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A REVIEW OF THE ADMINISTRATION'S FY2007 HEALTH CARE PRIORITIES

HEARING

BEFORE THE

COMMITTEE ON ENERGY AND COMMERCE
HOUSE OF REPRESENTATIVES

ONE HUNDRED NINTH CONGRESS

SECOND SESSION

FEBRUARY 15, 2006

Serial No. 109-113

Printed for the use of the Committee on Energy and Commerce

Available via the World Wide Web: http://www.access.gpo.gov/congress/house

U.S. GOVERNMENT PRINTING OFFICE

30-310PDF WASHINGTON : 2006

For sale by the Superintendent of Documents, U.S. Government Printing Office
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CONTENTS

Page

Testimony of:

Leavitt, Hon. Michael O., Secretary , U.S. Department of Health and Human Services 26

Additional material submitted for the record:

Leavitt, Hon. Michael O., Secretary, U.S. Department of Health and Human Services, response for the record 102

A REVIEW OF THE ADMINISTRATION'S FY2007 HEALTH CARE PRIORITIES

WEDNESDAY, FEBRUARY 15, 2006

HOUSE OF REPRESENTATIVES,
COMMITTEE ON ENERGY AND COMMERCE,
Washington, DC.

The committee met, pursuant to notice, at 2:00 p.m., in Room 2123 of the Rayburn House Office Building, Hon. Joe Barton [chairman] presiding.

Members present: Representatives Hall, Bilirakis, Upton, Stearns, Gillmor, Deal, Whitfield, Norwood, Shimkus, Wilson, Fossella, Radanovich, Walden, Terry, Ferguson, Otter, Murphy, Burgess, Blackburn, Dingell, Waxman, Markey, Pallone, Brown, Rush, Eshoo, Stupak, Engel, Wynn, Strickland, DeGette, Capps, Allen, Schakowsky, Solis, Gonzalez, Inslee, Baldwin, and Barton.

Staff present: Chuck Clapton, Chief Health Counsel; Melissa Bartlett, Counsel; Ryan Long, Professional Staff Member; Nandan Kenkeremath, Counsel; Bill O'Brien, Research Analyst; David Rosenfeld, Counsel; Brandon Clark, Policy Coordinator; Chad Grant, Legislative Clerk; John Ford, Minority Counsel; Chris Knauer, Minority Investigator; Purvee Kempf, Minority Counsel; Amy Hall, Minority Health Professional Staff Member; Bridgett Taylor, Minority Health Professional Staff Member; Jessica McNiece, Minority Research Assistant; and Jonathan Brater, Minority Staff Assistant.

CHAIRMAN BARTON. The committee will come to order. The chair recognizes himself for a five minute opening statement and then we will recognize Mr. Dingell for a five minute opening statement. Then all the members who wish to make an opening statement will be recognized for one minute. Let us see as I set the clock.

Good afternoon, I want to begin by welcoming the Secretary of Health and Human Services, the Honorable Michael Leavitt, to the Energy and Commerce Committee. We look forward to working with you this year and we look forward to hearing from you today about the Administration's fiscal year 2007 health care priorities budget. I want to thank you for your assistance in developing the recent reform package that we put in place for the Medicaid Program. As a former governor, you understand and appreciate the need to improve this program.

Through the passage of the Deficit Reduction Act, we are beginning to sustain Medicaid for those people who most often need the health

care, and to get good health care through good jobs in a thriving economy instead of a Government welfare program. Reforms that we have adopted recently are beginning to rescue the program from the threat of financial collapse that has drug the program down over the last 10 to 15 years. We look forward to working with you in the future to implement this program and also to working with the governors of the 50 States to implement the program.

I want to highlight some of the changes in the law that has not yet received the public attention that they deserve. According to the Congressional Budget Office, 115,000 disabled children covered by the Family Opportunity Act will receive improved health care services as a result of the recently passed Deficit Reduction Act. The new law will provide access to new home and community based care to 120,000 additional individuals who will facilitate 100,000 nursing home residents to return to their communities through the Administration's Money Follows the Person Administration Program. These are the true results of Medicaid reform. Better access for better care for those in our society who need our assistance.

There is still much to do to improve long-term health care service delivery and financing, as well as to promote Medicaid managed care. I have received your proposals regarding additional improvements to the Medicaid program. I look forward to working with you this year on some of those programs.

This year, the Secretary and the Administration will also begin to implement the Medicare prescription drug benefit. Making this program succeed is a high priority of yours; it is a high priority of this committee that I chair. Since it began, critics have tried to make patients believe that they are not smart enough to understand the new Medicare drug benefit, that it would provide inadequate coverage, and that signing up is not worth their time because it cannot save them any money. The critics are wrong about this. They were wrong when they complained about the Medicare prescription drug card. They were wrong when they said nobody would offer any insurance plan, and they are wrong now. Some sense political advantage in condemning the program and others cannot bring themselves to admit that free markets actually work. Transparency in competition will drive down prices and provide lower costs to consumers. Even if the critics do not get it, the Medicare beneficiaries certainly appear to be getting it. That is why over 3.6 million Medicare beneficiaries have already signed up for the new benefit. You told me earlier today that there are close to 24 million Americans that have been enrolled in the program through one means or another, and enrollment is increasing at approximately 250,000 people per week. That sounds like a success story to me. If you add that to the fact that the premium which

we estimated was going to be $37 a month is now down to an average of $27 a month, that appears to me again to be a successful program.

This is a huge undertaking and there are going to be glitches. My goal is the same as yours, get rid of those glitches. The committee is going to work closely with you and with Dr. Mark McClellan at CMS to get these glitches noticed, number one, and solved, number two. We will have the first of what will probably be several hearings on that specific topic on March the 1st when Dr. McClellan is going to testify before the Health Subcommittee. I expect at that hearing that we will ask him some very direct questions about where the problems are and what is being done or has been done to fix those problems.

Another high priority for this committee this year is going to be the reauthorization of the National Institutes of Health and its related programs. I want to restate my deep commitment to reauthorizing the NIH and would ask your assistance in working out the technical details so that we can enact this long overdue legislation. In addition, this committee needs to authorize the Ryan White Care Act. I believe that funding unauthorized programs is not a responsible practice and I anticipate that the committee will work to reauthorize that program this year.

I also intend to work with you and your agency on ways to continue to reform Medicare reimbursement and particularly the focus on position payment reform. In order to preserve access to Medicare services for future generations, we must look at how we are spending our Medicare dollars today and what the incentives are to our physician community to continue to provide quality health programs and care for our senior citizens. Another priority of the committee is going to be to work with you and your agency on the proposals outlined in the Administration's budget to provide consumers with greater access to comparative price and quality data about their health care providers. I could go on but my time has expired.

Welcome to the committee and we look forward to your testimony and the questions that follow it as soon as every member has been given a chance to make an opening statement. With that, I want to recognize the distinguished Ranking Member of the committee and Dean of the House that has served the longest continuous service in the House of Representatives, the Honorable John Dingell of Michigan.

[The prepared statement of Hon. Joe Barton follows:]

PREPARED STATEMENT OF THE HON. JOE BARTON, CHAIRMAN, COMMITTEE ON ENERGY AND COMMERCE

Good afternoon. Let me begin by welcoming Secretary Michael Leavitt today to the Energy & Commerce Committee. We look forward to hearing him testify about the Administration's Fiscal Year 2007 Health Care Priorities.

First, Mr. Secretary, I want to thank you for your assistance in developing the important reforms we put into place for the Medicaid program starting this year. As a former governor yourself, you understood and appreciated the need to improve this program. Through passage of the Deficit Reduction Act, we will sustain Medicaid for those people who often need health care the most and can afford it the least. I want many more Americans to get their health care through good jobs in a thriving economy instead of from a government welfare program, but we will always need Medicaid to help the poor and disadvantaged. The reforms we adopted to rescue the program from the threat of financial collapse are the same ones that Democratic and Republican governors all requested. I look forward to working with you to see that the governors get the tools they need to better manage the program and deliver its benefits to the poor of their states.

I want to briefly highlight at least some of the changes in the law that have not recently received the public attention that they deserve. According to the Congressional Budget Office, 115,000 disabled children covered by the Family Opportunity Act will receive improved health care services. The new law will provide access to new home and community based care to 120,000 individuals; and it will facilitate 100,000 nursing home residents to return to their communities through the Administration's Money Follows the Person Demonstration. These are the true results of Medicaid reform –better access to better care for those who most need our assistance.

There is still much to be done to improve long-term care service delivery and financing as well as to promote Medicaid managed care. I have received the Administration's proposals regarding additional improvement to the Medicaid program and I look forward to working with you this year on them.

This year the Secretary and the Administration also are required to administer the new Medicare prescription drug benefit. Making this program succeed is a high priority of yours, and it is a high priority of mine, too.

Since it began, critics have tried to make patients believe that they are not smart enough to understand the new Medicare drug benefit, that it provides inadequate coverage, and that signing up isn't worth their time because it cannot possible save them a dime. The critics are simply wrong. They were wrong when they complained about the Medicare prescription drug card. They were wrong when they said nobody would offer any insurance plans. And they are wrong now.

Some sense political advantage in condemning the program, and others can't bring themselves to admit that free markets, transparency and competition will drive down prices and provide lower costs to consumers. Even if the critics don't get it, Medicare beneficiaries certainly do. That is why over 3.6 Million Medicare beneficiaries have already signed up for the new benefit. That is also why the premiums that these beneficiaries are paying have dropped from the initial estimate of $37 down to an average of $25 per month.

The implementation of this new drug benefit was a huge undertaking, and it has had its share of glitches. My goal is the same as yours: Get rid of the glitches. The Committee will work closely with the Secretary and Dr. Mark McClellan at C-M-S to get problems noticed, examined and solved, and to do it all sooner instead of later. We will have the first of what will likely be several hearings on this topic on March 1st, when Dr. McClellan will testify before the Health subcommittee. I expect that we ask him very direct questions about where the problems have been and what C-M-S is doing to fix them. The Energy & Commerce Committee and its chairman are committed to doing

whatever it takes to make sure this program provides the benefits that Medicare beneficiaries expect and deserve.

Another high priority for the Committee will be the reauthorization of the National Institutes of Health (NIH) and related programs. I want to restate my deep commitment to reauthorizing the NIH and would ask for the Secretary's assistance in working out the technical details so that we can enact this long overdue legislation. In addition, the authorization for the Ryan White CARE Act has now lapsed. I believe that funding unauthorized programs is not a responsible practice, and I anticipate that the Committee will work to reauthorize these programs this year.

I also intend to work with you this year on ways to reform Medicare reimbursement, and particularly focus on physician payment reform. In order to preserve access to Medicare services for future generations, we must look at how we are spending our Medicare dollars today and what are the incentives for providing quality health care.

Another top priority of the Committee will be to work with you on the proposals outlined in the Administration's budget to provide consumers with greater access to comparative price and quality data about their health care providers. I believe that with the development of health savings accounts and similar initiatives that encourage patients to become consumers, we have the potential to revolutionize the delivery of health care in this country. If these models are to succeed, however, we absolutely must be able to give patients the tools that they need to become smarter consumers.

As Chairman of this committee, I plan to work with President Bush, Secretary Leavitt, Members of Congress, and our health care colleagues to work to ensure our citizens continue to have access to the best health care in the world. Thank you again, Mr. Secretary, for appearing here today. I look forward to hearing your testimony.

MR. DINGELL. Thank you, Mr. Chairman.

Good afternoon, Mr. Secretary.

Forty-six million Americans are uninsured. Six million more Americans have become uninsured since President Bush took office. The public health infrastructure and all of its programs are limping. The President's Budget moves us in the wrong direction.

After signing into law reconciliation legislation with $28 billion in cuts to Medicaid over the next ten years, the President has returned with a fiscal year 2007 budget that makes another $42 billion in cuts to a program that provides health insurance for more than 58 million Americans. The Congressional Budget Office already documented that the first round of cuts would cause thousands to lose coverage each year. These additional cuts will likely have that same effect on thousands more.

Second, the Administration is proposing billions in tax breaks to encourage individuals and families to move out of decent employer-sponsored coverage into high-deductible health plans in the individual insurance market. For a "mere" $156 billion a year we will have a program but will erode employer coverage, discriminate against the sick, provide little benefit to those of modest means, and increase the deficit.

Third, the Medicare budget again moves in the wrong direction. The budget fails to include any proposals to fix the documented problems in the Part D--D for disaster--drug benefit. The budget also fails to include

one dime to address the pending Medicare payment cuts. According to the American Medical Association, physicians will see payment cuts totaling $102.5 billion in the next seven years. This has been ignored by the Administration. Likewise, the budget does not provide any of the MedPAC recommended cuts to HMO and private plan payments which alone would save $50 billion over that same time. Instead, it proposed $105 billion in cuts over the next 10 years to hospitals, skilled nursing home facilities, and other providers all of which are vital parts of the Medicare's Fee-for-Service Program that enrolls the vast majority of seniors today.

The President also proposes another increase in Part B premium for beneficiaries, the third premium increase brought forward by Republicans since 2003. The budget also proposes an automatic cut in provider payments at any time general revenue is funding more than 45 percent of the program.

Fourth, the Centers for Disease Control and Prevention, the National Institutes of Health, and the Health Resources and Services Administration, the Food and Drug Administration, and other Public Health Services agencies all play an important role in the protection of public health, yet they get the back of the Administration's fiscal hand in this budget.

The Food and Drug Administration is supposed to protect us every day from bad food, unsafe pharmaceuticals, and other dangers of this sort. The budget does not give us enough to protect against counterfeit drugs, adulterated food, or unsafe medical devices. The budget does not do enough to support people training, equipment, and facilities that we rely on to protect our homeland from public health emergencies that are caused by man or nature.

The budget does not do enough to support the discovery of new and improved treatments and cures for cancer, diabetes, stroke, and Alzheimer's, and other diseases that afflict so many of our Americans. In this budget, the National Institutes of Health will sponsor less research this year than it did last year. Clearly that is wrong. The community health centers remain under funded, as do the other health safety net public health programs.

Finally, the Administration is missing in action concerning the catastrophic healthcare situation facing the greater New Orleans region still hurting from Hurricane Katrina. Simply put, almost six months after the storm, with billions appropriated for recovery efforts, thousands of Americans are now receiving healthcare services in such facilities as tents and a city zoo. Americans deserve better from this budget. They expect better. And I hope we are able to get it for them.

Thank you, Mr. Chairman.

CHAIRMAN BARTON. Thank you, Mr. Dingell.

Mr. Upton from Michigan for one minute as soon as I get the clock set.

MR. UPTON. Thank you, Mr. Chairman.

I will use my time early here. Thanks for convening today's hearing, and I welcome the Secretary to be with us for sure.

I have to say that I know that putting together the HHS budget proposal must be a daunting one and some would say thankless task with many competing pressures and imperatives facing our country today and the difficult choices that obviously have to be made.

There are some very wise investment decisions reflected in the President's Budget. I was particularly encouraged by the proposal to provide a $55 million increase in funding for the Office of the National Coordinator for Health Information Technology to spur the widespread use of electronic medical records and other forms of Health IT. I am strongly committed to that goal because of the promise that Health IT has to substantially improve the quality, efficiency, and cost effectiveness of our Nation's health care delivery system. A recent Rand study found the widespread use of Health IT would save an estimated $168 billion a year, B as in big, money that can be reinvested to further strengthen our delivery system.

Obviously, I have some questions about the tough decisions you had to make related to the NIH budget and CDC budget and I look forward to your answers this afternoon.

I yield back the balance of my time.

CHAIRMAN BARTON. We thank the gentleman.

The gentleman from California, Mr. Waxman.

MR. WAXMAN. Thank you, Mr. Chairman.

Mr. Secretary, good to see you. Unfortunately, I am not looking forward to your presentation because I think the budget that you are presenting to us is not a good budget. After pushing through policies in the Deficit Reduction bill that took away protections for seniors and children and people with disabilities all in the name of helping States meet the financial burden of Medicaid, now the Administration brings us a budget that shirks massive cost onto the States. The agenda is clear, push the cost onto the States and let the States shift them onto the beneficiaries and once again we ask the least able to bear the burden.

We have 46 million uninsured, yet this budget cuts support for Medicaid. It undermines the strength of basic Medicare. It fails to address the difficult problems that have become glaringly apparent in the Prescription Drug Program. It endorses massive raids on the public treasury with tax breaks for health savings accounts that undermine employer base coverage which slashes funds for health care programs at

work. It shortchanges NIH in its life saving research. It cuts funds for State programs that provide for child immunizations.

I only have a minute to tell you a few of the things I dislike about this budget but I am always pleased to see you.

CHAIRMAN BARTON. Thank you.

The Health Subcommittee Chairman, Mr. Deal of Georgia.

MR. DEAL. Thank you, Mr. Chairman.

Mr. Secretary, I want to thank you for your superb service in helping all of us as we work with the Deficit Reduction Act. You were exemplary as was your staff. You are the kind of public servant that I think all of us take pride in acknowledging your service and it has been a difficult task.

I know that some of the questions today may evolve around the Medicare Part D and for the benefit of my colleagues, I would simply point out that we are going to have a full hearing on that subject on March the 1st. Dr. McClellan is scheduled to testify. We will also have representatives from the insurance community, representatives from the pharmacy community, as well as perhaps representatives from the constituent base itself to testify at that hearing. And I think that will amplify many of the questions that perhaps will surface today and we all look forward to that hearing.

Once again, I thank you for being here today and I look forward to your testimony.

I yield back, Mr. Chairman.

CHAIRMAN BARTON. We thank the gentleman from Georgia.

Does the gentleman from New Jersey wish to make an opening statement, Mr. Pallone?

MR. PALLONE. Thank you, Mr. Chairman for holding this hearing.

The priorities laid out in the President's Budget are exceedingly misguided in my opinion and prove yet again that when it comes to health care, Republicans still do not get it. The President's proposal once more puts Medicare and Medicaid on the chopping block, makes radical changes to our health insurance market, and eliminates programs that provide critical health services to those in need. At the same time, the President has proposed $285 billion in tax cuts that largely benefit the highest of earners. And make no doubt about it, if enacted, this budget will leave gaping holes in our Nation's social safety net and endanger our most vulnerable citizens while further enriching the wealthiest Americans. Once you break through the President's rhetoric, it becomes clear that the only health care priority for this Administration is to divest itself of any responsibility to ensure every American has access to affordable and quality health care.

Thank you, Mr. Chairman.

CHAIRMAN BARTON. I thank the gentleman from New Jersey.

The Chairman of the Oversight and Investigations Subcommittee, Mr. Whitfield of Kentucky.

MR. WHITFIELD. Mr. Chairman, I will waive.

CHAIRMAN BARTON. Okay, Mr. Norwood of Georgia.

MR. NORWOOD. Thank you very much, Mr. Chairman, and I will be very brief.

Secretary Leavitt, we are all very pleased and proud of you and appreciate all the hard work you have. I believe you have probably one of right now the hardest jobs in Washington, D.C., between the Avian Flu and dealing with the Medicaid and Medicare and all that and I thank you for the way in which you have handled it and handled yourself. I look forward to your testimony.

CHAIRMAN BARTON. The Ranking Member of the Health Subcommittee, Mr. Brown of Ohio.

MR. BROWN. Thank you, Mr. Chairman.

Mr. Secretary, I know you have strongly held views and are exceptionally dedicated to your job. We thank you for that.

I wish I could comment the Administration's stewardship equally commend over our health care system. First, they write a prescription drug law that bypassed the popular reliable and efficient insurance program we call Medicare in favor of complete and utter chaos. The drug industry wanted private drug plans. The privatization zealots wanted private drug plans so Medicare beneficiaries were forced into private drug plans. Medicare beneficiaries were simply an afterthought. Then the Administration writes a budget reconciliation bill that takes medically necessary health care away from the poor, the sick, and the elderly while preserving billions in overpayments, not just payments, but overpayments to HMOs. That is not compassion, it is not conservative, it is negligent and it is fiscally corrupt. Now the Administration proposes a budget that turns our health care system into a country club where the healthy and wealthy get tax breaks, the poor and sick can get in line at the free clinic. Whether it is the drug bill, the reconciliation package, or the President's Budget, it is clear that the wellbeing of everyday Americans carries no weight with Republican leadership.

Mr. Chairman.

CHAIRMAN BARTON. I thank the gentleman.

The chair notes the presence of Dr. Gingrey, a visitor to the committee and Member of the full House. We welcome him.

The chair asks Mr. Ferguson of New Jersey if he wishes to make an opening statement.

MR. FERGUSON. I do, thanks, Mr. Chairman.

Mr. Secretary, thank you again for being here. We welcome you and we certainly appreciate your service. I know how hard you have worked on these implementation issues with Part D. You have been traveling the entire country. You have been working tirelessly and we thank you very much for those efforts.

I have two quick points of interest that I want to just raise. One is how the budget treats pandemic preparedness. We continue to see reports of Asia and Europe about the spread of Avian Flu. Thankfully it has been limited to birds and a few human cases have been found primarily are people who handle fowl. But I know you would agree, Mr. Secretary, that it remains a matter of time before this or some other pandemic strain mutates and it is spread from person to person. I am very interested and concerned about how the requested funds will be spent for combating the flu and the spread of the flu.

I also want to just raise a second issue about a new dual eligible low income subsidy access problem on the horizon for Medicare Part D, specifically for people who need vaccines. New vaccines will now be covered under Part D which may create problems for the coverage. Given that vaccines are largely administered in physician's offices and many vaccines need special storage requirements, beneficiaries in most cases will not be able to purchase them are regional pharmacies like mostly all other Part D covered drugs. Currently the guidance given requires the beneficiaries to pay the charges out of pocket at the physician's office and then somehow seek reimbursement from their drug plan. In effect, their co-pay protections are not relevant or workable at this time.

CHAIRMAN BARTON. The gentleman's time has expired.

MR. FERGUSON. Thank you, Mr. Chairman.

CHAIRMAN BARTON. All right, the gentleman from Illinois, Mr. Rush.

MR. RUSH. Thank you, Mr. Chairman.

Mr. Chairman, last year's proponents of the budget touted the cost of Medicaid and other low income programs as "reform." Last year, I asked the question why is the majority for "reform" always focused on programs that affect the neediest, most vulnerable members of our society. No doubt this year with this budget and the billions of dollars in cuts from Medicaid, Medicare, and other social programs the Administration will similarly characterize these funding cuts as "reforms." And so like last year, I again ask the question, why is it then when it comes to reform, this Administration always wants to reform safety net programs and other low income initiatives that protect the poor, the elderly, the disabled, and our children? Why aren't any

reforms directed towards wasteful programs and initiatives that benefit the wealthy and the powerful?

Mr. Chairman, I do welcome Secretary Leavitt to this committee.

CHAIRMAN BARTON. We thank you, Mr. Rush.

The gentleman from Idaho.

MR. OTTER. Mr. Chairman, I waive my time and submit my statement for the record.

[The prepared statement of Hon. C.L. "Butch" Otter follows:]

THE PREPARED STATEMENT OF THE HON. C.L. "BUTCH" OTTER, A REPRESENTATIVE IN CONGRESS FROM THE STATE OF IDAHO

Thank you, Secretary Leavitt, for joining us today to discuss the direction of healthcare in this country for the upcoming fiscal year. I'm glad that we have the opportunity to hear from you about the priorities that the Administration has set for this year and to share with you those areas which are particularly important to us.

Idahoans are overwhelmingly concerned with the high cost of health insurance and rising number of people who do not have healthcare coverage. This issue invariably comes up nearly every time I talk with a constituent, whether he or she is a small business owner, a religious volunteer, a health care worker, or a concerned parent. They share with me their alarm over the growing cost of healthcare and their fear that they and those they love will be unable to afford or choose the care that they need.

Healthcare issues are extremely complex, and the cost of health insurance plays a major role in the high levels of uninsured in this country. We must look for innovative solutions to this problem, and I am pleased at the President's interest in further developing Health Savings Account choices for Americans. The creation of tax-free HSAs continues to have a profound impact on our healthcare industry, allowing Americans to have more control over their health care and providing coverage to those who might not otherwise have access to a good insurance policy. As an advocate of personal responsibility and giving individuals more power to make the best healthcare choices for themselves, I wholeheartedly support the expansion of HSAs into government healthcare programs like Medicare and Medicaid.

In addition, I greatly support the President's proposals aimed at encouraging individuals to purchase health insurance. As a businessman, I was able to deduct 100 percent of what it cost me to provide health insurance for my employees. Yet the law currently prohibits a single working mother without an employer-sponsored health plan from doing the same. We need to work to create an environment in which health insurance is more affordable, and extending tax benefits to individuals for the purchase of health insurance or a health savings account is a big step in the right direction.

Secretary Leavitt, I look forward to hearing about these proposals in more detail and hope to work with you to ensure that quality and affordable health coverage options are available to people in my state.

CHAIRMAN BARTON. All right, the gentleman from Texas, Dr. Burgess.

MR. BURGESS. Thank you, Mr. Chairman.

I do have a statement I will submit for the record but a few points I want to make in the minute I have and I agree with you, Mr. Secretary, these are important investments for the future. I am a big believer in consumer oriented, consumer directed health insurance, and I believe

there is no greater portability than allowing someone to own their own policy. But in order for consumers to make accurate decisions in regard to cost, price, and quality, we are going to have to increase the transparency in the medical system in this country. Health information technology, something that you have championed and I do agree with, it has taken a long time to get that program up and running and it will cost significant dollars but I support that effort. I would urge you, though, we need to keep our best and brightest physicians involved in the game, particularly in Medicare, if this system is to pay the dividends we expect it to. The same could be said for pay for performance. We have got to find a way to keep physicians my age and your age in the system and providing for our patients. These are the best trained, the most experienced physicians. They are leaving in droves right now because of reimbursement.

Finally, I just have to say as far as the Gulf Coast is concerned, I got a Blackberry earlier today about the reopening of the HCA Tulane Hospital. Mayor Ray Nagin asked them what was in their coffee. I do not know what you are taking at Tulane but I want some of that. Mr. Secretary, it is called the private sector. It is called American ingenuity and investment and it works every time it is tried.

CHAIRMAN BARTON. The gentlelady from California, Mrs. Eshoo.

MS. ESHOO. Thank you, Mr. Chairman. I hope you are taking good care of yourself.

CHAIRMAN BARTON. I am, I lost about 18 pounds.

MS. ESHOO. Good for you. Well, continue doing that. We want you to be well and stay well.

CHAIRMAN BARTON. I recommend highly fat-free crackers and every form of chicken known to man.

MS. ESHOO. Good. That is great.

Well with that, welcome Mr. Secretary. It is good to have you before the committee today and I am sure that we are going to have many other discussions as well this year.

First, along with many of my colleagues on the committee, I have deep concerns about many, many parts of the President's Budget. I think that there are some opportunities that are really lost that the President does not speak to but I hope that the Congress and especially this committee will rise to the occasion and hopefully with your cooperation on a number of fronts.

One of them, one of the spots in the budget where I do find some good news is that there is support for personalized medicine and in the role genetics will play in health care. And to be specific in that area, the statements of the Administration's policy on S. 306, the Genetic Information Non-Discrimination Act of 2005. To my colleagues, that

passed unanimously in the Senate and the Administration obviously supports it and I thank you for that, Mr. Secretary.

I hope that you will be a positive influence--

CHAIRMAN BARTON. The gentlelady's time has expired.

MS. ESHOO. If I might just finish this statement, this sentence. I hope that you will be a positive influence on members of this committee to support that legislation, which is H.R. 1227 here in the House, to accomplish it. Thank you.

CHAIRMAN BARTON. The gentlelady from Tennessee, Mrs. Blackburn.

MS. BLACKBURN. Thank you, Mr. Chairman.

You know, I think it is unfortunate that some of our colleagues today are trying to claim that budget challenges are related to tax reductions from '03 and not out of control or unaccountable Washington spending. So just for the record, according to the CBO in fiscal year 2005, the Federal Government received more revenue than in any other year. Revenue has increased $274 billion from '04 to '05. The tax reductions by this Congress have not crippled Federal programs; they have indeed provided more money for Federal programs.

And I do not agree with everything in the President's Budget. We must continue working to reform and renew some of the entitlement programs that are restraining and work on restraining our Federal spending. And I appreciate the budget steps in that direction and I think it is unfair to the American people to hide the fact that our existing health and entitlement programs are on a sustainable path because they are not, they are on an unsustainable path and I thank the Chairman and welcome the Secretary and look forward to working with you on the situation.

CHAIRMAN BARTON. I thank the gentlelady.

The gentleman from New York City, Mr. Engel.

MR. ENGEL. Thank you, Mr. Chairman and glad you are looking so well and you see, you can eat lots of chicken and not worry about bird flu.

I welcome Mr. Secretary and thank you for coming. I also want to associate myself with those on this side of the aisle who are looking at the budget and feel very badly about it. I feel that we are going in the wrong direction in terms of providing health care. The uninsured are becoming more and more, and cuts to the needy and working people are growing with leaps and bounds and I think this is just a very, very bad direction.

With all due respect to the gentlewoman who just spoke before me, it is clear to us that the tax cuts are the reason why the poor have to suffer in terms of getting less and less health care. This Administration has made its priority the priority for tax cuts and war and therefore there is

nothing left to benefit the American people in terms of health care, in terms of education, in terms of childcare, and all the things that the American people know. So I believe that the priority of the Administration ought to change, ought to be considered with health care. More for health care and less for tax cuts. And while the tax cuts are not the source of the entire problem, it is clear that there is so much more revenue coming in--

CHAIRMAN BARTON. The gentleman's time has expired.

MR. ENGEL. --therefore we have these widening deficits that are going sky high and crazy. That has to stop.

Thank you, Mr. Chairman.

CHAIRMAN BARTON. The gentleman from Florida, Mr. Stearns.

MR. STEARNS. Thank you, Mr. Chairman.

I am delighted to have the Secretary here and we are all anxious to hear from him.

I appreciate your staff working with my staff over the past few years on a Cash and Counseling delivery system that we provided that came from Governor Jeb Bush and is used in Medicaid and we have incorporated into Medicare to provide beneficiaries with flexibility and self design of their own personal care. And I am pleased to see Cash and Counseling provision in major pieces of legislation this committee has moved, in first the demonstration in Medicare, and then this year in the Deficit Reduction Act in Medicaid where we made it a permanent option for Governors.

Mr. Secretary, in the short time I have left, I just want to talk to you a bit about the NIH budget. I support Chairman Barton's plans for the committee to reauthorize the NIH to make it flexible and more accountable for our future needs. I think we all have to say to ourselves we doubled NIH so I think we better stop just a second and take a breath and say, "Are Americans getting a good return on investment here and does the director have the authority it needs to manage the program as it should be?"

So I just leave you with that thought and I thank you, Mr. Chairman.

CHAIRMAN BARTON. Thank you.

The gentleman from Texas, Mr. Green.

MR. GREEN. Thank you, Mr. Chairman for you and Mr. Dingell for holding this hearing on the HHS budget proposal and I would like to welcome the Secretary.

My concern I guess is the health savings account. It seems like HHS has worked for only small portion by 46 million uninsured but they cannot reduce our uninsured significantly. They worked for a significant segment of our population and I notice in the poll a week ago that the number one domestic concern people have is health care.

One program I do agree with the Administration on and I--we support the Health Community Centers Program. I applaud the Administration for increasing funding for health centers and have proven so effective in delivering primary and preventative care to uninsured and underinsured. I am disappointed that HCAP Program which helps put together collaboratives to develop these health centers are again not in the budget but I hope to be able to work with the Appropriations Committee and the House and Senate to do that. I am concerned, like a lot of folks are, about the deep cuts in children's, graduate, and medical education and health preventions but I am looking forward to working with the appropriators to restore some of the funding.

But Mr. Secretary, I particularly want to thank you and Dr. McClellan for coming to Houston shortly after Labor Day. I know you were there on Labor Day and with the resources from HHS and the Public Health Service and we had a couple of hundred thousand folks, evacuees and providing the service and I look forward to working with you on our uninsured problem.

Thank you, Mr. Chairman.

CHAIRMAN BARTON. Thank you.

The gentleman from Texas, Mr. Hall.

MR. HALL. I was just reading the statement for the first time that I am going to make here so I will read it the first time, Mike, to you if you do not mind.

I do thank you for coming. The health care spending, of course, is one of the really major areas, one of the largest areas of the Federal budget and it is also the most important to citizens of our country. The money that we spend directly affects millions of people and it is important that America remain the leader in health care research and innovation for years to come. And as we all know, health care spending is only projected to increase in the future. There is just no question there is no way around that. We need to find ways to be fiscally responsible with our health care spending while delivering better outcomes. I know you are working toward that too and we have had meetings with you and you have been very generous with your time with us, and with this committee. So we are all on one road, and to this end I am very pleased to see that the President's Budget contains an increase for health information technology.

There are a lot of inefficiencies in the system that need to be addressed that more people can be covered with fewer resources. A recent study by the Rand Corporation estimated that if we did more to adopt health information technologies then we could save $77 billion a year and we would also deliver better health outcomes from reduced areas. As I understand as HHS and NICHT are partnering to develop

common standards to allow systems to work together seamlessly while protecting patient privacy.

CHAIRMAN BARTON. The gentleman's time has expired.

MR. HALL. And I applaud these efforts and I yield back my time.

CHAIRMAN BARTON. The gentleman yields back.

MR. HALL. Good to see you.

CHAIRMAN BARTON. Ms. Capps of California.

MS. DEGETTE. Ms. DeGette. I am going to waive my opening statement.

CHAIRMAN BARTON. Okay. I was going in order of appearance and I saw you come in after the gavel. Did you come in and leave and come back? Okay, then the gentlelady from Colorado is recognized to waive her opening statement.

MS. DEGETTE. I waive my opening statement.

CHAIRMAN BARTON. All right. The gentlelady is recognized, Mrs. Capps.

MS. CAPPS. Mr. Chairman, thank you for holding this hearing. I am going to submit my opening statement for the record and welcome the Secretary. I look forward to the discussion period.

[The prepared statement of Hon. Lois Capps follows:]

THE PREPARED STATEMENT OF THE LOIS CAPPS, A REPRESENTATIVE IN CONGRESS FROM THE STATE OF CALIFORNIA

Thank you Mr. Chairman.

I am glad that we are holding this hearing today in order to discuss our HHS budget priorities for FY2007.

Unfortunately, though, the President's proposals reflect a lack of real investment for our nation's true current and future health needs.

NIH is being level-funded, which is essentially a cut. I worry about the future of medical research if we cannot even keep up the pace with today's needs, let alone tomorrow's.

The President proposes cutting cancer research, yet we finally have evidence that our efforts are working and are beginning to see a *declining* death rate for cancer.

How can we justify delivering a setback to those efforts?

Nurse education funding is being level-funded, which is also an essential cut.

Back in 1974, Congress appropriated the equivalent of 609 million in today's dollars for nurse education programs.

And while the Administration is emphasizing preparedness for pandemic flu and the threat of bioterrorism, it seems to be ignoring the fact that nurses are first responders and will be critical to those efforts.

There simply aren't enough nurses now and there certainly won't be enough in the future if we cut funding from training and retention programs.

I hope today we can refocus attention to the true priorities of our public health infrastructure and ensure that we are doing the absolute best we can to serve America's health needs.

CHAIRMAN BARTON. All right. Seeing no Republicans, oh, Mr. Murphy of Pennsylvania, do you wish to make an opening statement?

MR. MURPHY. Real quick, sir, thank you. All I have is one minute right?

CHAIRMAN BARTON. Yes, sir, you got one minute.

MR. MURPHY. Mr. Chairman, Mr. Secretary, thank you.

We all know we have one of the best health care systems available with great dedicated folks, but we also recognize that some of the issues being presented in the President's Budget is also looking at some reform. When we talk about making reforms here with such things as health information technology, working on community health centers, it is important that we are aware of the idea that these things can save lives by the thousands and save money by the tens of billions of dollars. What that really means we have to stop just focusing upon who is paying and we look at what we are paying for. And I hope though that some of the issues being addressed today rather than simply reducing care or having people talk about reducing care, one of the things that we have done is I am the co-chairman of the Congressional Health Care Caucus. It has identified over $300 billion of savings that we can have in the health care arena with reforms and it is not a matter of reducing care, it is a matter of doing it better and I certainly hope today in your comments and your continued commitments, Mr. Secretary, we will continue on those things together. Thank you very much.

Thank you, Mr. Chairman.

CHAIRMAN BARTON. Does Mr. Markey wish to make an opening statement?

MR. MARKEY. I wish to waive.

CHAIRMAN BARTON. Okay. Mr. Allen?

MR. ALLEN. Thank you, Mr. Chairman and welcome Mr. Secretary.

The Administration's budget continues on a path of dismantling the health care infrastructure in our country and will leave more people uninsured and more employers unable to afford health care coverage for their employees. The Administration proposes to spend $156 billion over 10 years on a package of mostly recycled policies that promote health savings accounts and high deductible health plans. It is an attempt to move people from shared risk and shared pooling arrangements to fend for themselves in the more expensive and volatile individual market.

Recent studies indicate that the expansion of HSAs would in fact increase the number of uninsured and undermine the existing employer sponsored insurance system. To cut wasteful Federal spending, this Administration should simply eliminate the well documented overpayments to Medicare HMO's and insurance companies and allow

the Federal Government to negotiate lower prices for Medicare prescription drugs. But that agenda I suspect will have to wait for another Administration.

I thank you for being here.

CHAIRMAN BARTON. Does Mr. Bilirakis wish to make an opening statement?

MR. BILIRAKIS. No, I will just offer an opening statement into the record. I waive.

[The prepared statement of Hon. Michael Bilirakis follows:]

THE PREPARED STATEMENT OF THE HON. MICHAEL BILIRAKIS, A REPRESENTATIVE IN CONGRESS FROM THE STATE OF FLORIDA

Thank you, Mr. Chairman.

I am pleased that we are here to examine the Administration's Fiscal Year 2007 budget proposal for the Department of Health and Human Services.

I am eager to hear your insights, Mr. Secretary, on the health care provisions in the Administration's budget proposal. I am especially interested in learning how HHS continues to address problems experienced by Medicare beneficiaries enrolling in the prescription drug benefit.

