ancillary basic biological material studies. We also ask the NIDDK to continue to add glomerular disease to program announcements.

Too Little Education About a Growing Problem

When glomerular disease strikes, it results in a loss of protein from the urine and edema. The edema often manifests itself as puffy eyelids, a symptom that many parents and physicians mistake as allergies. With experts projecting a substantial increase in the number of cases of glomerular disease in the coming years, there is a clear need to educate pediatricians and family physicians about glomerular disease and its symptoms.

The NephCure Foundation has numerous education programs underway. A national FSGS conference will be held in Philadelphia from June 3rd–4th, 2006. This conference will aim to provide attendees with the most up to date information on this disease. Through speakers, information sessions, and informal conversations with other patient families, attendees will realize they are not alone and will be further energized for the effort to find a cause and a cure for FSGS.

Also, this summer, the NIDDK will sponsor a working group scientific conference. This working group will advise NIDDK on animal models, reagents, and other resources for the study of glomerular disease.

We also applaud the work of the NIDDK in establishing the National Kidney Disease Education Program (NKDEP), and we seek your support in urging the NIDDK to make sure that glomerular disease remains a focus of the NKDEP.

We ask the Committee to encourage the NIDDK to have glomerular disease receive high visibility in its education and outreach efforts, and to continue these efforts in conjunction with the NephCure Foundation's work. These efforts should be targeted towards both physicians and patients.

Glomerular Disease Strikes Minority Populations

Nephrologists tell us that glomerular disease strikes a disproportionate number of African-Americans. No one knows why this is, but some studies have suggested that a genetic sensitivity to sodium may be partly responsible. DNA studies of African Americans who suffer from FSGS may lead to insights that would benefit the thousands of African Americans who suffer from kidney disease.

As an African-American female and the mother of a son with FSGS, I ask that the NIH pay special attention to why this disease affects my race to such a large degree. The NephCure Foundation wishes to work with the NIDDK and the National Center for Minority Health and Health Disparities (NCMHD) to encourage the creation of programs to study the high incidence of glomerular disease within the African-American population.

There is also evidence to suggest that the incidence of glomerular disease is higher among Hispanic-Americans than in the general population. An article in the February 2006 edition of the NIDDK publication *Recent Advances and Emerging Opportunities*, discussed the case of Frankie Cervantes, a six year old boy of Mexican and Panamanian descent. Frankie has FSGS, and like Bradley, received a transplanted kidney from his mother. We applaud the NIDDK for highlighting FSGS in their publication, and for translating the article about Frankie into both English and Spanish. Only through similar culturally appropriate efforts can African American and Hispanic families learn more about glomerular disease.

We ask the Committee to join with us in urging the NIDDK and the National Center for Minority Health and Health Disparities (NCMHD) to collaborate on research that studies the incidence and cause of this disease among minority populations. We also ask that the NIDDK and the NCMHD undertake culturally appropriate efforts aimed at educating minority populations about glomerular disease.

PREPARED STATEMENT OF ONE VOICE AGAINST CANCER

One Voice Against Cancer (OVAC) appreciates the opportunity to submit written comments for the record regarding funding for cancer programs for research, prevention, detection, and treatment as well as programs that educate and train nurses in fiscal year 2007 at the National Institutes of Health (NIH), the Centers for Disease Control and Prevention (CDC), and the Health Resources and Services Administration (HRSA). OVAC is a collaboration of more than 40 major national organizations representing millions of Americans affected by cancer, unified to urge Congress and the White House to increase cancer-related appropriations. OVAC stands ready to work with policymakers at the Federal, State, and local levels to ensure

that these important cancer and nursing initiatives at NIH, CDC, and HRSA receive adequate funding in fiscal year 2007.

Our Nation's prior investments in cancer research-related programs have saved thousands of lives and accelerated our progress toward the Administration's goal of eliminating death and suffering due to cancer by the year 2015. However, the challenge remains—cancer will strike one of every two men and one of every three women in the United States. This year alone, more than 1.4 million men and women in this country will receive the devastating news that they have cancer; yet, more than 10 million cancer survivors can attest to the fact that we are making real progress against this disease.

The Congress took a bold step forward in 1998 when it promised to double the budget of the National Institutes of Health (NIH) within five years. By keeping that promise, Congress opened the floodgates to countless new opportunities and advances in cancer research and programs. Thanks to the advances spawned by that infusion of support for biomedical research, cancer survivorship rates have steadily increased each year. For the first time since 1930, the number of cancer deaths in the United States decreased in 2003. Congress must maintain that promise with a stable and reasonable level of funding increases to sustain the momentum of this exciting research. Since fiscal year 2003, NIH funding levels have fallen far short of keeping pace with inflation alone, and fiscal year 2006 resulted in a hard cut to both NIH and National Cancer Institute funding levels.

Less funding translates immediately into fewer discoveries, fewer new drugs in development, and fewer new treatments reaching patients. We cannot reach the 2015 goal without the continued support of the Congress. We appreciate that our Nation faces many challenges and Congress has limited resources to allocate. However, the conquest of cancer and elimination of health disparities is truly within our grasp. Making cancer a national priority will save millions of lives, reduce untold suffering, and save the Nation billions of dollars in healthcare costs now and for the foreseeable future. The investment is surely worth it.

SUSTAIN AND SEIZE CANCER RESEARCH OPPORTUNITIES

The tremendous investment our Nation has made in the National Institutes of Health (NIH) has reaped remarkable returns and set the table for a period of unparalleled innovation in the fight against cancer and other diseases. For fiscal year 2007, OVAC joins with the broader public health community and urges Congress to provide \$29.7 billion for the NIH, a \$1.4 billion increase over fiscal year 2006. This is the minimal level of funding that will allow the NIH to maintain the current pace of discovery and innovation.

OVAC recognizes the fiscal challenges facing policymakers, but does not believe that those challenges require us to weaken our national commitment to conquering cancer. While the long-term goal of providing adequate funding to explore the most promising opportunities must remain paramount, for fiscal year 2007, OVAC urges Congress to provide the National Cancer Institute (NCI) with at least \$5.034 billion, a \$240 million increase over fiscal year 2006. This level of funding is the bare minimum required to protect our cancer research enterprise and maintain the current pace of discovery.

While a minimal increase of \$240 million will maintain current programs, it is not sufficient to allow us to move forward with advances that we know are possible. For fiscal year 2007, OVAC would recommend an increase closer to that of the professional judgment budget prepared by the NCI Director. This budget, which calls for \$5.9 billion for fiscal year 2007, represents our national battle plan against cancer, outlining the critical core research that is currently underway and the most promising and extraordinary research opportunities. These exceptional research opportunities include expansion of the NCI-designated cancer centers program from 60 to 75 centers; implementation of the plan to reengineer cancer clinical trials for greater standardization, speed, and efficiency; construction of linkages between science and the new technologies of advanced imaging, proteomics, and computational modeling; expansion of the use of medical informatics and bioinformatics to cancer-specific applications; and development of an integrative site-based approach to cancer research through interdisciplinary team science and collaboration. The professional judgment budget is developed through an open and public process; it reflects the best thinking of cancer researchers, patients, clinicians, and other constituency groups and is focused on the Institute's goal of eliminating suffering and death from cancer by the year 2015.

The National Center on Minority Health and Health Disparities (NCMHD) was created by Congress to help address the undue burden of chronic and acute disease, morbidity and mortality, and lower survival rates borne by racial and ethnic minor-

ity groups, rural populations and other medically underserved populations. OVAC urges the Congress to provide the NCMHD with \$200 million for fiscal year 2007 to advance its critical work coordinating and advancing health disparities research across the NIH. OVAC seeks to ensure that NCMHD has the resources to develop and enhance initiatives aimed at reducing and ultimately eliminating disparities in many chronic diseases, including cancer. Having worked with Congress to establish the NCMHD, the members of OVAC are committed to seeing it fulfill its mission and achieve its goals and objectives.

BOOST OUR NATION'S INVESTMENT IN CANCER PREVENTION, EARLY DETECTION, AND AWARENESS

The Centers for Disease Control and Prevention's (CDC) State-based cancer programs provide vital resources for cancer monitoring and surveillance, breast and cervical cancer screening, State cancer control planning and implementation, and awareness initiatives targeting skin, prostate, colon, ovarian and blood cancers. For fiscal year 2007, OVAC requests the following funding levels for these proven programs:

- National Comprehensive Cancer Control Program: \$50 million (+\$33 million).*—The Comprehensive Cancer Control program provides grants and technical assistance to help States develop and implement plans addressing the cancers most significantly affecting their communities through prevention, early detection and treatment. OVAC's request will allow this program to help more States implement previously developed plans.
- National Program of Cancer Registries: \$65 million (+\$16.89 million).*—The National Program of Cancer Registries facilitates State tracking of cancer trends and subsequent allocation of resources to address specific needs, while also identifying highly effective cancer control programs that can be emulated across the country. The registry provides critical data to ensure we remain on track in the fight against cancer. OVAC's request will enable States to continue to collect and analyze high-quality data as well as evaluate existing cancer prevention efforts.
- National Breast and Cervical Cancer Early Detection Program: \$250 million (+\$47.57 million).*—OVAC appreciates the Administration's longstanding commitment to this important program that provides free breast and cervical screening tests to low income and uninsured women. Unfortunately, millions of eligible women lack access to these critical tests due to lack of funding. The CDC estimates that the program currently only reaches 20 percent of eligible women aged 50 to 64. OVAC's funding request for fiscal year 2007 would allow at least an additional 130,000 women to be served by the program.
- Colorectal Cancer Screening, Education & Outreach Initiative: \$25 million (+\$10.51 million).*—Strong scientific evidence has shown that regular screening and treatment is a cost-effective way to reduce colorectal cancer incidence and mortality. However, screening rates for CRC are currently lower than for other cancer screening services. The Colorectal Cancer Screening, Education & Outreach Initiative helps increase public awareness of colorectal cancer, educate health care providers about colorectal screening guidelines and assist State programs with colorectal cancer priorities. With additional resources this program will be able to expand its awareness initiatives and reduce the number of preventable colorectal cancer deaths.
- National Skin Cancer Prevention Education Program: \$5 million (+\$2.93 million).*—Skin cancer is the most common form of cancer in the United States and is largely preventable. OVAC's request will allow the program to educate the public about ways to protect themselves and reduce the risks of getting skin cancer.
- Prostate Cancer Control Initiatives: \$20 million (+6.07 million).*—This initiative provides the public, with special emphasis on men and their physicians, with information about prostate cancer screening and early detection. OVAC's request will allow the program to expand and improve its outreach efforts.
- Ovarian Cancer Control Initiatives: \$7.5 million (+\$2.98 million).*—The Ovarian Cancer Initiative partners with academic and medical institutions to spur discovery of techniques that will detect this cancer and develop more successful treatments. OVAC's request will increase public and professional awareness of the symptoms and best treatments for ovarian cancer, restoring hope to the more than 20,000 women who will be diagnosed with this devastating illness this year.
- Geraldine Ferraro Blood Cancer Program: \$5 million (+\$0.46 million).*—Authorized under the Hematological Cancer Research Investment and Education

Act of 2002, this program was created to provide public and patient education about blood cancers, including leukemia, lymphoma and myeloma. OVAC's request will allow the program to continue to provide patients with educational, disease management and survivorship resources to enhance treatment and prognosis.

SECURING AND MAINTAINING AN ADEQUATE ONCOLOGY NURSING WORKFORCE

OVAC joins with the nursing community in asking Congress to provide \$175 million in fiscal year 2007 for the Nurse Reinvestment Act and the other nursing workforce programs at the Health Resources and Services Administration (HRSA). Over the next 15 years, the number of Medicare beneficiaries with cancer is expected to double, while more than 1.1 million nursing positions go unfilled. The critical role of nurses in our health care system cannot be overstated. Oncology nurses are on the front-lines of the provision of quality care for cancer patients and are vital to administering chemotherapy, managing patient treatments and side-effects and providing counseling to patients and family members.

Without an adequate supply of nurses, there will not be enough qualified oncology nurses to provide quality, comprehensive cancer care to a growing patient population in need. Nurses are also vital to helping conduct cancer research through clinical trials, and a shortage will slow down the pace of medical research progress. These programs will help address the multiple factors contributing to the nationwide nursing shortage, including the decline in student enrollments, shortage of faculty and poor public perception of nursing as a viable and worthwhile profession.

CONCLUSION

OVAC stands ready to work with policymakers to ensure that funding for cancer research and related programs is a top priority in fiscal year 2007 and beyond. We thank you for this opportunity to discuss the funding levels necessary to ensure that our Nation continues to make gains in our fight against cancer and has a sufficient nursing workforce to care for the patients with cancer of today and tomorrow.

PREPARED STATEMENT OF THE OVARIAN CANCER NATIONAL ALLIANCE

On behalf of the Ovarian Cancer National Alliance (the Alliance), I thank the subcommittee for this opportunity to submit written testimony regarding the fiscal year 2007 funding allocations for programs in the Labor-Health and Human Services and Education appropriations measure that the Alliance and ovarian cancer community believe are necessary to help reduce and prevent suffering from ovarian cancer. Since its inception nine years ago, the Alliance has worked to increase awareness of ovarian cancer and boost Federal resources to support scientific research into diagnostics and treatments for the disease. Among the most urgent challenges in the ovarian cancer field are late detection and poor survival of women.

As a national umbrella organization with 50 regional, State, and local groups, the Alliance unites and reaches more than 800,000 grassroots activists, women's health advocates, health care professionals and the public to bring national attention to ovarian cancer. As part of this effort, the Alliance advocates for a sustained Federal investment in ovarian cancer research, awareness, education and early detection. To that end, the Alliance respectfully requests that the subcommittee provide the following in fiscal year 2007 funding:

- \$7.5 million to the Centers for Disease Control and Prevention's (CDC) Ovarian Cancer Control Initiative;
- \$29.7 billion to the National Institutes of Health (NIH); and
- \$5.034 billion to the National Cancer Institute (NCI).

These three agencies are working relentlessly to achieve much-needed gains in ovarian cancer early detection, treatment and survivorship. Consistent investment in ovarian cancer research and public awareness campaigns at CDC, NIH and NCI is vital to our fight against this deadly disease. The Alliance believes all women should have the opportunity to survive ovarian cancer, but unfortunately, unless our Nation makes significant investment in ovarian cancer research and awareness efforts, thousands of women will continue to lose their lives every year.

OVARIAN CANCER'S DEADLY STATISTICS

Today, it is both striking and disheartening to see that despite progress made in the scientific, medical and advocacy communities, ovarian cancer mortality rates have not significantly improved during the past decade. According to the American Cancer Society, in 2006 more than 20,000 American women will be diagnosed with

ovarian cancer and approximately 15,300 will lose their lives to this disease, making it the fifth leading cause of cancer death in women (behind lung, breast and colorectal cancers). Every woman is at risk for ovarian cancer and one in 58 will develop it in her lifetime.

Behind the sobering statistics are the lost lives of our loved ones, colleagues and community members. The country recently lost a national treasure to the disease when Mrs. Coretta Scott King died from stage III ovarian cancer in January. Her disease was considered terminal after a late-stage diagnosis. Unfortunately, Mrs. King's story is common for women in our community. When detected early, the five-year survival rate for women with ovarian cancer increases to more than 90 percent. However, a valid and reliable screening test—a critical tool for improving early diagnosis and survival rates—still does not exist for ovarian cancer. With no early detection test, more than 75 percent of women diagnosed with ovarian cancer are diagnosed in stage III or IV. At these stages prognosis is worst as the five-year survival rate drops below 30 percent. In simple terms, today, almost half (45 percent) of all women with ovarian cancer will die within five years of their diagnosis.

Until a screening test is developed, public knowledge of the symptoms of ovarian cancer and comprehensive, effective treatment protocols are the keys to reduced mortality rates. The CDC Ovarian Cancer Control Initiative, NIH and NCI work together to support programs and research grants that seek to improve early detection and treatment and educate women and health care providers about ovarian cancer, thereby increasing awareness and ultimately saving lives.

THE OVARIAN CANCER CONTROL INITIATIVE AT THE CENTERS FOR DISEASE CONTROL AND PREVENTION

The CDC Ovarian Cancer Control Initiative plays an essential role in our Nation's fight to eliminate suffering and death from ovarian cancer. Created by Congress in 2000, the program coordinates and funds health activities aimed at identifying and filling any gaps in knowledge of ovarian cancer diagnosis and treatment. According to the program website, "CDC enhances the limited knowledge about ovarian cancer by initiating research projects with partners, colleagues and national organizations to help identify factors related to early disease detection and treatment and survivorship." The CDC Ovarian Cancer Control Initiative actively partners with State cancer registries and cancer centers across the country.

As the Nation's leading public health agency, the CDC plays an important role in translating and delivering research discoveries at the community level, especially ensuring that those populations disproportionately affected by cancer receive the benefits of our Nation's investment in medical research. With its extensive network of health professionals and cancer registries, the CDC is the optimal Federal agency for such work.

EARLY DETECTION AND AWARENESS

Most women and many health professionals remain unaware of the signs and symptoms associated with ovarian cancer. Consequently, many women suffer with the disease for months, even years, prior to receiving an accurate—and often fatal—diagnosis. Since there is no effective screening tool for ovarian cancer, it is imperative that women and their health care providers be aware of the multiple ways that ovarian cancer can present in a woman through symptoms. The CDC Ovarian Cancer Control Initiative is unique among CDC cancer programs. With no screening tool, the goal of the Ovarian Cancer Control Initiative is to learn more about current practice and identify areas of knowledge and practice patterns that need improvement to reduce the overwhelming burden of ovarian cancer.

STANDARDS OF CARE AND TREATMENT

The efforts of the CDC Ovarian Cancer Control Initiative also are targeted at improving prognosis for women currently living with and fighting the disease. Investigation into early symptoms, survival trends based on care provided, and research into general epidemiology will fill in information gaps to provide a stable body of knowledge which will guide future research. Most significantly, examination of survival trends based on care received contributes to the development of best practice guidelines for women with ovarian cancer. Currently, research funded by the Ovarian Cancer Control Initiative addresses four public health questions:

- What factors influence risk perception and how does risk perception affect screening behaviors?
- What are the primary diagnostic pathways in the diagnosis of ovarian cancer?
- Are women receiving optimal surgical and chemotherapy treatments?
- Are women receiving optimal end-of-life care?

Investigation into these questions will allow the CDC to maximize screening effectiveness by primary care physicians, improve early detection and diagnosis and provide physicians with “best practice” guidelines for women diagnosed with ovarian cancer. According to the CDC, \$2.2 billion is spent on treatment for ovarian cancer each year. This figure could greatly be reduced with earlier diagnoses and more efficient practice guidelines.

CDC OVARIAN CANCER CONTROL INITIATIVE-FUNDED GRANTS

Grants supported by the CDC Ovarian Cancer Control Initiative have covered a diverse array of activities over the past six years, all aimed at accomplishing the program’s mission of increasing awareness and improving treatment and survivorship of ovarian cancer. Current on-going ovarian cancer studies include the following:

- The Division of Cancer Prevention and Control (DCPC) at the CDC is investigating the influence of perceived risk of ovarian cancer on screening behaviors. This information will be used to maximize screening effectiveness in average and high risk women.
- Analysis of records of ovarian cancer patients and healthy women presenting symptoms similar to those associated with ovarian cancer to create more specific guidelines for symptom-recognition.
- Investigation into the relationship between patient characteristics, provider characteristics, diagnostic procedures and referral patterns leading to a positive diagnosis to create best practice guidelines for primary care physicians.
- Investigation into current surgical and chemotherapy practices for women diagnosed with ovarian cancer to develop best practice guidelines and to identify the demographics of women who typically receive poor treatment plans.
- Research and development of end-of-life care guidelines to prevent undue suffering in women with ovarian cancer.

BOOSTING THE CDC’S OVARIAN CANCER PREVENTION AND AWARENESS EFFORTS

In only six years of existence, the CDC Ovarian Cancer Control Initiative has made important contributions to better understanding and awareness of the disease. However, until the development of a valid and reliable screening test, more must be done to increase awareness and recognition of the symptoms of ovarian cancer. The full impact and benefits of CDC Ovarian Cancer Control Initiative efforts will not be fully realized unless the results are effectively translated into public health interventions.

The CDC Ovarian Cancer Control Initiative must continue to build its research efforts, but needs enhanced funding to move research results out to health care providers and women. Most significantly, increased resources are needed for a national effort to educate primary care providers on the signs and symptoms of ovarian cancer. These physicians and nurses are the most likely group to encounter women presenting with ovarian cancer warning signs and symptoms that, if recognized early, could lead to a faster diagnosis and therefore an increased chance of survival.

Additional funding in fiscal year 2007 will enable the CDC to expand the reach and scope of its current ovarian cancer initiatives to help advance our Nation’s efforts to reduce and prevent ovarian cancer morbidity and mortality. The allocation of \$7.5 million in fiscal year 2007 will continue the excellent progress being made and would help expand the program’s efforts to include:

- Development and implementation of two critical and complementary national campaigns about the signs and symptoms of ovarian cancer:
 - (A) A public education campaign with a focus on the signs and symptoms of ovarian cancer, the importance of regular monitoring for high risk populations and strategies for risk reduction.
 - (B) A targeted education and awareness campaign involving primary care physicians.
- Examination of the epidemiology of ovarian cancer and development of appropriate strategies for addressing issues related to incidence and survival in minority populations.
- Training of health care professionals in best practices for treating ovarian cancer, emphasizing referral to gynecologic oncologists for optimal survival outcomes.

A SUSTAINED COMMITMENT TO FUND CANCER RESEARCH

Our Nation has reaped many benefits from past Federal investments in biomedical research at the NIH. The Alliance has joined with the broader health community in urging Congress to provide NIH \$29.7 billion and NCI \$5.034 billion in

fiscal year 2007 to allow these agencies to sustain their efforts while also having the resources to avoid the severe disruption to that progress that would result from a minimal funding increase. The requested increase in NCI allocations represents our national battle plan against cancer, focusing on critical ongoing research and promising research opportunities.

When funding stagnates or does not keep pace with inflation, progress in critical research programs can be halted or slowed significantly. Inadequate funding for the NIH, NCI and the CDC can result in inadequate funding for the lesser-known or less popular—yet terribly devastating—diseases such as ovarian cancer. The requested funding levels would provide the minimum resources required to preserve our cancer research enterprise and maintain the current pace of discovery.

SUMMARY AND CONCLUSION

The Alliance maintains a long-standing commitment to work with Congress, the Administration, and other policymakers and stakeholders to improve the survival rate from ovarian cancer through education, public policy, research and communication. Please know that we appreciate and understand that Congress has limited resources to allocate, but we believe the health and safety of American women are imperative to the strength of our Nation and should be a national priority. We are concerned that without increased funding to bolster and expand ovarian cancer education, awareness and research efforts, the Nation will continue to see growing numbers of women losing their battle with this terrible disease.

On behalf of the entire ovarian cancer community—patients, family members, clinicians and researchers—we thank you for your leadership and support of Federal programs that seek to reduce and prevent suffering from ovarian cancer. Thank you in advance for your support of the funding allocations we have requested for the CDC Ovarian Cancer Control Initiative, NIH and NCI. Please know that we stand ready to serve as a resource for any information you may need. Thank you for the opportunity to submit testimony on fiscal year 2007 ovarian cancer funding.

PREPARED STATEMENT OF THE POPULATION ASSOCIATION OF AMERICA/ASSOCIATION OF POPULATION CENTERS

INTRODUCTION

Thank you, Mr. Chairman Specter, Mr. Ranking Member Harkin, and other distinguished members of the subcommittee, for this opportunity to express support for the National Institutes of Health (NIH) and the National Center for Health Statistics (NCHS)—two agencies important to our organizations.

BACKGROUND ON THE PAA/APC AND DEMOGRAPHIC RESEARCH

The PAA is a scientific organization comprised of over 3,000 population research professionals, including demographers, sociologists, and economists. The APC is a similar organization comprised of over 30 universities and research groups that foster collaborative demographic research and data sharing, translate basic population research for policy makers, and provide educational and training opportunities in population studies. Over 30 population research centers are located throughout the country, including two in Ohio (Bowling Green State University and Ohio State University) and two in Pennsylvania (Pennsylvania State University and the University of Pennsylvania).

Demography is the study of populations and how or why they change. Demographers, as well as other population researchers, collect and analyze data on trends in births, deaths, and disabilities as well as racial, ethnic, and socioeconomic changes in populations. Major policy issues population researchers are studying include the demographic causes and consequences of population aging, trends in fertility, marriage, and divorce and their effects on the health and well being of children, and immigration and migration and how changes in these patterns affect the ethnic and cultural diversity of our population and the Nation's health and environment.

The NIH mission is to support research that will improve the health of our population. The health of our population is fundamentally intertwined with the demography of our population. Recognizing the connection between health and demography, the NIH supports population research programs primarily through the National Institute on Aging (NIA) and the National Institute of Child Health and Human Development (NICHD).

Over the next 25 years, the number of individuals age 65 and older will likely double, reaching 70.3 million and comprising a larger proportion of the entire population, rising from 13 percent today to 20 percent in 2030.¹ This substantial growth in the older population is driving policymakers to consider dramatic changes in Federal entitlement programs, such as Medicare and Social Security, and other budgetary changes that could affect programs serving the elderly. Further, the macroeconomic and global impact of population aging on competitiveness in the world economy is becoming a bigger issue. To inform this debate, policymakers need objective, reliable data about the antecedents and impact of changing social, demographic, economic, and health characteristics of the older population. The NIA Behavioral and Social Research (BSR) program is the primary source of Federal support for research on these topics.

In addition to supporting an impressive research portfolio, that includes the prestigious Centers of Demography of Aging Program, the NIA BSR program also supports several large, accessible data surveys. Two such surveys, the National Long-Term Care Survey (NLTCS) and the Health and Retirement Study (HRS) have become seminal sources of information to assess the health and socioeconomic status of older people in the United States. By using NLTCS data, investigators identified the declining rate of disability in older Americans first observed in the mid-1990s—a trend that continued and even accelerated. This trend, if continued, could have momentous impact on reducing the need for costly long-term care. The HRS, which was launched in 1992 and has tracked 27,000 people, has provided data on a number of issues, including the role families play in the provision of resources to needy elderly and the economic and health consequences of a spouse's death. The Social Security Administration recognizes and funds the HRS as one of its "Research Partners" and posts the study on its home page to improve its availability to the public and policymakers. In 2005, the Center for Medicare and Medicaid Services (CMS) funded a supplemental survey using the HRS to provide CMS with timely information on who is likely to enroll in the new Medicare Part D prescription drug program and how those decisions are related to knowledge of the program, drug costs, and use.

With additional support in fiscal year 2007, the NIA BSR program could fully fund its existing centers and support its ongoing surveys. Additional support would allow NIA to expand the centers' role in understanding the domestic macroeconomic as well as the global competitiveness impact of population aging. NIA could also use additional resources to support individual investigator awards by precluding an 18 percent cut in its existing grants, improving its funding payline, which is now in the 10th percentile, and sustaining training and research opportunities for new investigators, which are being heavily cut back.

NATIONAL INSTITUTE ON CHILD HEALTH AND HUMAN DEVELOPMENT

Since its establishment in 1968, the NICHD Center for Population Research has supported research on population processes and change. Today, this research is housed in the Center's Demographic and Behavioral Sciences Branch (DBSB). The Branch encompasses research in four broad areas: family and fertility, mortality and health, migration and population distribution, and population composition. In addition to funding research projects in these areas, DBSB also supports a highly regarded population research infrastructure program and a number of large database studies, including the Fragile Families and Child Well Being Study and National Longitudinal Study of Adolescent Health.

NICHD-funded demographic research has consistently provided critical scientific knowledge on issues of greatest consequence for American families: work-family conflicts, marriage and childbearing, childcare, and family and household behavior. However, in the realm of public health, demographic research is having an even larger impact, particularly on issues regarding adolescent and minority health. For example, in 2006, researchers with the National Longitudinal Study of Adolescent Health, reported findings illustrating that by the time they reach early adulthood (age 19–24), a large proportion of American youth have begun the poor practices contributing to three leading causes of preventable death in the United States: smoking, poor diet and physical inactivity, and alcohol abuse. This study is striking in that it found the health situation of young people—in terms of behavior, health conditions, and access to and use of care—deteriorates markedly between the teen and young adult years. The study reinforces the importance of educating young peo-

¹Federal Interagency Forum on Aging Related Statistics. Older Americans 2000: Key Indicators of Well-Being. 2000.

ple about adopting healthy lifestyles after they leave high school and the parental home.

Understanding the role of marriage and stable families in the health and development of children is another major focus of the NICHD DBSB. Consistently, research has shown children raised in stable family environments have positive health and development outcomes. Therefore, NICHD supports research to elucidate factors that contribute to family formation and strong partnerships. Recent findings have identified factors that can destabilize relationships between new parents. These factors include serious health or developmental problems of the parents' child, lower earnings, less education, and a father who has other children with different mothers. Policymakers and community programs can use these findings to support unstable families and improve the health and well being of children.

With additional support in fiscal year 2007, NICHD could restore full funding to its large-scale surveys, which serve as a resource for researchers nationwide. Furthermore, the Institute could apply additional resources toward improving its funding payline, which has gone from the 20th percentile range in 2003 to the 10th percentile in January 2006. Additional support could be used to preclude cuts of 17 percent to 22 percent in applications approved for funding and to support and stabilize essential training and career development programs to prepare the next generation of researchers.

NATIONAL CENTER FOR HEALTH STATISTICS

Located within the Centers for Disease Control (CDC), the National Center for Health Statistics (NCHS) is the Nation's principal health statistics agency, providing data on the health of the U.S. population and backing essential data collection activities. Most notably, NCHS funds and manages the National Vital Statistics System, which contracts with the States to collect birth and death certificate information. NCHS also funds a number of complex large surveys to help policy makers, public health officials, and researchers understand the population's health, influences on health, and health outcomes. These surveys include the National Health and Nutrition Examination Survey, National Health Interview Survey, and National Survey of Family Growth. Together, NCHS programs provide credible data necessary to answer basic questions about the state of our Nation's health.

In fiscal year 2006, Congress provided NCHS with the same level of funding as in fiscal year 2005, and the Administration has recommended NCHS receive the same level in fiscal year 2007. For fiscal year 2007, the Friends of NCHS recommends the agency receive \$139 million, a \$30 million increase over the fiscal year 2006 level. This funding is needed to, among other things, cover cost increases in basic survey operations, improve data timeliness and access to data, and expand and improve data collection to capture much needed information on issues such as health disparities, assisted living, and community health centers.

RECOMMENDATIONS

At a time when our Nation is poised to reap the promise of the past investment made in the NIH, the agency is facing the prospect receiving flat funding in fiscal year 2007. When inflation is factored in, the NIH could actually be facing being funded for the fourth year in a row below the rate of biomedical research inflation. PAA and APC join other organizations in expressing our concern about the precarious NIH funding trajectory. Already, NIH has seen a 15 percent reduction in new grants between fiscal year 2003 and fiscal year 2006. For population research, increased support is needed to ensure the best research projects, including new and innovative projects, are being awarded, surveys and databases are supported, and training programs are stabilized. With respect to NCHS, funding is needed to sustain and update its major operations.

The PAA and APC join the Ad Hoc Group for Medical Research in supporting an fiscal year 2007 appropriation of \$29.75 billion, a 5 percent increase over the fiscal year 2006 appropriation, for the NIH. In addition, the Friends of NCHS, support a fiscal year 2007 appropriation of \$139 million, a 30 percent increase over the fiscal year 2006 appropriation, for the NCHS. Finally, PAA and APC urge the subcommittee to include language in the fiscal year 2007 bill, allowing continuation of the National Children's Study at the NICHD.

Thank you for considering our requests and for supporting Federal programs that benefit the field of demographic research.

PREPARED STATEMENT OF THE PULMONARY HYPERTENSION ASSOCIATION

SUMMARY OF FISCAL YEAR 2007 RECOMMENDATIONS

- \$250,000 within the Centers for Disease Control and Prevention for a pulmonary hypertension awareness and education program.
- A 5 percent increase for the National Heart, Lung and Blood Institute and the establishment of “Specialized Centers of Clinically Orientated Research” on Pulmonary Hypertension at the Institute.
- \$25 million for the Health Resources and Services Administration’s “Gift of Life” Donation Initiative.

Mr. Chairman, thank you for the opportunity to submit testimony on behalf of the Pulmonary Hypertension Association.

I am honored today to represent the hundreds of thousands of Americans who are fighting a courageous battle against this devastating disease. Pulmonary hypertension is a serious and often fatal condition where the blood pressure in the lungs rises to dangerously high levels. In PH patients, the walls of the arteries that take blood from the right side of the heart to the lungs thicken and constrict. As a result, the right side of the heart has to pump harder to move blood into the lungs, causing it to enlarge and ultimately fail.

PH can occur without a known cause or be secondary to other conditions such as; collagen vascular diseases (i.e., scleroderma and lupus), blood clots, HIV, sickle cell, and liver disease. PH does not discriminate based on race, gender or age. Patients develop symptoms that include shortness of breath, fatigue, chest pain, dizziness, and fainting. Unfortunately, these symptoms are frequently misdiagnosed, leaving patients with the false impression that they have a minor pulmonary or cardiovascular condition. By the time many patients receive an accurate diagnosis, the disease has progress to a late stage, making it impossible to receive a necessary heart or lung transplant.

While new treatments are available, unfortunately, PH is frequently misdiagnosed and often progresses to late stages by the time it is detected. Although PH is chronic and incurable with a poor survival rate, the new treatments becoming available are providing a significantly improved quality of life for patients. Recent data indicates that the length of survival is continuing to improve, with some patients able to manage the disorder for 20 years or longer.

Fifteen years ago, when three patients who were searching to end their own isolation founded the Pulmonary Hypertension Association, there were less than 200 diagnosed cases of this disease. It was virtually unknown among the general population and not well known in the medical community. They soon realized that this was unacceptable, and formally established PHA, which is headquartered in Silver Spring, Maryland.

Today, PHA includes:

- Over 6,000 patients, family members, and medical professionals.
- An international network of over 120 support groups.
- An active and growing patient telephone helpline.
- A new and fast-growing research fund. (A cooperative agreement has been signed with the National Heart, Lung, and Blood Institute to jointly create and fund five, five-year, mentored clinical research grants and PHA has awarded eleven Young Researcher Grants.)
- Numerous electronic and print publications, including the first medical journal devoted to pulmonary hypertension—published quarterly and distributed to all cardiologists, pulmonologists and rheumatologists in the United States.

Mr. Chairman, at the age of 5, my wife and I noticed that our daughter, Emily, could not keep up with the other kids in the neighborhood. She seemed to lack the energy and strength to run and play. This condition seemed to worsen to the point to where she would have to stop and rest after coming down the steps in the morning. We noticed that when she was sitting on the bottom step in the morning, her lips appeared to have a bluish color.

After pressing for an answer to these problems for several months, Emily was finally diagnosed with pulmonary hypertension and the doctors gave a probable remaining lifespan of three years. That unforgettable day was 8 years ago and, as you can see, Emily is still here today. She is here because of continued advances in the treatment of pulmonary hypertension and by the grace of God. There is however, NO cure for pulmonary hypertension. Thanks to congressional action, Emily’s chances of a full life have greatly increased. We need, however, additional support for research and related activities to continue to develop treatments that will extend the published NIH life expectancy beyond the 2.8 years after diagnosis.

