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SETTING THE PATH FOR REAUTHORIZATION: IMPROVING PORTFOLIO MANAGEMENT AT THE NIH

HEARING

BEFORE THE

SUBCOMMITTEE ON HEALTH

OF THE

COMMITTEE ON ENERGY AND COMMERCE

HOUSE OF REPRESENTATIVES

ONE HUNDRED NINTH CONGRESS

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SETTING THE PATH FOR REAUTHORIZATION: IMPROVING PORTFOLIO MANAGEMENT AT THE NIH

THURSDAY, MARCH 17, 2005

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

The subcommittee met, pursuant to notice, at 9:37 a.m., in room 2123 of the Rayburn House Office Building, Hon. Nathan Deal (chairman) presiding.

Members present: Representatives Deal, Hall, Bilirakis, Upton, Gillmor, Shimkus, Shadegg, Pitts, Ferguson, Rogers, Myrick, Burgess, Barton (ex officio), Brown, Rush, Eshoo, Green, DeGette, Capps, and Baldwin.

Asso present: Representative Bass.

Staff Present: Cheryl Jaeger, professional staff; Chuck Clapton, chief health counsel; Brandon Clark, health policy coordinator; Eugenia Edwards, legislative clerk; John Ford, minority counsel; Jessica McNiece, research assistant; and David Vogel, research assistant.

Mr. DEAL. Good morning. I will start off this hearing today by welcoming Dr. Zerhouni here to testify with regard to the National Institute of Health. We appreciate your joining us here today to talk about one of the most important priorities, I think, of the jurisdiction of our committee.

As we are well aware, and many of you have attended the 10 hearings that have taken place over the last 2½ years on NIH. We hope that we can continue in the spirit of working together to achieve some much-needed reform in the administrative structure of this vital component of our Federal Government.

As many of you know, we have been working to reauthorize NIH longer than some of have been in Congress itself. And I think it is well past time that we get something done in that direction. It is time for us to put aside the petty projects or areas of concern that each of us might have, and work together to try to reorganize and make some changes to this very important agency and to modernize its organizational structure so that we can have the scientific discovery that will benefit everyone.

This is one of the most important issues I think that we can address in terms of challenging our ability to put aside partisanship, not only along party lines, but along particular issue lines, and simply do what is right for the American people.

Dr. Zerhouni, I think you truly are one of the heroes in Washington. You have been trying to fight against what is a siphoning of bureaucracy, and oftentimes, unjustified mandates that we have placed upon at you at the Agency and that you have responsibility for. I hope that all of us, as we listen to you today, will learn and hopefully avoid some of those mandates that we have tried to impose in the past.

We do appreciate your attendance. We appreciate your expertise of the subject matter that you are going to talk to us about. And we look forward to hearing your testimony.

I will now recognize my ranking member, Mr. Brown.

Mr. BROWN. Thank you, Mr. Chairman. Thank you, Dr. Zerhouni, for your excellent work in the National Institute of Health.

I want to begin by thanking Chairman Deal and Chairman Barton for your willingness to tackle NIH reauthorization in a bipartisan manner. We must support NIH so it can remain the world's flagship medical research institution, and we must prepare NIH, as well as our entire public health infrastructure for the challenges of the 21st century.

These challenges are significant. Emerging and as yet incurable diseases threaten millions of our citizens, even as we move forth with research on thousands of conditions, from asthma to myloma to spinal cord injury, educating the public on strategies for prevent and treatment and cure continues to remain a significant challenge.

Millions of Americans find themselves without access to any care, much less to the cutting edge work enabled by NIH funding. Around the world, we fail to remedy curable diseases, such as TB and malaria, that take millions of lives each year. These challenges require us to keep three things in mind as we move forward with reauthorization.

First, we must examine and improve the oversight rule of this Congress and this committee.

Second, we have—we must recognize the need for adequate funding for NIH, funding that reflects the evolution of medicine and lets us buildupon our monumental successes. After the successful doubling of NIH funding between 1998 and 2003, President Bush's budget suggests that NIH can make progress with flat funding. While this House and the White House tries to extend tax cuts for the wealthiest in our society, health care for the poor becomes the scapegoat, and NIH's innovative research becomes the target. This year, the President's requested a level of funding well below the level of inflation.

My question is, is that sufficient to sustain the current pace of medical progress? What are the consequences of flat funding? Before we enter the process of reauthorization, we should have concrete understanding of the impact on the budget—on this budget of the research and the mission of NIH.

Dr. Zerhouni, flat funding NIH makes things especially difficult for you as you set your own priorities each year, and as Congress weighs in with the priorities of the public. I am interested in hearing more about how you would like this committee to help you set priorities, accommodate and inform the public, and build a success-

ful research, given the challenge of the flat line budget and the kinds of budgets that constrict research and undermine medical progress.

I look forward to hearing about your plans for the Office of Portfolio Analysis and Strategic Initiatives, how this office can improve coordination not only among institutes, but between NIH and other agencies charged with protecting the public health. I hope it brings us closer to the transparency and effective dialog that is expected of us by the American people. It should be a goal of this reauthorization to understand not only what money NIH spends and how it is spent, but what these resources mean to you and to your researchers and what tangible returns the public should expect on its investment.

Third, we must examine NIH in the context of how each of our publicly funded health care agencies moves our society forward. We can be sure that moving forward as society in terms of the health care that we provide is a function of research and resources. Without either, we stop progress dead in its tracks. With this reauthorization, however, we have the opportunity to influence whether the public investment in medical progress is used to the benefit of all of our citizens, including the sickest and the most vulnerable and the poorest.

The AIDS drug Norvir was developed using inventions produced by NIH, so the American taxpayer footed the bill for its development. Norvir's manufacturer, Abbott Labs, decided late 2003 to increase the price of that critical AIDS drug by 400 percent, and to apply that price increase only to U.S. sales. I thought it was an unreasonable abuse of the American taxpayer's research dollars for Abbott Labs to quadruple the price of the resulting product, especially since that price hike was applied only to American consumers. NIH concluded it was neither responsible nor equipped to involve itself in prescription drug pricing, but at the very least, a lot of us believe NIH should weigh in in acknowledging investing in research, but ignoring access is a counterproductive exercise, and one that runs against the American publics' interest, if you say your goal truly is to promote the public health.

In its mission statement, NIH is charged with using its research to "to extend healthy life and reduce the burdens of illness and disability." That mission is promoted every day in the offices, the clinical facilities, and the laboratories at NIH, but oftentimes, the potential and inherent NIH sponsored research is neither fully nor equitably exploited or distributed.

As Congress considers the budget and as we in this committee work to reauthorize NIH, I hope that we remember that the mission of NIH is not just to fund and promote research, but equally importantly, maybe more importantly, to bring the benefits of that research to bear for all Americans.

Thank you, Dr. Zerhouni.

Mr. DEAL. Thank you, Mr. Brown.

Now recognize Mr. Hall of Texas.

Mr. HALL. I have no opening statement, Mr. Chairman. Thank you.

Mr. DEAL. Recognize Mr. Bilirakis, Florida.

Mr. BILIRAKIS. Thank you, Mr. Chairman. I, too, am pleased that we are here this morning to examine portfolio management at the NIH. And I want to welcome Dr. Zerhouni. I want to congratulate him for being appointed again to head the NIH, and to thank you so you very much for your willingness to continue to serve.

Dr. Zerhouni testified before us several years ago and said that "No outstanding organization can remain great without regularly reviewing its operating principles and plans, and subjecting itself to critical reexamination." Since becoming director, he has held NIH to that standard by undertaking an aggressive and ambitious plan to ensure that the Agency maintains a diverse portfolio of research founded both on public health need and scientific opportunities. I am eager to learn of the progress of these initiatives, as well as the potential the new portfolio management proposals may have to profoundly impact the progress of medical research and more quickly transform research into real treatments to help people.

The Institute has worked to advance knowledge and discover opportunities to prevent, treat, and cure the diseases and disabilities which affect so many is daunting, indeed, especially since more than 80 percent of its budget flows through the extramural community, which supports the work of research personnel affiliated with universities, hospitals, and other research facilities. Only about 10 percent of its budget supports the basic and clinical research activities conducted by NIH's world-class physicians and scientists. This challenge has become more pronounced, I think, in light of the considerable funding increases NIH has received over the past decade. Congress has doubled the NIH budget, which has opened new opportunities to further research and find better cures and treatments for diseases and disabilities. The increased funding has brought increased scrutiny, and does call for greater public accountability and transparency. Our constituents expect and demand that we hold NIH accountable for its use of scarce taxpayer resources. They deserve to know that NIH and its various institutes and centers are using their money as effectively as possible.

I believe that today's hearing will provide important information to help us, and them, to understand the factors and objectives NIH considers in the management of its research portfolio, and ultimately ensure that our national investment in biomedical research is doing as much good as it possibly can.

I know we all look forward to your testimony, sir.

Thank you very much, Mr. Chairman.

Mr. DEAL. Thank you.

Now recognize our colleague, Ms. DeGette.

Ms. DEGETTE. Mr. Chairman, I will waive my opening statement in favor for more time for questions.

Mr. DEAL. Recognize Ms. Capps for an opening statement.

Ms. CAPPS. I will also defer for more time for questioning.

Mr. DEAL. Ms. Baldwin.

Ms. BALDWIN. Thank you, Mr. Chairman, and thank you, Dr. Zerhouni, for being here today.

I represent Wisconsin's second Congressional district, and I am honored to have the University of Wisconsin, Madison, one of the Nation's premiere research institutions, as a part of the district that I represent. I am continually amazed at the research done at

the UW and the depth of expertise that they house in so many different areas of research.

From the initial discovery of how to grow and sustain stem cells made by Dr. Jamie Thompson back in 1998 to more recent discoveries involving skin tests for cholesterol levels, the UW has been a continuing leader in a number of exciting research fields. This is made possible largely by NIH funding, so I welcome this opportunity to talk about the NIH, and I look forward to engaging in a conversation.

These are such exciting times for scientific research. As we continue to learn more and more about the world works and the way that our bodies function, and couple this with advances in technologies, the research possibilities are truly exploding. The ability to conquer a variety of different diseases is within our reach, and I feel strongly that we, as Members of Congress and as government officials, should do everything we can to aid and encourage our researchers, not to discourage them or tie their hands in any way.

I personally continue to strongly oppose the President's arbitrary limits on embryonic stem cell funding because this area of research holds so much potential for learning more about and possibly developing cures for a whole host of conditions and diseases, from juvenile diabetes to spinal cord injuries to Parkinson's disease. Countless numbers of people continue to suffer because of this arbitrary limitation on this promising research, and I find this unacceptable.

But I would also like to ensure that we protect the time-honored practice of peer review. I was raised by a research scientist, an NIH-funded research scientist, and I have family members who continue to work in this area, conducting scientific research. So I have firsthand knowledge about the amount of scrutiny and close study that goes into the peer review process. This process is not simply a formality, it is a thorough, thoughtful process that ensures that limited research dollars are being directed toward research that is best needed and is best designed.

For the most part, members of this legislative body do not have backgrounds in technical, scientific matters that are involved in peer review studies, and I would hope that we, as Members of Congress, remember this and that we resist politicizing science. We must allow the peer review process to continue unfettered without Congressional interference.

Dr. Zerhouni, again, I thank you for coming here, and I look forward to today's discussion.

Mr. DEAL. Thank you. I recognize Mr. Barton, chairman of the full committee.

Chairman BARTON. Thank you, Mr. Chairman. I want to welcome you, Dr. Zerhouni. I know some of the questions today may be a little bit biting, but it is our job to serve as the oversight watchdog for the people, and I can say from personal conviction that you are doing the same thing at NIH as you try to reform and revise that agency and bring it into the 21st century.

It is not a part of my prepared statement, but I want to applaud you on your determination to clean up the consulting situation. I think your policies that you have implemented are in the right direction, and at the degree of the reform that we need to be moving. So I am going to applaud you for that.

According to the NIH annual review of spending, reprioritization of resources at NIH is critical. According to the NIH missions statement, deciding how and where to distribute money is a challenge the NIH faces each year. It requires fresh assessment of the Nation's health needs, and renewed evaluation of scientific opportunity. That is from your own mission statement, and I agree with that.

Expanding biomedical research in the 21st century requires the NIH to function in the most efficient manner so that each and every penny that is spent on medical research to prevent, treat, or cure disease is counted and expended meaningfully. To do so, the NIH has to be able to justify the scientists and the public alike why some research projects are advanced ahead of others.

Unfortunately, NIH has grown like topsy-turvy. In 1960, the NIH was comprised of a director and seven institutes. Today, there are 27 institutes and centers. The motivation behind this explosive growth has certainly been sincere. The individual organizations were created arbitrarily, usually without benefit of systemic analysis or review of the efficiency of the structure. This growth has resulted in an almost random collection of structure in which largely independent institutes and centers are tasked to advanced research programs, not in cooperation with one another, but according to diseases, organ systems, or stage of life in which they specialize. Thus, we study diabetes and ages in separate places with separate staffs and separate directors overseeing the research. Plainly, there is some collegiality and professional cooperation, but it defies reasons to believe that they will produce the efficiencies that can be achieved by logically unified structure.

Furthermore, this silo system produces thousands of pages of strategic plans, one for each of the 27 institutes and centers comprising the NIH. Read separately, each institute and center produces an impressive list of research goals and targets. Realistically, however, scientific progress can not be accurately measured and strategic plans set by evaluating the research activities of one institute alone, when modern science, as we all know, transcends the research activities at several institutes and centers.

Dr. Zerhouni, you have accomplished great feats in your brief time there. You deserve our admiration for taking on one of the most difficult and important jobs in government, and I applaud you for your courage and for your success. NIH is the premiere research organization of its kind in the world, and your absolute determination to make it even better, in my opinion, is already paying off. You are going to present to the committee today why you believe the creation of the new Office of Portfolio Analysis and Strategic Initiatives will help to minimize the problems that we have outlined by providing your agency with the tools to facilitate planning for trans-NIH initiatives and provide greater accountability to NIH research programs. That is an important first step, but it is only a first step. The difficulties that you face are monumental. In order to achieve fundamental changes that are needed, it is my opinion, and I think you share this opinion, that the Congress must act to restructure and reform the NIH.

This hearing today is an opportunity for us discuss the reforms and the restructuring that is needed. Based on the information and

the experience that we have gained from the past 2 years of committee hearings and investigative work, there are three changes that I believe will help you in your job better manage resources and increase research investments at NIH.

First, I believe we need to expand your authority—the authority of the NIH director. Congress should allow the director to transfer a greater percentage of funds between institutes and centers and to increase the working budget of the office of the director to fund more extensive portfolio management projects, as well as cross-cutting research initiatives.

Second, we need to better align the budget line items at the agency. Congress has created over 60 separate research programs, 60, at NIH with authorizations that no longer exist or are set to expire. Authorization for the National Cancer Institute, for example, which is the largest institute at NIH expired in fiscal year 1996. That, as we all know, is 9 years ago.

The Appropriation Committee allocates funding for NIH through 26 separate line items aligned primarily with the institute and center designations. Responsible budget planning requires Congress to evaluate whether the current funding allocations and mechanisms meet the scientific demands of NIH. I believe this committee should consider new creative approaches, such as budget clusters for allocating resources throughout the NIH. This concept would build on several thoughtful recommendations recently circulated to improve the NIH.

Finally or third, we need to create a new, more transparent reporting system. Congress should eliminate unnecessary reporting requirements, such as reports on specific diseases. We should instead require reports that comprehensively track research progress in broad areas of interest.

These are just three ideas, Doctor, but I think they are three that should be analyzed and worked on together. And I am sure that you have others. I look forward to working with you and other members of this committee to reform and restructure and revitalize the National Institute of Health.

Thank you, Mr. Chairman.

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

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

Thank you, Mr. Chairman, for holding this hearing today. It is with great enthusiasm that I welcome Dr. Zerhouni, once again, before this Committee.

According to NIH, the annual review of spending and priorities is critical. According to the NIH mission statement: "Deciding how and where to distribute the NIH's money—is a challenge the NIH faces each year. It requires fresh assessment of the nation's health needs and renewed evaluation of scientific opportunity." I agree.

Expanding biomedical research in the 21st century requires the NIH to function in the most efficient manner so that each and every penny that is spent on medical research—to prevent, treat, and cure disease—is counted and expended meaningfully. To do so, the NIH has to be able to justify to scientists and the public alike why some research projects are advanced ahead of others.

Unfortunately, NIH has grown like Topsy. In 1960, NIH was comprised of a director and seven institutes. Now there are 27 Institutes and Centers. While the motivation behind this explosive growth was certainly sincere, the individual organizations were created arbitrarily, usually without benefit of systemic analysis or review of the efficiency of this structure.

This growth has resulted in an almost random collection of structures in which largely independent institutes and centers are tasked to advance research programs

not in cooperation with one another, but according to diseases, organ systems, or stage of life in which they specialize. Thus we study diabetes and aging in separate places, with separate staffs and separate directors overseeing the research. Plainly there is collegiality and professional cooperation, but it defies reason to believe they will produce the efficiencies that can be achieved by logically unified structure.

Furthermore, this "silo" system produces thousands of pages of strategic plans, one for each of the 27 Institutes and Centers comprising the NIH. Read separately, each Institute and Center produces an impressive list of research goals and targets. Realistically, scientific progress can not be accurately measured and strategic plans set by evaluating the research activities of one Institute alone when modern science transcends the research activities at several Institutes and Centers.

Dr. Zerhouni, has accomplished great feats in his brief time there. He deserves our admiration for taking on one of the most difficult and important jobs in government, and our applause for his successes. NIH is the premier research organization of its kind in the world, and Dr. Zerhouni's absolute determination to make it even better already is paying off. Dr. Zerhouni will present to the Committee today why he believes the creation of the new Office of Portfolio Analysis and Strategic Initiatives will help to minimize this problem by providing the Agency with the tools to facilitate planning for trans-NIH initiatives and provide greater accountability to NIH research programs. It's an important first step. But the difficulties he faces are monumental. In order to achieve the fundamental changes that are needed at NIH, Congress must act.

Based on the information and experience that we have gained from the past two years of Committee hearings and investigative work, I have identified three changes that will help Dr. Zerhouni to better manage resources and increase research investments at the NIH.