This new benefit represents the most significant change to Medicare since the program was created. I supported it then, as I do now, because I believe that it will help provide much needed assistance to many Medicare beneficiaries, especially the poorest, sickest, and those with the highest drug costs.

And while those of us who helped create it could reasonably expect there to be certain administrative and management challenges associated with its implementation, I must tell you that I have heard from constituents who have told me that they have had trouble getting the prescriptions they need.

I am eager to hear what steps HHS has taken to ensure that seniors who sign-up for prescription drug coverage get the medicine they need, when they need it, at the proper price. I am hopeful that the problems about which I have heard are being addressed so that my constituents can obtain affordable prescription drugs.

I look forward to working with you, Mr. Secretary, and members of this Committee as we continue to monitor implementation of the prescription drug benefit and determine how to meet the health care needs of the American people now and in the future.

Thank you, Mr. Chairman.

CHAIRMAN BARTON. Does Mr. Walden wish to make an opening statement?

MR. WALDEN. Mr. Chairman, I just look forward to hearing the Secretary's remarks.

CHAIRMAN BARTON. Does Mr. Terry wish to make an opening statement? He waives, too.

All right, Mr. Gonzalez?

MR. GONZALEZ. Waive opening.

CHAIRMAN BARTON. Mr. Inslee?

MR. INSLEE. Waive opening.

CHAIRMAN BARTON. Ms. Baldwin?

MS. BALDWIN. Thank you, Mr. Chairman and Mr. Secretary.

Our Nation is in the midst of a health care crisis. Forty-six million Americans are uninsured, an additional 16 million are underinsured. In aggregate, 62 million Americans have either no insurance, sporadic coverage, or have insurance coverage that leaves them exposed to high health care costs. This is unacceptable. But what is even more unacceptable is that the President's Budget proposes harsh cuts to both Medicare and Medicaid, programs that actually do provide affordable comprehensive health care. And it offers a reform proposal that will make many Americans worse off.

I want to say just a few words about health savings accounts. In my opinion, the President is proposing to do to health care what he proposed last year to do to Social Security and that is moving from a system whose fundamental philosophy is promoting the common good--recognizing that we are all Americans and we are all in this together--to a philosophy of each man, woman, and child for themselves, sink or swim if you can. We must recommit as a Nation to a fight for the common good including health care for every American and I believe this budget brings us further from that goal.

Mr. Chairman, I yield back, thank you.

CHAIRMAN BARTON. The gentlelady yields back.

Mr. Shimkus?

MR. SHIMKUS. Waive.

CHAIRMAN BARTON. Mr. Stupak?

MR. STUPAK. Thank you, Mr. Chairman.

Mr. Secretary, welcome. Briefly, Mr. Secretary looking through your testimony you did not say anything about New Orleans. We were down there the 24th through the 26th of January and health care is dismal if you can even call it that. What I see in New Orleans is--and the rest of the Gulf Region--is business as usual. There does not seem to be any urgency to get health care moving again in New Orleans. I am looking at a newspaper article right here from the Times Picayune where people are waiting nine and a half hours to get into emergency rooms. But in our hearing, their representatives said that the Secretary had a vision of health care for New Orleans. Hopefully during your oral testimony you can tell us what that vision is and what do we do to get medical profession and medicine and health care delivery being done in New Orleans in the rest of the Gulf Region and a more aggressive proactive approach my--Secretary, I think would be helpful down there.

Thank you, Mr. Chairman.

CHAIRMAN BARTON. I thank the gentleman.

The gentleman from Maryland, Mr. Wynn.

MR. WYNN. Thank you, Mr. Chairman.

Welcome Mr. Secretary. Thank you for your work over the years. Unfortunately I am a little distressed with this budget. First of all, I note that you do not have a fix for the problems of the Medicare Prescription Drug Program. Our seniors are confused, our seniors are actually losing access because of some of the problems with this program. I do not see anything to address those concerns.

The second problem I am concerned with is basically the severe cut $160 billion of Medicaid and Medicare on top of the 50 that was already put in the Deficit Reduction Act. The problem being that only shifts the problem down to the States. The States are already strapped and so I see that as very problematic.

But finally the thing I wanted to express concerns about these health savings accounts. Over and over people said this so-called cost sharing does not work for the people who need it the most. The people who are the working poor, the mother with two kids who does not have insurance or cannot afford insurance, how is she going to afford a high deductible? That issue was never addressed in this proposal and so what you have is less usage because of these--with these health savings accounts and more long-term costs.

So I think there are a lot or problems with this budget. I hope you will be able to address some of these issues in the course of your testimony.

Thank you.

CHAIRMAN BARTON. I thank the gentleman.

I see no other Member present who has not had an opportunity. The chair asks unanimous consent that all Members not present have the requisite number of days to put their opening statement in the record. Without objection, so ordered.

[Additional statements submitted for the record follow:]

THE PREPARED STATEMENT OF THE HON. BARBARA CUBIN, A REPRESENTATIVE IN CONGRESS FROM THE STATE OF WYOMING

Thank you, Mr. Chairman, for holding this timely hearing. I'd also like to thank Secretary Leavitt for joining us here today. I realize what a critical time this is for your agency, and I appreciate you making it a priority to discuss our budget concerns.

As the Secretary has noted, every program is important to someone, and difficult choices have to be made when it comes to distinguishing spending priorities. I am a champion of fiscal discipline, but I cannot endorse the cuts the President has recommended to rural health care programs.

Among the cuts to rural grant funding, the President proposes to eliminate the Rural Hospital Flexibility Grants, the Small Hospital Improvement Program, and the Rural and Community Access to Emergency Devices programs. His budget also eliminates the Rural EMS program and essentially eliminates the Rural Health Outreach Grant Program. In total, the President has recommended cutting $133 million in rural health dollars. This

is a humble part of the overall Federal budget, but these funds are critical to states like Wyoming, and the citizens I represent.

While almost 25% of America's population lives in a rural area, only 10% of America's physicians serve these areas. The administration has justified these cuts to programs within the Office of Rural Health Policy, saying this funding is duplicative. Today, I hope to hear explanation of what other programs are supposedly filling this need. I would also appreciate being shown where rural-serving health entities may find support in the President's Budget. As a Member of the House Rural Health Care Coalition, I support programs that aide access to quality health care for rural America, and I will continue to advocate for the funding necessary to support these programs.

Again, thank you Chairman for calling this hearing, and I reserve the balance of my time.

THE PREPARED STATEMENT OF THE HON. HILDA L. SOLIS, A REPRESENTATIVE IN CONGRESS FROM THE STATE OF CALIFORNIA

- Thank you Mr. Chairman and good afternoon Secretary Leavitt.
- There is no other issue that is of greater concern to my constituents in East Los Angeles and the San Gabriel Valley in Los Angeles County than health care.
- More than 1 out 3 residents in my district lacks health insurance.
- As you know, our state and federal governments play a critical role in helping to ensure that many low-income families, particularly the young, the elderly, and the sick, have some sort of access to medical services.
- That is why I am so troubled by the President's Budget proposal, which includes deep cuts to Medicare, Medicaid, the State Children's Health Insurance Program (SCHIP), and other vital health programs.
- At a time when 44 million Americans, including 13 million Latinos, lack health insurance, we should not be cutting health programs that benefit families that otherwise will not have any health care.
- In fact, a recent study by the Congressional Budget Office (CBO) of the Medicaid cuts in the reconciliation bill found that sixty percent of those losing coverage due to new Medicaid premium charges would be children!
- Our nation's economic health depends on the good health of its families.
- I urge the Administration to reevaluate its budget proposal and the negative impact it would have on the Latino community and other communities across this country.
- Thank you, again, Mr. Secretary, for your presence here today, and I appreciate your attention to these concerns.

THE PREPARED STATEMENT OF THE HON. TED STRICKLAND, A REPRESENTATIVE IN CONGRESS FROM THE STATE OF OHIO

Thank your Mr. Chairman.

Mr. Secretary, I have deep concerns that the President's Budget we have before us today will do more harm than good to the American people and their ability to access good quality and affordable health care. This budget would lead to increases in Medicare premiums, cut funds for Medicare and Medicaid, and shift more of the cost of health care onto individual consumers through health savings plans.

This budget devastates rural health care by zeroing out Rural Hospital Flex Grants and Rural Access to Emergency Devices, like defibrillators, and cuts state offices of rural health. Hospitals and patients in my rural district already face unique challenges, and this budget puts them at a disadvantage. Also worrisome are this budget's dangerous health

tax proposals, which will create greater obstacles to affordable health care for the elderly, people who are already sick, and low-income families. In addition, the President's proposals to expand health savings accounts provide only meager hope, at best, to those of modest income.

And, as you know, the recent budget reconciliation bill included over $50 billion in cuts to Medicare and Medicaid. Now, the President's Budget seeks to continue down that dangerous path, threatening the wellbeing of the most vulnerable in our society by making $160 billion in new cuts to these programs. Unfortunately, this budget asks states to bear the brunt of these cuts while failing to take meaningful steps to control rising health care costs.

I strongly oppose these cuts and am hopeful that the members of this committee can work together to protect these vital programs.

Thank You. Mr. Secretary, I look forward to your testimony.

THE PREPARED STATEMENT OF THE HON. HEATHER WILSON, A REPRESENTATIVE IN CONGRESS FROM THE STATE OF NEW MEXICO

Thank you, Mr. Chairman, for holding this hearing today to review the President's Budget for health care. And thank you, Secretary Leavitt, for being here today.

I am concerned about many areas in this budget, including Medicare, rural health programs, health professions programs, and the National Institutes of Health. But let me focus on two areas: Medicaid and the Indian Health Service.

Last year Congress made changes in Medicaid that achieved about $7 billion in savings over five years, changes I did not support. Now the Administration proposes additional Medicaid changes yielding an addition $13.5 billion in savings over five years, without making substantial improvements in the program that would improve people's health. Most of these savings would come from administrative changes in areas HHS may not have the authority to change. These changes include reductions in Disproportionate Share Hospital payments, rehabilitation services, and school-base health services: changes rejected by Congress last year. I am concerned of the impact these changes would have on providers and services to Medicaid beneficiaries.

We must strengthen and improve Medicaid to make it a better program for low-income children, pregnant women, disabled, and elderly Americans. These changes simply fall short and could actually harm access to health care for these populations.

The administration has also chosen to eliminate the Urban Indian Health Program, an important program within HIS providing health care to Indian people living in urban areas. In Albuquerque, the Urban Indian Health Program provides $1.5 million annually in health care services to the 48,000 urban Indians living in the Albuquerque area. Two non-profit health organizations, First Nations Community Healthsource and the Albuquerque Indian Health Service Dental Clinic, receive grants from this program to provide services.

We already have shortfalls within HIS, particularly for urban Indians. Only 1% of the $3.1 billion HIS budget is earmarked for urban Indian health, while 75% of Indians now live in urban areas. Now the Administration wants to take away that 1%. The Urban Indian Health Program is important for the health of urban Indians in Albuquerque and we must work to strengthen health care for Indians living in urban areas.

Thank you, Mr. Chairman.

CHAIRMAN BARTON. Mr. Secretary, welcome to the committee. We look forward to hearing your testimony and then we are going to have some questions. We are going to recognize you for such time as you

may consume. I am going to set the clock at 10 minutes but take as much time as you wish. Welcome to the committee.

STATEMENT OF HONORABLE MICHAEL O. LEAVITT, SECRETARY, U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES

SECRETARY LEAVITT. Thank you, Mr. Chairman.

I have submitted a prepared opening statement. I will briefly summarize and then be eager to get directly to the questions of the members.

The budget that has been presented to you today is nearly $700 billion. It is roughly broken into two categories; all of you are familiar with them. One is entitlement programs, that is to say decisions that we have made as a country to provide health care and other important human services to those in our Nation who are poor, elderly, or disabled. And then there is the discretionary budget. That would be a large group of programs that upon which you act each year. We will have an opportunity, I am sure, to talk about both. I will just comment briefly.

Particularly Medicare is of grave certain to me. It currently occupies nearly 3.4 percent of our gross domestic product. That is to say one program is 3.4 percent of every dollar that is generated in our economy and if it is allowed to continue to grow as it is, by 2040 it will be nearly 8 percent of our entire gross domestic product. Again, unchanged by 2070, and it will be 14 percent of our gross domestic product. I do not think there is a person in this room who believes that that can continue as it is. We will not be competitive as a Nation. The jobs that are underlying our economy that ultimately generate the tax revenues that make possible for Medicare to be paid for and to be a commitment that we make as a Nation will disappear and the equation will no longer work. And I just want to acknowledge that. We will have some discussion about things that could be done in the near term and perhaps in the long-term but it is an important part of our conversation.

I suspect that much of our discussion today will center around the discretionary budget. If I may acknowledge that the budget that I am presenting here today is $1.5 billion less than the '06 budget. This is a period of deficit reduction. As many of you know, much of my public service was spent as a governor of one of our States. I was governor during the periods of time when we had tax revenues sufficient to expand programs. I was the governor during times when we had difficult periods where we had to reduce our expenditures so as to balance our budget. And while this is not a balanced budget, it is clearly consistent with the President's proposal to reduce the deficit by half by 2009. In

doing that, may I just acknowledge that whenever you are doing a budget and whenever you are reducing deficits you are faced with choices between very good options. Everything in this option is good because someone feels passionately about it and because it represents something that I feel confident and my heart responds to it in the same way yours does. There will be disagreement today with the decisions that we have made, I acknowledge that.

My purpose today is to simply outline for you the rationale that I used and that was used by the Administration to make these decisions. If you disagree, obviously that will now go into the legislative process and that opportunity will present itself. I think it might be valuable rather than try to enumerate each part of this very large and complex budget if I were to provide you with a sense of the philosophy that went behind it, the general guidance that I gave to those who prepared it under my direction. You will find, for example, in this budget though there are fewer dollars, you will find new initiatives. You will find initiatives, for example, on health information technology or what I refer to as critical path to personalized medicine. You will find new initiatives on providing our older Americans and disabled Americans with a choice to have health care in their homes and you will find new programs on HIV/AIDS. All of these are very important new programs. You will see a continued commitment on the part of the President on community health centers. You will find that we have represented new dollars here for bioterrorism and for pandemic flu and for certain high demand highly efficient programs that we felt simply needed to be nurtured even during the period of deficit reduction. We have chosen to fund those programs by looking for dollars within the budget that were one time dollars that may not have been repeated. We have looked for programs whose purposes might be found in multiple places and we have looked for ways to tidy that up and to put it under one program. You will see that we have used carryover funds in certain situations. You can in times like this sweep the corners and find ways in which to accomplish more with less. It is a time that drives efficiency.

I have also said to my colleagues there are a series of principles that I would like you to follow as you look at each program. It might be valuable for you to know what those principles are. I will likely through the course of our discussion today refer to those principles when I explain to you why I have made a reduction in a program that you might not agree with. For example, in many programs, I found that they tend to approach a problem in a very general way, whereas there is a specific part of the problem that we could target. In most cases, the principle is let us target the real problem, and while we might be brilliant at the

general distribution of funds, let everyone get something, let us focus on the real problem and target funds.

The second principle is in working to prevent as opposed to simply pay for after people are sick or after some disruptive damage has been done. You will see an emphasis placed on prevention in this budget. You will also see me biasing my judgments toward the direct delivery of services. You will find places where there may have been a building program before that I have in this budget suggested we cannot afford this year, but I do not want to cut direct services and so we have not invested in infrastructure to the extent that it would have, in fact, compromised our ability to provide services to people. You will see a bias on my part with respect to programs that allow markets or individuals to make choices, whereas government often might make choices that were less specific to their needs. I believe that markets and individuals make choices that government-wide programs often do not and I think they are better choices.

You will see a substantial emphasis here to invest in new technology. We are going to talk, I think, later I am sure about some of the places that HHS funds research. Hard choices needed to be made there and I concluded that if a grant for example had run its course and if the research had been concluded, that rather than continue that grant, we ought to emphasize new investigators. We ought to find new technologies on which we are simply now just starting so you will see emphasis on investment there.

HHS is a very large department. I have 27 different operating divisions that report to the Secretary. It is large, as I said $700 billion. Many of those investments tend to be quite stove piped rather than look across the department where there is something happening in other operating divisions and they tend to see them as separate programs. I try to look across the department which means in some cases you may find a program that has been eliminated, but it may be quite well funded in another or it may be that by putting the program together in A and B we can create a better program. So you will see an approach that will be far more department wide as opposed to the stove pipe.

You will also see heavy emphasis on my part on accountability and being able to measure. In my judgment, if I cannot measure its benefit, there may be some measurement there but it T's it up in my mind for very heavy scrutiny. And you will find places where there may have been good being done, but if I cannot measure it in a time of deficit reduction, I have just concluded that those were candidates for reduction. So you will see targeting--you will see prevention orientation, you will see direct services over infrastructure. And those are the kinds of principles that I used.

Mr. Chairman, that gives you a broad overview of the way I have approached this budget. Again, I want to acknowledge that this is a time for deficit reduction. There will be suggestions I have made that you will not like and I understand that. I am here to hear your thoughts and give you mine and the legislative process will then march forward.

Mr. Chairman?

[The prepared statement of Hon. Michael O. Leavitt follows:]

PREPARED STATEMENT OF THE HON. MICHAEL O. LEAVITT, SECRETARY, U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES

Good afternoon, Mr. Chairman, Representative Dingell, and Members of the Committee. I am honored to be here today to present to you the President's FY 2007 budget for the Department of Health and Human Services (HHS).

Over the past five 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 31st 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 FY 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 high-performing Presidential initiatives, including Health Centers, Access to Recovery, bioterrorism and pandemic influenza; and we are also maintaining effective programs such as Indian Health Services, Head Start, and NIH medical research.

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 FY 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 through NIH 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. This budget includes a $2.3 billion allowance for the second year of the President's Pandemic Influenza plan. These funds will enable us to meet several important 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.

The President's FY 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.

Last July, the Administration emphasized five key principles for reauthorization of the Ryan White CARE Act: (1) serve the neediest first; (2) focus on life-saving and life-extending services; (3) increase prevention efforts; (4) increase accountability; and (5) increase flexibility. The President has made fighting the spread of HIV/AIDS a top priority of his Administration, and he will continue to work with Congress to encourage prevention, and the provision of appropriate care and treatment to those suffering from the disease. The President's FY2007 budget request for the CARE Act HIV/AIDS activities is $2.16 billion, an increase of $95 million for several elements of the new domestic HIV/AIDS initiative. The request will support a comprehensive approach to address the health needs of persons living with HIV/AIDS, consistent with the reauthorization principles. The budget also includes a new authority to increase program flexibility by allowing the Secretary to transfer up to five percent of funding provided for each Part of the Ryan White CARE Act to any other Part.

The budget maintains the President's commitment to the doubling of NIH, and includes important cross-cutting 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. And it promotes independence and choice for individuals through vouchers that increase access to substance abuse treatment.

In the area of entitlements 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. Last year when I made my

statement before this Committee, I said that the growth in Medicaid spending is unsustainable. 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 five years in Medicaid and S-CHIP and several administrative proposals saving $12.2 billion over five years.

This Administration has also pursued a steady course toward Medicare modernization. In just the past three 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 provides seniors and people with disabilities with comprehensive prescription drug coverage, the most significant improvement to senior health care in 40 years. Millions of seniors and people with disabilities are already using this benefit to save money, stay healthy, and gain peace of mind. According to CMS' Office of the Actuary, Medicare's drug coverage will have significantly lower premiums and lower costs to federal taxpayers and states, as a result of stronger than expected competition in the prescription drug market. Moreover, beneficiary premiums are now expected to average $25 a month – down from the $37 projected in last July's budget estimates. The Federal government is now projected to spend about 20 percent less per person in 2006 and, over the next five years, payments are projected to be more than ten percent lower than first estimated. So taxpayers will see significant savings. And state contributions for a portion of Medicare drug costs for beneficiaries who are in both Medicaid and Medicare will be about 25 percent lower over the next decade. All these savings result from lower expected costs per beneficiary; projected enrollment in the drug benefit has not changed significantly.

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 by about $1.5 billion in the next fiscal year.

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, given that HHS administers 225 health and social services programs that provide resources to rural areas. In addition, the Medicare Modernization Act contained several provisions to support rural health, including increased spending in rural America by $25 billion over ten 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 FY 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.

CHAIRMAN BARTON. Okay, thank you, Mr. Secretary.

Let me reset the clock here quickly. The Chair recognizes himself for the first five minutes of questions.

The President's Budget for the National Institute of Health is $28.6 billion, which is basically a freeze over the fiscal year 2006. As you know, it is a high priority of mine to reauthorize the National Institutes of Health. It has not been reauthorized in 14 years. In reauthorization, we need to put some reforms in place to make the institutes more able to address the health care research needs for our country. What is your view of the need to reauthorize the programs at NIH?

SECRETARY LEAVITT. Mr. Chairman, we look forward to working with you on that matter. I would like to tell you that as that discussion begins, that my time as Secretary has provided me with some insights I think I would be interested to express. I mentioned the fact that across HHS is a lot of stove piping. We do not often look at programs in the context of the larger purpose. And that is true in a lot of Government agencies and a lot of Governments. It is in part true at NIH. You will see in this budget an emphasis on what I refer to in the budget as trans-institute initiatives. There are certain initiatives that will help every one of the institutes. For example, an important part of our effort this year is a human genome and environment study. Nearly all of the disease specific institutes have at their heart or the heart of their new science is the human genome and how we can connect what is going on in the environment with genetics. That is something that will benefit every one of the centers or institutes. You will also see what we refer to as road map. Again it is emphasizing the need for science to be looked at on a multi-jurisdictional way. Medicine in the future needs to be more personalized, it needs to be more predictive, it needs to be more preemptive so that we are emphasizing prevention. And as we begin that discussion, I would like to suggest that those are important considerations.

CHAIRMAN BARTON. Okay. In the budget reconciliation package that the President signed last week, we found savings to offset the

proposed, I think it is 4.4 or 4.7 percent cut in physician reimbursement. That was a one year fix. So we held our physicians harmless for a year but under the current physician reimbursement formula, every year that we do not reform the program for determining how to reimburse our physicians, it reports these cuts and these cuts are cumulative. What steps do you feel the President and yourself can make to work with this committee to reform the reimbursement scheme for our physicians so that we get something that is fair to them and fair to the taxpayers that accurately reflects the cost of the physician to providing health care services for our Medicare beneficiaries?

SECRETARY LEAVITT. Mr. Chairman, this is a perplexing difficult problem and it is one that is a collision that is going to occur every year until we come up with a new way of approaching this. And in my judgment, the best way is for us to begin to assign a value on performance and not simply quantity. We need to be focusing on pay for performance where we are rewarding physicians in a way that acknowledges the value they bring. What we have seen over time often is that when rates are cut, the quantity of procedures increases. And that is not going where we want it to go. Where we want it to go is for us to have lower costs, fewer medical mistakes, and we want there to be higher quality. A key to that is having health information technology that allows us to measure when quality is occurring. You will see in this budget substantial emphasis on health information technology. Several of the members mentioned health information technology in their opening statements. That in my judgment is a critical element not only to reforming our payment structure but in reaching better quality as well.

CHAIRMAN BARTON. Well, are you willing to work with the committee and make it a priority to engage stakeholders, before the Congress adjourns, to try to come up with a new system?

SECRETARY LEAVITT. Mr. Chairman, yes, in fact, we have a number of pilots already that we are working to develop experience in this area. And we think it is crucial that we find new ways of solving this problem. This will be a perennial collision until we are done.

CHAIRMAN BARTON. All right, I agree with that.

With that, I recognize the Ranking Member, Mr. Dingell for five minutes.

MR. DINGELL. Mr. Chairman.

Again, welcome, Mr. Secretary. In December Chairman Barton wrote you forwarding several follow up questions of mine. In December, I along with Mr. Stupak, Mr. Brown, and Mr. Waxman sent you a letter with many key questions about the catastrophic healthcare crisis in the New Orleans region. Finally, several Democratic Members and I wrote you after last year's budgetary hearing asking follow-up

questions which were forwarded to you by Chairman Barton. When will you answer these letters, Mr. Secretary?

SECRETARY LEAVITT. Mr. Dingell, I had hoped I would have that letter when I came today. I feel like a student who forgot his homework.

MR. DINGELL. Three, Mr. Secretary, not one, three.

SECRETARY LEAVITT. Well those letters need to be thoughtfully considered and within a day or two you will have an answer. I would like to tell you that that is an area that I do see tremendous opportunity. Mr. Stupak mentioned it in his opening statement. I have been in New Orleans a number of times. I am going again next week. I do believe that there is an opportunity to replace what was a clearly dysfunctional--

MR. DINGELL. Mr. Secretary, I just want the letter. I have got other questions I want to ask--

SECRETARY LEAVITT. --talk about the letters.

MR. DINGELL. Mr. Secretary, we are sad. We feel that you are disregarding your friends up here on the Hill since you were not being responsive. This is not the kind of person I thought you are. Maybe it is indifference. It is even possible, although unlikely, that it is arrogance. When are we going to get a response to these letters?

SECRETARY LEAVITT. That is, Mr. Dingell, not something I would want to be tagged with. I think that is a letter I need to personally deliver to you very soon.

MR. DINGELL. Well I look forward to receiving it. I hope that we are both alive and in good health when it comes.

Mr. Secretary, yesterday the New York Times featured a story by Robert Pear detailing private insurance plans, under Part D, that had been using a variety of tools that are designed to make it harder for seniors to get their drugs though the plan claims they are covered. Mr. Secretary, one of the tools that the plans are using is called prior authorization which requires seniors to get approval from the plan before they can get their medicine. This is a trick that has been used throughout the years to prevent people from getting adequate and proper care that the plan should provide and that their doctor thinks they happen to need. There are a number of priority drugs that should be covered at least the cost to one beneficiary on a plan's formula that are still subject to prior authorization.

Mr. Secretary, there are a number of drugs that are on the second level of plan formularies that are subject to prior authorization. There are a number of prior authorization forms in total all across the plans. Mr. Pear, in this article had, in just one plan, 39 prior authorization forms alone. Given that there are some 40 to 50 stand-alone drug plans in each area, that amount could be significant and it could be an unreasonable amount of paperwork for everybody concerned. Now this plan referred

to with 39 prior authorization requirements when it was approved to sell coverage under Part D. Mr. Secretary, what are you going do about this? You have a mess on your hands. You have a plan that will not work. What are you going to do?

SECRETARY LEAVITT. Mr. Dingell, for the others who may not be as familiar with this, we have like any other plan there is a formulary for every plan. And if--

MR. DINGELL. And some people are getting in the plan because the drug is on the formulary and then they find out all of a sudden it ain't.

SECRETARY LEAVITT. And I identified precisely the same problem that you have spoken to and I have--

MR. DINGELL. What are you going to do about it?

SECRETARY LEAVITT. Well I am going to do something about it. In fact--

MR. DINGELL. Well I hope you and I are both alive and in good health when this occurs.

SECRETARY LEAVITT. Well I hope you are still alive by the 30th of March because that is when I intend to have this problem solved. I have told my colleagues at CMS and I have met with the insurance plans and we are working toward a standardization of that process. It is unacceptable in my judgment as well to have that many forms--

MR. DINGELL. Mr. Secretary, you have got thousands of people that are walking away, that stand in line for a long time, without a plan. They do not get their drugs filled. They are charged more than the plan is supposed to charge. The dentists or the doctors or the pharmacists do not know what the plan is or whether these people are covered and they are sent off. You got people who have heart conditions or other serious conditions that cannot get their pharmaceuticals because the situation isn't working. What are you going to do about that?

SECRETARY LEAVITT. Actually, Mr. Dingell, millions of people are having their prescriptions filled every day.

MR. DINGELL. And millions are not.

SECRETARY LEAVITT. I do not know in the millions there may be--

MR. DINGELL. The thousands, hundreds of thousands.

SECRETARY LEAVITT. No, there is not even that. The system is working better every single day. We have worked 46 days under this implementation. We have 250,000 people a day who are enrolling. This system is working. By the end of this year, we are going to have 28 to 30 million people who are participating and...

CHAIRMAN BARTON. Two hundred and fifty thousand a week, not a day.

SECRETARY LEAVITT. That is what I meant to say, millions of people--

MR. DINGELL. I hope, Mr. Secretary you are back here because I do not think you are going to be singing the same song next year.

Mr. Chairman, thank you.

CHAIRMAN BARTON. Thank you.

MR. DINGELL. Mr. Secretary, thank you.

SECRETARY LEAVITT. Thank you.

CHAIRMAN BARTON. Mr. Hall of Texas.

MR. HALL. Mr. Secretary, the Chairman interrupted me before I was through reading to you a while ago. I want to get back to the ovarian cancer problem. You know, within the budget it would seem that ovarian cancer research was lagging behind. We passed a resolution to the House last year that pointed out while other cancer deaths had declined, the same cannot be said of ovarian cancer. And there was a cut in the ovarian cancer research. I just want to ask you what is to be done for the decrease for this disease and how does the Administration propose to advance survivability rates of this and other diseases with the current rate of funding, particularly for ovarian cancer. Can you take a good hard look at that?

SECRETARY LEAVITT. Mr. Hall, I would be very pleased to do that.

MR. HALL. That is all I ask you to do, be responsive on today. Thank you and I yield back.

SECRETARY LEAVITT. Thank you.

CHAIRMAN BARTON. Is Mr. Waxman ready?

MR. WAXMAN. Why don't you call Mr. Pallone and I will have a couple minutes to--

CHAIRMAN BARTON. All right, Mr. Pallone?

MR. PALLONE. Thank you, Mr. Chairman.

Mr. Secretary, I have to say that the system is definitely not working in my State of New Jersey and we continue to experience significant problems with implementation of the new Medicare prescription drug benefit. It continues to take--I mean, basically the State is continuing to pay the drug bills of many low income people who have fallen through the cracks of the new program. To date, New Jersey has paid $113 million in claims for its dual eligibles and State pharmacy assistance programs or i.e. PAAD as we call it or approximately $2.6 million a day. Now despite the incentives from Medicare and Medicaid's efforts to reimburse States, it remains unclear whether New Jersey will be fully repaid under the waiver program designed by CMS. Under the program, CMS will not reimburse New Jersey for its expenditures on behalf of 125,000 Medicare beneficiaries enrolled in the pharmaceutical assistance program or those who are eligible for the Part D low income subsidy. The waiver strictly applies to those low income seniors who are duly eligible for Medicare and Medicaid.

And a large part of the problem, Mr. Secretary, is that CMS has yet to confirm to New Jersey which of the 190,000 PAAD beneficiaries are eligible to the low income subsidy. Presently, only 4,467 PAAD members were automatically deemed eligible for a Part D low income subsidy while CMS's record shows 26,676 have enrolled in the slim D or qualified individual programs. Slim D or qualified individual status should have automatically deemed all 26,767 as eligible for Part D low income subsidy in my opinion.

Also, New Jersey has yet to confirm which PAAD beneficiaries were successfully enrolled in the Part D plan. There is a lot of misinformation regarding the enrollment of these beneficiaries into Part D plan. The State currently has no way of knowing how much was supposed to be covered by either one, the Part D prescription drug plan, two, the beneficiary I call sharing, or three, the State through wrap around coverage. So New Jersey in my opinion should not be penalized for providing coverage in light of this missing information. CMS should reimburse the State for part of the cost that was supposed to be paid for by the TDP just like it is doing for dual eligibles who have their costs covered by the State. I understand that you had ongoing discussions with Governor Corzine about this issue but I do not think have come to any resolution. You can tell me differently. I have a letter here I would like to give to you if I could, Mr. Chairman from both of our Senators--

CHAIRMAN BARTON. Without objection.

[Insert Letter]

Congress of the United States
Washington, DC 20515

February 15, 2006

The Honorable Michael Leavitt
Secretary
U.S. Department of Health and Human Services
200 Independence Avenue, S.W.
Washington, D.C. 20201

Dear Secretary Leavitt,

We are writing to request your assistance in ensuring that New Jersey is fully reimbursed for prescription drug claims that it has paid on behalf of Medicare beneficiaries who are dually eligible for Medicaid, as well as for Medicare beneficiaries who are enrolled in New Jersey's state pharmacy assistance program, the Pharmaceutical Assistance to the Aged and Disabled (PAAD) program. More specifically, we are seeking reimbursement for the coverage these beneficiaries would have received from their Medicare prescription drug plan (PDP) had their information been made available through CMS's computer system from the date of their enrollment in a plan. We also seek your assurance that the Part D waiver reimbursement program will be extended beyond February 15th if claims processing and enrollment problems persist.

Despite the Centers for Medicare and Medicaid's (CMS) efforts to make whole states who have paid such claims, the Part D reimbursement waiver program that CMS has designed will not reimburse New Jersey for its expenditures on behalf of 125,000 Medicare beneficiaries enrolled in PAAD. That is because the waiver will only reimburse states for their costs on behalf of those who are dually eligible for Medicaid and those who are eligible for the Part D low-income subsidy. We project that approximately 65,000 PAAD beneficiaries—less than half New Jersey's PAAD population—meet these requirements.

As you know, in November, New Jersey began submitting Part D enrollment applications on behalf of its PAAD beneficiaries. CMS granted New Jersey the authority to facilitate enrollment on behalf of this population to ensure that these beneficiaries enjoyed a seamless transition into the new Medicare benefit on January 1, 2006. Despite this effort, a majority of New Jersey's PAAD beneficiaries have been unable to access the new Medicare benefit. As a result, the State has stepped in to provide prescription drug assistance to these beneficiaries.

Since January 1, 2006, New Jersey has paid more than $55 million in prescription drug claims on behalf of Medicare beneficiaries enrolled in PAAD. (During this time, New Jersey has also paid $37 million in claims on behalf of New Jersey's dual eligibles.) CMS has not yet informed the State which of the 190,000 beneficiaries are eligible for the low-income subsidy. Additionally, the State has been unable to confirm which PAAD beneficiaries were successfully enrolled a Part D plan and in which plan they are enrolled. Without this vital information, New Jersey has had to pay full prescription drug

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claims for PAAD beneficiaries who should be receiving their primary prescription drug coverage through Medicare.

Consequently, we are requesting that the Part D reimbursement waiver program be revised to provide reimbursement for all SPAP claims to the extent that they should have been covered under Medicare Part D. We also seek your assurances that the waiver program will be extended beyond its scheduled February 15th end date should problems persist in the program.

Thank you for your commitment to addressing these concerns. We look forward to working with you to address this issue.

Sincerely,

Sen. Frank R. Lautenberg

Sen. Robert Menendez

Rep. Chris Smith

Rep. Frank Pallone, Jr.

Rep. Jim Saxton

Rep. Donald Payne

Rep. Rodney Frelinghuysen

Rep. Robert Andrews

Rep. Frank LoBiondo

Rep. Bill Pascrell

Rep. Michael Ferguson

Rep. Steve Rothman

Rep. Scott Garrett

Rep. Rush Holt

MR. PALLONE. It is our entire New Jersey Congressional Delegation and it asks you to revise the waiver program to provide reimbursement for all State pharmacy assistance program claims that should have been covered by Medicare Part D and this press is also made the waiver application which they submitted to CMS. I have two questions. First, can you tell me to what extent the Administration will reimburse New Jersey and other States for these costs and why the Bush Administration has resisted reimbursing States for covering SPAP claims in the first place. It seems logical to me to the extent that Medicare was responsible for covering a portion of these claims, the State should be reimbursed for it. So would you agree with that or, you know, if you could answer, that is my first question.

SECRETARY LEAVITT. Congressman, as you have indicated I have been in on-going discussions with Governor Corzine. I spoke with him last night as late as 9:30 and we have 50 different States that we are working with. I will suggest to you that we have struggled to get New Jersey working well for reasons that are not as clear to me nor them, but we are working on it. And the important thing is that no one is going without their prescription drugs. They are getting their drugs when they go to the counter and we will continue to do that so long as we need to, to make sure that that happens. Let me be responsive to your specific question. We are prepared under this demonstration waiver to assure that New Jersey is reimbursed for anything that a plan would have paid for either a participant in the program or a participant who should have been enrolled in this system that was not identified because of the system problem. They are getting their prescription drugs, New Jersey will be reimbursed. Now New Jersey and a number of other States have State prescription drug benefits that are paid for by State dollars at their choice. We will not be reimbursing them for moneys that would have been paid under a State program unless they would have been eligible for Medicare Part B. We do not have legal authority to do that and it would not seem fair. We honor the fact that New Jersey and a number of other States have chosen to pay for parts of prescription drugs that the Federal program does not and that continues to be their obligation and their payment requirement.

MR. PALLONE. I have a second question in the letter, Mr. Chairman. I do not know--let me say the letter requested the Administration extend the waiver program's end date, which as you know, is today because the State continues to experience significant problems with implementing the new program and the large amount of information that is still missing, it is highly unlikely that all the problems will be fixed today. So New Jersey would be forced to either continue to pay for the cost of drugs which should have been covered on Medicare Part D or let people go without their medications. And obviously that latter is not an option. So Mr. Secretary, you realize that the problem still exists, what steps are you taking to extend the waiver program and reimburse States for the cost that they incur beyond today?

SECRETARY LEAVITT. It is our judgment that under the waiver that New Jersey has signed we can take care of their reimbursement needs and continue to work with them. I think New Jersey will be reimbursed in the way that you have outlined.

CHAIRMAN BARTON. The gentleman's time has expired.

MR. PALLONE. Okay. I will submit this, Mr. Chairman.

Thank you, Mr. Secretary.

SECRETARY LEAVITT. Thank you.

CHAIRMAN BARTON. The gentleman from Florida, Mr. Bilirakis.

MR. BILIRAKIS. Thank you, Mr. Chairman.

Mr. Secretary, back in the mid-60's when Medicare was devised and admittedly it was a plan that was submitted by the other party, certainly Congressman Dingell's father was a major part of that procedure with nine of us often times and had a lot of problems. I do not know the date on the floor of this Part D of Medicare--we lose an awful lot of the clippings from the newspapers regarding these problems. And I dare say that if those who oppose that program and if the media, particularly the editorial letters who may or may not have opposed that program, if they had basically slandered it because of the problems, the complexities, and that not, we probably would not have Medicaid today. And what is happening with this Part D. So let me ask you, will every Medicare beneficiary who wishes to enroll in the Part D plan be able to do so by the May 15 deadline?