(A) National Heart, Lung and Blood Institute

Mr. Chairman, PHA commends the National Heart, Lung and Blood Institute (NHLBI) for its strong support of PH research. According to leading researchers in the field, we are on the verge of significant breakthroughs in our understanding of the disease and the development of new and advanced treatments. Ten years ago, a diagnosis of PH was essentially a death sentence, with only one approved treatment for the disease. Thanks to advancements made through the public and private sector, patients today are living longer and better lives with a choice of five FDA approved therapies. Recognizing we have made tremendous progress, we are also mindful that we are a long way from where we want to be, and that is; (1) the management of pulmonary hypertension as a treatable chronic disease, and (2) A CURE.

Mr. Chairman, it is our understanding that NHLBI is poised to establish "Specialized Centers of Clinically Orientated Research" in pulmonary hypertension later this year. We are very excited about the promise these Centers hold for the future development of new treatments and we encourage the subcommittee to support this worthy investment. In addition, we applaud NHLBI and the NIH Office of Rare Diseases for their plans to co-sponsor a two-day scientific conference on pulmonary hypertension this Fall. This important event will bring together leading PH researchers from the United States and abroad to discuss the state of the science in pulmonary hypertension and future research directions.

In order to facilitate the establishment of the Specialized Centers of Clinically Orientated Research and maintain promising research currently underway on PH, the Pulmonary Hypertension Association encourages the subcommittee to provide NHLBI with a 5 percent increase in funding in fiscal year 2007.

(B) Centers for Disease Control and Prevention

PHA applauds the subcommittee for its leadership over the years in encouraging the Centers for Disease Control and Prevention to initiate a Pulmonary Hypertension Education and Awareness Program. We know for a fact that Americans are dying due to a lack of awareness of PH, and a lack of understanding about the many new treatment options. This unfortunate reality is particularly true among minority and underserved populations. However Mr. Chairman, you don't have to rely solely on our word regarding the need for additional education and awareness activities. On November 11, 2005 the CDC released a long awaited Morbidity and Mortality Report on pulmonary hypertension. In that report, the CDC states:

(1) "More research is needed concerning the cause, prevention, and treatment of pulmonary hypertension. Public health initiatives should include increasing physician awareness that early detection is needed to initiate prompt, effective disease management. Additional epidemiologic initiatives also are needed to ascertain prevalence and incidence of various pulmonary hypertension disease entities." (Page 1, MMWR Surveillance Summary—Vol. 54 No. SS-5)

(2) "Prevention efforts, including broad based public health efforts to increase awareness of pulmonary hypertension and to foster appropriate diagnostic evaluation and timely treatment from health care providers, should be considered. The science base for the etiology, pathogenesis, and complications of pulmonary hypertension disease entities must be further investigated to improve prevention, treatment, and case management. Additional epidemiologic activities also are needed to ascertain the prevalence and incidence of various disease entities." (Page 7, MMWR Surveillance Summary—Vol. 54 No. SS-5)

Mr. Chairman, we are grateful to CDC for their recent support of a DVD highlighting the proper diagnosis of PH. However, despite repeated encouragement from the subcommittee over the past 5 years, CDC has not taken any steps to establish an education and awareness program on PH. Therefore, we respectfully request that you provide \$250,000 in fiscal year 2007 for the establishment of a PH awareness initiative through the Pulmonary Hypertension Association.

(C) "Gift of Life" Donation Initiative at HRSA

Mr. Chairman, PHA applauds the success of the Health Resources and Services Administration's "Gift of Life" Donation Initiative. This important program is working to increase organ donation rates across the country. Unfortunately, the only "treatment" option available to many late-stage PH patients is a lung or heart and lung transplantation. This grim reality is why PHA established "Bonnie's Gift Project." "Bonnie's Gift" was started in memory of Bonnie Dukart, one of PHA's most active and respected leaders. Bonnie was a PH patient herself. She battled with PH for almost 20 years until her death in 2001 following a double lung transplant. Prior to her death, Bonnie expressed an interest in the development of a pro-

gram within PHA related to transplant information and awareness. PHA will use “Bonnie’s Gift” as a way to disseminate information about PH, transplantation and the importance of organ donation to our community and organ donation cards.

PHA has had a very successful partnership with HRSA’s “Gift of Life” Donation Program in recent years. Collectively, we have worked to increase organ donation rates and raise awareness about the need for PH patients to “early list” on transplantation waiting lists. For fiscal year 2007, PHA recommends an appropriation of \$25 million (an increase of \$2 million) for this important program.

Mr. Chairman, once again thank you for the opportunity to present the views of the Pulmonary Hypertension Association. We look forward to continuing to work with you and the subcommittee to improve the lives of pulmonary hypertension patients.

PREPARED STATEMENT OF THE SOCIETY FOR INVESTIGATIVE DERMATOLOGY
SUMMARY OF THE SOCIETY FOR INVESTIGATIVE DERMATOLOGY’S FISCAL YEAR 2007
RECOMMENDATIONS

(1) A 5 percent increase for all of the National Institutes of Health (NIH) and for the National Institute of Arthritis and Musculoskeletal and Skin Diseases (NIAMS).

(2) Establishment of a skin disease clinical trials network that will collect baseline data for specific orphan diseases and facilitate the exchange of scientific data across disciplines and institutes.

(3) Encourage NIAMS to develop collaborative funding mechanisms with other NIH institutes and private foundations that leverage skin biology studies as a developmental model that will serve for the advancement of research across a multitude of diseases and specialties.

(4) Encourage NIAMS to sponsor studies that capture general and skin disease specific measures in order to generate incidence, prevalence and quality of life data attributable to skin diseases.

(5) Increase the number of training awards through the NIH designed to facilitate the entry of more individuals into careers in skin disease research.

BACKGROUND

The Society for Investigative Dermatology (SID) was founded in 1938. Its 2,000 members represent over 40 countries worldwide, including scientists and physician researchers working in universities, hospitals and industry.

Our members are dedicated to the advancement and promotion of the sciences relevant to skin health and disease through education, advocacy, and the scholarly exchange of scientific information along with our colleagues from the American Academy of Dermatology.

This collective commitment to research is evidenced in the scientific journal published by the SID, the *Journal of Investigative Dermatology*. The *Journal* is a catalyst for the exchange of scientific information pertaining to the 3,000 skin diseases that afflict nearly 80 million Americans annually.

The purpose in presenting testimony is to increase awareness of the need for more skin research, based on the burden attributable to skin disease. It will also highlight some of the advancements that past support has enabled.

We join with the Ad Hoc Group for Medical Research Funding in asking for a 5 percent increase to the National Institutes of Health (NIH) and the National Institute of Arthritis and Musculoskeletal and Skin Diseases (NIAMS).

BURDEN OF SKIN DISEASE

Prior bill report language directed NIAMS to “consider supporting the development of new tools to measure the burden of skin diseases, and the training of researchers in this important area”. There only a handful of researchers working on NIH-sponsored research that will provide such measures.

Skin disease impacts our citizens more than previously estimated. A recent report released by the Society for Investigative Dermatology and the American Academy of Dermatology, “The Burden of Skin Disease”, compiled data from only 21 of the known 3,000 skin diseases and disorders. The estimated economic costs to society each year from those 21 diseases totaled nearly \$39 billion.

The true impact extends far beyond mere economics. These patients encounter discomfort and pain, physical disfigurement, disability, dependency and death. Skin conditions affect an individual’s ability to interact with others and compromise the self-confidence of those inflicted.

One of the most striking findings in the study was the lack of general and skin-disease specific measures that are needed to generate data surrounding the incidence, prevalence, economic burden, quality of life, disability and handicaps attributable to these diseases.

We ask the Committee to devote the resources needed to develop components of national health surveys that capture dermatological data above and beyond skin cancer incidence and prevalence.

RESEARCH ADVANCES

Skin is the body's largest organ and serves as the primary barrier to external pathogens and toxins. Researchers at the NIH campus and institutions around the country are working diligently to define how the skin functions to protect us, how this fails in disease, and how compromised functions in disease can be restored.

Cell biology allows scientists to understand the life cycle of skin and hair-producing cells and identify the causes of disease, leading to better treatments and preventative measures. Advances in wound healing and skin ulcers are helping the growing aging population, those with diabetes, burn victims and our veteran population. Lasers continue to provide less invasive options for patients requiring surgery.

Fundamental discoveries resulting from skin biology and translational research have yielded advances that are broadly applicable to human development and disease. Continued investment is required to fully capitalize on these ground-breaking advances.

Important new research findings include the following:

- The genes responsible for skin cancer and inherited skin disorders have been identified, making targeted therapy possible.
- The molecular mechanisms of auto-immune and inflammatory skin diseases are better understood, allowing for the use of focused, selective immunosuppressive therapy with greater safety and efficacy.
- Oral medications to treat and prevent viral and fungal diseases have become available.
- Lasers have made possible the removal of disfiguring skin malformations.
- Modern phototherapy and photochemotherapy allow for more effective treatment of inflammatory skin disease, lymphoma, depigmenting disorders and auto-immune diseases.
- Retinoids and sunscreens have reduced the risk of skin cancer in the elderly, in transplant patients, and in other populations.
- Painless transdermal drug delivery has become available.

Recent developments in the areas of clinical epidemiology, biostatistics, economics, and the quantitative social sciences have begun to provide objective evaluation measures, although additional and improved measures are still desperately needed. These measures will help to identify effective interventions and allow us to better quantify contributions to the quality of life and health of Americans.

A significant portion of skin disease is chronic, resulting from aging, genetics and environmental and occupational exposure.

We ask the NIH to work to identify additional biomarkers in order to better understand skin disease pathways and interaction with other diseases and environmental factors.

TRANSLATING DISCOVERY TO TREATMENTS FOR AMERICANS

The goal of skin disease research is to improve the quality of life for the one in three Americans that suffer from skin disease. That goal is embedded in the collective missions of the SID and the intramural and extramural scientists funded through the skin portfolios of many of the 27 Institutes and Centers of the NIH.

Medical research organizations such as the SID are the direct recipients of the awards made possible through the rigorous peer-reviewed grant system in place at the NIH. The ultimate beneficiaries are the nearly 80 million Americans that stand to benefit from the discoveries resulting from research grants.

Inadequate levels of Federal funding have forced Institute administrators to reduce certain types of the available funding mechanisms currently in place at the NIH, to decrease success rates, to increase administrative cost reductions, to consider decreasing the number of awards, and to cut award levels in existing programs.

Unfortunately, this reality impairs the ability of hypothesis-driven research, the source of countless discoveries, to drive the research system. Adequate funding levels will allow the peer-review system to work at full potential, leading to findings that translate into better care for those suffering from debilitating diseases. Without

sufficient funding provided specifically for skin research, nearly one third of the Nation would be denied any hope for a better quality of life.

We are grateful for the past support that has been given to the NIH and ask you to look for innovative ways to avoid flat or decreased funding levels to these Institutes that are charged with improving the health of Americans.

PREPARED STATEMENT OF THE SOCIETY FOR MATERNAL-FETAL MEDICINE

The Society for Maternal-Fetal Medicine appreciates the opportunity to comment on the fiscal year 2007 budget for the National Institutes of Health. We are especially grateful for the Committee's support of the National Institute of Child Health and Human Development over the past years and urge your continued commitment to the critical medical research conducted and supported by the National Institutes of Health.

Established in 1977, the Society for Maternal-Fetal Medicine (SMFM) is a not-for-profit organization of over 2,000 members that are dedicated to improving perinatal care through research and education. Maternal-fetal medicine doctors have advanced knowledge of the obstetrical, medical, genetic and surgical complications of pregnancy and their effects on both the mother and fetus. The many advances in research have allowed the maternal-fetal medicine physician to provide the direct care needed to treat the special problems that high risk mothers and fetuses face.

The SMFM applauds the National Institute of Child Health and Human Development (NICHD) for its efforts to pursue research to understand, prevent and treat the abnormal events that can occur during pregnancy. For example:

Preterm birth.—Remains a leading cause of death, illness, and disability among infants during their first year of life. It poses great risks to both the infant and mother. Infants born too early are at higher risk than full-term babies for medical and developmental complications. The earlier the birth, the more risk of complications. In addition even without any neonatal conditions, these infants face serious adult complications including heart disease and diabetes resulting from their intra-uterine environment and low birthweight.

NICHD-supported research has improved the outlook for preterm infants and families. The Maternal-Fetal Medicine Units (MFMU) Network established in 1986, to address issues pertaining to preterm births and low birth weight deliveries, has made steady and impressive strides in these areas.

Researchers recently found that:

—A substance in the urine of pregnant women can be measured to predict the later development of preeclampsia—a life-threatening complication of pregnancy.

—Weekly injections of 17-hydroxyprogesterone can reduce preterm birth by more than one third among women who are at increased risk of preterm delivery.

However, despite these efforts, the rate of preterm births continues to rise. SMFM therefore urges full support of the MFMU Network so that it can continue to address these issues.

In addition, full funding of the new Genomic and Proteomic Network will hasten a better understanding of the pathophysiology of premature birth and discover novel diagnostic biomarkers. Studies to be undertaken by this network will ultimately aid in formulating more effective interventional strategies to prevent premature birth.

Stillbirth.—Is a major public health issue with morbidity equal to that of all infant deaths. Despite this significant and persistent burden of stillbirths, they have remained largely unstudied and, for at least half of all stillbirths, the cause is undetermined. The NICHD cooperative network has initiated a pilot study with the full study planned to start this year. The information that will be obtained will aid in future research to improve preventive and therapeutic interventions and to understand the pathologic mechanisms leading to fetal death. Increased knowledge regarding the causes of stillbirths will benefit families who have experienced a loss, pregnant women, and their physicians, and may lead to the development and evaluation of improved clinical and preventive interventions. Full funding of this study is urgently needed.

Near-Term Births.—The preterm birth rate is now over 12 percent of all live births, and of these 75 percent are near term births. Near-term birth occurs after 35–37 weeks of gestation. It is estimated that this group encompasses 40 percent of Neonatal ICU admissions. These infants are at risk for sepsis; pneumonia; feeding difficulties; white matter damage; seizures; apnea; and remain at risk for higher morbidities in early infancy. This group of infants has not been well studied and may account for a portion of the increase in adverse long-term outcomes such as

autism, attention deficit disorders, and neurodevelopmental disorders. Additional funding will allow NICHD to facilitate the critical need for research in this area.

In addition to the need for funding for research, the state of funding for physician scientists and researchers has become a major problem and is in dire need of a fix.

Over the last decade, NICHD has responded to the scientific community's need for enhanced training programs to provide a solid framework for the development of physician scientists and researchers. The expansion of research training programs has included a substantial investment in the "T" (Training Programs) and "F" (Fellowship Programs) line and the expansion of the "K" (Research Career Awards) line. After completion of these programs it is anticipated that investigators will be competitive for research awards. However, given the substantial reduction in the payline, the new investigator's ability to be successful is severely restricted. It is imperative that NICHD identify and provide an opportunity for funding to investigators that NIH has already invested in through completion of training programs and who have demonstrated a commitment to a research career. It is of major concern to the scientific community that a cadre of scientists may be lost due to the stringent funding payline.

RECOMMENDATIONS

- The Society for Maternal-Fetal Medicine supports a 5 percent increase in fiscal year 2007 for the National Institutes of Health (above the fiscal year 2006 funding level) as recommended by the Ad Hoc Group for Medical Research, along with the National Health Council, the Campaign for Medical Research and Research!America.
- SMFM supports a 5 percent increase for the National Institute of Child Health and Human Development and urge full funding support for:
 - the Maternal Fetal Medicine Unit Network
 - the Genomic and Proteomic Network
 - Research in the area of near-term births
 - The stillbirth collaborative research network (SCRN)
 - Physician scientists and researchers

Again, thank you for allowing SMFM the opportunity to express its concerns regarding the need for sustained funding in fiscal year 2007 for the critical research programs supported by the National Institute of Child Health and Human Development and the National Institutes of Health overall.

PREPARED STATEMENT OF THE SOCIETY OF NUCLEAR MEDICINE

The Society of Nuclear Medicine (SNM) appreciates the opportunity to submit written testimony for the record regarding Federal funding for biomedical research in fiscal year 2007. SNM is an international, scientific, professional organization with more than 16,000 members dedicated to promoting the science, technology, and practical application of nuclear medicine. Over the last 50 years, since biomedical imaging first began, the nuclear medicine community has had a positive working relationship with the National Institutes of Health (NIH). The research and development supported by NIH have made ground-breaking discoveries in the field of nuclear medicine. Similarly, NIH has benefited from the nuclear medicine research conducted through Federal funding of the Medical Applications and Measurement Science Program at the Department of Energy (DOE). Unfortunately, that \$37 million in funding was eliminated in the fiscal year 2006 Energy and Water Appropriations bill. Therefore, the Society requests and strongly recommends that the Labor, Health and Human Services, and Education (LHHS) Appropriations Subcommittee work with the Energy and Water Development Appropriations Subcommittee to ensure that dedicated funding for nuclear medicine research is fully restored in fiscal year 2007.

WHAT IS NUCLEAR MEDICINE?

Nuclear medicine is an established specialty that performs noninvasive molecular imaging procedures to diagnose and treat diseases and determine the effectiveness of therapeutic treatments, whether surgical, chemical, or radiation. It contributes extensively to the treatments and diagnoses of patients with cancers of the brain, breast, blood, bone, bone marrow, liver, lungs, pancreas, thyroid, ovaries, and prostate. Molecular imaging continues to provide critical information to help doctors, technicians, and other health care personnel manage abnormalities of the heart, brain, and kidneys. In fact, recent advances in the detection and diagnosis of Alzheimer's disease can be attributed to nuclear medicine imaging procedures, specifi-

cally positron emission tomography (PET) scans. These advances—which were made possible by research performed by nuclear medicine professionals—helped lead the Centers for Medicare and Medicaid Services (CMS) to extend Medicare coverage to include PET scans for some beneficiaries who suffer from Alzheimer's and other dementia-related diseases.

The effect nuclear medicine has on the lives of men, women, and children suffering from cancer, heart, and brain diseases is far-reaching. Annually, more than 20 million men, women, and children require noninvasive molecular/nuclear medical procedures. These safe, cost-effective procedures include PET scans to diagnose and monitor treatments in cancer, cardiac stress tests that analyze heart function, bone scans for orthopedic injuries, and lung scans for blood clots. In addition, patients undergo procedures to diagnose liver and gall bladder functional abnormalities and to diagnose and treat hyperthyroidism and thyroid cancer.

IMPACT OF THE LOSS OF FEDERAL FUNDING FOR NUCLEAR MEDICINE RESEARCH ON NIH

In fiscal year 2006, the government abandoned its fifty-year commitment to supporting nuclear medicine research by eliminating funding for the Medical Applications and Measurement Science Program at the DOE and making no accommodation to transition nuclear medicine programs to another government agency. Over the years, the DOE Medical Applications and Measurement Science Program has generated advances in the field of molecular/nuclear medicine. For example, DOE funding provided the resources necessary for molecular/nuclear medicine professionals to develop PET scanners to diagnose and monitor the treatment of cancer. PET scans offer significant advantages over CT and MRI scans in diagnosing disease and are more effective in identifying whether cancer is present, if it has spread, if it is responding to treatment, and if a person is cancer free after treatment. In fact, the DOE has stated that this program supports “research in universities and in the National Laboratories, and occupies a critical and unique niche in the field of radiopharmaceutical research. The NIH relies on our basic research to enable them to initiate clinical trials.”

The advances in molecular/nuclear medicine made possible by Federal funding of nuclear medicine research at the DOE include:

- Modeling Radiation Damage to the Lung: Treatment of thyroid disease and lymphomas using radioisotopes can cause disabling lung disease. Investigators at Johns Hopkins University have developed a Monte Carlo model that can be used to determine the probability of lung toxicity and be incorporated into a therapeutic regimen. This model will optimize the dose of radioactivity delivered to cancer cells and avoid untoward effects on the lung.
- New Radiopharmaceuticals with Important Clinical Applications: The DOE radiopharmaceutical science program has developed a number of innovative radiotracers at the University of California at Irvine for the early diagnosis of neuro-psychiatric illnesses, including Alzheimer's disease, schizophrenia, depression, and anxiety disorders.
- Imaging Gene Expression in Cancer Cells: Images of tumors in whole animals that detect the expression of three cancer genes were accomplished for the first time by investigators at Thomas Jefferson University and the University of Massachusetts Medical Center. This advanced imaging technology will lead to the detection of cancer in humans using cancer cell genetic profiling.
- Rapid Preparation of Radiopharmaceuticals for Clinical Use: The DOE-sponsored program at the University of Tennessee has developed a new method for preparing radiopharmaceuticals by placing a boron-based salt at the position that will be occupied by the radiohalogen. The method has been used to prepare a variety of cancer-imaging agents.
- Smaller, More Versatile PET Scanners: Brookhaven National Laboratory (BNL) has completed a prototype mobile PET scanner, which will record images in the awake animal. The mobile PET will be able to acquire positron-generated images in the absence of anesthesia-induced coma and correct for motion of the animal. The long-term goal is to develop PET instrumentation able to diagnose neuro-psychiatric disorders in children.
- Highest Resolution PET Scanner Developed: Scientists at the Lawrence Berkeley National Laboratory (LBNL) have developed the world's most sensitive PET scanner. The instrument is 10-times more sensitive than a conventional PET scanner and became operational in 2005.

With restored Federal funding, essential molecular/nuclear medicine research will continue at universities, research institutions, national laboratories, and small businesses. Moreover, research with radiochemistry, genomic sciences, and structural biology will be able to usher in a new era of mapping the human brain and using

specific radiotracers and instruments to more precisely diagnose neuro-psychiatric illnesses and cancer.

The future of life-saving therapies and cutting-edge research in molecular/nuclear medicine and imaging depends on the restoration of Federal funding for nuclear medicine research.

SUSTAIN AND SEIZE RESEARCH OPPORTUNITIES

For decades, Americans and people from across the world have benefited from the strong Federal investment in nuclear medicine and biomedical research at NIH. SNM hopes that the LHHS subcommittee will continue that trend and fund NIH and the National Institute of Biomedical Imaging and Bioengineering (NIBIB) and the National Cancer Institute (NCI) at sufficient levels in fiscal year 2007.

SNM is proud to join its colleagues in the public health community in recommending that NIH receive \$29.7 billion in fiscal year 2007 funding—the same level of funding that is included in the Senate-passed budget resolution. This funding level would permit NIH to sustain and build upon its current research activities, which are a byproduct of the recent NIH budget-doubling effort. Even a minimal decrease or slowed momentum in increased funding for NIH could cause severe disruption in the Institutes' research activities and capabilities.

Research in biomedical imaging and bioengineering is progressing rapidly, and recent technological advances have revolutionized the diagnosis and treatment of disease. In 2000, NIBIB was created to specifically focus on biomedical imaging and bioengineering. It has made great strides in helping the health care community and patients recognize and understand different diseases and disorders. Pancreatic transplantation, brain scans, and improvement in epilepsy surgeries are just a few examples of how NIBIB research is helping to diagnose and treat patients. In order for NIBIB to continue its important work, SNM requests that Congress provide it with \$388 million in Federal funding for fiscal year 2007. This funding level would allow NIBIB to further its research, development, and application of emerging and cutting-edge biomedical technologies to facilitate improved disease detection, management, and prevention.

In addition, SNM advocates that NCI receive \$5.034 billion in fiscal year 2007. The American Cancer Society predicts that more than 1.4 million Americans will be diagnosed with cancer in 2005. Significant gains have been made in the war on cancer, and there have been successful breakthroughs in diagnosing and treating this terrible disease. Currently, PET scans are available to detect more than a dozen types of cancer. Cancer research is leading to new therapies that translate into longer survival and improved quality of life for cancer patients. Extraordinary advances in cancer research have resulted because of the strong commitment by the Federal, State, and local governments in combating cancer.

CONCLUSION

As outlined above, SNM has a strong interest in making sure that biomedical research in the United States is sufficiently funded. Also, since NIH relied on the pool of research conducted by the DOE's Medical Applications and Measurement Science Program, SNM would like to stress the impact that the loss of Federal funding for nuclear medicine research will have on NIH. In order to ensure that the positive effects and results of research and development are not seriously compromised, SNM advocates the allocation of \$29.7 billion for NIH, including \$388 million for NIBIB and \$5.034 billion for NCI, and requests that the LHHS Appropriations subcommittee work with the Energy and Water Development Appropriations Subcommittee to ensure that Federal funding for nuclear medicine research is fully restored.

SNM stands ready to work with policymakers on both sides of the aisle to advance biomedical research and innovation to help reduce and prevent suffering from disease for all Americans. Again, on behalf of the members of SNM, I thank you for the opportunity to submit testimony regarding the need for increased Federal funding for biomedical research.

PREPARED STATEMENT OF THE SOCIETY FOR WOMEN'S HEALTH RESEARCH AND WOMEN'S HEALTH RESEARCH COALITION

On the behalf of the Society for Women's Health Research and the Women's Health Research Coalition, we are pleased to submit the following testimony in support of biomedical research, and more specifically women's health research.

The Society for Women's Health Research is the only national non-profit women's health organization whose mission is to improve the health of women through research, education, and advocacy. Founded in 1990, the Society brought to national attention the need for the appropriate inclusion of women in major medical research studies and the need for more information about conditions affecting women disproportionately, predominately, or differently than men. In 1999, the Women's Health Research Coalition was created by the Society as a grassroots advocacy effort consisting of scientists, researchers, and clinicians from across the country that are concerned and committed to improving women's health research.

The Society and Coalition are committed to advancing the health of women through the discovery of new and useful scientific knowledge. We believe that sustained funding for biomedical and women's health research programs conducted and supported across the Federal agencies is necessary if we are to accommodate the health needs of the population and advance the Nation's research capability.

NATIONAL INSTITUTES OF HEALTH

From decoding the human genome to elucidating the scientific components of human physiology, behavior, and disease, scientists are unearthing exciting new discoveries which have the potential to make our lives and the lives of our families longer and healthier. The National Institutes of Health (NIH) has made this all possible by conducting and supporting our Nation's biomedical research. World-class researchers, scientists, and programs at NIH are dedicated to understanding how the human body works and to gain insight into countless diseases and disorders. Congressional investment and support for NIH has made the United States the world leader in medical research and has had a direct and significant impact on women's health research and the careers of women scientists in the last decade.

Great strides and advancements have been made since the doubling of the NIH budget from \$13.7 billion in 1998 to \$27 billion in 2003. However, we are concerned that the momentum driving new research will erode under the current budgetary constraints. Medical research needs to be considered an essential investment—an investment in thousands of newly trained and aspiring scientists; an investment to remain competitive in the global marketplace; and an investment in our Nation's health. In fact, a recent national poll indicated that a 58 percent of Americans believe that a strong investment in research and science is critical not only for our global scientific leadership but for the health of our economy and citizens. Furthermore, 94 percent consider accelerating medical research an important national priority—comparable to homeland security.

The administration's fiscal year 2007 budget request of \$28.6 billion for NIH is unraveling the successes from the doubling of NIH's budget. The proposed budget would freeze NIH funding at the fiscal year 2006 appropriated level of \$28.57 billion and cut most individual Institute budgets from 0.5 to 0.8 percent. The proposed decrease does not keep pace with the inflation rate. The annual change in the Biomedical Research and Development Price Index (BRDPI) will increase to 4.1 percent in fiscal year 2006 and 3.8 percent in fiscal year 2007 and fiscal year 2008. BRDPI indicates how much the NIH budget would need to change to maintain purchasing power to compensate for the average increase in prices and to maintain research activity at the previous year's level.

A flat-funded budget will have a negative impact on the number of grants NIH will be able to fund. NIH predicts total the total number of grants funded will decrease by 656. The number of new grants funded by NIH has already dropped by nearly fifteen percent from 10,393 in fiscal year 2003 to an estimated 9,062 for fiscal year 2006. The shrinking pool of available grants will have a significant impact on scientists as they depend upon NIH support to help cover their salaries and laboratory expenses. If one fails to obtain a grant they will be less likely to achieve tenure and new, less established researchers will be forced to consider other careers, resulting in a loss of the critical workforce needed to sustain America's cutting edge in biomedical research.

In order to continue the momentum of scientific advancement and expedite the translation of research from the laboratory to the patient, the Society calls for a five percent increase for the NIH fiscal year 2007. In addition, we request that you strongly encourage the NIH to assure that women's health research receives resources sufficient to meet the health needs of all women.

Scientists have long known of the anatomical differences between men and women, but only within the past decade have they begun to uncover significant biological and physiological differences. Sex-based biology, the study of biological and physiological differences between men and women, has revolutionized the way that the scientific community views the sexes.

Sex differences play an important role in disease susceptibility, prevalence, time of onset and severity and are evident in cancer, obesity, coronary heart disease, autoimmune, mental health disorders, and other illnesses. This research needs to be supported and encouraged. Congress recognizes this importance and should support NIH at an appropriate level of funding and direct NIH to continue expanding research into sex-based biology.

Sex differences research in heart disease has long been neglected. Heart disease is the number one killer of women in United States, killing 493,623 women. Information gaps related to the development, diagnosis, and treatment of heart disease among women are enormous, in part because women continue to be underrepresented in heart-related research studies. As a result, women face misdiagnosis, delayed diagnosis, under-treatment and mistreatment of their heart problems. In fiscal year 2005 the Centers for Medicare and Medicaid Services highest expenditure in women's health 2005 was cardiovascular/pulmonary services. Despite large expenditures to treat heart disease, little funding is targeted at research that could lead to more effective prevention, diagnosis, and treatment. In order to address the discrepancies, the Society in conjunction with WomenHeart: the National Coalition for Women with Heart Disease compiled a list of ten questions that must be answered if women are to receive optimal cardiovascular care and treatment. The 10 unanswered research questions are:

1. Why do women receive significantly fewer referrals for advanced diagnostic testing and treatments for heart disease than men, and how can the referral rate for women be increased?
2. What are the best tools and methods for assessing women's risk of heart disease?
3. What are the best strategies for preventing heart disease in women?
4. What treatments for heart disease work best for women?
5. What are the most effective methods and treatments for diastolic heart failure, which is the most common form of congestive heart failure in women?
6. How can the heart disease diagnosis and care disparities between white women and women of color be eliminated?
7. What are the biological differences between men and women in the location, type, and heart disease risk level associated with fat deposits, and what determines these differences?
8. How do sex differences in the regulation of heart rhythm affect risk of heart disease and response to treatment?
9. What is the role of inflammation in heart disease in women?
10. Why are women ages 50 and younger more likely to die following a heart attack than men of the same age?

We strongly believe and encourage that these questions serve as a guide for NIH and other health related agencies while developing research portfolios.

OFFICE OF RESEARCH ON WOMEN'S HEALTH

The NIH Office of Research on Women's Health (ORWH) has a fundamental role in coordinating women's health research at NIH, advising the NIH Director on matters relating to research on women's health; strengthening and enhancing research related to diseases, disorders, and conditions that affect women; working to ensure that women are appropriately represented in research studies supported by NIH; and developing opportunities for and support of recruitment, retention, re-entry and advancement of women in biomedical careers. ORWH strives to address sex and gender perspectives of women's health and women's health research, as well as differences among special populations of women across the entire life span, from birth through adolescence, reproductive years, menopausal years and elderly years.

Two highly successful programs supported by ORWH that are critical to furthering the advancement of women's health research are Building Interdisciplinary Research Careers in Women's Health (BIRCWH) and Specialized Centers of Research on Sex and Gender Factors Affecting Women's Health (SCOR). These programs benefit both women's and men's health through sex and gender research, interdisciplinary scientific collaboration, and provide tremendously important support for young investigators in a mentored environment.

The BIRCWH program is an innovative, trans-NIH career development program that provides protected research time for junior faculty by pairing them with senior investigators in an interdisciplinary mentored environment. What makes BIRCWH so unique is that it bridges advanced training with research independence across scientific disciplines. It is expected that each scholar's BIRCWH experience will culminate in becoming an established independent researcher in women's health. Since 2000, 197 scholars have been trained in the twenty-four centers recording over 634

publications and 526 abstracts. The scholars have secured forty NIH grants and seventy awards from industry and institutional sources.

The SCOR program, administered by the National Institute of Arthritis and Musculoskeletal and Skin Diseases, was developed by ORWH in 2001. SCOR's are designed to increase the transfer of basic research findings into clinical practice by housing laboratory and clinical studies under one roof. The program was designed to complement other federally supported programs addressing women's health issues such as BIRCWH. The eleven SCOR programs are conducting interdisciplinary research focused on major medical problems affecting women and comparing gender difference to health and disease. Each SCOR works hard to transfer their basic research findings into the clinical practice setting.

Despite the advancement of women's health research and its innovative programs, we were disappointed to see ORWH receive a \$250,000 cut in fiscal year 2006 from the Office of the Director. Congress must direct NIH to continue its support of ORWH and its programs.

DEPARTMENT OF HEALTH AND HUMAN SERVICES

The Department of Health and Human Services (HHS) has several offices that enhance the focus of the government on women's health research. Agencies with offices, advisors or coordinators for women's health or women's health research are the Department of HHS, the Food and Drug Administration, the Centers for Disease Control and Prevention, the Agency for Healthcare Quality and Research, the Indian Health Service, the Substance Abuse and Mental Health Services Administration, the Health Resources and Services Administration, and the Centers for Medicare and Medicaid Services. These agencies need to be funded at levels adequate for them to perform their assigned missions. We ask that the Committee Report clarify that Congress supports these offices and would like to see them continued and strengthened in the coming fiscal year.

The focus on women's health within HHS has been critical to the advances made in women's health in getting the appropriate message out to patients and providers. Scientists have only just scratched the surface of understanding female biology, with new information forthcoming as a result of the recent sequencing of the human X chromosome. Now is the time to press ahead with this vital research to make discoveries and educate women about their health and clarify the misinformation they have been given for years and these offices are critical to the success of this effort. There are many important programs that we could identify from these women's health offices but we would like to specifically mention two in particular.

HHS OFFICE OF WOMEN'S HEALTH

The HHS Office of Women's Health (OWH) is the government's champion and focal point for women's health issues. It works to redress inequities in research, health care services, and education that have historically placed the health of women at risk. The OWH coordinates women's health efforts in HHS to eliminate disparities in health status and supports culturally sensitive educational programs that encourage women to take personal responsibility for their own health and wellness. An extraordinary program initiated by the OWH is the National Centers of Excellence in Women's Health (CoEs).

Developed in 1996, the CoEs offer a new model for university-based women's health care. Selected on a competitive basis, the current twenty CoEs throughout the country seek to improve the health of all women across the lifespan through the integration of comprehensive clinical health care, research, medical training, community outreach and public education, and medical school faculty leadership development. The CoEs are able to reach a more diverse population of women, including more women of color and women beyond their reproductive years. However, CoEs are vulnerable to pressures of obtaining adequate funding and having to compete for scarce resources. A CoE designation by the OWH is critical not only to patients and surrounding communities but also to establishing foundation and other non-government funding.

In fiscal year 2006 OWH received a decrease in its budget and the proposed fiscal year 2007 would flat fund the office. We urge Congress to provide an increase of \$1.5 million for the HHS OWH to allow it to continue to sustain and expand the National Centers of Excellence in Women's Health.

AGENCY FOR HEALTHCARE AND RESEARCH QUALITY

The Agency for Healthcare Research and Quality (AHRQ) is the lead Public Health Service agency focused on health care quality, including coordination of all Federal quality improvement efforts and health services research. AHRQ's work

serves as a catalyst for change by promoting the results of research findings and incorporating those findings into improvements in the delivery and financing of health care. This important information provided by AHRQ is brought to the attention of policymakers, health care providers, and consumers who can make a difference in the quality of health care women receive.

AHRQ has a valuable role in improving health care for women. Through AHRQ's research projects and findings, lives have been saved and underserved populations have been treated. For example, women treated in emergency rooms are less likely to receive life-saving medication for a heart attack. AHRQ funded the development of two software tools, now standard features on hospital electrocardiograph machines that have improved diagnostic accuracy and dramatically increased the timely use of "clot-dissolving" medications in women having heart attacks.