First, we need to expand the authority of the NIH Director. Congress should allow the Director to transfer a greater percentage of funds between Institutes and Centers and increase the working budget of the Office of the Director to fund more extensive portfolio management projects as well as cross-cutting research initiatives.

Second, we need to better align the budget line items at the Agency. Congress has created over 60 separate research programs at NIH with authorizations that no longer exist or are set to expire. Authorization for the National Cancer Institute, the largest institute at NIH, expired in FY96. The Appropriations Committee allocates funding through 26 line items, aligned primarily with Institute and Center designations. Responsible budget planning requires Congress to evaluate whether the current funding allocations and mechanisms meet the scientific demands of the NIH.

Personally, I believe that this Committee should consider new, creative approaches, such as "budget clusters," for allocating resources throughout the NIH. This is a concept that builds on several thoughtful recommendations recently circulated to improve the NIH.

Finally, we need to create a new, more transparent reporting system. Congress should eliminate unnecessary reporting requirements such as reports on specific diseases. We should instead require reports that comprehensively track research progress in broad areas of interest.

I look forward to working with Dr. Zerhouni and the Members of this Committee to get this project done.

Mr. DEAL. Thank you, Mr. Chairman.

Now recognize Mr. Green from Texas.

Mr. GREEN. Thank you, Mr. Chairman. I would like to welcome Dr. Zerhouni and reserve my time so I have more time for questions.

[The prepared statement of Hon. Gene Green follows:]

PREPARED STATEMENT OF HON. GENE GREEN, A REPRESENTATIVE IN CONGRESS FROM THE STATE OF TEXAS

Thank you, Mr. Chairman, for calling this hearing on the NIH's management of its research portfolio.

As we go about a long-overdue reauthorization of NIH, it is important that we continue to gain knowledge about the structure and management of the NIH in order to maximize research efforts.

Without a doubt, the work performed at the NIH is invaluable.

Groundbreaking research has provided a lifeline of hope to countless Americans living with diabetes, cancer, HIV/AIDS and many other illnesses.

Dr. Zerhouni, thank you for your stewardship of the Institutes and Centers that have offered our constituents suffering from illnesses with hope for the future.

I also commend your efforts to place additional focus on trans-NIH collaboration to better address many of the problems that plague our society. These days, Americans live with chronic conditions that cannot be remedied by studying one particular organ, or one part of the body.

Obesity and diabetes, for example, affect virtually the entire body, and we will hinder real progress on these pervasive conditions if we don't fully encourage cooperation among the NIH's Institutes and Centers.

Dr. Zerhouni's increased focus on inter-disciplinary research teams is a step in the right direction toward achieving the successful collaboration that will solve our most pressing health problems.

I am particularly interested in learning more about how and whether these initiatives should be formally incorporated into NIH reauthorization legislation and what additional authority—if any—Dr. Zerhouni and future NIH Directors need to ensure that NIH research can evolve to meet the health care needs of our nation.

If there are obstacles in our current structure that slow the path of lifesaving research from reaching the patient, then we must overcome them.

Thank you, Dr. Zerhouni, for appearing before us again today.

I look forward to hearing your testimony.

With that, Mr. Chairman, I yield back the balance of my time.

Mr. DEAL. I recognize Mr. Shimkus.

Mr. Ferguson, the vice-chairman of the committee.

Mr. FERGUSON. Thank you, Mr. Chairman. I would like to submit my statement for the record for additional time for the questioning.

Thank you.

Mr. DEAL. Mr. Rogers.

Mr. ROGERS. I will yield, Mr. Chairman, for more questions.

Mr. DEAL. Ms. Myrick.

Ms. MYRICK. I don't have an opening statement, but I just want to thank you because you have made great strides so far, and I support very much what you are doing and hope that we can make happen a lot of what you want to see done, because I think you are on the right track.

I agree with the chairman's statement, there are some things that we do have control over that we could do to help you, so I look forward to hearing from you.

Mr. DEAL. Dr. Burgess.

Mr. BURGESS. Thank you, Mr. Chairman. Thank you for calling this hearing. Dr. Zerhouni, I thank you for being here today, braving all the press outside our room. Apparently they are very interested in what your testimony is going to be here today.

Dr. Zerhouni, when I was in practice, we had two kinds of doctors. We had doctors like me that we called "doing doctors," and then we had doctors like Dr. Zerhouni. Dr. Zerhouni is what we call a "thinking doctor" and we are grateful that we have got a thinking doctor in charge of the NIH.

I am glad you could join us here today to offer your insight into the inner workings of the NIH, and how difficult your task is to administer the 27 institutes and centers that make up the NIH. And today we have an opportunity to look at how this country prioritizes our health research and the future of your institute, the National Institute of Health.

The NIH has its roots in researching medical treatment for our soldiers in World War II, but has since evolved into a world-class research institution. I believe that the institution must continue to evolve with medicine and shouldn't be stymied by bureaucratic lethargy.

It can not be understated, Dr. Zerhouni, that you have a very difficult job ahead of you. As NIH director, you are allocated only 3 percent of the overall NIH budget to coordinate the 27 institutes and centers at the NIH. And last year in this chamber, in the House, when we debated the Nation's—restructuring of the Nation's intelligence, we wanted to created a national intelligence director, it was broadly recognized that if we created that director of national intelligence, we had to give that individual budgetary authority. And unfortunately in your institute, you lack some of that budgetary authority.

I appreciate what the administration has done with the increase in the NIH budget during the Bush Administration. Perhaps it would have been a little more useful to begin the restructuring and the reauthorization process before adding the additional money. So perhaps as additional monies are added in the future, the work that we are going to do here over the next several months will embellish that and make that pay greater dividends.

Mr. Chairman, we shouldn't take the NIH for granted. We shouldn't let it succumb to bureaucratic drift. I look forward to working with you, Mr. Chairman, and Mr. Barton and with Dr. Zerhouni as we seek solutions on improving quality and direction of our medical research in this country.

And I will yield back.

Mr. DEAL. Thank you.

Recognize Mr. Upton.

Mr. UPTON. Thank you, Mr. Chairman. I am going to put my statement in to get my extra 3 minutes and defer.

Mr. DEAL. We are pleased to have a member of the full committee, Mr. Bass, with us. Do you have an opening statement you would like to make?

Mr. BASS. Mr. Chairman, I appreciate the courtesy. I have no opening statement.

Mr. DEAL. Thank you.

Mr. BROWN. Mr. Chairman, I ask unanimous consent to put into the record Mr. Dingell's statement and the statements of anybody on our side and yours, too, who is not here today.

Mr. DEAL. Without objection.

Mr. BROWN. Thank you.

Mr. DEAL. Dr. Zerhouni, we are very pleased to have you here, and thankfully, we have not taken too much of the time with opening statements, and we look forward to hearing from you at this time.

STATEMENT OF ELIAS A. ZERHOUNI, DIRECTOR, NATIONAL INSTITUTES OF HEALTH

Mr. ZERHOUNI. Thank you, Mr. Chairman, and members of the committee. I am really pleased to be here. I think there is no more important discussion to have than the one we are undertaking today.

I have written testimony that I have submitted. I would like to place it into the record.

What I would like to do instead of reading my testimony is to make a presentation about some of the issues we are facing from the standpoint of public health, science, and how we manage our

science at NIH and where opportunities could be found to improve on the functioning of NIH.

[Slide.]

I would like to direct your attention to the screens, if I may, and begin by telling you that if you looked at the past 100 years, what you would observe is that we have been able to accomplish something that has unprecedented in human history, and that is that we have increased life expectancy by about 1 year every 5 years. And at the beginning of the century, this was accomplished primarily through hygienic approaches, better water supply. There was 1 dip that you can see in the screen in 1918, and that was the pandemic flu. And besides that dip, everything else has been upward. And you can trace the improvements to significant discoveries. The discovery of penicillin and antibiotics, polio vaccine, the discovery of the DNA structure, chemotherapy for cancer starting in the 1950's, and then in 1976, the first cholesterol reducing drug, Statens, which have made a huge impact on cardiovascular disease. And more recently, the completion of the human genome.

So every 5 years of investment over the past 30 years where everyone agrees that the improvements that we have seen in health overall have been due to medical discoveries. Every 5 years of investment at NIH have produced 1 year of increased life expectancy.

Why is that, and what kind of research outcomes have we seen tangibly that you can then base a decision on how to go forward in the 21st century. The first one I will show you is essentially our impact on AIDS and AIDS research. When you look at the picture that we had in the late 1980's, early 1990's, what you were projecting was essentially a death rate that would dominate cancer, mental health, suicide, in the young population, young age groups. But because of behavioral sciences and prevention, as well as discovery of new drugs, we have reverted that curve in the United States with a rate of disease and death that is ⅙ of what it would have been if we hadn't made those discoveries.

Most impressive in our past 30 years' history has been the progress we have made in controlling coronary heart disease and stroke. If you looked at our situation in 1970 and you projected out what the number of death would been in this year—in the year 2000 for which this statistic was built, you would have seen 1.3 million deaths a year from heart disease. Currently, we are seeing about 514,000 too many, but you can see that the decrease in mortality and morbidity from heart disease is leading us to a new age in medical research whereby acute diseases that tended to be very short-term and lethal are now being transformed into diseases that last a longer time and where surviving a particular disease is now the rule rather than the exception, and whereby we spend 75 percent of our healthcare dollars on chronic conditions rather than acute conditions.

So progress in itself brings new challenges. More recently, I would like to show you what the discoveries that we have made over the past 10 years have led us to in terms of performance in terms of public health. Because of our advances in fundamental understanding of the molecular biology of cells, viruses, and microbes, and our advances in genetic technologies, our ability to identify DNA, just like we do in criminal courts, the DNA signatures of mi-

crobes and viruses, what we have been able to do over the past 2 years, alone, we have developed the first ever vaccine for Ebola. And it is in trial today, 2003. This took 2 years. Typically, a vaccine in historical terms takes 15 years to develop.

Anthrax, the problem we knew about but we didn't really know how to attack it more effectively, we now understand what is making anthrax so deadly, and we are developing new drugs for that.

Another one that was totally unknown to us was SARS. When it happened, nobody knew what it was. We identified the cause of SARS in 1 month. It took us 4 years to identify the cause of HIV AIDS. And we are now, at NIH, starting the first trial of a new vaccine developed at the vaccine research center and on controlling SARS if it ever comes back to haunt us.

So we are seeing two things. One is a progressive increase in life expectancy and health, with better health indicators for the entire population across the board. Second, a shift from acute to chronic diseases, and third, an acceleration in the pace of science. Our discoveries are coming at a much faster pace than they were coming 15 years ago.

How do we tackle that is the real issue that we have to face? The public health challenges that can—I think we need to understand what they are at the strategic level. First and foremost is what I mentioned. There is a shift from acute to chronic diseases. Second, because of our success, we now have an aging population and we need to tackle the issues that come with that. Third, we still see health disparities. Although I am showing you great curves going all in the right direction for all populations, there are still significant differences between the populations within the United States. Fourth, we are talking about emerging diseases and reemerging diseases. I am not talking about just SARS or pandemic flu. I am also talking about obesity. For us, this is a new disease. This is something that is emerging as a challenge for our society, and we need to focus on that. And last is obviously a new mandate for NIH biodefense, and I just showed you some results that came from that biodefense research effort, which started in 2002.

When you look at this, you can ask yourself "where are we going next? What are we going to do in the 21st century?"

[Slide.]

And this slide, I would like to summarize for you what our strategic view is. In the 21st century, we have to transform the way we practice medicine. And the way we practiced medicine over the past 5,000 years has been the same one, and it is the one on the left side. What did we do? We basically waited until someone showed symptoms of a disease or lost some function, whether it be diabetes or Parkinson's disease or cancer, we did not intervene before the disease struck us. And the reason for that was very simple. We just didn't know what the normal evolution of a disease was. We didn't know that heart disease started 30 years before you had a heart attack. That diabetes started 25 years, in molecular terms at the cell biology level before you became deficient in insulin and diabetic. We just didn't know that. Today, we do. And the problem with intervening so late is that it is very expensive. As a physician myself, I have witnessed the growth in technology and the growth in sophistication that has allowed us to provide miracles to pa-

tients. We have the best medical care in the world, but we may not have the best health care strategies in the world.

So what has happened is that as we increased our knowledge, a new view has come in front of us. And that would require, as I mentioned, faster adaptation of a structure like NIH to adapt to the speed of change in research, the speed of change in public health and our requirements, and what is the best strategy? We believe in the 21st century, if we don't change the way we practice medicine today, the costs of practice medicine as we know it, without new discoveries and new strategies will be unsustainable. And the best way for us to overcome that is to intervene before symptoms occur, to prevent the disease from forcing someone to become disabled. To understand a disease years before it strikes, and intervene at that time. Can we really do this? And my belief is we can. We have completed the human genome, we have engaged in new research that makes us understand that, in fact, when you look at diabetes for example, we discovered a major gene last year called the HNF-4 gene, and we now know that that gene is a control gene when mutated, increases the chance of someone getting diabetes. Intervention at that stage is more likely to be cost effective and orders a magnitude more rewarding, if you will, in terms of health and in terms of cost as well.

Why can we predict this? Because we do understand much better than we ever did the preclinical molecular and cellular events. We can now increasingly see how we could define which patients are more likely to develop what disease and intervene at that time. We have already seen that. I mean, we have reduced, for example, the damage due to high blood pressure, the damage due to high cholesterol, the damage due to not recognizing that a colon polyp that we now can eliminate through a minor colonoscopy was the source of cancer. We didn't know that 15 years ago.

So we need to continue that progress, and NIH has been sort of the agency tasked to do this. So let us talk about, I think what you are concerned, rightly—concerns rightly are. How are we doing our job? What is the infrastructure and the strategy—what are the strategies to make sure that we are doing an optimal job?

And as Chairman Barton mentioned, I would like to go over the evolution of the NIH from the standpoint of the structure that is supposed to do its job. If you looked at 1937, we were part of the Public Health Service. There was a National Institute of Health, and in 1937, the National Cancer Institute as a division of the National Institute of Health was created. The next even was in 1944, the Public Health Service Act, and by 1947, 1949, what you saw is a combination of what I would call policy setting and management structures like the Division of Research Grant, and then the realization that we did have public health challenges that were extremely important. We knew about cancer. Very early, we realized that heart disease was going to be a major public health problem if we did not intervene. A National Heart Institute was created. Infectious diseases were a problem in the 1940's, if you recall. These were the days when we developed penicillin and streptomycin and the very first miracle antibiotics. The National Microbiological Institute was created. We also knew that without basic knowledge, we would not make progress. There is no way for us to translate

a discovery if there is no discovery to start with. So the Fundamental Experimental Biology and Medicine Institute was created.

The next snapshot I can give you is 1968, 1969. So by that time, specific missions needed to be accomplished. So you see the National Institute of Neurological Disease and Stroke, a problem that was rising in the 1960's, arthritis and metabolic diseases, and so on. I do not want to belabor the point, but what you can see is that as the depth of the problem was better understood, you needed to have the structures to fight those problems in depth. At that time, however, no one really knew that the fundamental biology of a disease in the neurological system and how cells signaled each other would be the same than it was in the heart, or it would be the same fundamental mechanisms in Parkinson's disease versus diabetes or others.

What has happened over the past 30 years is through our understanding of DNA, DNA reproduction, genetics, molecular biology, we understand now that every cell in the body contains the same DNA, and it is regulated maybe in different ways, but there is a convergence in our science. The second is progress in our research technologies, whether it be imaging or microscopy, or our computer sciences, allowed us to understand biology to an extent never before possible. In that time, no one knew that 30 years later we would have the entire human genome at our disposal. No one could even predict that.

So what has happened is obviously with the optimism and the application of this research with the results that we were obtaining, the structure continued to grow. And this is the current structure, 27 institutes and centers. As Chairman Barton said, different appropriation lines. And more interestingly, over the last 10 years, something that wasn't mentioned which I would like to point out to you, has been the creation of offices in—under the office of the director. So the office of the director's budget is about $300 million. About $80 million is for administration, about $220 million is for these offices.

What are these offices doing? They are responding to a need that I think all of us see: the need for coordination, a strategic coordination, a strategic optimization. So what happened in the 1990's is creation of the Office of AIDS Research, which has special authorities to look across institutes and across silos to maximize the investments in AIDS research. And you have seen the results in AIDS research. I mean, we can be proud of the fact that in less than 15 years, we have developed over 80 drugs that are effective in HIV. And today, we have five candidate vaccines ready to enter trials. Whether they will work or not, I can't tell. I can't tell.

But the Office of Women's Health was another creation, which was also responding to the same underlying theme that I hear for this hearing, and that is how do we make sure that we have a cross view that maximizes the taxpayers' dollars? Then you have the Office of Rare Diseases and the Office of Behavioral and Social Sciences. We have the Office of Minority Health and Health Disparities, which then became a center. So you can see historically over the past 10 years, the same theme has recurred.

Where do we go from here? There is one thing I think we need to recognize, and that is that despite the complexity, there is no

doubt that NIH has accomplished extraordinary results. And as a director, I can tell you that there are reasons for that. One is in the 1944 Public Health Service Act, the requirement to have peer review, independent peer review at two levels. And this is recognized as probably the feature which has made NIH most successful. Whenever I go around the world, the first thing I get asked is "how do you run your peer review system in such a way that it is, in fact, adapting to the science?" And the reason is simple. First and foremost, we do respect ideas from individual scientists, because that is where innovation comes from. And we, unsolicited, get about—⅔ of our grants come from ideas from the field. One-third of our grants, on the other hand, are determined by our institutes. So for example, we decide that something is important. We then put out requests for application or contracts to stimulate one area of research or another. There is always an independent review of the quality of the science, and it is recognized worldwide that the peer review system that we have prevents bad science from being funded, and really promotes high quality science. These then are going to a second structure called the Institute Advisory Councils. It is very important to realize that these advisory councils are, in law, authorized to supervise independently each institute. So they are made up of scientists and public members. They assess the programs. They approve the applications, and they define the priorities from the standpoint of the public members of that particular institute. And at that time, they release then funding authorizations for the particular grants. At the peak of the doubling, we are able to fund 30 percent of applications that would come to NIH. Today, we fund about 22 percent of applications, simply because we have been very successful in having more ideas come to NIH from different fields of science, and we have an increased number of applications, particularly when you look across the spectrum of what we do.