SECRETARY LEAVITT. I will resolve this to make certain everyone has an opportunity. It is a voluntary program. We have 90 days longer. We are hopeful that Members of Congress will join with us in helping people enroll. We are enrolling about 250,000 a week--

MR. BILIRAKIS. You said 90 days longer--

SECRETARY LEAVITT. No, no, we have roughly 90 days left between now and the 15th of May.

MR. BILIRAKIS. Okay.

SECRETARY LEAVITT. We feel quite optimistic that it can be done. If the Congress chooses to extend the period that will be a policy decision that you will make.

MR. BILIRAKIS. Yeah, if it turns out as a result of information available to all of us--you and to the Congress--that there are people out there who have not really decided yet who probably will want to and whatnot, would you oppose extending the deadline?

SECRETARY LEAVITT. Well, we will make known to you at the time any ramifications such a policy change would make. At this point, we are moving with the assumption that it would be May 15. We think we can accomplish the task period, but at the end of that time if you choose to do so, then obviously we will follow along and do our best to make certain that people are enrolled.

MR. BILIRAKIS. And I realize that we should not even be talking about doing so this early in the game obviously. But the point of the matter is that we want to make sure that everybody has that opportunity and so, HHS would be unbiased and honest in terms of telling us or sharing with us if there are people out there that probably would need more time. Is that right?

SECRETARY LEAVITT. Mr. Bilirakis, our shared goal, I think everyone in this room is to make certain people have prescription drugs. For the first time in our Nation's history a senior should not have to worry about having their prescription drug costs wipe out their savings. We are working very hard to make certain people have opportunities to purchase a plan and we hope we can all work together in whatever way is necessary to accomplish that task.

MR. BILIRAKIS. So regarding the budget, NIH budget is at last year's level, the National Cancer Institute will be reduced by $40 million this year. Comments?

SECRETARY LEAVITT. Well, we are spending $4.8 billion a year on cancer research, that is up substantially from earlier in 2001 and the whole NIH has been doubled since 1998. We are committed to continuing to make progress on cancer and believe we can. Earlier I mentioned the fact that much of our new investment at NIH is in the area of genetics and the environment. We are also working with what I call the critical path project which is to dramatically cut in the amount of time it takes to have a drug that comes from research able to go from bench to bedside. We are working to make it more personalized, more preventative, and more preemptive. All of those are new objectives of NIH and we are targeting the money in that way. Would it be nice if we were able to dramatically increase the spending in NIH, yes. And do we think in future years that will be possible, I do. But this year, we are doing deficit reduction. We have been able to keep it flat and that was the judgment we made.

MR. BILIRAKIS. So were the National NCI people, the National Cancer Institute people coordinated with before you decided to reduce the project by $40 million?

SECRETARY LEAVITT. Well we have had extensive conversations with the community. Obviously no one is enthusiastic about not having a big increase.

MR. BILIRAKIS. Yes.

SECRETARY LEAVITT. And we hope in time that our continued investment will be possible. Right now we are reducing deficits and being able to keep it flat was something that was very important to me and in the sense of being able to not see substantial cuts, $40 million is a lot of money in specific terms but in the context of a $30 billion budget at NIH it is relatively--

MR. BILIRAKIS. Many of us are concerned about that and we thank you, Mr. Chairman.

MR. DEAL. [Presiding] Mr. Waxman?

MR. WAXMAN. Thank you, Mr. Chairman.

Mr. Secretary, just to follow up on Mr. Bilirakis' question, you hope to put more money into NIH but now we are doing deficit reduction. The President said he is going to halve the deficit by 2012. Many of us doubt that is going to be possible. Should we look to 2012 to find more money into the research of NIH and NCI?

SECRETARY LEAVITT. The good news is, Mr. Waxman, we do our budgets one year at a time.

MR. WAXMAN. Well especially when you cut back on some of this research we do not just lose one year but we lose a lot of research and hope for the future.

Now I want to get back the Medicare drug proposal because I think the rollout has been an absolute disaster. People were turned away without their drugs. Pharmacies could not determine a person's eligibility. Sometimes they waited for hours on the phone just to try to get through to the plans. People were charged too much. Many vulnerable Medicaid beneficiaries including people in nursing homes were assigned a plan randomly and then it turned out to be inappropriate. Some of these things are implementation problems and they will get worked out as time goes by but some of them are really based on the flawed concepts of the bill. There have been a lot of legislative proposals out there designed to address some of the most immediate problems. I would like us to have a fundamental fix where we have a drug benefit as part of Medicare itself. But since we are not going to get to that, the budget that is submitted to us has no legislative proposals to remedy any of the problems which have become so obvious. Is it your position that this program is working just fine? Do you take the position that no legislative fixes are necessary to address the problems we are already facing and the ones that we will obviously see on May 15 if we do not change the deadline and remove the penalty?

SECRETARY LEAVITT. Mr. Waxman, we are 46 days into its implementation, the biggest change in Medicare's history. No logical person would see a transition that complex and that large happening without some unexpected problems and we have had them. We make no excuses. The measure of our success is not what it looks like after 46 days it is what is going to look like when it is fully operational.

MR. WAXMAN. You do not see any legislative changes now?

SECRETARY LEAVITT. I do not see any change that I cannot do regulatorily right now. Now I will tell you that we are already beginning to look at what I refer to as a Part B 2.0 that is the next plan year. And I think you will see substantial changes evolving because the market is evolving. The market has driven the cost down from about $37 a month to $25.

MR. WAXMAN. Mr. Secretary, I appreciate your conclusion and I gather that is the statement of the Administration that they are asking for legislation. If you decide to, we are here and we certainly want this drug system to work. And I want to give you an example of a problem that we had come up a number of times especially at a briefing that I had recently. You have people on Medicaid who are also on Medicare, they are called dual eligibles. And they had a program under Medicaid where they were provided drugs. It was a stable system, they knew what was covered and their drugs were going to be covered. Now they are shifted over to Medicare. Yet on Medicaid there was a limit on what the drug companies could charge. It was the best price because of the rebates the companies had to provide. Well now that they are under Medicare there are no rebates. There are no limits. And it seems to me that what we have had because of this shift is a multi-billion dollar increase in the money that the drug company is going to make. Dr. Steven Shandomyer of the University of Minnesota estimated the drug prices for these dual eligible beneficiaries are now 20 to 30 percent higher than when they were on the Medicaid. So it seems to me that we are talking about a windfall some say as much as $30 billion for drug manufacturers all at the taxpayer's expense. Can you explain the rational of this to me? It makes no sense for the Federal Government to be paying millions of dollars more for drugs they were getting at a discount price prior to January. What is your response to that?

SECRETARY LEAVITT. Well the prices for pharmaceuticals are going down, not up and this program is representing a substantial savings for every senior who enrolls. This is a good deal for seniors. I mentioned to you--

MR. WAXMAN. Well not for dual eligibles. They are getting less of a benefit and it is going to cost the taxpayers more money.

SECRETARY LEAVITT. I would disagree with that assumption.

MR. WAXMAN. Well, I am going to take it then that you disagree with me and I would like you to look at it more carefully.

The last point I want to raise in the few seconds I have left is that generic drugs play an important role in lowering the prices and yet we have seen a drastic increase for generic drug applications. At the same time there has been a dramatic decrease in the number of people at the FDA to process these drugs and there is a 16 month time lag to review generic applications and then the budget does not call for an increase in the amount of money for FDA to ever meet its performance standards. Do you think that there is any way we can get an increase in the number of staff to address this backlog or are we going to find ourselves falling further and further behind in getting generic drugs approved?

SECRETARY LEAVITT. Mr. Waxman, we are in agreement actually as you know with the need for us to continue to enhance the approval of generics. We have, in fact, made substantial increases in years past in our staff and we have been able to increase dramatically the number of approvals. We do have a backlog. They tend to be a backlog of applications that are on medications that there is already one, two, or three in that category and we are anxious to get to as many different categories as we can at one time. We share your goal of having more generics. We think it is an important part of the reason the prescription drugs costs are coming down.

MR. WAXMAN. So you are prioritizing generics based on the categories?

SECRETARY LEAVITT. We want to make sure we have generics in every category. If we have one that is--I am told that if we have one which there is already three in a category, we are better off approving one or two that we do not have, where we do not have approvals than just having a fourth or a fifth added.

MR. DEAL. The gentleman's time has expired.

Mr. Upton?

MR. UPTON. Mr. Chairman. Again, welcome, Mr. Secretary and I just want to thank you from what I heard from a number of different answers particularly the answer to Chairman Barton because I too hear a lot from my providers. My hospitals, my nursing homes, equipment suppliers, and others all are concerned about the across the board cuts in inflation updates. That is usually what they talked about. And I think having a new system put into place where you are looking at a number of different pilot programs would solve some perennial problems that need to be resolved. I look forward to working with you to see that that can happen in a constructive way.

I want to follow-up just briefly on a question that Mr. Bilirakis asked. He asked specifically about perhaps extending the deadline from May 15 for folks to sign up for Part D. You answered it well. But the question that I have is what about the idea, whereas plans can change as they provide the medications to the beneficiaries but, in fact, the beneficiary is not able to change from one plan to the other. Michigan has, I think, 42 different plans now and someone's own medication may change, the plan may change, and as I understand it, they are locked in for a year. Is that right, into that plan, prescription--more that you are having so many enrollees sign up virtually every week, hundreds of thousands, millions across the country. What would be the problem with allowing folks as plans change, they can change their plan for the beneficiary, what would be wrong with allowing the beneficiary to change the plan maybe a limit per year or something along that line so

that they can make better accommodations for their own personal needs? Would the Administration have any objection to that if we were able to pursue something like that?

SECRETARY LEAVITT. Mr. Upton, there are very good reasons that I will enumerate in a moment why it is valuable to have the capacity for a plan to change their formulary, many of which could endure to the benefit of a beneficiary. It is important to acknowledge that this problem is talked a lot about. People worry that a plan could try to change their formulary. In order to do that, they have to go through an extensive process that includes the approval of HHS. Now granted we are only 46 days into this but we have had exactly zero applications to change formularies and put another way this is a problem people are concerned about but it is not happening. On the other hand, there are good reasons. If there are, let us just assume that a generic drug was approved or one was clearly it was a drug safety problem. A formulary needs to be changeable with the process in order to protect the beneficiary as well as to provide equity for the plan. They cannot do it without approval. They have to get HHS approval. In order to have approval, they have to go through an extensive process including an independent panel, demonstrating that it is in the interest of the beneficiary. So this is just one of those problems where people worry about it and I understand that, but it is just not happening and therefore, I believe it is overstated as a challenge.

MR. UPTON. Well that is good, thank you.

As I mentioned in my opening statement, I talked a little bit about health information technology and I am very supportive of the budget you have presented in that regard. I also chair the technology subcommittee. Are there any statutory changes that we should be taking a look at to make sure that these budget increases can be accommodated?

SECRETARY LEAVITT. We are proceeding in the absence of Health IT bill that is currently being discussed, to develop standards. If your question is are there things that could help us in that process legislatively, the answer is yes. But we are making good progress. We will see by the end of this year substantial deliveries or deliverables in important areas that will drive this forward.

MR. UPTON. Well I look forward to working with you and your department. I appreciate your being here this afternoon and I yield back the balance of my time. Thank you.

SECRETARY LEAVITT. Thank you.

MR. DEAL. The Chairman yields back.

Mr. Rush is recognized for five minutes.

MR. RUSH. Thank you, Mr. Chairman.

Mr. Secretary and I have got three questions I want to get to rather quickly. My question number one is would you be in favor giving all the angst and confusion around signing up for the Medicare Part D, would you be a supporter of extending the deadline from May 16 to another date, May 15 to another date?

SECRETARY LEAVITT. As we have spoken earlier, we are seeing enrollment of more than 250,000 a week. We have 90 days left. We believe that we can accomplish this task. If in fact Congress chooses to extend it, obviously we will continue to enroll people. That is a policy decision that will need to be made by the Congress. I will say that people need deadlines. If we did it indefinitely, people will not feel the need to investigate this. Now that is a decision or a judgment that the Congress will need to make. I believe by the time we have reached the period of enrollment, we will have reached our goal of 28 to 30 million in the first year. This is not an easy population to find at time and I am sure there will be ongoing enrollment that will be valuable.

MR. RUSH. Well, in light of that, can you or your office provide some members of this committee on a district by district basis how many eligible people have already signed up for Medicare Part B?

SECRETARY LEAVITT. Yes, I expect that we will deliver that information to you, each of the Members of the Congress some time next week. It will not only demonstrate how many are eligible but it will also show how many have actually enrolled.

MR. RUSH. Okay.

SECRETARY LEAVITT. And I hope that information will be of value.

MR. RUSH. Thank you. In your opening statement, you said that you had put an emphasis on prevention in this budget and I appreciate that emphasis and I share your belief that this is cost effective in the long run. But giving this emphasis on prevention, can you explain why does the budget, your budget eliminate or make steep cuts in prevention programs such as the Universal Need and Learn Program, the Preventative Health Services block grant, the Community Services block grant, even the Health Professionals Training Program or scholarships for disadvantaged students? Can you explain to me why those cuts here are those preventative in nature?

SECRETARY LEAVITT. Earlier I reflected the fact that during my period as governor I became quite conscious of the fact that any time you are dealing with reducing budgets you are dealing with a conflict between the good programs. And there are many of those programs that I understand their purpose and I understand why people feel passionately about them. I laid out a series of investment principles that talked about things like whether we are targeting our investments or whether we are going after prevention. And without responding to all of those, I will tell

you that the reasons that I did it would have been embodied in those principles, one that you mentioned that would I think bare reflecting on. Also as governor, I came to understand the value of having the block grants that the social services or the community services block grants. At various times during my time as governor I wrote to Congress to advocate for them. So I find myself as Secretary now on the other side of the table. Well the governors like those and they like those because they are very flexible and you can put the money where you need it. Frankly during many of the years when most budgets went up, it was times in which the States were having very difficult times financially. But the States are doing better right now and we are cutting deficits and I made a decision that during this period I could not measure the impact they were having. The States are in better shape financially than we were and I made a decision to make that as one of my cuts. Now you may disagree with that judgment but that is the basis on which I made my decision.

MR. RUSH. So you still characterize this budget as being a pro-preventative in nature?

SECRETARY LEAVITT. Oh, absolutely. I have made investments that have focus on these programs and many of the cuts that you reflect some of them are not in my judgment oriented to prevention. In some cases, they are oriented toward covering a large general population but were not targeted, were not preventative, and I made those judgments.

MR. RUSH. I applaud your increase in the dollars allocated for community based health clinics. Can you explain to me what is your vision in regards to community based health clinics? I understand that you are proposing at least 80 new community based health clinics?

SECRETARY LEAVITT. We actually--and I share the President's vision here. I want to see community health centers expanded, 1,200 of them. In fact, this budget has enough for 302 centers to either expand or to start new ones, 80 of them will be in low income or in specifically targeted low income counties. I see this as a way in which we can provide access to the basic health care to literally millions of people and for that reason we have that is a good example of the targeted program, one that clearly gives people a medical home in which they have prevention. That is a good example of the kind of decision I made based on those principles.

MR. RUSH. Mr. Chairman, I yield back the five minutes of my time.

MR. DEAL. The gentleman yields back.

Mr. Secretary, my turn now I suppose. I have a couple of questions. First of all, we have heard references made on both sides to situation in the Katrina aftermath and I would like for you to comment generally on where you think we are in terms of compensating those pharmacists and

other providers who feel that they have been left out in the process and does this budget include specific dollars to address that problem and if not what kind of information can you give us with regard to resolving that question?

SECRETARY LEAVITT. The issues related to Katrina were in large measure dealt with in our Deficit Reduction Act where as much as $2 billion was allocated for us to deal with uncompensated care and in some cases to use whatever was left over to help rebuild the health infrastructure. Comments have been made already about the need to do that. I will not repeat those except to say that we see a grand opportunity. The health care system there frankly did not function very well before. Now we see an opportunity to develop an extraordinary health care system that will show the way for many others in the future.

MR. DEAL. So those funds in the Deficit Reduction Act would be more than adequate to cover the claims for care that some might claim are still uncompensated?

SECRETARY LEAVITT. We believe they are.

MR. DEAL. All right, thank you.

As you know, this committee has held two hearings on the issue of our preparedness for a potential pandemic influenza outbreak and I want to thank you again for testifying at our hearing we had back in November. And I know that you have been working closely on the implementation of the plan itself. We appropriated money during the last steps for the beginning of that process and I believe there is money in this proposed budget for additional funding to go forward with a further preparedness plan. Would you sort of outline for us what you think the steps we need to be taking during this next year are and how the funds that you are requesting would implement those steps?

SECRETARY LEAVITT. As you are aware, the President requested a $7.1 billion emergency supplemental. The Congress funded $3.3 billion of that in the course of the last deliberations. Those dollars are being used for a combination of different efforts. One would be State and local preparedness. I am in the middle of--I am not in the middle I am at the beginning of 50 State summits. I have been to ten and we have 36 of them either held or being planned but we will have 50 State summits where we are rallying local communities, business organizations, community groups, churches, schools, colleges, to prepare and $350 million will be used for that. A large measure of it will be used for international and domestic monitoring so that we are able to bulk up the capacity we have to gather information about when the disease strikes and how broad it is. We are also purchasing antivirals. We will reach by the end of 2006 our targeted 20 million courses in stockpiles and we are developing jointly with the State's distribution needs. We are also on the

well advanced stages of developing new technology, cell based technology for vaccines and additional capacity to manufacture it. As to the next phase, it is basically a continuation of what we are now doing. We are in the process of doing RFPs, we have done one RFP for different manufacturers to help us build capacity and new technology. What we have now will get us through the first phase of that but we are confident there will be promising technologies that we will need to nurture through it. So this gets us into the game but we are clearly going to need the help of Congress and being able to fulfill that plan and be able to complete our preparation. I will say, Mr. Chairman, that when it comes to a pandemic we are overdue and we are under prepared and there is a lot of work going on right now but we have still, we are still a long ways from the point of being able to rest with the assurance that we are ready.

MR. DEAL. Am I correct, though, that there would be other funds under the Public Health Security Act that could also be used for some of these purposes that you have outlined?

SECRETARY LEAVITT. Well we clearly recognize that every part of our public health infrastructure needs to be tuned in a way that it will meet multiple demands. And so we are working to create a sense of synergy on what we are doing here with what we are doing in the other areas of concern such as bioterrorism or any natural disaster. We are not just using these pandemic funds for pandemic. We are generally expanding the preparation that is available to Americans for all natural disasters or all disasters rather they are manmade or natural.

MR. DEAL. Now in conclusion as one who has just toured the new facilities of the CDC in our State, I was very impressed with the improvements and the technology that is going to go forward in their future efforts there.

Mr. Engel, you are recognized for five minutes.

MR. ENGEL. Yes, thank you, Mr. Chairman and thank you, Mr. Secretary. It is not easy obviously testifying before the committee and I want to just again reiterate my disappointment in a lot of the things that my colleagues have mentioned about the budget but I welcome you.

I want to first talk to you about a letter that I sent along with every colleague in New York, Democrat and Republican, all 29 of us signed a letter to you last October expressing our concerns about the Ryan White Care Act and funding concerns. We--it is four months later and we have not received a response to that letter. I would say respectfully that since every New Yorker again, Democrat and Republican, signed onto the letter, I think that four months is really too long to wait for a reply and I would hope that we could at least get an answer to some of our questions as soon as possible.

As you know, no State spends more than New York to care for its residents with HIV and AIDS, over $3 billion last year. Unfortunately one of the epicenters of the AIDS crisis in the United States is in New York and we have always viewed this funding as a partnership between State, cities, and the Federal Government. And we rose to the occasion bringing the financial resources to finance HIV services long before the Federal Government committed substantial resources for HIV. We are concerned because we think that the intent of the funding and the way it is going to be done sort of borrowing from Peter to pay Paul and we feel that reducing the Ryan White resources that State's use to care for people with HIV and AIDS punishes those States that have been forthcoming in terms of money and we think that is really the wrong way to go. People living with AIDS and HIV is increasing, and the demand for the Care Act services there is no justification we feel to hurt New York because we have done the right thing. And would it not make more sense to the Federal Government to prioritize significant new dollars for HIV/AIDS care rather than pitting regions against each other in the fight for dollars. I do not want to go into everything. I do not have the time that we said in our letter, but it was a very well written thoughtful letter and I think again the fact that 100 percent of the New York delegation, you know, it is hard to get 29 members to agree on anything, but we agreed on this and I would just appreciate, and I say this not to embarrass you because I know you are obviously working as hard as you can but we would like an answer to our letter and I would like you to comment on some of the questions that I raised.

SECRETARY LEAVITT. Thank you, Congressman. I am disappointed that your letter has not been responded to and I will find out why that is.

MR. ENGEL. Thank you.

SECRETARY LEAVITT. I would like to make clear that we are supportive of the reauthorization of the Ryan White Care Act. As you are probably aware, we have laid out a series of principles that we think improve our capacity to respond and we want to serve the neediest first. We want to focus on the lifesaving and life extending services. We are interested in increasing our prevention efforts going again back to prevention. In keeping with that, I would like to add that in this budget we are proposing a substantial new initiative that the President has announced that will test an additional 3 million Americans and will take as many as 4,400 people off a State waiting list. We see that as a significant new investment in this area, particularly during a time when we are working so hard to reduce deficits. I mentioned it early today as one of the new initiatives that we have worked hard to find other ways and places where we could reduce them in order to fund that. And so I wanted to mention that given the fact that I am sure there are a lot of

programs that people are unhappy about. I wanted to make sure I got a chance to mention this one and I am sure would be favored to you.

MR. ENGEL. I would like to thank you. I have obviously some more questions which I will submit but they are all stated in the letter.

I want to talk to you about SAMHSA. There is a SAMHSA funded Substance Abuse Prevention Program run by Bronx Aid Services. They came to visit my office in Washington, D.C. Kids in the Bronx which I represent have the highest rate of substance abuse in New York City and the program works to increase self esteem, counseling, and opportunities for these kids. There are huge cuts to SAMHSA's budget and many programs are receiving cuts or flat funding this year and again I want to just express my dismay at getting such large cuts to SAMHSA of this treatment opportunities for substance abuse and mental health is so devastating and I am wondering if you could comment on that.

MR. DEAL. This will have to be the gentleman's last question.

SECRETARY LEAVITT. I will just acknowledge that we are focusing our efforts on the transformation of the SAMHSA which will allow us to deliver better with the dollars we are investing and I am quite enthusiastic about this transformation effort and recognizing the limits of time obviously with that.

MR. ENGEL. All right, thank you, I just wanted to point and I have no other questions but there is a $71 million dollar cut so we think that is overboard.

Thank you, Mr. Chairman.

MR. DEAL. The gentleman from Kentucky, Mr. Whitfield.

MR. WHITFIELD. Mr. Chairman, thank you very much and Mr. Secretary thank you for joining us today. We all appreciate the great job you are doing a very difficult position.

But first I want to mention a couple of things to you. The first thing I want to mention to you is that we have heard a lot of discussion about budget reductions and loss of funds. And the first thing that I want to talk to you about is an offer that we made to give you money and you all did not take it. And I want to point out specifically what I am talking about. Appropriators back in 2001, without any authorization from any authorizing committee, particularly this one that has exclusive jurisdiction on the issue relating to prescription drug monitoring programs, started funding unauthorized programs and over the last three years have received something like $33 million. This committee unanimously passed a National Drug Monitoring Bill that was passed on the House floor. It was passed in the Senate by overwhelming majority. The President signed it in August. We sent letters to OMB to Josh Bolton and said because this is a new program at HHS and we work closely with HHS staff and even prior to your assuming the

responsibilities of Secretary, we worked with Secretary Thompson who was very supportive of it and we were shocked really that there was zero dollars in authorized program under HHS to implement this new program and there was $10 million over Department of Justice for the old unauthorized program. And I would just like to urge you to work with us in trying to correct that error and get it over at HHS where we think it belongs, and after many hearings on the subject, we found some flaws in the DHA Program and I would ask you would you be willing to work with us to get additional money for this program?

SECRETARY LEAVITT. Mr. Whitfield, I am aware of this. And I am most aware of it because we like the program. I am also conscious of the fact that there is this ongoing discussion as to whether or not it ought to be in the Justice Department or at HHS, and the Chairman has made very clear to me where he thinks my allegiances ought to be and we just need to work out among the various committees how best to fund this. We like it, we will be cooperative, we will do all we can. We need your help as well on--

MR. WHITFIELD. Well when you are saying an ongoing discussion, who are you referring to?

SECRETARY LEAVITT. Well I recognize there is a little bit of a jurisdictional discussion going on between the committees of Congress and also we are very anxious to see the program succeed.

MR. WHITFIELD. Yes. You know our view on this is the appropriators never had it authorized, not all of us are shocked that appropriators would do something like that, but this is the committee with jurisdiction and we did it overwhelmingly, passed it unanimously, and I know that you are supporting us so hopefully the Chairman and the rest of us can let our leadership know that we feel very strongly that the money should be at HHS and not DOJ so thank you for that.

The second issue I would like to raise, and I am not the only member of Congress that has been focused on this issue, there are also a number of Senators as well and we have had discussions with Dr. McClellan and that relates to the calculation of the average sales price for prescription medicines under Part B of Medicare used by oncologists and whether or not service to these should be included in that calculation. And in the letter that Dr. McClellan wrote to some groups, he made it very clear that it was the position of CMS that these service fees, if they are valid service fees, should not be a part of the calculation of average sales price. But that has never really been placed into a regulation at HHS or CMS and I was just curious do you have any thoughts on that particular matter?

SECRETARY LEAVITT. Your recounting of the history of this is consistent with my own understanding. It is also my understanding that

the regulations are under consideration currently and that we are working through that. I think Dr. McClellan has stated the department's policies clearly as I could.

MR. WHITFIELD. Well I hope that they will take some action on it. They have been working on it for some time and I do think it would clarify and even help alleviate a number of problems and any influence that you might have over there if you agree with us we would appreciate it.

SECRETARY LEAVITT. Thank you. Well I do not know if I have influence there, I will test it out.

MR. DEAL. Thank you. And Mr. Whitfield I am going to weigh in on that, too. We passed a good bill and they are our friends on appropriations. They need to understand that once we have done it, that we expect them to receive the wishes of the authorized program. I will be working with you, Mr. Lewis, Mr. Rogers, and the ranking members of the minority side to make that happen.

MR. WHITFIELD. Thank you, Mr. Chairman.

MR. DEAL. Mr. Markey?

MR. MARKEY. Thank you, Mr. Secretary very much for coming here today.

You have got a very tough job. Donald Rumsfeld says to the President, I need a massive increase in defense spending, he gets it. Secretary of Treasury says to the President I need a massive cut in taxes, he gets it. In line comes health care, you are next, you get to deal with what is left over and as a result you have to make cuts and you have to make tough decisions because it is not given in this Administration the same priority that I am sure you would give it.

So we have a situation here where you were talking about what happens if there is, if it is unchecked what happens to the Medicare budget. What happens to the Medicaid budget in terms of the percentage of gross domestic product that it will consume in the years ahead. What is happening in this budget though, Mr. Secretary, is a cut once again in the NIH research budget including inflation. And there has been a 9 percent cut in the purchasing power of NIH over the last three years that is a reduction. Now I was born in the same month as President Bush and President Clinton and we are the first baby boomers. And there is going to be millions and millions coming every year after us and the estimate is that 16 million of us will have Alzheimer's, 16 million of us. Now it seems to me that the best cost containment we can have is if we invest the extra few billions now to find a cure to work on prevention rather than what is estimated to be a $100 billion a year bill for our baby boomers with Alzheimer's in nursing homes under Medicaid in a relatively short number of years. This year it is $20 billion for Medicaid

for Alzheimer's patients. At that time, all the baby boomers are in today's dollars. In other words, 20 percent of today's defense budget would go just to one disease, Alzheimer's and Medicaid much less all the other costs related to Alzheimer's. So Mr. Secretary, do you not think it makes sense for us to increase NIH research, to increase the likelihood we find the cure, that we find a preventative way of avoiding the trillions of dollars which are going to have to be spent just on the treatment and care for Americans, baby boomers who have Alzheimer's. That would be one disease would be $150 billion a year every single year, trillions of dollars. Would it not make sense for us to make that investment today with additional research and the same way that the preceding generations had 36 years of unchecked increase in NIH research for heart disease and stroke and for cancer that has actually made it likely that the average baby boomer sitting here if they are healthy today will live to 85 to 90. In other words, the cost for Alzheimer's is going to be explosive because of the success of the preceding generations of research. So can you explain to me how the White House can give you a budget but kind of forces you to cut NIH research when I know you know that the best thing you could do is to engage in that research in that prevention to avoid the long-term costs which are hundreds of times higher than any budget saving this year or next year or the year after.

SECRETARY LEAVITT. Mr. Markey, you pointed out the fact that Medicare and Medicaid make up a huge portion of our entire national budget. We often refer to bills as cuts in the proposals we have made but the reality is we will see dramatic increases both as a percentage and in real dollars in that area. And the point you have made is that many of those expenses will be driven by demographics that are very clearly in front of us and that if we can find ways of preventing those illnesses that it will ultimately create somewhere to our benefit. That is a strategy that makes sense. It is a strategy that we have followed. It is a strategy that I suspect over time we will continue to follow. This is a year which we are doing deficit reduction and we have worked hard and fought hard to be able to protect the integrity of the funding of NIH that we have--

MR. MARKEY. Well wouldn't you prefer honestly to have to have $5 billion less in tax breaks for the upper 2 percentile and $5 billion more in research for Alzheimer's and Parkinson's and these other diseases that are going to hit just about every family in America in terms of changing and altering the whole history of those families. Wouldn't it be better now to rather than those tax cuts to invest in that research and that prevention because of the payoff we know will come because we have seen it in health, in heart disease, we have seen it in cancer. Wouldn't it be better for this generation to make that same investment and to not have those tax cuts?

SECRETARY LEAVITT. What I feel very good about is that we are targeting our investments of NIH in a way that will go across not just Alzheimer's but across all disease categories. That we are going to be able to begin to explore the value of the human genome and the environment which I believe will in fact have a substantial impact on the demographics you have spoken of. It is a new way of investing our dollars and we are deploring in the context of our critical path initiative, our road map initiative, and other efforts to make certain that we are focusing on the--

MR. MARKEY. I know what you are saying, Mr. Secretary, but after 36 years of NIH budget increases, we now have a 9 percent cut in purchasing power over a three year period. It cannot have anything other than a negative long-term impact on the likelihood that we are going to find a cure for Alzheimer's and Parkinson's which tragically will probably affect unfortunately about, you know, a third of the people who are sitting up here today. And I just think that in the long run whatever tax cuts, you know, the White House, President Bush, and Vice President Cheney might want to give to wealthy people has to be dwarfed by the epidemic, I mean literally an epidemic which is going to hit America in Alzheimer's and Parkinson's.

SECRETARY LEAVITT. But it is important to remember we are still investing $645 million a year. It is not as though we are terminating our investment, $645 million a year is not chump change, it is a big investment and one that--

MR. MARKEY. But you are cutting the National Institutes of Aging the baby boomers retiring--

MR. DEAL. The gentleman's time has expired.

The gentleman from Georgia, Mr. Norwood.

MR. NORWOOD. Thank you very much, Mr. Chairman and Governor, thank you so much for being with us.

Let me just ask a quick question. I know you have only been here a year and I bet you have figured out already that in this town everything is measured by how much you spend and if you do not spend more things are going bad rather than measuring things by what the results are. We are trying to get to that but most people still believe if you do not add more money every year then you are really not doing things. Now the comment was made there would be 9 percent cut. Is that correct?

SECRETARY LEAVITT. We will continue to see dramatic increases in investment in all those categories. What we are talking about is allowing programs to grow more slowly.

MR. NORWOOD. To my knowledge, we have doubled NIH in the last 10 years, doubled. And all we are really saying as I understand it is okay one year in order to try to get all this spending under control they are just

simply not going to get an increase. I hardly think that is the end of the world. Certainly they ought to be able to manage it so it is not the end of the world. If they cannot, they need to change the focus at NIH.

SECRETARY LEAVITT. I have learned over time, I have been through a number of budget years where things were not as good as others. I have learned over time that it is during these periods where we find new ways and improved ways to invest and I think what I pointed out earlier where we are beginning to invest in trans-institute initiatives that benefit every disease category. It did not take me a full year to figure out that at NIH there are 27 institutes--

MR. NORWOOD. Right.

SECRETARY LEAVITT. --all of which are devoted to some kind of disease or a major component of health. Every one of them has things in common and if we are investing generally in the basic science of genes and the environment and other things it helps us.

MR. NORWOOD. I have three questions and I will probably never get to them but I will try. One of the things that has concerned me in the budget is that we ignore the fact that our physicians treating Medicare patients are going to get a cut of 4.6 percent and that means we will have to fix it because that is not just a reasonable thing to do. And then we also ignore the fact that MedPAC has recommended the 2.8 percent increase, which I happen to think MedPAC is a pretty darn good outfit. Now my understanding is, my feeling I guess I should say is, that at least CMS thinks we are going to solve all this problem by going to pay for performance and I am just not so sure we are going to solve all these problems. I understand the goal of pay for performance and I understand there can be some good things that come out of that, but a lot of the legislation that we are hearing about or listening to does not talk necessarily about quality of care but it talks about efficiency. And I am concerned that if we write that language wrong, we are going to be actually rewarding our physicians for providing the cheapest care and not necessarily the best care. Now I do not believe, and you can correct me, but I do not believe you would think that physicians ought to be rewarded for providing cheap care unless there are strong measures at CMS that show that they are also providing quality care. In other words, it needs to be quality care for less money for this to work. And if your crew has any suggestions about legislative language that can assure efficiency measures that are going to be created out of this, I really would appreciate it. And I have listened to Dr. McClellan for hours on end. We have talked about this and the potential unattended consequences there I think are very, very high, and if we are going to wait to get to pay for performance before we ever solve the physician payment formula, we are going to face this every year. Why don't we

face up to the fact that we are losing docs now because of payment in Medicare and let us give a modest increase as NIH keeps talking about wanting and everybody else wants Federal employees wants, give them a modest increase so we can work this out.

Next question, I just need to go on. What are you going to do, what is HHS going to do with at least the insurance plans in Part B that are engaging in inappropriate conduct? And since we have no patient protections, I am fairly certain we can count on that and that is going to affect the pharmacists as it today affects the dentists and the physicians. And I just hope you guys are going to be ready to get in there and fight for them.

SECRETARY LEAVITT. The plans need to keep their commitments and if they do not, we have regulatory authority and we will use it. One example of that, plans are required to have a 24 hour response. There needs to be an adequate or rather let me restate that. They have a requirement to have a 1-800 response. We are now inventorying to find if they all do. If they do not, you can count on the fact that I am going to use the regulatory authority given to me in the law to assure that they start.

MR. NORWOOD. Well they are already out there telling dual eligibles oh no, you are not a dual eligible you need to sign up for this plan. They are doing that now. And in conclusion, I think you are doing a great job with this. We are 44 days out. Pharmacists of course are upset and confused and got a cash flow problem. But to a man when I talk to them or a woman, they tell me this is going to get better. We think in time this is going to get better and this is going to work itself out. I think it is, too.

MR. DEAL. The gentleman's time has expired. We appreciate the comments.

Mr. Green of Texas.

MR. GREEN. Thank you, Mr. Chairman.

And again, thank the patience of the Secretary. We only have these opportunities maybe a couple times a year so thank you for listening.

Mr. Secretary, we all know that the President, you and the President share commitment with members on both sides of the aisle for a community health center program. I have a health center in my district, Pasadena Health Centers, one of the 88 HRSA's that announced that it received new access points beginning last December 1. And I understand the funding date was pushed back because Congress did not finish the work on appropriations until late December and yet to date this money has not been approved and appropriated and has not gone out the door. Community health centers like Pasadena operate on a very slim margin. They provide terrific care and are uninsured in our communities and they count on this grant funding to sustain their operations. I know

you and Dr. Duke at HRSA are committed to delivering the funding so can you give us a date certain when the centers may receive this grant funding and more importantly when this money is delivered will it be retroactive to December 1?

SECRETARY LEAVITT. When I was in Houston and you mentioned on Labor Day we talked a little bit about community health centers and the mayor, actually Mayor White at that point indicated the impact that the evacuees were having on your city.

MR. GREEN. In fact, you actually backdated for those five new centers in our area.

SECRETARY LEAVITT. Are you talking about those funds or are we talking about the funds after that point?

MR. GREEN. No, we are talking about the new center funds that they were supposed to receive December 1 for that designation.

SECRETARY LEAVITT. I do not know the answer to this. I am going to have to get back to you.

MR. GREEN. Okay, if you could because I know that center happens to be in my district and we have four other ones and I am sure the rest of them around the country are calling their Members of Congress saying well when are we going to see the money now that it is February 1. And again, that was Congress's fault because we did not do it until the reconciliation or they passed the budget.

The next question and again I want to thank you for your response to Hurricane Katrina at least in my area. Many health care providers stepped in and took care of the evacuees without regard to their ability to pay. And when the City of Houston called to let us know that hurricane survivors were having significant problems accessing their prescription drugs, our office received an immediate response from a lot of the large pharmacies, the chain pharmacies. In fact, it took action within hours to form an agreement with the State to get evacuees the prescriptions they needed. And I know you were at the Reliant Park and also at George R. Brown. I know the First Lady was there and saw these pharmacies that were set up literally within hours. Despite the creation of an uncompensated care pool in the Texas Medicare Labor, these pharmacies have still not been reimbursed for the prescriptions provided to evacuees. And to make matters worse, the Texas Medicaid Program has informed the pharmacies that CMS headquarters directed them to require patient's original zip code for reimbursement information, and that is extremely difficult to obtain retroactively, particularly four months later and given the mobility of the evacuee population. Was it true that CMS directed State Medicaid programs require this information to the collection which is overly burdensome in my view, and can you clarify whether the pharmacies should seek reimbursements from Medicaid or FEMA as it

seems these providers have consistently received conflicting information. Again, these are the ones set up under the emergency situation with 200,000 people coming in.