While AHRQ has made great strides in women's health research, the Administration's budget for fiscal year 2007 could threaten life-saving research. If a budget request of \$319 million were enacted, AHRQ would be flat funded for the third year in a row at fiscal year 2005 levels. Flat funding prior to application of taps by Congress seriously jeopardizes the research and quality improvement programs that Congress demands or mandates from AHRQ.

We encourage Congress to fund AHRQ at \$443 million for fiscal year 2007. This will ensure that adequate resources are available for high priority research, including women's health care, gender-based analyses, Medicare, and health disparities.

In conclusion, Mr. Chairman, we thank you and this Committee for its strong record of support for medical and health services research and its unwavering commitment to the health of the Nation through its support of peer-reviewed research. We look forward to continuing to work with you to build a healthier future for all Americans.

PREPARED STATEMENT OF THE HUMANE SOCIETY OF THE UNITED STATES

On behalf of The Humane Society of the United States (HSUS) and our more than 9.5 million supporters nationwide, we appreciate the opportunity to provide testimony on our top funding priorities for the Labor, Health and Human Services, Education and Related Agencies Subcommittee in fiscal year 2007.

ALTERNATIVES TO ANIMAL TESTING

The ICCVAM Authorization Act (Public Law 106-545) requires Federal regulatory agencies to ensure that new and revised animal and alternative test methods be scientifically validated prior to recommending or requiring use by industry. The internationally agreed upon definition of validation, supported by the 15 Federal regulatory and research agencies that compose the ICCVAM, is: "the process by which the reliability and relevance of a procedure are established for a specific use."

Function of the ICCVAM

The ICCVAM performs an invaluable function by assessing the validation of new, revised and alternative toxicological test methods that have interagency application. After appropriate independent peer review, the ICCVAM recommends the test to the Federal regulatory agencies that regulate the particular endpoint test measures. In turn, the Federal agencies maintain their authority to incorporate the validated test methods as appropriate for the agencies' regulatory mandates. This streamlined approach of assessing the validation of test methods has reduced the regulatory burden of individual agencies; provided a "one-stop shop" for stakeholders for consideration of methods; and set uniform criteria for what constitutes a validated test method. The ICCVAM can also serve to appropriately assess test methods that can refine, reduce and replace the use of animals in toxicological testing.

The ICCVAM's representatives have rigorously assessed several test methods that are now deemed scientifically valid and acceptable. In addition, the ICCVAM is working to streamline assessment of methods from the European Union (EU) that have already been validated for use within the EU.

Request for Appropriations

Since passage of the "ICCVAM Authorization Act" in 2000, which makes the entity a permanent standing committee, NIEHS has provided between \$1 and \$2.6 million per fiscal year to NICEATM for ICCVAM's activities. In order to ensure that Federal regulatory agencies and their stakeholders benefit from the work of the ICCVAM, NIEHS funding is important. We respectfully request \$4 million for this purpose in fiscal year 2007.

Request for Committee Report Language

The NIEHS should support the NICEATM/ICCVAM in creating a five-year roadmap for assertively setting goals to prioritize ending the use of antiquated animal tests for specific endpoints. It is also imperative that the ICCVAM take a more proactive role in isolating areas where new methods development is on the verge of replacing animal tests. These areas should form a collective call by the Federal agencies that compose the ICCVAM to fund any necessary additional effort that is required to eliminate the animal methods. We also strongly urge the NICEATM/ICCVAM to closely coordinate efforts with its European counterpart, the European Centre for the Validation of Alternative Methods (ECVAM), to ensure the best use of available funds and sound science and to ensure industry has a uniform approach to worldwide chemical safety evaluation.

We also respectfully request that the Committee consider including the following report language: "The Committee commends the National Interagency Center for the Evaluation of Alternative Methods/Interagency Coordinating Committee on the Validation of Alternative Methods (NICEATM/ICCVAM) for its leadership role in the assessment of new, revised and alternative scientifically validated methods for the Federal Government. The Committee also commends the National Toxicology Program (NTP) for finalizing its "Roadmap to Achieve the NTP Vision, A Toxicology Program for the 21st Century," which commits to "develop and validate improved testing methods and, where feasible, ensure that they reduce, refine or replace the use of animals" as one of its top four goals.

The Committee directs the NICEATM/ICCVAM, in partnership with the relevant Federal agency program offices and the NTP, to build on the NTP Roadmap to create a five-year plan to research, develop, translate and validate new and revised non-animal and other alternative assays for integration of relevant and reliable methods into the Federal agency testing programs. In this 5-year plan the Federal agency program offices shall be directed to identify areas of high priority for new and revised non-animal and alternative assays or batteries of those assays to create a path forward for the replacement, reduction and refinement of animal tests, when this is scientifically valid and appropriate. The Committee directs a transparent, public process for developing this plan and recommends the plan be presented to the Committee by November 15, 2007. Funding for developing the plan shall be from the NIEHS and the NTP, and shall not reduce the NICEATM/ICCVAM funding base."

BREEDING OF CHIMPANZEES FOR RESEARCH

The HSUS requests that no Federal funding be appropriated for breeding of chimpanzees for research, or for research that requires breeding of chimpanzees, for the following reasons:

- The United States currently has a surplus of chimpanzees available for use in research due to overzealous breeding for HIV research and subsequent findings that they are a poor HIV model.¹
- The cost of maintaining chimpanzees in laboratories is exorbitant, totaling between and \$9.3 million each year for the current population of 850 federally owned or supported chimpanzees (\$15–30 per day per chimpanzee;¹ \$500,000 per chimpanzee's 50-year lifetime).
- The National Center for Research Resources has a publicly-declared moratorium on breeding chimpanzees.
- Use of chimpanzees in research raises strong public concerns.

Background and history

Beginning in 1995, the National Research Council (NRC) confirmed a chimpanzee surplus and recommended a moratorium on breeding of federally owned or supported chimpanzees,¹ who now number approximately 850 of the 1,300 total chimpanzees available for research in the United States. According to a National Research Resources Advisory Council September 15, 2005 meeting, the National Center for Research Resources (NCRR) of NIH extended the moratorium until December 2007 because of high costs of chimpanzee care, lack of existing colony information, and failure of chimpanzees as an HIV model. There are, however, cases in which the moratorium is not being obeyed, prompting the need for Congressional action.

¹NRC (National Research Council) (1997) Chimpanzees in research: strategies for their ethical care, management and use. National Academies Press: Washington, D.C.

Deviations from the moratorium

Despite the NCRR breeding moratorium, which prohibits breeding of federally owned or supported chimpanzee or NIH funding of projects that require chimpanzee breeding (NCRR written communication, February 28, 2006), chimpanzee breeding is still being funded by NIH. For example, the National Institute of Allergy and Infectious Diseases maintains a contract with New Iberia Research Center in Louisiana to provide 10 to 12 infant chimpanzees annually for research projects. The 10-year contract entitled “Leasing of chimpanzees for the conduct of research” has been allotted over \$22 million, with \$3.9 million awarded since its inception in September 2002.

Chimpanzees have often been a poor model for human health research

The scientific community recognizes that chimpanzees are poor models for HIV because chimpanzees do not develop AIDS. Similarly, though chimpanzees do not model the course of the human Hepatitis C virus, they continue to be widely used for this research. According to the chimpanzee genome, some of the greatest differences between chimpanzees and humans relate to the immune system,² calling into question the validity of infectious disease research using chimpanzees.

Ethical and public concerns about chimpanzee research

Chimpanzee research raises serious ethical issues, particularly because of their extremely close similarities to humans in terms of intelligence and emotions. Americans are clearly concerned about these issues: 90 percent believe it is unacceptable to confine chimpanzees individually in government-approved cages, and 54 percent believe that it is unacceptable for chimpanzees to “undergo research which causes them to suffer for human benefit” (conducted by Zogby International for Chimpanzee Collaboratory, 2001).

We respectfully request the following committee report language:

“The Committee directs that no funds provided in this Act be used to support the breeding of chimpanzees for research or to support research that requires breeding of chimpanzees.”

PAIN AND DISTRESS RESEARCH

It is estimated that at least \$10.2 billion per year of the current National Institutes of Health budget is devoted to some aspect of animal research.³ At this time, no funding is set aside specifically for determination of ways to reduce the amount of pain and distress in animal research. Knowledge regarding recognition, assessment, and alleviation of animal pain and distress is critical for both the quality of scientific research and animal welfare.

NIH may receive \$28.6 billion in fiscal year 2007 if Congress fulfills the President’s budget request. Out of this funding, we seek \$2.5 million (0.009 percent) for research and development focused on recognizing, assessing, and alleviating animal pain and distress in research. This is not a request for basic research on pain pathways or for application to the study of human pain, for example, but for the benefit of animals used in painful and distressful research.

In addition to our request for \$2.5 million for this purpose, we also urge the Committee to specify in report language that this research should be conducted in conjunction with, or “piggy-backed” onto, ongoing research that already causes pain and distress. Infliction of pain and distress on additional animals is unnecessary, given the volume of existing research that is believed to involve moderate to significant pain and/or distress (we estimate a minimum of 20–25 percent of all animal research). Furthermore, it is expected that the amount of research that involves animal pain and distress will increase as animal use in biodefense research increases, as one example.

NIH has a statutory mandate to conduct or support research into alternative methods that produce less pain and distress in animals; this was specified in the NIH Revitalization Act of 1993 regarding a plan for the use of animals in research. Earmarked funding will assist NIH in meeting this mandate. Additionally, researchers themselves often comment publicly about the urgent need for funding in order to properly understand and mitigate pain and distress in research animals and to

²The Chimpanzee Sequencing and Analysis Consortium/Mikkelsen, TS, et al.,(1 September 2005) Initial sequence of the chimpanzee genome and comparison with the human genome, *Nature* 437, 69–87.

³NIH extramural funding accounts for approximately 90 percent of the NIH budget, or \$25.5 billion. Of this, approximately 40 percent is devoted to some aspect of animal research—totaling approximately \$10.2 billion. Intramural research also accounts for some animal research, but the exact figure is unknown.

follow Animal Welfare Act and Public Health Service policy requirements to minimize pain and distress.

It is well known that uncontrolled, undetected, and unalleviated pain and distress has adverse effects on animal welfare, which leads to adverse effects on the quality of science. Ultimately, the lack of information on pain and distress leads to misinterpretation of research results that could result in harmful effects in human beings when animal research results are applied to human clinical trials.

Numerous surveys indicate that concern about animal pain and distress strongly influences public opinion about animal research in general. For example, 75 percent of the American public opposes research that causes severe animal pain and/or distress, even when the goal of the research is to benefit human health (survey conducted by an independent polling firm for The HSUS, 2001).

Our Nation takes pride in leading the world in biomedical research, yet we lag behind many other countries in our efforts to minimize pain and distress in animal subjects. We urge the Committee to make this small investment of \$2.5 million to promote animal welfare and enhance the integrity of scientific research. We also respectfully request this accompanying committee report language:

“The Committee provides \$2.5 million to support research and development focused on improving methods for recognizing, assessing, and alleviating pain and distress in research animals. No pain and distress should be inflicted solely for the purpose of this initiative, since the investigations can and should be conducted in conjunction with ongoing research that is believed to involve pain and distress under Government Principle IV of Public Health Service Policy, which assumes that procedures that cause pain and distress in humans may cause pain and distress in animals.”

Thank you for the opportunity to submit these requests on behalf of The Humane Society of the United States.

DEPARTMENT OF EDUCATION

PREPARED STATEMENT OF AMERICANS FOR THE ARTS

REQUEST

Americans for the Arts is pleased to submit testimony supporting fiscal year 2007 appropriations of \$53 million for the Arts in Education program of the U.S. Department of Education (USDE). We call on the Senate Labor/HHS/ED Appropriations subcommittee to reject the severe cuts to the Corporation for Public Broadcasting and instead provide \$430 million in fiscal year 2009. However, we support the President's request of \$41.39 million for the Office of Museum Services within the Institute of Museum & Library Services (IMLS), also funded through this subcommittee.

Americans for the Arts is one of the leading national nonprofit organizations for advancing the arts and arts education in America. With a 45-year record of objective arts industry research, we are dedicated to representing and serving local communities and creating opportunities for every American to participate in and appreciate all forms of the arts.

ARTS EDUCATION

Our belief in the importance of practical research causes us to take special pleasure in supporting USDE's Arts in Education program, which is generating impressive evidence on the best ways to improve overall academic achievement by integrating the arts into the school curriculum.

As members of the subcommittee know, the Elementary and Secondary Education Act [20 USC 7271] provides that funding up to \$15 million be directed to the John F. Kennedy Center for the Performing Arts and VSAarts. Prior to fiscal year 2001, funding never exceeded that level. Since fiscal year 2001, however, Congress has appropriated funding sufficient to support a broader array of arts education programs—for fiscal year 2006, Congress appropriated \$35.6 million.¹ In addition to the Kennedy Center and VSAarts, USDE now supports grant competitions to further develop established arts education models and support professional development for arts educators in four arts disciplines.

¹This appropriation was reduced by a 1 percent across-the-board rescission to \$35.3 million.

Three Reasons to Increase Arts Education Funding

Arts education works for children.—The most important reason to support arts education is simply stated: arts education works for children. Research increasingly confirms the beneficial effects of arts education in several areas, including but not limited to academic achievement. We refer the subcommittee to the research compendium *Critical Links: Learning in the Arts and Student Academic and Social Development*, released by the Arts Education Partnership in 2002, which includes 62 separate studies pointing to “critical links” between arts education and reading, writing, mathematics, cognitive skills, motivation, social behavior, and the school environment. The studies indicate that arts education is especially useful for students who are economically disadvantaged and/or in need of remedial instruction.²

Arts education provides training for a competitive workforce.—According to the 2002 National Governors Association publication *The Impact of Arts Education on Workforce Preparation*, “School districts are finding that the arts develop many skills applicable to the ‘real world’ environment. In a study of 91 school districts across the Nation, evaluators found that the arts contribute significantly to the creation of the flexible and adaptable workers that businesses demand to compete in today’s economy.”³

In addition, with more than 548,000 arts-centric businesses employing nearly three million people, arts education becomes a critical tool in fueling the creative industries of the future with arts-trained workers. Arts education is critical to the sustainability of an industry that comprises more than 4 percent of all U.S. businesses. We know from published research studies on the benefits of arts education that early learning in the arts nurtures the types of skills and brain development that are important for individuals working in the new economy of ideas.

In his State of the Union address this January, President Bush said “We must continue to lead the world in human talent and creativity.” The arts are core to the development of creativity in our children. The arts develop skills and talents that foster imagination, critical thought, and teamwork: skills that are transferable to the workplace.

In the documentary “The Arts and Children: A Success Story,” Dr. Sol Snyder—2003 recipient of the National Medal of Science and Distinguished Service Professor of Neuroscience, Pharmacology and Psychiatry at the Johns Hopkins University—said:

“In the arts, one trains one’s senses to perceive and integrate what’s going on either in the visual environment, auditory involvement, or even in the senses of smell, taste, and touch. The arts are very good for building those talents, those abilities. Sensory perception becomes quite important in mathematics, science, business.

“From my own background as a physician and research scientist, I have noticed that the most talented, the most productive people in the field are those who actually have a background in the arts because simple narrow scientific training is not enough to make major discoveries. The greatest scientists actually are artists in a sense. They are creative; they put together disparate things.”⁴

A similar theme on the essential integration of the arts and innovation was mentioned in a recent New York Times column by Thomas Friedman when he wrote, “Innovation is often a synthesis of art and science, and the best innovators often combine the two.” He went on to write that America’s growing emphasis on math and reading must maintain a balance with creative learning in the arts to optimize human talent.⁵

There is solid research measuring how the arts are integrated into the classroom and how they boost achievement in math and science. Students who took four years of arts coursework outperformed those of their peers who had one half-year or less of arts coursework by 38 points on the math portion of the SAT. Students who include art in their studies are four times more likely to be recognized for academic achievement and four times more likely to participate in a math and science fair.

For example, the “Math in a Basket” program in the Long Beach, CA, school district—funded through a U.S. Department of Education Arts in Education Model Development & Dissemination grant—teaches students how to plan, design, and make baskets from scratch. Students become familiar with art concepts, measurement, algebraic formulas, and geometric concepts as they work with their baskets to find the surface area, perimeter, and volume of each basket. Participants in the “Math

² <http://www.aep-arts.org/CLhome.html>.

³ <http://www.nga.org/Files/pdf/050102ARTSED.pdf>.

⁴ <http://www.nasaa-arts.org/publications/artsandchildren.shtml>.

⁵ “Worried About India’s and China’s Booms? So Are They,” Thomas Friedman, New York Times, March 24, 2006.

in a Basket” program score an average of 20 points higher than the control group on State math tests.⁶

Model programs are a wise investment.—Despite increases in overall Federal spending for K–12 education, evidence is beginning to accumulate that schools are neglecting those areas of the curriculum that are not subject to the mandatory testing requirements of No Child Left Behind (NCLB). The National Association of State Boards of Education (NASBE) identified the threat in its 2003 report “The Lost Curriculum.”⁷ In 2004, the Council for Basic Education released a survey of school principals in four States; one quarter of them reported that they have decreased instructional time in the arts.⁸ This finding was confirmed just last month in the Center for Education Policy’s (CEP) report “From the Capital to the Classroom: Year 4 of the No Child Left Behind Act,”⁹ when it found that almost a quarter of school districts surveyed reported that time in science, art, and music had been reduced due to an increased emphasis on reading and math.⁹ The CEP report recommends that USDE should promote “effective practices being used by school districts to enhance instruction in tested subjects without cutting time for other important subjects.” The USDE arts education program is a wise investment in developing and disseminating these effective practices.

USDE Needs to Maintain Research Efforts in Arts Education

Meaningful research from USDE is needed to further determine the status of dance, music, theater, and visual arts education. The Fast Response Survey System (FRSS) report “Arts Education in Public Elementary and Secondary Schools” is the only research produced by USDE on the delivery of arts education and the last FRSS reported data collected in the 1999–2000 school year. The next round of data collection for an updated report is long overdue. We urge the subcommittee to direct USDE to execute the FRSS study as intended. Similarly, the National Assessment of Education Progress (NAEP)—the national arts “report card” last performed in 1997—is scheduled to be administered in 2008, and must stay on track. The next NAEP will provide critical information about the arts skills and knowledge of our Nation’s students. Both of these quantitative studies are essential to studying and improving access to the arts as a core academic subject.

The Model Development & Dissemination program and the Professional Development program in the Arts in Education initiative at USDE receive targeted funding and are tested and measured in a limited number of implementation projects, and finally disseminated field-wide. This is a highly appropriate use of Federal dollars. Through this program, USDE promotes educational excellence, demonstrating how small projects can be brought to scale across entire school districts. Increased funding means more help for State and local departments of education to develop models that will work in highly disparate school districts across the Nation. We urge the Senate Subcommittee on Labor, Health and Human Services, and Education to recommend \$53 million in funding for USDE’s Arts in Education programs, with the bulk of the increase to be allocated to the Arts in Education Model Development and Dissemination Program and the Professional Development Program.

CORPORATION FOR PUBLIC BROADCASTING

We urge the subcommittee to reject the Administration’s proposed funding cuts to the Corporation for Public Broadcasting (CPB) in the fiscal year 2007 Labor-HHS–Education appropriations bill. Any reduction in CPB’s budget will drastically reduce the access that many Americans have to public broadcasting, and thus to high-quality arts and cultural programming.

CPB supports public television through its partner, the Public Broadcasting Service (PBS). A trusted community resource, PBS brings quality programs and education services to nearly 100 million people each week. With community-based arts programming and nationally televised shows, PBS is often the only source of arts programming in many rural parts of the country.

Public television airs arts programming that is not available on commercial television. For example, the Legends of Jazz television series on PBS marks the first time in 40 years that jazz has been the focus of a national network weekly series. Hosted by noted jazz pianist and radio personality Ramsey Lewis, the 13 weekly, 30-minute episodes debuted in June 2005 on PBS stations nationwide.

Budget cuts will weaken National Public Radio (NPR) stations and thus the availability of high-quality arts programming. Budget cuts will impact public radio

⁶ <http://www.dramaticresults.org/results.php>.

⁷ http://www.nasbe.org/Research_Projects/Lost_Curriculum.html.

⁸ <http://www.ecs.org/html/Document.asp?chouseid=5058>.

⁹ <http://www.cep-dc.org/nclb/Year4/Press/>.

broadcasting, as CPB funding represents an average of 13 percent of the budget for individual member stations of NPR. If NPR loses CPB support, many stations will have to make severe cuts to their programming and local services. This will especially impact rural areas and stations serving minority populations, as these stations heavily rely on Federal funding for their operating budgets. While local and State arts agencies also support these stations, they could not make up for a loss of Federal funding on this scale.

We join a broad coalition of public broadcasting supporters with this request for funding:

CPB General Appropriations—\$430 million for fiscal year 2009

CPB Digital Funding—\$40 million for fiscal year 2007

CPB Interconnection—\$36 million for fiscal year 2007

Ready to Learn—\$32 million for fiscal year 2007

Ready to Teach—\$15 million for fiscal year 2007

INSTITUTE FOR MUSEUM & LIBRARY SERVICES

We urge the subcommittee to support no less than the President's proposed increase to \$41.39 million for the Office of Museum Services within IMLS in the fiscal year 2007 Labor-HHS-Education appropriations bill.

IMLS encourages excellence and leverages State, local, and private funds. National competition is a catalyst for excellence and improves museum service nationwide. Federal leadership helps disseminate models and puts a spotlight on the remarkable resources that museums bring to education and to communities across the United States. In addition, peer-reviewed IMLS grants assure State, local, and private funders that a museum has met high national standards and is worthy of their additional support.

IMLS reinforces the role of museums in lifelong learning. Funding supports projects that address a full range of learning opportunities in museums, including developing exhibitions, working with schools to develop curriculum and programs, creating family and adult programs, and developing internet content. American museums provide over 18 million instructional hours to K-12 schoolchildren. Seventy-one percent work with school curriculum specialists to tailor programs to support local and State curriculum standards, according to the 2003 edition of the IMLS's report "True Needs, True Partners."

CONCLUSION

As the research cited above demonstrates, Federal funds boost the quality and quantity of support for arts education as well as the knowledge that can be gained and disseminated across the education establishment. Increased funding means more help for State departments of education, educators in schools, and local education agencies. Most importantly, it means a better education and more career opportunities for our children.

Americans for the Arts is the leading nonprofit organization for advancing the arts in America. With offices in Washington, DC, and New York City, it has a record of more than 45 years of service. Americans for the Arts is dedicated to representing and serving local communities and creating opportunities for every American to participate in and appreciate all forms of the arts. Additional information is available at www.AmericansForTheArts.org.

PREPARED STATEMENT OF THE AMERICAN GEOLOGICAL INSTITUTE

Thank you for this opportunity to provide the American Geological Institute's perspective on fiscal year 2007 appropriations for the Department of Education. The President's fiscal year 2007 request for the Department of Education places an emphasis on increasing U.S. competitiveness through math, science, and foreign language programs in keeping with the Administration's American Competitiveness Initiative announced in the President's State of the Union address. While \$380 million is devoted to new funds for projects based on this initiative, these new funds would be offset by significant cuts to other programs within the Department of Education. The Department of Education budget would be reduced by \$3.2 billion for a total requested budget of \$54.4 billion. AGI strongly supports the President's initiative and in particular funding for improved science literacy for teachers and students, however, we do encourage the subcommittee to retain and provide support for other proven and effective programs.

The National Math and Science Partnership (MSP) program as part of No Child Left Behind effectively strengthens K-12 science and math education. The Presi-

dent's request includes \$182 million for the MSP program within the Department of Education, which is the same level of funding appropriated in fiscal year 2006. AGI supports this stable funding and encourages appropriate emphasis on science education. Science often includes mathematical exercises applied to real-world problems, giving students a comprehensive and interesting learning experience.

The President's request for fiscal year 2007 focuses much new spending on math education and less on science education. Funding proposals based on the initiative include \$125 million for Math Now for elementary school students and \$125 million for Math Now for middle school students, plus an additional \$10 million to create a National Math Panel to review and develop math curricula. While a solid math education is important, additional funding should also be devoted to science education, which complements and expands upon a mathematical foundation to understanding and exploring how physical, chemical and biological processes work.

It is essential that highly qualified science teachers develop the energetic, eager and curious next generation of scientists and engineers. Skilled geoscientists and geoenvironmental engineers, in particular, are needed to find, develop and maintain our energy, agricultural, water and air resources, to understand and mitigate natural hazards and to ensure an educated public with a general understanding of the Earth environment to enhance our public and private quality of life.

AGI is a nonprofit federation of 44 geoscientific and professional societies representing more than 100,000 geologists, geophysicists, and other Earth scientists. Founded in 1948, AGI provides information services to geoscientists, serves as a voice for shared interests in our profession, plays a major role in strengthening geoscience education, and strives to increase public awareness of the vital role the geosciences play in society's use of resources and interaction with the environment.

In 1999, the Third International Math and Science Study found that the longer U.S. students are in school, the farther they fall behind in math and science proficiency in international comparisons. That prompted President Bush to propose the National Math and Science Partnership (MSP) program as part of No Child Left Behind. The goal of the partnership program is to strengthen K-12 science and math education by promoting a vision of education as a continuum that begins with the youngest learners and progresses through adulthood with teacher training. Among its activities, the program supports partnerships that unite K-12 schools, institutions of higher education and private industry.

Congress took the President's suggestion and authorized an MSP program at the National Science Foundation (NSF) and another partnership program at the Department of Education in 2002. These acts of Congress fund two different types of partnerships to achieve the overall goal of highly qualified math and science teachers ensuring that all students have the basic knowledge to compete in the ever changing and competitive job market. The funds allocated for the NSF's MSPs go to the highest quality proposals chosen through a competitive peer-reviewed grant program. The program focuses on modeling, testing and identification of effective mathematics activities. The funds allocated for the Department of Education MSPs go directly to the States as formula grants, providing funds to all States to replicate and then implement the best of the NSF partnerships throughout the country. Once States receive the money, they make competitive grants to local partnerships.

The \$120 million in funds for Secondary Education Mathematics Initiative is part of the overall High School Initiative, which will expand the application of No Child Left Behind principles to improve high school education and raise achievement, particularly the achievement of students most at risk of failure. This new initiative combines a number of categorical programs in order to give States and districts more flexibility and contains stronger accountability mechanisms.

AGI believes the two MSPs are the most effective approach to rapidly improving the abilities of all students to enhance their future prospects regardless of their ultimate career goals. The two programs, designed and authorized by Congress, are complementary. AGI supports funding at NSF for competitive grants for teaching tools and teacher training and funding at the Department of Education for formula grants for implementation of these tools in K-12 education. The peer-review process in the NSF program should be safeguarded as should the formula grants for all States as administered by the Department of Education. Moreover, the program within the Department of Education should not suffer a net reduction in funding in order to support a new initiative for mathematics. These funds should serve the Math and Science Partnership with no earmarks or set-asides.

Thank you for the opportunity to present this testimony to the subcommittee. If you would like any additional information, please contact me at 703-379-2480, ext. 228 voice, 703-379-7563 fax, rowan@agiweb.org, or 4220 King Street, Alexandria VA 22302-1502.

PREPARED STATEMENT OF THE ASSOCIATION OF MINORITY HEALTH PROFESSIONS
SCHOOLS

SUMMARY OF FISCAL YEAR 2007 RECOMMENDATIONS

- (1) \$550 Million for HRSA's Health Professions Training Programs, Including:
 - \$34 million for Minority Centers of Excellence.
 - \$36 million for the Health Careers Opportunity Program.
 - \$47 million for Scholarships for Disadvantaged Students.
 - (2) \$83 million for HRSA'S Healthy Communities Access Program.
- (3) 5 percent increase overall for the National Institutes of Health, including \$250 million for the National Center on Minority Health and Health Disparities.
- (4) \$119 million for the National Center for Research Resources Extramural Facilities Construction Program.
- (5) \$65 million for the Department of Education's Strengthening Historically Black Graduate Institutions Program.
- (6) \$65 million for the HHS Office of Minority Health, including support for a new health disparities initiative.

Mr. Chairman, thank you for the opportunity to present the views of the Association of Minority Health Professions Schools (AMHPS). I am Dr. Wayne Harris, Dean of the College of Pharmacy at the Xavier University of Louisiana.

AMHPS is comprised of the Nation's twelve historically black medical, dental, pharmacy, and veterinary schools. Combined, our institutions have graduated 50 percent of African-American physicians and dentists, 60 percent of all the Nation's African-American pharmacists, and 75 percent of the African-American veterinarians.

Mr. Chairman, historically black health professions institutions are addressing a pressing national need in carrying out their mission of training minorities in the health professions. While African-Americans represent approximately 15 percent of the U.S. population, only 2–3 percent of the Nation's health professions workforce is African-American. Studies have demonstrated that when African Americans and other minorities are trained in minority institutions, they are much more likely to: (1) serve in medically underserved areas, (2) care for minorities, and (3) accept patients who are Medicaid dependent or otherwise poor.

This is important Mr. Chairman because the gap in health status between our Nation's minority and majority populations continues to widen due in part to the lack of access to quality health care services in minority communities. As a result, we believe it is imperative that the Federal commitment to training African Americans and other minorities in the health professions remains strong.

In spite of our proven success in training health professionals, and the important contribution these professionals make, our institutions continue to face a financial struggle inherent to our mission. The financial challenges facing the majority of our students affect our institutions in numerous ways. For example, we are unable to depend on tuition as a means by which to respond to any discontinuation of Federal support. Moreover, the patient populations served by the AMHPS institutions are overwhelmingly poor. As a result, our institutions cannot rely on patient care income at a time when the average medical school gets 40–60 percent of its operating revenue from health care services.

Mr. Chairman, before I go into a discussion of our Association's fiscal year 2007 recommendations, I would like to share Xavier's experience with Hurricane Katrina and update you on our recovery efforts. Xavier is located in New Orleans and the entire campus was flooded with 3–6 feet of water. Each building on campus had significant damage on the first floor and the campus was shut down until January 9, 2006. The University developed an ambitious plan to repair damage and resume operations on January 17, 2006 using a revised academic calendar to complete the entire academic year in August 2006. I am happy to report that the University resumed classes on January 17 as planned. Overall University enrollment dropped, however, from approximately 4,000 students in August 2005 to approximately 3,000 students post-Katrina. The College of Pharmacy enrollment was less severely affected with enrollment dropping from 619 to 600.

Significant challenges still remain, including cash flow problems as we deal with recovery costs in the range of \$30 million for construction and equipment and disruption of operations of key health care institutions in New Orleans. These institutions are vital to the clinical education program of the College of Pharmacy and to our continued recovery. It is absolutely essential to the University that health care delivery services are restored as quickly as possible.

The University recognized the need to resume our academic programs as quickly as possible in order to continue to produce African American health professionals and contribute to rebuilding the City of New Orleans. By working with other Colleges of Pharmacy across the country, we were able to allow senior pharmacy students to continue their clinical education while under evacuation and we are pleased to report that pharmacy students will graduate on May 20, 2006. Our rebuilding effort is well underway but disruption of Federal support for important programs such as HRSA'S Center of Excellence would severely hinder this rebuilding effort.

FISCAL YEAR 2007 RECOMMENDATIONS FOR FEDERAL PROGRAMS OF INTEREST TO AMHPS
Health Resources and Services Administration

Health Professions Training

Mr. Chairman, we are disappointed that the President's budget all but eliminates funding again this year for health professions training programs focused on diversity in the workforce. The health professions training programs administered by the Health Resources and Services Administration are the only Federal initiatives designed to address the longstanding under-representation of minority individuals in health careers. HRSA's Minority Centers of Excellence, Health Careers Opportunity Program, and Scholarships for Disadvantaged Students, support health professions institutions with a historic mission and commitment to increasing the number of minorities in the health professions. For fiscal year 2007, AMHPS joins with the Health Professions Nursing and Education Coalition in recommending an overall funding level of \$550 million for health professions training.

For the health professions programs specifically focused on enhancing minority representation in the health care workforce, AMHPS recommendations are as follows:

Minority Centers of Excellence

The purpose of the Minority Centers of Excellence program (COE) is to assist schools that train minority health professionals by supporting programs of excellence in health professions education at those institutions. The COE program focuses on improving student recruitment and performance; improving curricula and cultural competence of graduates; facilitating faculty/student research on minority health issues; and training students to provide health services to minority individuals by providing clinical teaching at community-based health facilities. For fiscal year 2007, AMHPS recommends a funding level of \$34 million for Minority Centers of Excellence (an increase of \$22 million over fiscal year 2006).

Health Careers Opportunity Program

Grants made to health professions schools and educational entities under the Health Careers Opportunity Program (HCOP) enhance the ability of individuals from disadvantaged backgrounds to improve their competitiveness to enter and graduate from health professions schools. HCOP funds activities that are designed to develop a more competitive applicant pool through partnerships with institutions of higher education, school districts, and other community based entities. HCOP also provides for mentoring, counseling, primary care exposure activities and information regarding careers in a primary care discipline. Sources of financial aid are provided to students as well as assistance in entering into the health professions school.

For fiscal year 2007, AMHPS recommends a funding level of \$36 million for the Health Careers and Opportunities Program (an increase of \$32 million over fiscal year 2006).

Scholarships for Disadvantaged Students

The Scholarships for Disadvantaged Students program was established to make scholarship funds available to eligible students from disadvantaged backgrounds who are enrolled (or accepted for enrollment) as full-time students. To be eligible for funding, a school must have in place a program to recruit and retain students from disadvantaged backgrounds (including racial and ethnic minorities) and demonstrate that the program has achieved success based on the number or percentage of disadvantaged students who graduate from the school. For fiscal year 2007, AMHPS recommends a funding level of \$47 million for the Scholarships for Disadvantaged Students program (an increase of \$47 million over fiscal year 2007).

Healthy Communities Access Program

Mr. Chairman, Congress passed legislation in 2003 to reauthorize the Community Health Centers program. Included in this important measure was a provision which established a demonstration authority within the Healthy Community Access Pro-

gram to foster greater collaboration between historically black health professions and federally qualified CHC's. Specifically, this provision:

(1) Establishes a demonstration program for the development of research infrastructure at historically black health professions schools affiliated with federally qualified Community Health Centers.

(2) Establishes joint and collaborative programs of medical research and data collection between historically black health professions schools and federally qualified Community Health Centers with the goal of improving the health status of medically underserved populations.

(3) Supports the cost of patient care, data collection, and academic training resulting from these partnerships.

Mr. Chairman, several of our member institutions received funding in fiscal year 2005 under this promising new demonstration authority. Unfortunately, the H-CAP program was eliminated in the fiscal year 2006 Labor-HHS bill, and the President's budget for fiscal year 2007 does not provide any funding for the coming year. AMHPS encourages the subcommittee to restore support for this important program in fiscal year 2007 at the fiscal year 2005 level of \$83 million.

National Institutes of Health

The National Center on Minority Health and Health Disparities

Established in 2000 by the Minority Health and Health Disparities Research and Education Act (Public Law 106-525), the National Center on Minority Health and Health Disparities at NIH is charged with addressing the longstanding health status gap between minority and majority populations. The National Center has the authority to:

- Directly support biomedical research, training, and information dissemination focused on eliminating health status disparities.
- Serve in a leadership capacity in developing a comprehensive plan for minority health research at NIH.
- Participate as an equal when NIH institute and center directors meet to determine research policy.
- Support the enhancement of biomedical research capacity at minority health professions institutions through a "Research Endowment" program.
- Support the development of health professions institutions with a history and mission of serving minority and medically underserved communities through a "Centers of Excellence" program.

