S. HRG. 108–710

AVOIDING CONFLICTS OF INTEREST AT THE NATIONAL INSTITUTES OF HEALTH

HEARING

BEFORE A

SUBCOMMITTEE OF THE

COMMITTEE ON APPROPRIATIONS

UNITED STATES SENATE

ONE HUNDRED EIGHTH CONGRESS

SECOND SESSION

SPECIAL HEARING

JANUARY 22, 2004—WASHINGTON, DC

Printed for the use of the Committee on Appropriations

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

U.S. GOVERNMENT PRINTING OFFICE

92–255 PDF WASHINGTON : 2004

For sale by the Superintendent of Documents, U.S. Government Printing Office
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AVOIDING CONFLICTS OF INTEREST AT THE NATIONAL INSTITUTES OF HEALTH

THURSDAY, JANUARY 22, 2004

U.S. SENATE,
SUBCOMMITTEE ON LABOR, HEALTH AND HUMAN SERVICES, AND EDUCATION, AND RELATED AGENCIES,
COMMITTEE ON APPROPRIATIONS,
Washington, DC.

The subcommittee met at 9:33 a.m., in room SD–192, Dirksen Senate Office Building, Hon. Arlen Specter (chairman) presiding.

Present: Senators Specter, Stevens, and Harkin.

OPENING STATEMENT OF SENATOR ARLEN SPECTER

Senator SPECTER. Good morning, ladies and gentlemen. The Appropriations Subcommittee on Labor, Health and Human Services, and Education will now proceed with this hearing on the issue of potential conflict of interest in the National Institutes of Health with the consulting arrangements for the private pharmaceutical companies.

The issue has been raised about whether there is a conflict where employees of the National Institutes of Health consult with private pharmaceutical companies. The employees of NIH, like all Federal employees, have a fiduciary obligation to the Federal Government and may not use their positions for collateral financial gain.

There is a public policy interest in having an exchange of ideas with the pharmaceutical companies, but that has to be conducted in an organized, systematic way with transparency and integrity, and the employees of the NIH are compensated on a very modest basis, so there is some public policy interest in having those incomes supplemented. But in reviewing the compensation level, I find that they are higher than the compensation of my distinguished colleague, Senator Harkin, and other Members of Congress.

The issue of integrity is one of utmost importance. I am pleased to report that Dr. Zerhouni has taken an active role in moving forward to try to deal with this issue. Our staffs have conferred. He and I have met and discussed the matter, but there has to be a thorough public airing, and I believe there will have to be some very substantial remedial steps taken to make sure that the wall of separation between public duties and private gain is maintained.

There had been in the past highly notarized situations where researchers at a prominent university were disclosed to have a finan-

cial interest in the company which was involved with a medicine, and that has to be prevented.

There had been some question as to whether this hearing would go beyond the conflict of interest issue and take up some of the studies that the National Institutes of Health has conducted on truck stops and sexual habits of older men and the two spirited Indians and the arousal issues, but this hearing is going to be very, very involved with a very large number of witnesses and we'll be fully occupied with this subject.

The other issues have already been the subject of oversight by this subcommittee. Staffs have already been working. Dr. Zerhouni and I have discussed it and we are now making inquiries as to whether there ought to be a separate oversight hearing on that subject, and we will make that determination after we complete the preliminary inquiry which has already been underway.

Now, fresh back from Iowa, I am delighted to welcome my distinguished colleague, Senator Harkin, who is the author of the famous Harkin amendment on overtime pay—which is holding up a $373 billion appropriations bill. When Senator Harkin offers an amendment, he does not have an instinct for the capillaries. He has an instinct for the jugular.

I think that he was right on his amendment. And we had a very detailed hearing day before yesterday when we understood Senator Harkin could not be with us because he was heavily engaged to very late the night before in the Iowa caucuses.

I am sorry to see the provision in the bill. It is worth just a minute. The grave difficulty is that the regulation on overtime pay will cut back on compensation to many workers in America, men and women, at a time when they need every dollar they can get with a fragile economy, I think recovering but still not fully recovered. And the new regulation which we have analyzed is no improvement over the old regulation. There is general agreement that we ought to make the regulation specific to avoid litigation, but the new regulation does not do that.

In the interest of reciprocity, we had hoped that the Secretary of Labor would accommodate a brief delay. We are not talking about very much, just a few weeks, perhaps a few months, less than 6 months, in the interest of reciprocity where we try very hard to accommodate the Department of Labor's interests.

But we are not between a rock and a hard place on this issue. It is just a total loser. If we hold up the omnibus appropriations bill, we have a continuing resolution, and the overtime regulation goes into effect because there is nothing in the continuing resolution to stop it. And if we take the omnibus appropriations bill, the regulation goes into effect because there is nothing in the bill to stop it. So either way we go, we lose the issue on the regulation, and in our subcommittee alone, we lose $3,700,000,000, a large chunk of which would go to NIH and others, to Head Start and education.