SECRETARY LEAVITT. Congress was responsive to our request to provide funds and we have, there is not an unlimited number of funds that were provided and we want to make sure that we are using them to compensate the right people. We want to make sure we do not get to a situation where because of poor record keeping we are paying people for things they did not provide. And so I suspect that people at CMS have created criteria to try to make certain we are doing the right things with taxpayer dollars. If it has become more onerous than it need be then perhaps we need to take a look at it and I would be happy to ask CMS to do that. I am not aware of those requirements and this is the first I have heard of it.

MR. GREEN. Then I will probably just follow up with a letter because the pharmacies actually provided it at those shelters and again they took the information that they knew they could get at that time, but the pharmacies are the ones who were not receiving reimbursement. The prescriptions were filled on an emergency basis because people showed up without their prescriptions, without anything, but they did go through the system out there at the Reliant Stadium and all positions that were literally from all over and they took down their information and so they were able to fill pharmaceuticals for them but I will get a letter to you--

SECRETARY LEAVITT. Thank you.

MR. GREEN. --on that so we can do that.

The last question I have in the 18 seconds is the elimination of health professions grants. It has become clear that in the past decades we have problem with capacity for providers of primary health care, and at the same time the budget seeks to stand HHS programs that direct, in direct care service is given budget cuts in health profession programs, how can the agency plan, enable, and secure a primary health care workforce? And again, we are looking at the health care centers that we are creating all over the country, community health centers, and is there something we can make sure that the personnel are there for our community centers?

Thank you, Mr. Chairman.

MR. BILIRAKIS. [Presiding] I thank the gentleman.

The gentlelady from New Mexico, Mrs. Wilson to inquire.

MRS. WILSON. Mr. Chairman, I came in late. I think there were some other members who--

MR. BILIRAKIS. Well I have been asked to go right on down the line so I am just following orders.

MRS. WILSON. Thank you, Mr. Chairman, I appreciate that.

Mr. Secretary, thank you for being here today. I have gone through the budget and there are a number of things, I think that are going to be issues of continuing concern and discussion, but one of them I wondered if you could talk about a little bit is the union Indian program. There is a set aside that urban Indian health program in the past of 32 million that I think has been eliminated in this budget proposal. And 75 percent of Indians live in urban areas and that is only a 1 percent set aside in the Indian health budget which is now being eliminated. And I wondered if you could talk about how folks who do not live near the reservation are going to get their health care.

SECRETARY LEAVITT. I can. This is a good example of a situation I found where we are funding in one side of HHS community health centers and in another operating division in HHS the Indian Health Service we were providing urban clinics for Native Americans. And so I am just asked a question and I think it is the right response. Why are we creating separate facilities in the same department to serve essentially some of the same population. And so what I have proposed is to combine those in a sense so that we are serving those populations through our community health centers. Rather than have two less than ideally developed facilities, why don't we have one extraordinarily good one and that is the strategy here.

MRS. WILSON. What does that mean for a member of the Navajo Nation who is living in Albuquerque, New Mexico and for the service where they get it, how they are enrolled, whether there are co pays and so forth, how is this transition going to take place?

SECRETARY LEAVITT. We need to reach out to them and make certain that they know that health care is available to them and make certain it is extraordinarily good health care and that it is a both welcoming environment and in quality. At least by my assessment it does not make any sense for us to be funding two facilities and sometimes in the same town and some cases serving very similar populations when we could have one significantly better facility if they were combining forces. And I recognize that there are perhaps cultural reasons that they have chosen to be served there but I do not think we are doing that entire population any favors by dividing our capacity to provide care. And so we are obviously going to have to change a pattern there but it will not only be more efficient but I think they can get better health care.

MRS. WILSON. Have the tribes been involved in the planning that has gone into this budget recommendation?

SECRETARY LEAVITT. There has been a lot of discussion about this through the Indian Health Service. Now, you know, can I testify today that all of them are crazy about the idea, probably not because people

like to have their own facilities. It will undoubtedly affect a community of health care providers in a way but this is efficient. It is a good use of taxpayer funds. And frankly, it is a better way to serve people because we are going to provide them with I think superior health care and better facilities because we are combining them.

MRS. WILSON. And in Albuquerque we have multiple community health centers and we have the Albuquerque Indian Hospital and Clinic right next to UNM. I know that this is--have you worked through, is your intention to close the Indian Health Centers or is your intention to expand the community health centers to cover the existing infrastructure for the ISS?

SECRETARY LEAVITT. I hesitate to make a blanket statement on that matter because I am guessing there will be situations where both will be true. There will be places where we might be advised to close one. I suspect there is or there will be. But again the purpose here is to serve people better and to not duplicate services. I think this is a very good use of taxpayer funds and it looks after the way we can best serve people.

MRS. WILSON. I am asked to stay engaged with you on this as this develops because if it is news to me, I am betting that it is news to many of the Governors and pueblos who I represent and there are 48,000 urban Indians in Albuquerque who have had continual problems with the decline in funding in the Indian Health Service. And we cannot just say well this it the way we are going to do it and not plan it.

SECRETARY LEAVITT. A budget is a proposal for discussion and obviously we will begin that conversation. The extent of which has happened in Albuquerque I cannot attest to that. I can tell you we have some of the most compassionate people on the planet in the Indian Health Service who want very much to serve the population.

MRS. WILSON. Thank you, Mr. Chairman.

MR. BILIRAKIS. Mr. Stupak?

MR. STUPAK. Thank you, Mr. Chairman.

Mr. Secretary, if I may, let me ask you a few questions about Accutane and then I want to ask you a little bit Hurricane Katrina again back in the Gulf Region. Last Friday, Mr. Secretary, the FDA Advisory Committee met for the second time in two years to discuss the safety of Accutane. The Advisory Committee was updated on a new pregnancy risk management program called ipledge. While I am pleased to see some progress that has been made to better protect the public from the risk of pregnancy from Accutane, I have some concerns about the ipledge that I expressed in written comments to the Advisory Committee. For instance, I am concerned that the implementation of the program has been delayed and the Academy of Dermatologists has called for another delay. The FDA said at the Advisory Committee's hearing after the

Advisory Committee hearing that it would not delay the implementation. Can you reaffirm that it will not be delayed?

SECRETARY LEAVITT. On August the 12th of 2005, FDA approved new labeling for Accutane and included a strengthened risk management program. The sponsors agreed to implement the risk management program that requires registration in the program of wholesalers and prescribers and pharmacies and patients who agreed to specific responsibilities designated to minimize pregnancy exposures in order to distribute and to prescribe and dispense them. I am not sure, I am not familiar enough directly with this to give you the assurance you seek and maybe those who can and I think this is likely something I need to get back to you on.

MR. STUPAK. Okay, if you would. Also I have given you a slide there and also a sort of like a little outline of things that have happened since February 1, 2001, and it ends at November 21, 2002. And I am pretty concerned that the FDA is failing to protect the American public from the psychiatric effects of this drug. The FDA put a new advisory on their website last May after reviewing a study by Dr. Bremner of Emory University. In fact, that is the study I just handed you. If you take a look at the study, it says in the website the FDA says the FDA continues to assess reports of suicide or suicide attempts. All patients should be observed carefully. Patients should stop use if the patient has any of the symptoms. But the Bremner study here shows us there is a 21 percent decrease of brain metabolism in the area of the brain that mediates depression and in the study by Mr. Bremner 50 percent of the subjects experienced headaches which were associated with the decrease in brain function. So you have over 160,000 people taking Accutane and of that 160,000 if half of them are having these headaches as the Bremner study shows, that is 80,000 people who could be experiencing the lack of brain metabolism of this drug. So my question to you is this. The FDA has received reports of 282 suicides since as of December 31, 27 suicides alone last year, and according to the FDA that only represents two or up to as much as 10 percent of the real number that is out there.

So my question, Mr. Secretary with all these web updates, which studies, research, tracking and information sharing is going on between the FDA and National Institutes of Health to ensure that teenagers and their families are being protected from this drug other than just posting something on a website.

SECRETARY LEAVITT. Mr. Stupak, that seems like a very good question. It is not one I am technically capable of answering today.

MR. STUPAK. If I may, Mr. Chairman, I will put those in the record. Could you respond back in writing to the committee then?

SECRETARY LEAVITT. I would. And speaking of responding back in writing, earlier in your opening--

MR. STUPAK. Right.

SECRETARY LEAVITT. You talked about the Katrina letter.

MR. STUPAK. December 15 letter.

SECRETARY LEAVITT. Yes, I spoke to Mr. Dingell and told him that we had hoped to deliver a response. I have the response now. I did not an hour ago. I will be delivering this in person to Mr. Dingell. I just want you to know about it and also Mr. Brown and it will be responsive.

MR. BILIRAKIS. Without objection that will be made a part of the record.

[The information follows:]

01Feb01 NIMH/FDA meeting on Accutane

Isotretinoin and the Central Nervous System

Background

According to the manufacturer of Accutane®, there were 5665 *serious* adverse event reports in the post-marketing adverse event database as of April 30, 2000. Of the 28 organ system categories, the one with the largest percentage of *serious* reports is Psychiatric (18.8%), followed closely by Nervous System. The most recent Periodic Adverse Drug Event Report for a *12-month period* includes over 750 *new* psychiatric adverse event reports, including 200 coded as serious, 9 suicide attempts and 6 completed suicides.

An understanding of causality in drug-associated adverse reactions is important for maximizing safe and effective use. Causal linkage between isotretinoin treatment and psychiatric events cannot be established from the observations in post-marketing reports due to under-reporting, the high background incidence of psychiatric illness in the population, and the incomplete nature of spontaneous reports.

FDA's analysis of the association between Accutane and psychiatric adverse events included an examination of published literature to address biologic plausibility. The following research topics are suggested by:

- Published work on the role of retinoids in the adult CNS
- Observations from a recent clinical trial
- Post-marketing adverse event reports
- Advice obtained from the panel at the 19 September 2000 advisory committee meeting.

Possible Areas for Basic Science/Pre-Clinical Research

- Effects of isotretinoin on retinoic-acid mediated learned behaviors; is there an age effect (young animals vs. adults)

  Denisenko-Nehrbass NI, Jarvis E, Scharff C, Nottebohm F, Mello CV. *Site-specific retinoic-acid production in the brain of adult songbirds*. Neuron 2000; 27(2):359-70

  Chaing MY…Evans RM. *An essential role for retinoid receptors RARbeta and RXRgamma in long-term potentiation and depression*. Neuron 1998; 21(6):1353-61

01Feb01 NIMH/FDA meeting on Accutane

- Effects of isotretinoin on modulation of MARCKS in neural cells by retinoic-acid

Watson DG, Wainer BH, Lenox RH. *Phorbol ester- and retinoic acid-induced regulation of the protein Kinase C substrate MARCKS in immortalized hippocampal cells.* J Neurochem 1994; 63(5): 1666.

Watson DG, Wainer BH, Lenox RH. *Chronic lithium-induced down-regulation of MARCKS in immortalized hippocampal cells:potentiation by muscarinic receptor activation.* Ibid 1996; 67(2):767

Wang L, Watson DG, Lenox RH. *Myristoylation alters retinoic acid-induced down-regulation of MARCKS in immortalized hippocampal cells.* Biochem Biophys Res Commun 2000;276(1):183-8

- Effects of isotretinoin on dopamine signaling pathways in the CNS

Krezel W, Ghyselinck N, Sama TA, Dupe V, Kastner P, Borelli E, and Chambon P. *Impaired locomotion and dopamine signaling in retinoid receptor mutant mice.* Science 1998; 279: 863-867

Farooqui SM. *Induction of adenylate cyclase sensitive dopamine D2 receptors in retinoic acid induced differentiated human nueroblastoma cells.* Life Sciences 1994;55(24):1887-93

LaMantia AS. *Forebrain induction, retinoic acid, and vulnerability to schizophrenia: Insights from molecular and genetic analysis in developing mice.* Biol Psychiatry 1999; 46:19-30

- Effects of isotretinoin on hippocampal concentrations of cAMP regulatory element protein

Heery DM, Kalkhoven E, Hoare S, Parker MG. *A signature motif in transcriptional co-activators mediates binding to nuclear receptors.* Nature 1997;387: 733-6.

Nibuya M, Nestler EJ, Duman RS. *Chronic antidepressant administration increases the expression of cAMP response element binding protein (CREB) in rat hippocampus.* J Neurosci 1996;16: 2365-72.

Dowlatshahi D, MacQueen GM, Wang JF, Young LT. *Increased temporal cortex CREB concentrations and antidepressant treatment in major depression.* Lancet 1998: 352: 1754-5.

01Feb01 NIMH/FDA meeting on Accutane

Possible Areas for Clinical Research

- Characterization of the neuropsychiatric events that occur during/ soon after isotretinoin therapy:
  - Are there features, such as a pattern of aggressive behavior change/impulsiveness, that distinguish this syndrome from idiopathic mood disorders?
  - Are psychiatric symptoms associated with isotretinoin-induced benign intracranial hypertension?
  - Is there a dose threshold that is within the minimum effective dose for treatment of severe acne?
  - Effects of different classes of anti-depressants in management of isotretinoin associated psychiatric adverse events
  - Does dosing regimen (timing) affect the incidence of CNS adverse events?

    Rationale: Could sustained levels of isotretinoin have less CNS toxicity than lower amounts of isotretinoin administered such that peaks and troughs occur due to retinoid receptor down-regulation in neural effector cells, regulation of CNS penetration, regulation of retinoid degradation, etc?

    Adamson PC et al. *Time course of induction of metabolism of all-trans-retinoic acid and up-regulation of cellular retinoic-binding protein.* Cancer Res 1993; 53:472-476

- Effects of isotretinoin therapy on brain metabolism (e.g. PET) and bio-markers for neuropsychiatric disease

- Pharmacogenomics: SNP disequilibrium profiling/other approaches to investigate possible role of cystic fibrosis genes in susceptibility to isotretinoin associated CNS events (such as, retinal dysfunction, benign intracranial hypertension, psychiatric events)

  Rationale: A co-factor effect of CF genes was suggested at the Sept 2000 advisory committee meeting by Dr. Hager, a physician whose son developed severe psychiatric symptoms while taking Accutane. A search of the literature revealed an interesting overlap of CF-related problems and well-known toxicities of isotretinoin, as well as problems with vitamin A homeostasis in patients with CF:

  Welsh BM et al. *Night blindness precipitated by isotretinoin in the setting of hypovitaminosis A.* Australas J Dermatol 1999; 40(4):208-10
  (Patient had cystic fibrosis)

Eid N et al. Vitamin A in CF: *Case report and review of the literature*. J Pediatric Gastroenterology 1990; 10:265-69

James DR et al. *Vitamin A absorption in CF: risk of hypervitaminosis A*. Gut 1992; 33:707-710

Monaghan KG et al. *Mutation analysis of the CF and cationic trypsinogen genes in patients with alcohol-related pancreatitis*. Am J Med Genet 2000; 94(2):120-4

- Possible effect of low body fat composition on susceptibility to neuropsychiatric adverse events

Rationale: At the September advisory committee meeting, Dr. Alan Byrne, an Irish psychiatrist, presented his experience with patients who developed Accutane-associated psychiatric symptoms. He noted that all of his cases involved very lean patients and hypothesized that lipid in the brain absorbed more drug in setting of reduced peripheral "sink" (note that Accutane dosing is adjusted for weight and that we are aware of no evidence that isotretinoin in stored in fat).

Informal (not comprehensive) Accutane Log 11/27/02
Linda H. Fossom, P/T reviewer, HFD-120/CDER/FDA

1/16/02: "Meeting with NIMH to rec[ommend] safety/tox studies for Accutane." Grayson Norquist (Director of NIMH Division of Services and Intervention Research) basically said it (Accutane and depression and suicide) wasn't a big enough issue for NIMH to deal with at present (e.g., by RFA), but he offered to collaborate with us (FDA) on a workshop. I'm not sure whether the topic was specified at this time, but has since been related to CNS effects of retinoids. Linda Brady (NIMH Division of Neuroscience & Basic Behavioral Science, Director of Molecular and Cellular Neuroscience Research Branch), who was not present at this meeting, was to be the contact person.

3/20/02: Seminar "Isotretinoin, depression and suicide" by Eric Caine: from the (epidemiological) data in the public domain, he thinks that evidence for a causal link between Accutane and depression and/or suicide is lacking and that "psychological autopsy" is the way to look at the data. Andy and I had lunch with Speaker and several others including Kathy O'Connell.

Current (4/15/02) status of preclinical studies "undertaken" by/for the Agency to assess Accutane's potential for inducing suicide and/or depression:

Linda Brady (NIMH): As of 3/18/02, initial screening studies: affinites of isotretinoin and 5 derivatives/metabolites was determined at 62 cloned human molecular targets including 5-HT receptor subtypes 1A, 1B, 1D, 2A, and 2C; transporters SERT, NET, and DAT; adrenergic receptor subtypes alpha-2 and beta; protein kinase C isoforms; and metabotropic receptor subtypes. None of the evaluated derivatives had affinities < 1 uM at any of the tested molecular targets; several of the compounds had "modest" inhibitory activity at nicotinic acetylcholine receptors (Ki's of 50-235 uM).

Awaiting results of microarray studies on whether isotretinoin or derivatives modulate the expression of proximal targets (see above).

Joe Hanig (OPS/CDER): As of 2/14/02, preparing a protocol for the use of mouse models of behaviors (e.g., aggression, locomotor activity, lack of affect, apathy) that serve as surrogates for human behaviors that predict risk of suicide. Will also focus on 5HTb [*sic*] receptors and levels of brain serotonin.

Sherry Ferguson (NCTR/FDA): As of 4/8/02, proposing to investigate behavioral and neurochemical effects of isotretinoin administered daily for 12 weeks to adult rats (52 days old at the start of dosing). Behavioral measures of locomotor activity, anhedonia, behavioral despair, and anxiety will be determined several times (2 times for anxiety, 3 times for behavioral despair and anhedonia, 4 times for locomotor activity) during the 12-week dosing schedule. Dose-response curves will be determined for Sprague-Dawley rats and 2 strains that were originally selectively bred (from Sprague-Dawley rats) for sensitivity to DFP (an acetylcholine esterase inhibitor), but which have been used as a model of depression (Flinders sensitive line) and as a negative control (Flinders resistant line). Neurochemistry will be measured in a separate study using microdialysis of n. accumbens and/or striatum, with focus on 5-HT and DA and their metabolites.

Additionally, brains from rats used in the behavioral studies will be dissected and frozen for future analysis, as needed.

4/16/02: Meeting "POC for NIMH Workshop," me with Rusty and Lee Lemley (Policy Analyst, Exec Operations Staff, seemed to control meeting), Teri Rumble (CSO for ODE V, also in control of meeting), Jon Wilkin (Sup MO, Derm/Dent, little if any input, observer), Mary Kozma-Fornaro (Sr Sup Reg, Derm/Dent, little if any input), Kathy O'Connell (MO Derm/Dent, interactive), Jonca Bull (Acting Dir ODE V, did not attend). Bottom line: I will be the POC for the Agency for the Workshop and will be included in a meeting with NIMH (Linda Brady), to be arranged by Lee Lemley. NB After the meeting conversation with Rusty: level of involvement is up to me, but I should keep him informed (viz., results of meetings) and involve Barry. NB I talked with Barry: he was concerned with why we, as an Agency, were committing so much energy to this issue and also that I shouldn't be pressured into doing more than I wanted to do (that would interfere with my primary responsibilities, i.e., P/T reviewing for HFD-120).

4/17/02: Andy Mosholder forwarded to me Joe Hanig's "Draft of Accutane Protocol," which Joe had sent to Ferguson, Sherry; Slikker, William; O Connell, Kathryn A; Wysowski, Diane K; Bashaw, Edward D; Wilkin, Jonathan K; Mosholder, Andrew D; Bull, Jonca, for comment and cc'ed Davis, Hirsch D; Pine, Patrick S; Sistare, Frank D; Sadrieh, Nakissa; Nasr, Moheb M; Hussain, Ajaz S; Winkle, Helen N; Osterberg, Robert E. I'll send comments to Joe Hanig ASAP. Presumably I'll be included on "the list" soon, but Andy has been doing a great job of forwarding this sort of thing to me when I'm not included.

4/23/02: received Draft Protocol from Joe, with request for comments.
4/23/02: Andy forwarded me an e-mail from Sherry Ferguson re dinner this Thursday when she is in town…I'll plan on attending and contact someone on the original recipient list.
4/23/02: received from Lee Lemley a copy of e-mail to Pierre Chambon, asking his interest/availability for FDA/NIMH workshop in November of this year.

4/25/02: had dinner (at Cottonwood Café, Bethesda) with Joe Hanig, Hirsch Davis, Sherry Ferguson (and Tucker Patterson, from NCTR and here with Sherry for NIH workshop on Genomics tomorrow): interesting discussions: I said I would try to get copies of Accutane preclinical reviews for Joe, Sherry, and me. Sherry will see Kathy O'Connell at the workshop tomorrow, so I will contact Kathy on Monday about how best to get the P/T reviews distributed to me, Joe, and Sherry.

4/26/02: spoke with Lee Lemley (went to her office): she will try to set up a meeting with Linda Brady through her secretary; I will see if I can contact Linda Brady or her lab [to see if I can figure out what's going on, what's her position, etc]. Consider tagging the workshop around the SFN meeting in November. [NB The SFN meeting is in Orlando, FL, Nov 2-7, 2002; no schedule available yet, but I'll watch in web-site for announcement of symposia.]

Informal (not comprehensive) Accutane Log 11/27/02
Linda H. Fossom, P/T reviewer, HFD-120/CDER/FDA

4/26/02: I spoke with Linda Brady: she is excited about the workshop, but is tied up until after May 9th (Council review on May 8, 9); suggested FTF meeting on ~May 15th; she suggested Ron Evans as a speaker (cloned RAR) and behaviorists that we might want to encourage to do research; she was also agreeable to contacting P. Chambon. NB I conveyed this info to Lee L and asked her to set up the meeting ~May 15th.

M4/29/02: called Kathy O'C: She was excited about the preclinical prospects, after talking with Sherry Ferguson last Friday (genomics workshop). She recommended getting NDA review for P/T from Amy Nostrandt. I told her about talking with Linda Brady and she wants to be kept in the loop. I'll e-mail Linda Brady and explain that while I am the POC, Kathy is still involved. We will wait to contact P. Chambon until out FTF meeting ~May 15th. I'll remind Lee to set up a meeting with Linda Brady and me and Kathy as required, … as optional.

4/29/02: Lee has set up the meeting with LB, KO'C and me for W5/15/02, 9-10am, NIMH/Exec Blvd Rm 7185.

4/29/02: I e-mailed LSB letting her know about the meeting and that Kathy would attend and was still very interested in the project.

4/29/02: I e-mailed Rusty and Barry a pre-clinical update re 1) dinner with Joe and Sherry and about their proposals; 2) the May 15th meeting with LSB and KO'C.

5/3/02: e-mail from Linda B: prelim data from gene-chip experiments (on SH-SY5Y human neuroblastoma cells treated for 48 hr with 100 nM), retinoids upregulated galanin and 5-HT-2B receptor (Bryan Roth).

5/14/02: e-mail from Linda B: data from gene-chip exp (see above).

5/15/02: meeting with NIMH group…they're very excited and had come up with a list of ~12 potential participants. They will contact them for availability for workshop some time in November. I made it clear that we wanted this to be a science-based, non-political workshop (not does Accutane cause depression and suicide; but more like how do retinoids work in animal CNS). I asked Linda B. if Bryan Roth's microarray results could be shared with others in the Agency; she said yes, but should be treated as confidential until it is published. I'll speak with Joe Hanig and Sherry Ferguson (rather than e-mailing them).

5/15/02: Andy M and I met with Rusty to update him.

5/20/02: Told Joe Hanig about the microarray results; told him it was confidential until published.

5/20/02 e-mail to Linda B: thanked her for taking lead in developing the Workshop; expressed my willingness to help; asked for list of NIMH attendees at last week's

meeting. Reply (5/21/02): Beth-Anne Sieber, PhD - Chief, Developmental Neurobiology Program; Lois Winsky, PhD - Chief, Psychopharmacology/Chief Neuroendocrinology & Neuroimmunology Programs; Jamie Driscoll, BS - Program Analyst.

5/20/02: reply from Linda B: list of proposed participants for NIMH/FDA Workshop, "Functional effects of retinoids on the adolescent and adult central nervous system."

- Bryan Roth, MD, PhD, Case Western Reserve University, Director, NIMH Psychoactive Drug Screening Program, Gene expression and receptor binding studies,
- Wesley Kroeze, PhD, Case Western Reserve University, NIMH Psychoactive Drug Screening Program

Molecular actions, signaling, and metabolism:

- Tomas Perlmann, MD, Karolinska Institute, plasticity, metabolism, functional effects, nuclear receptors
- Peter McCaffery, PhD, University of Massachusetts, plasticity, signaling
- Hector F. Deluca, PhD, University of Wisconsin at Madison, metabolism of retinoids, brain permeability

Behavioral actions and paradigms to assess CNS activity:

- Wojciech Krezel, PhD, IGBMC, France
- Jane Taylor, Yale University - behaviors to assess positive & negative motivation; antidepressant activity; stress
- James O'Donnell, PhD, University of Tennessee - adrenergic activity, antidepressant effects, behaviors sensitive to antidepressants
- Irwin Lucki, PhD, University of Pennsylvania - microdialysis, stress, behaviors to assess antidepressant activity
- Fred J. Helmstetter, PhD, University of Wisconsin - anxiety behaviors; cognitive tasks
- Norman B. Keele, PhD, Baylor University - impulsive aggression neurochemistry:
- Bita Moghaddum, PhD, Yale University - neurochemistry, cognitive behavior, striatal-limbic-cortical circuits

Suicide/depression:

- John Mann, MD - neurobiology of suicide, depression, neuroimaging studies cancer trials with 13-cis retinoic acid:
- RJ Motzer, MD, Memorial Sloan-Kettering Cancer Center
- Andrew Miller, MD, Emory University

Long-term followup of children exposed to retinoic acid in utero:

- Jane Adams, PhD, University of Massachusetts.

Informal (not comprehensive) Accutane Log 11/27/02
Linda H. Fossom, P/T reviewer, HFD-120/CDER/FDA

5/21/02: "Accutane group meeting": Lee Lemley handed out Linda B's list of perspective workshop participants and Kathy's original abstract. Andy and I said we thought this was a clinical issue, not a preclinical one; Kathy et al., think the preclinical studies will let them design a clinical study that will work/be acceptable, by providing surrogate markers. Also, told the group about the microarray data, with confidentiality caveat.

5/22/02: E-mail to Linda B, recommending not having clinicians (e.g., Motzer and Miller) speak about adverse psychiatric events from cancer trials, since this would not present a full/balanced story and might be provocative.

5/23/02: Spoke (Phone) with Sherry F: gave her the news on microarray result...confidential until abstract/publication, (June 15th, she's going to meetings in Rome then Scottsdale).

6/7/02: left message for Linda Brady: "Just touching base with her, to see how things are going and to see if there is anything I can do."

6/13/02: called Linda B...left message with secretary.

6/11/02: Joe Hanig called to see how to get Accutane from Roche...not Sigma. He'll contact Jonca tomorrow.

6/18/02: Linda B will contact proposed participants this week; would like to present clinical info to provide rational for Workshop.

6/25/02: e-mail to Linda B offering to have Dr. Robert E. Osterberg, the Acting Associate Director for Pharmacology/Toxicology at CDER/FDA, present a brief introduction for the Workshop, to establish the clinical relevance of studying retinoids in the CNS. Reply that she will discuss this with me next week.

7/19/02: e-mailed Linda B re status of Workshop.

7/26/02: Phone and e-mail messages for Linda B re status of Workshop. Phone reply/discussion (8/14/02): Omitting the outside clinical participants from the Workshop, as we had requested (in my e-mail of 6/25/02), will not fulfill NIMH's purpose for the workshop. They are developing this as a small, informal, interactive workshop on pre-clinical (not clinical) effects of retinoids in the CNS, to present the available data, but, perhaps more importantly, to stimulate interest in further research. However, NIMH has enough interest to organize the Workshop themselves, without FDA involvement.

8/7/02: Accutane Core Group Meeting: The Core Group agreed that it would be acceptable if NIMH sponsored the Workshop without co-sponsorship by FDA.

8/23/02: Spoke with Jonca B regarding what restrictions FDA co-sponsorship would place on the Workshop, e.g., adequate public notice, etc. Conveyed concerns to Linda B,

Informal (not comprehensive) Accutane Log 11/27/02
Linda H. Fossom, P/T reviewer, HFD-120/CDER/FDA

but also assured her that we (FDA) do want the Workshop to for forward, preferably with us as attendees, not co-sponsors or participants. She will get back to me ASAP.

8/27/02: e-mail from Linda B confirming that NIMH will solely sponsor the Workshop early in FY02 and that we (FDA) are welcome to attend.

8/28/02: Accutane Group Meeting: told group that NIMH will solely sponsor the Workshop early in FY02 and that we (FDA) are welcome to attend.

10/8/02: e-mail to Linda B re status/date of Workshop.

10/21/02: e-mail to Linda B re status/date of Workshop.

10/25/02: e-mail from Linda B: Workshop set for Nov 19th.

10/31/02: Call from Linda B and Lois W: re Roche's attendance at Workshop. Responded 11/1/02 (after communication with Jonca B): I reminded them that we (FDA) are no longer sponsoring this workshop, so we have no involvement in this issue. However, I assured them that we (FDA) always understood that this was never a strictly-closed workshop and no one would/could be barred from attending.

11/12/02: e-mailed Linda B a tentative list of FDA attendees for the Workshop.

11/15/02: final agenda from Linda B.

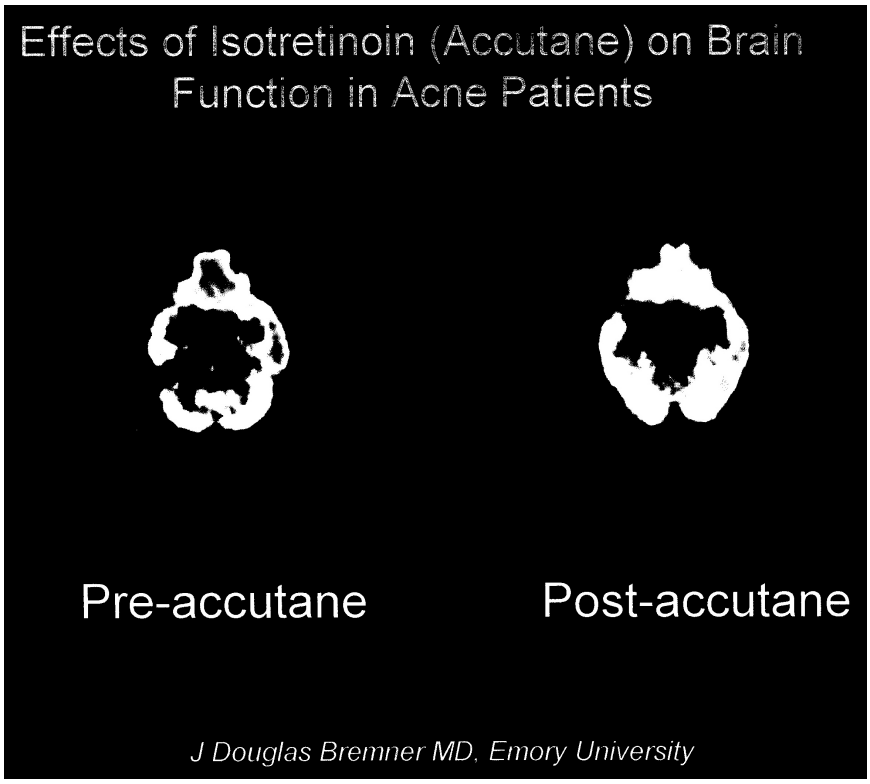
11/19/02: Retinoid Workshop.

11/21/02: e-mail from Lee L re a congressional request for all documents for the period 9/17/01 through 11/19/02 that relate to the drug isotretinoin.

MR. STUPAK. And without objection can that slide and document I submitted to him be--

MR. BILIRAKIS. Got it.

[The information follows:]



MR. STUPAK. Thank you, Mr. Chairman.

Getting back to Katrina and I appreciate the letter a few months ago. We appreciate it. Again, yesterday the Government Reform or I should say Mr. Davis released a report: A Failure of Initiative. And as I said in my opening comments that it seems like now in New Orleans it is business as usual. And when I read this report of Mr. Davis he said passivity did the most damage. The failure of initiative costs lives, prolonged suffering, and left all Americans justifiably concerned our Government is no better prepared to protect its people than it was before 9/11 even if we are. So when I asked you earlier that I would hope that you would become more aggressive in the health care in New Orleans, we were down there for three days and they have not been reimbursed since August. Big Charity has not been reimbursed since August 29 when the hurricane hit through January and there are some questions like, "well they have not submitted proper documentation." But if you do not have power, no computers, you are delivering care, everybody agrees they are delivering care, they have to be reimbursed. We have to

cut through the red tape and get these folks some money if they are ever going to provide health care material. My time is up already. The point is this is being done to expedite and provide health care down there.

MR. BILIRAKIS. Brief response, please.

SECRETARY LEAVITT. We do not lack aggressiveness on this. I will be down there again on Tuesday. I was there just a couple of weeks ago. I think it was one of the great opportunities to demonstrate not just a renewed health care system but an exemplary health care system. And I could act philosophic on it but the time is up and I think in the letter you will see our vision is real and our commitment is too.

MR. STUPAK. And more than vision we need health care. What about them there? Their vision may be great but how do you implement vision if no one is implementing that on the ground?

SECRETARY LEAVITT. I think what you will find is that much of the health care that is there is being provided by HHS and you saw uniformed people running all over New Orleans that were providing it.

MR. BILIRAKIS. Mr. Fossella may inquire.

MR. FOSSELLA. Thank you, Mr. Chairman, thank you, Mr. Secretary for your patience and the job you do, appreciate it and appreciate you being here today.

The first question deals with Ryan White funding and I am going to follow up a little bit to Mr. Engel's question before but a little more specific. I guess one of the President's principles calls for the creation, the severity of need for core services index to be used and the revision of Title 1 and Title 2 funding formulas. The index as I understand it to include among other measures the availability of other resources including local, State, and private resources. It is my understanding that HRSA has formed advisory panels to help the development of such an index and the panels have discussed including an end adjustment that factors available resources in State's capacities to pay for services. New York City is in New York State and has stepped up to the plate when it comes to administering the Ryan White from the dedication of significant resources. Such an index includes an adjustment for available resources. I guess the question we have then does this create a disincentive for jurisdictions like New York and will HHS if they have express that they will not--they have in the past, I believe pursued policies with inherent disincentives. So are we with this new sort of proposal creating a disincentive for cities or States like New York?

SECRETARY LEAVITT. I hope not. I mean, I do not, I have not thought that through deeply enough and I appreciate you raising it and I will give it more thought. I will investigate that. I do not know that I have got a response that would be satisfying to you because I have not thought it through deeply enough.

MR. FOSSELLA. That is fair enough. And along those lines and I will follow up on our conversation then because it complements in a way with the notion of double counting as referred to and we are just concerned that with New York City, New York State sort of leading the way, perhaps other municipalities and States around the country have a lot to learn in administering Ryan White and servicing those most in need and will be prepared.

SECRETARY LEAVITT. Thank you.

MR. FOSSELLA. A second series of questions just deals with bioterrorism. As you know, Mr. Secretary, we have a similar problem with Homeland Security funding. There are two little pockets of money. One sends money to 50 States and four cities for detection and monitoring both from CDC and hospital readiness. And the other is Cities Readiness Initiative or CRI sends money directly to 23 cities. And the program as you know is new, it is the first year. Its primary purpose is local planning and coordination for bioterror preparedness. A concern we have is that under the first part called CRI, New York City which we believe is still about the number one threat when it comes to terrorist activity is 23rd out of 23 cities in terms of per capita. It may be solid in terms of absolute but it is 23rd of 23. And the second part for CDC for public health preparedness in terms of hospital preparedness it ranks respectively 24th of 54 and hospital preparedness 54 out of 54. I guess my question to you, Mr. Secretary, is do you believe that we should be moving more towards a risk based approach when it comes to allocating bioterrorism formula or is it status quo acceptable?

SECRETARY LEAVITT. I believe that risk based is more appropriate and we are beginning to tilt our grants in that way.

MR. FOSSELLA. So places like New York City, or wherever that risk may be, should expect to see an increase in formula at least on a per capita basis if we move in that direction you think?

SECRETARY LEAVITT. In Government we are masters of proportionate distribution. We are not as good at risk based. We need to get better. There are times when proportionate distribution is appropriate but where we are measuring risk it is my judgment we ought to be tilting toward risk as opposed to proportion.

MR. FOSSELLA. Well I thank you because I know the House is on record in moving that direction, the Administration is on record with both Secretary Chertoff and yourself and we know it is the other body that seems to be an impediment to this but for the good I think of the American people who deserve the best when it comes to this type of funding and I appreciate your efforts in helping us move in that direction.

I yield back, thank you.

MR. BILIRAKIS. The chair thanks the gentleman.

Ms. DeGette for six minutes.

MS. DEGETTE. Thank you, Mr. Chairman.

And welcome, Mr. Secretary. Along with Mr. Stupak and Ms. Schakowsky, I was one of the three Democrats on the O&I Subcommittee who went to New Orleans a couple of weeks ago. And certainly everybody is concerned about the situation down there. But we were appalled but what we saw so many months later. I do not think anybody could agree that we are in good shape with the health care delivery system in New Orleans and I am sure you would not think that either. I mean Charity Hospital which is the safety net hospital remains closed to this date with no clear reopening date. The have the tents set up in the convention center which I guess they will be leaving in March. The ambulances do not have a place to go. There is no level one trauma center. I guess there is one opening 6 miles or so away soon, but in the meantime, and even after that opens with the surrounding hospitals that are open, what we were told is people who need to go to the emergency room have to wait four to 24 hours to be seen in the emergency room and it is the type of thing they have got 25 percent of their population back in New Orleans if as is projected which I think is optimistic but if 65 percent of the population returns by the fall, we are not going to be just in a delay situation, we are going to be in a crisis. So kind of based on those observations, I have some questions for you.