For fiscal year 2006, AMHPS recommends a funding level of \$250 million for the National Center. This is an increase of \$54 million. This new funding will enable the Center to support all of its new programs and begin to meet the challenge of eliminating health status disparities within minority and medically underserved communities

Extramural Facilities Construction

Mr. Chairman, if we are to take full advantage of the historic funding increases for biomedical research that Congress has provided to NIH over the past decade, it is critical that our Nation's research infrastructure remain strong. The current authorization level for the Extramural Facility Construction program at the National Center for Research Resources is \$250 million. The law also includes a 25 percent set-aside for "Institutions of Emerging Excellence" (many of which are minority institutions) for funding up to \$50 million. Finally, the law allows the NCCR Director to waive the matching requirement for institutions participating in the program. We strongly support all of these provisions of the authorizing legislation.

Unfortunately, funding for NCCR's Extramural Facility Construction program was completely eliminated in the fiscal year 2006 Labor-HHS bill. For fiscal year 2007, AMHPS encourages the subcommittee to restore funding for this program to its fiscal year 2004 level of \$119 million, or at a minimum, provide funding equal to the fiscal year 2005 appropriation of \$40 million.

Research Centers in Minority Institutions

The Research Centers at Minority Institutions program (RCMI) at the National Center for Research Resources has a long and distinguished record of helping our institutions develop the research infrastructure necessary to be leaders in the area of health disparities research. Although NIH has received unprecedented budget increases in recent years, funding for the RCMI program has not increased by the same rate. Therefore, AMHPS recommends that funding for this important program grow at the same rate as NIH overall in fiscal year 2007.

Strengthening Historically Black Graduate Institutions—Department of Education

The Department of Education's Strengthening Historically Black Graduate Institutions program (Title III, Part B, Section 326) is extremely important to AMHPS institutions. The funding from this program is used to enhance educational capabilities, establish and strengthen program development offices, initiate endowment campaigns, and support numerous other institutional development activities. For fiscal year 2007, AMHPS recommends an appropriation of \$65 million (an increase of \$7 million over fiscal year 2006) to continue the vital support that this program provides to historically black graduate institutions.

HHS Office of Minority Health

The HHS Office of Minority Health (OMH) has the potential to play a critical role in addressing health status disparities throughout the country. Unfortunately, the office does not currently have the authority or resources necessary to support activities that will truly make a difference in closing the health gap between minority and majority populations. For fiscal year 2007, AMHPS recommends a funding level of \$65 million for the Office, with \$10 million designated for the following programs focused on medically underserved communities and capacity building for the training of minorities in health professions:

(1) OMH sponsored programs to assist medically underserved communities with the greatest need in solving health disparities and attracting and retaining health professionals;

(2) Assistance to minority institutions in acquiring real property to expand their campuses to increase the capacity to train minorities for medical careers;

(3) Support of conferences for high school and undergraduate students to pursue health professions careers; and

(4) Support for cooperative agreements with minority institutions for the purpose of strengthening their capacity to train more minorities in the health professions.

Once again, thank you for the opportunity to present the views of the Association of Minority Health Professions Schools. We look forward to working with you in support of these important programs.

PREPARED STATEMENT OF THE CENTER FOR EDUCATION

EXECUTIVE SUMMARY

The Department of Education's (ED) justification for eliminating funding for the Education for Democracy Act is essentially the same as it was for fiscal year 2006. It also includes the same omissions and errors, as noted in the following response.

The Center for Civic Education (Center) and others supported under the Act believe the three major findings of the ED report are not adequately supported by the facts. Brief responses to the three findings are presented here. More detailed responses follow.

1. "Limited impact." The first paragraph of the ED justification for eliminating the Civic Education program states that it is "eliminating small categorical programs that have limited impact. . . ." The statement appears to be contradicted in the next paragraph which recognizes the extent of the Center's programs: "Districts in nearly every State and major urban area participate in We the People program activities."

The Center's programs provide sound, sustained, and effective instruction in the fundamental values and principles of constitutional democracy annually to approximately 3 million domestic students and 2 million students in other nations at a cost of approximately \$5-6 per student. Research and evaluation have demonstrated the significant impact of these programs that provide a cost-effective means of reaching a significant number of students. Since its inception, the Center's We the People program alone has reached more than 28 million students in the United States.

2. "Little or no reliable evidence of effectiveness." The ED justification fails to cite or recognize the extensive research and evaluation of Center programs as well as other significant evidence of program effectiveness, none of which is matched by any other program in the field.

3. "Additional funding is not necessary for the successful operation of this program." To anyone aware of the history of support for civic education, and the policies, priorities, and practices of private sector funding, it is clear that support for national and international programs in civic education of the magnitude of those implemented by the Center is simply not available from sources other than the Federal Government. Federal funding is essential for the continuation of this program.

The following information provides a more detailed response to the ED report.

INTRODUCTION

The Department of Education's (ED) justification for eliminating funding for the Education for Democracy Act is essentially the same as it was for fiscal year 2006. It also includes the same omissions and errors as will be noted in the following response.

ED's justification is composed of three major parts: that the Civic Education programs supported under the act (1) have "limited impact," (2) have "little or no reliable evidence of effectiveness," and that (3) "additional funding is not necessary for the successful operation of this program." The Center for Civic Education (Center) and others supported under the Act believe these findings are not adequately supported by the facts. The Center's responses follow.

1. Response: The Civic Education program has "limited impact"

The first paragraph of the ED justification for eliminating the Civic Education program states that ED is "eliminating small categorical programs that have limited impact. . . ." In the next paragraph it states that "The Center . . . is an established non-profit organization with a broad network of program participants, alumni, volunteers, and financial supporters at the local, state, and national levels. Districts in nearly every State and major urban area participate in We the People program activities." It is difficult to square the first statement with the second, because for a relatively small amount of Federal funds, the Center's domestic and international programs have a significant impact on the education of students at the pre-collegiate level as well as their teachers in the United States and abroad. The following information supports this premise.

The fiscal year 2006 appropriation for the Education for Democracy Act is \$29.1 million. In round figures, the allocation of these funds is as follows:

- Center for Civic Education (directed funding)
- Domestic programs = \$17 million
- International programs = \$4.5 million
- National Council for Economic Education (directed funding)
- International program = \$4.5 million
- Competitive international exchange program = \$3.1 million
- Note: The Center currently has a \$1 million grant under this program for Latin America and a \$1 million grant for Africa

Impact of the Center's Domestic Programs

Approximately 70 percent of the Center's \$17 million for domestic programs is allocated to public- and private-sector institutions or organizations at State and local levels in the form of sub-awards, free curricular materials, and subsidized teacher training programs. These funds are managed by approximately 120 coordinators located in public or private sector agencies or organizations at State levels. They are assisted by approximately 630 congressional district coordinators, many of whom are affiliated with school districts. These coordinators, essentially volunteers, receive a modest stipend to cover operating costs. These coordinators in turn coordinate thousands of additional volunteers who serve as judges, academic coaches, timers, facilitators, and in other roles required by the size and scope of this endeavor. The value of this volunteer network greatly amplifies the value of the Federal investment and the reach of the program and exemplifies American civic virtue in action. The remaining 30 percent of the funds pays for technical assistance to this network and the administrative operating costs of the Center.

The domestic network of coordinators oversees the implementation of three major curricular programs that reach approximately 3 million students annually at a cost of approximately \$5.67 per student. For this sum, each student receives the use of a free textbook and an estimated 10 to 40 or more hours of instruction in the fundamental values and principles of American constitutional democracy and how to participate competently and responsibly in political life. As noted below, ample research testifies to the positive outcomes of these programs.

The Department of Education's rationale for cutting the Civic Education program claims that its "contribution to the Department's mission is marginal." This statement does not seem to be in line with the policy of President Bush, who stressed the importance of civic education in the 2002 introduction to his initiative in History, Civics, and Service, in which he stated that:

"American children are not born knowing what they should cherish—are not born knowing why they should cherish American values. A love of democratic principles must be taught. At this very moment, Americans are fighting in foreign lands for principles defined at our founding, and every American—particularly every American child—should fully understand these principles."

The question might be asked: What other programs in civic education does ED support, if any, that accomplish the mission set forth in President Bush's speech and which, if any, have the impact on students per Federal dollar that result from programs supported under the Education for Democracy Act? It should be noted that the Federal funding for this program is matched by cost sharing at State and local levels estimated at from \$5–\$8 in value for every Federal dollar spent.

The need for improvement in the civic education of our Nation's students has been demonstrated repeatedly by research findings over the past several decades. This need was clearly illustrated in a recent survey in which only 28 percent of Americans could list two or more First Amendment freedoms, while more than 50 percent could name at least two cartoon characters from "The Simpsons" (McCormick Tribune Freedom Museum Poll, March 1, 2006). The programs supported by Congress under the Education for Democracy Act are a proven cost-effective means of remedying this shortcoming in the education of our Nation's youth.

Impact of the Center's International Programs

As with its domestic programs, approximately 70 percent or more of the Center's international funding is allocated to public- and private-sector institutions or organizations at State and local levels in the United States and similar organizations in approximately 70 emerging and advanced democracies throughout the world. This support is provided in the form of sub-awards, free curricular materials, and subsidized teacher training programs. These funds are managed by public- and private-sector organizations in 28 States and similar organizations in the participating countries. The remaining 30 percent of the funds pay for technical assistance to this network and the administrative operating costs of the Center.

The international network of coordinators oversees the implementation of curricular programs focused on education for democracy. It is difficult in many cases to get accurate figures on participation in these programs from the participating countries. We believe that 2 million students per year is a modest estimate. The students in these countries are being provided instruction in the fundamental values and principles of constitutional democracy and how to participate competently and responsibly in political life. As noted below, ample research testifies to the positive outcomes of these programs.

The \$4.5 million in baseline funding for this program from ED is augmented by approximately \$8 million more in grants from ED, the Department of State, USAID, and other domestic sources. The program has also precipitated funding from other sources of approximately \$15 million to augment its impact. These sources include the European Union, the Russian Ministry of Education, the InterAmerican Development Bank, the World Bank, the Mexican Institute for Federal Elections, and other public- and private-sector sources in other countries. This additional support could not have been generated without the funding from ED that has served as "seed" money for the establishment of successful education for democracy programs in other nations.

The impact and success of these programs is supported by research findings and numerous reports from U.S. Embassies and AID missions, which have assisted the Center in their establishment. In many cases, the successful impact of pilot programs supported by ED funds has prompted these entities to add their own funds to augment the programs. A notable example of such an occurrence was the Center's ED-supported Jordanian pilot program in democracy education, which has received approval for nationwide implementation by the Ministry of Education. The success of this program led the State Department to provide an additional \$3.2 million to implement democracy education programs in ten Arab nations in North Africa and the Middle East. In turn, the success of that program led the State Department to request that the Center submit a proposal for three years of funding for the region at \$3–4 million per year. None of this would have been possible without the sustained funding from ED that enables the Center to initiate and maintain education for democracy programs in spite of the changing priorities of other sources of funding. It is important to note that the State Department funding does not eliminate the need for the baseline ED funding for the international civic education program and that with continued ED funding, similar advances might be made in other parts of the world.

It is clear that these programs are a significant and cost-effective contribution to the administration's effort to further the worldwide growth of democracy, which is why President Bush has met with the Center's Russian partner, and Secretary of State Condoleezza Rice has met with the Center's partner in Pakistan. It is also clear that the international civic education for democracy movement, central to the administration's foreign policy, is at risk without significant continuing funding. Although a fledgling nongovernmental membership organization—Civitas Inter-

national—was founded by the United States Information Agency in 1995 to assist efforts in this field, the organization was never able to raise sustaining funds from other organizations or individuals that would permit it to function independently. Instead, the organization asked the Center to assist it by folding its meetings and functions into the Center's civic education network.

Note: In addition to those students reached by the Center's international programs, the economics program funded under this Act and implemented by the National Council for Economic Education reaches an estimated 2.4 million students annually. The goal of this effective program is to help students understand the principles and institutions of market economies and their relationship to democracy.

Summary

Contrary to the Department of Education's assertion in its justification for eliminating funding for the Education for Democracy Act, the Center's programs have a significant impact on the civic education of pre-collegiate students and their teachers in the United States and abroad.

The Center's programs are proven, cost effective, and reach millions of students throughout the world. Approximately 3 million students in the United States benefit from the Center's curricular programs at a cost of approximately \$5.67 per student. The Center's programs directly contribute to the mission of the Department of Education by accomplishing the mission set forth in President Bush's initiative in History, Civics, and Service.

Approximately 2 million students per year outside of the United States are provided by the Center and its network of coordinators with instruction in the fundamental values and principles of constitutional democracy and learn how to participate competently and responsibly in political life. Funding provided by the Department of Education is essential for the establishment of successful education for democracy programs in other nations. The spectacular success of Center initiatives in Jordan and other Arab nations demonstrates the Center's cost-effective contribution to the Bush administration's effort to advance the worldwide growth of democracy.

2. Response: There is "little or no reliable evidence of [the] effectiveness" of the Center's programs

The Department's document claims that studies of the programs of the Center are not sufficiently rigorous to yield reliable results about their overall effectiveness. To that end, a single study conducted by the Center on students participating in the national finals of the Center's annual We the People competition was cited. The study employs nationally normed items from the National Assessment of Educational Progress (NAEP), the National Election Studies, and the College Freshman surveys. The positive results of this study were challenged by ED because the students were a select sample—even though that fact had always been clearly identified and understood as such, and the Department accepted it as a valid performance indicator. Indeed, the study in question is performed annually in partial fulfillment of requirements placed on the Center by the Department of Education.

Since its inception in 1965 at the University of California at Los Angeles, the Center has conducted numerous studies on the effectiveness of its curricular programs and contracted with third parties that have also conducted such studies. (Most of these studies are not referred to in the ED report.) Indeed, the We the People programs have been more thoroughly researched than any other programs in the field.

Each of the recent studies cited below falls within the recommendations of the What Works Clearinghouse at the Institute of Educational Sciences (IES) of the Department of Education. IES encourages the methodological rigor of studies that include experimental or high-quality quasi-experimental design and cites them as the best determinants for measuring curricular effectiveness.

Study: MPR Associates, Inc.— A high-quality quasi-experimental study of the We the People: The Citizen and the Constitution program conducted in 2003 by MPR Associates, Inc., in collaboration with noted research scholars Dr. Richard Niemi, University of Rochester, and Dr. Elizabeth Theiss-Morse, University of Nebraska-Lincoln, found statistically significant differences between We the People and non-We the People students. Specifically, We the People students enrolled in AP classes performed, on average, 30 percent better on the knowledge survey than students enrolled in non-We the People AP classes. We the People students in regular classrooms also significantly outperformed their non-We the People counterparts.

The study also found that We the People students were more likely than their peers to show greater growth in their sense of political efficacy, sense of citizen responsibility, appreciation of obligations of citizenship, and a greater sense of political and community responsibility than the control group. The results of these studies show the degree to which the Center's programs meet President Bush's request

for civic education initiatives that “improve students’ knowledge of American history, increase civic involvement, and deepen their love for our great country.” (Bush 2002, 1)¹ It should be noted that the Center was unable to obtain funding for a proposal submitted to the Department of Education in 2005 for a study employing random assignment of students to the curriculum. The Center is still seeking funds to use the instruments it has developed to conduct a longitudinal study over seven years.

Study: University of Texas.—Dr. Kenneth Tolo, University of Texas at Austin, found that the Center’s We the People: Project Citizen program had positive effects on student attitudes and skills, including students’ attitudes about their own effectiveness and their engagement in their communities. The program also enhanced student communication and research skills.

The study also details seven key areas of Project Citizen implementation—State administration, the recruitment of and outreach to teachers and school administrators, teacher training, teacher and class use, Project Citizen competitions, benefits to students, and financial and political support—and offers recommendations for maximizing implementation efforts in each of these areas. These recommendations have been invaluable to improving the implementation strategies of Project Citizen in the United States and abroad.

Study: RMC Research.—In 2004–2005, RMC Research used qualitative and quantitative measures in a quasi-experimental study of students taking part in the Project Citizen program in Oklahoma, Michigan, Colorado, the Czech Republic, and Slovakia. The study found that students in grades 6–12 increased their global knowledge of democracy. The study found significant gains in students’ knowledge of public policy, support for freedom of belief, the right of citizens to question government messages, and the right to join organizations. Students’ civic skills improved as well. Based upon these results, RMC is improving item reliability and will conduct a second study in 2006.

Study: Indiana University at Bloomington.—A high-quality quasi-experimental study of students in Indiana, Latvia, and Lithuania by Thomas S. Vontz, Kim K. Metcalf, and John J. Patrick, Indiana University at Bloomington, found that We the People: Project Citizen develops students’ civic knowledge, skills, and dispositions positively and significantly, irrespective of nationality. The full report has been published in a volume titled Project Citizen and the Civic Development of Adolescent Students in Indiana, Latvia, and Lithuania.

Study: Center for Civic Education, Bosnia and Herzegovina.—A high-quality quasi-experimental study of students in Bosnia and Herzegovina in 2000 by Dr. Suzanne Soule, Center for Civic Education, found that Project Citizen students showed greater confidence in their knowledge of local government, were more skilled at explaining problems; showed greater analytical abilities in using facts and reason to analyze other people’s positions on problems, had more positive attitudes with regard to their own power in the community and internal efficacy, and showed a greater propensity to hold public officials accountable. In 2002, First Lady Laura Bush praised the program in remarks to the Organization for Economic Cooperation and Development:

“The United States is also a partner in the Balkans, working with the International Community and Civitas in Bosnia and Herzegovina to develop a course in democracy and human rights. This course is taught in (primary) schools throughout the region, including Brcko, and it has been translated for all three ethnic groups. The course is part of a larger effort called ‘Project Citizen.’ Through ‘Project Citizen’ programs, children learn to identify and solve problems in their own communities, from supplying clean water to improving dangerous traffic crossings. Citizenship—a sense of belonging and responsibility—strengthens societies.”

Study: Center for Civic Education, Indonesia.—A high-quality quasi-experimental study of students in Indonesia in 2002 by Dr. Suzanne Soule found Project Citizen participants’ political participation increased as a result of their involvement with the program. In contrast to the control group, they participated more in the political process, conducted more research by contacting experts to obtain information on issues they cared about, and participated in protests at higher rates. They also paid more attention to public affairs in the media. The dispositions of students who participated more fully in the program—by selecting their problems, presenting their proposals, and engaging in other programmatic activities—changed more. They became more interested in politics and public affairs. Their confidence in their ability

¹ Bush, George W. (2002). “President Introduces History and Civic Education Initiatives.” Remarks of the president on the Teaching History and Civic Education Initiative, September 17. www.whitehouse.gov.

to participate, along with their sense of political efficacy, increased. Further, high-involvement participants increased their expectations of the proper responsiveness of government, an important component of accountability.

Study: WestEd.—The Center is currently working with WestEd, a leading survey-design firm, to devise knowledge and attitude tests for We the People: Project Citizen domestic and international use. The standardized test will be refined and used within and outside the United States with various quasi-experimental and experimental studies to ensure a maximum scale of comparability. The knowledge tests have been piloted in Nigeria and South Africa and are to be utilized in an experimental study in Colombia and Mexico in 2006.

State Department Report.—In a report released by the State Department's Bureau of Western Hemisphere Affairs, the Center's ED-supported Civitas Latin America program is presented as a model for developing Cuban democracy (see Chapters 2 and 3). The report cites success in training teachers and effectiveness of programs as important for encouraging democratic thought and practice.

USAID Report.—The State Department report is in accord with an independent assessment of civic education programs funded by USAID from 1990 to 2000, which found that "We the People: Project Citizen has many of the characteristics of the most effective civic education programs. It is highly participatory, it relates to issues that affect the participants in their daily lives, it produces tangible as well as intangible results, and it is firmly rooted in the community in which it takes place." (Brilliant, 2000, 38).²

Other Evidence of the Effectiveness of the Center's Programs

In addition to previous references to visits with program participants by President Bush, Mrs. Bush, and Secretary Rice, the obvious effectiveness of the Center's programs has been recognized at other times at the highest levels of government in the United States and other nations. For example:

- In 1996, the Supreme Court hosted the newly elected U.S. Senate in the Great Hall of the Court. The event was attended by seven Justices and more than ninety senators. The major attraction of the evening was a well-received demonstration of the We the People competitive hearing by students from the State of Oregon.
- In 1998, students from the We the People program were honored by the Department of Education when Secretary Riley announced the release of the findings of the NAEP study of student knowledge of civics and government.
- In 2000, We the People students were invited to testify in Congress on the subject of school violence. Members of the committee before which the students testified said that they were better prepared than many of the expert witnesses who had testified earlier.
- In 2004, the Bush administration hosted a White House Conference on History, Civics, and Service. The only civics program featured was the We the People program. Students from Arizona demonstrated their outstanding knowledge of the U.S. Constitution and Bill of Rights before a panel composed of a noted scholar and two Federal judges. One of the Federal judges commented that the students had a firmer grasp of constitutional principles than most attorneys who appear in her court.
- In 2005, the Department of Education invited teachers of the We the People program to speak to a Constitution Day assembly at the Department, at which they were extremely well received.
- Other nations: The following are a few of the many incidences where other nations have recognized the quality and effectiveness of the Center's programs:
 - The Russian Ministry of Education has approved the use of the Center's We the People and Project Citizen texts in all Russian schools.
 - The Mexican Institute for Federal Elections has translated and adapted the Project Citizen text and is implementing it in classrooms in all States of Mexico.
 - The Center has helped the U.S. Embassy in Bosnia and Herzegovina develop a K-12 civic education program that is being implemented in all schools in that country.
 - The Jordanian Ministry of Education has approved the implementation of Project Citizen in all schools in Jordan.
 - The Kurdish Regional Authority in Iraq has translated and adapted the Center's Foundations of Democracy program and implemented it with more than 400,000 students in their region.

²Brilliant, F. (2000). Civic Education Assessment—Stage II. Civic Education Programming Since 1990—A Case Study Based Analysis. Report for the U.S. Agency for International Development.

—The U.S. Embassy in Baghdad recently supported the training of teacher trainers in the Center's curricular materials and intends to support their implementation throughout the country.

—The textbook division of the Chinese Ministry of Education has translated and adapted material from the Center's texts to be used in schools throughout China. The division has also signed a memorandum of understanding with the Center to work together to develop more curricular materials.

Summary.—The following generalizations can be made from internal and external research and evaluation studies conducted during the past seventeen years. Students who participate in the Center's curricular programs show the following results. In comparison with their peers and some adults, students in Center programs:

—demonstrate a greater understanding of and commitment to fundamental values and principles of constitutional democracy, such as individual rights, the common good, the rule of law, and civic responsibility. They are also less cynical, more politically engaged, more politically tolerant, and think that they can and do make a difference in the political life of their communities and nations;

—demonstrate a greater understanding of politics and government at local, intermediate, and national levels and a deeper knowledge of how to participate effectively in the political process;

—possess better research, analytic, and communication skills. This includes an increased capacity to evaluate, take, and defend positions on public issues;

—demonstrate a greater capacity to work with others to effectively monitor and influence the decisions of their government;

—pay more attention to politics and the media, discuss politics more often, volunteer to work for candidates, register to vote, and vote at significantly higher rates than their peers. Students also take active roles in the enactment of policies to improve the life of their communities and nations.

Please see the attached bibliography for a list of studies conducted on Center programs.

3. *Response: "Additional funding is not necessary for the successful operation of this program"*

The Department's justification claims that "additional funding is not necessary for the continuation of this program." Further, the Department asserts that:

"[the] Center also has a long history of success raising additional funding support through such vehicles as selling program-related curricular materials, trainings, and workshops, partnering with non-profit groups on core activities, lobbying, and seeking support from foundations. For example, the Center has received financial support from such organizations as the Pew Charitable Trusts, the National Endowment for the Humanities, the Joyce Mertz-Gilmore Foundation, the Lincoln and Therese Filene Foundation, Inc., and an increasing number of State and local entities. Also with a national board that includes . . . noted scholars (etc.), the Center will have many opportunities to generate additional support for core program activities."

The statements in this section of the report do not reflect a sound knowledge of the history, policies, and practices of public- and private-sector support for civic education programs in the United States over the past fifty years, nor a firm grounding in the facts regarding past and present funding of the Center or the probability of obtaining the level of support necessary from sources other than the Federal Government. To anyone aware of the history of support for civic education, it is clear that support for national and international programs in civic education of the magnitude of those implemented by the Center and described above is simply not available from sources other than the Federal Government. Federal funding is essential for the continuation of this program.

The Center has always sought and sometimes received support from other sources. In reference to the sources the ED report notes above, the Center did receive \$1 million from the Pew Charitable Trusts in 1988 to develop and promote the implementation of CIVITAS: A Framework for Civic Education. In 1991, the Pew Charitable Trusts provided a grant of \$400,000 to match funds the Center received from the Department of Education to develop the National Standards for Civics and Government. For several years the Joyce Mertz Gilmore Foundation awarded the Center \$20,000 to partially offset the costs of an annual bilateral conference on civic education the Center conducted with the Federal Center for Political Education of Germany. For the past three years the Lincoln and Therese Filene Foundation has provided about \$100,000 annually to support a summer institute for teachers. A similar level of support has, in some years, been provided for the same purpose by the National Endowment for the Humanities. The Center receives

\$250,000 each year from the California State Department of Education to augment its Federal funding for the implementation of Project Citizen in California. Despite its efforts, the Center has never been able to secure sustained funding in more substantial amounts from such sources for its major programs.

The ED report claims that the Center receives income from “such vehicles as selling program-related curricular materials, trainings, and workshops.” Support from ED enables the Center to provide approximately 450,000 free textbooks to schools each year. The Center grosses approximately \$1 million each year from the sale of these texts, with the majority of these funds paying for printing, handling, and other overhead costs connected to the materials. The remainder of these funds is used to support and augment the programs supported with Federal funds. The Center does not receive funds for “trainings and workshops” which are, in fact, provided free to thousands of teachers each year under its federally supported programs.

Summary.—Although the expansion of the Center’s efforts has at times been assisted through supplemental funding provided by States and foundations, the core of its efforts depends on the Federal dollars that the administration seeks to eliminate. Without these crucial funds, much of the Center’s national and international networks and their many volunteers and programs in education for democracy will simply cease to exist. The Center seeks to continue to develop relationships with other agencies, nonprofit organizations, and funding sources to expand its operations and ultimately to institutionalize its efforts. However, if successful, the administration’s attempt to discontinue funding would undermine the very possibility of institutionalizing the foremost civic education for democracy programs in the world by prematurely cutting the lifeline of the Center’s networks and programs.

4. *Chronological List of Research and Evaluation Studies Conducted by Internal and External Evaluators on Center Domestic and International Programs*

1. *A Programmatic Evaluation of Civitas: An International Civic Education Exchange Program 2004–2005* (2006). Gary Marx, Center for Public Outreach. A report to the Center for Civic Education.

2. *We the People: The Citizen and the Constitution: 2005 National Finalists’ Knowledge of and Support for American Democratic Institutions and Processes* (2006). Sharareh Frouzesh Bennett and Dr. Suzanne Soule, Center for Civic Education.

3. *Evaluation of We the People: Project Citizen Summer Institutes: How the Teachers Translated the Experience into Classroom Instruction* (2006). Jennifer Nairne, Center for Civic Education.

4. *Political Education Beyond National Borders: Teaching Democracy Abroad to Promote More Peaceful International Relations* (2005). Dr. Alden Craddock, Bowling Green State University. Paper presented at the 2005 German-American Conference—Responsible Citizenship, Education, and the Constitution.

5. *Project Citizen: Evaluation Report* (2005). RMC Research Corporation.

6. *An Analysis of the Depiction of Democratic Participation in American Civics Textbooks* (2005). Sharareh Frouzesh Bennett, Center for Civic Education. Paper presented at the 2005 German-American Conference—Responsible Citizenship, Education, and the Constitution.

7. *Changes in the Political Landscape and Their Implications for Civic Education* (2005). Dr. Margaret Branson, Center for Civic Education. Paper presented at the 2005 German-American Conference—Responsible Citizenship, Education, and the Constitution.

8. *Differences in Gender and Civic Education in Ukraine* (2005). Dr. Alden Craddock, Bowling Green State University. Paper presented at the European Consortium of Political Research General Conference.

9. *Advancing Peace and Stability through Active Citizenship: The Role of Civic Education* (2005). Dr. Margaret Branson, Center for Civic Education. Speech delivered at the Ninth Annual World Congress on Civic Education.

10. *Voting and Political Participation of We the People: The Citizen and the Constitution Alumni in the 2004 Presidential Election* (2005). Dr. Suzanne Soule, Center for Civic Education.

11. *Monitoring the Effectiveness of Youth Participation in Project Citizen: A Civitas-Russia Evaluation Project: Summary of Preliminary Findings* (2005). Dr. Charles White, Boston University.

12. *Civitas Latin America: A Civic Education Exchange Program Annual Evaluation Report, Year 2* (2005). West Ed. A report to the Center for Civic Education.

13. *A Programmatic Evaluation of Civitas: An International Civic Education Program 2003–2004* (2005). Gary Marx, Center for Public Outreach. A report to the Center for Civic Education.

14. *We the People: The Citizen and the Constitution Summer Institutes: How the Teachers Translated the Experience into Classroom Instruction* (2005). Jennifer Nairne, Center for Civic Education.

15. *American Identity, Citizenship, and Multiculturalism* (2005). Dr. Diana Owen, Georgetown University. Paper presented at the 2005 German-American Conference—Responsible Citizenship, Education, and the Constitution.

16. *Knowledge of and Support for American Democratic Institutions and Processes by Participating Students in the National Finals 2005* (2005). (Reports available from previous years 1999–2004). Dr. Suzanne Soule and Sharareh Frouzesh Bennett, Center for Civic Education.

17. *An Independent Evaluation of Civic Education Programs in Jordan, Egypt, and West Bank 2002–2003* (2004). Glaser Consulting Group.

18. *A Rising Tide in Indonesia: Attempting to Create a Cohort Committed to Democracy through Education* (2004). Dr. Suzanne Soule, Center for Civic Education.

19. *We the People Curriculum: Results of a Pilot Test* (2004). Dr. Ardice Hartry and Kristie Porter, MPR Associates, Inc.

20. *Civitas Latin America: A Civic Education Exchange Program Annual Evaluation Report, Year 1* (2004). WestEd.

21. *Evaluation Report on 2003 We the People: Project Citizen Summer Institutes* (2004). Sharareh Frouzesh Bennett, Center for Civic Education.

22. *Foundations of Democracy Program and Prevention of Aggressive Behavior of Children in Preschool Educational Institutions* (2003). Ivan Glasovac, Croatian evaluator.

23. *Learning to Live Together: An Evaluation of Civic-Link* (2003). Work Research Co-operative, independent evaluator.

24. *Creating a Cohort Committed to Democracy? Civic Education in Bosnia and Herzegovina* (2002). Dr. Suzanne Soule, Center for Civic Education.

25. *Voting and Political Participation of the We the People: The Citizen and the Constitution Alumni in the 2000 Presidential Election* (2001). Dr. Suzanne Soule, Center for Civic Education.

26. *Programmatic Evaluation of Civitas: An International Civic Education Exchange Program 2000–2001* (2001). Gary Marx, Independent Evaluator.

27. *Civic Education Assessment—Stage II. Civic Education Programming Since 1990—A Case Study Based Analysis* (2000). Dr. Franca Brilliant. Report for the U.S. Agency for International Development.

28. *Project Citizen and the Civic Development of Adolescent Students in Indiana, Latvia, and Lithuania* (2000). Drs. Thomas Vontz, Kay Metcalf, and John Patrick, Indiana University.

29. *Prevention of School Violence through Civic Educational Curricula: Year One of a National Demonstration Program* (2000). Dr. Kenneth Tolo, LBJ School of Public Affairs, University of Texas at Austin.

30. *Beyond Communism and War: The Effect of Civic Education on the Democratic Attitudes and Behavior of Bosnian Youth* (2000). Dr. Suzanne Soule, Center for Civic Education.

31. *Programmatic Evaluation of Civitas: An International Civic Education Exchange Program 1999–2000* (2000). Eva Stahl, independent evaluator.

32. *An Assessment of We the People . . . Project Citizen: Promoting Citizenship in Classrooms and Communities* (1998). Dr. Kenneth Tolo, LBJ School of Public Affairs, University of Texas at Austin.

33. *Bell Gardens Study on Fifth and Sixth Grade Participants in Center and Constitutional Rights Foundation Curricula* (1997). University of California, Los Angeles.

34. *Program Effectiveness Panel Validation of We the People* (1995). United States Department of Education National Diffusion Network.

35. *Civic Education and Political Attitudes: Examining the Effects on Political Tolerance of the We the People Curriculum* (1994). Dr. Richard Brody, Stanford University.

36. *Testing for Learning: How New Approaches to Evaluation Can Improve American Schools* (1992). Dr. Ruth Mitchell.

37. *An Evaluation of the Instructional Impact of the Elementary and Middle School Curricular Materials Developed for the National Bicentennial Competition on the Constitution and Bill of Rights* (1991). Educational Testing Service.

38. *A Comparison of the Impact of the We the People . . . Curricular Materials on High School Students Compared to University Students* (1991). Educational Testing Service.

39. *An Evaluation of the Instructional Effects of the Nationals Bicentennial Competition on the Constitution and Bill of Rights* (1988). Educational Testing Service.

PREPARED STATEMENT OF THE COLLEGE BOARD

ANCHORING MATHEMATICS AND SCIENCE EDUCATION REFORM IN AN EXPANDED
ADVANCED PLACEMENT PROGRAM*Introduction*

The College Board is a national not-for-profit association of more than 5,000 member schools, colleges and universities, with a challenging mission: To connect students to college success and opportunity. One of the College Board's most ambitious and important teaching and learning programs is the Advanced Placement Program (AP). As a set of 38 college-level courses taught in high school, AP has become the most influential general education program in the country, and it represents the highest standard of academic excellence in our Nation's schools. The AP Program is a collaborative effort between motivated students, dedicated teachers, expert college professors, and committed high schools, colleges, and universities. Ninety percent of the colleges and universities in the United States, as well as colleges and universities in 30 other countries, have an AP policy granting incoming students credit, placement or both on the basis of their AP Exam grades. Many of these institutions grant up to a full year of college credit (sophomore standing) to students who earn a sufficient number of qualifying AP grades. Since its inception in 1955, the AP Program has allowed millions of students to take college-level courses and exams, and to earn college credit or placement while still in high school.

President Bush's request for \$90 million in new funding to train 70,000 new AP math, science, and world language teachers over the next five years will dramatically improve the quality of instruction in these areas. The ultimate outcome will include a substantial increase in the number of high school graduates who enter college with the desire and ability to succeed in science, technology, engineering, and mathematics (STEM) fields and compete in a global marketplace. Moreover, increased support for an expanded AP Program in these content areas will contribute to raising standards and achievement in all of our Nation's high schools. The AP Program benefits both the students who take AP courses and those who do not take AP by promoting higher standards and better teaching in all classes. As such, a significant investment in the expansion of AP math, science, and world language programs will have a profound effect on the overall quality of education in our Nation's schools.

AP is a 50-year-old, time-tested program with an existing infrastructure of tens of thousands of teachers and a network of hundreds of training sites across the country. Funds invested in this program will not need to be dedicated to creating a new system for teacher professional development, course development, or the administration and scoring of assessments. That system already exists as a result of our efforts over the past 50 years, and as a result of the involvement of thousands of schools, colleges and universities in the operation of the AP Program. Thus, new Federal dollars invested in AP can go directly into teacher training and student preparation and support.

The table on page four of this statement provides a summary of the total dollars that each State would receive through this initiative, and provides one model for the use of those funds that illustrates how many students and teachers could be served if the full \$90 million request were supported.