Then the research priorities obviously are made in a way that I think has been a question, a continuous question for members of this committee and other committees. How do you do this? And frankly, I think the one thing that NIH does well, it organizes a tremendous amount of interfaces between patient advocacy groups, scientific organizations, professional societies, industry. We have 21,000 nongovernmental advisors who come to NIH to review grants, review strategic plans, give advice to the NIH, and that is what forms, if you will, the fundamental direction that institutes will then take.

So the institutes, as Chairman Barton said, are the core of what gets planned within NIH. First, through all of this analysis of the science, analysis of the disease burden, public health opportunities, different requests, different mandates. These are put, as you mentioned, in the plan, and this we have been better at over the past 10 years. We have now a formal process that each institute has to follow in different ways, but a formal process that can explain what the plan is. And then the funding priorities are then determined at that time, depending on what the science is, and then the decisions are made by the Advisory Council. So think of this 26 times. That is what we do.

As you mentioned, the scope of the challenge is not a small challenge. When you look at the institutes, they are different in size and budgets. They are, depending upon their mission area—but the challenge for me is how do you do this job best? And the challenge for you us how do you structure, if you will, an organization that will do this as best as possible?

So the way I look at it is obviously, everybody looks at the total budget, $28 billion, thereabouts, and they look at it that way. I look at it differently, and I would like to share with you the way I look at it. I really see that there are patients at the end of every dollar that we invest, and there are individual human beings that will eventually suffer from one disease or another. How do I then change the paradigm as I told you between the 20th century and the 21st century? Well, we need to make those investments that are orders of magnitude more effective than what we do today.

So the way I look at is basically $28 billion is $96 per American, per year. And as you can see, we distribute that differently. For example, the National Cancer Institute has $16, and I am asking my directors to think in those ways, because that is how you become very, very good at making sure that your investment is well used. That you are counting pennies, not just big dollars. And in fact, if you look at the Cancer Institute at 16, the Infectious Disease is 15, Heart and Lung, $10, and so on. And that is the investment that we need to make over a continuum.

When I said the sciences converging, we need more disciplines in biomedical research. We need computer scientists and physicists and so on, and that is the 21st century challenge for NIH. And I think this is where the opportunity to have an interaction with your committee is going to be fruitful.

Obviously, we also are aware that this investment needs to have an impact on the 5,500 per American, per year, health costs, and fast-rising. So we are not oblivious to the sense that we need to have an impact, not just do research that has no practical applications.

One thing that we have tried to do since I became director was to try to, in fact, put a glue—the glue together. Not the budget glue, but the intellectual glue that will then dictate budgetary decisions. I mean, clearly, as I mentioned in the public at the main before, what we have is a hand with 27 very strong fingers, but I am not sure the palm is as strong as it needs to be to coordinate all those activities. Everything that you do within the mission area is very strong, but do we have a perfectly organized orchestra, if you will. And that, I think, is where we pushed our focus and our efforts.

The first year, I asked the question to all the institute directors, "what is it in science that has advanced to a point where no institute sees that as their responsibility or know that any one institute can fund, that all of NIH needs to do to advance and accelerate medical research?" And this is what led to the NIH roadmap for medical research, with its detailed planning to accelerate and introduce the concept of interdisciplinary research, and the concept of understanding molecular systems 20 years before the disease strikes.

In 2005, we then analyzed and scanned the public health horizon, and realized that obesity was something that needed a strategic response. And I put together a strategic group to come up with what we call the NIH Strategic Plan for Obesity Research. And we funded this plan, we increased the budget for that plan within the limits that we could, and within the limits that you all know well about how budgetary decisions can get made.

And in 2006, we decided that the next target would be neuroscience. And the reason for that is if you combine mental health issues, degenerative neurologic disorders like Parkinson's, Alzheimer's disease, substance abuse, and addiction, the total burden of disease is about $500 billion in economic costs. It is four times larger than obesity, if you combine all of these issues. So I asked the 15 institutes to come together in a coordinated fashion to try to come up with a neuroscience blueprint that would address, if you will, and accord more synergistic fashion, more optimized fashion, the issues that we are facing.

Where do we go from here? I think it is important, at least within my authority, to explicitly address the problem. And the way we want to do this is by proposing something that I can do within my authority, to create and Office for Portfolio Analysis and Strategic Initiatives. As the portfolio is expending, we need to have tools. We need to have a vision that tells us exactly if there are redundancies in the portfolios, if there are inefficiencies, if there are gaps. In other words, you need radar. And this office, to me, is the radar that will help NIH navigate the complicated and complex waters of science today.

How would it do this? Essentially, what we will do is introduce the concept of that office and provide this office with the authority to do strategic analysis using modern management tools. For example, reporting on public health burdens, having a uniform way of reporting on disease code, disease efforts, and how much are we making and how do you measure whether or not this is effective or not? One of the policies we proposed this year was the Public Access Policy, in which we are going to have an archive of all of our scientific papers so we can combine the investment with the output.

The second is evaluation, and I agree, someone on your committee said that unless you have an explicit way of knowing whether you are getting the results you are getting, you can't define success. There is no planning that is necessary because you just can't spend the money and spend the resources and strategize without having an endpoint. That is easy to do. But it is not so easy to measure and evaluate progress in medical research. As you know, good research often fails. And this is the challenge, and that is why I wanted a structure that would tackle that challenge openly.

And the third is strategic coordination. We need to do a nationwide planning as a matter of institutional policy, not as a new director's preference. I think it needs to be institutionalized. I think it needed to develop common processes across NIH, and work with the IC's to develop plans as needed.

I think this is essentially what we can do within our ability to move the agency. We have shown that it can work through the roadmap and obesity and neuroscience. It will enhance the priority

setting process and improve the coordination. And it will also provide sound decision support systems, something that will be transparent with broad public and scientific input. And it will definitely, in my view, ensure you that, in fact, we are making the efforts to try to be as efficient as we can within our resources, while showing where resources need to be invested, additional or not, in the public health domain, when we can see data that indicates indeed, it needs to be done.

So my goal is to really enter into this discussion whereby authorities versus mechanisms versus vision get together to serve, I think, science, the public health, and society in a more—much more effective balancing, I believe, of all of the opportunities we have and all the challenges we have.

Thank you very much for your attention. I am sorry I took a little more time than planned.

[The prepared statement of Elias A. Zerhouni follows:]

PREPARED STATEMENT OF ELIAS A. ZERHOUNI, M.D., DIRECTOR, NATIONAL INSTITUTES OF HEALTH, DEPARTMENT OF HEALTH AND HUMAN SERVICES

Throughout history, the toll of suffering from disease and injury on individuals and societies has been a constant and unforgiving reminder of the human condition. We have never stopped trying to overcome this suffering. Our goal is to help people, regardless of age, gender, race, or nationality. The torment of those who are afflicted by illness is the main reason that medical research is one of America's top priorities.

Since the mid-twentieth century, the National Institutes of Health (NIH), currently the largest supporter of biomedical research in the world, has been the pilot and engine of the machine that drives biomedical research. Congress's investment in NIH has paid quantifiable human health dividends. We have come far in our quest for discoveries that lead to improvements in diagnostics, prevention therapies, disease or condition management, and actual cures. Life expectancy continues to rise steadily; death from heart disease and stroke has sharply declined; cancer mortality has fallen while survivability increases; vaccines and drug therapies have proliferated—we can expect these and other improvements in human health to accelerate as a result of advances in genomics, molecular biology, proteomics, and computational biology.

Yet as far as we have come in our journey, we still have a seemingly infinite and difficult road to traverse. We understand perhaps ten percent or less of the human biology necessary for the prevention, diagnosis, and treatment of disease and injury. Our understanding of the molecular underpinnings of cells and other aspects of human biology offer promising theoretical applications for medical treatment, but years of research efforts lie ahead before theories are translated to concrete discoveries. The challenge of emerging and reemerging infectious diseases will not lessen. The difficulty of treating chronic illnesses is a persistent dilemma. Health disparities continue to affect segments of our population. The threat of bioterrorism represents yet another challenge.

These challenges are a reminder that NIH must continue to strive to improve, to seek innovations, and to constantly subject itself to review and examination. As I testified before this Subcommittee on June 2, 2004, "Great organizations can maintain greatness only by continuous reassessment and adaptation." Or as the Institute of Medicine observed two years ago, "While NIH's success is to be celebrated, success alone does not answer fully the question of whether there is a better way to proceed, particularly as one faces a future where the world of biomedical science is being rapidly transformed in virtually all its dimensions."

To meet these challenges, the NIH works very hard to maintain a research portfolio that balances public health needs and scientific opportunities. We seek input through multiple channels, both formal and informal, and maintain an open door policy for communication with our stakeholders. Ideas for scientific initiatives in specific areas of science come from many sources—advocacy groups, the biomedical research community, Congress, and NIH staff, among others. Ideas for stimulating a particular field or letting it lie fallow become reality only after rigorous vetting at a number of levels.

The NIH's two-tiered peer review system, which is world-renowned and respected, has a major influence in the priorities set by NIH. In this system, the assessment

of the scientific and technical merit of an application is separate from its consideration for funding. In the first level, the peers of the applicant assess the application's scientific and technical merit. Advisory councils and boards, which consist of senior scientific experts and lay members of the public, provide the second level of review—advice and recommendations to the Institutes and Centers on the programmatic relevance of the applications and areas of science that should be emphasized (or not). Advisory councils and boards are also, however, the NIH's top vetting place for ideas for scientific initiatives that will receive set-aside funds, and they are expected to provide advice on the Institute's or Center's scientific priorities.

NIH's priorities are driven, in part, by the ideas and opportunities presented to us through the grant applications we receive. By placing most of our resources in investigator-initiated peer-reviewed research, NIH ensures that federal dollars support the latest and best science. But the ideas generated by the scientific community represent only one factor in a complex, multifaceted process. Some of the variables in choosing resource allocations include public health needs such as the burden of disease, new scientific opportunities, the quality of research proposals, the experience of applicants, and the ability to sustain research through adequate staffing and infrastructure. These factors are often lost in the public debate about NIH funding, in which the discussion is sometimes simplified by focusing attention on apparent differences between the toll of certain diseases and the amount spent on research about those diseases.

While I believe this process has served the public well—in fact, there is evidence that NIH priorities match well with existing disease burdens—we can do better. Currently, many priorities are set by the planning programs at each of the Institutes and Centers at NIH that support research grants. In recent years, NIH has facilitated collaborations and co-funded innovative trans-Agency research. In the case of HIV/AIDS research, we are shifting resources to fund vaccine research to respond to urgency as well as opportunity. As scientific fields and disciplines are increasingly becoming interdependent and advances in one area often make progress possible in another, NIH needs a horizon view of our research portfolio—a view that complements and oversees the views of the individual Institutes and Centers with very specific mission areas.

It is not only the nature of science that is changing. The condition of our patients has evolved differently as well. Our success in prolonging life and treating acute diseases means that more patients are living with chronic and multiple illnesses. Our treatment methods must adapt to older patients with multiple symptoms just as our methods of conducting research must adapt to changes in science.

I testified before this Subcommittee last year that we cannot be static, that NIH must enhance the current process for determining priorities and allocating resources as part of a balanced research portfolio across the Agency and within each Institute and Center. I noted that the system of funding research by allocating resources directly to disease, organ, or special population-based Institutes and Centers has been successful. I also observed that science is changing, driven by new technologies and discoveries. Modern research is often best conducted by teams, which may include biologists, mathematicians, chemists, physicists, engineers, bioimagers, computer scientists, behavioral scientists, and physicians, and which may cut across the expertise of many different NIH Institutes and Centers. Several fertile areas of research—genomics, proteomics, molecular engineering—serve all fields of endeavor and cannot be pigeonholed or accounted for according to specific diseases.

I told you that I was thinking about ways to refine the priority setting process and the management of our portfolio. In particular, I have been examining new and sustained approaches for evaluating NIH's crosscutting science. While maintaining the support for existing Institute and Center research programs, we are now using trans-NIH resources to address emerging challenges and opportunities. These new areas of investment involve research that no single Institute can support alone, but that all of NIH needs to pursue because of the impact on all diseases and scientific areas of inquiry.

I understand the questions about priority setting at NIH that many have. There are several factors to be considered as we ponder the answers.

- Our challenges are different. The burden of illness has shifted from acute to chronic diseases as health care costs rise and the population ages.
- As the Institute of Medicine concluded, "*The frontier of biomedical science has rarely been as exciting and as full of spectacular opportunities as it is today. From basic science through clinical research to health services research, the opportunities made available through the impressive advances of recent decades in the biomedical as well as the physical, computational and behavioral and social sciences have brought us to a frontier of unprecedented opportunity*."

- There is a dearth of reliable, integrated data on which to base priority setting decisions, including insufficient information on the human and financial costs of disease.
- Numerous areas of science continue to rapidly converge in conducting research, erasing the disease boundaries that had characterized such research in the past.

After consulting with scientific leaders within and outside NIH, and in order to meet these challenges while enhancing the priority setting process at NIH, I have decided that the Agency needs a new organization that will complement the existing process for determining strategic research initiatives. I have requested $2 million in the FY 2006 budget to establish this new entity, the Office of Portfolio Analysis and Strategic Initiatives, within the Office of the Director. This office will be charged with evaluating the entire Agency research portfolio to ensure that urgent public health needs are addressed in a timely way and that a sound decision support system is established that is based on rigorous and uniform sources of evidence.

Individual research grants remain the mainstay of NIH, and research in priority areas will always be awarded competitively. However, NIH also needs a global view of the totality of what we fund in our overall research portfolio. This new office will provide—with input from the Institutes and Centers and from the public, health care providers, policymakers, and scientists—tools that facilitate trans-NIH planning. It will drive data collection and sharing of information about research fields, diseases, and conditions, and collect and analyze data on the burden of disease. More effective analysis and management of our portfolio will lead to even better progress against disease.

An expanded approach to portfolio analysis will enable NIH to enhance the priority setting process while increasing coordination, identify appropriate cycles of change, maintain proper turnover rates for grants and provide much more accountability to Congress and the public. Under such processes, in concert with the Institutes and Centers, we would identify crosscutting research that requires common investments from the various NIH Institutes and Centers. This approach must include a regular overview of all research so that we can have sufficient information to improve management of the entire NIH research portfolio.

My intent in creating the office is to have a transparent process and better decision-support tools characterized by a defined scope of review with broad input from the scientific community and the public; a solid, uniform database of information; an institutionalized process of regular trans-NIH evaluations; better tools for weighing scientific opportunity against public health urgency; and a process that enhances accountability to Congress, scientists, patients and the public at large.

The creation of the Office of Portfolio Analysis and Strategic Initiatives is an important step in the process I began when I became the NIH Director to increase collaboration among our 27 Institutes and Centers and to pool resources, where necessary, to expedite research and adapt to changes in scientific methods and new discoveries. Soon after becoming the NIH Director, in May 2002, I convened a series of scientific meetings to chart a "Roadmap for Medical Research" in the 21st century. Our purpose was to identify gaps and obstacles in biomedical research that no single institute at NIH could fill or overcome alone, but requires efforts by the entire Agency.

Three themes for the Roadmap were identified: Finding New Pathways to Discovery; Creating Research Teams of the Future; and Re-engineering the Clinical Research Enterprise. The Roadmap is currently funding $235 million in this trans-NIH initiative and we have requested an additional $98 million for FY 2006.

The focus of the initiatives under New Pathways to Discovery is to build a better ″toolbox″ for medical researchers in the 21st century. By FY 2006, a network of Molecular Libraries Screening Centers will identify novel small molecules with potential as biochemical probes for investigating cellular pathways, and an Imaging Probe Development Center will be fully operational and servicing the extramural community.

Scientists need to move beyond the confines of their own discipline and explore new organizational models for team science. The initiatives within the Research Teams of the Future theme provide support to academic and research institutions that focus on creating interdisciplinary research training programs, workshops and courses for development of new scientists, new science teams, and new scientific inter-disciplines. In addition, specific support for high risk and innovative research will continue to be supported by the NIH Director's Pioneer Awards in FY2006.

The Re-engineering the Clinical Research Enterprise theme initiatives aim to integrate and strengthen clinical research networks and train multidisciplinary clinical researchers in order to accelerate clinical studies and trials. Efforts to inventory existing networks and test approaches to enhance informatics infrastructure will

culminate in the launch of the National Electronic Clinical Trials and Research (NECTAR) network.

Implementation groups have been established to support each of the three themes. For example, under the initiative to find New Pathways to Discovery, there are separate groups for Building Blocks, Pathways and Networks; Molecular Libraries and Imaging; Structural Biology, Bioinformatics and Computational Biology; and Nanomedicine. These groups are funding such initiatives as National Technology Centers for Networks and Pathways; Molecular Libraries; a database of chemical structures; a core synthesis facility to produce imaging probes; and planning for nanomedicine centers.

Under the Research Teams of the Future theme, NIH is funding planning grants to establish Interdisciplinary Research Centers; an initiative to remove barriers to interdisciplinary research; and an initiative to facilitate public-private partnerships in science.

Projects are also underway in support of the third theme, Re-engineering the Clinical Research Enterprise. Initiatives include Harmonizing Regulatory requirements; integrating clinical research networks; and establishing core services for the translation of research findings.

The Roadmap has been a significant step in shifting the culture of NIH from single-purpose research funded by individual Institutes and Centers to research that will benefit all endeavors and is funded by multiple Institutes and Centers for the benefit of the entire Agency. NIH has been gradually moving in this direction for the last decade, but now we are advancing by leaps and bounds.

As an illustration of our responsiveness to emerging public health threats, NIH launched the Strategic Plan for Obesity, a multi-disciplinary approach to addressing a burgeoning health crisis. There are 130 million obese American adults who are at risk of premature death, chronic illness, and reduction in quality of life. In addition, the obesity epidemic could cost the Nation $117 billion in medical costs and lost wages. Obesity is an example of a public health emergency that cannot be addressed by a single Institute, but must be a trans-NIH research initiative. We have 18 Institutes and Centers conducting research on such factors in the epidemic as behavioral, sociocultural, economic, environmental, genetic and biological causes.