The first question I have, Mr. Secretary, is FEMA is making a lot of the key decisions regarding the funding of Charity Hospital and some of the other public hospitals. And so my question is FEMA regularly briefing HHS and you as to the funding decisions that are being made with respect to health care?

SECRETARY LEAVITT. We are focused primarily on rebuilding the system. And the extent of the actual deliberation or briefing that is going on I cannot personally attest to.

MS. DEGETTE. Would you mind supplementing your testimony to let me know if there are regular briefings, how often, and if there are minutes kept at those briefings?

SECRETARY LEAVITT. You may have other things you would like to outline that I am prepared to answer. Obviously I am not saying anything, but at some point it might be helpful for you to for me to outline the process we are going through to help--

MS. DEGETTE. Well let me ask my next question which may lead to that, because what I saw is that Charity Hospital, which is operated by Louisiana State University, estimated that it would cost $257 million to basically redo that facility because the old hospital was really not in line with modern medicine so they had this sort of exciting vision but then FEMA under the Stafford Act, FEMA cannot pay for a brand new

hospital if the cost for rehabilitation of the original hospital is 50 percent or more of the cost of a new facility. So Charity is sitting here saying we do not have a dime from FEMA. In the meantime, the private hospitals are reopening but they are not level one trauma centers and furthermore, they are not set up to deal with the poor and uninsured like we have in New Orleans. And so it is like the worst nightmare of bureaucracy for the Charity Hospital folks because they have no money from FEMA. The private hospital across the street is opening up later this month because private insurance money paid for it. And so my concern is how--I know you have got a vision and I would like it if you would briefly talk about that vision but how long is it going to take?

SECRETARY LEAVITT. First, let me say that we are compensating or will be soon with the dollars that were recently appropriated the interim health care providing that is going on in parking lots and in tents--

MS. DEGETTE. Well that is fine but that is not a health care system. You would agree with that.

SECRETARY LEAVITT. No, it is not. And the second thing I would say is I ironically was in New Orleans on the week before the hurricane and I was told by the head of public health there that if I were to go through an emergency room anywhere in New Orleans on that day private or public, I would have a 24 hour waiting system. Reality is that it was a lousy system before and--

MS. DEGETTE. So you can only imagine what it is like now.

SECRETARY LEAVITT. No, I have seen it. I know exactly what it is and it needs to be improved. The third thing I will point out is that in best estimates the City of New Orleans will be a different place and will have different meaning than before. There are a lot of proprietary interests right now and I do not mean that just to imply profit and non-profit. I mean to say that there are a lot of large hospitals and they are not going to need all the large hospitals they had before and they do not want, we do not want to have a system that is like they had before where the only place you got treated was in an emergency room. What we want is a system that responds where everybody has a medical home where they are able to get help in community health centers and centers that ultimately funnel people into a primary care system and where people have the capacity to get health care when it is needed.

MS. DEGETTE. That is great. When is it going to happen, Mr. Secretary?

SECRETARY LEAVITT. Well it is going to happen as rapidly as the local community can rebuild it. We stand ready--

MS. DEGETTE. Well how can they rebuild? I mean Charity Hospital cannot rebuild under any scenario because they do not have private insurance like the private hospitals do. They rely on State and Federal

dollars and the Federal Government has not given them a dime or any indication when they are going to approve some plan that will give them a dime.

SECRETARY LEAVITT. We obviously need to continue this conversation. We are paying their Medicare and their Medicaid or will be paying their Medicare and Medicaid claims. There are questions in the medical community, the broader medical communities as to how to reconstruct it. The role of Charity Hospital is still very much part of discussion there. And that is the reason there is a delay because they need to have a plan, a comprehensive plan that will say here is what we want this to look like. And just going off and building or rebuilding one hospital is not going to--

MS. DEGETTE. Right, but Mr.--I know my time is up and not to beg the question but it is like the cart and the horse. They cannot have a plan if the Federal Government is not working with them as a partner to let them know how much Federal funding they are going to have.

SECRETARY LEAVITT. We are working with them every day.

MR. BILIRAKIS. Mr. Terry for six minutes.

MR. TERRY. Thank you.

Thank you, Mr. Secretary for being here and I have a series of questions regarding Part D dual eligibles long-term health care and our pharmacists and if that was answered in the ten minutes I had to excuse myself for another meeting and come back I apologize but in the old Washington list and if it has been said before it has not been said by me and therefore you are going to hear it again. As mentioned to you at another time at least in the State of Nebraska, I am sure it is similar in other States regarding the prescription D sign up of dual eligibles there seems to be several that have been put into a program that did not meet their prescription needs. That is one issue. I think that one is the manageable one. The other one is that the State seems to have just missed many dual eligibles that are in no program and there seems to be some confusion about the dual eligibles that are in long-term care facilities that are not being covered or in the alternative if they were put into a prescription D program, the policy there being sent rather large bills for their co pay. Sometimes the co-pays being hundreds of dollars which seems to defy what we passed. So with that little bit of background, can you explain to me and my pharmacy and my dual eligible constituents what is being done so that the States or the Federal Government pays with dispensing pharmacists and the costs of the drugs that they are observing themselves which I think is pretty darn heroic of them to do. They do not have to do that but they are, as well as, the fact that they are being held responsible for the co pays for these folks. And as I understand there is a difference between long-term care facility as

well and just your ordinary non long-term health care folks that are dual eligible. And the other part is there seems to be some growing fight over dispensing fees and whether or not your organization, or CMS under your leadership, can get involved and start resolving some of those dispensing fee issues that they, the pharmacists are being paid is less than the contracted price or that they are making a pharmacist submit the claim so many times and at 10 cents a shot in essence they are eating up their dispensing fee just in submitting the claim. So if you could answer those three questions I would sure appreciate it.

SECRETARY LEAVITT. If a person who is a dual eligible walks into a pharmacy and they do not have a plan or do not think they know what plan it is and the pharmacist cannot identify where they are, the pharmacist has the ability to enroll them in a plan on the spot. And when they enroll in the plan, it is called the Well Point Plan, they are then eligible to be reimbursed for that drug through the Well Point Plan and the reconciliation will be made by CMS as that the pharmacist will get reimbursed. In the case of co-pay, now I have been in 20 States in the last two weeks. I have been in pharmacies in most of them. I have stood at the counters, I have walked through the process with people. I have stood and waited for the 1-800 line to answer. I think I have got a pretty clear picture of what is happening. And what I find happening at the pharmacies is that at the beginning of the day or through the course of the day a pharmacy may accumulate a handful of prescriptions that they were not able to reconcile. At the end of the day, they have to go back and make the calls to Medicare but they ultimately find or work through the problems. What I am finding is that there are limited numbers. And it is limited numbers of situations where people are literally outstanding more than a day or two or three on a prescription. Now I acknowledge the fact that it has required additional work for them, and pharmacists have been heroic. There is little question in my mind that the entire pharmacy industry is being affected by this, not just Part D, but we are seeing a dramatic change in the way pharmacies work right now and it has created the same kind of problem that happened when any market changes. I do not know if that is responsive to all three of your questions, but I hope it is responsive to at least two of them.

MR. TERRY. Well it did not hit on the enforcement of dispensing, but we will get to that on different date or something.

SECRETARY LEAVITT. I can quickly just tell you that with respect to Medicare Part D, the pharmacies work with their networks and if there is a cost reimbursement issue it is with the network, not with CMS.

MR. TERRY. All right, 44 seconds left. Getting back to payments for those pharmacists that when they had not filled prescriptions when there was not a plan for a dual eligible, can they be reimbursed for that or are

they going to have to eat those costs since they did not sign somebody up?

SECRETARY LEAVITT. No, if a person is over 65 and a dual eligible, they are in a plan. If they are not in a plan they should have been in a plan and the State--

MR. TERRY. But some are not.

SECRETARY LEAVITT. Well let us work on that together because there are very few situations that I am aware. I know there is a solution to it, I just cannot come up with it sitting here.

MR. TERRY. I appreciate that.

I yield back as my time is up.

MR. BILIRAKIS. Ms. Capps for six minutes.

MS. CAPPS. Thank you.

Thank you, Mr. Secretary. I appreciate the opportunity to talk with you. Back in 1974, Congress appropriated the equivalent of $609 million in today's dollars for nurse education programs. The Administration is now emphasizing preparedness for pandemic flu and a threat of bioterrorism--and earlier this afternoon you mentioned increased dollars for pandemic flu stockpiling. I want to talk with you about the people who will be giving those antivirals. And I also want to talk about the fact that our first responders in our communities, which nurses are a major player for a bioterrorist attack or a flu attack are critical to the efforts to respond to such a situation and I'm thinking about the hurricanes that affected the gulf coast. Do you think you can--we know who is in great need and some often in short supply. The disconnect is the fact that the President's Budget proposes level funding for Title 8 nurse education programs at $150 million. This is $1 million below fiscal year '05 funding. And yet HHS's own Budget in Brief quotes the HRSA report which predicts that the nursing shortage is expected to grow by 229 percent in 2020. Last year, the shortage of nurses in this country was around 7 percent, which is close to 150,000 nurses not at their jobs doing work that is needed for today's health care needs. By 2020, given this scenario, we will have over 800,000 nurse positions going vacant. That is without a Katrina, without the surge effect of a bioterrorist or pandemic flu attack. You said it is only a matter of time. It takes two to five years to educate and prepare a registered nurse. I am one, I know. You said yourself in your testimony that a budget is an investment in the future. Funding for nurse education needs to be invested now in order to expand the nurse workforce shortage. That would be to meet today's needs. I want to ask you to respond to whether or not we have adequate nursing staff levels and preparation for such to provide the health care that we will surely need in the event of a disaster.

SECRETARY LEAVITT. Ms. Capps, may I say that I am fully conscious and agree with you that we have to train more nurses. I would like to talk about this at two levels. One is the current budget and then I would like to spend most of my time if I could talking with you about 800,000 nurses in the existing system may or may not be even achievable. We need to begin to think about how we--we need to think about new ways of training nurses to step outside the traditional method of training where people are able to--there are a number of different hospitals for example who have the capacity to train credential nurses within the hospital.

MS. CAPPS. And many of them already do.

SECRETARY LEAVITT. And we need to expand that kind of thing because it allows us to do it more efficiently, and I think the argument can be made that it is very high level of quality. We are focused in this budget on actually targeting the areas where specific nurses are needed or specific types of nurses and types of areas we need nurses as opposed to a more generalized approach. We also recognize the faculty is the big problem.

MS. CAPPS. That is what I am talking about. Nurse education is what has declined so dramatically in funding.

SECRETARY LEAVITT. So we have chosen to focus our funding on faculty and not just the broad not--

MS. CAPPS. But I do not see evidence of that.

SECRETARY LEAVITT. As we appropriate the dollars there will be over $100 million. That is the way we will be targeting our outlines.

MS. CAPPS. Well nurse education programs are being flat funded. They are going to be receiving less funding. And another thing you said is you would want to target them for certain specific needs but they are needed in every community. And now we have a model, mostly it is community colleges. I know particularly one challenge, which is the reimbursement rate for faculty positions with a master's degree in the community college, are less than what is provided for a critical care nurse or a public health nurse within the community system. That is just one challenge but there are not enough dollars there to do any of the things that you have talked about.

SECRETARY LEAVITT. Well as you know our method of funding medical education particularly for nurses comes from a number of different of sources. For example, our graduate medical reimbursement is one method. And here--

MS. CAPPS. Is that for nurses or for doctors?

SECRETARY LEAVITT. Well it is primarily for doctors.

MS. CAPPS. Yes.

SECRETARY LEAVITT. It does not--

MS. CAPPS. It is much higher than that for nurses. It is woefully short in that area, too.

SECRETARY LEAVITT. Your point is a good one and I concur. What I am suggesting to you is that our effort here is to fund faculty positions more intensely.

MS. CAPPS. Well whatever model you are using, like some innovative plan within a hospital, I am open to any ideas but I have not seen it yet and I am hoping now that my time is just about up that there would be a way that I can stay in touch with you on this. I work regularly with schools of nursing and nurse faculty. They have talked with me individually and professionally within their groups and this is a crisis, meeting today's needs and we can only shudder to think of what we will face. You can stockpile all the antivirus you want but unless you have somebody there to care for the sick and the dying it is not going to do a lot of good.

SECRETARY LEAVITT. Thank you. I would like to continue the conversation. There are some areas that I think--

MS. CAPPS. Thank you.

MR. BILIRAKIS. Dr. Burgess for five minutes. Mr. Murphy?

MR. MURPHY. Thank you, I appreciate that.

MR. BILIRAKIS. Mr. Murphy for six minutes.

MR. MURPHY. I have to run out of here. Three things I want to mention. One Mr. Secretary has to do with the previously mentioned issues of the cuts in mental health funding and I recognize there are concerns for overlap but still the areas of mental illness are I think the funding for them is woefully inadequate. And as so often happens in Congress and in part because OMB only scores spending, they do not ever score savings and we have a warped sense of looking at things. That integrated health care what we look at how mental health funding and, excuse me, mental health treatment can save the costs of treating such things as heart disease, diabetes, lupus, back pain, and so many things half. I mean they are massive savings. And so I really am concerned about these cuts and I hope that that is something you can take back and look at how we can do it better. It is not just a matter of cutting the funding. It is doing it better, more efficiently, and looking at integrated care. And I just want to leave that as a comment.

The second thing I want to talk about with you is community health centers and you and I talked about this as we were walking down the hall here. But is legislation going to try and help us get more doctors in those centers? I think building these centers are a marvelous aspect, it brings health care to the underinsured and the uninsured. It helps to reduce the cost of such things as Medicaid funding by 30 percent, but we do not have enough doctors, nurses, podiatrists, physiologists, dentists, and we

have legislation that allows doctors to volunteer. As you know that it is--they cannot because they cannot be covered by insurance at this point. And I just wanted to give comment on some thought you might have about helping to move that.

SECRETARY LEAVITT. Well I was surprised that that was the case in our conversation and I have asked a member of my staff to help me understand what barriers there would be to changing it. I am in community health centers all over the country and I see doctors who are there in one fashion or another and they must be employed there and not volunteering. We need to enable people no matter what their capacity to volunteer and I am looking forward to working with you on this.

MR. MURPHY. I appreciate that. And you understand that if Dr. Burgess or I wanted to volunteer somewhere we could not do it, the community health centers would turn us away, but if they wanted to pay us it would cost even more to have us, so I appreciate that.

The other thing I wanted to mention is an area that the CDC has identified as a great concern. Another area where I think massive cost savings could come if we reward how hospitals and physicians and clinics can make an improvement. Instead we only pay for problems if it has to do with infections: pneumonia, methadone resistance, staph infections, or urinary tract infections. If a patient is in a hospital or a clinic or nursing home and they contract one of these, Medicare, Medicaid, other funds, the VA pays for that. And even if the clinic loses money in the process we would still pay more, and yet we recognize that some hospitals have made tremendous advances in reducing infection rates and I believe we should be doing it and drafting legislation on this is be able to offer some funding stream to reward them for that. CDC estimates there are 90,000 deaths a year from infections that occur in medical settings. And I wonder if you have any thoughts about this, if this is something the Department of Health has been looking into that finding a way to work with hospice clinics and practices to reduce infection rates and how that can save money. Again, it is one of those things that CDC cannot possibly score because if we were to say let us pay whatever that fee would be if you show, if you demonstrate reduced infection rates. And yet it would save, things like this could save more money than the other things that we are looking at in terms of--let me just speak to it as a potential patient, I would like to know that. I would like to know what the facility I am going into, how its performance has been on this matter because I think it speaks very much to the quality and this gets back to the idea of transparency and being able to give a sense of disclosure as what a facilities results have been.

We ought to be prepared to pay people better who have fewer infections and it ought to be known to patients if they are in a facility that

has a disproportionately high number. There are some hospitals I know in my area in Pittsburgh which have really focused on this, and there are other places around the country which in essence have been able to reduce some infection rates post operative where everything is to near zero. It is I think a massive benefit and one that I would hope that HHS could take a careful look at. I would love to work with you in terms of crafting some ways of awarding hospitals. I know one of their concerns is once they start finding the data and reporting it that someone will sue them because they are finding these problems and quite frankly I think it is a greater benefit to our patients if we start seeing how we can help them so I appreciate that.

SECRETARY LEAVITT. Thank you.

MR. MURPHY. I thank you, Mr. Secretary.

I yield back.

MR. BILIRAKIS. Mr. Allen to inquire.

MR. ALLEN. Thank you.

Thank you, Mr. Secretary for being here. I have a comment I want to make and then some questions for you. The comment relates to the opening statement of the gentlelady from Tennessee who is no longer here but in her opening statement, she said that tax cuts lead to greater Federal revenues. It is not true. She has lots of company and many colleagues of mine on the other side of the aisle routinely say that tax cuts lead to increased Federal revenues. The President and the Vice President go out and say on a regular basis tax cuts cause added Federal revenues. It is not true. Last week Josh Bolton, the head of OMB when pinned down and he is not easy to pin down, admitted that tax cuts reduce Federal revenues. But he said there is probably, there is certainly some stimulative effect to tax cuts properly structured but the net effect is to reduce Government revenues. And therefore, you said in your opening this was a time for deficit reduction. It was a time for tough choices but my only point is to say in these circumstances, many of us feel it is morally offensive to continue to promote tax cuts at the upper end of the income scale and to withdrawal health care services from low and middle income people. That is the statement.

The question goes like this. The question really relates to how we can save money because we both agree that we need to find savings in these programs. I look at the proposals in your budget and I do not see proposals that will actually reduce the cost of health care. I see proposals in your budget that shift costs to States. I see proposals that shift more costs to seniors. I see proposals that will shift more costs to American families but I do not see anything in there that will actually reign in health care costs. It seems to me that the Administration's idea of controlling costs is simply to pass the buck or the bill to someone else. If

this Administration were really interested in saving money, there are several proposals that would save money for both the Federal Government and beneficiaries.

Right now the Medicare Payment Advisory Commission I think Mr. Miller would refer to it as a pretty darn good outfit and I agree. MedPAC nominated a number of ways that we could save money. We were overpaying Medicare HMO's. MedPAC recommends eliminating the double payments to HMO's for indirect medical education. Medicare makes direct payments to teaching hospitals, it does not need to also pay insurance plans for the same service. MedPAC says that would save $5.5 billion. Does the Administration's budget include any proposal to eliminate that wasteful spending?

SECRETARY LEAVITT. Mr. Allen, let me just enumerate a number of proposals we have that I believe will--

MR. ALLEN. Well can I just get an answer to that question? Does your, does the President's Budget include any proposal to eliminate that wasteful spending?

SECRETARY LEAVITT. We do not view that as you have characterized it. We think it is critical in order to assure that we have availability of health choices in rural communities all across America. If it is not used at some point in time, the Congress may choose to consider it, but at this moment we believe it is necessary.

MR. ALLEN. Okay. MedPAC also recommends eliminating the slush fund. That is $10 billion at the Administration's discretion to further increase overpayments to the plans. And according the CBO that would save $10 billion. Does the Administration support a proposal to eliminate this overpayment to plans?

SECRETARY LEAVITT. We believe that the payment structure as it is currently constituted is necessary in order to assure that we see a continued availability in every marketplace in those plans. We think that there is a good reason in the long-term, as well as the medium term, to create a competitive market that will, in fact, force the cost of structured health care down as we have seen it in the prescription drug benefit.

MR. ALLEN. Let me get to my last question. MedPAC--I take it your answer to both of those questions is no. MedPAC also recommends fixing the overpayment currently built into the risk adjustment payments to Medicare HMO's, private plans that are supposed to get lower payments if they serve healthy and therefore cheaper beneficiaries and higher payments if they serve sicker and more expensive beneficiaries. The Reconciliation spending cut bill that just passed has phased out those extra payments for a few years but there is still $19 billion in savings on the table for that recommendation. These are all free recommendations

from MedPAC. I take it that the Administration's proposal does not include that final savings either. Is that right?

SECRETARY LEAVITT. We very clearly believe that the way to reduce health care costs, one of them is to have a competitive marketplace and we believe that is being achieved. One example I was prepared to cite was the prescription drug benefit where we have seen the costs go from $37 on average to $25 that will result in not just beneficiary savings but literally billions of dollars of taxpayer savings.

MR. ALLEN. Have you seen the study that shows that those payments are 80 percent higher than the VA pays for the same drugs?

SECRETARY LEAVITT. I have seen that and they are nowhere near an apples to apples comparison.

MR. BILIRAKIS. The gentleman's time has expired.

Dr. Burgess to inquire.

MR. BURGESS. Thank you, Mr. Chairman.

Mr. Secretary, you have been here a long time and I appreciate your indulgence of this committee. I am going to make more of a statement and there will be embedded within that statement questions and perhaps just like Mr. Dingell I can get answers from your office on those questions. I will go back to the point I was making during my opening statement and it seems like a long time ago now but the reimbursement for physicians, we have got to focus on that this year. The Chairman brought it up, Dr. Norwood brought it up as well. There was not a single day when I was in the private practice of medicine or during my residency or during medical school where I woke up and on the way to work that day I said boy, I hope I can be inefficient and duplicative today. I always went to work to deliver my best products. So the concept of pay for performance is something that a lot of physicians look at with a lot of disdains because we came to work to do our best work that day anyway and you better pay up for that performance. And currently we are not being paid. Now you know that I spoke with everyone that I could find between Christmas and New Years to beg for administrative relief about the what is euphemistically called the negative update that physicians got the 1st of January because although it was a legislative issue and the Deficit Reduction Act did attend to that, there was a technical glitch that kept the Deficit Reduction Act from going into and having a course of law before the 1st of the year.

As a result, there was a negative update to physicians and I have a sheet of letters from doctors in my district and indeed around the county who sent me the letters that they are sending to their patients that I will no longer be able to see you on Medicare because I can no longer afford this continued string of cuts that is happening to my reimbursement. As a consequence, we are losing the doctors who are the peaks of their

careers, the doctors who are the best diagnosticians, the doctors who in fact take the least amount of money to come to a conclusion and treatment plan for patients. And that is doctors that are my age. And if we eliminate them from the playing field, what we are going to have are doctors who are just out of training who inherently it costs more for them to deliver their care. Now if you want to structure the pay for performance system on top of that quandary of physicians, I submit to you that you are going to be diminishing the value that you are ultimately going to get from a pay for performance system.

The same would be true of an information technology system. I know Mr. Murphy wants to put millions and millions of dollars into information technology. I do, too, but if we do not pay to keep the doctors in the system who do the best care, then it does not matter what kind of information system that we have, we are not going to derive the value that we intend from that.

So again, I think we need to think outside the box. Can we pay doctors under Part A? I think we should look at that. I think that is a valid expenditure to make. Should we allow doctors to balance bill? We have already income related the Part B premium, why not allow doctors to balance bill? Chairman Barton brought that up last year during one of our hearings on physician payment. We have got to come up with a better solution than what we have been doing because just standing pat we are losing doctors out of the system.

As far as the issues in the City of New Orleans, I was a part of that hearing and I have to tell you that it is a stark difference between what is happening at LSU and what is happening across the street at Tulane and I eluded to that in my opening statement. Tulane was up and ready to go. They had stripped all the sheetrock off the walls, they had reconditioned their electrical equipment and refurbished their emergency room on the first floor of the hospital they are ready to go. Now if on your ironic trip to New Orleans a month or a week before the hurricane hit had you stopped in Tulane, you would have seen a hospital that was ready for a disaster. They did not know what was coming. They could have been the North Ridge Earthquake but it did not matter, they were ready and they had as a corporation sponsored DMAT teams so they had people to come and help them when things got tough. Now during the week of the storm and the flood afterwards they were in just as bad a shape as everyone else. But in the months that have followed, they have put a plan in place and yes they have some insurance money but they have also made a commitment to invest new capital because they want to be there on the ground when the city is reborn. Contrast that, and we heard testimony during the end of our hearing in New Orleans, other hospitals had a plan but they never intended to use it. And you go to the other

health care facilities and they had a plan that they had purchased because they are required to under Medicare, but they had never opened the plan. Their plan remained call 911 if we get into trouble, and we all know what happened to that system. So all I would ask is as we funnel millions and millions of dollars into this recovery process, and I know we must, we do have to look at the things that went right and how can we capture those best practices for other parts of the country that may be exposed to other types of disasters.

Finally, I had an amendment on the Deficit Reduction Act that would have streamlined the set-up of Federal qualified health centers in areas that had been impacted by Hurricane Katrina and their evacuees and that would have included some places in Texas. For whatever reason, the other side pulled this out at the eleventh hour in conference committee. I hope you will work with us to streamline this set-up federally qualified health centers and these are not poor counties but they are counties that have significant poor populations. I have some of the highest infant mortality rates in the country in the City of Fort Worth in some of my zip codes. We needed a federally qualified health center there before Katrina. Now that we have so many displaced persons from Katrina, we need it even more or the numbers are only going to be worse this year.

Thank you very much for your time.

Thank you, Mr. Chairman.

MR. BILIRAKIS. I thank the Doctor.

Ms. Solis to inquire.

MS. SOLIS. Thank you, how many minutes, sir? I did not have an opening statement but six minutes?

MR. BILIRAKIS. You were not here, you waived.

MS. SOLIS. Okay. All right, then I will be quick.

Thank you, Mr. Secretary for being here. I think you may be aware I represent a heavily minority district in California, East Los Angeles in the San Diego Valley. One in three residents lacks any form of health care coverage and about a third of our population are children under the age of six without any form of health care coverage. In terms of the Latino community though I have some issues and concerns with respect to how we provide assistance to cover the 13 million Latinos that are currently uninsured out of the total 44 million Americans that do not have any health care coverage. And I say that because I understand that there are some programs that are currently due to be reduced and these programs as I understand them have provided how could I say bridging the gap between communities of color that would perhaps not always get the fair and same treatment as other communities. And I am talking in particular about programs like the Office of Minority Health, the National Center on Minority and Health Disparities, and the Preventative

Health and Health Services block grant racial and ethnic program known as REACH. I understand that these programs are due to be cut back. Do you have any response to that?

SECRETARY LEAVITT. I am not able to respond to each of those individually. If you--maybe we could get that list and I could do--

MS. SOLIS. I will be happy to turn this over to you so you can respond.

And the other is that in 1996, illegal immigrant restrictions to Medicaid and SCHIP where put into place through the welfare reform package but there was an attempt to try to provide coverage for the Latino community, vulnerable community, illegal immigrants, pregnant woman, children through the passage of the Immigrant Children Health Improvement Act. Will the Administration's budget address the high number of uninsured rates in the Latino community and what potential for any efforts there to provide coverage to this community that receives now disparate treatment in health care?

SECRETARY LEAVITT. Well we are working with the minority populations in general. I would suggest that the most significant one would be the expansion of our community health center system. We have money in the budget for 302 additional or expanded services that will bring additional services to literally millions. A high proportion of those who use those centers tend to be in the communities that you have described.

MS. SOLIS. One of the concerns I have in my own district is that as of late in the last two years, LA County our health delivery system there closed 11 community health centers and I have not seen any movement on the part of the Federal Government to try to help provide some assistance there to fill that gap. I would ask that if there is a way that I could ascertain information as to what your plans are in that immediate area that you and I know is a high need locale, if you could provide us with evidence of any attempts or how we can work with you to see that these qualified health care clinics are indeed full of, listed in full capacity funding and helping us bridge that gap.

SECRETARY LEAVITT. You are probably aware that I worked with Governor Schwarzenegger to develop a waiver specifically targeted at Los Angeles County, and I am guessing the heart of your district.

MS. SOLIS. Yes.

SECRETARY LEAVITT. To provide several billion dollars over the course of years to assure that we are able to provide a medical home for them and hospital care. This was a specifically targeted waiver, and that would have expanded dramatically access to health care. And we are beginning to work to develop a pool that can in fact be used to give people not just uncompensated care, but actually access to a health care

home, and I believe the number was a couple of hundred thousand that would be added to the roles of the insured through this waiver.

MS. SOLIS. I would like to get more detailed information.

And then just lastly in the last two or three months we have been holding our own town hall meetings and visits with seniors regarding the prescription program that you all are rolling out and we have heard from our seniors, particularly Spanish language Latino elderly that are having problems with interpreters providing services and the long wait on the telephones. And I am very discouraged with the response from the Administration. Many of our constituents do not have access to the Internet. Information has not been given to them in their language appropriately and culturally in my opinion and I would hope that you would provide us with the information on what attempts you are taking to make sure that that happens. I had a constituent that called me who had problems getting her heart medication and so I am very, very concerned and would like to, you know, to get feedback from you.

MR. BILIRAKIS. Response?

SECRETARY LEAVITT. I will provide you, and you will be provided, along with other Members of Congress next week a list of statistics on how many people in your district have actually enrolled and how many are eligible. I will also tell you that we now have the call wait time on our 1-800 Medicare line down to under a minute and we are offering Hispanic language choices that are necessary or needed. So I hope that will meet the needs of your constituents better.

MS. SOLIS. Thank you.

MR. BILIRAKIS. Mr. Walden to inquire.

MR. WALDEN. Thank you very much, Mr. Chairman.

Mr. Secretary, welcome and thank you for your endurance and patience and all of us have been able to get up and leave and come back and you have not moved and I admire that.

SECRETARY LEAVITT. Thank you.

MR. WALDEN. I want to follow up on what Dr. Burgess said about the reimbursement of physicians and other providers, especially in rural areas. You know, my district is somewhat like the State you were governor in and it is very rural, and I have got a physician out in the far regions of Eastern Oregon who is an internist who is probably in his 50's. Every time I get out there he tells me he is the last one in town. He oversees a health clinic that he helped the community establish that is 60 miles from the little town he is in, and he is not making any money literally, and cannot quit, and cannot afford to keep going. And I am just concerned about the rural safety net, and I think what the Administration has done on clinics and expanding federally qualified clinics is terrific, and the Bush Administration will never get the credit that it deserves in

this area, but you all hoped to save one in little old Fossil, Oregon and helped us establish one elsewhere and I think they are a real safety net and I congratulate you for that. But this issue of physician reimbursement is something we all need to work on in the Congress and the Administration.

SECRETARY LEAVITT. I realize that this is the time for you to ask the questions, but perhaps you would entertain a question. We put $25 billion into rural health with the idea of specifically targeting reimbursement rates in rural America. Has that not had a positive impact on you?

MR. WALDEN. It is certainly better than not having it, but the problem is that it is so acute in some of these rural areas I am finding the same thing Dr. Burgess is. I met with a group of physicians in Bend, Oregon, which is not exactly a rural area in the terms of my district, and yet two or one of them have said they are not taking anymore Medicare patients in their practices because they cannot afford to. And that is an echo I hear throughout the district that is a real problem. Now Oregon has got its own set of issues. In my take we, you know, there is no cap on medical malpractice and that is a cost driver that is affecting them and how they practice medicine certainly. But it is still a major issue. I am one of the co-chairs of the Rural Health Care Caucus, and I thought what we had done when we passed the Medicare Bill was a big help and certainly one of the biggest packages to move forward on rural health care and the Administration supported it, and I think the add on we did for home health care made a real difference, but as you know that 5 percent add on expired. And so we continue to just struggle.

SECRETARY LEAVITT. This is obviously a matter of grave national focus, it has to be. I hear what you are saying with respect to physicians who get up in the morning and go to work and what their reimbursements are and what they would like them to be. On the other hands, we are looking at a health care system that now occupies 16 percent of the gross domestic product. Medicare alone is almost 3.5 percent of the gross domestic product. So we have got to find some way, and I agree with Dr. Burgess, people do not get up in the morning and say, you know, I am going to go out and--

MR. WALDEN. Be inefficient.

SECRETARY LEAVITT. --be inefficient. But they also do not get up in the morning and go off and say I am going to go off and resist change.

MR. WALDEN. Yeah.

SECRETARY LEAVITT. But they do. So this is really about finding ways to implement private practices.

MR. WALDEN. And that is right. I think what you are doing on expanding community health care centers makes a big difference for a lot

of people who would otherwise when their child is ill they wait and go to the emergency room. If they can work with a local clinic, we can all save costs and they can get better health care quicker before it is an emergency.

I want to go back to Medicare in the literally one minute I have left because good news is never news. And I recognize when I hear from my pharmacists and their issues you and I have discussed, and their issues on the sign up and we are actually going to host two sign up sessions for people in March in my district in working with CMS and I thank you for that to help them navigate. But I am amazed 250,000 Americans a week are signing up. Do you have any numbers that look at how many people who lacked coverage, had no prescription drug coverage that now have it as a result of this plan? Because that was what I used to hear when I would go to senior centers and I know I heard in this committee nobody is going to offer a plan and then the drumbeat is there are too many choices.

SECRETARY LEAVITT. Over time we will find that out, but I can tell you it is millions that now have coverage that never had it before. And another figure that is not fully appreciated is the millions that will keep it who would have lost it. We had very impressive acceptance among corporate plans and retirement plans many of whom were dropping prescription drug benefits because of their expense, and they are now able to keep it. There are literally millions who have it who did not before. There are literally millions who are keeping it who would have lost it.

MR. WALDEN. My time has expired. Thank you, Mr. Chairman. Thank you, Mr. Secretary.

MR. BILIRAKIS. I thank the gentleman.

Mr. Gonzalez for six minutes.

MR. GONZALEZ. Thank you very much, Mr. Chairman.

Mr. Secretary, we may disagree some of us on this side of where I sit on the aisle with you but it does not mean that we do not appreciate your service and admire you.

SECRETARY LEAVITT. Thank you, Mr. Gonzalez.

MR. GONZALEZ. The first thing is that we will get a majority staff report and then we get a minority staff report and you cannot believe that they are analyzing the same budget. So the first question is would you agree or disagree with this statement. The President proposed legislative changes that cut $35.8 billion from Medicare Fee for Service Program over five years for a total of $105 billion in Medicare budget cuts over ten years. Yes, sir?

SECRETARY LEAVITT. Would that come from a majority or minority staff?

MR. GONZALEZ. Well I am not going to tell you but do you agree that is--

SECRETARY LEAVITT. Well that is not one I am able to give you a technical response to. If you would like to give it to me I can make an analysis. Questions like that deserve a very thoughtful answer.

MR. GONZALEZ. You are starting to sound like Alan Greenspan.

SECRETARY LEAVITT. That is a real compliment, thank you.

MR. GONZALEZ. It was not meant as a compliment. I served on Financial Services and we never got an answer from Alan Greenspan.

SECRETARY LEAVITT. He was very skilled about it.

MR. GONZALEZ. Well he may now, now that he is a private citizen of sorts. Let me ask you something else that is somewhat troubling and of course I am reading from the minority analysis. For the first time, payments to Medicare providers would be automatically cut in the event general revenues exceed 45 percent of program funding unless Congress acts with its own proposals to meet the 45 percent cap. The Medicare Modernization Act provided that if the 45 percent was exceeded, the trustees would issue a warning and Congress was supposed to act. But the Medicare Modernization Act included no automatic cuts. That is true.

SECRETARY LEAVITT. That is true.

MR. GONZALEZ. Why? Why the changes?

SECRETARY LEAVITT. Well I think it is an acknowledgement that at some point in time we have to decide how many tax dollars can go into Medicare and how many dollars can beneficiaries and others and we just have to decide where the point is that we are prepared to make the changes. Change is not easy. I indicated earlier it is now Medicare alone is 3.4 percent of the gross domestic product. If it goes on until 2040 it becomes 8 percent. We will not have an economy that will sustain jobs at that point. And if we do not have sustainable jobs, we have no revenue to sustain Medicare.

MR. GONZALEZ. Wouldn't it be more appropriate to just not leave it in the hands of Congress should we reach the trigger or the threshold? Is it not the responsibility of representatives of the people to make that determination on how we would address that shortage? If the trigger is there and we know there is a consequence, would it not be more appropriate rather than to have something that is automatic in nature?

SECRETARY LEAVITT. But Congress--the proposal is that the Congress could. They could implement changes that in fact would make it unnecessary.

MR. GONZALEZ. Well that leads me to my next question. Under what we presently have and the threshold is met as opposed to what you propose and it would pass obviously that it is automatic what would

happen under the two different scenarios from the 45 percent when the threshold or the trigger is reached under the present scheme of things if Congress did not do anything?

SECRETARY LEAVITT. What we do is if Congress does nothing in the long-term that this system is not sustainable and we end up with a lot of people who lose whatever they have and that is unacceptable and we are proposing here is an alternative. If Congress will not act, then it will take an act of Congress to put into place this automatic decrease. Congress could very easily avoid it by taking the steps to do things that were hard. Let us face it, making any change in Medicare would be hard. So at some point if Congress is unwilling to do it, then there is at least a remedy that creates--

MR. GONZALEZ. Then why not have this in all our different budgets? When we have thresholds and triggers if something would automatically happen rather than Congress taking the initiative or being proactive, I mean--

SECRETARY LEAVITT. Well I think that we are in agreement that Medicare, it sounds as though we are in agreement that Medicare is unsustainable but we have got the figures of which to resolve that and this is one idea and I think it is a pretty good one.

MR. GONZALEZ. It is also a question of priorities and not just unsustainability so that leads me to the next question then. If we move forward with real fixes for Medicare, would it not be prudent to figure out what it is really going to cost to provide health care to so many Americans in this program? And of course I am leading right up to the sustainable growth rate. I always forget that. Sustainable growth rate formula which since 2001 everybody has been saying we have to change but we are not changing and we have kind of discussed it. Dr. Burgess had touched on it. Greg Walden touched on it. Anyone talks about it but we do nothing. Well there is something out there right now, some legislation by Clay Shaw. Do you believe that the sustainable growth rate formula is accurate, fair, and realistically reimburses doctors in this Nation for their services to Medicare patients.

SECRETARY LEAVITT. I think the system is not a good system.

MR. GONZALEZ. No, I am asking you if this particular formula that, under which we operate right now. This is what--the doctors are not going to get any more, any less unless this formula changes. I mean is it a fair formula, does it realistically reimburse physicians for their services?