THE AP PROGRAM

The principles and values of the AP Program can be stated quite simply:

- AP supports academic excellence. AP represents a commitment to high standards, hard work, and enriched academic experiences for students, teachers, and schools.
- AP is about equity. The AP Program should be open to all students, and we believe that every student should have access to AP courses and should be given the support he or she needs to succeed in these challenging courses.
- AP can drive school-wide academic reform. Schools that use AP as an anchor for setting high standards and raising expectations for all students see significant returns not just in terms of AP participation but in terms of increasing the overall quality and intensity of their academic programs.

Across the Nation, every State, and most school districts are exploring ways to raise standards and ensure that all students take challenging courses that prepare them for success in college and work. AP is recognized as a powerful tool for increasing academic rigor, improving teacher quality, and creating a culture of excellence in high schools. Students who take AP courses assume the intellectual responsibility of thinking for themselves, and they learn how to engage the world critically and analytically—both inside and outside of the classroom. This is an invaluable experi-

ence for students as they prepare for college or work upon graduation from high school. Moreover, schools in which AP is widely offered—and accessible to all students—experience the diffusion of higher standards throughout the entire school curriculum.

AP MATHEMATICS AND SCIENCE COURSES

Increasing rigorous math and science education in the United States will significantly boost our high school graduates' math and science proficiency—and also increase the number of students who enter college ready to succeed in science, technology, engineering, and mathematics (STEM) careers. And we urgently need to create those opportunities for our students. Today, only 32 percent of American undergraduates are earning degrees in science and engineering, compared to 66 percent of undergraduates in Japan, 59 percent in China, and 36 percent in Germany. In 2004, China graduated 600,000 engineers, India graduated 350,000, and the United States graduated 70,000.¹

The AP Program is an important tool in this Nation's efforts to increase its economic competitiveness. AP math and science students are much more likely than other students to major in STEM disciplines than students whose first exposure to college-level math and science courses is in college. For example:

- Sixteen percent of students who take AP Chemistry go on to major in chemistry in college. By way of contrast, only 3–4 percent of students who take general chemistry instead of AP chemistry major in that field in college.
- More than 25 percent of students who take AP Calculus go on to major in a STEM field in college, and 40 percent of students who take AP Physics major in physics in college.

Furthermore, research indicates that AP math and science courses prepare American students to achieve a level of proficiency that exceeds that of students from all other nations. For example, in the most recent TIMSS assessments, U.S. Calculus students ranked number 15 (out of 16 countries) in the international advanced mathematics assessment. But AP Calculus students who scored a 3 or better on the AP Calculus Exam ranked first in the world. Even AP Calculus students who scored a 1 or 2 on the AP Calculus Exam—below “passing”—were ranked second in the world. AP Physics students, as compared to other U.S. physics students and physics students internationally, were also at the top of the ranking.

Most significantly, there are many, many more U.S. students who can succeed in AP math and science courses—if they are simply given the chance. This year in the United States, we anticipate that more than 100,000 students will earn a grade of 3 or above on the AP Calculus Exam—the grade typically required for college credit. But in a national analysis of the math proficiency of students enrolled in U.S. high schools during the 2005–2006 academic year, we can identify, by name and school, an additional 500,000 students who have the same academic background and likelihood of success in AP Calculus as the 100,000 students who currently are fortunate enough to have an AP Calculus course available. If we look at Biology, we see an even larger gap; we expect that about 74,000 students will earn exam grades of 3 or higher on the AP Biology Exam this year, whereas we know that at least 640,000 additional U.S. students have the academic skills that would enable them to succeed in AP Biology if they only had a course available to them and the encouragement to take on this challenge. There are literally hundreds of thousands of high school students in the United States who are prepared and ready to succeed in rigorous high school courses such as AP Calculus, AP Biology, AP Physics, and AP Chemistry. In many cases, the only thing preventing them from learning at this higher level is the lack of an AP teacher in their school or the lack of adequate encouragement and support to take the AP course.

The College Board believes AP has tremendous potential to drive reform in a powerful way in all of our Nation's schools. No single program can have as strong an impact on overall student and teacher quality as AP. AP is not for the elite, it is for the prepared. The Committee's support for expanded AP math, science, and world language courses and exams will prepare many more students for the opportunity to compete in a global environment and succeed in STEM fields in college and work. We respectfully urge that you fully fund the Administration's request for AP expansion.

¹Committee on Science, Engineering and Public Policy. *Rising Above the Gathering Storm: Energizing and Employing America for a Brighter Economic Future*. National Academies Press, 2006. This report notes that America appears to be on a “losing path” today with regard to our future competitiveness and standard of living.

State	Potential New 2007 AP funding Under President's Proposal	Total number of middle and high school teachers pro- vided with Pre-AP or AP training	Number of students ben- efiting from teachers re- ceiving Pre-AP training (20 students per 5 sections)	Number of students ben- efiting from teachers re- ceiving AP training (25 students per AP teacher)
Alabama	\$1,600,989	750	60,037	3,752
Alaska	453,123	212	16,992	1,062
Arizona	2,074,097	972	77,779	4,861
Arkansas	1,016,284	476	3,8111	2,382
California	12,527,993	5,872	469,800	29,362
Colorado	933,670	438	35,013	2,188
Connecticut	542,351	254	20,338	1,271
Delaware	453,123	212	16,992	1,062
District of Columbia	453,123	212	16,992	1,062
Florida	4,948,272	2,320	185,560	11,598
Georgia	2,823,013	1,323	105,863	6,616
Hawaii	453,123	212	16,992	1,062
Idaho	453,123	212	16,992	1,062
Illinois	3,228,779	1,513	121,079	7,567
Indiana	1,254,941	588	47,060	2,941
Iowa	482,954	226	18,111	1,132
Kansas	537,051	252	20,139	1,259
Kentucky	1,335,985	626	50,099	3,131
Louisiana	2,012,675	943	75,475	4,717
Maine	453,123	212	16,992	1,062
Maryland	978,436	459	36,691	2,293
Massachusetts	1,093,966	513	41,024	2,564
Michigan	2,431,666	1,140	91,187	5,699
Minnesota	746,455	350	27,992	1,750
Mississippi	1,349,629	633	50,611	3,163
Missouri	1,418,338	665	53,188	3,324
Montana	453,123	212	16,992	1,062
Nebraska	453,123	212	16,992	1,062
Nevada	575,422	270	21,578	1,349
New Hampshire	453,123	212	16,992	1,062
New Jersey	1,500,749	703	56,278	3,517
New Mexico	827,151	388	31,018	1,939
New York	6,191,847	2,902	232,194	14,512
North Carolina	2,401,977	1,126	90,074	5,630
North Dakota	453,123	212	16,992	1,062
Ohio	2,504,484	1,174	93,918	5,870
Oklahoma	1,132,521	531	42,470	2,654
Oregon	902,459	423	33,842	2,115
Pennsylvania	2,659,829	1,247	99,744	6,234
Rhode Island	453,123	212	16,992	1,062
South Carolina	1,338,960	628	50,211	3,138
South Dakota	453,123	212	16,992	1,062
Tennessee	1,661,104	779	62,291	3,893
Texas	8,742,609	4,098	327,848	20,490
Utah	479,572	225	17,984	1,124
Vermont	453,123	212	16,992	1,062
Virginia	1,443,618	677	54,136	3,383
Washington	1,340,908	629	50,284	3,143
West Virginia	615,683	289	23,088	1,443
Wisconsin	934,028	438	35,026	2,189
Wyoming	453,123	212	16,992	1,062
American Samoa	453,123	212	16,992	1,062
Guam	453,123	212	16,992	1,062
Northern Mariana Islands	453,123	212	16,992	1,062
Puerto Rico	3,877,930	1,818	145,422	9,089
Virgin Islands	453,123	212	16,992	1,062
Freely Associated States
Indian set-aside
Other (non-State allocations)	455,400	213	1,7078	1,067
Total	91,080,000	42,694	3,415,500	213,469

PREPARED STATEMENT OF THE COUNCIL OF STATE ADMINISTRATORS OF VOCATIONAL REHABILITATION (CSAVR)

This testimony is submitted on behalf of the Council of State Administrators of Vocational Rehabilitation (CSAVR). The CSAVR is composed of the chief administrators of the State Vocational Rehabilitation (VR) Agencies serving individuals with physical and/or mental disabilities in the United States, the District of Columbia and the Territories. These agencies constitute the State partners in the State-Federal Program of Rehabilitation Services provided under Title 1 the Rehabilitation Act of 1973, as amended. State VR agencies provide individualized services and supports to eligible individuals with significant disabilities that are required for them to go to work. These services may include, but are not limited to, counseling and guidance, job training, higher education, physical and mental restoration services, and assistive technology. Nearly 1 million individuals with disabilities are served annually. In fiscal year 2005, these agencies placed 206,695 individuals with disabilities into competitive employment.

The CSAVR, founded in 1940 to furnish input into the State-Federal Rehabilitation Program, provides a forum for State administrators to study, deliberate, and act upon matters affecting the rehabilitation and employment of individuals with disabilities. The Council serves as a resource for the formulation and expression of the collective points of view of State rehabilitation agencies on all issues affecting the provision of quality employment and rehabilitation services to persons with significant disabilities.

CSAVR'S RECOMMENDATION FOR THE FISCAL YEAR 2007 APPROPRIATION FOR THE PUBLIC VOCATIONAL REHABILITATION PROGRAM

For fiscal year 2007, CSAVR recommends an increase in the Vocational Rehabilitation (VR) appropriation of \$258 million above the President's budget request for fiscal year 2007. The President's budget proposes a 4.3 percent increase in funding for the Public VR program, which is the mandated CPI increase, called for in law. However, the President's budget request also eliminates funding for several smaller programs, Supported Employment (SE), Projects with Industry (PWI), and Migrant and Seasonal Farm Workers (MSFW), with a total loss of funding of 51.7 million. With the majority of State VR Agencies operating under an Order of Selection, a system of prioritization whereby individuals with the most significant disabilities are served first, it is unlikely that the State VR Agencies would be able to continue to provide services, under Title 1 of the Rehabilitation Act, to all of the individuals previously served under the programs that lost their funding.

In addition to the proposed elimination of the SE, PWI, MSFW, and Recreation programs, which CSAVR does not support, HR 27, the House bill to reauthorize the Workforce Investment Act (WIA), and S 1021, the Senate bill to reauthorize the WIA, expands the requirements for VR to provide transition services to students with disabilities. Based on the significant internal and external challenges facing the Public VR Program, (i.e., staffing shortages, State budget shortfalls, increased numbers of consumers seeking services, and increased service costs and expectations, the CSAVR believes that an increased appropriation of 258 million above the President's budget request for VR, for fiscal year 2007, is an appropriate recommendation.

The CSAVR is requesting a \$206 million increase specifically for the purposes of implementing the new transition requirements in the Rehabilitation Act. The most recent data on transition students, published in 2003 in the Individuals with Disabilities Education Act (IDEA) 25 Annual Report to Congress, indicates that there were 2,791,886 students between the ages of 12-17 and 283,265 between the ages of 18-21. A small sample survey of State VR Agencies revealed that the average annual cost to serve a transition student is \$2062.00. The CSAVR will have the capacity to serve 100,000 new transition students in fiscal year 2007, with a funding increase of \$206 million.

In addition, CSAVR is requesting that you restore the \$51.7 million to the MSFW, the SE and the PWI programs, whose budgets were eliminated in the President's budget request for fiscal year 2007.

These three programs are vital to VR consumers and desperately needed to assure that vital support services, necessary for successful employment of certain populations, are maintained.

THE PUBLIC VOCATIONAL REHABILITATION PROGRAM

The Public VR Program is one of the most cost-effective programs ever created by Congress. It enables hundreds of thousands of individuals with disabilities to go

to work each year and become tax-paying citizens. In fiscal year 2005, the VR Program assisted 984,315 individuals with disabilities who wanted to work, by providing them with the job skills, training and support services they needed to become employed. Of those served, 206,695 entered into competitive employment. Funding for the VR Program requires a State match of 21.3 percent, and creates a State-Federal partnership that has worked effectively for more than 86 years, and has assisted approximately 16 million individuals with disabilities to engage in employment and become tax-paying citizens.

The Rehabilitation Act mandates that the annual Federal appropriation for the VR Program grow at a rate at least equal to the change in the Consumer Price Index (CPI) over the previous fiscal year. While the mandate was intended to create a floor for the VR appropriation, Congress has not appropriated funds above the mandated CPI increase since 1999. This is particularly problematic because the formula used to distribute these funds, which is based on a State's per capita income and population, results in significant variations in the increases in individual State's allotments. When the increase is limited to the CPI increase and the formula is applied, not all States receive increases that are equal to the annual rate of inflation. In fiscal year 2006, 30 States did not receive the required CPI increase in their State allotment.

CHALLENGES FACING THE PUBLIC VR PROGRAM

Over the last several years, the Public VR Program has faced a number of external challenges that have been compounded by the minimal increases in Federal funding.

SPECIAL EDUCATION

Between 1990 and 2004, the Federal appropriation for special education increased by approximately 333 percent. During the same time period, the Federal appropriation for the Public VR Program increased by only 22 percent. As a result of these very significant increases in special education funding, an ever-increasing number of special education students are exiting the education system and seeking adult services, including Vocational Rehabilitation, in order to participate in post secondary education, job training, and/or to go to work.

IMPACT OF THE WORKFORCE INVESTMENT ACT OF 1998 (WIA)

The Public VR Program is a mandatory partner in the WIA and, as such, is required to contribute significant resources to support the infrastructure and other costs associated with the operation of the One-Stop Centers. While VR's involvement in State Workforce Investment Systems is critically important, WIA has placed yet another financial burden on an already strained program, further reducing the percentage of VR funds that are available to provide services and supports to eligible individuals with disabilities. In addition, the House bill to reauthorize the WIA, H.R. 27, proposes to take significant resources from the Public VR Program far beyond the resources contributed to the One-Stop Centers under current law. The Senate bill, S. 1021, also requires resources from VR to fund the infrastructure costs and other common costs associated with the operation of One-Stop Centers; however, the CSAVR is very grateful for the graduated CAP on infrastructure funding for VR in S. 1021.

- A 2002 Longitudinal Study of the Public VR Program provided evidenced based research that the VR Program is effective in putting people with disabilities to work in good jobs with opportunities for advancement.
- A fiscal year 2006 Program Assessment Rating Tool (PART) Review, conducted by the Office of Management and Budget (OMB) to rate program performance, rated the VR Program favorably, and in general, successful in meeting its program goal.
- A report by the Social Security Administration, released annually, provides detailed information on the funds disbursed to State VR Agencies, based on their successfully serving beneficiaries on Social Security Disability Insurance (SSDI) and Supplemental Security Income (SSI). In fiscal year 2004 SSA projected a 470.3 million savings to the Trust Fund by the VR Program, and established that every \$1.00 that SSA spends on VR results in a \$6.00 savings.

In this era of significant Federal and State budget deficits, and an increase in the unemployment rate for individuals with disabilities, we urge you to consider an increase in funding for the Public VR Program, through which you can be assured to have positive outcomes, based on the three factors mentioned above.

Our Nation's ability to be competitive in a global economy depends on the quality of our workforce. According to information provided by the Department of Labor,

Employment & Training Administration, during the fiscal year 2006 Budget Briefing, the American workforce will be vastly different than it is today, as the 21st century unfolds. The fastest growing jobs of the future will need to be filled by “knowledge workers,” who have specialized skills and training. Ninety percent of the fastest growing jobs in the United States (U.S.) require some level of post-secondary education and training. Yet, the U.S. Census Bureau reports that in the United States, just 28 percent of those 25 and older in 2004 had a bachelor’s degree. Integrating all available workers into the workforce, including workers with significant disabilities, will be required for employers to meet the demands of the 21st century economy. Significant numbers of large and small employers have acknowledged that hiring individuals with disabilities makes good business sense. It provides them with dependable workers and access to a market of individuals with spending power, which has historically been untapped. These same employers also have long-standing, positive relationships with VR, to whom they look to provide them with qualified workers with disabilities. Integrating all available workers into the workforce, including workers with disabilities, will require significant resources.

Recently, the CSAVR developed a National VR/Business Network for the purposes of increasing significantly, the number and quality of employment opportunities for VR’s consumer. This National Network, spearheaded by CSAVR’s Director of Business Relations, has already expanded the number of employment opportunities available to VR’s consumers in a significant number of States, and is continuing to grow. VR’s positive relationships with employers, who rely heavily on the Public VR Program to meet their hiring needs, further emphasizes and documents the need for additional resources for VR.

The Public VR Program, 86 years of history, 16 million individuals served, and a demonstrated return on investment. With additional resources, the Public VR Program can do more of what it does best—provide the resources for individuals with disabilities to go to work and live the American Dream.

The CSAVR thanks the Chairman and Members of the Senate Appropriations subcommittee for the opportunity to submit written testimony on behalf of the Public VR Program.

PREPARED STATEMENT OF GALLAUDET UNIVERSITY

Mr. Chairman and members of the committee: I would like to express my appreciation to you and to Congress for the generous support that we received in fiscal year 2006 to continue maintaining and enhancing academic programs and salaries at Gallaudet University. I am especially grateful that Congress continues to support us during these challenging times, and I am testifying in support of our appropriation request for fiscal year 2007. As I prepare to retire as President at the end of this calendar year, I would particularly like to express my appreciation for the support that Congress has provided to Gallaudet during the 18 years of my administration and of majority control of the Board of Trustees by deaf individuals. One of my proudest accomplishments is the increase in the percentages of our employees who are deaf or members of minority groups. These percentages now stand at 41 percent and 38 percent respectively.

Consistent with our legal purpose, as stated in the Education of the Deaf Act (EDA), we have greatly expanded programs at the doctoral level. When I became President, we had only one doctoral level program in administration and supervision—we now have additional doctoral programs in audiology, clinical psychology, education, and linguistics. At the undergraduate level we have focused on programs, such as tutoring and first year seminars, designed for long term enhancement of our persistence and graduation rates, and we have initiated a much needed bachelor’s level interpreter training program. At the Clerc Center, following guidance from Congress during the 1992 reauthorization of the EDA, we have refocused our demonstration and outreach activities at the pre-college level on high priority student populations throughout the United States.

During my presidency, Gallaudet responded to the Government Performance and Results Act (GPRA). In 2005, we had 31 ambitious goals published under GPRA, with 17 of those fully accomplished in that year. These goals reflect the wide array of programs and services that Gallaudet provides as required by legislative mandate and performance expectations as agreed to with the U.S. Department of Education. During 2005, Office of Management and Budget (OMB) conducted a Program Assessment Rating Tool (PART) of Gallaudet, and, based on a limited and narrow set of GPRA indicators, it gave Gallaudet an “ineffective” rating. I protested the rating in part because of the assessment’s limited scope and also because we were not involved in the assessment. I am pleased to inform you that OMB has agreed to con-

duct a reassessment of Gallaudet this year, and I will insist on a broader set of indicators that truly represent Gallaudet's complex mission.

When I became President in 1988, every building on the Kendall Green campus had been constructed with virtually 100 percent Federal funding. Since I became President, every major construction or renovation project we have undertaken has been supported either by cost-sharing with the Federal Government or by private fundraising alone. For example, the buildings constructed here most recently, the Kellogg Conference Hotel at Gallaudet University and the Student Academic Center, were constructed without any additional Federal appropriations. We are currently well on the way to raising the funds needed for a facility to house our language and communication programs, including a \$5 million leadership gift from the Sorenson family of Utah.

When I became President, the Gallaudet endowment was valued at \$10 million. Partly with the assistance of the Federal Endowment Program created by the 1986 passage of the Education of the Deaf Act, our endowment now stands at \$165 million and generates more than \$4 million in annual income to support programs and scholarships.

When I became President in 1988, total staffing at Gallaudet stood at about 1,450 employees. Following a comprehensive staffing reduction program, it now stands at just over 1,100, a reduction of more than 20 percent. This reduction provided much needed budget flexibility during a time when Congress was seeking to reduce the Federal budget deficit. During my tenure, we have also decreased the proportion of our operating budget that is supported by Federal appropriations by about 10 percentage points. This reduction was made possible in part by a long term plan to increase tuition charges to Gallaudet students, following an agreement between the University and the Department of Education. For many years, we increased tuition at 7 percent annually, more than twice the rate of inflation. Following expressions of concern by members of Congress and by a consulting group we retained to study our tuition policy, we reduced these increases to 3 percent annually starting in fiscal year 2006. I believe that we have been very responsible in our requests for Federal support and that we have done everything we could to seek additional sources of funding during a time when Congress has faced funding limitations.

Because of Congress's ongoing support of Gallaudet in fiscal year 2006, we have been able to maintain a competitive pay structure for our employees while retaining the flexibility to meet the needs of a changing student body. Given the unique student population we serve and the communication skills our employees are expected to possess, retaining skilled employees is critical to our mission. Gallaudet employees received general pay increases of 2 percent in fiscal year 2003, 3 percent in fiscal year 2004, 2 percent in fiscal year 2005, and 2 percent again in fiscal year 2006, increases that are below what Federal employees in the region received during the same timeframe, but in line with increases in the Consumer Price Index (CPI). During the most recent 12 month period, the CPI-U increased by 4 percent. It will be important for Gallaudet to ensure that our employees receive at least a 3 percent general pay increase in fiscal year 2007, commensurate with current increases in inflation. We are also requesting support for inflationary increases in non-salary areas, especially in the cost of utilities and benefits. In this regard, I need to point out that our benefits charges during the past several years have increased by more than 2 percent of base salaries, and we have had to fund those increases as part of our total payroll package.

The administration budget for fiscal year 2007 includes \$106.998 million for Gallaudet, the same as our current fiscal year 2006 appropriation. I have carefully analyzed our fiscal year 2006 funding needs and have determined that in order to award a 3 percent salary increase to our faculty and staff, and to meet other inflation-driven increases, we need an increase of about \$5 million, 4.7 percent above our current appropriation. All of our planning is now guided by a comprehensive strategic plan driven by eight goals, arrived at in consultations involving our Board, and our faculty and staff, relating to student academic achievement within the liberal arts tradition, excellence in research and other programs, diversity among students and employees, leadership in the deaf community, and maintenance of a strong resource base.

FUNDING REQUEST FOR FISCAL YEAR 2007

In our budget request to the Department of Education for fiscal year 2007, we addressed the need for inflationary increases as well as support for program development. Given the funding issues currently facing Congress, I am requesting support at this time for only our most pressing inflationary needs. Funding our need to cover inflationary costs will provide us some budget stability, but we will continue

to face the need for development and enhancement of our programs. Our strategy will be to seek alternative sources of funding for some of these program priorities and to defer others. We will continue to seek support for program growth from both Federal and private sources in the future.

Salaries.—I am requesting support for a 3 percent increase in salaries, approximately \$2.6 million.

Benefits.—I am requesting support for increases in benefits costs that have created the need for increasing charges to our operating units by 2 percent of base salaries, approximately \$1.4 million.

Utilities.—The total cost for utilities at Gallaudet rose by \$1.8 million, or 50 percent, between fiscal year 2002 and 2005, and I expect these costs to continue rising steeply in fiscal year 2006. I am seeking \$1 million to partially offset these increases.

My total request for fiscal year 2007 is, thus, \$112 million.

In summary, I appreciate the challenges that Congress faces in making appropriations decisions for fiscal year 2007, but I believe experience has shown that Gallaudet provides an outstanding return on Federal dollars that are invested here, in terms of the educated and productive deaf community that the Nation enjoys as a result.

PREPARED STATEMENT OF THE HEALTH PROFESSIONS AND NURSING EDUCATION
COALITION

The members of the Health Professions and Nursing Education Coalition (HPNEC) are pleased to submit this statement for the record in support of the health professions education programs authorized under Titles VII and VIII of the Public Health Service Act.

HPNEC is an informal alliance of over 50 organizations representing a variety of schools, programs, health professionals, and others dedicated to ensuring that Title VII and VIII programs continue to help educate the Nation's health care and public health personnel. HPNEC members are thankful for the support the subcommittee has provided to the programs, which are essential to building a well-educated, diverse health care workforce.

The Title VII and VIII health professions and nursing programs are essential components of Americans' health care safety net, bringing health care services to our underserved communities. These programs support the training and education of health care providers with the aim of enhancing the supply, diversity, and distribution of the workforce, filling the gaps in the health professions' supply not met by traditional market forces. The Title VII and VIII health professions programs are the only Federal programs designed to train providers in interdisciplinary settings to meet the needs of special and underserved populations, as well as increase minority representation in the health care workforce.

The final fiscal year 2006 Labor-HHS-Education Appropriations bill cut Title VII & VIII programs by 34.5 percent, including a 51.5 percent cut to Title VII programs. Moreover, the President's fiscal year 2007 budget proposes an additional 93.1 percent cut to Title VII and a 45.8 percent cut overall to both Title VII and VIII.

HPNEC members recommend that the Title VII and VIII programs receive an appropriation of at least \$550 million for fiscal year 2007. This recommendation would ensure the programs have sufficient funds to continue fulfilling their mission of educating and training a health care workforce that meets the public's health care needs, restoring some of the unprecedented cuts imposed on the programs in fiscal year 2006.

As described in an April 5 letter to the subcommittee, led by Senators Pat Roberts and Jack Reed, and signed by 56 of your colleagues (letter attached), restoring funding to Title VII health professions programs is vital to reversing health professions shortages in the Nation's neediest communities. An April 3 letter led by Senators Susan Collins and Barbara Mikulski was signed by 54 Senators in support of adequate funding for Title VIII nursing programs as well (letter attached).

The enacted and proposed cuts to the programs will:

Exacerbate existing provider shortages in rural, medically underserved, and federally designated health professions shortage areas

—With Title VII funding, the Department of Family Medicine at Pennsylvania State University increased the number of students entering primary care to 50 percent of all graduates. Through rural rotations and required primary care clerkships, Penn State placed 30 percent of graduates into medically underserved areas over the last three years. With cutbacks in Title VII funding, they

will lose their ability to continue producing physicians for underserved and rural areas.

—According to the University of Nebraska Medical Center, eliminating Title VII funding will cut off access to psychologists for many families in rural areas. Over the last four years, the Munroe Meyer Institute Department of Psychology has served children and families from over 140 Nebraska cities and towns (3,500 patients each year), and has placed Pediatric Psychologists in five rural primary care practices. The rural programs will be in severe financial crisis as a result of cuts, which would further reduce Nebraska's already severely limited mental health services to its rural citizens.

Impede recruitment of underrepresented minorities and students of disadvantaged backgrounds into the health professions and intensify health disparities among minority and underserved citizens

—The Saint Louis University School of Medicine operates a Health Careers Opportunity Program (HCOP). The negative impact of the elimination of Federal funding on the development of pipeline programming will be significant, as over 2,300 K–12 students annually participate in one or more pipeline programs. A correlative impact will be in the area of minority/disadvantaged recruitment, as pipeline programs heighten awareness of opportunities for medical and pre-medical training (i.e., research opportunities) at Saint Louis University. Elimination of Federal dollars will severely limit the ability of Saint Louis University to continue to impact young people at an early age to begin thinking about medicine. A reduction in minority enrollment is certain to occur at a time when enrollment diversity is having critical implications on institutional and faculty development, as well as on cultural competency initiatives.

—The University of Illinois' College of Medicine has received Federal funding for its HCOP program for over 25 years and has graduated over 1400 health professionals. With a loss of funds, the school expects that the breadth of its recruitment activities will be curtailed, resulting in fewer contacts with underrepresented students, truncating the opportunities for exposing students to medicine as a career choice, to financial aid information, to curriculum preparedness, etc. These programmatic impacts will shape the medical profession as a whole, as there will be fewer underrepresented minorities who are recruited, retained, and who graduate to become physicians; fewer underrepresented minorities who are able to assist in bridging the dearth of medical care in underserved areas; fewer underrepresented minorities who are able to continue eliminating health disparities and contributing to health policy; and fewer underrepresented minorities who are culturally competent to appropriately provide health care services to the Nation's historically underserved populations.

Negatively impact vulnerable populations such as the elderly

—Over four years, the South Carolina Geriatric Education Center (GEC) has trained over 6,000 physicians. The enacted cuts to Title VII programs eliminate funding for geriatrics programs, including those at the University of South Carolina School of Medicine and the Medical University of South Carolina. As one of the top five States in rate of growth for older individuals, the direct impact on educating physicians and other health professionals on the special needs of aging adults will reverberate throughout South Carolina. On a national scale, the cuts will affect 50 GECs throughout the country which train over 50,000 health care professionals representing 35 disciplines annually. These centers log 8.6 million patient encounters each year, and over two-thirds of GECs serve rural areas and underserved populations. The effect of this lost funding is devastating to both academic institutions and older individuals who will not receive care from health professionals equipped to address their unique needs.

Undermine efforts to encourage health professions students to enter primary care

—The University of California, San Diego School of Medicine reports that 71 percent of UCSD Hispanic Center of Excellence (HCOE) alumni completed or are completing primary care residencies, compared to only 57 percent of the UCSD alumni, graduating in 2002–2004, who have completed or are completing primary care residencies.

A November 2002 report by the Advisory Committee on Training in Primary Care Medicine and Dentistry emphasizes the essential role of the Title VII programs in enhancing public health training for the primary care health workforce. In its recommendations, the committee notes that in 1998, 42 to 56 percent of graduates from the Title VII-supported primary care programs entered practice in underserved areas, compared to a mean of 10 percent of health professions graduates overall. Data from 1998 also indicate that 35 to 50 percent of graduates of these programs

represented minority or disadvantaged groups, compared to 10 percent minority representation overall.

Community health centers (CHCs) also benefit from Title VII and VIII programs. A March 2006 study published in the *Journal of the American Medical Association* found that community health centers report high percentages of provider vacancies, including an insufficient supply of dentists, pharmacists, pediatricians, family physicians, and registered nurses; these shortages are especially pronounced among CHCs in rural areas. Because Title VII programs have a successful record of training providers who serve underserved areas, the study recommends increased support for the programs as its primary means of alleviating the shortages. Further, the publication serves as an important reminder that the success of CHCs is highly dependent upon a well-trained clinical staff to provide care.

During their 40-year existence, the Title VII and VIII programs have created a network of initiatives across the country that supports the training of many disciplines of health providers. These are the only Federal programs designed to create infrastructures at our schools and in our communities that facilitate customized training designed to bring the latest emerging national priorities to the populations at large and meet the health care needs of special, underserved populations.

HPNEC members urge the subcommittee to consider the vital need for these health professions education programs as demonstrated by the passage of the Health Professions Education Partnerships Act of 1998 (Public Law 105-392), which reauthorized these programs. The reauthorization provided additional flexibility in the administration of these programs and consolidated them into seven general categories: Minority and Disadvantaged Health Professions Training; Primary Care Training; Interdisciplinary, Community-Based Linkages; Health Professions Workforce and Analysis; Public Health Workforce Development; Nursing Workforce Development; and Student Financial Assistance.

—The purpose of the Minority and Disadvantaged Health Professionals Training programs is to improve health care access in underserved areas and the representation of minority and disadvantaged health care providers in the health professions. Minority Centers of Excellence support programs that seek to increase the number of minority health professionals through increased research on minority health issues, establishment of an educational pipeline, and the provision of clinical opportunities in community-based health facilities. The Health Career Opportunity Program seeks to improve the development of a competitive applicant pool through partnerships with local educational and community organizations. The Faculty Loan Repayment and Faculty Fellowship programs provide incentives for schools to recruit underrepresented minority faculty. The Scholarships for Disadvantaged Students (SDS) make funds available to eligible students from disadvantaged backgrounds who are enrolled as full-time health professions students. Nursing students receive 16 percent of the funds appropriated for SDS.

—The Primary Care Training category, including General Pediatrics, General Internal Medicine, Family Medicine, General Dentistry, Pediatric Dentistry, and Physician Assistants, provides for the education and training of primary care physicians, dentists, and physician assistants to improve access and quality of health care in underserved areas. As noted in the November 2002 Advisory Committee report, two-thirds of all Americans interact with a primary care provider every year, and approximately one-half of primary care providers trained through these programs go on to work in underserved areas, compared to 10 percent of those not trained through these programs. The General Pediatrics and General Internal Medicine programs provide critical funding for primary care training in community-based settings and have been successful in directing more primary care physicians to work in underserved areas. They support a range of initiatives, including medical student training, residency training, faculty development and the development of academic administrative units. Title VII is the only Federal program that provides funding for family medicine residency training, academic departments, predoctoral programs, and faculty development. The General Dentistry and Pediatric Dentistry programs provide grants to dental schools and hospitals to create or expand primary care dental residency training programs. Recognizing that all primary care is not only provided by physicians, the primary care cluster also provides grants for physician assistant programs to encourage and prepare students for primary care practice in rural and urban Health Professional Shortage Areas. Additionally, these programs enhance the efforts of osteopathic medical schools to continue to emphasize primary care medicine, health promotion, and disease prevention, and the practice of ambulatory medicine in community-based settings.

- Because much of the Nation's health care is delivered in areas far removed from health professions schools, the Interdisciplinary, Community-Based Linkages cluster provides support for community-based training of various health professionals. These programs are designed to provide greater flexibility in training and to encourage collaboration between two or more disciplines. These training programs also serve to encourage health professionals to return to such settings after completing their training. The Area Health Education Centers (AHECs) provide clinical training opportunities to health professions and nursing students in rural and other underserved communities by extending the resources of academic health centers to these areas. AHECs, which have substantial State and local matching funds, form networks of health-related institutions to provide education services to students, faculty and practitioners. Health Education and Training Centers (HETCs) were created to improve the supply of health professionals along the U.S.-Mexico border. They incorporate a strong emphasis on wellness through public health education activities for disadvantaged populations. Given America's burgeoning aging population, there is a need for specialized training in the diagnosis, treatment, and prevention of disease and other health concerns of the elderly. Geriatric Health Professions programs support geriatric faculty fellowships, the Geriatric Academic Career Award, and Geriatric Education Centers, which are all designed to bolster the number and quality of health care providers caring for our older generations. The Quentin N. Burdick Program for Rural Health Interdisciplinary Training places an emphasis on long-term collaboration between academic institutions, rural health care agencies and providers to improve the recruitment and retention of health professionals in rural areas. The Allied Health Project Grants program represents the only Federal effort aimed at supporting new and innovative education programs designed to reduce shortages of allied health professionals and create opportunities in medically underserved and minority areas. Health professions schools use the funding to help establish or expand allied health training programs. The need to address the critical shortage of certain allied health professionals has been repeatedly acknowledged. For example, this shortage has received special attention given past bioterrorism events and efforts to prepare for possible future attacks. The allied health project grants funding enables the training of much needed allied health professionals, including those experiencing significant shortages. The Graduate Psychology Education Program provides grants to American Psychological Association accredited doctoral, internship and postdoctoral programs in support of interdisciplinary training of psychology students with other health professionals for the provision of mental and behavioral health services to underserved populations (i.e., older adults, children, chronically ill, and victims of abuse and trauma, including returning military personnel and their families), especially in rural and urban communities. Since its inception in 2002, the GPE Program has supported 52 grants in 27 States.
- The Health Professions Workforce and Analysis program provides grants to institutions to collect and analyze data on the health professions workforce to advise future decision-making on the direction of health professions and nursing programs. The Health Professions Research and Health Professions Data programs have developed a number of valuable, policy-relevant studies on the distribution and training of health professionals, including the soon-to-be-released Eighth National Sample Survey of Registered Nurses (NSSRN), the Nation's most extensive and comprehensive source of statistics on registered nurses.
- The Public Health Workforce Development programs are designed to increase the number of individuals trained in public health, to identify the causes of health problems, and respond to such issues as managed care, new disease strains, food supply, and bioterrorism. The Public Health Traineeships and Public Health Training Centers seek to alleviate the critical shortage of public health professionals by providing up-to-date training for current and future public health workers, particularly in underserved areas. Preventive Medicine Residencies, which receive minimal funding through Medicare GME, provide training in the only medical specialty that teaches both clinical and population medicine to improve community health. Dental Public Health Residency programs are vital to the Nation's dental public health infrastructure. The Health Administration Traineeships and Special Projects grants are the only Federal funding provided to train the managers of our health care system, with a special emphasis on those who serve in underserved areas.
- The Nursing Workforce Development programs provide training for entry-level and advanced degree nurses to improve the access to, and quality of, health care in underserved areas. Health care entities across the Nation are experi-

encing a crisis in nurse staffing, caused in part by an aging workforce, an insufficient number of young people entering the profession, and a shortage of nurse faculty. At the same time, the need for nursing services is expected to increase significantly over the next 20 years, with the demand for licensed, registered nurses growing by over 29 percent within the next nine years alone. Congress responded to this dire national need by passing the Nurse Reinvestment Act (Public Law 107-205) which aims to attract more people into the nursing profession, increase the capacity for nurse education, and encourage practicing nurses to remain in the profession. The Advanced Education Nursing program awards grants to train a variety of advanced practice nurses, including nurse practitioners, certified nurse-midwives, nurse anesthetists, public health nurses, and nurse administrators. Workforce Diversity grants support opportunities for nursing education for disadvantaged students through scholarships, stipends, and retention activities. Nurse Education, Practice, and Retention grants are awarded to help schools of nursing, academic health centers, nurse managed health centers, State, and local governments, and other health care facilities to develop programs that provide nursing education, promote best practices, and enhance nurse retention. The Loan Repayment and Scholarship Program repays up to 85 percent of nursing student loans and offers individuals who are enrolled or accepted for enrollment as a full-time or part-time nursing student the opportunity to apply for scholarship funds. In return these students are required to work for at least two years of practice in a designated nursing shortage area. The Comprehensive Geriatric Education grants assist in training individuals to provide geriatric care for the elderly. The Nurse Faculty Loan program provides a student loan fund administered by schools of nursing to increase the number of qualified nurse faculty. The Title VIII nursing programs also support the National Advisory Council on Nurse Education and Practice, which is charged with advising the Secretary of Health and Human Services and Congress on nursing workforce, education, and practice improvement issues.