NIH researchers have identified an elaborate network of hormones and other molecules that connect the brain, gastrointestinal tract, fat cells, and other parts of the body to achieve energy balance. An increased level of one of the appetite-induced hormones was found in obese people following diet-induced weight loss. It may explain why people have difficulty in maintaining weight loss. These hormones are now targets for the development of drug therapeutics.

This year, another important example of greater trans-NIH collaborations and coordination is the Neuroscience Blueprint. NIH has 15 Institutes conducting research on the brain, ranging from the National Institute of Neurological Disorders and Stroke to the National Institute of Mental Health to the National Institute on Drug Abuse. This set of diseases exacts a burden estimated to reach $500 billion in future years. By pooling funds and expertise, our Institutes will collaborate on research addressing some of the most prevalent causes of death and disability, including Parkinson's disease, ALS, Alzheimer's disease, spinal cord injury, dementia, hearing loss, eye disease, and muscular dystrophy. The Blueprint will conduct research on economies of scale and train the next generation of neuroscientists.

These are prominent examples of how NIH is adapting to the need for new approaches to medical research. Another example includes collaboration on modeling simple organisms used in pre-clinical research, such as the mouse, the rat, budding yeast, the fruit fly, and the zebrafish. Also, NIH supports trans-NIH initiatives on health disparities research, liver disease, autism, pain research, biodefense, and imaging.

We will continue to facilitate trans-NIH research and assess priorities in response to public health urgencies and scientific requirements. However, the mainstays of NIH—peer review and investigator-initiated research—are the cornerstones of our success. This should be enhanced and not weakened. But with this in mind, NIH will continue to seek the best ways of funding the whole continuum of medical research with the ultimate goal of diagnosing, preventing, treating, and curing disease.

Mr. DEAL. That is all right. Thank you very much for that overview of your agency.

Let me just start off with a few questions.

First of all, the Institute of Medicine has made a—noted to us that Congressional disease-specific research mandates in the late

1980's and early 1990's actually total more than the overall NIH proposed budgeting, and required cuts in NIH desired research projects. Over the past decade, Congress generally has been reluctant to authorize new disease-specific mandates. How has this impacted NIH's priority setting process?

Mr. ZERHOUNI. This is an excellent question, and clearly, I think in the overall picture, when you look at specific disease mandates, without a scientifically sound and public health burden sound plan, then what you are doing is really essentially allocating resources, not knowing if the capacity is there, the opportunity is there, and so on. So by and large, I agree with the IOM statement that disease-specific mandates with dollars attached to them really distort the portfolio.

On the other hand, I think over the past 10 years, I have to say that Congress has been extremely generous with us, so that within years where increases were available, I think we have been able to match our resources to a larger spectrum of diseases than we did 10 years ago. So when you look across, as I said, we have several hundred common conditions, about 400-plus, and 6,000 rare conditions that we have to tackle within the NIH budget. I can tell you that we have made great progress in many areas because of this ability to move money within an institute without having these rigid mandates.

Mr. DEAL. Do you believe it would be helpful if a larger portion of the budget were—was in these trends, NIH initiatives, and if it was not agency institute specific? How would you go about in making the decision as to how to allocate those trends funds? Would it just be your decision or what process would you use?

Mr. ZERHOUNI. Again, I think that we have experimented with several processes the past 3 years. One is obviously—I don't think top down direction is the right way to go. What you really need to do is combine those three components. You need to have a sense of what the public health challenge is, you need to bring advice from the external scientific community with the institutes themselves being involved. That is the first step.

I think at the end of the day, what you really want is a set of priorities. This is a priority setting mechanism—with understanding where the scientific opportunity is, then have the budgets that go with that, and have that as an open process that would lead us to be able to make budget allocations in agreement with all of the relevant institutes, just like in the neuroscience blueprint. This is something that occurs with 14 institutes.

But I think the process needs to be institutionalized. I think you need to have better tools to measure what it is you are trying to accomplish, and this is what I would like this office to start doing. It is not the end all, be all of how you would do this, but if you have a very rigid appropriations structure, then everything is moot. I can talk all I want, but in tight budgets, it becomes very difficult to move monies for priority areas.

Mr. DEAL. The Office of Portfolio Analysis and Strategic Initiative that you put on the screen, is that something that would require legislative action by us to authorize, or is this something within your authority to put in place?

Mr. ZERHOUNI. Well, as you know, this is within my authority to put in place within the mandate that I gave the office. Clearly, moving money and having any authority over budgets and so on is not within the authority of that office.

Mr. DEAL. So the flexibility on the budget authority would be almost essential to make this work, I would assume.

Mr. ZERHOUNI. Right. So if you look at the office of the director, Mr. Chairman, I would suggest that you compare, for example, the authorities of the Office of AIDS Research with the authorities of that office. You will see that this office doesn't have the same authority of AIDS Research or Women's Health, they have their own appropriation, their own administrative structures, and their own ability to move money. So for example, this year—last year I asked all of the institutes to give me their 5-year forecast in terms of both budgets, but also scientific challenge, and the NIID told me about the 4 or 5 new vaccines that are coming—that are becoming ready to be tested. It is a very expensive proposition to test vaccines in a colloquial population. So that we could see that there would be a shortfall of about $200 million in 2006, a tight budget year.

So what we did within the AIDS, Dr. Whitescarver runs the Office of AIDS Research, reallocated across the entire portfolio over $100 million for vaccine trials away from other areas. That is an authority there that you don't necessarily have. This is in the authorization legislation for that office to coordinate that disease.

But I think what I am asking you to look at is instead of having a disease specific authority and everything every time you have a problem and a lot of mandates, you should see the number of reports that I sign for transagency this and transdisciplinary that and I think maybe this office should really play that role. It should be the point where, you know, things change. Priorities change. I mean, are we going to offer to create an office of obesity research? Isn't that a public health emergency? Why don't we create another one? Pretty soon, you will end up with 27 institutes and 27 offices to coordinate all these 27 players. No. you need one conductor, I think, and that should be a generic office that is charged and empowered to do what it needs to do to provide, with the institutes and centers, a sense of coordination and strategic partnership that is required.

Mr. DEAL. Thank you.

Mr. Brown.

Mr. BROWN. Thank you, Mr. Chairman.

Dr. Zerhouni, could you put the first chart up, the one you started with, the life expectancy? Could you put that up for us? And also, we would—I think many of us on the committee would request that we have that whole—that we could see all the charts, if we could. The first one was life expectancy. Thank you.

I find that interesting. I think what is left out of that chart and it is something that we all should celebrate in this country, the success we have had as a government, as a society, as a medical community of increasing life expectancy. But really what is left out of that chart is an awful lot of public health advances, and I would speak particularly—specifically about safe drinking water laws, clean air laws, seatbelt/airbag laws, social—the creation of Social Security, the creation of Medicare, minimum wage laws, workers'

compensation laws, prohibition on child labor laws, prohibition on child labor 100 years ago. All of those are very much a part of that, and I think if you took that chart and you overlaid it with the number of dollars we spend as a society on healthcare, it would make the chart look different. I think if we overlaid it with healthcare indocies of other rich countries, everything from life expectancy to infant mortality to maternal mortality to inoculation rate to all of those things, I think you would get a different picture.

My point of all of that is to be fair, we need to analyze this much—not that I am critical of your chart or of your presentation. We need to analyze it in a more encompassed way to show that our increase from 45-year life expectancy 100 years to 3, 3.5 decades longer today is more about—is less about medical technology and more about public health. And that is what—I think if you look in that direction and you think about where we are as a country, where we don't rank well, as much money as we spend on healthcare, we don't look all that good on a whole host of indocies except for one. Not our life expectancy, not our infant mortality rate, not our maternal mortality rate, we look very good on life expectancy at 65. So in this country, if you get to be 65, you are going to live longer than almost any other country in the world, and it just happens to be that we have a healthcare program that starts at 65 for everybody. That is my one point.

My more important point is—and question is what do we do—what do you do at NIH—and I know this is partly CDC's function, but what do we do at NIH—what kind of strategies of access? What are you thinking about? Your job is not just to develop incredible things as NIH does, but to find a better strategy to make them accessible. With the health disparities that we have in this country, people that wear ties to work like we do and have incomes like we do, and most of the people in this room have a very long life expectancy in this country. Many people don't that don't dress this way. The people that come into this building and clean it at night, their life expectancies are much, much less. Partly race, partly income, partly a whole lot of things.

What does—how does NIH structure itself so it does better with the whole health disparities issue?

Mr. ZERHOUNI. Obviously, you have studied the issue.

In terms of the life expectancy, I think if you look over the 100 years and you then say okay, what created the most progress in what time period, you will see that early on, clearly, clean water and the ability to have less taxing manufacturing jobs due to the industrial revolution, and having, you know, appropriate hygiene methods was the main driver of improvements in life expectancy.

Then you come to the midrange of the century. I think you can clearly see that social policies and others have played a big role.

If you come to the last third of the century to the 1970's onward, you can't help but say that the progress that we made has been primarily related to medical discoveries in prevention and treatment.

So that is my sense. You need to correlate it to what happened during that period of history. If you look at just global life expectancy, the best way to make your life expectancy look good is reduce infant mortality and childbearing health issues, and you have it

great. What is important is what is the life expectancy at given ages? And you pointed out that in America, if you live to be 65, you are going to be living at a higher percentage than other countries. The problem that we have in looking at statistics between our country and other countries is what I mentioned as health disparities. So if you look at different groups, different—you find statistics that are actually very good. But if you look at the, you know, combination, we have pockets in this country where we have healthcare performance and health indocies that we need to work on. And that is why I consider health disparities a top five priority of NIH.

In answering your question about what are we doing for access and making sure that—I consider that NIH has a continuum of duties, and I will give you an example. One study that we funded was called the OHAT study, which was the hypertensive drug trial where we compared five different drugs used in communities, 600 primary care communities. And we followed 40,000, I believe, patients over a period of 8 years. And two things were needed there. One, how do we improve access to effective medications? And we found that the old diuretics, the cheapest alternative, was actually the best alternative to start with if you wanted maximum compliance.

The second is a follow up. We are now working through all these community practices, and maintaining, if you will, the knowledge and finding ways by which you do this. And as part of the roadmap, one of the things that we have decided to do is to create what we call a core, a community physician core, that will be associated with NIH that understands that the translation to better practices and access to medication needs to be improved.

However, I would agree with you that you can not change that unless you have a comprehensive set of policies, because even though we have the best medical care in appointed areas, where if you had a significant disease, cancer, heart disease, this is the country to be treated in, but we don't have as effective a health care system as we should.

Mr. DEAL. Thank you.

Chairman Barton.

Chairman BARTON. Thank you, Mr. Chairman.

Dr. Zerhouni, again, I would like to compliment you on the steps that you have already taken and that you are continuing to take on revitalizing the agency.

I have a few questions here that some of this I think is going to be pretty straightforward, I think. Hopefully, you will agree with me.

I suggested three ideas for restructuring and reforming the agency in my opening statement. The first was that the center that your directorship should have expanded authority. Do you agree with that?

Mr. ZERHOUNI. I agree with that.

Chairman BARTON. Okay. I thought you would.

Mr. ZERHOUNI. Who is going to turn down authority?

Chairman BARTON. The second thing that I suggested was that we need to better align the budget authority within these various centers. Would you agree with that?

Mr. ZERHOUNI. I think we need to fluidify and make the budget authorities less rigid than intended in the statute, yes.

Chairman BARTON. Okay. Well, could you put up—and first, I compliment you on doing your own Powerpoint presentation. That is fairly impressive to be sitting here all by yourself looking at all these folks up here and doing that by yourself with no staff assistance.

Can you—let us just see how good you are with that Powerpoint.

Mr. ZERHOUNI. Now we are going to see.

Chairman BARTON. Yeah. I want you to put up the chart that showed the various centers and all—the latest organizational chart.

Mr. ZERHOUNI. Okay. Let us see if I can pass the test, here.

Chairman BARTON. It is the one that shows all 27 centers and various offices——

Mr. ZERHOUNI. Yes, I see it. I just need to—here we go. So we started with this one, and then we went to this one——

Chairman BARTON. Right.

Mr. ZERHOUNI. [continuing] and this one.

Chairman BARTON. There you——

Mr. ZERHOUNI. NIH today?

Chairman BARTON. Yes, sir. That is good.

Mr. ZERHOUNI. Thank you.

Chairman BARTON. I was hoping you would goof up on it so I wouldn't feel so bad.

Now, do you think that you could restructure that so that it was a little bit more effective and efficient?

Mr. ZERHOUNI. I think you have two ways of making it more efficient. One is having better tools, better management principles. And then this, as I said, is the picture of a holding company. The question is, what do you really have to make them hold together as functional units.

Chairman BARTON. Which box spends the most money up there?

Mr. ZERHOUNI. National Cancer Institute.

Chairman BARTON. How much is that?

Mr. ZERHOUNI. $4.8 billion.

Chairman BARTON. Which box spends the least money up there?

Mr. ZERHOUNI. The Fogarty International Center, $63 million.

Chairman BARTON. So we go from $4.5 billion to what, $63 million?

Mr. ZERHOUNI. Right.

Chairman BARTON. Okay. Should there be some order of magnitude similarity between boxes?

Mr. ZERHOUNI. You could definitely explore that question, Mr. Chairman, because for each box you create administrative structures. And the IUM report actually discussed that issue. Is it justified to create additional administrative structures every time you have some sort of a structure mission that you want?

Chairman BARTON. And my understanding is that every one of those boxes has their own administrative personnel, their own accounting personnel, their own——

Mr. ZERHOUNI. Advisory councils.

Chairman BARTON. [continuing] human factor personnel. I mean, you created 27 little corporations. Is that correct?

Mr. ZERHOUNI. Well, I have changed that over the past 3 years. So for example, personnel offices, there is only 1 now at NIH. We are going to an administrative restructuring plan, which I can do within my authority for budget and finance.

However, what can not be changed are the, you know, statutory structures that are there, such as you need a director, you need an advisory council, you need a staff infrastructure, FT and budget allocations. Those are things I can't touch, as you know. If I need to do that, I need prior permission for anything more than $1 million.

Chairman BARTON. Okay. Now, in the office of the director, the box that I am looking at that is to my right, you control inside that box, right?

Mr. ZERHOUNI. Inside the box that is on——

Chairman BARTON. On the right.

Mr. ZERHOUNI. [continuing] the right?

Chairman BARTON. Top right.

Mr. ZERHOUNI. Correct.

Chairman BARTON. Okay. What is the difference between the Office of Community Liaison and the Office of Communications and Public Liaison?

Mr. ZERHOUNI. Okay. Community Liaison is the office that deals with our immediate neighborhood around the campus. As you know, we have a large campus, a lot of friction between communities around NIH, traffic, the fence, biosecurity. That is what this office is supposed to do.

Chairman BARTON. And the other——

Mr. ZERHOUNI. But I would agree with you that you don't necessarily need to separate those 2.

Chairman BARTON. I mean, just even within a little box that you control, it seems a little bit convoluting to me. You have got extramural research and intramural research, for example. Why don't you just have research?

Mr. ZERHOUNI. That is a very good question. Actually, you need that by statute. You need to have—grants management, within our language, we have the obligation to manage grants to the extramural community differently than we do for Federal programs within NIH. So that has a good reason. I agree with you that this needs streamlining.

Chairman BARTON. Well, my time is expired and I don't want to abuse the privilege.

But I would sure like to get some of your people with some of my people and to coin a phrase, "Think outside of the box" a little bit. You know, if there—I don't want everybody that is in one of those boxes to be all of a sudden that Congress is out to get them. If that box needs to stay just like it is, then that is the judgment of the committee and the folks that we are going to be working with, so be it. But in this day and age, when you look at how corporate America and all the various communities are changing their culture and changing the way their management is structured, it would sure seem to me that we could create a lot less boxes and give a lot more transparency and cross-communication and just be much, much more effective at how we spend the dollars.

So I have said this before, and I want to repeat it. I really hope that we can work in a bipartisan basis in the next 2 to 3 months

to put an NIH restructure and reform bill on the floor with your help.

And with that, Mr. Chairman, I yield back.

Mr. DEAL. Thank you.

Ms. DeGette.

Ms. DEGETTE. Thank you, Mr. Chairman.

Dr. Zerhouni, I want to congratulate you for your leadership at NIH, and in particular, I want to congratulate you on your flexibility in your leadership role. Recently with the new ethics rules that you instituted, I found that to be an extraordinary experience where we sat here, we listened to the testimony of the witnesses about the conflicts of interest, and then you really thought about what you needed to do and you enacted that bright line role. So I want to thank you for doing that.

And I also want to ask you, I assume you are really planning to review these rules in 1 year to make sure you are not having a brain drain at NIH.

Mr. ZERHOUNI. That is correct. As I said, I think it is very important to do the right thing, and to me what is the most important goal of these interim final regulations is to have a bright line, but we intend fully to evaluate the impact of these rules. I don't think anyone can come up with rules and regulations that are perfect day 1.

Ms. DEGETTE. Thank you.

The main thing I want to talk to you about today—you will anticipate, I think, is the issue of stem cell research and the NIH. As you know, in 2001, President Bush enacted a stem cell research policy which said that the cell lines to be used, no embryonic cell lines past August of 2001 could be used for research. And I want to talk to you about what NIH is doing about that, and what we can expect.

The first thing is, as in our previous discussions, is there—is NIH funding any embryonic stem cell research right now?

Mr. ZERHOUNI. Yes, we are funding embryonic stem cell research under the President's policy.

Ms. DEGETTE. What is the level of that funding?

Mr. ZERHOUNI. About $25 million a year for human embryonic stem cell, and about—actually, you will see how it works at NIH here. Here is the dollars——

Ms. DEGETTE. You were expecting my questions, I see.

Mr. ZERHOUNI. I guess, or the staff was, anyway.

So here is embryonic stem cell research from 2002 to 2004. It goes from $10 to $24 million.

Ms. DEGETTE. So——

Mr. ZERHOUNI. For human embryonic stem cell research.

Ms. DEGETTE. So it is still $24 million. Do you have ethical oversight of that research? What kind of ethical oversight have you instituted?

Mr. ZERHOUNI. Well, within the research that we can fund, we have obviously all of the ethical oversight authorities that we need to have as in the guidelines.

Ms. DEGETTE. And do you have ethics rules over that research that you can fund?