SECRETARY LEAVITT. Congressman, I believe it is a bad system and by nature one that is not precise, and I believe that we would be far better off if we could go to a system that would begin to acknowledge the fact that what we are after here is not quantity, it is quality. And that if we do

not do that we will continue to have this collision every year. What happens when we cut the rate is that we just get more procedures and the system continues to march toward un-sustainability in a different in a different--

MR. GONZALEZ. But it is a flawed formula?

SECRETARY LEAVITT. It is a flawed system.

MR. GONZALEZ. Thank you very much.

MR. BILIRAKIS. Mr. Inslee for six minutes.

MR. INSLEE. Thank you, Mr. Secretary. You said a couple things in your opening statement that were intriguing to me. When I asked you about it and you said something to the affect that our hearts are full of compassion all of us for those who are afflicted but we hope to help through these programs. You also made repeated references to the concept that this is a time of deficits so we had to take that into consideration in our policies. And the budget in our review has in significant ways cut existing levels of programs to commit to help the people who are dear and tied to our compassion one of which that is particularly concerning to me is our rather wholesale cuts to our Institutes of Health research budgets which hold such tremendous potential. We cut the Cancer Institute for $40 million. That is real dollars it is actually more than in inflation adjusted dollars. I think it is $20 million dollars in the National Heart, Lung, and Blood Institute. This is very concerning because I think one of my colleagues said that we doubled the budget in NIH in the last ten years but we have gone up about 1,000 percent in our genetic knowledge and the like. We are just on the cusp of such tremendous advances and yet we are cutting these budgets at a time of tremendous advancement.

That causes me great concern. And I want to put this in the context of real people which is two citizens, Washington friends of mine. One has prostate cancer, a 55-year old guy had original diagnosis and surgery. He later had some recurrence and now is in radiation therapy. He will be looking for, I would think he would say it would make sense to make as much investment as we can in medical research to treat that disease but we are cutting $40 million of our existing level of research into cancer. Another friend of mine, he did well in the software business, and in this budget he is going to get about a $2 to $4 billion dollar tax cut, $2 to $4 billion tax cut. The fist guy with the cancer we will call Fred with the cancer. He is getting a cut in the promise of his Federal Government to do something about his potentially life threatening disease. The other fellow, let us call him William, is getting a tax benefit of $2 to $4 billion out this budget. How do we possibly say that, you know, the second guy with the billions is entitled to more compassion in this time of deficits that the first with cancer?

SECRETARY LEAVITT. Let me reconcile for you the approach that we are taking with this because I think you yourself made the point that our genetic knowledge, for example, is expanding and in many other areas. We are still investing $4.8 billion a year in cancer research. We are not stopping our research, we are simply saying $4.8 billion is what we can afford this year. At the same time, we have an entire group of initiatives that will benefit every one of the institutes of NIH and at the heart of that is cancer. Those were valued at several hundred million dollars. So you can say well we are reducing that by $40 million. What is going on at the NCI at the same time we are doing joint projects that go across the entire breadth of NIH that will have substantial benefit to NCI. You know, let us acknowledge the fact that we are flat funding in this budget the National Institute of Health.

MR. INSLEE. I think you are not seeing my question. My question is to compare two individuals in different circumstances, one with billions of dollars and one with billions of cells that we are trying to solve cancer of. And my question to you is why is the first with the billions of dollars in this budget entitled to compassion by giving them additional tax relief but the second with cancer is you are entitled to less compassion than we had in last year's budget because we are cutting the budget or we are getting dumber in our scientific knowledge and so it does not make sense to make any more investments, or we think we are maxed out on the potential human achievement for treatment of cancer. One of those three, or there is something about the genetic makeup of the billionaires in our country that exceeds in our compassion value than those with cancer. Now I would like to know from your Administration, and you are responsible for my citizens and my colleagues and my friends' health care, which one of those justifies this prioritization?

SECRETARY LEAVITT. You are asking me to make a judgment, a policy judgment on tax policy or something in a debate that obviously will go on here in Congress. I will add that another person who got a substantial or will likely get a substantial tax cut is making a remarkable contribution to science outside of the National Institutes of Health or in partnership with the National Institutes of Health. The only effort that is growing in this Nation is not--on cancer is not what is going on at NIH gratefully. There are sources coming from lots of places and one of the places are those who have researchers in this country and make donations and we make--and in making that donation we give them a tax deduction which is essentially we are saying you do not have to pay tax on that money and a good share of it will go into cancer research.

MR. INSLEE. I want to make sure we understand the tax cuts you are referring to are not deductions for charitable giving. I am talking about eliminating the State tax, significant decreases in marginal rates for

dividends and the like, do I hear you are asserting that the reason that you justify a cut in our Federal research budget for dealing with cancer is the fact that there are many generous Americans who are making individual contributions. Is that the reason for it?

SECRETARY LEAVITT. No, I am simply trying to reconcile the policy, the value judgment you are asking me to make and that is a tax issue that will be dealt with--

MR. INSLEE. Well would you if given a chance, would you advise the President as far as your position that it would make sense between these two individuals that one fellow perhaps should get less of a tax cut and the other fellow perhaps should get better research for his cancer?

SECRETARY LEAVITT. The equity of that is not the subject of this hearing nor is it in fact that it is a policy judgment that Congress will need to make.

MR. BILIRAKIS. The gentleman's time has expired.

Ms. Baldwin to inquire.

MS. BALDWIN. Thank you, Mr. Chairman.

And thank you, Mr. Secretary. I have a comment or at least a question for later evaluation and then a couple of additional questions. I know you listened attentively to all of our opening statements and I commented about some of my concerns with regard to the approach, the ideology behind how savings accounts versus other approaches we could take to deal with our crisis of the uninsured. On the way over here today, I was made aware of a report out of the Center on Budget and Policy Priorities that was released just today, so I do not expect you have had a chance to take it in, but it basically looks at the cost and coverage impacts of the President's Health Insurance Budget proposal, health savings accounts in particular. And computer modeling reaches an estimate that the proposals will raise the number of uninsured in this country when fully implemented by a fairly sizeable number of 600,000 people. Now I feel confident that the Administration would not be moving this forward had they not reached a different sort of analysis. But this report certainly embodies my concerns about this approach. And so at such time that you have had a chance to look at this and compare that to your own assumptions in putting together this package, I would be interested in hearing your evaluation and how many more people you think going ahead with a health savings account approach will ensure.

Now to my specific questions for now. Secretary Leavitt, in late August of last year, Dr. Susan Wood at the FDA Commission for Women's Health and the Director of the Office of Women's Health resigned over the Administration's refusal to issue a final decision on the Plan B application. And she said and I quote "I can no longer serve a

staff when scientists and clinical evidence fully evaluated and recommended for approval by professional staff here has been overruled." Furthermore, a GAO report released in November of 2005 concludes that political inference played a role in the FDA's delay on the Plan B application. I guess I want to know if you are as concerned as I am about the possibility or allegations that political ideology is being placed ahead of Women's Health and Science and an agency within the Department of Health and Human Services? And additionally, what are you specifically doing to ensure that scientists in your agency are not being censored by political appointees as we have seen in recent allegations in NASA and as we have seen and heard about in the case of the Plan B situation?

SECRETARY LEAVITT. Let me respond to both of your questions. First of all, I must say to you you are correct. I cannot imagine an analysis that would demonstrate that the President's proposal would have fewer people. It is very clear from the 3 million people that now have health savings accounts that roughly 40 percent of them have never had insurance or did not have insurance before. The estimate is that you will see as many as 20 million people with health savings accounts by 2010 if the statistics hold up and there is no reason to think they will not. That means we will have roughly 8 million people who have insurance, many of whom do not have it now because of cost considerations. I could spend more time--

MS. BALDWIN. Right. If I may, I am sure you would not have gone forward if you did not think there would be a net increase. I am going to be real interested in a more technical analysis of the different assumptions you make versus this report. This report that I have had a chance to scan today does raise the concerns that I have always had about using this model to address the situation but I would love to hear you address the question about censorship of scientists and--

SECRETARY LEAVITT. I am quite aware of the basis on which those decisions were made. We were presented with a new policy dilemma involving the use of what is now a prescription drug that is available today through a prescription to all populations. We have been asked to break new policy ground that involves splitting the approval process by age. The decision was made that because it provided new public policy questions that we needed to seek additional comment which we have done. The comment period ended in November and those comments are now being analyzed. This is a process that is followed in regulatory agencies across the Government and it is an appropriate one.

MR. BILIRAKIS. The gentlelady's time has expired.

All time has expired. I believe you have a unanimous consent request?

MR. BURGESS. Yes, Mr. Chairman, I have a unanimous consent request. I have some data from Texas that shows of the 2.5 million Medicare beneficiaries 500,000 now have prescription drug coverage that did not have it before January 1 and this was dated as of January 20 and I just wanted to submit that for the record.

MR. BILIRAKIS. Without objection that will be the case.

[The information follows:]

Texas - FACT SHEET

TEXANS HELPED BY NEW MEDICARE PRESCRIPTION DRUG BENEFIT

- As of January 19, 2006, more than 752,855 Texans are enrolled in prescription drug plans through Medicare, according to numbers recently released by the federal government.

- Of the 2,562,049 Medicare beneficiaries in Texas, some 55 percent (1,411,470 beneficiaries) now have some kind of drug coverage.

- **Robust competition among Medicare Drug Plans continues to drive down costs for beneficiaries and taxpayers.**
  - According to CMS, competition among private plans has reduced the average premium to $25—a 32 percent reduction from the estimate of $37 just one year ago.
  - According to CMS, the overall cost for the benefit in 2006 is expected to drop by 20 percent or $7.6 billion and by $130 billion over 10 years.[i]

COMPOSITION OF MEDICARE BENEFICIARIES IN TEXAS [ii]

Column 1	Column 2	Column 3	Column 4	Column 5	Column 6	Column 7	Column 8
Medicare Beneficiaries in Texas	**Stand-Alone Prescription Drug Plans Enrollment**	**Medicare Advantage with Prescription Drugs**	**Dual Eligibles (automatically enrolled from Medicaid)**	**Subtotal (2+3+4)**	**Medicare Retiree Drug Subsidy**	**Federal Retirees (TRICARE and FEHB)**	**Total (5+6+7)**
2,562,049[iii]	234,159	223,653*	295,043	752,855	410,590	248,025	1,411,470

*Medicare Advantage includes some Medicare-Medicaid beneficiaries

- Beneficiaries in Texans have a wide range of choices. They can choose to enroll in a stand alone private plan (PDP) that provides prescription drug coverage in addition to *Original* Medicare, or in a managed care plan that combines Medicare-covered health care and the drug benefit into a single plan (MA-PD).
  - Beneficiaries may choose among 47 PDPs. Two plans offer premiums less than $20 per month. The lowest premium available is $10.31 per month.[iv]
  - Beneficiaries may also choose among a variety of MA-PDs depending on what county they live in. Twenty-seven of these plans offer premiums less than $20 per month; seventeen plans do not charge any additional premiums for the drug benefit.[v]

- Significant savings are available to Texans. For example, consider a beneficiary in Texas who currently uses 3 brand prescription drugs per month commonly prescribed for diabetes, high cholesterol and hypertension, and does not have drug coverage. On average, the beneficiary can save $938.43 (or 34 %) by enrolling in a Medicare prescription drug plan. But this beneficiary can save as much as $1,912.01 (or 68 %) by using the mail order option and choosing a plan with higher savings.[vi]

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[i] Centers for Medicare and Medicaid Services, Media Release, "Medicare Drug Costs Drop Substantially; Lower Costs Helping Beneficiaries, Taxpayers, States," February 2, 2006
[ii] CMS Medicare Fact Sheet; "Medicare Releases State-by-State Prescription Drug Enrollment Figures; January 19, 2006; found at http://www.cms.hhs.gov/apps/media/press/release.asp?Counter=1754
[iii] Centers for Medicare & Medicaid Services, "Current Medicare Beneficiary Population by State" January 2006; found at http://www.cms.hhs.gov/PrescriptionDrugCovGenIn/
[iv] Landscape of Plan Options; Stand-Alone Prescription Drug Plans; found at http://www.medicare.gov/medicarereform/mapdpdocs/PDPLandscapene.pdf
[v] CMS plan information posted on the CMS website on September 30, 2005; www.cms.hhs.gov/map/map.asp.
[vi] Savings are calculated off a national retail benchmark, CVS.com, and by using the CMS Plan Finder Tool to determine total beneficiary costs for PDPs. These savings include the premium and copayments paid by the beneficiary.

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MR. BILIRAKIS. Mr. Secretary, you have been a trooper. What else can we say? Thank you so very much for your patience and your consideration and your fairness. Many here have already said they were going to submit written questions to you. As you know, we customarily do that so I would ask you of course to respond to those and others that are submitted by the committee staff over a period of time. Thank you so very much for being here.

SECRETARY LEAVITT. Thank you, Mr. Chairman.
MR. BILIRAKIS. The hearing is over.
[Whereupon, at 5:28 p.m., the committee was adjourned.]

RESPONSE FOR THE RECORD BY THE HON. MICHAEL O. LEAVITT, SECRETARY, U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES

The Honorable Joseph R. Pitts:

1.)
Question:

Mr. Secretary, the Deficit Reduction Act of 2005 (DRA) included language to reduce payments for certain imaging services provided in the physician office setting or at stand-alone imaging centers. The payment amounts will be reduced to the amount paid in the hospital outpatient setting. I am told that some codes may be reduced by over 30 percent - and even some as steeply as 75 percent, such as for vascular imaging using ultrasound. While I can understand the desire to address differences in payments between settings, I am concerned that the hospital outpatient value was settled upon simply because it saved money. Has there been an analysis of whether or not the outpatient payment amount is adequate or appropriate?

Answer:

In 2006 Medicare pays a physician $903 for doing an MRI of the brain or an MRI of the abdomen. Medicare will also pay a Hospital Outpatient Department (OPD) $506 for the exact same test. Thus, Medicare is paying almost $400 or 78 percent more for doing these MRI imaging tests purely depending on whether the test is performed in an OPD or a physician's office. Similarly, Medicare will pay 267 percent more for doing an ultrasound guidance for artery repair in a physician's office than an OPD ($228 vs. $62). These comparisons do not include a physician's interpretation of the test for which Medicare will pay a separate fee. There is no consistency in the percentage that the physician fee schedule exceeds the hospital OPD payment amount. The percentage difference varies by procedure.

In the context of: (1) significantly larger payments under the physician fee schedule than the OPD for the same service for certain imaging services, (2) site neutral payments for the same service identified by MedPAC as a long term goal under Medicare fee-for-service payment systems, (3) rapid growth in Medicare spending for imaging services for several years, (4) MedPAC raising methodological issues that suggest relative values under the physician fee schedule for imaging services would be too high, combined with a lack of procedure and equipment specific information on alternative equipment utilization assumptions to use in the practice expense formula to address such issues, section 5102(b) of the Deficit Reduction Act of 2005 establishes a payment limit for the technical component of imaging services. The provision requires that Medicare not pay a physician more than Medicare would pay the OPD for furnishing the same imaging procedure. A physician's interpretation of the test for which Medicare will pay a separate fee is not affected by the provision.

This step to level the playing field between physicians' offices and hospital OPDs only applies to procedures where Medicare pays more in physicians' offices; the DRA cap provision does not apply to all imaging procedures furnished in physicians' offices. In addition, the percent that Medicare payment rates for physicians exceeds OPDs are not all as large as the examples cited above; in numerous cases, the differential is 10 to 20 percent. Thus, the overall impact is not expected to be as dramatic as the example of some procedures.

The DRA provisions will be implemented through notice and comment rulemaking. These proposals are expected to be published this summer and will allow for a 60 day public comment period. A final rule will be published by November 1, 2006 and will be effective for services furnished on or after January 1, 2007.

2.)
Question:

As you know, the President's FY2007 budget calls for an inflationary increase in funding for the medical device user fee program. This Subcommittee has also shown support for this program by fully funding the program the last two years. Can you tell us how the agency is doing in regards to meeting the performance goals associated with the user fee program with the funding it has gotten to date?

Answer:

Secretary Thompson's November 14, 2002, letter to Congress defines the performance objectives FDA is pursuing under MDUFMA. The commitment letter defines a comprehensive set of challenging goals and a schedule for meeting them.

FDA's performance to meeting MDUFMA's performance goals is, to date, consistent with the high expectations established for the program. We have attached FDA's performance report for FY 2004. The FY2005 performance report is currently under review within the administration, and we will forward the report when it is complete.

To allow FDA time to build its capacity to meet the ultimate (FY 2007) goals set by MDUFMA, the commitment letter provides for a phased implementation of goals, with more goals and higher performance expectations each year. During FY 2005, 18 additional goals went into effect (two of these apply to workloads handled exclusively by CBER); six more go into effect this year (FY 2006). During FY 2007, FDA will be responsible for a total for 77 quantitative goals covering five receipt cohorts. In addition, FDA is expected to pursue eight additional nonquantifiable commitments, such as developing an appropriate bundling policy (where FDA imposes only one fee for two or more closely-related applications from the same applicant), continuing its efforts to develop mechanisms for the electronic receipt and review of applications, and improving the scheduling and timeliness of preapproval inspections.

Although FDA does not expect to meet *every* goal specified by MDUFMA, the trends are promising. FDA is, in general, showing better performance as it implements new policies and procedures designed to improve the timeliness of our review processes. Although it is too soon to know what FDA's final performance statistics will show – many goals still have applications that remain open – FDA's performance on applications within more recent receipt cohorts is better than performance in older cohorts, showing that the improvements we have been making are beginning to bear fruit. If you had taken a snapshot of performance for the FY 2003, FY 2004, and FY 2005 receipt cohorts on December 31, 2005, you would see that FDA is meeting or exceeding 19 of the 24 goals in effect, and is not meeting only two goals; no applications have qualified for the remaining three goals. Most of these goals still have, or may have, additional FDA actions, so these results may change, but we are very encouraged by what we have accomplished so far.

3.)
Question:

During operation of the medical device user fee program, has the agency been able to determine specific direct and indirect costs of performing the various types of premarket approval (PMA) and 510(k) device approvals? Will you be able to determine incremental direct and indirect costs that will be associated with improving review times under more aggressive performance goals in future legislation?

Answer:

FDA is engaging with industry and stakeholders as it works on MDUFMA reauthorization. If the MDUFMA reauthorization results in changes to the performance goals, we will be able to estimate direct and indirect costs.

During FY 2005, FDA contracted with Dr. Dale Geiger, a recognized expert in the field of government cost accounting, to prepare a report of the costs of FDA medical device review processes. Dr. Geiger examined FDA medical device reviews conducted during FY 2003 and FY 2004, including investigational device exemption applications, premarket approval applications (PMAs), PMA supplements, biologic licensing applications, BLA supplements, and 510(k) premarket notifications. Dr. Geiger examined both direct and indirect costs and this work will assist FDA with cost analysis in gard to the performance goals resulting from the MDUFMA reauthorization.

4.)

Question:

What criteria does the agency use to determine the allocation and priority for the distribution of any increase in staff across FDA components, including offices, divisions, branches, and districts resulting from the medical device user fees and related Congressional appropriations?

Answer:

When MDUFMA was first enacted, FDA developed an internal plan for the allocation of anticipated resources—both from fees and from appropriations. In doing this, the agency estimated the percent of the device review workload that was performed in CDRH and the percent that was performed in CBER. Those initial estimates indicated that 83 percent of the device review work in the two centers was performed in CDRH and 17 percent was performed in CBER. FDA's initial allocations to the two centers of the total of increases for device review from both fees and appropriations were based on these estimates, and allocations within each center were made by Center management after assessing where the resources were needed to enhance the device review process as defined in MDUFMA.

From subsequent data, it is evident that this allocation to CDRH needs to be increased and the allocation to CBER needs to be reduced. This is because CBER represents a smaller percent of the combined device review work between the two centers than originally estimated. In addition, CBER had a well-developed IT infrastructure and did not need to spend as much on IT as did CDRH, so CBER was able to focus more of its resources on personnel. In future allocations, increases are being given in larger measure to CDRH.

In addition to the funds allocated to the two centers and to the Office of Regulatory Affairs (a little over 80 percent of the total of increased funds), allocations have to be made to accounts that support the additional FTE in the Centers and ORA. These planned allocations provide about 7.3 percent of the total increased funds to the Office of the Commissioner, about 6.2 percent for rent and rent related costs for housing the additional staff, and about 7.1 percent to the FDA central account, which pays for a variety of support costs, including the cost of local and long distance phone services, operation of health units, mail and document storage, and HHS charges for facilities, human resources, and other employee support costs.

The Honorable Ed Whitfield

1.)
Question:
The Deficit Reduction Act of 2005 appropriates $2 billion for use by HHS to pay the uncompensated health care costs of providers who have delivered care to affected individuals or evacuees under a Section 1115 project as a result of Hurricane Katrina. It was Congress' intention that Federal Qualified Health Centers (FQHCs) and other providers would be eligible to receive funding under this uncompensated care pool if they provided care to evacuees of and individuals affected by Hurricane Katrina.

Does HHS intend to ensure that FQHCs are eligible to receive funding under the uncompensated care pool if they provide care to evacuees of and individuals affected by Hurricane Katrina?

Answer:
Reimbursement for qualified items and services provided by Federally Qualified Health Centers (FQHCs) to eligible individuals will not be prohibited from reimbursement under the uncompensated care pools (UCCP). Eight states have been authorized under Hurricane Katrina Multi-State section 1115 demonstrations to reimburse providers that incurred uncompensated care costs for Katrina evacuees who do not have other coverage. States have the discretion to reimburse providers, including FQHCs, in accordance with the state's approved UCC plan.

The Honorable John Dingell

1. The Budget includes Legislative cuts to Medicaid of $4.9 Billion over five years, and another $12.2 billion in cuts through regulatory changes, for total gross cuts of $17.2 billion over five years. These cuts are in addition to $28 billion in cuts to Medicaid over 10 years in the Republican reconciliation spending cut bill – the Deficit Reduction Act.

The reconciliation law will result in higher co-payments for healthcare services for 13 million working families, people with disabilities, and seniors (including 4.5 million children), higher co-payments for prescription drugs for 20 million individuals (including 6.6 million children), the loss of coverage for at least 65,000 people in just one year alone because they cannot afford higher premiums, and benefit cuts for at least 1.6 million people.

Now the President proposes a new round of cuts to Medicaid -- $42 billion over the next ten years. According to an independent analysis of your proposals, the primary savings come from shifting costs to states.

A.)
Question:
Please provide the State-by-State effect of each of the spending cuts you propose in Medicaid. If you cannot, explain why.

Answer:
The CMS Office of the Actuary does not prepare state-by-state impact analyses of Budget proposals.

B.)
Question:
The proposal to restrict funding for governmental providers saved $1.2 billion over five years when it was in last year's budget, and now saves $3.8 billion in this year's budget. Please state exactly what has changed in your proposal to make it cut an

additional $2.6 billion over five years. Why do you now think you can do this policy by regulation, when last year you claimed you needed legislative authority?

Answer:

The President's FY 2007 Medicaid Budget includes two related legislative proposals that curb questionable financing practices by providing a Federal match for only those funds kept by providers as payment for services (the "net expenditure" proposal) and limiting reimbursement levels to no more than the cost of providing services (the "cap at cost" proposal). It is anticipated that both of these proposals will be implemented through administrative authority.

Specifically, the Medicaid baseline for the President's FY 2007 Budget (which includes both regulatory and legislative proposals) only reflects a five year $3.8 billion savings estimate for the "net expenditure" provision. The additional savings from the "cap at cost" proposal are not included in the Medicaid Budget baseline. In other words, a portion of the total savings from the intergovernmental transfers (IGT) proposal was included in the FY 2007 Budget estimates, but not all the savings that should have been. The "cap at cost" proposal is estimated to save $1.5 billion over five years. After accounting for the interactions between the two proposals' estimates, the total net savings are estimated to be $5.1 billion over five years. Despite this oversight, the total savings for these FY 2007 Budget proposals is somewhat less than the estimate for the FY 2006 Budget proposals because additional states have eliminated their inappropriate use of financing practices to maximize federal Medicaid reimbursement in the intervening year.

This policy will be promulgated by regulation under the authority of section 1902(a)(30)(A) of the Social Security Act (the Act), which requires that payments be "consistent with efficiency, economy and quality of care." This provision of the Act requires the Secretary to protect against abuses by states and providers. The taxpayer should not pay more to a public entity than it costs to deliver the service to a Medicaid beneficiary. Additional authority to protect the fiscal integrity of the program is also found at 1903(i)(3) and (i)(17).

C.)

Question:

The budget includes a new proposal on school-based administration and transportation. This proposal is a regulatory change, not a legislative one, and it saves a considerable amount of money. Please explain what the Centers for Medicare and Medicaid Services (CMS) is proposing to change with respect to services in schools?

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.

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 President's 2007 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.

We estimate that these proposals will save $0.6 billion in FY 2007 and $3.6 over five years.

D.)

Question:

Under current law, the Social Security Act at section 1903(c) reads, "Nothing in this title shall be construed as prohibiting or restricting, or authorizing the Secretary to prohibit or restrict, payment under subsection (a) for medical assistance for covered services furnished to a child with a disability because such services are included in the child's individualized education program established pursuant to part B of the Individuals with Disabilities Education Act or furnished to an infant or toddler with a disability because such services are included in the child's individualized family service plan adopted pursuant to part H of such Act." In light of this language, what is the legal basis for the authority to terminate Medicaid payment for these services?

Answer:

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.

E.)

Question:

The budget states that CMS will also issue regulations that restrict the services that States can provide under the category of rehabilitation services. Please provide further details on the proposed rules and what services will continue to be permitted. Also, please cite the statute or regulation that gives you the authority to make this change. What States will this provision affect?

Answer:

Rehabilitation services are an optional Medicaid service under Section 1905(a)(13) of the Social Security Act (Act) and defined at 42 CFR 440.130(d). Rehabilitative services are typically offered to individuals with special needs or disabilities to help improve their health and quality of life. Under current practices, states are billing Medicaid for rehabilitation services that are intrinsic elements of non-Medicaid programs. For example, CMS has determined that the costs of therapeutic foster care services, adoption services, family preservation and family unification services are being shifted by some states from foster care to Medicaid. Under the rubric of therapy support services, states are also shifting costs of non-medical support services and routine supervision provided by teacher's aides in school settings to Medicaid. Also, states are claiming for services that are not rehabilitative, which were previously approved by CMS as rehabilitation services.

All states provide rehabilitation services as an optional benefit in Medicaid. States can also provide rehabilitation services through home and community based services (HCBS) waivers, but the provision of such services through HCBS waivers would not be impacted by this proposal.

The FY 2007 Budget proposes to prevent cost shifting by issuing a regulation that would clearly define allowable services that may be claimed to Medicaid as rehabilitation services and exclude payment for rehabilitation services that are intrinsic to programs other than Medicaid. The regulatory change will also clarify that Medicaid payments will be available for rehabilitation services that are intended for the maximum reduction of physical or mental disability and restoration of an individual to the best possible functional level.

Through review of State Plan Amendments (SPAs), CMS has found that, by using overly broad definitions of rehabilitative services and payment methodologies that are not tied to specific covered services, states are bundling services together which Medicaid is not supposed to pay for at all, such as room and board. CMS has also found that these methods serve to effectively circumvent the statutory IMD exclusion, and the principle that Medicaid is the payer of last resort. To address these concerns, we find authority in a variety of places in title XIX of the Social Security Act, including sections 1902(a)(4)(A), 1902(a)(30)(A), section 1903(i)(17), and section 1905(a).

The Administration does not develop state-by-state estimates on legislative proposals.

F.)

Question:

Given that many States already have preferred drug lists and requirements that beneficiaries use generic drugs, what new authority are you proposing to give States?

Answer:

The President's FY 2007 Budget proposal would allow States to use private sector management techniques to leverage greater discounts through negotiations with drug manufacturers through managed formularies.

The Administration is currently developing the specific details of this proposal.

<u>Formulary Classifications and Coverage:</u>

1.)

Question:

Last June, CMS issued an important clarification of its guidelines to drug plans submitting bids for the Part D program. This guidance stated that CMS would require "all or substantially all" drugs to be covered by the plans in six categories: antidepressants,

antipsychotics, anticonvulsants, anticancer drugs, immunosuppressants, and drugs for HIV/AIDS. The guidance was based on the complexity and high cost of the diseases that these drugs treat, as well as evidence-based practice. Also stated was CMS's expectation that plans would not use management techniques such as prior authorization or step therapy for patients stabilized on crucial drugs in these categories. Since January 1, 2006, however, a widespread problem of plans not fulfilling this guidance has been reported. Patients who had been stabilized on a drug from one of these six important categories are being told at their pharmacy that their drug will not be covered.

A.)
Question:
What enforcement measures will CMS provide to ensure plans provide access to these vital medications? Has CMS taken any enforcement action to date against plans that were not complying with these requirements?

Answer:
Plans are required to meet Part D program and contractual requirements as a condition of participation. In the formulary area, CMS has in place a thorough review process for Part D plan formularies, which must be satisfied before a plan can be approved to participate in the program. Formularies are reviewed pursuant to 13 different criteria that ensure beneficiaries have access to the medicines they need at competitive prices. CMS will continue to monitor plan formularies throughout a plan year to ensure that beneficiaries have appropriate access to covered drugs. A plan found out-of-compliance will be instructed by CMS to immediately resolve any formulary deficiencies. Plans also have been advised that failure to satisfactorily comply with Part D program requirements in 2006 is grounds for non-renewal in 2007.

B.)
Question:
This requirement is only in effect for the first year of the benefit. Does CMS plan to continue to require plans to cover all or substantially all drugs in these categories in the future as well?

Answer:
Yes. CMS has issued guidance on drug formulary requirements for the 2007 contract year. This guidance retains the requirement that plan sponsors include on their Part D plan formularies "all or substantially all" drugs in six categories: antidepressants, antipsychotics, anticonvulsants, anticancer drugs, immunosuppressants, and drugs for HIV/AIDS.

C.)
Question:
What is CMS's authority to require a 90-day transition period? Are plans required to follow this CMS guidance or is it optional? What recourse does CMS have against a plan that does not follow this requirement?

Answer:
Under 1860D-11(d)(2)(B) of the Social Security Act, CMS has authority, similar to the Director of OPM with respect to health benefits, to prescribe reasonable minimum standards for health plans. Under this authority we have required all Medicare drug plans to offer enrollees a transition process. CMS has an ongoing compliance monitoring program in place, and will follow-up with plans and take enforcement actions if necessary to ensure compliance with requirements.

2.)
Question:

On February 3, 2006, CMS released guidance on the coverage of Niacin, stating that beginning June 1, 2006, it would no longer be covered under the Part D benefit, but until that point, plans that had advertised covering Niacin must continue to do so. It is my understanding that the AARP plan was not in compliance with this CMS directive and was excluding coverage of this medicine. What actions has the Department of Health and Human Services (HHS) taken to ensure private plans are following this directive? What sanctions have been levied against noncompliant plans?

Answer:

CMS has issued more recent policy clarification regarding prescription Niacin products. This policy clarification supersedes our February 3, 2006 letter.

The Food and Drug Administration has determined Niaspan and Niacor to be safe and effective drugs, used therapeutically for the treatment of dyslipidemia, and that they do not serve as nutritional supplements or address vitamin deficiency. Additionally, these products are used at dosages much higher than appropriate for nutritional supplementation. For these reasons, CMS has superseded its initial February 3, 2006 letter and determined that these products should not be considered prescription vitamins for purposes of Part D coverage. The new policy guidance does not require plans to add these products to their formularies for 2006. However, for the 2007 contract year, prescription Niacin products should be considered for formulary inclusion similar to all other Part D drugs.

Part D

1.)
Question:

What steps is HHS taking to assist dual eligibles who have medicines that are not preferred (with respect to cost-sharing) under their plan's formulary to either appeal so that those medicines are moved to a preferred tier or to assist the beneficiary to either (a) move to an alternative but equally effective medicine or (b) move to a plan with lower out-of-pocket costs?

Answer:

It is important to keep in mind that the cost-sharing structure for dual eligible beneficiaries is outlined in statute. Therefore, dual eligible beneficiaries are not subject to specific formulary cost sharing structures of the various prescription drug plans.

With regard to off-formulary drugs for dual eligibles, CMS has required Medicare prescription drug plans to establish an appropriate transition process for new enrollees including full-benefit dual eligibles who are transitioning to the Medicare benefit from other prescription drug coverage. CMS believes that a requirement for an appropriate transition process balances the protection of certain vulnerable populations with the flexibility necessary for Medicare prescription drugs plans to develop a benefit design that promotes beneficiary choice and affordable access to medically necessary drugs. All plans transition processes address the plan sponsor's method of educating both beneficiaries and providers to ensure a safe accommodation of an individual's medical needs with the plan's formulary.

We understand that many plans have systems in place that trigger a written notice to the member when a plan provides a transitional first fill of their prescription. Other plans provide instructions through their contracted pharmacies. In whatever the form, we have noted to plans that the instructions to the beneficiary should:

(1) Explain that the supply is temporary,
(2) Indicate that the member needs to work with the plan and his or her physician to identify appropriate drug substitutions,
(3) Advise that the member has a right to request a formulary exception, and
(4) Provide the procedures for requesting such an exception.

Additionally, full benefit dual eligibles have the opportunity to change plans at anytime. We feel these protections will help ensure dual eligibles have access to necessary medications under the new Medicare prescription drug benefit.

The Honorable Elliott Engel:

1.)
Question:

Redistribution of Ryan White Resources: The Administration's Ryan White reauthorization principles make it evident that there is momentum toward the redistribution of CARE Act funds. It appears that the goal of the Administration is to shift funds among jurisdictions through drastic changes in funding formulas, restrictions on the use of funds, and the elimination of provisions that limit the loss of resources to jurisdictions over time. An examination of the effects of the principles indicates that funds would be redistributed in a manner that will harm persons living with HIV and AIDS in many of the States that are impacted most heavily by the epidemic. What is the rationale for shifting funds around? We are not faced with a shifting epidemic. Rather, we are faced with an expanding epidemic. There is not a single jurisdiction in which this epidemic has stabilized or diminished. I've heard references to jurisdictions with "older" epidemics and inferences that an "older" epidemic is somehow more stable. But the reality is that an older epidemic is likely to be a much more expensive one to manage. And we know that all jurisdictions are seeing new infections each year and increasing numbers of persons with HIV and AIDS requiring a range of services. The state of emergency associated with this epidemic is not confined to one region, but continues in heavily impacted States and throughout the Nation. It would seem that if Ryan White funds are to follow the epidemic, they must continue to flow to all jurisdictions and be increased in order to address overall increased need. I've heard discussion around "reforming" and "modernizing" the CARE Act, but I hope these are not euphemisms for taking resources away from some people living with HIV and AIDS in order to shift funds. Again I would ask, what is the rationale for redistributing funds, and why do the Administration's principles focus on shifting badly needed funds around instead of enhancing resources and services in all jurisdictions?

Answer:

The Administration's Principles and proposal focus on the best way to distribute the monies already appropriated by Congress and does not focus on new congressional appropriations. Both the IOM report "Measuring What Matters" and the recent GAO report, "Changes Needed to Improve the Distribution of Ryan White CARE Act and Housing Funds" have concluded that there are large disparities in per case funding of HIV/AIDS due to multiple provisions in the Act which result in a distribution of funds among grantees in a manner that does not reflect the relative distribution of AIDS cases in these jurisdictions. If additional funding were made available without removing these provisions, we would not achieve the goal of redistributing funds more equitably as funds would flow to the same jurisdictions that have higher per case funding at the present time.

2.)

Elimination of "Double Counting": I have a few questions about the Administration's reauthorization principle that calls for the elimination of so-called "double counting" of AIDS cases between Title I metropolitan areas and States, which the principle maintains contributes to an unequal distribution of Federal funds.

a.)
Question:

First, the principle suggests that an equal dollar-per-case distribution of Ryan White funds can be achieved by adjusting the Title I and Title II formula awards only, thus disregarding the rest of the CARE Act, including Title I supplemental awards as well as Title III, Title IV, and Part F awards. The principle states that its goal is to count every

AIDS case equally and distribute funds in a fair manner. How can this goal be achieved when the principle fails to consider funding from all titles of the CARE Act?

Answer:

The 80/20 provision was instituted in the 1996 reauthorization to adjust for concerns that combined Title I and Title II funds in states with EMAs caused more funding per AIDS case than states without EMAs. This provision created a two-part formula for Title II base funding that takes into account the number of AIDS cases that reside within the state but outside of any EMA's jurisdiction. The methodology is as follows: The most recent 10 years of ELCs are calculated for all states and territories. 80% of the ELCS (award is) are divided among all states and territories based upon each state's proportion of the total ELCs in all states and territories. The remaining 20% is based upon each state's proportion of the total ELCs in all states and territories that are located outside the EMAs within a state. However, this does result in the double counting effect. In effect, a portion, but not all of the cases attributed to an EMA in a state are counted twice in calculating the Title II base award. Eliminating the "double counting" phenomenon would mean that the state's base award, in a state with EMA(s), would be based solely on the ELCs in the non-EMA area of the state.

The Administration, after much deliberation, has determined that the Title structure of the Ryan White CARE Act should remain. The findings of both IOM and GAO are conclusive: without altering several legislative provisions that create structural barriers under Titles I and II in the CARE Act, funding per AIDS case will continue to vary greatly. Because of the current structural barriers, the CARE Act will be unable to distribute funds equitably and effectively address unmet need across the country. Our goal is to distribute CARE Act dollars equitably so that funding is available to serve individuals living with HIV/AIDS who cannot afford to pay for the care they need.

b.)