—The loan programs in the Student Financial Assistance support needy and disadvantaged medical and nursing school students in covering the costs of their education. The Nursing Student Loan (NSL) program provides loans to undergraduate and graduate nursing students with a preference for those with the greatest financial need. The Primary Care Loan (PCL) program provides loans covering the cost of attendance in return for dedicated service in primary care. The Health Professional Student Loan (HPSL) program provides loans covering the cost of attendance for financially needy health professions students based on institutional determination. The NSL, PCL, and HPSL programs are funded out of each institution's revolving fund and do not receive Federal appropriations. The Loans for Disadvantaged Students (LDS) program provides grants to health professions institutions to make loans to health professions students from disadvantaged backgrounds.

HPNEC members respectfully urge support for funding of at least \$550 million for the Title VII and VIII programs, an investment essential not only to the development and training of tomorrow's health care professions but also to our Nation's efforts to provide needed health care services to underserved and minority communities. We greatly appreciate the support of the subcommittee and look forward to working with members of Congress to achieve these goals in fiscal year 2007 and into the future.

PREPARED STATEMENT OF THE INSTITUTE FOR STUDENT ACHIEVEMENT

Mr. Chairman and Members of the subcommittee, thank you for the opportunity to submit testimony to the hearing record regarding the Institute for Student Achievement (ISA), a national not for profit educational organization.

INTRODUCTION TO THE INSTITUTE FOR STUDENT ACHIEVEMENT

The Institute for Student Achievement's mission is "to improve the quality of education for youth at risk so that they can succeed in our society." ISA has had a solid 15 year history of promoting high achievement for underserved students, first through its legacy direct service programs, COMET (for middle school) and STAR (for high school), and now through its school reform model. ISA launched its high school reform model in September 2001, with four pilot sites, three in New York City and one in Fairfax County, Virginia. As you know, funds to expand the work of ISA have been included in recent appropriations cycles, and we appreciate the support of the subcommittee. As a result we have created 31 small schools and

learning communities serving over 8,000 students in New York State, Virginia (in partnership with Fairfax County Schools), Atlanta, Georgia and Union City, New Jersey.

ISA partners with school districts to create new small schools or to transform large existing high schools into clusters of autonomous small schools or semi-autonomous small learning communities. The ISA high school reform model targets underserved, underperforming young people, including students from low-income families, students of color, recent immigrants and English Language Learners. ISA helps schools to develop small learning communities with the seven school design principles that have succeeded in preparing all high school students, including those who are disadvantaged and underperforming, to achieve, graduate, and go on to college.

Briefly described, the 7 ISA Principles are:

A College Preparatory Instructional Program promoting rigorous intellectual development, strong literacy and numeracy skills, critical thinking, habits of mind and work, and practical knowledge of the college application process.

A Dedicated Team of Teachers and a Counselor who collaborate to ensure that students develop and achieve academically and socially.

Continuous Professional Development that strengthens the capacities of teachers, counselors and school leaders to effectively provide a college preparatory program through rich professional growth experiences; regularly scheduled team meetings; classroom interventions for teachers; and customized professional development on topics ranging from inquiry in science to conflict resolution.

Distributed Counseling™ an approach in which faculty get to know all students well, as both learners and people, and integrate counseling into the education program so that students graduate ready for college. The counselor provides ongoing guidance to the teacher/advisors and direct services to students and their families.

An Extended School Day and School Year provide extra time for students to develop skills, complete assignments, engage in test preparation, participate in community service projects and internships, and have opportunities for talent development and enrichment.

Parent Involvement is integrated into school operations. The school program is designed to allow—and encourage—parents to be full partners in realizing educational excellence for their children.

Continuous Organizational Improvement focuses on optimizing student learning. ISA and its higher education partner, the National Center for Restructuring Education, Schools and Teaching (NCREST) of Teacher's College, Columbia University, work with the small schools and small learning communities to assess and evaluate in order to inform instruction and enhance program development.

In each ISA small learning community or small school, a team of at least four core subject teachers and a guidance counselor is dedicated to a group of 100–125 students, staying with the students over multiple years. Each ISA small school or small learning community selects an ISA coach, who is experienced in the development of small or restructuring schools, brings substantive knowledge of one or more core content areas, and has considerable background in working closely with teachers in reflecting on and improving their practice. The ISA coach works with the school over a four-year period at the school site, supporting school administrators and dedicated teacher/counselor teams as they implement the seven ISA principles to meet the needs of their school community.

The ISA coach works with individual teachers to strengthen their pedagogical skills and facilitates curriculum development and implementation. He or she helps the teacher/counselor teams to create a personalized, supportive environment that optimizes student learning. The team is further assisted with the implementation of ISA's Distributed Counseling™ model and their efforts to increase the level of parent involvement are informed by ISA best practices. ISA also helps schools to develop extended day programming that reinforces school day learning and offers young people opportunities to prepare for college and career.

THE CONCEPTUAL AGE

Our mission today is even more important than it was when ISA was founded because of the dramatic transformation of our economy and the nature of work. The fact is, we are charged with preparing our children to succeed in a world that in many ways bears little relation to the world we entered when we left school—or even the world we woke up in yesterday. In a microscopic measure of human time, we have moved through the Agricultural Age, to the Industrial Age, to the Information Age, and now to another era altogether. Author Daniel Pink calls this new era

the Conceptual Age. It requires us to be not only knowledgeable and competent, but creative and inquisitive as well.

Studies have shown that many of our high schools, even those that boast of high graduation and college-attendance rates, rarely demand that students use information, skills, and technologies to construct new knowledge and to solve complex problems, integrate concepts and ideas across disciplines, communicate effectively orally and in writing, and work in diverse groups. Yet this is precisely the kind of learning students need for a Conceptual Age. Students themselves tell us that they want to be held to high standards but that they find their high schools boring, unchallenging, and disconnected from their lives.

THE GLOBAL CHALLENGE

Microsoft Chairman Bill Gates recently told the Nation's governors that American high school education is "obsolete." He said, "When I compare our high schools to what I see when I'm traveling abroad, I am terrified for our workforce of tomorrow. . . . In 2001, India graduated almost a million more students from college than the United States did. China graduates twice as many students with bachelor's degrees as the United States and [has] six times as many graduates majoring in engineering. . . . America is falling behind."

Gates was describing a global economy in which the chance to move up into a better economic life is slipping overseas, along with jobs that can be performed anywhere—manufacturing in China, technology support in India, online order fulfillment across borders. The Internet brings Bhutan and Bangalore just as close to our offices and living rooms as Boise. Our children's competitors are not the other schools in the district or the State or even the Nation. They are the technologically literate young people in Taiwan, India, Korea, and other developing nations. For today's American students, learning and retraining will be a lifelong experience.

To be "competitive" now, U.S. students must develop sophisticated critical thinking and analytical skills to manage the conceptual nature of the work they will do. They will need to be able to recognize patterns, create narrative, and imagine solutions to problems we have yet to discover. They will have to see the big picture and ask the big questions. How many high schools do you know that are nurturing minds like that?

The 12th-grade data from the Third International Mathematics and Science Study showed that of the 20 countries participating, only two—Cyprus and South Africa—scored lower than the United States. American students enrolled in the most advanced courses in math and science performed at low levels compared to students in other countries.

LEAVING SOME STUDENTS BEHIND

Two serious gaps hold back most of our students and risk the prosperous future of the entire country. The gap we hear least about is the one between a rigorous, intellectually challenging curriculum and the rote instructional program that is commonplace in far too many classrooms. The gap we hear much more about is the one in student achievement that is exposed when data is disaggregated by race, ethnicity, and family income. Our challenge is to ensure that both gaps are closed and that all children—not just some of them—receive a high-quality education that will prepare them well for the world in which they will live and work.

There are tremendous gaps in achievement among racial and ethnic groups within our own country. We are systematically leaving behind large numbers of our poor and minority students. On the 2005 National Assessment of Educational Progress, 39 percent of white eighth-graders scored at or above proficient on the math exam, while only 9 percent of African-American and 13 percent of Hispanics achieved at that level.

A U.S. Department of Education study shows that the average 12th-grade African-American student is reading and doing math at around the level of the average eighth-grade white or Asian student. Hispanic students are about as far behind. On the 2004 SAT, black students, on the average, scored 104 points lower on the math test and 98 points lower on the verbal test than white students. Between 25 to 30 percent of America's teenagers fail to graduate from high school with a regular diploma. That figure climbs to more than 50 percent for black male and Hispanic students.

Clearly, this is not the path to global competitiveness. The quality and the inequality of education in this country should be at the top of the agenda for every meeting of the school board and superintendent. An uneven playing field is everybody's turf—and it needs tending.

THE INSTITUTE FOR STUDENT ACHIEVEMENT IS SUCCEEDING

At a time when the vast majority of jobs require a college degree or some type of postsecondary degree, most low-achieving students are relegated to classrooms where remediation and instruction in low-level skills are the norm. But poor performance and a shortage of vision are not inevitable characteristics of our educational system. ISA is addressing this challenge.

Typically ISA schools have attendance rates of over 90 percent average daily attendance. Over 95 percent of graduates from ISA schools and learning communities have gone on to college. The small size, 400 students grades 9–12, results in a high level of personalization, individual student attention, extensive, professional development, a challenging curriculum, and family and community involvement. Our research has shown that ISA small schools and learning communities have higher graduation rates, very low dropout rates, outstanding student attendance, increased teacher satisfaction and are more cost effective than large high schools.

In fiscal year 2007, ISA has requested Federal funding to help us continue our work in developing rigorous college preparatory high schools in the States of Georgia, Virginia, New Jersey and New York. Beyond that, our goal, with your help, is to expand the number of ISA schools to over 100 throughout the Nation, over the next three years. When we have met that challenge we will have demonstrated that there are model public high schools that are successfully educating all students in high need communities to be conceptual thinkers and ready for the challenges we are confronting in today's global economy. We hope that the subcommittee can be supportive of our efforts and our request for funding.

PREPARED STATEMENT OF THE NATIONAL WRITING PROJECT

I am Richard Sterling, Executive Director of the National Writing Project (NWP). NWP is authorized under Title II, Subchapter C, Subpart 2 of the Elementary and Secondary Education Act of 1965. It has been authorized as part of ESEA since 1991.

I appreciate the opportunity to present this testimony requesting continued support for the National Writing Project. As you know, the Department of Education's (ED) fiscal year 2007 budget request to Congress did not include funding for this program.

NWP is a national organization, a network of local writing project sites, working with teachers of all subject areas and at all grade levels to improve the teaching of writing in the Nation's schools. Today there are 195 university-based writing project sites in all 50 States, the District of Columbia, Puerto Rico, and the U.S. Virgin Islands. NWP sites promote core principles of effective instruction while they respond to the needs of local schools and communities. The fiscal year 2006 appropriation for the NWP is \$21.5 million. Another \$22 million in local support is leveraged by writing project sites across the country.

By statute, the purposes of the NWP are to (1) "support and promote the expansion of the NWP network so that teachers in every region of the United States have access to an NWP program," (2) "ensure the consistent high quality of sites through ongoing review, evaluation, and technical assistance," and (3) "support and promote the establishment of programs to disseminate effective practices and research findings about the teaching of writing."

The Department of Education's justification for elimination of the NWP states that the ED is "eliminating small categorical programs that have limited impact and for which there is little or no evidence of effectiveness." In addition, the ED States that, "These small categorical programs siphon off Federal resources that could be used by State and local agencies to improve the performance of all students." In relation to the NWP network these findings are not adequately supported by the facts. The NWP's response follows:

RESPONSE TO THE STATEMENT: THE NWP HAS "LIMITED IMPACT"

It is difficult to understand the basis for the finding that the NWP has "limited impact." The impact of a funded project is determined by the scale of services provided and the value of those services to districts, schools, teachers, and students. In terms of the scale of its services, the NWP is by far the largest provider of professional development in writing in the country.

Data gathered by an independent evaluator, Inverness Research Associates (IRA), show the scale of NWP as it affects students. Approximately 1.95 million students are taught every year by teachers who received professional development services from writing project sites. In addition, NWP programs also directly serve 45,000 stu-

dents through school-year and summer youth writing programs each year. (Data available from IRA, www.inverness-research.org.)

Data also demonstrate the scale of NWP's reach to teachers across the country. The NWP network provides 19 hours of professional development to 1 out of every 8 secondary language arts teachers and 1 out of every 35 elementary school teachers every year.

In 2004–2005 alone, more than 3,000 teachers attended intensive NWP summer institutes. These summer institute participants directly teach more than 60,000 students during the school year. (Their students are representative of the student population: 42 percent students of color, 13 percent English language learners, 46 percent in Title I programs.) These 2004–2005 teacher-participants join the more than 12,000 writing project teacher-leaders from past summer institutes who are serving their home communities. Together, these teachers conducted 7,288 professional development programs for more than 141,000 educators in 2004–2005.

The network of 195 local sites is a unique national asset now providing geographical access to teachers in two-thirds of the counties in the Nation. In 2004–2005, 1,657 districts (1 out of ten in the Nation) and 2,907 schools (1 out of every 30 schools) chose to invest their professional development dollars with NWP local sites. Local writing project sites have formed ongoing partnerships with 371 districts and schools.

Thus, not only is the scale of work of the NWP network of national significance, there is strong evidence that the services offered are highly valued by States, local districts, schools, and teachers.

Expanding the NWP

Since 2000, the NWP network has added 60 new writing project sites in 30 states. Each year between 6 and 10 new sites are established in areas of the country that previously had not been served. This addresses the statutory requirement to expand the NWP network “so that teachers in every region of the United States have access to an NWP program.” In addition to adding new sites, NWP has developed local satellite programs so that existing sites can provide services to teachers and schools at a distance from the host university. NWP receives an average of 12 requests for new sites and satellites each year from universities eager to bring the writing project to their local communities.

Assuring program quality

In order to ensure the quality of local sites, NWP has conducted an annual site performance review since 1994. As part of the process, each local writing project site completes an extensive performance survey of its programs as well as of its teacher and administrator participants. The statistical data from these surveys are independently analyzed and reported by IRA on an annual basis. Every site must re-apply for funding each year, and the analysis of these data, along with the site application, are used in the site performance review. During this annual review process, some sites are identified as in need of technical assistance from the NWP. If the sites are unable to resolve their issues after this technical support, they are no longer eligible for Federal funding. Over the last 10 years, 51 site grants were not renewed; however, 8 of these sites were re-funded after a transition period that resolved their issues.

While each local NWP site receives a small amount of core funding from the Federal grant, the vast majority of the work done by each local NWP site is supported by States, counties, local school districts, and individual teachers. States, districts, and schools must make careful decisions about how they spend their resources for professional development—the fact that they continue to invest in the work of the NWP over many years is strong evidence of both the value and the effectiveness of NWP services.

RESPONSE TO THE STATEMENT: THERE IS “LITTLE OR NO EVIDENCE OF EFFECTIVENESS” OF THE NWP

The Program Assessment Rating Tool (PART) review concluded that “there is insufficient evidence on the overall effectiveness of NWP interventions.” This assertion is based on incomplete information about a range of studies conducted on the effectiveness of NWP programs. In particular, the NWP PART section 2.1 provides incomplete information concerning long-term performance measures that NWP has employed to “focus on outcomes and meaningfully reflect the purpose of the program.”

In fact, since its inception in 1974 as a single writing project site located at the University of California, Berkeley, NWP has supported its sites in conducting numerous studies on the effectiveness of their professional development programs and

contracted with third parties that have also conducted such studies. (Only two of these studies are referred to in the ED report.) Multiple research studies have shown that NWP programs significantly increase the instructional knowledge of teachers to teach writing. High quality quasi-experimental studies confirm significant gains for students of teachers who have participated in writing project programs. The NWP's website (www.writingproject.org) contains information on these and other recent studies.

The PART assessment is based on incomplete information about the establishment of long-term measures to ensure that NWP sites disseminate effective practices in NWP teacher training programs. Beginning in 1999, following the establishment of GPRA performance indicators by ED, NWP contracted with IRA to collect and analyze additional data on teacher satisfaction with the summer training they received and to assess their implementation of effective instructional strategies in the teaching of writing in the year following the training. Targets were established by ED for this indicator in 1999.

NWP has exceeded the target established for every year of the evaluation to date, with an average of 96 percent of elementary and secondary teachers reporting that they gained effective teaching strategies and up-to-date research that they can apply to their teaching. The independent evaluation also showed that instructional strategies that NWP participants learn in the institutes and use in their classrooms correlate positively with greater student achievement in writing on the NAEP Writing Assessment. This study is performed annually in partial fulfillment of requirements placed on the NWP by ED. To date, more than 15,000 teachers have been surveyed, with consistent results across all six years of the evaluation. (These annual reports are available at www.inverness-research.org, including The National Writing Project Client Satisfaction and Program Impact: Results from a Satisfaction Survey and Follow-up Survey of Participants at 2004 Invitational Institutes, December 2005.)

The NWP PART assessment was also conducted before the conclusion of five rigorous quasi-experimental design studies that measured the extent to which students of teachers who received training by an NWP site improved their writing skills. Student learning in writing project teachers' classrooms was studied relative to student learning in comparable non-writing project teachers' classrooms. A team of external evaluators reviewed all of the research proposals and also designed and oversaw the independent national scoring of student writing. These five quasi-experimental studies have been completed and the results have been submitted to ED as well as posted on the NWP website.

Central to each of the five studies conducted in 2004–2005 was the writing project site's commitment to understand what difference writing project professional development makes for participating teachers' practices and, in turn, what difference those changes in instructional practices make for student learning. Each study employed direct assessments of student writing, and each included carefully matched comparison classes and/or students. In an independent national scoring of student writing, NWP students' improvement outpaced that of students in carefully constructed comparison groups.

Every comparison across all five studies shows positive effects of NWP programming. Student results were strong and favorable in those aspects of writing that the NWP is best known for, such as organization and the development of ideas. Students in writing project classrooms made greater gains than their peers in the area of conventions as well, suggesting that even these basic skills benefit from the NWP approach to teaching writing. These quasi-experimental studies uniformly indicate positive effects for the students of teachers who participated in writing project programs.

These studies conform to the advice regarding rigor in quasi-experimental designs as offered by the Institute of Educational Sciences (IES) of ED.

RESPONSE TO THE STATEMENT: "SMALL CATEGORICAL PROGRAMS SIPHON OFF FEDERAL RESOURCES THAT COULD BE USED BY STATE AND LOCAL AGENCIES TO IMPROVE THE PERFORMANCE OF ALL STUDENTS"

Rather than "siphon off" resources, the Federal investment in the NWP helps to augment and amplify local expenditures in the improvement of writing. All NWP sites match their Federal base grant with State, local, and private funding at a ratio of at least 1:1. The Federal investment provides core funding for the NWP and enables local sites to leverage additional funds from a variety of sources, including host universities, surrounding school districts, private corporations, and other entities. The quantity and quality of local professional development depends on the modest Federal investment that has so clearly demonstrated its power to attract and focus local resources. Without these crucial Federal funds, the core writing

project work that develops teacher expertise and leadership and supports the dissemination of research and effective practices will simply cease to exist.

An independent analysis by IRA of cost-efficiency over the past five years highlights the cost effectiveness of the Federal investment in the NWP. Local sites have leveraged an average of \$3.65 for every Federal dollar they received from the NWP.

The need for strong literacy skills for our Nation's students is a central tenet of all current school reform efforts. The NWP is a very good example of a Federal-local partnership that addresses this core need. The Federal funds: (1) enable local sites to maintain a minimal but critically important effective group of teacher-leaders, (2) develop ongoing working relationships between universities and school districts, (3) respond to local needs, and (4) provide support to all local sites so that they can continue to improve and expand their programs. In summary, the NWP provides high quality, large scale, and cost-effective support to teachers and students to improve writing and learning in the Nation's schools.

PREPARED STATEMENT OF THE STATE EDUCATIONAL TECHNOLOGY DIRECTORS ASSOCIATION

NCLB TITLE II, PART D—ENHANCING EDUCATION THROUGH TECHNOLOGY (EETT)

Members of the State Educational Technology Directors Association (SETDA) include the State directors of technology from the SEAs in all 50 States, D.C., and American Samoa. I am pleased to submit this information and data which demonstrates how EETT is being utilized in over 80 percent of school districts across this country. EETT supports all areas of NCLB, including:

- Closing the Achievement Gap
- Recruiting and Retaining Highly Qualified Teachers
- Improving Data Systems to Meet AYP

EETT is also a key foundation to address the critical STEM and Competitiveness issues and initiatives. EETT has already begun to address these needs and will continue to do so through programs with data to support their effectiveness, including:

- Improving math and science achievement
- Ensuring highly qualified teachers in math and science
- Ensuring students and teachers have skills to ensure that they are prepared for the global workforce

This testimony includes the following:

1. Key Examples that illustrate the key role EETT plays in helping schools, districts, and States to meet NCLB goals, but also demonstrate the focus on math, science, and improving students' abilities to compete in a global workforce.

2. Overview of National Trends Report on Round 3 of EETT Funding data and results; the entire report on how EETT funds were used in all 50 States and D.C. can be accessed at <http://www.setda.org/content.cfm?sectionID=185>.

1. KEY EXAMPLES

Improvements in Math and Science Achievement

Iowa's Success With Algebra.—In Columbus Community School District, with 70 percent high poverty and 65 percent Hispanic populations, the 8th grade in the 2001–02 school year scored only 51 percent of the students as proficient on the ITBS Math Assessment. Cognitive Tutor Algebra I implementation began in 2002 with the instructor rating a very high level of implementation by the CEO of the program. Columbus Students improved proficiency by 11 percent from Grade 8 to Grade 9. They continued to improve and were 74 percent proficient as 11th graders.

Louisiana's Online Algebra I Course.—Algebra I is often a predictor for success in high school and beyond. Louisiana implemented an online Algebra I course to provide additional opportunities for student achievement. Preliminary evaluations indicate that students in the online course, with similar pre-test scores are showing more significant achievement gains compared to the control group as indicated below:

Group	Pre-test (fall) mean	Post-test (spring) mean
Algebra I Online Students	13.3	17.2
Control Students	13.4	15.6

Michigan's Freedom to Learn Project.—This one-to-one initiative, which includes each student having a computer and professional development for teachers, showed significant impact with 7th-grade reading scores jumping from 29 percent to 41 percent and 8th-grade math scores increasing from 31 percent to 63 percent.

Closing the Achievement Gap

Missouri's eMINTS.—The eMINTS National Center provides tools to teachers in grades 3–5 to integrate multimedia into lessons. Three years of data analysis have demonstrated the highly positive effect of the program on student achievement. Performance in the fourth grade in the fiscal year 2002 cohort was essentially equalized between African-American and white students. Indeed, African-American students in eMINTS classrooms had a slightly higher average score in social studies for fiscal year 2002 than white students not enrolled in those classrooms; and in mathematics, the average performance between these two groups was almost identical.

West Virginia's Basic Skills Computer Education Program.—Researcher Dale Mann (ASBO, 2003) cited a direct correlation between pupil performance and technology in instruction through West Virginia's Basic Skills/Computer Education program. The study found that while per capita income had not changed between 1991 and 1998, the infusion of technology was the single factor that accounted for the State moving from 33rd among the States for student achievement to 11th. In a similar study, Mann found that the cost of advancing students one unit in reading by decreasing the class size cost \$636 and using technology to achieve the same result cost \$86 (Mann, 2003). Technology provides a key opportunity to increase student achievement.

Providing Opportunities to Rural and Small School Districts Through Distance Education.—The U.S. Department of Education and NCES' recent Distance Education Courses for Public Elementary and Secondary School Students: 2002–2003 (2005) documents the fact that smaller and rural schools use distance education opportunities more often, with a strong emphasis on foreign language courses. Additionally, 50 percent of districts that provide distance learning opportunities had students enrolled in Advanced Placement (AP) Courses. The recent NGA Summit on High School reform indicated the importance of students' access and participation in AP Courses. At least 80 percent of districts noted that distance education allowed them to increase the course offerings for their students. EETT provides a significant funding for these opportunities.

Recruiting and Retaining Highly Qualified Teachers

North Carolina's IMPACT Model Schools Grant.—This EETT grant program provides personnel, connectivity, hardware, software, and professional development to improve student achievement. A collaborative model, it focuses on using technology as a tool to encourage authentic, project-based learning incorporating 21st Century Learning Skills into all curriculum areas. In a time where more than one-half of all teachers leave the teaching field within the first three years, teachers who are scheduled to retire often choose to stay in these IMPACT schools, others request transfers into them, and new teachers clamor to be hired. "These teachers like the way technology is changing the way they teach, and the enthusiasm with which their students approach learning," says Frances Bryant Bradburn, Director of Instructional Technology for the North Carolina Department of Public Instruction. Additionally, the initial results from this quasi-experimental design evaluation demonstrate that:

- In first year, students in IMPACT schools had stronger growth than comparison school students, and for particular subgroups there was substantially stronger growth varying from small differences to about half a grade level of extra growth, depending on the outcome and grade level.
- IMPACT students often started lower than their comparison school counterparts, but caught up within one school year.
- In general, the most challenged IMPACT students showed the most growth in achievement.

Maryland Increasing Teacher Retention.—Nationally, 50 percent of teachers leave the field within the first three years of their careers. To provide additional support for new teachers, Prince George's County has utilized Intel's Teach to the Future to provide extensive technology integration training for teachers and opportunity for graduate credit. Associated with Towson University, the first cohort of 125 beginning teachers are demonstrating a very high rate of retention: 94 percent.

Improving Data Systems to Meet AYP

Vermont Education Data Warehouse.—EETT funds in Vermont are being utilized directly for the implementation of data systems to support NCLB Accountability requirements through the Vermont Data Consortium that is creating a statewide

“Education Data Warehouse.” The State grants provided through EETT funds support LEAs or schools in the development of local data systems to improve student achievement, support for teachers in analyzing data, improvement in evidence-based policy, and data standards to address local interoperability.

Philadelphia’s Instructional Management System (IMS).—A comprehensive reform effort that includes new resources, a standardized curriculum, after school programs, and professional development, IMS provides teachers and administrators with immediate data on student learning aligned to State and District standards. A benchmark assessment, given every five weeks, allows teachers to differentiate instruction, provide immediate remediation, and identify those students who need additional assistance. In 2003, before these technology tools were provided to teachers, only 9 of the 40 initial participating schools had met AYP; and 15 were identified for Corrective Action. At the end of the 2004 school year, 25 schools met their AYP targets, and only 10 remained in Corrective Action II.

2. OVERVIEW OF NATIONAL TRENDS REPORT ON EETT

Key Findings

1. Promising Interim Results at 3-Year Mark Warrant Continued Investment
2. States Have Set the Bar High for Professional Development
3. States Are Making Progress with Evaluation and Impact Research
4. States Are Leveraging Resources through Collaborations and Partnerships

Over 40 percent of States required LEAs that received NCLB II D competitive grant funds to focus on reading or mathematics. States are not only building the conditions essential to effective technology use, but they are also seeing results as measured in increased student learning.

Nearly 25 percent of States are funding or commissioning research studies on the impact of educational technology on learning in schools. Over 88 percent of States are collecting data annually from either districts, schools, or both. States are increasingly triangulating data sources (e.g., district surveys, school surveys, teacher surveys, student surveys, and site visitations).

43 percent of the States went beyond the Title II D’s 25 percent minimum funding requirement to focus additional resources toward professional development. Thus, over \$159 million of grant funds was dedicated to professional development during Round 3 of the NCLB II D program.

Key Facts

1. Within the 50 States and the District of Columbia, 14,291 districts were eligible for Title II D funds, representing 89.3 percent of LEAs. Collectively, the survey respondents administered \$635,027,468 in NCLB Title II D funding for Round 3, fiscal year 2004.

2. Most States are encouraging school districts and schools to integrate technology systematically and 23.5 percent actually require that technology planning and school improvement be conducted within the same process.

3. Funds are administered through both formula grants and competitive grants. Approximately 48 percent of the formula grants are under \$5,000. That means that less than 4 percent of the funds require almost 50 percent of the administrative support for formula grants.

4. The following States report that NCLB II D is the only source of funding in their State for educational technology: Arizona, California, Delaware, Illinois, Louisiana, Maryland, Michigan, Minnesota, Missouri, New Hampshire, Oklahoma, Vermont, Washington, and Wisconsin.

5. On the other hand, many States, including Virginia, Pennsylvania, Florida and Alabama, are leveraging EETT to secure significant State investments in education technology through on-line assessment, high school reform, one to one initiatives and on-line learning initiatives.

Full copies of the National Trends Report are available for download from the State Educational Technology Directors Association (SETDA) Website, www.setda.org. SETDA is the principal association representing the State directors for educational technology. SETDA’s membership includes all 50 States, the District of Columbia, and American Samoa.

Thank you for your consideration of this data. Please contact me at mwolf@setda.org or 410-647-6965 with any questions.

RELATED AGENCIES

PREPARED STATEMENT OF THE NATIONAL FEDERATION OF COMMUNITY BROADCASTERS

Thank you for the opportunity to submit testimony to this subcommittee regarding the appropriation for the Corporation for Public Broadcasting (CPB). As the President and CEO of the National Federation of Community Broadcasters, I speak on behalf of 250 community radio stations and related organizations across the country. Nearly half our members are rural stations and half are minority controlled stations. In addition, our members include many of the new Low Power FM stations that are putting new local voices on the airwaves. NFCB is the sole national organization representing this group of stations which provide service in the smallest communities of this country as well as the largest metropolitan areas.

In summary, the points we wish to make to this subcommittee are that NFCB:

- Requests \$430 million in funding for CPB for fiscal year 2009, a \$30 million increase over the fiscal year 2008 advance appropriation;
- Requests \$40 million in fiscal year 2007 for conversion of public radio and television to digital broadcasting. Also supports funding for the Public TV interconnection system;
- Requests that advance funding for CPB is maintained to preserve journalistic integrity and facilitate planning and local fundraising by public broadcasters;
- Rejects the Administration's proposal to rescind \$103 million of already-appropriated fiscal year 2007 and 2008 CPB funds;
- Supports CPB activities in facilitating programming and services to Native American, African American and Latino radio stations;
- Supports CPB's efforts to help public radio stations utilize new distribution technologies and requests that the subcommittee ensure that these technologies are available to all public radio services and not just the ones with the greatest resources.

Community Radio fully supports \$430 million in Federal funding for the Corporation for Public Broadcasting in fiscal year 2009. Federal support distributed through CPB is an essential resource for rural stations and for those stations serving minority communities. These stations provide critical, life-saving information to their listeners and are often in communities with very small populations and limited economic bases, thus the community is unable to financially support the station without Federal funds.

In larger towns and cities, sustaining grants from CPB enable Community Radio stations to provide a reliable source of noncommercial programming about the communities themselves. Local programming is an increasingly rare commodity in a Nation that is dominated by national program services and concentrated ownership of the media.

For the past 30 years, CPB appropriations have been enacted two years in advance. This insulation has allowed public broadcasting to grow into a respected, independent, national resource that leverages its Federal support with significant local funds. Knowing what funding will be available in advance has allowed local stations to plan for programming and community service and to explore additional non-governmental support to augment the Federal funds. Most importantly, the insulation that advance funding provides "go[es] a long way toward eliminating both the risk of and the appearance of undue interference with and control of public broadcasting." (House Report 94-245.)

For the last few years, CPB has increased support to rural stations and committed resources to help public radio take advantage of new technologies such as the Internet, satellite radio and digital broadcasting. We commend these activities which we feel provide better service to the American people but want to be sure that the smaller stations with more limited resources are not left out of this technological transition. A step in this direction is the \$3 million Internet Service Grant Fund that will help rural and minority stations serve their listeners and communities better through a website. We ask that the subcommittee include language in the appropriation that will ensure that funds are available to help the entire public radio system utilize the new technologies, particularly rural and minority stations.

NFCB commends CPB for the leadership it has shown in supporting and fostering the programming services to Latino stations and to Native American stations. For example, Satélite Radio Bilingüe provides 24 hours of programming to stations across the United States and Puerto Rico addressing issues in Spanish of particular interest to the Latino population. At the same time, American Indian Radio on Satellite (AIROS) is distributing programming for the Native American stations, arguably the fastest growing group of stations. There are now over 33 stations controlled by and serving Native Americans.

Last year CPB funded the establishment of the Center for Native American Public Radio (CNAPR). Based on a comprehensive assessment of the Native American Radio System, CNAPR will develop new funding sources for Native stations and programming; provide direct services to the Native Radio System; encourage collaborations; and represent the Native Radio System. These stations are critical in serving local isolated communities (all but one are on Indian Reservations) and in preserving cultures that are in danger of being lost. CPB's assessment recognized that ". . . Native Radio faces enormous challenges and operates in very difficult environments." CPB funding is critical to these rural, minority stations. CPB's funding of the Intertribal Native Radio Summit in 2001 helped to pull these isolated stations together into a system of stations that can support each other. The CPB assessment goes on to say: "Nevertheless, the Native Radio system is relatively new, fragile and still needs help building its capacity at this time in its development." The Center for Native American Public Radio promises to leverage additional, new funding to ensure that these stations can continue to provide essential services to their communities.

CPB also funded a Summit for Latino Public Radio which took place in September 2002 in Rohnert Park, California, home of the first Latino Public Radio station. These Summits have expanded the circle of support for Native and Latino Public Radio and identified projects that will improve efficiency among the stations through collaborations and explore new ways of reaching the target audiences.