Mr. ZERHOUNI. Well——

Ms. DEGETTE. You have written——

Mr. ZERHOUNI. Human subject ethics rules, yes. Obviously, ethics rules that relate to the conduct of the trial, a human trial——

Ms. DEGETTE. Right, but——

Mr. ZERHOUNI. [continuing] would be relevant, but at this point, there is none.

Ms. DEGETTE. You don't have any discreet stem cell research ethics—embryonic stem cell research ethics——

Mr. ZERHOUNI. Guidelines. We have guidelines.

Ms. DEGETTE. Mr. Chairman, I would like to ask Dr. Zerhouni if he can supplement his answer with a copy of those guidelines?

Mr. DEAL. Sure. I would appreciate it.

Ms. DEGETTE. Now, when the President enacted his executive order in August, 2001, Dr. Zerhouni, as you know, the administration thought there would be roughly 78 lines of stem cells. Correct?

Mr. ZERHOUNI. That is correct.

Ms. DEGETTE. And as I understand it, researchers at this point in the United States, NIH funded researchers, have access to only 22 lines. Is that correct?

Mr. ZERHOUNI. That is correct.

Ms. DEGETTE. Now, I am wondering if your researchers have any thought that there might be additional lines to those 22 lines that they could get access to in the future?

Mr. ZERHOUNI. So when we started in 2001, we had 87 derivations. In other words, cell lines that had——

Ms. DEGETTE. Yes, I understand.

Mr. ZERHOUNI. Right. Not been dropped. And in 2002, we had 1 that was widely available, and we developed 22 that are now widely available.

Ms. DEGETTE. Right, but are we going to have more in the future besides the 22?

Mr. ZERHOUNI. We don't know, because there are 31 of these derivations that have not been expended or made available by their owners.

Ms. DEGETTE. And most of those owners are abroad, correct?

Mr. ZERHOUNI. Most of them, yes.

Ms. DEGETTE. But I mean, certainly right now, you have the 22 lines, right?

Mr. ZERHOUNI. Um-hum.

Ms. DEGETTE. Now, do you know—there was an NIH internal report which said it is unlikely that the Federal Stem Cell Registry will ever have more than 23 lines available. Is that true?

Mr. ZERHOUNI. Well, I don't know if it is stated that way. When we looked and asked, I said what are the lines? What is the status of the lines? And we have a mechanism by which we develop these lines, which are called development grants, infrastructure grants. So based on that, we knew that we had institutions that were going to develop up to 23 lines. We had also attempted to develop others which didn't expand. They failed. And then there were 31 which are in India, Sweden, Korea——

Ms. DEGETTE. Right.

Mr. ZERHOUNI. [continuing] which we had no contractual relationship for them to develop.

Ms. DEGETTE. Right. And are you trying to pursue that contractual relationship to get those lines?

Mr. ZERHOUNI. We try, but right now most of them want to keep those in reserve——

Ms. DEGETTE. Right.

Mr. ZERHOUNI. [continuing] and when more is known——

Ms. DEGETTE. So you don't know if you will have access to those?

Mr. ZERHOUNI. I can not tell you that we will.

Ms. DEGETTE. Now, in May of 2004, you told me and Representative Mike Cassell, who had legislation pending on stem cell research "It is fair to say that from a purely scientific perspective, more stem cell lines may well speed human embryonic stem cell research." Correct?

Mr. ZERHOUNI. That is correct.

Ms. DEGETTE. So it would help you to have more cell lines to expand the research?

Mr. ZERHOUNI. It may. In other words, one can not—in the state of knowledge that we have now, one can not say that purely scientifically you could not have—make a discovery on lines that are not grown the way that we grow them for NIH scientists in the stem cell field as early as it is.

So purely—from a purely scientific standpoint—and many scientists will say that as well as I, that you can not argue that not having all cell lines at different ages may not be helpful. But the policy is predicated on its moral and ethical basis.

Ms. DEGETTE. I understand. And you and I have discussed this before, the President's policy is not based on a scientific principle, but rather the President's own moral beliefs, correct?

Mr. ZERHOUNI. That is my——

Ms. DEGETTE. Okay, thank you.

Now, are you aware that a recent scientific journal article reported that all of the 22 federally approved lines are currently contaminated with mouse feeder cells?

Mr. ZERHOUNI. All lines that have been developed worldwide have that problem.

Ms. DEGETTE. Oh, okay.

Mr. ZERHOUNI. Not just——

Ms. DEGETTE. Not just the 22, but all of them have the mouse feeders.

Mr. ZERHOUNI. It is not just the Federal lines, it is all 150 lines that we know about. There is 1 that may not have been exposed.

Ms. DEGETTE. Now, I thought there were some scientists with private funding who were developing some cell lines that were not contaminated with mouse feeder cells?

Mr. ZERHOUNI. Yes, they are attempting, but there is none that I know of.

Ms. DEGETTE. In the future, from a scientific standpoint, Doctor, don't you believe that it is going to be helpful to have an advancement of cell lines that is not derived from mouse feeder cells?

Mr. ZERHOUNI. Clearly, if you look at clinical indications, downstream, even though this issue of mouse cell line exposure is not an absolute no-no, because FDA currently approves things that are on mouse cell lines and so on. And so it is manageable, but clearly——

Ms. DEGETTE. It is manageable right now for the basic research state——

Mr. ZERHOUNI. That is right.

Ms. DEGETTE. [continuing] in its nascent stages. But as we go down the road, clearly, you are not going to be able to sustain that over time, correct?

Mr. ZERHOUNI. It is from the purely scientific standpoint, it would be desirable sources of lines that have not seen animal products.

Ms. DEGETTE. And that is not going to happen under the President's current policy limiting research to the lines in existence of August, 2004.

Mr. ZERHOUNI. The facts as we know them is that the—of the 31 lines that have not been expanded under the President's policy, 16 are said, to the best of our knowledge, not to have been exposed, and that the only——

Ms. DEGETTE. But we don't have access to those, they are fraught, right?

Mr. ZERHOUNI. No, but the owners of the lines are saying we will wait until we know more about how to grow these lines without mouse feeder cells before we expand them. So the theoretical possibility is that they could come and say we would like those lines to be available to be eligible for Federal funding, if that happens.

Ms. DEGETTE. Thank you, Mr. Chairman.

Mr. DEAL. Thank you.

Mr. Bilirakis.

Mr. BILIRAKIS. Thank you, Mr. Chairman, and thank you, Doctor, for your as usual fascinating presentation. There aren't too many of here—although I think most of the members of the subcommittee here, and I think they ought to just look at their faces. They were entranced with your comments.

As sensitive as disease specific is that you and I have talked about this over the years and it has been something that has been sort of a real problem for me over the years when I was chairing this subcommittee. But I am going to go into a question regarding it. It involves the granddaughter of a member of this House of Representatives, a member from the other side of the aisle, but it would help us, I think, understand. You know that the concern here is we can do all of this great stuff, but it is ultimately what it does at the bedside that counts. And so possibly, it can help us maybe get to that.

I am referring to—well, my understanding is that there has been a growing interest within the research community about a disease known as primary pulmonary hypertension. As you know and most of us don't know up here, this is a serious and often fatal condition in which blood pressure in the lungs rises to dangerous levels. It is a devastating disorder that disproportionately affects young women, and often leaves patients no treatment options other than a heart or lung transplant.

I wonder—and I have this great concern, too, about the use of clinical trials and how available that information is to the general public and whatnot, and to the loved ones of someone who has a particular disease. So in that connection, and also relating to this Office of Portfolio Analysis and Strategic Initiatives, could you up-

date us on how you feel setting up this office would further promising research into this disease? And maybe tie that into the clinical trial availability if you would, please.

Mr. ZERHOUNI. Thank you. In terms of trials, one of the good things we have done, which I think whoever you are talking to should really go look into, is what we call a clinicaltrials.gov data base. And this data base is public and we have over 12,600 trials listed in that data base. Actually, if you look at it, we have 12,667 trials listed, and 51 percent of those are sponsored by NIH, 21 percent by pharmaceutical companies, and 25 percent sponsored by universities. So I would encourage them to look at what could be in that——

Mr. BILIRAKIS. Does this contain all of the clinical trials?

Mr. ZERHOUNI. Every clinical trial we know about.

Mr. BILIRAKIS. Every one that you know about?

Mr. ZERHOUNI. Yes. In addition, I would say that in pulmonary hypertension, the institute that is charged with that mission is National Heart and Lung and Blood Institute. There are about 80 projects on that, based on the information that I have. But there are—in 2007, there is an initiative called specialized centers of clinically oriented research in pulmonary vascular disease that they are going to start. Because as we look at the total burden of this disease, it turns out that pulmonary diseases are really an issue that we need to invest more. Specifically in pulmonary hypertension, we are trying new drugs. As you know, some of the vascular active drugs, Sovenifil is used in pulmonary hypertension in adults. I don't know about the age of the patient that you are referring to. And we are putting an international scientific conference on that.

So clearly, a problem. We do realize that it affects younger individuals, and it is a very malignant disease, even though it is not a cancer. And we are clearly not focused on this——

Mr. BILIRAKIS. We are focused on it.

Mr. ZERHOUNI. Right. The National Heart, Lung, and Blood Institute, we have not looked at this as a trans-NIH initiative, sir, because we did not believe that it really goes across institutes in terms of missions.

Mr. BILIRAKIS. Thank you for that, sir.

Let me also ask you very quickly on the potential impact that the neuroscience blueprint may hold for research into paralysis and spinal cord injury and dysfunction. And I guess the question, principally is does the current structure inhibit research in those areas?

Mr. ZERHOUNI. That is a more difficult question to answer because in spinal cord injuries, you know, the National Institute of Neurological Diseases is primarily related. There is research now that is going in regenerative medicine, stem cell research that may have an impact on paralysis, bioengineering research in the National Institute of Bioimaging and Bioengineering. So there is more and more interdisciplinary activities in not just curing paralysis, but managing paralysis. I can show you the funding for it. This is the funding between 1997 and 2006, went from $60 to $91 million just for spinal cord injury alone across NIH. Most of the increase is related to other institutes coming together. We have a new clin-

ical trial network that is brought together, and the reason that we have—NINDS is doing this is because the time at which you intervene after a spinal cord injury is critical. It is like heart attacks. You can intervene early, you can have great results. We have had a tremendously promising set of research programs last year where early intervention seemed to lead to faster recovery, deeper recovery.

Where we are not making progress is long-term paralysis, where I think we need to search for more answers.

Mr. BILIRAKIS. Thank you so much, sir. Thank you, Mr. Chairman.

Mr. DEAL. As you see, we have a vote on. I think probably we need to go vote and come back. There are a series of votes. I would ask you to return and we will continue with the questioning at that time.

Mr. ZERHOUNI. I will go by the camera and see if they will interview me.

Mr. DEAL. Okay, you do that.

Mr. ZERHOUNI. I don't think so. Thank you, Mr. Chairman.

Mr. DEAL. We will stand in recess until after the vote.

[Recess.]

Mr. DEAL. Ms. Capps, you are next.

Ms. CAPPS. Thank you, Mr. Chairman and Dr. Zerhouni. Thank you very much for your thorough presentation and for being here today. I want to make a cautionary statement, a concern, and then ask you a series of questions with, I hope, brief answers so I can cover several topics.

I was pleased to see that you have put a new policy on enhancing public access to archived publications resulting from NIH-funded research. I think this a good step forward. But I have to say I am not convinced that the voluntary publication of research results is going to be effective, and I am concerned that this new policy should be as good as it possibly can be. Public access to the fruits of taxpayer-funded research really makes sense, and so my caution and concern is that I hope you will make sure that the policies uphold that priority.

I want to turn to the topic of NIH reauthorization. Chairman Barton and others have made it very clear that they want the committee to reauthorize the NIH this year. My question that could even have a yes or no answer is, do you think a reauthorization bill is necessary, emphasis on the word necessary?

Mr. ZERHOUNI. I think it is appropriate, given the description of how NIH needs to be more flexible to look into the opportunities for improvements in the authorization process, while we provide you with the information that you need to make that determination.

Ms. CAPPS. Maybe a better way to say it is would this be your No. 1 priority or if you had to rank a series of priorities, where would this fall?

Mr. ZERHOUNI. As I said, I think better portfolio management, the ability to integrate our research across more than one unit is certainly a priority for me.

Ms. CAPPS. Okay. So I am taking by that, that that would be your first priority?

Mr. ZERHOUNI. Right.

Ms. CAPPS. And our interest in supporting that is what you would prefer.

Another topic—I am all over the map, I am sorry. But another issue of great importance on NIH reauthorization is, of course, stem cell research that our colleague, Ms. DeGette asked you a series of questions about this. But I want to focus on your role. As the director of NIH, you would be involved in any discussion of reauthorization. So I am wondering and concerned about the flexibility that you have—the authority that you have, really, to negotiate changes in the administration's policy on stem cell research. I mean, you were handed something from the President and have implemented that. Now if we reauthorize the NIH, how do you see your role in that process?

Mr. ZERHOUNI. As you know, I am a Presidential appointee with Senate confirmations. I am part of the executive branch under the—and I report to the Secretary of HHS and the President. So from that position, I am, you know, bound to represent obviously, the policy of the administration and uphold—and the President, and uphold the laws passed by Congress. On the other hand, with my capacity as a scientific advisor, if you will, I provide information to the executive branch as well as to Congress, based on what we know from our scientific exploration of the field, and we have continued to do so as openly as possible to inform the authorization process.

Ms. CAPPS. I guess——

Mr. ZERHOUNI. I don't have authority to negotiate, is what I am saying.

Ms. CAPPS. You do?

Mr. ZERHOUNI. No, I do not.

Ms. CAPPS. You do not have the authority to negotiate——

Mr. ZERHOUNI. Independently, NIH does not have an independent authority to negotiate policies related to stem cells or any other issue.

Ms. CAPPS. When you give the President information——

Mr. ZERHOUNI. Right.

Ms. CAPPS. [continuing] do you have persuasive powers in that respect? I am trying to pin you a little bit.

Mr. ZERHOUNI. Most—I believe so. I think I have a great smile and——

Ms. CAPPS. All right. I am taking it to be that this policy comes from the White House, and that you—there is no or very little flexibility there?

Mr. ZERHOUNI. Actually, in law, we——

Ms. CAPPS. You are bound by law.

Mr. ZERHOUNI. [continuing] implement the policies of the President and the laws passed by Congress.

Ms. CAPPS. So you cannot, for example, support further limits on stem cell research?

Mr. ZERHOUNI. Support further limits?

Ms. CAPPS. Yes.

Mr. ZERHOUNI. I can not set policy, and policy is not set at the NIH level. We can inform policy, and we do so.

Ms. CAPPS. You can——

Mr. ZERHOUNI. Inform policy, and we do so.

Ms. CAPPS. But you can't support tightening restrictions on stem cell research, and you also can not—oh, I see. You can support tightening research on stem cell research? You can support that?

Mr. ZERHOUNI. No, I can not——

Ms. CAPPS. You are supporting it, because that is the President's policy.

Mr. ZERHOUNI. I inform policy, obviously, and I can talk about the state of science and how it is evolving, inform the President and the Secretary of Health and Human Services on the evolution——

Ms. CAPPS. Right.

Mr. ZERHOUNI. [continuing] of science and policymakers like yourself.

Ms. CAPPS. Do you——

Mr. ZERHOUNI. But we do not determine policies.

Ms. CAPPS. Right. Do you advise the President about his changing policy?

Mr. ZERHOUNI. When asked, yes.

Ms. CAPPS. If you are asked?

Mr. ZERHOUNI. Yes.

Ms. CAPPS. Okay. I have a lot of questions on that topic still, but I want to turn to a very important topic to me and to many of us here in Congress. The goal of the National Cancer Institute, which it has set, I am co-chair of the cancer policy group here in the Congress. You have set out, NCI has set out the goal—very impressive goal of eliminating all cancer death by 2015. It is certainly a laudable goal. And we in Congress were very proud of our record—track record of doubling the funding for NIH a few years ago. But—and in the subsequent years, NIH however, has only received an increase of about 3 percent in the last few budgets. But this President's budget this year, the NIH is restricted in its budget, really flat lined. And in fact, the NCI has been budgeted in this year's budget to receive less than a 1 percent increase in funding. Which given inflation and all the costs of everything, is really a cut.

So I want to hold on to that goal with you, but I wondered if you think you have any chance of meeting it at this current funding level?

Mr. ZERHOUNI. Any chance of—I am sorry, I missed the——

Ms. CAPPS. Of meeting that goal, given this budget. This budget is about to be voted on in the House, but it isn't appropriated yet.

Mr. ZERHOUNI. As you know, this is a very laudable goal that Dr. Von Eschenbach sort of created as a vision, as a reach goal for the National Cancer Institute to eliminate pain and suffering—death and suffering from cancer by 2015. This has the advantage of galvanizing, if you will, the scientific community, the patient advocacy community, and you know, the institutions that we work with.

It is clear that as we look at very difficult budgetary times and increases that require us to make tough choices, the NCI is going to have to balance. And I think Dr. Von Eschenbach said it, in this budgetary environment, you are going to have make choices between what it is you want to do at the expense of something you no longer will do.

Ms. CAPPS. I don't want to interrupt you, but I want to be able to frame the last few seconds on this topic. If NIH reauthorization comes up, I am hoping from my role that we can count on your support to make sure that NCI's special status—I mean, this is a huge part of the budget, but it has this goal that will be better achieved, if you will, if there is the proper support for it.

Are you willing to keep that status?

Mr. ZERHOUNI. I think the authorities of NCI have been historically very helpful since they started in 1971. I think some of these authorities, I mean, we should look at them and maybe have other institutes gain from that. I mean, from my experience at this time, the authorities have been a positive thing that I don't think pose a problem for NCI or for NIH. So it should continue, I believe, to be a positive development for NCI.

Ms. CAPPS. The special status of NCI?

Mr. ZERHOUNI. Right. And what I am saying is if you look at the authorities, there are different ones, but there are some that I think we should look into and maybe expand them to other institutes. The construction authorities, some of the training authorities, I think there is a debate to have about maybe expanding the authorities that are in the cancer field to some other of these groups, because they have been helpful historically.

Ms. CAPPS. I understand. Thank you.

Mr. DEAL. Gentlelady's time is expired.