So it is my hope that we will be able to pass the bill today, but that remains to be seen as the political process works out. And as Winston Churchill said, a democracy is a very terrible system except when compared to every other system.

Senator Harkin.

OPENING STATEMENT OF SENATOR TOM HARKIN

Senator HARKIN. Mr. Chairman, thank you very much for a number of things, first, for being a really great chairman of this very vital and important subcommittee. I can say without any hesitation that our relationship has been one of working together mutually for the benefit of the public policy that we cover in this subcommittee, which covers a wide range of different things, from health to education and labor. Someone once described this subcommittee as the subcommittee that defines America and what we stand for. And so I have been proud to work alongside you now for, I guess, 15 years now I think it has been, either as chairman or ranking member, which bounces back and forth periodically. Of course, I always hope it bounces my way, but that is another thing. But we have had a great collaboration and working relationship. I thank you for that.

I thank you for your comments regarding the overtime. We have worked closely on that, and I know of your strong support for ensuring that people in this country do not lose their overtime pay protections.

I also want to thank you for calling this hearing today and thank all the witnesses for being here.

Everyone knows how strongly we support the National Institutes of Health. It is Senator Specter who has said many times that it is the crown jewel of our Federal Government. I think that is your phrase. Thanks to NIH, countless lives have been saved and new cures and treatments developed. A thriving biomedical research industry has been created in this country.

That is why we worked so hard to double the funding for NIH between 1998 and 2003. We take pride in the fact that this was a truly bipartisan effort, spanning two presidential administrations. And when we reached the goal last year, I think for both Senator Specter and I, it was one of our proudest moments in the Senate.

So when I read in the press about concerns that some NIH scientists are receiving consulting fees that may pose a conflict of interest with their duties at NIH, I became very concerned. I became concerned not only because of my personal passion for NIH, but also on behalf of the taxpayers, the advocacy groups, and researchers who lobbied so diligently to increase funding for this agency.

As appropriators, we have a responsibility to exercise oversight of NIH. So this hearing is not only appropriate, it is required. We come here with open minds. We have made no pre-judgments. I appreciate this opportunity for us to ask questions and find out for ourselves whether there is a problem at NIH. If so, how do we address it?

NIH is the premier biomedical research agency in the world. It has an unparalleled reputation for honesty and integrity and I want to make sure it stays that way.

Thank you very much, Mr. Chairman.

Senator SPECTER. Thank you, Senator Harkin. Thank you for your outstanding service to the country and the Senate and this subcommittee.

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

Senator SPECTER. We turn now to Dr. Elias Zerhouni, the Director of the National Institutes of Health. Prior to becoming Director, Dr. Zerhouni was executive vice dean of John Hopkins University School of Medicine, had the Chair of the Russell Morgan Department of Radiology, and Martin Donner Professor of Biomedical Engineering. He received his medical degree from the University of Algiers School of Medicine and completed his residency in diagnostic radiology at Johns Hopkins. Dr. Zerhouni brings an extraordinary record to this very, very important position.

I have had the privilege of working with him in some detail and I find him to be very, very thoughtful, very, very responsive, and very, very dedicated to the duties of the very important position which he holds. And when this issue arose, which has some potential for embarrassment, he and I agreed immediately that we would work it through, we would let the chips fall where they may, and we would see to it that whatever problems existed would be corrected and corrected promptly.

Dr. Zerhouni, we again welcome you here and look forward to your testimony.

Dr. ZERHOUNI. Thank you, Mr. Chairman, Senator Harkin, and other members of the subcommittee. Thank you for the opportunity to testify today about the implementation of ethics rules at the National Institutes of Health.

Clearly, as Senator Harkin mentioned, NIH has historically been successful because of its outstanding record of excellence in independent scientific inquiry and its reputation for high integrity. Our mission is too important to the health of this Nation to have it undermined in any way by any real or perceived conflict of interest. And I personally want to do everything possible to make sure that that perception does not persist.

I personally began reviewing ethics rules policies and practices last July when the House Energy and Commerce Committee raised questions about NIH employees receiving monetary lecture awards, and based on my initial review of policies and procedures, I announced on November 20, 2003 the formation of a new trans-NIH ethics advisory committee in the Office of the Director to provide independent peer review of outside activity. I asked all senior managers to exercise great prudence in entering into any arrangement that reflects poorly on NIH or creates the appearance of conflict, even in cases where the arrangements are allowed.

In addition to the questions from the House committee, a recent press report has suggested that arrangements between our scientists and outside organizations have potentially harmed individual patients and tainted the integrity of administrative decisions at NIH. There cannot be more serious allegations against an institution, and I felt that it was imperative that NIH tackle this issue as quickly, transparently, and aggressively as possible.

From my experience as a an administrator at a major institution prior to this job and my experience at NIH, there are four fundamental tenets that we absolutely need to honor. One is full transparency. The second is full disclosure of these relationships, inde-

pendent peer review, and active management and monitoring of any and all relationships.