CPB plays a very important role for the public and Community Radio system. They are the convener of discussions on critical issues facing us as a system. They support research so that we have a better understanding of how we are serving listeners. And they provide funding to programming, new ventures, expansion to new listeners, and projects that improve the efficiency of the system. This is particularly important at a time when there are so many changes in the radio and media environment with new distribution technologies and media consolidation. An example of this support is the grant that NFCB received to update and publish our Public Radio Legal Handbook online. This provides easy-to-read information to stations about complying with governmental regulations so that stations can function legally and use their precious resources for programming instead of legal fees.

Finally, Community Radio supports \$40 million in fiscal year 2007 for conversion to digital broadcasting by public radio and television. It is critical that this digital funding be in addition to the on-going operational support that CPB provides. The President's proposal that digital money should be taken from the fiscal year 2007 CPB appropriation would effectively cut stations' grants by over 20 percent. This would have a devastating impact as stations trying to recover from hard economic times. And it would come at a time when the local voices of community and public radio are especially important to notify and support people during emergency situations and to help communities deal with the loss of loved ones—things that commercial radio is no longer able to do because of media consolidation.

While public television's digital conversion needs are mandated by the FCC, public radio is converting to digital to provide more public service and to keep up with what commercial radio is doing. The Federal Communications Commission has approved a standard for digital radio transmission. CPB has provided funding for 461 transmitters to convert to digital, is supporting additional research on AM radio conversion, and is working with radio transmitter and receiver manufacturers to build in the capacity to provide a second channel of programming. Most exciting to public and community radio is the encouraging results of tests that National Public Radio has conducted, with funding from CPB, that indicate that stations can broadcast at least two high-quality signals, even while they continue to provide the analog signal. The development of second audio channels will potentially double the public service that public radio can provide, particularly in service to unserved and underserved communities. This initial funding still leaves nearly 400 radio transmitters that will ultimately need to convert to digital or be left behind.

Federal funds distributed by the CPB should be available to all public radio stations eligible for Federal equipment support through the Public Telecommunications Facilities Program (PTFP) of the National Telecommunications and Information Agency of the Department of Commerce. In previous years, Federal support for public radio has been distributed through the PTFP grant program. The PTFP criteria for funding are exacting, but allow for wider participation among public stations. Stations eligible for PTFP funding and not for CPB funding include small-budget, rural and minority controlled stations and the new Low Power FM service.

We appreciate Congress' direction to CPB that it utilize its digital conversion fund for both radio and television and ask that you ensure that the funds are used for both media. Congress stated, with regard to fiscal year 2000 digital conversion funds:

“The required (digital) conversion will impose enormous costs on both individual stations and the public broadcasting system as a whole. Because television and radio infrastructures are closely linked, the conversion of television to digital will create immediate costs not only for television, *but also for public radio stations* (emphasis added). Therefore, the Committee has included \$15,000,000 to assist radio stations and television stations in the conversion to digitalization . . .” (S. Rpt. 105–300)”

Community Radio also supports funding for the public television interconnection system. Interconnection is vital to the delivery of the high quality programming that public broadcasting provides to the American people.

This is a period of tremendous change. Digital is transforming the way we do things; new distribution avenues like digital satellite broadcasting and the Internet are changing how we define the business we are in; the concentration of ownership in commercial radio makes public radio in general, and Community Radio in particular, more important as a local voice than we have ever been. New Low Power FM stations are providing new local voices in their communities. Community radio is providing essential local emergency information, programming about the local impact of the major global events taking place, culturally appropriate information and entertainment in the language of the native culture, as well as helping to preserve cultures that are dying out. During the natural disasters of this last year, radio proved once again to be the most dependable, available medium to get emergency information to the public.

During these challenging times, the role of CPB as a convener of the system becomes even more important. The funding that it provides will allow the smaller stations to participate along with the larger stations which have more resources, as we move into a new era of communications.

Thank you for your consideration of our testimony.

PREPARED STATEMENT OF THE NATIONAL MINORITY CONSORTIA

The National Minority Consortia (NMC) submits this statement on the fiscal year 2009 appropriation for the Corporation for Public Broadcasting (CPB). The NMC is a coalition of five national organizations dedicated to bringing a significant amount of programming from our communities into the mainstream of public broadcasting and to other media. The role we fulfill in this regard is crucial to public broadcasting’s mission. We are unique as organizations and as a coalition of organizations in the services we provide to our communities and to public broadcasting. In summary, we ask the Committee to:

- Direct CPB to increase its efforts for diverse programming with commensurate increases for minority programming and the National Minority Consortia
- Direct CPB to continue its support for the Native radio system
- Recommend at least \$430 million for CPB core funding for fiscal year 2009, a \$30 million increase over fiscal year 2008 and the amount being requested by CPB
- Reject the Administration’s proposal to end advance funding for CPB
- Reject the Administration’s proposal to rescind \$103 million of already-appropriated fiscal years 2007 and 2008 CPB funds

REPORT LANGUAGE

We ask for Committee report language, as a follow-up to report language from last year, which recognizes the contribution of the NMC and directs that the CPB partnership with us be expanded. The report from last year stated:

“The Committee recognizes the importance of the partnership CPB has with the National Minority Public Broadcasting Consortia, which helps develop, acquire, and distribute public television programming to serve the needs of African American, Asian American, Latino, Native American, Pacific Islander, and many other viewers. As many communities in the Nation welcome increased numbers of citizens of diverse ethnic backgrounds, the local public television stations should strive to meet these viewers’ needs. With an increased focus on programming to meet local community needs, the Committee encourages CPB to support and expand this critical partnership.” (S. Rpt. 109–103, p. 298)

We request that the above language be modified to direct CPB to increase its support of the NMC and that it also include a reference to radio.

FISCAL YEAR 2009 APPROPRIATION

We support a fiscal year 2009 Federal appropriation for CPB of at least \$430 million. This would be a reasonable, albeit modest, contribution toward our national treasure of public broadcasting. The quality gap between network television and public television has never been wider, and it continues to grow with each new “reality” show.

Public broadcasting, including PBS, NPR, and Native Radio is particularly important for our Nation’s growing minority and ethnic communities. While there is a niche in the commercial broadcast and cable world for quality programming about our communities and our concerns, it is in the public broadcasting industry where minority communities and producers are more able to bring quality programming for national audiences. Additionally, public television and radio is universally available.

ADVANCE FUNDING

We strongly oppose the Administration’s proposal that the advance funding for CPB be eliminated, a proposal that would stop CPB funding for two years. We appreciate that Congress has rejected this proposal each of the last five years. Reasons to continue advance funding for CPB include:

- The development of production of programming for public broadcasting usually takes several years and substantial lead time is necessary for planning productions.
- Public broadcasting programs are supported by multiple funding sources, and two years advance knowledge of the amount of Federal funding allows CPB to more effectively leverage its Federal funds to bring in other sources of revenue.
- The NMC administers a significant amount of CPB programming monies, and elimination of advance funding would negatively affect our organizations’ planning, fundraising and producing work for public television and radio.

RESCISSION OF FISCAL YEAR 2007 AND 2008 FUNDS

We are extremely concerned about the Administration’s proposal to rescind \$103 million of already appropriated fiscal year 2007 and 2008 CPB funds (\$53.5 million of fiscal year 2007 and \$50 million of fiscal year 2008 funds). Such a rescission/diversion of funds would wreck havoc on our organizations and the independent producers that we help support as well as many radio and television stations.

NATIVE RADIO

Native American Public Telecommunications—one of the five National Minority Consortia organizations—works with both the radio and television sides of public broadcasting. NAPT operates American Indian Radio on Satellite (AIROS) which distributes programming to Native-owned and other radio stations. Koahnic Broadcasting Corporation, headquartered in Alaska, also produces and distributes Native American programming.

Native-owned radio is the fastest growing area of community radio. There are currently 33 Native-owned stations, all but one of which is located in Indian country. We greatly appreciate CPB’s central role in the establishment late last year of the Center for Native American Public Radio (CNAPR), an organization that will provide technical and other services to Native radio stations. CNAPR’s mission also includes developing new sources of revenue for the Indian radio system and being an advocate for Native radio. CPB is providing \$1.5 million over a three-year period for CNAPR.

We ask that this Committee urge CPB to continue its support for Native radio.

ABOUT THE NATIONAL MINORITY CONSORTIA

With primary funding from the Corporation for Public Broadcasting, the NMC serves as an important component of American public television. By training and mentoring the next generation of minority producers and program managers we are able to ensure the future strength of public television and radio television programming from our communities. Individually, each Consortia organization is engaged in cultivating ongoing relationships with the independent producer community by providing technical assistance, program funding, programming support and distribution. Often the funding we provide is the initial seed money for a project, thus allowing it to develop. We also provide numerous hours of programming to individual public television and radio stations, programming that is beyond the production reach of most local stations.

While the Consortia organizations work on projects specific to their communities, the five organizations also work collaboratively. One example is our joint effort on the public television four-part series, *Matters of Race* that aired in the Fall of 2003. That series explored the complexity of our rapidly changing multiracial, multicultural society in America. The project resulted in more than television programming. The project was designed so that modules could be pulled out for classroom use. It was also formatted for radio broadcast and for the internet, and included extended interviews. This project provided a great opportunity for extensive and diverse community outreach and collaboration throughout its development, distribution, and use.

We also worked with American Public Television on 6 one-hour programs (named *Colorvision*) featuring the work of Native American, Asian American, Pacific Islander, Latino and African American filmmakers and television producers. It is now in national distribution for all public television stations.

Below is information about our individual organizations.

Center for Asian American Media

The Center's mission is to present stories that convey the richness and diversity of the Asian American experience to the broadest possible audience. Over our 25-year history we have provided funding for more than 200 projects, many of which have gone on to win Academy, Emmy and Sundance awards, examples of which are *Daughter from Danang*, *Of Civil Wrongs and Rights*; *The Fred Korematsu Story*; and *Maya Lin: A Strong Clear Vision*. The Center reaches large audiences through the annual International Asian American Film Festival and distributes Asian Pacific American media to schools, colleges, and universities.

Latino Public Broadcasting

LPB supports the development, production, acquisition and distribution of non-commercial educational and cultural television, representative of Latino people. The resulting programs, disseminated to public television and other public telecommunications entities, provide a voice to the diverse Latino community throughout the United States. Productions that have received LPB support include *Mirror Dance*; *Visiones: Latino Art and Culture*; *Life and Time of Frida Kahlo*; *The Blue Diner*; *Farmingville*; and *The New Americans*.

National Black Programming Consortium

The mission of NBPC, founded in 1979, is to preserve and promote complex and dynamic stories of the African Diaspora through program development, outreach and audience development, and professional development. NBPC has provided hundreds of hours of programming to the national PBS schedule; provided seed money to hundreds of projects by African American and other producers, and served as a window for emerging producers to break into the national; public broadcasting system. Currently under production is a film on issues surrounding Hurricane Katrina. During Black History Month in 2005, over 30 hours of programming were fed to stations. Examples of NBPC-supported programs are *Two Towns of Jasper*; *The Murder of Emmett Till*; *A Doula Story*; and *Daughters of the Dust*.

Native American Public Telecommunications

NAPT, founded in 1977, utilizes various media—public television, public radio, and the internet—to bring awareness of Indian and Alaska Native issues to the Nation. We market and distribute up to 10 hours per year on public television stations nationwide and fund 5 to 10 new Native productions annually. NAPT operates American Indian Radio on Satellite (AIROS) which distributes programming to the 33 Native-owned radio stations and other radio stations. Among the programming we offer is a national daily radio talk show, *Native America Calling*, on Native subjects, and we also cover live major Indian events. Between 2002 and 2005, NAPT delivered or supported the delivery of 24 hours of programming to public television. We also funded 30 projects, represented by 54 producers. NAPT projects garnered 3 national awards and 15 film festival awards during this time period.

Pacific Islanders in Communications

PIC delivers programs and training that bring new voice and visibility to Pacific Islands. A recent program which we helped bring into being is the award-winning *Whale Rider*, a story about a young Maori girl who confronts years of tribal tradition to fulfill her destiny as the leader of her people. When this program was aired on PBS, 107 million households watched the film. In partnership with the Girl Scouts, we held free screenings of the film and developed a website about the Maori people. PIC offers a wide range of development opportunities for Pacific Island producers through travel grants, seminars and media training.

CPB Funds for the National Minority Consortia

The National Minority Consortia currently receives funds from two portions of the CPB budget, organization support funds from the Systems Support and programming funds from the Television Programming sections. CPB financial support is critical to the work of our organizations. We believe that we make a major contribution to public broadcasting with a very modest amount of funding, but there is so much more that should be done.

The organizational support funds we receive from CPB are used not only for operations requirements but for also for a broad array of programming support activities and for outreach to our communities. We received \$1.8 million in fiscal year 2006 CPB funds for organizational support (\$370,000 for each organization). This represents 0.45 percent of the fiscal year 2006 CPB appropriation. We have received only very small increases in operations support funds in the past several years.

The programming funds we receive from CPB are re-granted to producers, used for purchase of broadcast rights and other related programming activities. Each organization solicits applications from our communities for these programming funds. We received \$3.1 million in fiscal year 2006 CPB funds for programming (\$636,363 for each organization). This represents 0.78 percent of the fiscal year 2006 CPB appropriation. Our CPB programming funds have remained virtually flat over the past nine years, despite increases in CPB appropriations.

Thank you for your consideration of our recommendations. We see new opportunities to increase diversity in programming, production, audience, and employment in the new media environment, and we thank Congress for support of our work on behalf of our communities.

 PREPARED STATEMENT OF THE RAILROAD RETIREMENT BOARD

Mr. Chairman and Members of the Committee: We are pleased to present the following information to support the Railroad Retirement Board's (RRB) fiscal year 2007 budget request.

The RRB administers comprehensive retirement/survivor and unemployment/sickness insurance benefit programs for railroad workers and their families under the Railroad Retirement and Railroad Unemployment Insurance Acts. The RRB also has administrative responsibilities under the Social Security Act for certain benefit payments and Medicare coverage for railroad workers. During fiscal year 2005, the RRB paid nearly \$9.2 billion in retirement/survivor benefits to about 634,000 beneficiaries, and \$72.9 million in unemployment/sickness insurance benefits to about 29,000 claimants.

We are requesting \$103,517,570 for agency operations in fiscal year 2007, which is the same as the amount included in the President's proposed budget. We are also requesting a legislative change to permit the RRB to continue using the services of the Department of the Treasury for disbursement of retirement and survivor benefits. In addition, we are requesting that the appropriations language for the Dual Benefits Payments Account be revised to make it clear that a rescission does not preclude the availability of the 2 percent supplemental funding in that appropriation.

AGENCY ADMINISTRATION

The President's proposed budget would provide \$2 million more than the RRB's appropriation for fiscal year 2006. The increase is intended to provide for information technology improvements, which are needed to maintain the agency's service delivery systems. We estimate that under current legislation, the President's proposed budget would provide sufficient funding for a staffing level of 895 FTE's, which is 53 FTE's less than we expect to use in fiscal year 2006. In order to reach this level, we would need to conduct a reduction-in-force (RIF) of about 31 employees at an estimated cost of \$394,000. However, the RIF could be avoided if the RRB is not required to contract for the services of a nongovernmental disbursement agent in fiscal year 2007, as discussed in the following section.

Administrative funding requested for fiscal year 2007 includes a total of \$2.7 million for information technology investments, of which \$1,557,000 would be used for a project begun in fiscal year 2005, to transition our mainframe non-relational database management system to a current technology relational database management system, DB2. The project, which directly correlates with our Enterprise Architecture Strategic Plan, will reduce the RRB's dependency on declining technologies, with their attendant risk of failure, and enable the agency to move ahead with further improvements to the benefit payment systems. In fiscal year 2007, we plan to use contractual support to optimize the performance of our databases and further reduce

data redundancy in order to ensure acceptable response times and system availability.

We are also moving forward to streamline the RRB's field service operations. In fiscal year 2005, we approved a high-level plan to restructure the field service into a hub and satellite configuration that will enhance the agency's ability to distribute work more efficiently among offices. In fiscal year 2006, we hired a consultant to assist in developing a 5-year plan that will include consolidation, co-location, and/or the establishment of virtual offices in the field service. The plan is to identify out-year savings while maintaining good customer service.

NONGOVERNMENTAL DISBURSEMENT AGENT

Section 107(e) of the Railroad Retirement and Survivors' Improvement Act of 2001 (Public Law 107-90) provides for contracting with a nongovernmental agent for the disbursement of railroad retirement benefits. However, initial market research has indicated that the cost of doing so would be about three times the cost of having similar services provided by the Department of the Treasury. In addition, our Inspector General has questioned whether certain services provided by the Department of the Treasury, such as reclamations, would be provided as effectively by a nongovernmental disbursement agent.

We have concluded that outsourcing this function would be inconsistent with the President's policy of outsourcing only where the government would reduce costs. For fiscal years 2005 and 2006, the Congress added language to our appropriations bill prohibiting this transfer: Section 516 of Public Law 109-149, the Departments of Labor, Health and Human Services, and Education, and Related Agencies Appropriations Act, 2006 provides that none of the funds appropriated under the Act are to be used to contract with a nongovernmental disbursement agent. The RRB also submitted separate legislation to the Congress on May 5, 2005, to address this issue.

Our estimates indicate that the cost of contracting with a nongovernmental disbursement agent would be about \$3 million for the first year and \$2.3 million in subsequent years. By comparison, the annual cost of having these services provided by the Department of the Treasury is about \$800,000. Enactment of legislation to remove this requirement would provide sufficient savings in fiscal year 2007 to enable the RRB to cover essential operating costs at the proposed budget level.

VESTED DUAL BENEFITS PAYMENTS APPROPRIATION

The President's proposed budget includes \$88 million to fund the continuing phase-out of vested dual benefits, plus a 2 percent contingency reserve, \$1,760,000, which "shall be available proportional to the amount by which the product of recipients and the average benefit received exceeds \$88,000,000."

The requested funding level of \$88 million reflects the RRB Chief Actuary's current estimate of the amount needed to pay full benefits in fiscal year 2007. However, the estimate does not provide for the effect of a possible rescission, which could significantly reduce the total amount provided in the budget year. Because the Dual Benefits Payments Account is classified as discretionary rather than mandatory, appropriations to the account have been reduced in recent years by across-the-board rescissions enacted as part of the annual appropriations process. The reductions have created a risk that vested dual benefits payments would need to be reduced due to insufficient funding in the account.

The Railroad Retirement Act provides that vested dual benefits payments in a fiscal year may not exceed the amount appropriated for that year. If the amount appropriated is not sufficient to fund full payments, individual vested dual benefits must be reduced on a pro rata basis. However, the current appropriations language is unclear as to whether the 2 percent contingency reserve would be available to cover a shortfall due to a rescission. We request that the appropriations language be revised to clarify that the contingency reserve may be used if needed to prevent a reduction of current-year benefits for any reason.

In addition to the requests noted above, the President's proposed budget includes \$150,000 for interest related to uncashed railroad retirement checks.

FINANCIAL STATUS OF THE TRUST FUNDS

Railroad Retirement Accounts.—The RRB continues to coordinate its activities with the National Railroad Retirement Investment Trust (NRRIT), which was established by the Railroad Retirement and Survivors' Improvement Act of 2001 to manage and invest railroad retirement assets. Through fiscal year 2005, the RRB transferred a total of \$21.276 billion to the NRRIT for this purpose. During the same period, the NRRIT transferred \$2.673 billion to the Railroad Retirement Account for payment of retirement and survivor benefits. As of September 30, 2005, the market

value of NRRIT-managed railroad retirement assets was approximately \$27.7 billion.

In June 2005, we released the annual report on the railroad retirement system required by Section 22 of the Railroad Retirement Act of 1974, and Section 502 of the Railroad Retirement Solvency Act of 1983. The report, which reflects changes in benefit and financing provisions under the Railroad Retirement and Survivors' Improvement Act of 2001, addresses the 25-year period 2005–2029 and contains generally favorable information concerning railroad retirement financing. The report includes projections of the status of the retirement trust funds under three employment assumptions. These indicate no cash flow problems throughout the projection period. The findings represent an improvement over last year's report and reflect continued favorable employment experience in the railroad industry.

Railroad Unemployment Insurance Account—The equity balance of the Railroad Unemployment Insurance Account at the end of fiscal year 2005 was \$94.2 million, an increase of \$14.3 million from the previous year. The RRB's latest annual report on the financial status of the railroad unemployment insurance system was issued in June 2005. The report indicated that even as maximum daily benefit rates rise 39 percent (from \$56 to \$78) from 2004 to 2015, experience-based contribution rates maintain solvency, with the exception of small, short-term cash flow problems in 2007 and 2008. Projections show quick repayment of the loans, even under our most pessimistic assumption. The average employer contribution rate remains well below the maximum throughout the projection period, but a 1.5 percent surcharge is now in effect and is expected for calendar year 2007. We did not recommend any financing changes based on this report.

In conclusion, we want to stress the RRB's continuing commitment to improving our operations and providing quality service to our beneficiaries. Thank you for your consideration of our budget request. We will be happy to provide further information in response to any questions you may have.

PREPARED STATEMENT OF THE RAILROAD RETIREMENT BOARD

Mr. Chairman and members of the subcommittee: My name is Martin J. Dickman, Inspector General of the Railroad Retirement Board (RRB). I would like to thank you, Mr. Chairman, and the members of the committee for your continued support for the Office of Inspector General. I wish to describe our fiscal year 2007 appropriations request and our planned activities.

The Office of Inspector General requests funding of \$7,606,000 to ensure the continuation of its independent oversight of the RRB. The agency is responsible for managing benefit programs which paid \$9.2 billion in retirement and survivor benefits to approximately 634,000 beneficiaries in fiscal year 2005 and an additional \$73 million in net railroad unemployment and sickness insurance benefits to 29,000 claimants. The RRB also administers Medicare Part B, the physician services aspect of the Medicare program, for qualified railroad retirement beneficiaries. Through this program, approximately \$870 million in annual Medicare benefits are paid to approximately 535,000 beneficiaries.

In fiscal year 2007, the Office of Inspector General will continue to concentrate its efforts on the performance of reviews of significant policy issues and program operational areas. We will coordinate our efforts with agency management to identify and eliminate operational weaknesses. We will also continue our investigation of allegations of fraud, waste and abuse, and refer cases for prosecution and monetary recovery action.

We also request the removal of the prohibition on the use of appropriated funds for any audit, investigation or review of the Railroad Medicare program. The RRB manages a nationwide contract for processing Medicare Part B claims for railroad beneficiaries. The agency is responsible for the enrollment of beneficiaries, premium collection, answering beneficiary inquiries and conducting the annual Carrier Performance Evaluation for the Medicare carrier.

The prohibition does not permit this office to fulfill its statutory oversight responsibilities for a major agency program. Removal of the prohibition would benefit both the Railroad Retirement Board and its constituents, and would be consistent with the priorities established by the Administration and the Congress to reduce fraud in one of the largest Federal programs.

We also request oversight authority to conduct audits and investigations of the National Railroad Retirement Investment Trust (NRRIT), the body responsible for the investment of approximately \$29 billion in trust funds used to support Railroad Retirement Act benefit programs. This office would ensure sufficient reporting mechanisms are in place and that the NRRIT members are fulfilling their fiduciary

responsibilities. We have repeatedly expressed concerns about RRB management's passive relationship with the NRRIT, and identified the issue as a serious challenge for the RRB.

We are currently required to reimburse the agency for office space, equipment, communications, office supplies, maintenance and other administrative services. We are the only Federal OIG that cannot negotiate a service level agreement with its parent agency, and, therefore, request that the current appropriation language be amended accordingly.

OFFICE OF AUDIT

Auditors will perform the audit of the RRB's 2006 financial statements and preliminary work for the 2007 financial statements to ensure the issuance of reliable financial information. The OIG will obtain contractor actuarial services to audit the statement of social insurance.

Audit staff will work with agency management to ensure detailed and verifiable financial information is available from the National Railroad Retirement Investment Trust (NRRIT). As discussed above, we believe RRB management should take a more active interest in NRRIT activities.

Auditors will conduct the annual evaluation of the RRB's information systems security to meet the requirements of the Federal Information Security Management Act of 2002. They will also monitor the agency's information systems operations to determine if the agency is meeting the goals established in its Strategic Information Resources Management Plan and to ensure the agency is in compliance with the provisions of the Information Technology Management Reform Act.

Auditors will continue to monitor agency actions to address security deficiencies and complete corrective actions. They will ensure that network and system security safeguards are in place to protect the confidentiality of sensitive financial and personal information. Auditors will also perform assessments of the agency's e-government initiatives to identify and eliminate system vulnerabilities, and to ensure compliance with the E-Government Act of 2002. We will continue our monitoring efforts of the RRB's document imaging activities and the expansion of paperless processing to ensure the integrity of records.

Auditors will continue to review RRB benefit processes and procedures to identify ways to reduce administrative and adjudicative errors. They will offer recommendations to strengthen the agency's debt collection program to reduce the outstanding receivables.

OFFICE OF INVESTIGATIONS

The Office of Investigations (OI) identifies, investigates and presents cases for prosecution, throughout the United States, concerning fraud in RRB benefit programs. In fiscal year 2007, OI will continue to focus its resources on the investigation of cases with the highest fraud losses. OI currently has approximately 500 active investigations involving fraudulent benefit payments and fraudulent reporting with fraud losses of approximately \$11.8 million. These cases involve all RRB programs that provide sickness and unemployment insurance benefits to injured or unemployed workers, retirement benefits, and disability benefits for workers who are disabled.

We will coordinate our efforts with agency program managers to address weaknesses in agency programs that allow fraudulent activity to occur, and will recommend changes to ensure program integrity.

We will concentrate resources on cases with the highest fraud losses, those related to the RRB's retirement and disability programs. OI will dedicate considerable time to the investigation of nationwide schemes to defraud the RRB disability program. Disability cases currently constitute about 44 percent of our investigative caseload. These cases involve more complicated schemes and result in the recovery of substantial funds for the agency's trust funds.

In fiscal year 2007, we will continue to use the Department of Justice Affirmative Civil Enforcement (ACE) program for those cases which do not meet the criminal guidelines of U.S. Attorneys. Through this program, we are able to obtain civil judgements and recover trust fund monies for the RRB.

SUMMARY

In fiscal year 2007, the Office of Inspector General will continue to focus resources on the reviewing RRB program operations and ensuring the integrity of agency trust funds. We will also continue to aggressively pursue individuals who engage in activities to fraudulently obtain RRB funds.

PREPARED STATEMENT OF THE NATURE CONSERVANCY

Mr. Chairman and members of the subcommittee, I appreciate this opportunity to present The Nature Conservancy's recommendations for fiscal year 2007 appropriations. The Nature Conservancy is an international, nonprofit organization dedicated to the conservation of biological diversity. Our mission is to preserve the plants, animals and natural communities that represent the diversity of life on Earth by protecting the lands and waters they need to survive. Our on-the-ground conservation work is carried out in all 50 States and in 27 foreign countries and is supported by approximately one million individual members. We have helped conserve nearly 15 million acres of land in the United States and Canada and more than 102 million acres with local partner organizations globally.

The Conservancy owns and manages approximately 1,400 preserves throughout the United States—the largest private system of nature sanctuaries in the world. We recognize, however, that our mission cannot be achieved by core protected areas alone. Therefore, our projects increasingly seek to accommodate compatible human uses, and especially in the developing world, to address sustained human well-being.

The focus of my testimony is on the Americorps National Civilian Conservation Corps (NCCC) program, which has made a tremendous contribution, as well as provided cost savings, to conservation and public recreation in the United States. The President's fiscal year 2007 Budget proposes to cut funding for the program from \$26.7 million to \$4.9 million, with the intention of eliminating the program completely. The Nature Conservancy urges the Committee to retain funding for the NCCC program at its current levels.

NCCC has been known in recent months for the critical support its participants provided to disaster relief efforts after Hurricane Katrina. We applaud those efforts. We also want to highlight the important conservation work that NCCC participants have engaged in over the past years. Many Federal, State, and local government agencies, as well as non-profit conservation organizations, use the NCCC program to implement Federal programs and to achieve significant public benefits at low cost. At the Conservancy, we have employed NCCC participants to do the following:

- Provide outdoor recreational opportunities and health benefits for Americans across the country;
- Use prescribed fire to reduce hazards to communities and restore ecosystems;
- Control invasive species; and
- Train the next generation of natural resource managers.

The program has saved our organization millions of dollars in recent years, and has provided work that would otherwise take years to accomplish, or simply would not get done at all. Below are some examples of specific results that NCCC has achieved.

PROVIDING AMERICANS WITH RECREATIONAL OPPORTUNITIES AND HEALTH BENEFITS

As the country's appetite for outdoor recreation grows—and issues like childhood obesity demonstrate the importance of increased outdoor activity—there is a growing need to provide safe, beautiful places for Americans to use and experience. The Nature Conservancy and our partners help provide these opportunities through a system of preserves and parks. Our efforts are significantly augmented by NCCC participants. The NCCC has built and maintained trails and boardwalks, restored campsites, repaired interpretive signs, provided wildlife protection, planted trees and developed archaeological dig sites. These activities provide the public with greater access to the outdoors, at low cost, and enhance the outdoors experience.

USING PRESCRIBED FIRE TO REDUCE HAZARDS AND RESTORE ECOSYSTEMS

As reflected in recent legislative actions, including passage of the Healthy Forests Restoration Act of 2004, reduction of hazardous fuels on the Nation's forested lands is one of the country's greatest land management challenges. President Bush has emphasized the need to reduce fire hazards to communities, and restore ecosystems, through prescribed burning and other management techniques. Each year, the U.S. Forest Service and the Department of the Interior set acreage goals for burning and related treatments. The Nature Conservancy provides training and personnel to assist in meeting these goals.

In recent years, NCCC participants have comprised a new cadre of fire managers, bringing skills and knowledge to individual projects, and assisting government agencies and non-profit land managers alike. The Nature Conservancy has used NCCC participants in at least eleven States to assist in burning tens of thousands of acres at a cost savings of several hundred thousand dollars. We also work with NCCC to

burn on military bases, U.S. Forest Service lands, State parks and natural areas, and other public lands.

On some projects, fire management results in restoration efforts that ease the burden on private landowners and Federal land managers in complying with the Endangered Species Act. For example, in Virginia, NCCC-assisted burns have restored habitat and supported the recovery of an endangered species, the red-cockaded woodpecker. Finally, NCCC participants assist land managers and public agencies in measuring performance and evaluating the success of fuels treatment efforts.

REDUCING THE THREAT OF INVASIVE SPECIES

Invasive species—primarily weeds and insects—are one of the principal threats to our natural resources across the United States; they have damaged many natural landscapes as well as reduced the value of working lands. NCCC participants have assisted in abating impacts of invasive species at many locations. Their activities have included controlling invasive plants that are destroying valuable salt marshes and fens in New York; restoring natural tallgrass prairie by removing invasive trees in Minnesota; and preserving riparian and old growth forest habitat in Oregon.

Along with actual removal of invasive species, NCCC participants have worked to educate the public on threats of invasive species and measures to control them.

BUILDING A NEW GENERATION OF NATURAL RESOURCE MANAGERS

As the country's population grows and threats to the environment increase, we face constant challenges to the conservation of our natural heritage. We will not be able to meet those challenges unless we encourage young people to pursue conservation careers and we provide them with the necessary training. The NCCC program has succeeded in doing this. Our experience is that NCCC participants are organized, well-trained and enthusiastic, and that they care deeply about conservation—in part because they understand the benefits to communities and to people that conservation provides.

In particular, because of the job training focus of NCCC, its participants make up a substantial portion of the country's future fire managers—a group of professionals we cannot afford to lose, given the hazards that wildfire poses to our communities. A significant portion of the Federal fire workforce will retire in the next five years, and the NCCC program plays a critical role in replenishing that workforce.

NCCC makes an important contribution to Americans' access to and enjoyment of the outdoors, as well as to conservation of our natural heritage. We urge the Committee to provide funding at current services levels for this important program.

Thank you again for the opportunity to testify. If you have questions, please contact Louise Milkman at 703-247-3675.

PREPARED STATEMENT OF THE VOICES FOR NATIONAL SERVICE

Mr. Chairman and members of the subcommittee: We are writing as members of Voices for National Service to urge you to reject funding cuts to AmeriCorps, Learn and Serve America, and the National Civilian Community Corps (NCCC) included in the Administration's fiscal year 2007 budget.

Voices for National Service is a coalition of more than 160 community-based organizations, faith-based groups, governor-appointed State commissions, private sector partners, institutions of higher education, and others dedicated to expanding opportunities for Americans to serve community and country.

Our message to the Labor-HHS Subcommittee is quite simple: AmeriCorps, Learn and Serve America, and the NCCC are cost-effective programs that meet critical community needs, and funding for these programs should be sustained and increased. While we recognize the fiscal constraints that lawmakers must operate under, now is not the time to cut funding for national service. We urge you to fund these programs at their fiscal year 2004 enacted levels:

- \$441 million for AmeriCorps;
- \$43 million for Learn and Serve America; and
- \$26 million for the NCCC.

We would like to note the following areas of concern and consideration as they relate to the appropriation for these programs:

- We are concerned that the Administration's budget proposes to cut funding for the NCCC to \$5 million in fiscal year 2007, and to eliminate the program by 2008. As numerous first-hand accounts by Gulf Coast residents, newspaper stories and op-eds have attested in the past weeks, the NCCC responded to the

crisis in the Gulf Coast heroically, deploying 1,600 members to the region who have provided critically needed services and support. This is not the time to eliminate a program with a proven track record in strengthening America's disaster preparedness and relief capacity.

- While we are eager for NCCC's funding to be reinstated, we hope that you will not preserve this program at the expense of other critical programs like AmeriCorps State and National and Learn and Serve America. Like the NCCC, these programs have had a profound impact in the Gulf Coast and in the communities they serve. Americans want to serve. We should be expanding their opportunities, not eliminating them.
- We are concerned that despite strong bipartisan support, the proposed budget would result in a 17 percent reduction in AmeriCorps State and National funding since fiscal year 2004. AmeriCorps is a critically needed program that provides opportunities for 70,000 Americans to serve each year, and its funding should be sustained or increased, not cut.
- We are concerned that the proposed funding cut to Learn and Serve America would have serious negative consequences for both the 1.5 million students who participate in this program and the communities they serve. Compared to its fiscal year 2004 funding level of \$43 million, the proposed cut to \$34.2 million would mean:
 - 300,000 fewer students serving their communities through Learn and Serve America;
 - A loss of \$34 million in leveraged private and community resources; and
 - A decline of 7.3 million service hours to communities.

We are concerned that the Corporation for National and Community Service's plan to continue to recruit 75,000 AmeriCorps members in spite of the program's proposed cuts will be detrimental to programs running full-time, stipended corps. The proposed cuts include a \$300 reduction in the average Federal contribution per full-time corps member. AmeriCorps programs have been required to absorb an increasing percentage of their program operating costs. As fixed and mandated costs grow, annual reductions in operating support are destabilizing the AmeriCorps field. Efforts to do more with less threaten AmeriCorps' historic mix of full-time and part-time, stipended and non-stipended corps.

ABOUT AMERICORPS, LEARN AND SERVE AMERICA, AND THE NCCC

AmeriCorps State and National is a network of local, State, and national service programs that connect at least 70,000 Americans each year in intensive service to meet our country's needs in education, public safety, health, and the environment.

Learn and Serve America provides State formula and competitive grants to support service-learning in K-12 schools, colleges and universities, and non-profit organizations. Service-learning integrates community service with academic study to enrich learning, teach civic responsibility, and strengthen communities. At an average cost of only \$28 per participant, Learn and Serve America leverages private and community resources to yield \$4 in services to the community for each \$1 invested by the government. The program also fosters collaboration between educational institutions and civic, faith-based, and community groups to engage youth in meaningful service to address local needs, help young people answer President Bush's Call to Service, and assist in meeting the Corporation's strategic goal of having quality service-learning in half of all K-12 schools by 2010.