Question:

Second, I have a concern about the impact of this principle on the jurisdictions with the largest numbers of persons living with HIV and AIDS. Consistent with its intent – to direct assistance to the jurisdictions disproportionately affected by the epidemic – the CARE Act has provided direct funding to metropolitan areas impacted by the epidemic to ensure a coordinated local response. At the same time, the CARE Act has recognized the key role of States -- which administer Medicaid and regulate the health care, health insurance and other key sectors -- in coordinating a statewide response, by giving States partial credit for their AIDS cases in Title I cities. These considerations are equally valid today. Any application of this principle will lead to a devastating loss of resources to high-prevalence States. For example, eliminating the statewide component of the Title II formula would lead to a loss of about $54 million in the five highest prevalence States – New York, California, Florida, Texas and New Jersey. These five States are home to more than half of all Americans living with AIDS. Six additional jurisdictions would lose more than half of their Title II base funding for HIV care – the District of Columbia, Massachusetts, Connecticut, Missouri, Nevada, and Minnesota. In all, 18 States would lose more than $76 million in Title II funding. While some areas undeniably need additional funding, is it reasonable to reduce resources in the jurisdictions that are hardest hit by the epidemic?

Answer:

The President's Principles call for more equitable distribution of CARE Act funds, which is paramount in the reauthorization. Changes in the CARE Act are not intended destabilize services, but are designed to assure that persons in need of HIV services and unable to pay for them shall be able to receive those services, both in urban communities

and in rural communities. By maintaining important provisions in the legislation, such as maintenance of effort and matching fund requirements, the Administration will ensure that states continue to contribute state and local funds to critical HIV/AIDS services to minimize any impact that redistribution of CARE Act funds might have.

b.)ii.
Question:
How would the Administration propose to address possible funding reductions in the highest prevalence States? Wouldn't a more reasonable approach involve increasing resources to address overall increased need and to assure that all persons living with HIV and AIDS have access to care?

Answer:
The Administration's Principles related to equity in funding distribution are based on current funding levels and do not address additional Congressional appropriations as a means to attain equity among jurisdictions and States. If additional funding were made available without removing these provisions, we would not achieve the goal of redistributing funds more equitably as funds would flow to the same jurisdictions that have higher per case funding at the present time.

3.)
Question:
My question on the SNCSI principle relates to the index itself. The development of a needs-based index is of concern insofar as data that would be used to make allocation decisions might not be universally available. For example, one important measure of need would be HIV cases, but we know that name-based HIV surveillance data is collected in only 33 states. When data are not universally available for eventhe most basic measure of need for HIV services, is it your belief that a meaningful, scientifically sound, feasible needs-based funding formula is possible at this time?

Answer:
The Administration's CARE Act reauthorization principles call for the establishment of objective indicators to determine severity of need (SON) for funding of core medical services and proposes that such an index take into account HIV prevalence, poverty rates, availability of resources including local, state and Federal programs and support, and private resources. There are established national data bases from sources including Census, Labor, CDC, CMS, HRSA that are being examined by HRSA in response to the IOM report, "Measuring What Matters: Allocations, Planning, and Quality Assessment for the Ryan White CARE Act," that may be utilized in the development of a meaningful and scientifically sound needs-based funding formula. Insofar as the status of HIV surveillance data collection by all states, the CARE Act requires that all states have HIV reporting in place by 2007 to receive formula grants under Titles I and II of the Act. The fact that the SON index will need to take into account HIV data means that there will need to be close coordination in the implementation of both HIV data and the SON index proposals.

b.)
Question:
My question relates to the existing Title I and Title II formulas, which are based on estimated living AIDS cases involving a weighted, ten-year case count. The formula does not account for people living with AIDS diagnosed more than ten years ago, who are likely to be the persons requiring the most intensive services. The formula might have been appropriate when the CARE Act was first authorized, but today, due to

successes in terms of treatment, people with AIDS are living much longer. I know the Administration's principles support changing the formula to incorporate a SNCSI, but if a scientifically sound, feasible needs-based index is not forthcoming, how would the Administration propose to distribute resources in a manner that considers all persons living with this disease that need services?

Answer:

The Administration's Principles for reauthorization of the CARE Act, propose key new provisions that will distribute resources in a manner that follows the epidemic, including:

- Using HIV Cases in Formula -- Maintain the current statutory requirement that all states submit HIV data by the start of fiscal year 2007. Having the full scope of HIV is critical to successful care and treatment programs that prevent people from advancing to AIDS.
- Eliminating Double Counting -- Eliminating the double counting of HIV/AIDS cases between major metropolitan areas (Title I) and the states (Title II).
- Eliminating Hold-Harmless Provision -- Eliminating current provisions that entitle cities to be "held harmless" in funding reductions.

The elimination of these provisions will better target funds to heavily impacted communities and aid in getting persons with HIV/AIDS into care earlier in disease progression by assuring every AIDS case is counted equally and areas get the funding assistance they need.

c.)

Question:

Still another concern about the SNCSI principle is the proposal to use HIV incidence – or new cases of HIV per year – as an indicator of need, when the true indicator of need would be HIV/AIDS prevalence – the total number of persons living with HIV and AIDS. Medical advances, reductions in deaths, and new infections each year result in more and more people living with this disease. The goal of addressing this epidemic can only be achieved by recognizing all persons living with HIV and AIDS who need services. All that said, why propose a formula that fails to consider all of the individuals we are seeking to serve by awarding funds based only on new cases of HIV?

Answer:

One variable under consideration for the Severity of Need Index is HIV prevalence. A number of other data elements from CDC's HIV/AIDS Reporting System (HARS) will also be considered in the development of the index. HIV prevalence will be examined by stage of disease (HIV or AIDS); progression to an AIDS diagnosis with a year of the HIV diagnosis; AIDS diagnosis without a previous HIV Diagnosis; HIV prevalence by age, race/ethnicity, and gender.

d.)

Question:

A final concern about the SNCSI principle is that it cites significant differences in access to HIV care throughout the country and recommends a drastic change to the formula for allocating funds to States and localities. The principle suggests that differences in Ryan White Title I and Title II funding to States are responsible for different levels of HIV/AIDS services among States. I think we can safely say that differences in access to services are attributable to many factors, including the differences in resources that States, themselves, provide for the care of persons with HIV/AIDS as well as the services available through medical assistance programs. Is it realistic to view

a single financing mechanism – specifically, the CARE Act -- as the means to equalize these inherent differences?

Answer:

It is not realistic to view a single financing mechanism as a means to equalize differences in HIV/AIDS resources across the country. Congress has had an implicit expectation that State and local governments, other funders, grantees, and subgrantees would share the financial burden of HIV treatment and support services. The expectation that States would contribute financially to HIV services was underscored through the CARE Act State payer of last resort, maintenance of effort, and matching funds requirements. While the current economic climate is compounding the pressure on the federal government, states, and localities to control health care expenditures, these CARE Act legislative provisions go far in assuring that all other private and public financial resources are utilized before CARE Act funds are tapped for payment of HIV/AIDS care and treatment. Thus provisions in the CARE Act such as these serve as a means to require states and localities to maintain existing HIV/AIDS financing resources and protect critical CARE Act dollars from being used to supplant other available resources.

4.)

Question:

Seventy-five Percent Set-Aside for Core Medical Services: One of the Administration's principles calls for the establishment of core medical services and would impose a requirement to use 75 percent of Ryan White funds for these core medical services. This requirement is inconsistent with years of publicly funded health and social services that have recognized the key interplay between medical care and other services, including but not limited to adequate nutrition, housing, case management (especially for persons with complex medical care needs), and outreach and education to bring people into care and to prevent further transmission. Recognizing that the CARE Act is but one component of a wide array of publicly financed health and medical care programs, and that the CARE Act is intended as payer of last resort, it would seem more efficient to allow jurisdictions to utilize funding as appropriate based on local needs and priorities. Variability among States in terms of populations impacted and their needs, alternative sources of financing and health coverage, and a wide array and composition of health and social service providers suggest that the flexibility that has been a hallmark of the CARE Act should continue. Perhaps encouraging Medicaid expansion programs for people with HIV would prove to be more beneficial than imposing restrictions on CARE Act funds with regard to core services. The Early Treatment for HIV Act, which I tried to pass in the Energy and Commerce Medicaid markup comes to mind as a reasonable means of enhancing access to medical services. It is not clear that creating parameters regarding allowable uses of CARE Act funding will result in increased or enhanced coverage. Finally, it is my understanding that most, if not all, jurisdictions that receive Ryan White funding do not support this principle. What is the rationale for or proposed benefit of imposing this sort of restriction? Is there research to suggest that imposing this type of requirement will result in better managed services?

Answer:

Advancements in HIV/AIDS care and treatment mean that people living with HIV/AIDS are living longer and healthier lives. Efforts to identify persons earlier in disease progression and bring them into care also means an increasing numbers of uninsured or underinsured are dependent on the CARE Act for care and treatment. In 2004, 71% of CARE Act funding was directed to health care services and medications. An additional 9% of CARE Act funding supported case management services. The establishment of a minimum limit of 75% reflects the amount of CARE Act resources

that will minimally need to continue to meet this need. HRSA does include housing assistance in its definition of health related support services. Job assistance services are not eligible for funding under the CARE Act. We are not aware of any research that suggests increasing the threshold to 75% will result in better managed services. It is important that care coordination is an integral part of core medical services provided under the CARE Act in order to assure optimum management of patient care and program services.

a.)
Question:

AIDS Drug Assistance Program (ADAP) I have two questions about AIDS Drug Assistance Programs. My first question relates to fiscal year 2006 funding. AIDS Drug Assistance Programs across the country currently have nearly 1,000 people (954) on waiting lists. After rescissions, the FY06 budget provides a negligible $2.2 million appropriation increase nationally for this vital program that has a historical growth rate of more than $100 million per year. We applaud the President's proposal to add $70 million to the FY 07 budget to address ADAP need. In light of the President's FY 07 proposal, will the Administration support an emergency appropriation for ADAPs during FY06 to prevent the growth of waiting lists, or will people living with HIV/AIDS in need of medications have to wait another year for relief?

Answer:

The Administration does not plan to seek an emergency appropriation for ADAP at this time.

b.)
Question:

Second, again, while we applaud the Administration's proposal to provide $70 million in additional funding to address ADAP waiting lists, my concern is that limiting the use of the funding to the elimination of waiting lists does not address the complexity of the issue. I think we all agree that all Americans should have access to the medications they need to stay alive. ADAP was constructed and continues as a payer of last resort, providing access to costly medications when there is no other source of coverage or the individual cannot afford to pay for the medications. Similar to variations in Medicaid, States have constructed widely varying ADAP programs in terms of eligibility, formularies, etc. Because Federal funding has not kept pace with ADAP program growth, some States have waiting lists for medications. But it is also true that in order to avoid the development of waiting lists, some States have instituted other cost containment measures, such as eligibility restrictions and reduced formularies. The end result is even more variation in access to care. It seems that providing funding for States that have ADAP waiting lists, without considering the composition of ADAP programs and eligibility standards, especially in those States that have initiated or plan to initiate cost containment measures, will not be an equitable way in which to address the ADAP crisis. Instead of limiting the additional ADAP resources to States with waiting lists, wouldn't it be more beneficial to expand the eligibility for these funds in order to enhance ADAP resources in all jurisdictions that are struggling to provide medications to their residents with HIV and AIDS?

Answer:

The $70 million will be used to help the States end current ADAP waiting lists and help support care for additional patients. The funding mechanism is under discussion within the Department.

6.)
Question:

Elimination of "Hold Harmless" Provisions: The principle that calls for the elimination of provisions that entitle cities and States to be held harmless is a major concern. The "hold harmless" provisions limit the extreme service disruptions that would result from the precipitous loss of resources to a jurisdiction and give time for a local response to ensure that no one loses critical services. It is in light of the Administration's apparent intent to redistribute CARE Act resources that I raise this concern. The elimination of the "hold harmless" provisions might be viewed as a means of fostering shifts in funds to address disparities. However, these disparities cannot be corrected through major shifts in resources between states without compromising services for persons living with HIV and AIDS in jurisdictions that lose funding. How would the Administration propose to address the disruption in services that would accompany drastic reductions in resources in some jurisdictions as a result of the Administration's principles? And again I have to ask – wouldn't a better approach be to increase resources to keep pace with the continued growth of the epidemic and address overall increased need?

Answer:

The Administration is attempting to respond in two ways: 1) by seeking to increase funding resources for HIV/AIDS care and treatment as reflected in the President's FY2007 budget; and 2) by proposing through the Admnistration's Principles the elimination of structural barriers in the CARE Act to allow better targeting of these new dollars to respond to the epidemic in our hardest hit communities.

7.)
Question:

Ryan White CARE Act Feedback Meetings and Alternatives to Principles Has the Administration considered any alternative proposals? For example, I understand that the National Alliance of State and Territorial AIDS Directors, or NASTAD – an organization that represents State health department HIV/AIDS program directors – has developed alternative recommendations for a reauthorized CARE Act. In addition, I understand that a Ryan White Legislative Group has been established to offer alternative solutions to reauthorization issues. Has the Administration considered alternative proposals to address the need for enhanced resources and resolve variations in access to care?

Answer:

The Administration began work on CARE Act reauthorization in January, 2003. Since then, there have been many opportunities provided by the Administration for HIV/AIDS organizations, persons affected by HIV/AIDS, and the public to offer comments and proposals on the reauthorization of the CARE Act. The Administration has had discussions with key constituent national groups including National Alliance of State and Territorial AIDS Directors (NASTAD) and Communities Advocating Emergency AIDS Relief (CAEAR) to hear their views and alternative proposals on changes to the CARE Act. In addition, both the CDC/HRSA Advisory Committee on HIV and STD Prevention and Treatment (CHAC) and the Presidential Advisory Council on HIV/AIDS (PACHA) developed reauthorization proposals resulting from public meetings (which were attended by hundreds of people representing themselves and many organizations) and other opportunities to hear constituency groups' views and proposals on the CARE Act reauthorization. Both the CHAC recommendations and the PACHA resolution included, among other proposals, better targeting of CARE Act resources to follow the epidemic in order to promote equity in the allocation of CARE Act resources.

8.)
Question:
Restructuring the Ryan White CARE Act While it does not appear to be among the Administration's principles, I have heard proposals that call for drastic modifications to the structure of the CARE Act, including eliminating or collapsing titles. Is it the Administration's intent to change the basic structure of the CARE Act in an extreme manner, such as eliminating or collapsing titles?

Answer:
No, the intent of the Administration is not to collapse or eliminate the CARE Act Titles or the programs funded under the various Parts and Titles of the CARE Act

Irritable Bowel Syndrome (IBS)

1).
Question:
Secretary Leavitt, I hold great interest in the National Institute of Diabetes and Digestive and Kidney Diseases' (NIDDK) research portfolio on Irritable Bowel Syndrome or IBS. Can you provide the Committee with the level of funding that NIDDK has dedicated to gastrointestinal functional and motility disorders over the last five years?

Answer:
The NIDDK supports a broad-based research approach to IBS that includes fundamental research in gastrointestinal motility, immunology, and cell biology, and clinical research in patients with IBS. This research is aimed at understanding the development of the pathways that control motility mechanisms in the gut; research on the integration of pain, motility and behavioral neural circuits, and the relationship of gut inflammation to these pathways; translational research aimed at moving discoveries in animal models into studies in humans; and clinical studies. NIDDK funding for IBS research for fiscal years 2001 through 2005 was: FY 2001, $9.3 million; FY 2002, $10.8 million; FY 2003, $16.5 million; FY 2004, $16.9 million; and FY 2005, $19.4 million.

The Honorable Charles Gonzales

1.)
Question:
Secretary Leavitt, as you know under current law, there is a problem with the Medicare physician payment system. According to the American Medical Association, Medicare payments to doctors are slated to be cut every year for the foreseeable future. Beginning in 2007 doctors will see a cut of 4.6 percent in their Medicare payments, and a total cut of 34% over the next nine years, about $26,000 per physician per year. First, I would note that the President's Budget includes no proposal to address this matter. There is language indicating you may wish to address this issue, but I would like to know – is it correct to state that at this time the Administration has no proposal, legislative or otherwise, to fix physician payments?

Answer:
The Deficit Reduction Act (DRA) of 2005 eliminated the negative physician update that would otherwise have taken place for 2006. In 2006, the physician community is developing quality measures that would cover a broad group of physician specialties and a wide range of clinical areas for physicians to begin reporting in 2007. We are working closely with the physician community to develop these evidence-based quality measures. During 2006, we are conducting a physician voluntary reporting program to allow physicians to report some existing quality measures and to allow us to test administrative mechanisms for reporting such measures. We are also examining the administrative issues that would be involved with alternative mechanisms to reward physicians who report information on quality measures. As the year transpires, we will assess progress in the development of performance measures for physicians, as well as mechanisms for the reporting of measures in 2007. This will provide physicians with the opportunity to report measures first, leading to payment for reporting and performance on such measures in the future. We would be happy to work with you and your colleagues on the physician update issue for 2007 and future years.

2.)
Question:
This is not a new and unexpected problem. Congress has had to make adjustments to Medicare physician payments over the past number of years since President Bush has been in office. The Medicare Payment Advisory Commission (MedPAC) first called for a new formula in March of 2001- two months after the beginning of President Bush's first term. How is it that after this many years of having a problem that is clearly identified and has been discussed in numerous hearings, letters to the Administration, public forums and other venues, the Administration still has absolutely no proposed solution? Can you tell me when the Administration will have a proposal to address the physician payment cuts in Medicare

Answer:
The President's Budget indicates support for linking quality to Medicare payment in a cost neutral manner. Given concerns about the overall financing of the Medicare program, we do not believe that providing additional aggregate funding to finance incentive payments is either supportable or necessary. On the other hand, we believe that savings from reducing care that is unnecessary or otherwise inappropriate affords opportunities to fund incentive payments. We believe we should examine possibilities of improving care coordination and using some of the savings generated in one payment system to fund incentives in another, as long as these reforms do not provide inappropriate incentives not to furnish necessary care.

The foundation of effective pay-for-performance initiatives is collaboration with providers and other stakeholders to ensure that valid quality and efficiency measures are used, that providers are not being pulled in conflicting directions, and that providers have support for achieving actual quality improvement. Consequently, to develop and implement these initiatives, we are collaborating with a wide range of health care providers, other public agencies, and private organizations who share our goal of improving quality and avoiding unnecessary health care costs. CMS is working with the provider community to identify and test budget-neutral incentives that will stimulate Medicare providers to improve performance on quality and efficiency measures.

3.)
Question:
Is this current reimbursement formula for physicians a fair and realistic reimbursement formula for doctors

Answer:
The current physician payment system focuses on payment for individual services, but does not provide incentives for physicians to take into account all of the services furnished to beneficiaries to treat an episode of care, or furnished during a period of time to treat chronic disease. This often has the effect of directing more resources to delivering care that is not of the highest quality (for example, duplicative tests and services, as well as hospital admissions or visits to treat potentially avoidable complications). Conversely, providers who have good ideas and want to take action to improve quality of care find that Medicare's physician payment system does not provide them with the resources or the flexibility needed to do so. As a result, providers are unable to invest in activities that, properly implemented, have the potential to improve quality and avoid unnecessary medical costs.

Linking a portion of Medicare payments to valid measures of quality and effective use of resources would give providers more direct incentives and financial support to implement the innovative ideas and approaches that result in improvements in the value of care that our beneficiaries receive. CMS supports provider payment reforms that would encourage quality and efficiency, and discourage increased complications and costs.

4.)
Question:
Secretary Leavitt, I am deeply concerned about the potential impact of proposed reductions in federal Medicaid spending on children and on children's hospitals, since Medicaid pays for the health care of one in four children and nearly half of the patient care in children's hospitals. CHRISTUS Santa Rosa Children's Hospital in my district is the largest provider of Medicaid services in the state of Texas—more than 70% of all of its patients are covered by Medicaid. Additionally, Texas has the fastest growing child population in the nation. Please explain to me what the administration proposes to do to make sure that the $60 billion reduction in Medicaid spending won't jeopardize the ability of children to receive the care they need, particularly the sickest children in the country who rely on children's hospitals.

Answer:
Last year when you addressed this question to me I reported that the President's FY 2006 Budget had the goal of cutting the budget deficit in half by 2009. Some of the savings to achieve that goal were proposed to come out of the budget for Medicaid and SCHIP-- in fact, the budget proposed $60 billion in savings over ten years for Medicaid

and SCHIP. The net savings for these two programs, however, was $44.5 billion because the budget also included $16.5 billion in proposed new spending.

The President's commitment to Medicaid reform proposals culminated in the Deficit Reduction Act of 2005 (DRA) which helps to achieve a transformation of Medicaid from a 1960s welfare program to a 21st century, innovative and adaptable provider of health care services for a broad spectrum of Americans. The President's FY 2007 builds on the success of the DRA by including both legislative and administrative proposals. Taken together these modest changes would save approximately $13 billion over five years.

With regard to specific services for children and other vulnerable populations, the DRA provides that States can choose to implement benefit flexibilities authorized by a new Section 1937 of the Social Security Act. However, the statute prohibits states from requiring certain groups of individuals to enroll in benchmark coverage, such as pregnant women, certain low-income parents, adults and children with disabilities, dual eligibles, and certain other aged and disabled individuals in need of long term care or adults and children with special needs.

Non-disabled children can be offered the benchmark or benchmark equivalent coverage specified in Section 1937, and for those children under 19, states will be required to provide wrap-around coverage consisting of EPSDT services if the benchmark and/or benchmark equivalent package does not offer these services. CMS policy is that EPSDT services will remain intact for children, and CMS will not approve any State plan amendment submitted under the new section 1937 that does not include the provision of EPSDT services for children under 19 as defined in section 1905(r) of the Social Security Act.

5.)

Question:

Secretary Leavitt, you have identified targeted case management as one area where states should cut their Medicaid expenditures, yet targeted case management is an extremely valuable service for many children. For example, a child in foster care who has asthma, depression from suffering abuse and learning disabilities may need his caseworker to coordinate treatment with his teachers, doctors, therapists, foster parents and birth family. This coordination is not waste, fraud or abuse, and in many states this targeted case management provides a critical service and a significant portion of the funds to serve these vulnerable special needs children. In the face of billions of dollars worth of additional tax cuts for millionaires, why are you suggesting cutting this support out from under these children?

Answer:

The Deficit Reduction Act of 2005 (DRA) included a provision to clarify what is reimbursable under the Medicaid case management benefit and the targeted case management (TCM) benefit. The Centers for Medicare and Medicaid Services (CMS) is currently drafting regulations to implement section 6052 of the DRA.

The FY 2007 President's Budget proposes to reimburse case management at the administrative matching rate of 50 percent. This legislative proposal was in the FY 2006 Budget and the Administration is proposing it again because there is evidence to indicate that states have attempted to shift costs associated with other social service programs to Medicaid. There are instances where the Medicaid program is being charged improperly for case management services when another program should maintain responsibility for payment.

Under the proposal, the match for case management will be the same as it is for an administrative activity. It does not eliminate federal financial participation (FFP) for case management services, nor does it affect Medicaid eligibility for those services or any other Medicaid services. In addition, the proposal does not affect the amount of

reimbursement that states will receive for Medicaid services to which an individual may be referred by a case manager.

6.)
Question:

Secretary Leavitt, the budget proposes investing an additional $1 billion in outreach efforts to enroll eligible children in CHIP. Yet the budget also proposes freezing SCHIP funding at next year's level. Given that health care costs continue to rise and that many states have already cut back on services, reduced eligibility or increased co-pays because they have the funds to service children at current levels, isn't it disingenuous at best to spend money on enrollment without adding funds to actually serve the children enrolled?

Answer:

The FY 2007 President's budget proposal does not "freeze" SCHIP funding; it assumes SCHIP will continue at its current level. We look forward to working with Congress on the reauthorization of SCHIP.

Approximately $9.5 billion in federal SCHIP allotments is available to states for FY 2006, not including the FY 2003 redistribution ($171.6 million) or the FY 2006 additional allotment ($280 million) to eliminate funding shortfalls (as appropriated by the Deficit Reduction Act of 2005).

In addition, there are sufficient funds in SCHIP to meet current state needs, as well as to cover additional children that would be enrolled as a result of the comprehensive outreach efforts that the President has proposed through the "Cover the Kids" campaign. Therefore, if the President's redistribution and outreach proposals are passed, we estimate that there will be plenty of funding in the system to cover these children.

7.)
Question:

Secretary Leavitt, the passage of the Medicare Modernization Act last Congress created a new program, Part D, to provide prescription drug benefits for seniors. In regards to Part D benefits and Preferred Drug lists, what criteria are going to be used to determine the drugs available for Medicare beneficiaries? Will the limited Oregon-style evidence-based medicine approach be utilized or will the more complete EBM system, as originally described, be the basis for medication reviews? How limited will the drug formularies be and how will inclusions or exclusions be determined?

Answer:

The MMA required that CMS develop, in consultation with the United States Pharmacopoeia (USP), model formulary guidelines for Part D plans. The USP guidelines identify categories and classes of drugs, and plan formularies must include at least 2 drugs per category and class outlined by the USP. For six categories of drugs of critical concern -- antidepressants, antipsychotics, anticonvulsants, anticancer drugs, immunosuppressants, and drugs for HIV/AIDS -- CMS requires plan formularies to cover "all or substantially all" available drugs.

CMS reviews all Part D plan formularies to ensure that beneficiaries have access to a broad range of medically appropriate drugs to treat all disease states. In addition, a plan formulary design must not discriminate or substantially discourage enrollment of certain beneficiaries. CMS created rigorous formulary standards that rely on existing best practices in the industry to ensure beneficiaries have access to medically necessary drugs, while offering flexibility for plans to offer benefits in the most cost efficient manner. Each formulary is reviewed by CMS pursuant to 13 different criteria:

1. Review of USP categories and classes (USP Model Guidelines)

2. Comparison with American Hospital Formulary System categories and classes
3. Two drugs per category and class
4. Review for USP formulary key drug types
5. Review of tier placement for all drugs
6. Review of widely accepted treatment guidelines
7. Review for 6 therapeutic categories or pharmacologic classes requiring uninterrupted access ("all or substantially all" requirement)
8. Review for common drugs used by Medicare population
9. Quantity limit review
10. Prior authorization review
11. Step therapy review
12. Insulin supplies and vaccine review
13. Long-term Care accessibility review

Additionally, CMS has provided detailed guidance to plans regarding the process for making formulary changes within a plan year.

8.)
Question:

Secretary Leavitt, how does the FY 2006 Health care budget address reimbursements for acute care health services that are mandated for hospitals to provide?

Answer:

The Administration recognizes and supports the important part hospitals play in our health care delivery system through the federal health care programs that we administer. I believe that the mandated services you are referring to in your question relate to those required under the Emergency Medical Treatment and Labor Act (EMTALA). In 1986, Congress enacted EMTALA to ensure public access to emergency services regardless of a patient's ability to pay. The statute imposes specific obligations on hospitals participating in the Medicare program that offer emergency services, which include providing a medical screening examination when a request is made for examination or treatment for an emergency medical condition, including active labor, regardless of an individual's ability to pay. Hospitals are then required to provide stabilizing treatment for patients with emergency medical conditions. The provisions of EMTALA apply to all individuals (not just Medicare beneficiaries) who attempt to gain access to a hospital for emergency care.

Although the President's Budget does not specifically address reimbursements for acute care health services that hospitals are mandated to provide under EMTALA, the Centers for Medicare & Medicaid Services is currently implementing a program that reimburses certain health care providers for these services. Section 1011 of the Medicare Modernization Act (MMA) set aside $250 million a year for fiscal years 2005 through 2008 to assist hospitals, physicians, ambulance providers, and Indian Health Service and Tribal organizations to recoup a portion of their costs associated with providing emergency services required by EMTALA. Individuals for which eligible services may be reimbursed include qualified undocumented immigrants who are uninsured or cannot afford emergency care. Two-thirds ($167 million) is allotted to all 50 States and the District of Columbia, based upon their relative percentages of the total number of undocumented immigrants. The remaining one-third ($83 million) is allotted to the six States with the largest number of undocumented immigrant apprehensions. The first and second rounds of payments to providers under Section 1011 has been completed and was made for services rendered during the third and fourth quarters of FY 2005.

9.)

Question:

The President's budget calls for $169 million for Health Information Technology (HIT), an increase of $58 million over FY2006. Some may consider this a significant increase. I don't think it is enough. Any practicing physician will tell you about the significant inefficiency in our current system of health care with respect to medical records/health information. I think tremendous gains in better care and cost savings can be achieved with better health information infrastructure. And sooner is better than later. How is the $169 million for HIT going to be used in FY2006? Is this money going toward demonstration programs and what is the process by which these demonstration programs are chosen?

Answer:

The FY 2007 budget request includes a total of $116 million for the Office of the National Coordinator for Health Information Technology (ONC). In addition to funds requested within ONC, the FY 2007 request includes $50 million in the Agency for Healthcare Research Quality to advance the use of health IT to enhance patient safety. There is also $4 million in the Office of the Assistant Secretary for Planning and Evaluation for independent evaluations of EHR adoption and economic factors influencing health IT implementations in the health sector.

ONC will continue to build upon foundational initiatives underway through its contractors to develop the long-term capacity to support widespread adoption of interoperable health IT. Core activities include

- Developing and harmonizing standards that are required for health information and data portability, which will include a process to maintain and update these standards over time;
- Continuing the development of a certification process for health IT, which will include refinements to existing certification criteria for inpatient and ambulatory EHRs as well as new criteria related to the NHIN architecture.
- Continuing the development of production-quality prototypes for Nationwide Health Information Networks (NHINs) which will enable secure exchange of electronic health records (EHR) and other health data;
- Developing personal health record architectures that will be integrated with the NHIN architecture, which will allow personal health information data to be controlled by the consumer and not just by clinicians and providers;
- Evaluating variations in the State laws and organization-level business policies around privacy and security practices, including variations in implementations of HIPAA privacy and security requirements. Lessons will be incorporated into the NHIN prototypes.

The Honorable Edward J. Markey
Medicare Part D

Looking at the President's Budget, I was surprised that the President has not proposed any changes to his Medicare Prescription Drug Program. Clearly we have seen a chaotic implementation of a confusing and overly complex program. Seniors have been calling for an easier solution and democrats have proposed providing seniors with the option of comprehensive plan that is run by Medicare which offers low cost drugs that have been negotiated by the Secretary

1.)
Question:
The President says that he wants to offer seniors choices. Would you support offering seniors the opportunity to choose a plan that is administered by Medicare?

Answer:
We are very pleased that following the Part D prescription drug benefit's initial enrollment period, more than 90 percent of people with Medicare are now receiving coverage for prescription drugs. Surveys by independent analysts have shown that a majority of enrolled beneficiaries are satisfied with their coverage and are saving money on prescription drugs. Ongoing analysis conducted by CMS continues to show that the Medicare prescription drug program is providing significant discounts on prescription drugs, with available savings remaining stable over time. Cost estimates of the Part D program are much lower than expected, in part because of aggressive price negotiation. Lower than expected bids, which were a direct result of price negotiations, have in turn resulted in lower costs for both beneficiaries (in the form of lower premiums and better benefits) and taxpayers. The Medicare prescription drug benefit experience thus far demonstrates that government price negotiation is unnecessary because competition is working.

2.)
Question:
When seniors encounter problem getting their prescriptions filled and they have to call their plan. They are usually either put on hold (literally for hours), are hung up on or are not able to speak with an actual person in customer relations to help resolve their issue. 1-800-MEDICARE has gotten faster, but it can't answer many specific questions and often tells beneficiaries that they have to call their plans. Has CMS or HHS done anything to force plans to reduce the plans' wait times and become more user friendly?

Answer:
We are very serious about overseeing plan call centers and enforcing their adherence to the requirement that beneficiaries get the information they need. Medicare beneficiaries should be able to count on a high level of customer service from their plans. For this reason, CMS has implemented a broad set of requirements for plan call centers that reflect the services they should be expected to provide reliably. CMS has been tracking actual plan performance and complaints, and we have been taking enforcement actions when necessary. CMS also has publicly released comparative information on plan call center performance and complaint rates to assist beneficiaries in identifying plans with a high level of customer service.

3.)
Question:
On May 16th will seniors be able to go to the pharmacy and fill their prescriptions without hassle, or will millions be turned away once again while the states are left to pick up the tab? What has been done to ensure that the problems in late December and early January won't be repeated on May 15th when there will be another wave of enrollment?

Answer:
CMS has been reaching out to beneficiaries and educating our partner network about the importance of enrolling in the first half of the month to maximize chances of a smooth transition to new Part D coverage. We also have taken steps to improve the regularity and consistency of data exchanges between plans and CMS to increase the likelihood that pharmacies will have enrollment and cost-sharing information available to them when new enrollees first try to fill a prescription using their new coverage. These efforts have resulted in significant improvements.

Public Health Service Evaluation Funding Questions:
It is my understanding that after appropriations have been made, the Secretary reduces funding for some programs and moves that money to other programs or even other agencies at HHS using the PHS Evaluation funding system.

1.)
Question:
What is the purpose of PHS Evaluation funding?

Answer:
PHS Evaluation funding supports critical evaluation activities throughout HHS. These evaluations, and the data collection and analysis that support them, improve program performance by ensuring that timely and accurate information is available to support funding and management decisions. PHS Evaluation funds finance the entire budget of the Agency for Healthcare Research and Quality, major data collection activities in the Centers for Disease Control and Prevention and the Substance Abuse and Mental Health Services Administration, and other evaluation and research activities across the Department.

2.)
Question:
What is the legal authority for PHS Evaluation funding?

Answer:
The use of PHS Evaluation funding is authorized by section 241 of the Public Health Service Act. The annual Labor, Health and Human Services, and Education Appropriation Acts specify the amount of funding that may be transferred from one program to another (2.4% for FY 2006 – see Section 207, General Provisions of P.L. 109-149), and specify, in each agencies' annual appropriations language, the amounts of PHS Evaluation funding to be received by specific HHS programs.

3.)
Question:
How much money was been moved within HHS though this process in the last fiscal year? How much over the last five years? How much do you anticipate moving in FY 2007?

Answer:

In FY 2005, the last fiscal year for which final data is available, $827.1 million of PHS Evaluation Funds were utilized by HHS agencies. For the five years between FY 2001 and FY 2005, a cumulative total of $2,911.2 million of PHS Evaluation Funds were utilized. In FY 2007, the President's Budget requests that $845.3 million of PHS Evaluation Funds be used.

4.)

Question:

What programs within each agency are sources of PHS Evaluation funding and which programs within each agency are the "recipients" of PHS Evaluation funding?

Answer:

As for the sources of PHS Evaluation funding, Section 241 of the Public Health Service Act allows the Secretary of Health and Human Services to use up to one percent of funds appropriated for all programs authorized under the Act for evaluation of such programs. The actual amount to be transferred is also specified in the annual appropriations bills. The programs of the Food and Drug Administration and the Indian Health Service, although part of the Public Health Service, are not authorized by this Act and, therefore, do not participate in the PHS Evaluation program. Some of the programs in the other PHS agencies are not financed by the Public Health Service Act (e.g., the Maternal and Child Health Block Grant in the Health Resources and Services Administration). Likewise, these programs also do not participate in the PHS Evaluation program

Recipient programs, as directed by Congress through the annual Labor-HHS Appropriations Act, include: the entire Agency for Healthcare Research and Quality; numerous health surveys and occupational disease and workplace safety activities within the Centers for Disease Control and Prevention; health surveys within the Substance Abuse and Mental Health Services Administration; research and evaluation conducted by the Assistant Secretary for Planning and Evaluation in the Office of the Secretary; activities of the Office of the National Coordinator for Health Care Information Technology; Ryan White Special Projects of National Significance within the Health Resources and Services Administration; research and evaluation activities within the Administration for Children and Families; the National Library of Medicine's National Information Center on Health Services Research and Health Care Technology in the National Institutes of Health; other research and evaluation activities in the Office of Public Health and Science and the Office of Public Health Emergency Preparedness in the Office of the Secretary; and other agency-specific efforts to evaluate the effectiveness of individual programs.

5.)

Question:

At what point in the budget process are decisions about PHS Evaluation funding made?

Answer:

Decisions about usage of PHS evaluation funds are made at the same time in the budget process as decisions about the usage of appropriated funds. The President's Budget and HHS's Appropriation Acts specifies how PHS evaluation funds are to be used.

6.)
Question:
What is the process by which the donor programs and recipient programs are determined and what the process for determining the amounts that are either given or received for each program?

Answer:
Recipient programs are identified in HHS's budget submission to Congress and are ultimately chosen by Congress when it passes HHS appropriation bills. Donor programs are billed proportionately to the amount of budget authority each has for programs authorized by the PHS Act (not counting exclusions).

7.)
Question:
Is comprehensive, understandable information about PHS Evaluation funding available any public form? If so, where?

Answer:
As required by law, HHS submits an annual report to the Labor-HHS Appropriations Subcommittees. This report shows the amount each Agency receives and the amount each agency donates.

8.)
Question:
Is comprehensive, understandable information about the various programs affected by PHS Evaluation funding compiled in any public form? If so, where?

Answer:
The annual report to Congress includes information on the amounts that each agency donates. Some agencies are routinely requested by the Appropriations Subcommittees for additional line item detail in Questions for the Record following budget hearings.

9.)
Question:
If PHS Evaluation funding were reduced or eliminated, what would the Secretary do with the money? If that is not known, what process would be used to make those decisions?

Answer:
In FY 2005, each donor agency contributed 2.4% of amounts appropriated for eligible programs under the PHS Act authorization and not otherwise excluded. If less PHS Evaluation funding were allocated by Congress, then the contribution from these programs would be less than 2.4%, more money would stay where it was originally appropriated, and less would be transferred to places where it is used for evaluation activities and the support of other ongoing programs, as currently directed by Congress.

<u>Avian Flu /pandemic</u>

1.)
Question:
With Katrina, we had a situation where because everyone was in charge, no one was in charge. I am afraid that we are setting ourselves up for another case of this with our plans for pandemic flu. Who is ultimately in charge of pandemic preparations? Are you

in charge, is Dr. Gerberding in charge, is Secretary Chertoff in charge or does the buck stop with someone else?

Answer:

The Department of Health and Human Services serves as the Federal Government's primary agency for the public health and medical preparation and planning for and response to a pandemic. The Secretary of Health and Human Services will lead Federal health and medical response efforts, will serve as the primary Federal spokesperson for pandemic health issues, and coordinate the actions of other departments and agencies in the overall public health and medical emergency response efforts. The Secretary of Homeland Security will provide overall incident management for the Federal response, and coordinate with HHS and other Federal, State, and tribal agencies in providing non-medical support. The Secretary of Homeland Security will also gather and fuse information in order to provide a "common operational picture" for the Federal Government.