Mr. Ferguson.

Mr. FERGUSON. Thank you, Mr. Chairman.

I have some questions for Dr. Zerhouni. I thank you very much for being here. I know you have appeared before our committee before and I appreciate the opportunity to talk with you a little bit.

I want to follow up on some of the questions about stem cells. Of course, one of my colleagues stated earlier that policy that the President instituted in 2001 had to do with the President's own personal ethics. Of course, the question of when life begins is not a question of someone's personal ethics or their religion or anything else. It is a question of science. I think that is important to note for the record.

Dr. Zerhouni, are you familiar with Laura Dominguez? She was a patient who was paralyzed from the chest down through an injury, and today walks because she has been treated with an adult stem cell treatment, and she walks today with the help of braces. It is an incredible story. She was here in Washington last year telling her story. I am not sure if you are familiar with a woman named Patricia Durante, who is a leukemia patient. She was 6 months into her pregnancy when she was diagnosed with acute leukemia, and they delivered her baby, her daughter early because she had to be treated for her leukemia. And she was treated with some of her daughter's umbilical cord stem cells. And her leukemia has been cured. It is an incredible story. Both of these treatments had nothing to do with embryonic stem cell research. And of course, these are just two of the thousands and thousands and thousands of people who have actually been treated with varying degrees of success, some very successfully with adult stem cells or stem cells taken from placentas or umbilical cords.

My mom passed away a year and a half ago from multiple myeloma. She was 59 when she died, young woman. When she was diagnosed, her physicians told her that she would have a year. She was stage 4 multiple myeloma, bone marrow cancer. When she was diagnosed, her doctors told her that she had a year, possibly 2, to live. She ended up living for 6 years. She got a bone marrow transplant, which didn't work all that well, unfortunately. And then she was given an experimental adult stem cell treatment, which enabled her to live an additional 4 years. Absolutely confounded the physicians and her doctors at Johns Hopkins Hospital in Baltimore with the success of this treatment. I tell you that story not because—just because I am happy that my mom was able to live an additional 4 years, but when she was diagnosed, she had no grandchildren. And when she died, she had been able to meet three of her grandchildren. Three of our children had been born by that time. It is not just important, of course, because my mom got to meet her grandkids, but frankly, more importantly, her grandkids got to meet her, and they will have that for the rest of their lives because of this incredible treatment, which did not come from embryonic stem cells. It came from adult stem cells. And to my knowledge, there are exactly 0, not people today who have been treated with any degree of success at all with embryonic stem—technology that has come from embryonic stem cell research. When, in fact, there are thousands and thousands and thousands of people, dozens and dozens of clinical trials, incredible work being done. And you know all this, being done with adult stem cell treatment.

So I think that is certainly important to point out for the record that the real promise in this field is in adult stem cell research. And I have a ton of biotech in my district in New Jersey. We have some of the leading companies, researchers, and scientists in our district in New Jersey. And I sit with them and I meet with them on a regular basis. And I ask them about this. I say, do you do—you know, a lot of them do work with stem cell research. And I am a big proponent of stem cell research. I am a proponent of ethical stem cell research, research that does not destroy human life, that does not destroy a human embryo. And I think it is important to point out, after all the hype and the propaganda sometimes, that the facts are that there are thousands of people today who have been treated successfully with adult stem cell technology and research. There are dozens and dozens of clinical trials and applications from this type of research, and there are 0, none, that have come from embryonic stem cell research. The most optimistic proponents of embryonic stem cell research say that those types of advances are 15 or 20 years away. And why we would continue to pour money into this frankly most unpromising field when we have such a promising and ethical form of research which is already showing such great promise seems to me should be an easy call.

I want to continue this and I actually do have a couple of questions. According to a recent RAND Institute study—and I am sure you have seen this, and I will quote from it. It says "Using a conservative estimate between the two conversion rates from blastocytes to stem cells, noted above 27.5 percent, the research team that calculated this that about 275 embryonic stem cell lines could be created from the total number of embryos that are avail-

able for research." Of course, we are talking about frozen embryos in banks today. Even this number is probably an overestimation, because it assumes that all of the embryos designated for research in the U.S. would be used to create stem cell lines, which is highly unlikely. That is a quote from the RAND Institute.

In your opinion, when the proponents of research as I have described kills human embryos, say that they can cure more than 100 million people from any number of diseases and conditions if they can just get their hands on those human embryos in the IBF clinics. Are they basing these claims on hype, or is that completely backed up by science?

Mr. ZERHOUNI. Well, thank you for putting me in an area where I think what you are seeing in the debate is the cross section or an intersection between science and society. I think in the context of what you just described, how can you make a projection of 100 million this or that? I think we are too early in our knowledge of this field to be able to predict how or where and when you will be able to truly implement a cure or a palliation for degenerative process, whether it be diabetes or Parkinson's disease.

So I think there is no logical connections, I think, scientifically to connect one to 100 million. I would say, on the other hand, that the issues that we are dealing with right now are a more basic level than clinical applications. And at this point, no one really knows what direction this whole field will take. It is impossible to tell if it is going to be 100 million in a revolutionary process. But from the scientific standpoint, there is no doubt that we need to understand what goes on in stem cells, adult and embryonic, in terms of their DNA being programmed and reprogrammed and what is the best pathway? There is no doubt that all scientists would like to have their science evolve without being in conflict with any societal or moral issues. But scientists have to also look at the question in front of us, and that is that can you program or reprogram the DNA of the cell so that it can do things that you have lost the natural ability to do to get the miracles that you are describing?

So I would say that there is no logical connection that you can drive, as long as you haven't really understood the fundamentals of this field.

Mr. FERGUSON. And of course, I am sure you would agree—and my time is up. I am sure that you would agree that unbridled science research is not a virtue in and of itself. Of course, as in all of these decisions, our ethics must form and inform our science.

Mr. ZERHOUNI. I have to tell you, I agree that science has to evolve within its social context, and scientists do that. I mean, frankly, when you look at—I just received an award on behalf of NIH for the recombinant advisory committee, which was the committee that looked at genetic engineering, a very concerning area from the standpoint of morals and ethics in society, and it was created by scientists. There was a moratorium for a year and a half on all that study until good guidelines could be put together.

So I think there is no doubt that the question, as you pose it, is we need to engage in a balanced dialog and a balanced mechanism to make sure that science evolves in conjunction with our moral and ethical principles.

Mr. FERGUSON. Thank you. Thank you for being here today.

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

Ms. Baldwin.

Ms. BALDWIN. Thank you, Mr. Chairman.

Dr. Zerhouni, you deal very gracefully with issues, controversy in science. And I have two questions that deal with controversy in science. One really following up on the last two questioners regarding embryonic stem cells.

Clearly, embryonic stem cells have a different set of traits than adult stem cells, including the capacity to be coaxed, if you will, into becoming other specialized cells, a capacity that adult stem cells do not have. In answer to a question posed by Mrs. Capps, you talked about your role as a scientist advising the administration, advising the Secretary, advising the President. And so I guess I would ask you at this juncture, how would you advise the President with regard to what future policy ought to be on embryonic stem cell research and the limitations?

Mr. ZERHOUNI. I think I wrote a letter to Congress about the issue that was asked.

I think right now what we are dealing with is a very basic stage of the research. We really need to understand better at the molecular level what draws the differentiation. I mean, you are talking about the potential of embryonic stem cells to be pluripotent versus adult stem cells being multipotent, have different potentials. But frankly, if you look at the data, if you look at the signs, right now we are even still working on how to characterize the particular cell lines that we have, the 22 cell lines. So last year, we advised to create a stem cell bank, a national stem cell bank so we can have side-by-side comparisons of these lines. We have also pushed for experimentation in terms of stem cell specialists working with disease specialists. Remember, embryonic stem cell is a young field. It is only been funded for 3 years.

So I think my advice is that we need to continue our exploration of the fundamentals of this field to be able to really determine where we need to be in the next few years.

Ms. BALDWIN. Okay. On another issue, we know that 6 of the 10 leading causes of death in the United States are based in part on behavioral factors, such as smoking, violence, diet, and substance abuse. And that other behavioral factors are also known to increase an individual's risk for disease, disability, even early death. This is certainly the case in the obesity epidemic. In a document entitled "Fiscal year 2006 Justification of Estimates for Appropriations Committee" put out by the Department of Health and Human Services, the importance of behavioral research is underscored, especially as it relates to the obesity epidemic.

For example, the document reads "The obesity epidemic has been fueled by a complex interplay of behavioral, sociocultural, economic, and environmental factors acting against a backdrop of genetic and other biological factors." And it continues, "Continued behavioral research should greatly enhance the understanding of factors that contribute to obesity and may assist with future design of both pharmacologic and lifestyle interventions." Now, despite the promise that behavioral research holds in a number of areas, we have seen it attacked in recent years. These attacks have sometimes oc-

curred in the media. Periodically, we have even seen legislative interventions or threats of legislative interventions. And given the sometimes hostile climate toward behavioral research, but given its importance to understanding and combating some of these epidemics, I am asking you what sort of efforts have you taken to ensure that behavioral research receives appropriate resources and does not become skewed, if you will, by political influence?

Mr. ZERHOUNI. Well, in the context of—first of all, let me agree with your overall statement that behavioral factors are a main driver of disease burden, and we need to understand better what—why is that.

NIH spends about $2.9 billion, you know, on behavioral social science research, so it is not something that we ignore. We have an Office of Behavioral Social Science Research in my office to stimulate and coordinate these activities. The neuroscience blueprint program that I announced this year includes a major component to it that focuses on behavioral research.

In terms of obesity research, what I would like to show you is the NIH strategic plan, which is on our website, which was developed last year. And if you look at that plan, you will see that a major component, in fact, is behavioral research. One of the things that we are very concerned about is if you look at obesity and the relationship of obesity in children, relative to the body mass index of their mothers, what you can see here is that if you have a patient who is in the normal range of weight between 18 and 25, there is a 10 percent chance of obesity in their children, with the mother being in that weight. There is a 10 percent chance. If you go to an over 40 index, there is almost three times more chances of obesity. So what the plan talks about is how to intervene behaviorally, not just in adults or teenagers, but now intervene in the stage of intrauterine life, and very early preschool. And the NIDDK, the institute that is leading this effort, is running, actually, trials to change the behavior.

Now, one of the things that is clear is that this is not going to happen without a lot of collaboration across multiple entities of the Federal Government. And we need to really underscore that. It is going to require changes on the ground in terms of the set up of cities, and how much walking, how much diet, exercise you can fit in into a normal life pattern. But I think I am very clear that behavioral and social science research is going to take an important—an increasingly important role.

Mr. DEAL. Gentlelady's time is expired.

Mr. Upton.

Mr. UPTON. Thank you, Mr. Chairman. I won't use, I don't think, all of my time.

Dr. Zerhouni, we welcome your opening statement. It was terrific and I certainly join with all my colleagues on both sides in very strong support of the NIH and its budget requests. I was one of those, many years ago, that helped on doubling the money, and I am glad to see that it was successful.

I have two basic questions. The first is I want to get a better understanding of the new grants submission from start to finish, in terms of review and funding selection as it works, and then use that—what it is under present, then look and see how that process

changes under the reforms that you are advocating. That is my first question.

And why don't you go ahead. And I have one other question I want to make sure I get in, but go ahead.

Mr. ZERHOUNI. So new grants. Every year, we fund about a grant for about 4 years. We fund about 43,000 total grants, so every year we have about 10,000 new grants to make, on average. Of those, about ⅔ come from scientific advances and changes in scientific fields that are of great importance, whether it be genetics or genomics and so on.

Those come to NIH, and we get about 40,000 applications for these 10,000 grants. So we fund about 1 in 4, a little less than 1 in 4. At the doubling, we funded about 1 in 3, but the doubling, you know, was 3 years old now, and the post-doubling has led to more applications for new grants.

When the new grant comes in, we have a center for scientific review which is independent of the institutes. And there are peer review sections there. They review all of the grants and they score them in terms of quality of research, potential public health impact. One of the things we have done over the past 2 years is to make sure that the public health relevance of every grant is explained in plain language. Then those grants go in and they go to the—they are referred to the various institutes. If it is a cancer grant, it goes to the Cancer Institute, and so on.

Then within the budget that you have, you have to make a priority list. In the past, the top 30 percent were given grants. Now it is the top 22 percent. And it goes to the advisory council of the institute. They review that and then they say, you know, we need to fund that many, but we need to fund more in this area rather than this area. And what they could see, also, is that perhaps we are not getting enough grants in a given area of science. Maybe we don't have enough grants in leukemia, or not enough grants—so what they would do then, they will instruct institute staff. We need to have more presence in leukemia or obesity, for that matter, which is what we did last year.

Then the institute informs the scientific community that we are interested in receiving applications that deal with obesity. So when we did obesity last year, this year we have had in increase in the number of proposals and applications for obesity research, including behavioral science research.

So I think it is a cycle, Mr. Upton. It really goes from scientific field, peer review, assessment of——

Mr. UPTON. Does that change at all in terms of the reforms? How does it change from——

Mr. ZERHOUNI. So what would change, for example, is what we did with the road map. So we told all the institutes to put a pool of dollars in the pot, if you will, about 1 percent of the total NIH budget, and we decided jointly what were the areas that were not being developed that we needed to push and develop. And that is what we did through the road map.

Mr. UPTON. My second question is this. You said in your statement that you wanted to prevent bad science from being conducted. And remember, I am a supporter of the NIH. For the last number of Congresses, we have had a vote in the House on an amendment

that would de-fund certain grants. And as I reflect back, it has often galvanized the entire research community against the amendment.

But you know, as I listen to my colleagues, and as I have a survivor, a cancer survivor in my family. I have got—I know many, many people that have utilized the NIH. Your terrific examples of raising the age that we all live 5 years because of the research that you do. It just seems—and when you talk about all of the requests that come in for assistance—and I have been to the University of Michigan. I have seen some of their requests. I was there when the researcher in Ann Arbor actually located the gene for the breast cancer cell. It seems that some of the projects that get funded that we sometimes vote on—I'll use the example of the behavior of prostitutes at trucks stops, I think was one of the votes that we had in the last year or 2. I voted to stop that. It just seems that that doesn't measure up to some of the same things that the NIH ought to be really doing. And I would be anxious to hear your comments on that.

Mr. ZERHOUNI. So I reviewed that issue, because this was raised—Mr. Pitts raised that. And what I did is I reviewed the entire portfolio. Asked all my scientists, all my institute directors to explain to me what is the public health relevance of this research? Because I don't think we can look at this issue without seeing what the societal impact is, and why is it.

For this particular example, you should know that sexually transmitted diseases and HIV AIDS are a rising problem in our populations. It is not a problem that is going away. And in particular, when you look at these diseases, unfortunately, their main root of transmission is the trucking industry around the world. And in fact, prostitution at truck stops is one of the main roots of transmission. Not knowing that—not doing research on that would have been a decision, I think, that would not serve public health.

I think, on the other hand, that we need to have a better understanding of the research that is done so that it does not come across as being, you know, without a public health purpose. The balance of that is really what I think we need to focus on. I think focusing on a single grant, sir, I really—and I have said that. I don't think it is the right way to look at it, but look at it as a matter of policy. What is the public health relevance versus how you—what you do and how you do it. So I have to tell you that I understand very much your point of view, but I don't think that the public health burden of that should be ignored, either.

Mr. UPTON. Thank you. Yield back.

Mr. ZERHOUNI. Thank you.

Mr. DEAL. Mr. Green.

Mr. GREEN. Thank you, Mr. Chairman, and again, welcome and thank your for your patience because of votes and everything else.

Dr. Zerhouni, I represent a district in Houston and I had the opportunity last fall to visit the President's Cancer Panel when it came to M.D. Anderson in Houston, and I am proud of the M.D. Anderson Cancer Center, and particularly, the Cancer Institute with Dr. Eschenbach.

Time and again during the discussions of that cancer panel, speakers identified the lack of collaboration between scientists as

a hindrance to progress in the field of cancer research, and I assume, in lots of other fields. This collaboration was not borne out of structural problems at NCI, maybe, but rather by the tremendous sense of competition between our academic researchers and the unwillingness to cooperate, because that would mean having to share the accolades and the fame that accompanies a discovery.

I am pleased to see that you stress the research teams of the future initiative to create interdisciplinary research programs, yet I would like to hear how the structural changes you envision would invoke a change in the mindset of researchers. Because every once in a while, even Members of Congress get jealous of each other's share in credit. But I understand that, and if you could just explain to us how we might institutionally change that mindset.

Mr. ZERHOUNI. You are absolutely correct. Culture has to change, and the way we try to do this is to lower the barriers to the cultural change. One thing we are doing this year is we are allowing grants to be held by multiple investigators rather than just 1 master of the tribe, if you will. We want every type of discipline to be able to have an equal role.

The second is the—through the initiatives that we are taking, we are stimulating for the creation of interdisciplinary centers, interdisciplinary teams, and so on. But at the end, you are correct. The change will have to occur in the institutions. And when—as you know, getting an NIH grant right now is the main determinant of promotions in the academic world, worldwide. It has become the label of quality. If you can get through it, it is almost as good as getting a diploma. And that is why it is so competitive. It is the only thing the Federal Government, I think, gives out there that leads to a professorship is an NIH grant.

So frankly, I think you are right. If we don't change that from an individual centered thing to a team centered approach, then the scale of the problems that you have to tackle is going to be reduced.

Mr. GREEN. I would offer whatever we can do to help.

Another concern is the research study gains the most legitimacy through its publication in a medical or science journal, and subscriptions to these publications are expensive for the public to have access to. And since the advent of the Internet, the public increasingly seeks out information about the latest medical research to determine treatment options. And since the NIH funded research is openly funded with tax dollars, I believe the public should have as wide an access to those research findings as we can.

Can you explain NIH's rationale behind its recent policy on open access to NIH funded research findings? I know the proposal originally was to open it after 6 months, and then it was changed to 12 months. Can you tell us the——

Mr. ZERHOUNI. So first of all, there was nothing before this policy.

Mr. GREEN. That is true.

Mr. ZERHOUNI. You have a venue for any scientist to make anything available to the public. So the value of this policy is that it creates a precedent and a new pathway for the public to have access to NIH funded research, number 1.