The AmeriCorps NCCC is a full-time residential program for men and women ages 18-24 that strengthens communities while developing leaders through direct, team-based national and community service. The NCCC is a trained force that can be immediately deployed. Four trained NCCC teams were pulled from other assignments and sent to support shelters in Mississippi and Alabama one day after Hurricane Katrina hit.

THE ROLE OF NATIONAL SERVICE IN MEETING CRITICAL NEEDS IN THE GULF COAST

The Administration's budget provides the NCCC with a modest \$5 million appropriation to graduate its final class of corps members and permanently close the program's five regional campuses. The budget also proposes to cut funding for AmeriCorps State and National, reducing funding levels by 17 percent since fiscal year 2004. And yet as we write, thousands of AmeriCorps and NCCC members are on the front lines in the Nation's response to the greatest natural disaster in U.S. history, serving our Nation in the Gulf Coast.

To date, more than 13,000 national service members have contributed to hurricane relief efforts in the Gulf and around the country. NCCC members were among the first on the scene, and to date, 1,600 NCCC members have served on more than

100 separate disaster service projects in the Gulf Coast region, providing humanitarian aid and physical service, as well as managing the thousands of outside volunteers who want to help. This program embodies the important role that citizens must play in partnering with government to respond to community crises and national disasters.

According to Malcolm Jones, City Attorney of Pass Christian, Mississippi who worked closely with a team of NCCC members to provide services to town residents, “Our town, on the Gulf Coast of Mississippi, 7,000 people, we got the hardest part of [the storm]. When I came back after evacuating for Katrina. . . . I found out that AmeriCorps [is] a very powerful, powerful thing. [W]hen we lost hope, [AmeriCorps] came.”

Because of AmeriCorps, young people from around the country are putting their talents to work in the Gulf Coast region by doing everything from clearing debris and repairing roofs in Mississippi, to preventing further damage to historic buildings in New Orleans, to managing a supply warehouse in Louisiana, and serving displaced residents aboard ships in Alabama. We would like to share a few of their stories with you as examples of the critical services that AmeriCorps and NCCC members are providing:

Kenye Quiroga was sent to Louisiana one week after joining AmeriCorps. He writes that, “While in D’Iberville we stayed on pallets in an old community center with only half a roof. The living definitely wasn’t easy, but I had the opportunity to get to know some great people. By the end of our mission in D’Iberville, my team had assessed every household in the town and brought food, water, and medication to families who needed emergency supplies.”

According to Kimberly Walker of Jackson, Mississippi, “In the aftermath of the Hurricane, Mississippi Primary Health Care Association served as one of the many distribution points to assist Hurricane victims with basic supplies. Our team . . . carried supplies to a larger designated distribution site and was able to meet and talk first hand to some of the victims. . . . We assisted in directing them to other services available to them.”

Carrie Ann Smith from the West Seneca, New York AmeriCorps program was deployed to Slidell, Louisiana. She writes, “I felt like I was entering a war zone. I felt the pain and frustration that still loomed in the air, but most of all I felt the need to help, to serve, and to make a difference. That’s what AmeriCorps does and I am proud to be a member of such a noble and upstanding organization. But even more so, I am proud to be an American who was given the opportunity to help my fellow Americans in a time of tragedy and such utter devastation. I would not have had that opportunity if not for AmeriCorps.”

These young people, and thousands like them, served and continue to serve with great distinction, bringing hope and relief to fellow citizens, and learning the value of civic engagement and giving to communities in need. The national service response, however, has not been limited to the on-the-ground effort in the Gulf. In communities across the country, national service programs are joining with local, State and Federal agencies and nonprofit organizations to provide long-term relief to those uprooted and displaced by the storms. For example, tens of thousands of students supported by Learn and Serve America are collecting school supplies, raising funds and preparing disaster relief kits.

NATIONAL SERVICE ACCOMPLISHMENTS ACROSS AMERICA

In addition to responding to needs in the Gulf Coast region, AmeriCorps members are also serving in thousands of communities across the United States. Every day, 70,000 AmeriCorps members add value to school curricula by tutoring and mentoring, operating after-school programs, expanding the reach of community health centers, teaching in underserved public and parochial schools, and improving our environment.

Below are just a few examples of the many community needs that AmeriCorps members met in 2004–2005:

- In Florida, members recruited 2,000 community volunteers to provide education services, maintained and expanded 200 acres of habitat for threatened and endangered species, and built 40 homes for low-income families.
- In Kentucky, members educated more than 1,000 at-risk elderly about home safety and conducted 265 Home Safety Assessments for seniors.
- In Maryland, members removed 453 tons of trash, improving the quality of storm water run-off into the Chesapeake Bay and 1,900 homeless families received food, clothing, or furniture.
- In Mississippi, members conducted life skills trainings with 715 people with disabilities, helped train mentally and developmentally disabled adults for employ-

- ment, and mentored 1,100 low income and underachieving middle school students.
- In New York, members transported 1,000 children to medical appointments, delivered meals and snacks to about 58,000 children and seniors, and provided literacy activities to almost 17,000 children.
- In Ohio, members trained more than 9,000 youth in conflict resolution, built repaired, or rehabilitated 364 housing units, and provided educational support services to 1,500 students during the summer months.
- In Pennsylvania, members tutored almost 14,600 elementary and high school students and more than 6,800 citizens received either needs assessment or support in the areas of domestic violence, foster care, mental health, and housing for homeless veterans.

IMPACT OF NATIONAL SERVICE PROGRAMS

In the last decade, more than 500,000 young Americans dedicated themselves to either full or part-time service through AmeriCorps to improve their communities and their country. Through dedicated service to our Nation, AmeriCorps members have earned Education Awards worth more than \$1.5 billion that have helped them afford higher education or career training.

Evaluations prove that AmeriCorps works. Recent studies by the Center for Leadership and Public Service at Harvard University and Bridgestar indicate that the United States is facing a significant leadership gap in the next decade. Given the need for an emerging group of young leaders to fill leadership positions in the social, private, and public sectors, the results of AmeriCorps programs in terms of building civic skills and a commitment to public service are striking. To cite but a few examples of some of the positive results of recent program evaluations:

- A rigorous multi-site control group evaluation by Abt Associates and Brandeis University reported significant employment and earnings gains by young people who join service or conservation corps.
- A study of Teach for America (TFA) by Mathematica Research Group found that “it supplies low-income schools with academically talented teachers who contribute to the academic achievement of their students. TFA teachers . . . produce higher student test scores than the other teachers in their schools.”
- An evaluation of City Year alumni by Policy Studies Associates showed that more than three-quarters of alumni reported an increased commitment to public responsibility and greater knowledge and skills that improved their ability to address and solve community problems.

Learn and Serve America has tremendous impact and support. According to a 2004 study by RMC Research, “Service-learning, when implemented with high quality, yields statistically significant impacts on students’ academic achievement, civic engagement, acquisition of leadership skills, and personal/social development.” Evaluations also indicate that the program correlates with a reduction in the number of behavioral problems, and reduced sexual activity and pregnancy among students.

THE FISCAL YEAR 2007 REQUEST

We understand the funding constraints of the current appropriations process, and appreciate your leadership in seeking to provide support to the many programs that are meeting community needs across the Nation in a challenging fiscal environment.

Given the track record of AmeriCorps, Learn and Serve America, and the NCCC in serving children, families, and communities and in responding effectively and efficiently to the recent disasters in the Gulf Coast region, we urge you to reject the funding cuts to these programs in the administration’s fiscal year 2007 budget request and to fund these programs at their fiscal year 2004 levels. These programs have proven to be worthy of your investment.

LIST OF WITNESSES, COMMUNICATIONS, AND PREPARED STATEMENTS

	Page
Alexander, Dr. Duane, Director, National Institute of Child Health and Human Development, National Institutes of Health, Department of Health and Human Services, prepared statement	135
Alving, Dr. Barbara M., Acting Director, National Center for Research Resources, National Institutes of Health, Department of Health and Human Services, prepared statement	138
American:	
Academy of:	
Family Physicians, prepared statement	319
Pediatrics, prepared statement	322
Association:	
For:	
Cancer Research (AACR), prepared statement	384
Geriatric Psychiatry, prepared statement	387
Of:	
Colleges of:	
Nursing, prepared statement	327
Osteopathic Medicine, prepared statement	331
Immunologists, prepared statement	391
Nurse Anesthetists, prepared statement	394
College of Obstetricians and Gynecologists, prepared statement	398
Diabetes Association, prepared statement	401
Foundation for the Blind, prepared statement	403
Geological Institute, prepared statement	541
Lung Association, prepared statement	407
Nephrology Nurses' Association, prepared statement	410
Nurses Association, prepared statement	332
Physiological Society, prepared statement	404
Public:	
Health Association, prepared statement	412
Power Association, prepared statement	338
Society:	
For:	
Clinical Pathology, prepared statement	415
Microbiology, prepared statements	417, 429
Of Nephrology, prepared statement	423
Americans:	
For:	
Nursing Shortage Relief, prepared statement	336
The Arts, prepared statement	538
Association of:	
Academic Health Centers, prepared statement	426
American Cancer Institutes, prepared statement	428
Farmworker Opportunity Programs, prepared statement	311
Independent Research Institutes, prepared statement	430
Maternal and Child Health Programs, prepared statement	338
Minority Health Professions Schools, prepared statement	543
Women's Health, Obstetric and Neonatal Nurses (AWHONN), prepared statement	431
Auerbach, Judith, Ph.D., vice president, Public Policy and Program Development, Amfar, the Foundation for Aids Research	208

	Page
Berg, Dr. Jeremy, Director, National Institute of General Medical Sciences, National Institutes of Health, Department of Health and Human Services, prepared statement	140
Centers for Disease Control and Prevention Coalition, prepared statement	340
Central Valley Opportunity Center, prepared statement	313
Chao, Moses, M.D., Christopher Reeve Foundation	209
Charles R. Drew University of Medicine and Science, prepared statement	435
Coalition of Northeastern Governors, prepared statement	406
Cochran, Senator Thad, U.S. Senator from Mississippi:	
Prepared statement	33
Statement	32
College Board, prepared statement	555
College of New Rochelle, NY, prepared statement	344
Collins, Francis S., M.D., Director, National Human Genome Research Institute, National Institutes of Health, Department of Health and Human Services	105
Prepared statement	125
Comstock, Amy L., chief executive officer, Parkinson’s Action Network	209
Prepared statement	210
Cooley’s Anemia Foundation, prepared statement	437
Council of State Administrators of Vocational Rehabilitation (CSAVR), prepared statement	558
Craig, Senator Larry, U.S. Senator from Idaho	64
Crohn’s and Colitis Foundation of America, prepared statement	439
Diabetes Care Coalition, prepared statement	346
Digestive Disease National Coalition, prepared statement	441
Doris Day Animal League, prepared statement	444
Durbin, Senator Richard, U.S. Senator from Illinois	65
Dystonia Medical Research Foundation, prepared statement	446
Emerson, Stephen, M.D., associate director for clinical research, Abramson Cancer Center, University of Pennsylvania Hospital	211
Prepared statement	212
Eng, Lauren A., president, Spinal Muscular Atrophy Foundation	213
Prepared statement	214
Fauci, Anthony S., M.D., Director, National Institute of Allergy and Infectious Diseases, National Institutes of Health, Department of Health and Human Services	105
Prepared statement	128
Foster Grandparent Program, prepared statement	453
Fox, Dr. Philip C., director of clinical research, Department of Oral Medicine, Carolinas Medical Center on behalf of the American Association for Dental Research	215
Friends of:	
NIDA Coalition, prepared statement	458
The National Institute on Aging, prepared statement	456
FSH Society, prepared statement	449
Furlong, Patricia, co-founder and chief executive officer, Parent Project Muscular Dystrophy	216
Prepared statement	217
Gallaudet University, prepared statement	560
Gandy, Sam, M.D., Ph.D., Chair, Medical and Scientific Advisory Council, Alzheimer’s Association	217
Prepared statement	218
Gibbons, Ann, member, board of directors, Autism Speaks	219
Prepared statement	220
Goldstein, Robert, M.D., Ph.D., chief scientific officer, Juvenile Diabetes Research Foundation	221
Prepared statement	221
Grady, Dr. Patricia A., Director, National Institute of Nursing Research, National Institutes of Health, Department of Health and Human Services, prepared statement	143
Harkin, Senator Tom, U.S. Senator from Iowa:	
Prepared statements	10, 108

	Page
Questions submitted by	97, 256
Statements	64, 107
Health Professions and Nursing Education Coalition, prepared statement	562
Heart Rhythm Society, prepared statement	461
Hemophilia Federation of America, prepared statement	464
Hepatitis Foundation International, prepared statement	465
HHT Foundation International, prepared statement	478
Hodes, Dr. Richard J., Director, National Institute on Aging, National Institutes of Health, Department of Health and Human Services, prepared statement	145
Holzman, Lawrence B., M.D., chairman, scientific advisory board, Nephcure Foundation	225
Prepared statement	226
Houser, Steven R., Ph.D., director, cardiovascular research center, Temple University School of Medicine on behalf of the American Heart Association	227
Prepared statement of	228
Hrynkow, Dr. Sharon, Acting Director, Fogarty International Center, National Institutes of Health, Department of Health and Human Services, prepared statement	148
In Defense of Animals, prepared statement	468
Independence Technology, prepared statement	471
Industrial Minerals Association—North America, prepared statement	477
Inouye, Senator Daniel K., U.S. Senator from Hawaii, questions submitted by	53, 100, 258
Insel, Dr. Thomas R., Director, National Institute of Mental Health, National Institutes of Health, Department of Health and Human Services, prepared statement	151
Institute for Student Achievement, prepared statement	566
International Foundation for Functional Gastrointestinal Disorders, prepared statement	474
InterTribal Bison Cooperative, prepared statement	349
John B. Amos Cancer Center, prepared statement	351
Katz, Dr. Stephen I., Director, National Institute of Arthritis and Musculoskeletal and Skin Diseases, National Institutes of Health, Department of Health and Human Services, prepared statement	153
Kington, Raynard, Deputy Director, Office of the Director, National Institutes of Health, Department of Health and Human Services, prepared statement	156
Knapp, Richard M., M.D., Chair, Ad Hoc Group for Medical Research	205
Prepared statement	206
Kohl, Senator Herb, U.S. Senator from Wisconsin:	
Prepared statement	18
Questions submitted by	55, 101, 269
Koo, Daniel, M.D., on behalf of the Deaf and Hard of Hearing Alliance	233
Prepared statement	234
Landis, Dr. Story C., Director, National Institute of Neurological Disorders and Stroke, National Institutes of Health, Department of Health and Human Services, prepared statement	159
Landrieu, Senator Mary L., U.S. Senator from Louisiana	2
Prepared statement	235
Landrigan, Philip J., M.D., MSC, FAAP, president, Campaign for American Children's Health	235
Leavitt, Hon. Michael O., Secretary, Office of the Secretary, Department of Health and Human Services	61
Prepared statement	68
Summary statement	66
Li, Dr. Ting-Kai, Director, National Institute on Alcohol Abuse and Alcoholism, National Institutes of Health, Department of Health and Human Services, prepared statement	162
Lindberg, Dr. Donald A.B., Director, National Library of Medicine, National Institutes of Health, Department of Health and Human Services, prepared statement	164
Lupus Foundation of America, Inc., prepared statements	242, 480

	Page
March of Dimes Birth Defects Foundation, prepared statement	482
Matria Healthcare, prepared statement	352
Mayer, Emeran, A.M.D., on behalf of the Digestive Disease National Coalition	239
Prepared statement	239
McDonnell, Peter, M.D., on behalf of the National Alliance for Eye and Vision Research	240
Medical Library Association and the Association of Academic Health Sciences Libraries, prepared statement	485
Mildenberg, Juanita M., Acting Director, Office of Research Facilities Development and Operations, National Institutes of Health, Department of Health and Human Services, prepared statement	167
Montgomery County (Maryland) Stroke Association, prepared statement	490
Murray, Senator Patty, U.S. Senator from Washington:	
Prepared statement	23
Questions submitted by	56
Statement	63
Nabel, Elizabeth G., M.D., Director, National Heart, Lung, and Blood Institute, National Institutes of Health, Department of Health and Human Services	105
Prepared statement	133
National:	
AHEC Organization, prepared statement	500
Alliance to End Homelessness, prepared statement	353
Association:	
For State Community Services Programs, prepared statement	359
Of:	
Children's Hospitals, prepared statement	491
Community Health Centers, prepared statement	357
County and City Health Officials, prepared statement	494
Workforce Boards, prepared statement	301
Coalition for:	
Heart and Stroke Research, prepared statement	503
Osteoporosis and Related Bone Diseases, prepared statement	496
Community Action Foundation, prepared statement	499
Consumer Law Center, prepared statement	362
Federation of Community Broadcasters, prepared statement	575
Job Corps Association, prepared statement	305
Kidney Foundation, prepared statement	366
League for Nursing, prepared statement	367
Minority Consortia, prepared statement	577
Multiple Sclerosis Society, prepared statement	504
Primate Research Centers, prepared statement	509
Prostate Cancer Coalition, prepared statement	511
Sleep Foundation, prepared statement	512
Writing Project, prepared statement	569
Youth Employment Coalition, prepared statement	306
NephCure Foundation, prepared statement	514
Niederhuber, John E., M.D., Acting Director, National Cancer Institute, National Institutes of Health, Department of Health and Human Services	105
Prepared statement	123
NIH Task Force of the Bioengineering Division of the Basic Engineering Group of the Council on Engineering of ASME, prepared statement	507
Oncology Nursing Society, prepared statement	368
One Voice Against Cancer, prepared statement	515
Oregon Human Development Corporation, prepared statement	309
Ovarian Cancer National Alliance, prepared statement	518
Pancreatic Cancer Action Network, prepared statement	371
People for the Ethical Treatment of Animals, prepared statement	373
Pettigrew, Dr. Roderic I., Director, National Institute of Biomedical Imaging and Bioengineering, National Institutes of Health, Department of Health and Human Services, prepared statement	168
Population Association of America/Association of Population Centers, prepared statement	521
Project R&R, prepared statement	376

	Page
Pulmonary Hypertension Association, prepared statement	524
Railroad Retirement Board, prepared statements.....	580, 582
Raymond, Sandra, on behalf of the Lupus Foundation of America	241
Reid, Senator Harry, U.S. Senator from Nevada, questions submitted by	261
Roberts, Senator Pat, et al., letter from	378
Rodgers, Dr. Griffin P., Acting Director, National Institute of Diabetes and Digestive and Kidney Diseases, National Institutes of Health, Department of Health and Human Services, prepared statement	170
Ruffin, Dr. John, Director, National Center on Minority Health and Health Disparities, National Institutes of Health, Department of Health and Human Services, prepared statement	173
Schwartz, Dr. David A., Director, National Institute of Environmental Health Sciences, National Institutes of Health, Department of Health and Human Services, prepared statement	176
Shelby, Senator Richard C., U.S. Senator from Alabama: Prepared statement	109
Statement	108
Sieving, Dr. Paul A., Director, National Eye Institute, National Institutes of Health, Department of Health and Human Services, prepared state- ment	179
Skelly, Thomas, Director, Budget Service, Office of the Secretary, Department of Education	1
Society: For:	
Investigative Dermatology, prepared statement	526
Maternal-Fetal Medicine, prepared statement	528
Women's Health Research and Women's Health Research Coalition, prepared statement	531
Of Nuclear Medicine, prepared statement	529
Specter, Senator Arlen, U.S. Senator from Pennsylvania: Opening statements	1, 61, 105
Prepared statement	2
Questions submitted by	33, 88, 250, 274
Spellings, Hon. Margaret, Secretary, Office of the Secretary, Department of Education	1
Prepared statement	6
Summary statement	4
Spina Bifida Association, prepared statement	379
State Educational Technology Directors Association, prepared statement	572
Straus, Dr. Stephen E., Director, National Center for Complementary and Alternative Medicine, National Institutes of Health, Department of Health and Human Services, prepared statement	181
Tabak, Dr. Lawrence A., Director, National Institute of Dental and Craniofacial Research, National Institutes of Health, Department of Health and Human Services, prepared statement	184
Taylor, Herman A., Jr., M.D., on behalf of the Jackson Heart Study	243
Prepared statement	244
The:	
Humane Society of the United States, prepared statement	535
Mended Hearts, Inc., prepared statement	489
Nature Conservancy, prepared statement	584
Tuomey Healthcare System, prepared statement	382
Vogel-Scibilia, Suzanne, M.D., president, National Alliance on Mental Ill- ness	246
Voices for National Service, prepared statement	585
Volkow, Dr. Nora, Director, National Institute on Drug Abuse, National Insti- tutes of Health, Department of Health and Human Services, prepared statement	186
Zerhouni, Elias A., M.D., Director, National Institutes of Health, Department of Health and Human Services	105
Prepared statement	111
Summary statement	109

SUBJECT INDEX

DEPARTMENT OF EDUCATION

OFFICE OF THE SECRETARY

	Page
A Broad Emphasis on Competitiveness	6
Academic Competitiveness:	
And National Smart Grants	21
Smart Grants	56
Additional Committee Questions	33
Addressing the High School Dropout Problem	31
Adjunct Teachers	20
Program	19
Advanced Placement Incentive Program	49
Advancing America Through Foreign Language Partnerships	50
And DOD National Flagship Language Initiative	50
Allocation of Budget Resources	17
America's Opportunity Scholarships for Kids.....	38, 57
American Competitiveness Initiative	4, 18, 33
Arts Education	44
Building State Capacity for School Improvement	7
Civic Education	59
Commission on the Future of Higher Education	49
Comprehensive School Reform as School Improvement Strategy	34
Data Management Initiative	43
Department:	
Expenditures for Public Relations and Outreach	53
Lauded for Hurricane Response	3
Department's Comments on the Silent Epidemic	32
Distribution of Highly Qualified Personnel	14
Early Childhood Education Funding	55
Education:	
Funding in High-Poverty and Low-Poverty Districts	15
Funds Disbursed for Hurricane Recovery	4
Response for Hurricane Recovery	13
Effectiveness of Supplemental Services	9
Elementary and Secondary School Counseling Program	56
Enforcement of Highly Qualified Teachers Requirement	41
Ensuring Highly Qualified Teachers for Students of all Socioeconomic Sta- tus	42
Equitable Distribution of Education Resources	14
ESEA Title I:	
Funding	30
Proposed Funding Decrease	29
Expansion of the SES Pilot Program	38
Federal:	
Efforts to Address Inequitable Distribution of Highly Qualified and Un- qualified Teachers	42
Perkins Loans	34
Student aid	49
Fiscal Year:	
2006 Funding Level of Proposed Terminations	26
2007:	
Budget:	
Request	4, 13

	Page
Fiscal Year—Continued	
2007—Continued	
Budget—Continued	
Request—Continued	
Priorities	8
Education Department Budget Request	11
Foreign Language Assistance Program	43
Funding for Higher Education	50
HEA Title IX	22
High School:	
Dropouts—the Silent Epidemic	31
Reform Initiative	25, 27
Highly Qualified Teachers	39
Impact of Medicaid Change on Children With Disabilities	58
Improving Teacher Quality Programs	39
Information Dissemination on Highly Qualified Teacher Requirements	41
Innovative High School Restructuring in Idaho	19
Investment in:	
Advanced Placement	48
Secondary Education	16
Limitation on Reduction of Title I Grants for School Improvement Purposes ..	35
Math and Science	7
Education	48
Math now Program and Math and Science Partnerships	47
Partnerships and Math now Program Activities	47
Measuring Performance of the Impact Aid Program	39
National:	
Assessment of Educational Progress	52
Mathematics Panel	47
Native Hawaiian Education	53
No Child Left Behind Flexibility Provisions	11
Office of Communications and Outreach	52
OMB PART Ratings for Programs Proposed for Termination in the Fiscal	
Year 2007 Budget Request	27
Other Programs	7
Pell Grants	12, 17
Per Pupil Expenditures Across the Nation	15
Perkins Loans and Other Student Aid Programs	55
Proposed:	
Education Budget Cuts	11
GEAR UP Program Elimination	24
Public School Choice and Supplemental Services	8
Ready to:	
Learn:	
Continuation Projects	46
Program	45
Teach Program and Math and Science Education	45
Requirements of Advancing America Through Foreign Language Partnerships	
Grantees	51
Rigorous High School Curriculum	21
School:	
Dropouts	32
Improvement:	
And High School Reform	5
Grants Program and Effective School Improvement Activities	36
Categorized as Needing Improvement	30
Within-Schools	20
Selection of Districts for SES Pilot Program	37
Special Education	12
Funding	55
Start of GEAR UP Program	25
States' Reporting of Highly Qualified Teacher Data	41
Statewide:	
Data Systems Program	51
Longitudinal Data Systems	52
Student Participation and Achievement Under the SES Pilot Program	38
Supplemental Educational Services	37
Pilot Program	37

	Page
Teacher Quality Enhancement Program and Teacher Recruitment and Retention	42
Title I:	
Funding	3
Grants to LEAS	12
Improvement Funding Generated by 4 Percent Set-Aside	35
School Improvement:	
Monitoring	36
Set-Aside	35
Title IX:	
Report	57
Technical Assistance	57
12th Grade NAEP Initiative—Reading and Math Assessments	52
21st Century Community Learning Centers	58
Use of Title I School Improvement Funds for Comprehensive School Reform ..	34
Vocational Education Funds	16
Women in Technology	54
Workshop Approach to Outreach and Impact on Student Learning Outcomes	46

DEPARTMENT OF HEALTH AND HUMAN SERVICES

NATIONAL INSTITUTES OF HEALTH

A:	
Record of Real Success	124
Winning Strategy Against Cancer	194
Additional Committee Questions	250
Addressing the Threat of Emerging and Re-Emerging Infectious Diseases:	
Prediction and Preemption	149
Advanced Technologies Accelerate Progress	125
Advances:	
Against the Threat of Pandemic Influenza	113
In:	
Cancer	112
Cardiovascular Disease and Stroke	112
Diabetes and Related Illnesses	113
Health Information for Scientists and the Public	114
HIV/AIDS	113
Image-Guided Microsurgery	114
Age-related Macular Degeneration	270
Alzheimer's Disease	269
And the Neuroscience of Aging	146
Asthma	135
Autoimmune Diseases	198
Baccalaureate to Doctoral Programs	259
Battle Against HIV/AIDS	149
Better Pain Treatments for Jaw Condition	185
Biodefense Research	131
Bridging the Physical and Life Sciences	168
Budget Request	111
Buffergel Shown to be Safe Contraceptive	137
Burden and Cost of Mental Illness	151
Cancer:	
Centers	259
Genome Atlas	193
Cataract	180
Changing Landscape of Disease	115
Chronic Fatigue Syndrome (CFS)	261
Clinical:	
And Translational Science Awards	253
Research	160
Collaborating:	
Across NIH	184
Among Institutes	256
Collaborative Research	162
Community-based Rehabilitation Intervention	138
Complex Genetics	154

	Page
Conflicts of Interest	257
Consultation Protocol	260
Corneal Diseases	180
Creating Partnerships: Rare Diseases Network	139
Current Challenges	177
Dawn of Personalized Medicine	141
Developing Nurse Researchers	259
Development of Biodefense Research	113
Disseminating Information	183
Drug Addiction Treatment Works	189
Dry Mouth and Radiation Therapy	186
Emerging and Re-Emerging Infectious Diseases	129
Enhanced Support for New Investigators	170
Envisioning Personalized Care	151
Epilepsy	269
Expand Community-Linked Research	178
Expanding Training and Career Development	183
Facilitating Integration	183
Fetal Development: Jump Start on Life	136
Fiscal Year 2007 Budget Summary	167
From Bench to Bedside to Community	190
Funding for Pandemic Influenza	192
Furthering the Research Mission	182
Future Research: Newborn Screening	137
Gene:	
Environment and Health Initiative—a Novel Partnership	178
Programs Early Development and Neural Migration	137
Genes:	
And Neurological Disorders	160
May Hold the Key to Treating Uterine Fibroids	137
Environment, and:	
Behavior	187
Health Initiative	204
Glaucoma and Optic Neuropathies	180
Global Burden of Trauma and Injury	150
Greater Emphasis on Large Clinical Studies	185
Health:	
Communications and Promotion	148
Disparities Research Agenda	174
Healthy Mothers and Healthy Children	143
HIV/AIDS:	
And Minority Disparities	190
Research	130
Heart Truth Road Show	252
Impact of Budget Cuts	191
Importance of Early Intervention	171
Improving the Nation's Oral Health	186
Increase Funding:	
At the Centers for Disease Control (CDC)	230
For:	
NIH Heart and Stroke Research	229
The:	
Agency for Healthcare Research and Quality (AHRQ)	231
Carol M. White Physical Education Program (PEP)	231
National Institutes of Health (NIH)	228
Information Services for the:	
Public	165
Scientific Community	165
Integrating Clinical and Translational Science	138
Integrative Research on Human Disease	177
Interagency Collaborations	125
Irritable Bowel Syndrome	270
Liver Disease Research Branch	250
Loan Repayment and Scholarship Program	159
Looking Toward the Future	184
Lupus	199
Management Innovations	116
Mathematics and Science Cognition and Learning	137

	Page
Molecular Medicine and Oral Cancer	185
Multi-bug Approach on Vaccines	203
Nanotechnology for Disease Detection and Drug Delivery	169
National:	
Children's Study	196
Primate Research Center	256
NCMHD Health Disparities Efforts	174
New:	
Diagnostic and Therapeutic Technologies	114
NHGRI Initiatives	127
Research Tools	114
Next Generation Minimally-Invasive Technologies	169
NIEHS Strategic Plan—A New Outlook	178
NIH:	
And Diabetes Research—A Strong Return on Federal Investment	223
Blueprint	170
Neuroscience Blueprint	181
Roadmap	181
For:	
Biomedical Research	170
Medical Research	156
NIMH Initiatives for Fiscal Year 2007	153
NINR and the NIH Roadmap	145
Nursing Shortages and Training Nurse Researchers	144
Obstetric Pharmacology—Treatment for Pregnant Women	136
Office of:	
AIDS Research	156
Behavioral and Social Sciences Research	157
Disease Prevention	158
Portfolio Analysis and Strategic Initiatives	159
Research on Women's Health	157
Science Education	158
Ongoing NHGRI Initiatives	126
Opasi Trans-NIH Funding Program	252
Other:	
Aging-related Research	147
Areas of Interest.....	128, 166
Our Goal Remains the Same	123
Pandemic Flu	257
Patients and Families at the End of Life	144
Pediatric Heart and Lung Disorders	134
Periodontal Disease and Preterm Birth	185
Polycystic Kidney Disease	255
Power of the Mind	142
Practical Clinical Trials	152
Practice-based Research Networks	184
Predicting Preeclampsia	136
Prednisone	199
Preempting Chronic Diseases and Their Complications	171
Premature Birth Research	136
Preparedness for Pandemic Influenza	191, 201
Prescription Drug Abuse—the Problem With Painkillers	187
Preventive Medicine	153
Program Funding	200
Promoting Science and Health Literacy	140
Providing Critical Links: Nonhuman Primate Research	140
Rapid Advances in the Genomic Era	116
Re-evaluate Programmatic Investments	178
Recruit and Train the Next Generation	177
Reducing Disparities in the Nation's Oral Health	186
Regenerative Medicine	155
Research Collaborations	175
Research on Immune-Mediated Diseases	132
Restore Funding for the Rural and Community Access to Emergency Devices Program	231
Retinal Diseases	179
Return on Investment on NIH Funding	110
Role in the Research Mission	167

	Page
Selected Accomplishments of NIH and Their Impact on Health	112
Setting the Course	182
Sickle Cell Disease	135
SMedical Robotic	169
Social Neuroscience	188
Spurring Advances Through Data Sharing	139
Staying Healthy Throughout Adulthood	143
Strabismus, Amblyopia and Visual Processing	179
Strategic Vision for NIH: From Curative to Preemptive Care	115
Strengthening the:	
Evidence Base in Dental Care	184
Pipeline	141
Stroke	253
Teaming Science for Public Health Gains	141
Technologies to Improve Health Care Delivery	168
Traditional Healing Practices	258
Training:	
A New Generation of Scientists	117
For the Future	170
Translating:	
Discoveries Into Better Medical Treatment	117
Technology Into Clinical Practice	168
Translational Research	155, 161
Understanding Aging and Caring for the Elderly	144
Urology Research Strategic Planning	251
Value of a Systems Approach	142
Widening the Net: Under-represented Populations and Areas	139
Women's:	
Health Initiative	197
Heart Disease	196

OFFICE OF THE SECRETARY

Additional Committee Questions	88
Administration on Aging (AoA) Budget Cuts	79
Aging Services Programs	86, 87
Alzheimer's Demonstration Grants	80
Baccalaureate to Doctoral Programs	100
CDC:	
Budget Cuts	80
Physical Plant	81
CMS:	
Adequate Provider Reimbursement	96
Power Wheelchairs	97
Prompt Pay Discount	97
Regulatory Authority for Reimbursement	97
Status of Quality Demonstration Project	95
Community Health Centers	75
Compassion Capital Fund	85
Disease Prevention	83
Emergency Medical Services for Children	100
FDA Generic Drug Applications	78
Fiscal Year 2007 HHS Budget	67
Generic Drugs/FDA	101
Health:	
Centers Program	100
Professionals Training	88
Historical Pandemics	71
Institute of Medicine Policy Recommendations	84
Medicaid/Special Education Benefits	98
Medical Professional Availability	66
Medicare:	
Drug Benefit Enrollment Deadline	102
Electronic Payments	88
Fraud	97
Improper Payments	94
Integrity Program	89, 94
Part D:	
Deadline Extension	63

	Page
Medicare—Continued	
Part D—Continued	
Enrollment	76
Deadline	76
Formulary Prices	65
Plan Choice	78
National Institutes of Health:	
Budget Cuts	65
Funding	103
Levels	82
Research	84
Grants	81
Sleep Disorders Conference Report	90
Office of Minority Health	90
Pandemic Influenza:	
Infrastructure	75
Preparedness	72, 91
Plan Implementation	93
Respirator Masks	93
Surge Capacity	92
Vaccine	83, 92
Distribution	73
Stockpile	72
Programs Serving Older Americans	101
Rural Health	102
Rural Healthcare	80
Special Exposure Cohorts	99
Underage Drinking Prevention	90
Uninsured Access to Pandemic Influenza Treatment	93
Wellness and Disease Prevention	75

DEPARTMENT OF LABOR

OFFICE OF THE SECRETARY

Administration and Management	280
Adult Training Funds	294
Appalachian Council/Working for America Institute	290
Asbestos Exposure	276
Built-in and Program Changes	284
Career Advancement Accounts	295
Comments on Cecil Roberts Testimony	278
Competitiveness Agenda	291
Economic Growth Efforts	295
Elimination of:	
Job Bank Program	296
Migrant:	
Job Training	275
Programs	292
Youth Training Grants	295
Employment Service Cuts	292
Foreign Labor Certification	298
Immigration Bill	276
Impact of Job Training Cuts	275
Job:	
Corps Funding	274
Training Staff	290
Medical Leave Program	277
Mine Safety	274
National Reserve Fund	293
Older Worker Employment Program	279
OSHA Penalties for Asbestos Violations	276
Program Direction	282
Proposed Workforce Legislation	296
Rapid Response:	
Funds	277, 298
Services	293
Rational for Workforce Training	291

	Page
Re-allocation of Unspent Funds	277
Reintegration of Youthful Offenders	275
Safe Places in Mines	290
Voucher Proposal	291
Women in Apprenticeship	290
Workforce Training Cuts	276