The National Response Plan (NRP) stipulates mechanisms for coordination of the Federal response, but sustaining these mechanisms for several months to over a year will present unique challenges. While day-to-day situational monitoring would likely occur through a central operations center, critical decision-making would be accomplished through an interagency body comprised of senior decision makers from across the Government. This would occur through a mechanism such as a joint interagency task force. These and other considerations applicable to response to a pandemic will be incorporated in the NRP review process and inform recommendations on revisions and improvements to the NRP and associated annexes.

Irrespective of the mechanism used for interagency coordination, and pursuant to the NRP, policy issues that cannot be resolved at the department level will be addressed through the Homeland Security Council/National Security Council-led policy coordination process.

2.)

Question:

A special interest legal liability exemption rider was inserted into Department of Defense Appropriations Conference Report at the last minute. This rider provides virtually unlimited liability protection to the drug industry and no money for compensation to victims if you make a declaration that a qualified pandemic or epidemic product deserves this liability protection. I am concerned that the term "epidemic product" is overly broad and I would like to get your opinion on what is covered by this term and how you plan to use this power to exempt the drug industry from liability.

Answer:

We are very pleased that Congress has provided limited liability protections in this area. As you know, we have proposed a dramatic plan to ensure the nation's preparedness against a possible pandemic influenza that would have devastating effects.

One of the key barriers to our preparedness is the need for a strong and robust domestic vaccine manufacturing infrastructure that has the capacity to quickly ramp up production to provide vaccines for 300 million Americans. Since 1979, the number of U.S. licensed vaccine manufacturers has declined from 26 to 8. And for many vaccines, there is no longer a US-based manufacturer.

One reason for this, along with an uncertain market and other factors, is the continuous threat of liability facing vaccine manufacturers. As we developed our plans for pandemic flu, the vaccine industry made clear to us that there were three barriers that had to be addressed:

1. The threat of unwarranted liability

2. The lack of a guaranteed purchaser
3. The importance of streamlining regulatory barriers.

With Congress' help, we are now able to address each of these barriers. We are pleased that Congress has acted to provide limited liability protections for vaccine manufacturers and providers, with an exception to allow suits to proceed against companies who act with willful misconduct. We believe this strikes an appropriate balance of removing the threat of frivolous and unwarranted tort suits, while still retaining appropriate access to court remedies. With respect to our pandemic influenza vaccine contracts, we do plan to make use of the authorities afforded under the PREP Act.

It seems clear to me that Congress intended to focus this Act on products to meet the threats of pandemic flu and bioterrorism. While it is premature to discuss future hypothetical situations, I assure you we will strive to use this authority in a manner consistent with good policy and Congressional intent. We are also pleased that Congress has acted to put in place a structure to ensure that Americans injured by a vaccine to treat or prevent pandemic flu are appropriately compensated.

3.)

Question:

Do you think it would be appropriate to use this power to protect Merck who did not follow up on critical studies that indicated that Vioxx was linked to heart attacks from liability claims? Yes or no?

Answer:

We are very pleased that Congress has provided limited liability protections in this area. As you know, we have proposed a dramatic plan to ensure the nation's preparedness against a possible pandemic influenza that would have devastating effects.

One of the key barriers to our preparedness is the need for a strong and robust domestic vaccine manufacturing infrastructure that has the capacity to quickly ramp up production to provide vaccines for 300 million Americans. Since 1979, the number of U.S. licensed vaccine manufacturers has declined from 26 to 8. And for many vaccines, there is no longer a US-based manufacturer.

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has acted to put in place a structure to ensure that Americans injured by a vaccine to treat or prevent pandemic flu are appropriately compensated.

4.)
Question:

Do you think it would be appropriate to use this power to protect GlaxoSmithKline who concealed information showing that their product Paxil increased the risk of suicidality in children from liability claims? Yes or no?

Answer:

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5.)
Question:

What other "epidemic products" do you think it would be appropriate to protect from liability?

Answer:

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6.)

Question:

The legal liability exemption rider passed last year also created a compensation fund, but did not provide any money for it. Does the Administration plan to ask for funds to assure that compensation funds would be available for those who might be injured and no longer have recourse to the courts to seek compensation for damages? If there's no funding, or not enough funding, in the compensation fund, are the drug companies still exempted out from legal liability for injuring the public?

Answer:

We are very pleased that Congress has provided limited liability protections in this area. As you know, we have proposed a dramatic plan to ensure the nation's preparedness against a possible pandemic influenza that would have devastating effects.

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9. The importance of streamlining regulatory barriers.

With Congress' help, we are now able to address each of these barriers. We are pleased that Congress has acted to provide limited liability protections for vaccine

manufacturers and providers, with an exception to allow suits to proceed against companies who act with willful misconduct. We believe this strikes an appropriate balance of removing the threat of frivolous and unwarranted tort suits, while still retaining appropriate access to court remedies. With respect to our pandemic influenza vaccine contracts, we do plan to make use of the authorities afforded under the PREP Act.

It seems clear to me that Congress intended to focus this Act on products to meet the threats of pandemic flu and bioterrorism. While it is premature to discuss future hypothetical situations, I assure you we will strive to use this authority in a manner consistent with good policy and Congressional intent. We are also pleased that Congress has acted to put in place a structure to ensure that Americans injured by a vaccine to treat or prevent pandemic flu are appropriately compensated.

7.)

Question:

If only some states agree to accept the federal subsidy of 25 percent to stockpile antiviral drugs, how will the U.S. government ensure that all Americans are equally protected in a pandemic? Shouldn't this be a federal responsibility, given all the other responsibilities that are left to the states?

Answer:

Preparedness is a responsibility of all levels of government, communities, organizations, families, and individuals. The federal government is taking the primary lead in a variety of areas including expanding the nation's vaccine production capacity, procuring and stockpiling antiviral drugs, engaging in international and domestic surveillance and monitoring, and stockpiling non-pharmacological interventions (masks, etc..).

Specifically, for antiviral drugs, the federal government is purchasing the majority of these drugs without any state contribution. For the remaining 31 million, HHS is providing equal opportunity and equal access for states to prepare. Whether states take advantage of this opportunity will depend on their assessment of their level of preparedness and readiness.

Finally, it is important to note that Tamiflu does not equal preparedness; rather, it is only one of a number of tools that could help reduce the human health effects of a pandemic.

9.)

Question

What is the status of contract negotiations for the antiviral stockpile? By what date does the Administration anticipate meeting its objective of 81 million courses of antivirals?

Answer:

HHS has ordered 26 million treatment courses of influenza antivirals. By Decmber 31, 2006, 24 million courses will have been delivered to the Strategic National Stockpile. By March 31, 2007, an additional 2 million courses will have been delivered. The pandemic influenza supplemental appropriation in December 2005 provided funding for the majority of these 26 million courses.

The supplemental appropriation also provides funding with which HHS will establish arrangements for State purchases of 31 million treatment courses. Under these arrangements with antiviral manufacturers, States will pay 75 percent of the purchase price and the Federal government will contribute 25 percent. HHS has asked States to notify us of their intent to purchase the subsidized antivirals.

HHS' purchase of 26 million courses and the additional State purchases of 31 million courses are factors that have led antiviral manufacturers to expand production capacity.

HHS' purchase of another 24 million courses for the SNS depends on the appropriation of additional funding. HHS anticipates that for an HHS purchase placed during the first quarter of Fiscal Year 2007, a substantial portion of the 24 million additional courses will be available for delivery by the end of 2007. HHS will purchase the balance of the antivirals for delivery in 2008.

11.)

Question

Containing a pandemic is a global undertaking. Producing vaccine for all Americans is a worthy goal; but assuring that all people around the world can be vaccinated may provide additional protection from a pandemic's health, social, and economic impact. What would be the incremental cost were the U.S. to establish a larger goal (perhaps twice the planned 600 million doses) as part of a commitment by developed countries to contain a pandemic world wide?

Answer:

The Administration has established a goal to enable the production of 600 million doses of vaccine within six months of the emergency of a pandemic influenza virus. Funding requested by the Administration to date supports the expansion of manufacturing capacity to produce the necessary levels of vaccination for the United States. At this time we are unable to estimate the cost of purchasing the vaccine toward the 600 million dose goal. The Administration will work with the Congress to provide the resources necessary to support the purchase these vaccines.

We appreciate the funding Congress provided for the first year of our Pandemic Influenza Plan. However, additional funding is needed in FY 2007 to build on the momentum we have achieved this year. The FY 2007 budget includes a $2.3 billion allowance for the second year of our plan. These funds will allow us to more fully engage vaccine manufacturers and move us closer to achieving our goal of purchasing enough antivirals to cover 25% of the population.

We have met with industry about how we will manage the FY 2006 funding, given that we did not receive the advanced appropriations for FY 2007 and FY 2008. This funding and the liability protection provided by Congress have been an excellent first step in engaging industry to develop needed technologies, build domestic vaccine surge capacity, and increase domestic antiviral production capacity. We look forward to working with you to achieve our goals in these areas.

12.)

Question

Will the additional egg-based and the new cell-based production capacity that the federal government is funding be available for interpandemic production of flu vaccine?

Answer:

Our plan includes a number of investments for improving vaccine production capacity. These include expanding:

- Egg-based domestic vaccine production: to acquire 20 million additional pre-pandemic vaccine treatment courses and develop surge capacity to produce approximately 60 million courses within 6 months of a pandemic outbreak;
- Cell-based domestic vaccine production: to develop surge capacity to produce approximately 240 million courses within 6 months of pandemic outbreak by 2010;
- The development of dose-stretching technologies to extend the vaccine supply; and

•The development of commercially-produced vaccine to protect against multiple strains.

Our FY 2006 supplemental request included $6.7 billion over three years to meet our pandemic preparedness goals. Congress provided funding for the first year of this plan. The FY 2007 budget seeks funding for the second year.

Office of Generic Drugs Questions

Generic drugs save consumers billions of dollars each year and usually cost 60 to 90 percent less than the brand-name version. It is my understanding that the office of generic drugs has a backlog of 975 generic drug applications.

Question:

Why with a clear demand for more low cost generic drugs, this record backlog and increased number of applications has the President's budget asked for essentially flat funding for the Office of Generic Drugs?

Answer:

FDA understands that Congress and the public are concerned about the high cost of prescription drug products. Generic drugs play an 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 (ANDA), is imperative to making generic products available to American consumers at the earliest possible date.

FDA believes that making improvements in the process for the review of generic drug applications offers the best promise for reducing ANDA review time. With this goal in mind, in fiscal year (FY) 2005, FDA's Office of Generic Drugs (OGD), focused on streamlining efforts to improve the efficiency of the ANDA review process. OGD added chemistry and bioequivalence review teams and has taken steps to decrease the likelihood that applications will face multiple review cycles. OGD also instituted revisions to the review process such as early review of the drug master file as innovator patient and exclusivity periods come to an end, cluster reviews of multiple applications, and the early review of drug dissolution data.

In FY 2006, we will build on these process improvements. We have begun a major initiative to implement Question-based Review for assessment of chemistry, manufacturing, and controls data in ANDAs. This improvement builds on the Quality-by design and risk-based review initiatives of FDA's Center for Drug Evaluation and Research. 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 accelerate the review and approval of ANDAs. FDA also will continue to work very closely with the 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. We also will work with new foreign firms entering the generic drug industry. The Agency recognizes that it will take time for these new firms to understand the requirements for generic drug products. In the long term, however, these efforts should shorten overall approval time and increase the number of ANDAs approved during the first cycle of review. In FY 2006, FDA plans to spend $62.8 million relating to generic drugs and, specifically, $28.3

million in OGD. For FY 2007, FDA has requested $64.6 million relating to generic drugs, $29 million specifically in OGD.

1.)
Question

Why at a time when we are trying to reduce costs in health care, are we slowing down the approval of generic drugs?

Answer:

The approvals have continued to increase annually; FY 2003 – 284; FY 2004 – 320; FY 2005 – 361. Further, the average review time for approval has declined from 22.3 months in 2000 to 19.5 months in 2005 and the median review time has declined from 18.9 months in 2000 to 16.3 months in 2005.

2.)
Question

What percent of the 975 generic drug applications that are in the backlog are for first in class generics? Backlog as of 1/1/06.

Answer:

We currently do not distinguish "first generic" applications from other applications. We are presently committed to our long standing first-in, first-reviewed policy to review applications in turn. We also note that it is unclear as to what would constitute a "first in class generic" for this type of request. For example:

1) Is a "first in class generic" only the first ANDA received referencing a brand product?
2) Would "first in class generics" include all ANDAs received the first day that any ANDA was received for that reference product?
3) Would a second generic for a particular reference become the "first in class generic" if there were deficiencies in the preceding "first" application?
4) Would only the first ANDA for any drug in a therapeutic class be the "first in class generic"?
5) Or would an ANDA qualify as a "first in class generic" if it were the first ANDA for a particular strength or dosage form, say, even if other ANDAs had already been received for different strengths or dosage forms of the reference product?

3.)
Question

How much additional funding would the office of generic drugs need to eliminate this backlog?

Answer:

FDA's present backlog is approximately 1000 applications. FDA is currently receiving approximately 800 applications per year and approving about 500. To reduce the current backlog by one third (about 330 applications) annually over three years, we would have to approve or tentatively approve 1130 applications per year. That number includes all of the projected 800 applications that we receive in the fiscal year plus 330 more to reduce the current backlog. In order to approve or tentatively approve the approximately 90 applications per month, we would anticipate needing 70 FTEs for the first year and an additional 40 FTEs in each of the subsequent years, both to avoid having the backlog redevelop and to address anticipated increases in the number of ANDAs

submitted. It would be necessary to have all of the FTEs on board at the beginning of each of the fiscal years.

We should also point out that the backlog, as traditionally defined, includes ANDAs cycling through the Office of Generic Drugs. For example, if an ANDA is submitted and reviewed, and there are significant problems with the ANDA, a deficiency letter is issued to the applicant. The applicant's response, called an amendment, goes back into the review queue to await review. In some cases, the applicant does not respond in a timely manner due to their own resource limitation and priorities. These types of applications would also be considered to be part of the backlog. Because of this dependence on applicant responsiveness, it might not be possible to totally eliminate the backlog.

4.)

Question

On average how long does it take to conduct a first-in-class review of a generic drug? What is the longest amount of time it has ever taken? What is the shortest amount of time it has ever taken? (In both cases, please cite the name of the product and the date when it was approved.)

Answer:

As noted above, we do not differentiate between first-in-class ANDA reviews and other ANDA reviews. Review times are highly dependant on the complexity of the product and the quality of the application and do not necessarily reflect the resources or efficiency of the Office of Generic Drugs.

5.)

Question

On average how long after a brand name loses its patent protection do generics enter the marketplace? What is the longest amount of time it has ever taken? What is the shortest amount of time it has ever taken? (In both cases, please cite the name of the product and the date when it was approved.)

Answer:

The length of time for a generic drug to enter the marketplace depends on a number of factors, such as the applicant's commercial interest in the product, the ability of a generic manufacturer to produce the product, whether an application is ready for approval after the patent protections ends and if there is any exclusivity for the product (such as pediatric exclusivity). Even after approval, a firm may decide for its own business planning not to launch the product. FDA does not keep records in such a way that we would be able to readily discern the longest or shortest amount of time it has taken for a generic to reach the market after the brand name has lost its patent protections.

6.)

Question

It is my understanding that first-in-class applications must wait approximately 450 days before its bioequivalence can be evaluated, approximately 360 days before it gets a clinical review and approximately 530 days before it is reviewed by a microbiologist. Are these time periods correct? These seem to be unacceptably long periods of time. What are the agencies goals with regard to reducing these backlogs? How much additional funding and how many additional staff would you need in order to reduce the time to less than 120 days for each phase? To less than 90 days?

Answer:

As discussed above, the Office of Generic Drugs does not distinguish between first-in-class applications and other types of applications. It is true that the wait in the specific disciplines was at that level on the date the numbers were obtained. However, the applications do not all wait for that length of time. The chemistry reviews are the driving force of the review process and are reviewed according to the first-in, first-reviewed policy. When an application has been found satisfactory from the chemistry point of view (assessment of no deficiencies has been endorsed at the team level), this information is communicated to the other appropriate review disciplines (e.g., bioequivalence, microbiology). Those applications found acceptable from the chemistry standpoint are then moved to the top of the queue in the other disciplines so as not to hold up an action. Clear, high quality, complete applications are generally reviewed more easily and efficiently.

The overall goal for OGD is to meet the statutory timeframe and act on all applications within 180-days. The staffing needed to meet this goal and to reduce the backlog is discussed in the response to question 3.

To be able to have all review disciplines begin to review applications at 120 days, it could require an additional 30% increase over the figure provided in Question 3 (91, 52, and 52 FTEs in years 1, 2, and 3). To begin review in less than 90 days could require a 50% increase (105, 60, and 50). Since we have not contemplated these time frames, these estimates are highly speculative.

7.)

Question

On average how long does it take to approve a generic drug? How does this compare to the length of time that is needed to approve a brand name drug?

Answer:

During 2005 the average approval time for a generic drug was 19.5 months. The average time for NDA priority approvals is 10.1 months and the average time for other NDA approvals is 20.6 months. A comparison of these approval times would be misplaced because the goal dates for new drug applications are set by the user fee program and there are far fewer applications for new drug products.

8.)

Question

On average how much do drug companies make for each month that generics do not enter the market to compete with their brand name drug after it goes off patent?

Answer:

One cannot derive a meaningful average because of the product -specific nature of the potential profit. Further, we generally do not have access to such information.

Substance Abuse Cuts:

Drug abuse is a huge problem in my district. Educators and local police are struggling with how to prevent the problem from spinning out of control. This problem is not limited to my district. In fact, 23 million Americans struggling with severe substance abuse nationwide.

1.)

Question

Do you agree that prevention and treatment of substance abuse is critical to ensuring that people are healthy and productive members of our society?

Answer:

At the heart of the Administration's success in reducing drug use is a change in perceptions about the acceptability of using illicit substances. Education programs and outreach activities, backed up by scientific studies, have worked to spread the word that illicit substance use can be harmful to a person's health and well being, as well as a detriment to society as a whole. Effective education and prevention programs that focus on risk reduction and increasing resilience affect the perception of harm associated with drugs.

Despite all our attempts there are and will be some who will choose to use illicit drugs and many will become dependent. For some, early interventions will help them redirect their lives. For others, treatment will be necessary. The Administration has adopted a public health understanding of drug use and addiction and believes that drug use is a treatable disease. Like many other diseases, it is a relapsing condition that often requires not just the treatment itself but assistance in finding a job, a stable living environment and a social life that connects them to the society they are rejoining. Fortunately there are community-based programs, including faith-based programs, that are available to help.

2.)

Question

Then why does the President's budget cut $72 million from the Substance Abuse and Mental Health Services Administration include cuts to treatment and prevention of substance abuse? Shouldn't we be increasing our commitment to eradicating drug abuse?

Answer:

While the $71.6 million reduction in the budget request for SAMHSA for FY 2007 compared to its FY 2006 appropriation reflects a decrease of 2.25 percent, the actual decrease in funding for substance abuse is $35.9 million from FY 2006, which represents a decline of 1.5%. Despite this decrease, all continuation grants will be funded under the budget request, and the Administration is requesting funding for new grants under the Access to Recovery program that will offer choice to individuals in need of treatment, expand the array of services to include recovery and support services, and expand the array of providers to include new community-based programs, including faith-based programs. The Administration remains committed to prevention and treatment.

3.)

Question

Please provide a list of all of the HHS programs that provide funds to communities to help them address local issues of drug abuse. Please include programs that fund education, prevention and treatment.

Answer:

The Administration has requested $2.3 billion for Fiscal Year 2007 to help prevent and treat drug use. These funds will be available through the following programs:

<u>Substance Abuse Prevention and Treatment Block Grant</u> - FY 2007 request $1,758,591,000. This program distributes funds to States using a formula stipulated in statute to carry out substance abuse prevention and treatment activities in the State. Though there are some requirements that States must meet, States have tremendous flexibility in how they use the funds to address their State need. One requirement is that States must use at least 20 percent of their allotment for primary prevention.

Discretionary Grant Portfolio - FY 2007 request for prevention is $180.6 million and for treatment $375.4 million. These funds are made available to public and non-profit private entities on a competitive basis to address drug use. The following are the primary discretionary grant programs:

Access to Recovery - FY 2007 request $98 million. These grants are made to States to implement a voucher program for treatment that offers patients a clear and independent choice on treatment; expands the array of services, placing emphasis on recovery services that have been sorely needed in the treatment system; and expand the array of providers by including new community-based and faith-based programs to help drug users to recover. This program also brings accountability into the substance abuse treatment system. Fourteen States and one American Indian Tribe received the first cohort of these grants in FY 2004. FY 2007 funds would be used for the next cohort of Access to Recovery grants, giving the same States and all the other States a chance to compete for funds.

Strategic Prevention Framework - FY 2007 request $95.4 million. These grants provide program support to States to implement a comprehensive substance abuse prevention system in the State that relies on community involvement. At the end of FY 2006, 40 States and American Indian tribes will have received a grant.

Drug Free Communities - FY 2007 request $80 million (funds for this program are appropriated to the Office of National Drug Control Policy). The program is intended to reduce substance abuse among youth; help community coalitions strengthen collaboration; enhance intergovernmental collaboration, cooperation and coordination; enable communities to conduct data-driven, research-based prevention planning, and provide communities with technical assistance, guidance, and financial support.

Screening, Brief Interventions, Referral and Treatment - FY 2007 request $31.2 million. These grants expand and enhance State substance abuse treatment service systems by:

- expanding the State's continuum of care to include screening, brief intervention, referral, and brief treatment (SBIRT) in general medical and other community settings;
- supporting clinically appropriate treatment services for nondependent substance users;
- improving linkages among community agencies performing SBIRT and specialist substance abuse treatment agencies; and
- identifying systems and policy changes to increase access to treatment in general and specialist settings.

Targeted Capacity Expansion Grants - FY 2007 request $21 million. The purpose of these grants is to expand and/or enhance the community's ability to provide a comprehensive, integrated, and community-based response to a targeted, well-documented substance abuse treatment capacity problem and/or improve the quality and intensity of services. For example, a community might seek a Targeted Capacity Expansion grant to add state-of-the-art treatment approaches or new services to address emerging trends or unmet needs.

Grants to Benefit Homeless Individuals - FY 2007 request $34 million The purpose of these grants is to enable communities to expand and strengthen their treatment services for homeless individuals with substance abuse disorders, mental illness, or with co-occurring substance abuse disorders and mental illness. "Homeless" persons are those

who lack a fixed, regular, adequate nighttime residence, including persons whose primary nighttime residence is: a supervised public or private shelter designed to provide temporary living accommodations; a time-limited/ nonpermanent transitional housing arrangement for individuals engaged in mental health and/or substance abuse treatment; or a public or private facility not designed for, or ordinarily used as, a regular sleeping accommodation.

Children and Adolescent Programs - FY 2007 request $20.6 million. Key activities in this category include: State Adolescent Substance Abuse Treatment Coordination grants, which help build capacity in States to provide effective, accessible, and affordable substance abuse treatment for youth and their families; Child and Adolescent Mental Health and Substance Abuse State Infrastructure grants, which focus on children, adolescents, and youth in transition to adulthood with serious emotional disturbance, substance abuse disorder, or co-occurring disorders, and their families; and Family Centered Substance Abuse Treatment Grants for Adolescents and their Families, which provide services to adolescents and their families/primary caregivers using previously proven effective practices that are family centered and increase the likelihood of successful treatment and reintegration of the adolescents into their communities following the period of formalized treatment..

Criminal Justice - FY 2007 request $24 million There are several initiatives related to the criminal justice population. The Family and Juvenile Treatment Drug Courts (Drug Courts) Grant Program provides funds to be used by treatment providers and the courts to provide alcohol and drug treatment, wrap-around services supporting substance abuse treatment, assessment, case management, and program coordination to those in need of treatment drug court services. Grants are also available to expand and/or enhance substance abuse treatment and related reentry services in agencies that currently provide supervision of and services to sentenced juvenile and young adult offenders who are returning to the community from incarceration for criminal/juvenile offenses. Because reentry transition must begin in the correctional or juvenile facility before release, funding may be used for limited activities in institutional correctional settings in addition to the expected community-based services.

Pregnant and Postpartum Women - FY 2007 request $3.9 million. The purpose of these grants is to expand the availability of comprehensive, high quality residential substance abuse treatment services for low-income women, age 18 and over, who are pregnant, postpartum (the period after childbirth up to12 months), or other parenting women, and their minor children, aged 17 and under, who have limited access to quality health services.

KI Questions

1.)

The Public Health Security and Bioterrorism Preparedness and Response Act of 2002 contains an amendment, which I authored, that requires the President to make available Potassium Iodide, or KI, for populations within a 20 mile radius around a nuclear power plant. According to the U.S. Food and Drug Administration, "KI is a safe and effective means by which to prevent radioiodine uptake by the thyroid gland, … and thereby obviate the risk of thyroid cancer in the event of a radiation emergency." KI pills are available for approximately 18 cents a pill, making them a cheap and effective way to protect our citizens.

Question:

The guidelines issued August 2005 by HHS for the distribution and stockpiling of KI appear hostile to the intention of this provision, and appear to endorse sheltering and evacuation INSTEAD of KI distribution – rather than embracing KI distribution as part of an emergency plan that includes sheltering and evacuation options. Recent evacuations during the Katrina and Rita Hurricanes suggest that the Department's confidence that those living nearest to a nuclear facility can be easily evacuated is wildly optimistic. Even if citizens are able to evacuate, during their evacuation they will likely be exposed to radioactive iodine and they can easily be protected from debilitating side effects such as thyroid cancer by taking KI. Furthermore, the guidelines put the onus of responsibility for designing a plan for stockpiling and distribution of KI on State and local governments, rather than providing these governments with guidance on these procedures. Given that KI is cheap, easily administered, and highly effective, why does HHS continue to discount the benefits of KI and not provide clear guidelines for state and local governments to access, stockpile, and distribute KI?

Answer:

At the request of the President, HHS is working to make KI available up to 20 miles from a nuclear power plant. The guidelines for requesting, stockpiling and distributing KI within the 11-20 mile radius were published in the Federal Register in August 2005. We received comments on the guidelines from many sectors and have been working closely with other Departments and Agencies, as well as the States and the public to ensure that input is heard from all parties with concerns. For states who choose to participate in the program, the guidelines propose a process similar to that used by the NRC to distribute KI in the 0 -10 mile zone. As I am sure you know, there is not universal agreement that KI should be provided beyond the 10 mile EPZ. The KI guidelines present a balance perspective that addresses important considerations such as pediatric populations, sheltering-in-place, evacuation, special circumstances, current NRC protective action measures and more. The goal of the guidelines is to allow states to consider what distribution mechanisms, stockpiling, and utilization options best support their current planning initiatives. The guidelines have been submitted to OMB for review for compliance with all statutes, including the Paperwork Reduction Act, and budgetary considerations. HHS is eager to receive approval from OMB so we can publish the guidelines and move forward to provide KI to states that choose to apply for this program.

HHS has also taken steps to procure and make available enough pediatric (liquid) KI to protect children within the full 20-mile radius of a nuclear power plant in those states with approved KI distribution programs. This liquid form of KI is easier to administer to small children than the previously available tablet form. This acquisition was recommended by the interagency Weapons of Mass Destruction Medical Countermeasures Subcommittee, approved by the Secretaries of HHS and DHS and approved by the Office of Management and Budget (OMB), under delegated authority from the President.

<u>Stem Cell Question</u>

1.)

Question

Last year, when we urged the President to expand his policy on embryonic stem cell research and provide more funding for this exciting field of scientific research shows promise for helping treat and potentially cure juvenile diabetes, Alzheimer's and Parkinson's diseases, and spinal injuries, the Administration refused. However, the President said that he was very excited about the potential of research on stem cells that

are found in umbilical cord blood. However, the President's budget eliminates the Cord Blood Stem Cell Bank program. Why has the President decided to eliminate this program? Has the President changed his mind about the potential of cord blood stem cells?

Answer:

Because a balance of $18 million remains from appropriations made in FYs 2004, 2005, and 2006, the FY 2007 budget does not request funding for the National Cord Blood Stem Cell program. HRSA will use the funds remaining to implement the Cord Blood Stem Cell program during FY 2006 and FY 2007. Specifically, in each of these fiscal years, approximately $9 million of the remaining balance will be used toward the implementation of the program and the collection of an estimated total 13,800 new cord blood units. HRSA is committed to working with you as they begin to implement this important new program.

FDA Labeling

In the preamble of guidance that the FDA recently released on drug labeling, to the guidance included language that asserted that FDA decisions should preempt the states. I understand that this preamble does not have the force of law. But I want to make sure that I understand the Administration's position on federal preemption. Do you think that approval by the Food and Drug administration exempts the drug company from liability? If so, to what extent should companies be liable for the products they have on the market?

1.)

Question

Do you believe that people who are injured by drugs that were approved by the Food and Drug Administration should not have any recourse? Do you believe that they should not have any recourse through the state courts?

Answer:

As you know, the President has called for common-sense medical litigation reform that would allow individuals harmed to receive fair compensation for their actual losses, but that would put a stop to the frivolous, out-of-control lawsuits that are driving up health care costs so dramatically. By reining in non-economic damages, the legislation will improve access to care, by stabilizing the malpractice insurance market and encouraging doctors to keep practicing medicine, in particular treating high risk cases, in their communities.

Hearing Loss:

In a response to my letter about portable music players and hearing loss to Dr. James Battey, the director of the National Institute on Deafness and Other Communication Disorders (NIDCD) on February 14, 2006, Dr. Battey wrote that significant progress has been made in hearing research. The first program that he identified as one of the promising areas of research was the Newborn Hearing Screening and Early Intervention. The Director stated, "Results from NIDCD-supported research show that if children are identified with a hearing impairment by 6 months of age and then received appropriate intervention, they have significantly better language development than children whose impairment was identified after 6 months of age… Without appropriate and timely identification and intervention, early childhood hearing impairment interferes with the development of oral/aural communication, impedes academic performance, and results in negative long term vocational consequences."

Question

Why when approximately 2-3 out of 1,000 children are born each day who are deaf or who have a hearing loss significant enough to potentially affect their speech, language and cognitive development and NIH identified the importance of newborn screening does the President's FY07 budget eliminate the Universal Newborn Hearing Screening/Trauma program?

Answer:

The Universal Newborn Hearing Screening program has increased the percentage of newborns screened for hearing loss prior to hospital discharge. In FY 2004, 93.2 percent of newborns were screened for hearing loss prior to hospital discharge, exceeding the yearly target. The FY 2007 request continues the FY 2006 President's Budget policy and provides no funding for this program. The more flexible MCH Block Grant may address activities under this authority.

Ryan White:

According to the HHS Budget in Brief, the President's budget request increases Ryan White funding by $95 million dollars and directs $70 million to "address the on-going problem of State waiting lists and provide care and life-saving medications to those newly diagnosed as a result of increased testing efforts" and directs the other $25 million to expand outreach efforts by providing new HIV community action grants to intermediaries including faith and community based organization, and to provide technical assistance and sub-awards to grassroots organizations.

1.)

Question

How does the President intend to distribute the $70 million to the states?

Answer:

The funding mechanism is under discussion within the Department.

2.)

Question

Will it go to the ADAP program or through the Title II base grants?

Answer:

To allow maximum flexibility, the $70 million will be distributed to States. The States will have the option to use these funds to purchase medications through the State ADAP and to expand services for people living with HIV disease.

3.)

Question

Will the $25 million go to the Title II or IV programs or will it be distributed through another program?

Answer:

The President proposed $25 million in the FY 2007 budget is to expand outreach by providing as many as 25 HIV community action grants to community and faith-based organizations to provide technical assistance and sub-awards to grassroots organizations.

Drug Safety Questions

1.)
Question:
Adderall was approved in 1960, why did it take so long for the FDA to learn about the full range of potential risks associated with this product?

Answer:
Twelve reports of sudden death in children were reported to FDA between 1999 and 2003. The number of deaths reported was less than the number of sudden deaths that would be expected to occur in this population without treatment. For this reason, the FDA decided not to take any further regulatory action at that time. However, upon review of individual cases, we noted that some of these deaths occurred in patients with underlying heart defects. Although this is by no means proof that such patients are at increased risk from this drug, because these defects themselves place patients at increased risk of sudden death, we, nevertheless, decided to change the labeling for Adderall XR in August 2004 to include a warning that these patients should ordinarily not be treated with Adderall products.

In February 2005, FDA issued a Public Health Advisory and information sheets on its website at http://www.fda.gov to provide up-to-date information about Adderall's safety profile.

2.)
Question:
How long after the FDA became aware of the safety issues associated with Adderall did it start an investigation?

Answer:
In February 2005, when FDA became aware of Health Canada's decision to suspend sales of Adderall XR, but not revoke the approval in Canada, of Adderall XR as a treatment for Attention Deficit and Hyperactivity Disorder (ADHD), FDA reviewed the action it had already taken 6 months previously. Once FDA learned that Health Canada's action was based on precisely the same information upon which FDA had already acted, it concluded that no additional labeling changes were needed, but did decide to issue a PHA to inform the public about Health Canada's action and to explain that we had already acted and felt that Adderall and Adderall XR should remain on the market. It is noteworthy that Health Canada, upon receiving advice from its own advisory group 6 months later, decided to return Adderall XR to the Canadian market.

As with any drug, FDA will continue to carefully assess any new data that emerges which significantly affects the safety profile of this drug and will take immediate, appropriate action to promote the public health and make the public aware of its findings.

3.)
Question
Despite the many drug safety issues that have been raised over the past couple of years, the Office of Drug Safety only received a $4 million dollar increase. How much of the ODS funding will go to:

a. studying safety questions that have been raised about specific drugs?
b. updating the AERS system?
c. Setting up a program to collaborate with CMS?
d. Looking for concerning trends within epidemiological data?
e. the drug safety oversight board?
f. the Sentinel System?

Answer:

The 07 Drug Safety increase will be applied to the CDER Drug Safety Program, not specifically to the Office of Drug Safety. CDER's portion of the 07 Drug Safety Increase totals $3.564 million.

a.) $0.425 million
b.) $2.0 million
c.) $0.250 million - Please note that Line c is redundant to Line f. According to the FY 07 Congressional Justification Drug Safety Increase description, "collaboration with CMS will be known as the Sentinel System".
d.) $0.889 million
e.) We do not anticipate funding the costs of operating our drug safety oversight board from this funding increase.
f.) Please see note under Line c.

The Honorable Edolphus "Ed" Towns

1.)
Question:

Secretary Leavitt, beginning in 2007 physicians will experience a significant pay decrease totaling $176.9 billion over the next 7 years. This decline occurs in spite of the fact that physicians are taking measures to offset these cuts by providing increased services.

MedPac recommended giving physicians an update to address the significant Medicare payment cuts that will be made to physician payments over the next 10 years beginning in 2007. However, the President's budget does not adequately address the situation.

Additionally, Dr. Unterrick, a physician from my district strongly expressed the concern the physicians in my district have about the cuts to physician payments and their impact on the delivery of health care on my "News and Views" Television Program.

What measures are you taking to ensure that physicians who strongly desire to continue treating their Medicare patients will be able to do so in lieu of escalating health care costs and declining physician payments?

Answer:

The current physician payment system focuses on payment for individual services, but does not provide incentives for physicians to take into account all of the services furnished to beneficiaries to treat an episode of care, or furnished during a period of time to treat chronic disease. This often has the effect of directing more resources to delivering care that is not of the highest quality (for example, duplicative tests and services, as well as hospital admissions or visits to treat potentially avoidable complications). Conversely, providers who have good ideas and want to take action to improve quality of care find that Medicare's physician payment system does not provide them with the resources or the flexibility needed to do so. As a result, providers are unable to invest in activities that, properly implemented, have the potential to improve quality and avoid unnecessary medical costs.

Linking a portion of Medicare payments to valid measures of quality and effective use of resources would give providers more direct incentives and financial support to implement the innovative ideas and approaches that result in improvements in the value of care that our beneficiaries receive. Provider payment reforms should encourage quality and efficiency, and discourage increased complications and costs.

The physician community is developing quality measures that would cover a broad group of physician specialties and a wide range of clinical areas for physicians to begin reporting in 2007. We are working closely with the physician community to develop these evidence-based quality measures. During 2006, we are conducting a physician voluntary reporting program to allow physicians to report some existing quality measures and to allow us to test administrative mechanisms for reporting such measures. We are also examining the administrative issues that would be involved with alternative mechanisms to reward physicians who report information on quality measures.

2.)
Question:

Secretary Leavitt, I serve a very diverse congressional district, which is being devastated by the impact of HIV/AIDS. Fortunately, there are specialty pharmacies in the 10th congressional district of Brooklyn that are able to cater to those who are living with HIV/AIDS.

The President's FY 2007 Budget proposes states to exhaust all other third party sources of payments before paying Medicaid claims. Presently, states are able to pay claims as received and then later bill other sources of coverage. I'm concerned that the proposed policy will result in payment delays for pharmacies, and may result in reduced willingness of pharmacies to participate in the Medicaid program, thus reducing access to all beneficiaries and especially those in my district.

What measures are you taking to address this potential situation since it could prove fatal to many Brooklynites?

Answer:

Under current law, Medicaid agencies generally reject medical claims whenever there is another third party that is legally liable to pay the claims. The claims are returned to the provider instructing them to bill the third party. This is referred to as "cost avoidance." There are some exceptions to this rule. Exceptions to this rule are found in sections 1902(a)(25)(E) and (F) of the Social Security Act.

The FY 2007 President's Budget proposes administrative actions to discontinue all waivers of the cost avoidance standard for pharmacy claims. Without such waivers, states would be required to deny any pharmacy claim for which there is a liable third party payer. States will no longer have the option of "pay and chase," or paying the claim and pursuing payment from a third party.

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