Number 2, when we proposed the policy, we said, you know, we need to walk before we run. We believe that the scientists in their

majority want to make their research available to the public, so we said all right on the voluntary basis. We request that all our grantees put their papers up at 6 months, or sooner, if the publisher agrees. When we looked at all the issues through the comment period, we didn't change the policy. It was always voluntary at the beginning. And then what we decided to do, sir, was to instead of asking people to just wait 6 months, to ask them to basically give us the paper as soon as possible, not wait 6 months, if they can, but up to 12 months if they need to. Meaning that 12 months is an exception. Why is that? Because when we looked at the publisher world, it is clear that it is not just driven by for profit large companies, but you have small journals that really require—and societies that require and count on that revenue. So what we did is we provided—we didn't extend it from 6 to 12, sir. We really said instead of 6, we will give you a range, and we will tell you as soon as possible.

Mr. GREEN. Does that include—who makes the decision? Is it the publisher or the NIH researcher?

Mr. ZERHOUNI. No. We changed—this is a major change. In the policy, we said the researcher, the grantee, has the——

Mr. GREEN. Has the authority?

Mr. ZERHOUNI. [continuing] decision power, yes.

Mr. GREEN. Okay. And I know you have had these questions from both sides on it, as a scientist, and I understand the President makes the decisions, kind of like with our staff. You know, our job is to make the decisions with what they do.

When you are advising the President on stem cell research, would you advise him to reduce or increase the limitations on stem cell research?

Mr. ZERHOUNI. Like I said, I have advised the President, for example, on increasing the amount of funding. The National Stem Cell Bank is something that we said was needed. Or we needed to really work through the IP issues and provide that national resource. The same is true for increasing funding for translational activities. I provide all of the latest information on the field, not just federally funded research, but all of the federally funded research. But I don't determine policy, obviously.

Mr. GREEN. Okay. I understand.

For my last question, approximately half of the institutes and centers within NIH are created administratively, while others are mandated by Congressional action. I am particularly interested in the Center for Minority Health and Health Disparities, which Congress created in 2000. And since Congress, not NIH, created this center, do you believe that a separate Center for Minority Health has been a positive development, or in retrospect, is this an area of health research that you would prefer to be addressed through your plan for interdisciplinary research?

Mr. ZERHOUNI. Well, again, this is one of those areas where I think this is a top priority for NIH, health disparity. So the question is, at what time do you create a structure when you have a priority or what time do you let it sunset? That is the usual issue.

I think the National Center has played a very important role in doing two things. One is having resources of its own to leverage its ability to influence, but also, it has cross NIH authorities to look

at the strategic plan. And that is the combination that I am saying we need to have as a matter of institutional policy, not just for minority health or women's health or AIDS research, but as a process that will serve all emerging priorities as they come. Health disparities is here, in my view, as one of the top five priorities. NCMHD is really needed. It is an office that really coordinated things before. I think it is necessary, when you have a phase of challenge like this to have a focused effort.

But I don't think that maintaining these things forever is a good policy for any structure that we create, but I don't think NCMHD is at that phase. I mean, NCMHD needs to really do a lot of work. They just started. They are doing a good job.

Mr. GREEN. And I know the district that I have is majority of Mexican-American. Obesity and diabetes is an issue and it strikes across all ethnic lines. African-Americans and Hispanics have a higher percentage than the average population. But it is a problem with everyone.

Thank you, Mr. Chairman, for holding the hearing.

Mr. DEAL. Thank you.

Mr. Rogers.

Mr. ROGERS. Thank you, Mr. Chairman. Thank you, Doctor, for taking the time. It is a little bit sad that millionaire baseball players who abuse drugs get two dozen cameras, and the guy who is going to help set the pace and structure for curing AIDS and cancer, and we couldn't even arrange a Polaroid for you.

Mr. ZERHOUNI. And discovering steroids as well.

Mr. ROGERS. Yes, that is exactly right. And what they do wrong, right?

I do appreciate, thanks, Doctor. But please know that for at least those of us who are here today, we appreciate your work and your effort. And we know, literally, that it is lifesaving work that you and your organization and the scientists that plug into your organization do, and we are thankful for it. Nowhere else in the world does this exist in the way that we do it, and it shows. And I might disagree with one of my former members, it really wasn't, because we passed laws, and if that was the case, more Congressmen would cure more disease. But we know that your work and research and development in actually getting to the heart of this stuff has made a tremendous difference in the lives of every American. Thank you for that. I appreciate it, and what you are going through.

And I am intrigued by this cross cutting idea where we can try to give you the tools that you need versus by mandating it. And do you believe that if we can come up with a mechanism of which I hope that you will recommend to us, a cross cutting mechanism that we can address something I don't think is being addressed well, and that is pain. I have a huge interest in pain care and palliative care. Fifty million Americans will—are either partially or totally incapacitated because of pain. And I know less than 1 percent of your budget is on there now. And with your new Office of Portfolio Analysis, do you believe that is a way, or there is a way that we can start addressing real research education and access for physicians and patients across the country on pain care? And really, think about it. Cancer, AIDS, people who have been treated for a

disease are in pain, and people who have not been treated for a disease suffer a different kind of pain.

Mr. ZERHOUNI. I think you are absolutely right. Not only do we need to think about curing disease, but making sure that the quality of life you lead is maintained. And pain is a major determinant of that.

So we have now a pain—I mean, we had it last year and it started with Dr. Larry Taybach, who is the head of the National Institute of Dental and Craniofacial Research, who is now leading a trans-NIH pain consortium. And is doing really a review of all of our efforts across all the different fields, because pain in different fields is a different issue.

We also, as I will show you here, increased funding for pain significantly. And if you look at when we started, it was about 104 before the doubling. It is $233 million by 2004. So we recognize the issue. In addition, in the road map we have developed tools to measure pain that are objective across diseases. So it is a tool called "promise" which is part of the road map process where we are going to record subjective outcomes, not just what the doctor says, you know, when they say the patient is cured, and the patient says well, I am dying cured. Because in fact, what needs to happen is the measure of outcome as seen by the patient. And pain becomes, then, a major determinant. And in that context, I believe that what you are asking us to do will be enhanced by having the ability to cross correlate what these efforts are across—because they are just minor issues for each one, maybe, each disease, but they are major issues for all patients.

Mr. ROGERS. I mean, the number 1 issue that a patient shows up anywhere to get treatment is pain.

Mr. ZERHOUNI. Right.

Mr. ROGERS. And when you look at even our major educational institutions are medical institutions, try to find any physician graduating that has any understanding of pain cure for a patient where it is really chronic pain. You can't find it. And certainly, in my research, we have found that there is very little access for people who have chronic, disabling pain. And I hope—I would be interested in sitting down with Dr. Taybach, but you know, the Dental Institute, in my mind, maybe is not exactly the right place. Maybe that is what we have hoisted on you, but I would like to try to find a way that we can address this from a research position as well.

Mr. ZERHOUNI. And that would be role of the sort of super functional integrating structures like OPACE to sort of scan what is happening across, and then maybe have a response that is not just a tactical response when there is a pressure, but a strategic response when you look at it as a growing problem for the population.

I think we can achieve that with that sort of approach as you mentioned, functionally gluing together the science of pain management.

Mr. ROGERS. I look forward to working with you on that issue.

Mr. ZERHOUNI. Sure.

Mr. ROGERS. It is incredibly important to me and I think millions of Americans.

I have to tell you, when I introduced the bill on chronic pain cure, we got calls from all over the country on support groups who had developed all on their own that we didn't know existed, because they felt that they had no one paying attention to what is a really disabling problem for literally millions of Americans.

Mr. ZERHOUNI. I don't want to steal Dr. Taybach's thunder, but there is a research project that will be announced soon where they found a way to specifically disable pain neurons in patients with chronic intractable pain. And I think that is going to be a revolution, because it is almost like a magic bullet that goes through the neurons that indicate pain, and disables them. And we have had some very, very promising results there. Hopefully it will become confirmed and eventually established.

But I agree, and with that focus, you can make progress.

Mr. ROGERS. Well, I hope that you have the courage to come back and actually present—try to void of the political fallout of each institute. Each institute was created because of a political push somewhere in the system. $1 that we spend on administration at NIH that we don't have to is 1 person that may not get cured or 1 day that we don't get a cure for AIDS or a cure for cancer. And I think you will find that maybe after a little of that dust settles, you will have a lot of support from people that say look, we understand that it is best left to a strong peer review system. It is best left to one person's control of an umbrella to get that money to labs where it is doing the most good. It is a little disheartening to see that flow chart, because you know the duplication is there. It can't not be there. And it is disheartening when there are so many counting on your good work and the scientists' good work as well.

Mr. ZERHOUNI. But there is also—I agree with you. But again, if you look at the record, I think it is the balance that is key, not one or the other. Because my personal experience as the dean for research at Johns Hopkins and before is you do it all top down, you really tend to have a lower set of rich ideas. If you do it all peripheral, then you have disintegration. So we need a balance between the 2.

Mr. ROGERS. I have confidence that you will find it, and I have put in for the committee for a Polaroid to make you feel special.

Mr. ZERHOUNI. All right, sir.

Mr. ROGERS. Thank you, Doctor. I look forward to working with you.

Mr. ZERHOUNI. Thank you.

Mr. ROGERS. I yield back my time, Mr. Chairman.

Mr. DEAL. I thank the gentleman.

Recognize Mr. Rush.

Mr. RUSH. Thank you, Dr. Zerhouni. I am very much impressed with your testimony and with your performance.

One of the ways that I judge about how effective a leader of a department of an agency is that—particularly after they come and testify on our way to vote or on the train, I ask them, what do you think about the guy? And everybody that I have talked to—and it is not—it is just an incomplete unscientific assessment says that he is very good. Okay. So we want to let you know that you have our appreciation for the work that you do.

You indicated earlier, and I was very pleased to hear this, that you consider health care disparities one of the top five issues of NIH. And in light of this, would you—how would you advocate or what kind of position would you take on the elevation of the National Center for Minority Health and Health Disparities to an institute level as opposed to a center level? And what would be the difference in your mind?

Mr. ZERHOUNI. Functionally, there is no difference between an institute and a center, the way the Center for Minority Health works. It has its budget, has its advisory council, and it has authorities to look across the entire portfolio. So you call it a center, an institute, it is, I don't think, functionally there is a difference, to my knowledge. Right now, it is almost at the level where it can do its job as we speak. So calling it an institute or a center will not make a functional difference in my opinion.

Mr. RUSH. In your opinion, is there any room for improvement in terms of the performance of this office and this center and particularly in light of your new—the Office of Portfolio Management and Strategic Initiatives? Is there—do you see areas of where you might improve the effectiveness?

Mr. ZERHOUNI. Again, I think what you are seeing in that institute is exactly what I testified to about the need over the past 10 years to create what I would call "glue mechanisms." And this was created because there was a sense that health disparities did not get the focused attention that it needed to get. So that institute was created to do that. And my view is that we need to really have a sense of the strategic plans across all institutes. There was one strategic plan, the first one that was developed and submitted to Congress. We need to improve on that and continue to improve on it. So I think it is a good start. We need to, you know, continue the effort.

But here is the danger. From my standpoint, and I have said that to the institute directors and to the advisory council of the center, because you are not specifically focused on one disease, what you really need to do, you need to be able to work across diseases because the health disparity populations equally, whether it be diabetes or heart disease or cancer and so on, you need to have that.

So here is the tension. The tension is you create a center, people say well, there is a center now. Now they take care of it. And you say well, that is not the intent here. The intent here is to coordinate better. But then within the institute, you have an advisory council that is here and says you know what? We need to focus on this and focus on that. So the challenge for NCMHD and myself is to balance that crosscutting investment with the specific investment that NCMHD does. And that is work in progress. And I have told the NCMHD advisory board, you really need to have better links to the other advisory councils. And I told the institute directors that you can't not look at the health disparity research just within your own window, but you need to be able to do that across.

Now, is this a good fix? Yes. Is this something that you would want the institution to basically create a new structure every time you have a coordination problem? My answer is no. I think you

need to have one competent structure to do that repeatedly and continuously.

Mr. RUSH. Sure. Let me ask you—I am running out of time, here.

What is the NIH doing to increase the participation of ethic minorities in clinical trials, and not just as patients and subjects, but also as researchers and investigators?

Mr. ZERHOUNI. As you know, this is an issue that we have been working on for the past 20 years. So in terms of participation and trials, the numbers look very good. I think we have more participation from minority populations than we ever did before.

Where I think we need to make progress is to have members of those communities become health researchers and medical researchers themselves. I have a fundamental principle that I will share with you. "The diversity of those who serve has to be a mirror of the diversity of those who are served." That is the philosophy. But it is very had. I don't think it is that easy to identify scientists in the minority populations, and then direct them to a science career. Just like across society, you are seeing a decreased interest in science and technology fields. If you look at the National Science Foundation reports, one of the strategic problems that they are seeing is that our own children grow less and less in science and technology. More so in minority populations where economic opportunities that don't require many, many years of training and Ph.D.'s and so on, are more attractive.

So we have a double problem, if you will. We are working on that. We are committed to making sure that we have better representations. In terms of recruitment of our own leaders, I think we have done pretty well. I think there are many institutions out there that now have a cadre of scientists, but not enough.

Mr. RUSH. Thank you.

Mr. DEAL. The gentleman's time is expired. I would tell you that we are about to come up on a vote on the floor. Hopefully, we can finish this before we have to leave for the next vote.

Mr. Pitts.

Mr. PITTS. Thank you, Mr. Chairman.

Dr. Zerhouni, on the topic of stem cell research, how much is the NIH spending on clinical trials for adult stem cell research?

Mr. ZERHOUNI. In adult stem cell research, I can show you the information that I have here in terms of data. But we spend about 10 times more on adult stem cell than we do on the embryonic stem cell research. I will show the information so you can see. So if you are in the red, this is non-embryonic stem cell human research at the top left, it is $170 million in 2002. And if you looked at 2003, I think it is $190 million, for $20 million in embryonic stem cell—human embryonic stem cell.

Mr. PITTS. Now is that the total number? How much is spent on clinical trials?

Mr. ZERHOUNI. I don't have these exact figures, you sir. I will give you this. But I would say it is about half of it, just guessing.

Mr. PITTS. If you could provide that.

Mr. ZERHOUNI. Or more.

Mr. PITTS. How much would go toward adult stem cell plasticity? You know, turning adult stem cells into other tissue types.

Mr. ZERHOUNI. I am stymied, sir. I do not have the information in front of me, but I would bring it to the record.

Most of the research in adult stem cell has, as you know, has evolved for over 25, 30 years, and much of it is related to cancer treatment, and as you heard, some diseases like leukemia and lymphoma and multiple myeloma. So this is where the bulk of clinical trials are. In terms of plasticity research in adult stem cells, I don't know the number.

Mr. PITTS. If you could provide——

Mr. ZERHOUNI. I will provide that for the record.

Mr. PITTS. Are there still frozen embryo stem cells derivations on the President's approved list that have not yet been cultivated into ongoing cell lines yet, and therefore could be cultured on non-animal feeder cells?

Mr. ZERHOUNI. There are 31 cell derivations that have not been expanded. To our knowledge, to the best of our knowledge, there are 16 which we are told by the investigators at the University of Gutenberg that have not been exposed to animal products, we are told.

Mr. PITTS. Have you had to turn away any researcher requesting embryo stem cell research lines because you did not have any available?

Mr. ZERHOUNI. Not to my knowledge.

Mr. PITTS. Are the now-eligible lines, 22 I understand are getting funding, worthless because of mouse feeder cells?

Mr. ZERHOUNI. All lines—to my knowledge, every line available in the world, whether it be eligible for Federal fund or not, has been exposed to animal cell lines, mouse feeder cell lines. So they are not useless. They are very useful.

Mr. PITTS. For basic research?

Mr. ZERHOUNI. For basic research.

Mr. PITTS. Finally, do new breakthroughs in the bone marrow stem cell or adult stem cell or cord blood cell fields continue? There was an article in the "Washington Post" last month, it says "Researchers in Boston have isolated a kind of cell from human bone marrow that they say has all the medical potential of human embryonic stem cells." And I can submit that article for the record.

But the question, do these breakthroughs continue?

Mr. ZERHOUNI. They continue across the board, and clearly, the fundamental scientific issue, sir, is the issue of programming, deprogramming or reprogramming DNA in cells. When you take an adult stem cell, your problem is to deprogram it and then reprogram it to do something else. When you take an embryonic stem cell, you have a cell that has not been yet programmed, and you try to program it. Both are advancing, in terms of fundamental science, to understand how to do that.

Mr. PITTS. And I think I have time for one more question.

How long has embryo research been going on in animals?

Mr. ZERHOUNI. In animals, mouse embryonic stem cells, probably 20, 25 years. We do a lot of mouse embryonic stem cell research, in terms of creating animal models of disease. We have what we call "mouse knockout" or knock in, gene knock out, gene knock in where you can introduce a gene or remove a gene.

So it has been going on for at least 2 decades, to my knowledge.

Mr. PITTS. Thank you, Mr. Chairman.

Mr. DEAL. I thank the gentleman.

Dr. Burgess.

Mr. BURGESS. Dr. Zerhouni, on the—one of the slides you showed us, you talked about how the science is converging, and yet when we see what is happening with the NIH it still seems to be expanding.

Are there areas where you think you can get early successes in capturing this convergence of the science and perhaps making the flowchart for the NIH look a little less complex?

Mr. ZERHOUNI. Yes, I think we are doing that, quite frankly. I think the scientists themselves are realizing how much opportunity there is between disciplines and at the interface of disciplines. So we haven't really had a lot of opposition to the sense that we need to have a balanced portfolio.

What areas—right now, I think where we need the most progress is two things. One, understand the complexity of the genome and how it is functioning, its regulation. We are doing great progress there. We have now a map of all the variations between humans, and we are going to use this to identify disease genes.

Last year, we identified 12 genes, I believe, in mental health, something that had never happened before. So you are going to see a lot of progress.

The second area is translate that research more effectively, it is called translational research. I think we need to train more physicians who are dedicated to science and to make sure that there is a bench to bedside, bedside to bench relationship to accelerate research.

Mr. BURGESS. Do you feel like you are getting buyoff from your scientists——

Mr. ZERHOUNI. I think——

Mr. BURGESS. [continuing] both intramural and extramural?

Mr. ZERHOUNI. It is, you know, like when you are dealing with a complex situation with a tight budget, people really are worried about taking a chance. But my message is that there is no wrong time to do the right thing.

Mr. BURGESS. Correct.

Mr. ZERHOUNI. And that is what we will try to do. But it is not without tension, sir.

Mr. BURGESS. I understand.

On the slide that you have up there that you put up for Mr. Pitts on the human stem cell research, is that going to include both what you would call bone marrow stem cells as well as umbilical cord derived stem cells?

Mr. ZERHOUNI. Right. I think so. Umbilical cord, we don't have as much funding in umbilical cord as we do in adult stem cells. I don't have the exact number. I can look it up here. But I don't have it separated that way. But umbilical cord investments are in the same range as embryonic stem—human embryonic stem cells, I believe.

Mr. BURGESS. Is that something that we, as a Congress, need to pay attention to, or is that better left in your hands and the——

Mr. ZERHOUNI. You know, frankly, I think at this point I would prefer that we do our job, you know, have the stem cell task force

looking at things and through this process, I think we can see the relative merits. The National Heart and Lung and Blood Institute is charged to look at cord blood stem cell issues, and I am waiting for their advice.

Mr. BURGESS. Okay. When do you expect to receive those reports from the task force of the Heart and Lung Institute?

Mr. ZERHOUNI. They are working on them. They have already looked at the issue of stem cell banking for cord blood, so I am not clear, really. I will get back to you on the record about when that is.

Mr. BURGESS. Okay. Because there is a lot of that that I know as a private practitioner in obstetrics, there is a lot of that that goes on where people bank their own cord blood.

Let me just ask you a question. That was an intriguing figure of $16 per American, per year that is spent in research from the NIH perspective. Do you have any idea what is spent covering all levels, private research, university research, pharmaceutical research? What dollar per year figure?

Mr. ZERHOUNI. NIH for medical research is the main player, so typically if you look at a university, 80 percent of their funding is really NIH funded. Maybe 10, 20 percent is philanthropy and industry. That is research at universities, so if it is $96, you could say you could add $20 to that, and that is what universities will get.

If you look at the chart of investment—I wish I had it here—between industry R&D and industry from biotech versus NIH, for the longest part of history, NIH was the dominant funder. In 1991, pharma R&D went up relative to NIH. So NIH spends about $28 billion, and the pharma spends about $30, $31 billion in R&D, and biotech, $19 billion.

So if you add it up, it is $96 of Federal dollars, and probably $120, $130, $140 of private dollars.

Mr. BURGESS. Are we seeing that same situation occur in the stem cell arena? Are the private dollars really pouring in to stem—embryonic stem cell research?

Mr. ZERHOUNI. Yes, I think there is a much different distribution there. As you know, with the initiatives and the private investments, I think the Federal investments is maybe $25 million right now. And we had some studies that show that in a private sector was about $200, $233 million in the biotech area. You have companies like Geron, for example, that are investing and proposing new therapies with it. And with State initiatives, you have another influx. And as you know, California has a new initiative that counts about $300 million a year in spending.

Mr. BURGESS. What——

Mr. DEAL. The gentleman's time is expired.

Mr. BURGESS. Okay.

Mr. DEAL. We are getting close on vote.

Mr. Bass, do you have one question before we go?

Mr. BASS. Thank you, Mr. Chairman. I appreciate the courtesy. I will be very fast.

Dr. Zerhouni, I would be most grateful if you would be willing, in the interest of time, to answer four questions that I have in writing for the record. I appreciate that. And Mr. Chairman, I

would only say, I wasn't planning on asking questions, but I think that some of the comments made by some of the previous members of the subcommittee need to be addressed. To say that research has not been effective—has been unfunded and ineffective so therefore, it doesn't work, I don't think really is logical. If you don't fund research, you can't say it doesn't work. And the fact that embryonic stem cell research is receiving less than 10 percent of the total NIH funding, when you, yourself, said that NIH is the main player in research of this sort, I think begs the question a little bit. And to say that adult stem cells are more valuable to science than embryonic can't possibly be true, because the scientific community doesn't support that contention.

The fact is that adult stem cells have been studied, as you mentioned, for 35 years with limited success. I am hopeful that we can continue this debate. It is an important debate for the sake of science, for the sake of finding cures for most of America's intractable diseases, and I appreciate your leadership at NIH, and I am glad that the subcommittee is moving forward with reauthorization.

I yield back.

Mr. DEAL. I thank the gentleman.

Dr. Zerhouni, I want to thank you and your colleagues for being here today. A most impressive presentation. We look forward to working with you as we continue forward on an effort to reauthorize, and hopefully incorporate some of the suggestions, at least, that you have presented to us.

Thank you very much.

Mr. ZERHOUNI. Thank you, Mr. Chairman.

Mr. DEAL. This hearing is adjourned.

[Whereupon, at 1:06 p.m., the subcommittee was adjourned.]

[Additional material submitted for the record follows:]

CONGRESSMAN SHERROD BROWN
Question for NIH Director Elias Zerhouni
Subcommittee on Health
March 17, 2005, hearing entitled:
"Setting the Path for Reauthorization: Improving Portfolio Management at the NIH"

QUESTION 1: NIH Spends billions of dollars a year on clinical trials and billions on basic research, all designed to discern the most effective and safest response to a given medical condition.

But we also allow unregulated direct to consumer advertising (DTCA) to skew the marketplace, allowing manufacturers to suggest and imply that their product is the most effective when it may well not be.

Dr. Zerhouni—As the overseer of thousands of clinical trials and the country's flagship medical research laboratories—do you acknowledge that rampant advertising, for instance that in the case of Vioxx, can put the public at risk if disseminated before—or despite—the availability not only of comparative effectiveness data, but of complete or accurate safety data?

Are you of the opinion that DTCA provides consumers an honest or complete picture of the benefits and risks of prescription drugs?

ANSWER 1: The Food and Drug Administration regulates (21 C.F.R. Part 202) the advertising of prescription drug products as mandated by the Federal Food, Drug, and Cosmetic Act. The regulations require that advertisements present accurate information and fairly represent both the benefits and the risks of the advertised drug. Misrepresentation of benefits or risks in advertising certainly can place patients at risk. I am confident that FDA will continue to look closely at the advertising issue to ensure that consumers are not subject to misleading advertising about pharmaceutical products.

QUESTION 2: Dr. Zerhouni, as the result of the recent doubling of NIH by Congress, we've seen a remarkable increase in fundamental knowledge about diseases like Alzheimer's, Parkinson's and diabetes.

But I'm sure you understand that knowledge, in and of itself, is not enough unless it's put to use. Many of us are concerned that the next step in the process—the clinical research that translates into cures and improved treatments—isn't getting enough attention.

Please tell us specifically what's being done to get science from the bench to the bedside, and whether you have enough legislative authority to put more emphasis on that side of the equation?

ANSWER 2: NIH recognizes concerns that have been raised about the current status of clinical research and is accelerating and strengthening the clinical research process through the

Re-engineering the Clinical Research Enterprise" initiative, which is part of the NIH Roadmap. By integrating clinical and translational resources--such as informatics, biostatistics, career development, regulatory support--into a unified program, the NIH will greatly enhance the efficiency and scope of clinical research. This will allow more rapid translation of basic research into studies that can be performed in human subjects and will also provide tools for the rapid and broad dissemination of the results of clinical trials.

NIH is also fostering intergovernmental relationships with the Centers for Medicare and Medicaid Services (CMS), the Agency for Healthcare Research and Quality (AHRQ), and other agencies and health care plans to ensure that clinical research results are used to develop evidence-based, cost-effective healthcare.

NIH has sufficient legislative authority and flexibility to implement plans to invigorate and transform clinical research.

QUESTION 3: Norvir

Last year, the NIH decided not to consider invoking the government's "march-in" rights under the Bayh-Dole Act for an AIDS drug called Norvir. Norvir was developed using inventions produced by the NIH – so the American taxpayer footed the bill for its development. Norvir's manufacturer, Abbott Labs, decided in late 2003 to increase the price of that critical AIDS drug by 400% and to apply that price increase only to U.S. sales.

I thought it was an unreasonable abuse of the American taxpayer's research dollar for Abbott Labs to quadruple the price of the resulting product, especially since that price hike was applied only to those same American taxpayers. But NIH disagreed and chose not to intercede. Do you agree that Abbott Labs' 400% price increase for an essential AIDS drug developed by the American taxpayer was unreasonable?

ANSWER 3: Each year, a wealth of scientific discoveries emanates from the NIH intramural laboratories and from extramural activities under grants and contracts. Bringing these discoveries from **"the bench to the bedside"** requires drug and product development, scale-up, clinical testing, and finally marketing and distribution. Success in accomplishing this colossal task and fulfilling our primary mission of improving public health requires the participation of industry partners.

The NIH supports fundamental research that may lead to the development of pharmaceutical products. Occasionally, the NIH funds a technology that ultimately is incorporated into a commercial product or process for making a commercial product. It is important to the NIH that pharmaceutical companies commercialize new health care products and processes incorporating NIH-funded technology thereby making the technology available to the public. A central purpose of the Bayh-Dole Act involves the development and commercialization of such products out of federally-funded research.

In the case of Norvir, Abbott received $3.47 million in grant funding from NIH beginning in 1988 for early research on protease inhibitors, which was less than one percent of the more than $300 million Abbott stated it spent to develop Norvir.

On May 25, 2004, NIH held a public meeting to determine whether sufficient evidence existed to authorize NIH to initiate "march-in" proceedings in the case of Norvir. The march-in provision of the Bayh-Dole Act, 35 U.S.C. § 203, implemented by 37 C.F.R. § 401.6, authorizes the Government, in certain specified circumstances, to require the funding recipient or its exclusive licensee to license a Federally- funded invention to a responsible applicant or applicants on reasonable terms, or to grant such a license itself. On July 29, 2004, after careful analysis of the Bayh-Dole Act and considering all the facts in this case as well as comments received, the NIH determined that available information and the statutory and regulatory framework did not justify the initiation of a march-in proceeding. NIH's decision in this matter is attached.

I am concerned about the price of prescription drugs. But the issue of the cost or pricing of drugs that include inventive technologies made using Federal funds is one which has attracted the attention of Congress in several contexts that are much broader than the one at hand. In addition, because the market dynamics for all products developed pursuant to licensing rights under the Bayh-Dole Act could be altered if prices on such products were directed in any way by NIH, the NIH agrees with the public testimony during the May 25, 2004, public meeting that the extraordinary remedy of march-in is not an appropriate means of controlling prices. The issue of drug pricing has global implications and, thus, is appropriately left for Congress to address legislatively.

CONGRESSMAN ELIOT ENGEL
Question for NIH Director Elias Zerhouni
Subcommittee on Health
March 17, 2005, hearing entitled:
"Setting the Path for Reauthorization: Improving Portfolio Management at the NIH"

QUESTION 1: Dr. Zerhouni, thank you for your hard work and the important research NIH conducts to better the health of the American people. I would like to ask several questions about research on Charcot Marie Tooth CMT) disorder. As you know, CMT is one of the most common inherited neurological disorders, affecting approximately 1 in 2,500 people in the United States. It is characterized by a slowly progressive degeneration of the muscles in the foot, lower leg, hand, and forearm, weakness in the hands impairing normal daily functions, such as buttoning shirts and turning keys, and some loss of sensation in the limbs, fingers, and toes.

According to information provided by NIH to my office, from FY 2002 and FY 2006 (estimated), NINDS funding for CMT research declined in real terms, even as total NIH dollars and NINDS funding of neuropathy research increased. I have concern about these figures.

The following are NIH-supplied figures on CMT and neuropathy research:
NINDS funding for Charcot-Marie-Tooth Disorder (note that FY 2005 and FY 2006 are estimates only):
Dollars are in 000's FY 2001 $2,953 FY 2002 $4,422 FY 2003 $4,115 FY 2004 $4,171 FY 2005 (estimate) $4,262 FY 2006 (estimate) $4,276 NINDS funding for the broader category of "neuropathy" – which includes the peripheral neuropathies (note that FY 2005 and FY 2006 are estimates only): *Dollars are in 000's* FY 2001 $13,302 FY 2002 $22,676 FY 2003 $28,194 FY 2004 $31,644 FY 2005 (estimate) $32,343 FY 2006 (estimate) $32,449 The following information was provided by NIH to me last year: NINDS funding for Charcot-Marie Tooth Disorder is as follows (note that FY 2004 and FY 2005 are estimates only): *Dollars are in 000's* FY 2001 $2,953 FY 2002 $4,422 FY 2003 $4,115 FY 2004 (estimate) $4,208 FY 2005 (estimate) $4,267 NINDS funding for the broader category of "neuropathy" – which includes the peripheral neuropathies - is as follows (note that FY 2004 and FY 2005 are estimates only): *Dollars are in 000's* FY 2001 $13,302 FY 2002 $22,676 FY 2003 $28,194 FY 2004 (estimate) $28,865 FY 2005 (estimate) $29,247

What is apparent in these numbers is that while funding for neuropathy is increasing substantially, little if any of that money is directed toward CMT research. I welcome NIH's announcement in the recent report to the Appropriations Committee on CMT that it will begin a workshop on peripheral neuropathies. However, in light of the dollar trend, I am concerned that this workshop will not focus on CMT.

First, will the workshop on peripheral neuropathies concentrate substantially on Charcot Marie Tooth disorder?

Second, could you explain why CMT research dollars at NINDS have declined in real terms over a period (FY 02 – FY 06) when NIH and NINDS neuropathy funding increased substantially?

Third, is it possible CMT research opportunities could be woven into the current Blueprint for Neurosciences? If so, how?

ANSWER 1: The National Institute of Neurological Disorders and Stroke (NINDS) supports a wide range of studies on the causes of Charcot Marie Tooth disorder (CMT), including identification of genetic mutations involved, as well as on the basic processes involved in myelination of peripheral nerves. More broadly, the NINDS also funds research on other peripheral neuropathies, including those associated with diabetes and HIV/AIDS.

The NINDS is planning a workshop on the peripheral neuropathies and one focus of this workshop will be CMT. Participants will include NINDS-funded researchers working in this area, as well as those from other Institutes at the NIH with an interest in the peripheral neuropathies. The goals of the workshop will include the identification and discussion of research goals for improving our understanding of the peripheral neuropathies, and the identification of potential therapies for these disorders. We have deliberately planned that this initial workshop would include investigators studying a broad range of peripheral neuropathies since we believe that significant advances for one disease can come from investigators studying others or using novel tools.

For the purposes of reporting funding levels, "neuropathy" is broadly defined and includes a variety of nervous system diseases and abnormalities, such as the peripheral neuropathies, motor and sensory neuropathies, and certain types of nervous system damage due to trauma or injury. The apparent increase in NINDS neuropathy funding over the FY02-FY06 time period is a product of the broad applicability of this funding code. As the NINDS continues to refine and improve its coding system for grants, more consistent figures will be available, making it easier to accurately determine trends in funding from year to year. While it may appear that CMT research dollars have declined in real terms over the FY02-FY06 period, there has in fact been little change in the NINDS CMT research portfolio. Fluctuations in the budgets for individual grants account for the changes in overall dollar amounts from year to year.

The NINDS does not assign target funding levels for any individual disease; rather, the funding level for a particular disease is determined in large part by the number of meritorious investigator-initiated grant proposals received on that topic. For this reason, an effective way to increase funding for CMT is to stimulate interest among the scientific community. The NINDS hopes to increase interest in CMT and the peripheral neuropathies through the workshop mentioned above. The outcome of such a workshop may help to shape a solicitation for specific areas of research, or help the NIH to identify other ways to advance research on all peripheral neuropathies, including CMT. In addition, the recent discovery by NINDS-funded researchers of mutations that lead to a subtype of CMT may serve to stimulate scientific interest in understanding the role of these mutations in the disease process. It is also important to note that

basic science research on peripheral nerves as well as research on the causes, mechanisms, and progression of other peripheral neuropathies may eventually lead to better treatments for CMT.

Like the NIH Roadmap, the NIH Blueprint for Neuroscience Research does not directly address particular diseases, but the Blueprint will provide tools and resources that can be used for research on a broad range of diseases, including CMT. Examples of Blueprint initiatives that could impact CMT include training in neurobiology of disease to encourage graduate students and others to consider disease-focused research, and the development of mutant mouse models to study how mutations, like those causing CMT, can disrupt nervous system function and development.

QUESTION 2: In the fiscal year 2003, 2004, and 2005 appropriations bills, Congress asked the National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK) to develop a strategic plan on IBS. I was pleased to hear that the NIDDK is working to establish a second National Commission on Digestive Diseases. Since the first National Commission on Digestive Diseases did not focus on individual diseases, I want to continue to urge that NIDDK develop and implement an independent IBS strategic plan.

Expanding the IBS research portfolio at NIDDK would serve to advance our understanding of this disease, determine improved treatment options for IBS sufferers, and assist in recruiting new investigators to conduct IBS research.

Can you update this Committee on the timetable for development and implementation of a strategic plan for IBS at NIDDK?

ANSWER 2: The NIH agrees that a strategic plan for IBS will be very valuable. Our intent is to accomplish this through the scientific research plan that will be the charge of a new National Commission on Digestive Diseases. The United States Congress has expressed interest in encouraging digestive diseases research, in part through establishment of a National Commission. The Commission will primarily focus on digestive diseases research consistent with the mission of NIH; will deal with specific diseases, including IBS; and will address the training and education of researchers in digestive diseases research. The Commission will prepare a plan outlining the current status of knowledge and research, the major gap areas and challenges to further advances, compelling scientific opportunities, and specific goals for future research. One of the important advantages of including IBS as a part of a larger strategic planning effort, instead of conducting it as a stand-alone effort, is that there will be a greater opportunity to identify cross-cutting themes common to multiple digestive diseases and common hurdles shared by many.

The NIH currently supports a significant research portfolio in IBS and related motility disorders, including a research center that focuses on the identification of gender-related factors that play a role in the development, clinical manifestation, and treatment response of IBS and interstitial cystitis; and a grant to establish a gastrointestinal biopsychosocial (mind-body) research center. Using our available resources, we are committed to expanding the knowledge base about IBS as a foundation for developing treatment and prevention approaches.

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