So that is why I ordered an immediate review not only of the allegations in the press but of all existing outside activities to ensure that there have been no breaches of current rules and to determine the entire scope of these activities. Pending this review, applications to receive compensation from pharmaceutical or biotechnology companies and payments that exceed certain thresholds will be examined directly in the director's office by the new ethics advisory committee. As of this date, we have not approved any agreement, and the new committee has been formed, has met, and all of those will be reviewed personally in my office to make sure that indeed rules have been followed and no rules have been broken.

Further, I have ordered that the NIH ethics system be restructured to ensure consistency and rigorous oversight.

But my first and foremost concern as a physician was to ascertain whether or not any patient had been harmed as alleged or if decisions had been unduly influenced as a result of such outside relationships. Was there a reality of conflict here that harmed individuals or harmed our decisional processes?

I want to inform you that thus far we have not identified any situations where patients were harmed as a result of financial arrangements NIH employees had with outside parties. We have not identified any situations where outside activities resulted in undue influence on grant approvals or other decisions. I will, however, reserve final judgment until all internal and external reviews are completed.

Ethics standards are set by the Office of Government Ethics which promulgates rules for the entire Federal Government. Pursuant to new government-wide ethics regulations, NIH revised its policies in 1995. The Acting Director of the Office of Government Ethics is here today to testify about its role regarding NIH.

But in regard to supplemental compensation for NIH employees, I echo what Senator Specter said. We need to find the balance between the public interest at large of making sure that our knowledge gets translated into real applications and we have the question of figuring out what should be allowed and not allowed.

On one hand, I believe it's essential that NIH retain the ability to recruit and retain the best scientific researchers in the world. In order to do this, one must be able to compete for their services. So I think it is important that our scientists be allowed to be involved in the process of translation.

On the other hand, the research landscape has changed since 1995. Investments in research by pharmaceutical companies have surpassed the current budget of NIH. We have a new industry, the biotechnology industry, that has exploded with new companies and resources as well. There are now many more opportunities for NIH scientists to be asked to collaborate with the private sector to share their knowledge and help apply it for tangible treatments.

Given these events, I have reached the conclusion that it is appropriate for NIH and the Congress to completely review the 1995 policy and its implementation at NIH. This is why I have asked that a blue ribbon task force, as an adjunct to the existing advisory committee to the Director, be formed and review all of our ethics

policies and evaluate the policy issue of what types of collaborations are in the public interest and which ones are not, and how do we reform our policies to make sure that we achieve the goal of the highest integrity and transparency possible.

I am announcing today that the panel will be co-chaired by two distinguished individuals: Dr. Bruce Alberts, the president of the National Academy of Sciences, and Norman Augustine, former Chairman of Lockheed Martin and a noted government, industry, and academic expert. They will be joined by committee members of the highest reputation for independence and competence.

PREPARED STATEMENT

Finally and most importantly, I have reached the conclusion that NIH must make changes that will appropriately restrict current practices and manage current practices to the point where no questions will remain in anybody's mind that NIH is deserving of the trust of the Congress and has continuously made every attempt to make sure that the rules, first and foremost, serve the American people and no other interests.

Thank you very much.

[The statement follows:]

PREPARED STATEMENT OF DR. ELIAS A. ZERHOUNI

Mr. Chairman, Senator Harkin, Members of the Subcommittee, thank you for the opportunity to testify today about the implementation of ethics rules at the National Institutes of Health.

The NIH budget doubled over a recent five-year period. This milestone is a reflection of the trust that the American people have in our ability to advance scientific knowledge for their benefit.

NIH has historically been successful because of its outstanding record of excellence through independent scientific inquiry and its reputation for high integrity. But recently, the relationships of NIH employees with outside entities have raised the concerns of Congress and the media about conflicts of interest. Our public health mission—written in law—is too important to have it undermined by any real or perceived conflicts of interest.

So I am responding to these concerns. I am applying the principles I have learned from previous experience, that managing conflicts of interest in science is a continuous process best served by: transparency, full disclosure, independent review and continuous monitoring.

I personally began reviewing ethics rules, policies and practices last July, when the House Energy and Commerce Committee raised questions about NIH employees receiving monetary lecture awards. I was advised by NIH ethics officials that the receipt of lecture awards is proper under Federal ethics regulations in specific circumstances. Nonetheless, based on an initial review of policies and procedures, I announced on November 20, 2003 the formation of a new trans-NIH ethics advisory committee in the office of the director to provide independent peer review of outside relationships and advice for improvements in our policies and procedures. I advised all senior managers to exercise great prudence in entering into any arrangement that could reflect poorly on NIH or could create the appearance of conflict, even in cases where the arrangements are permitted by law. I ask that my memorandum be included in the hearing record.

In addition to the questions from the House Committee, recent press reports have suggested that arrangements between our scientists and outside organizations have potentially harmed individual patients and corrupted the integrity of administrative decisions at NIH. There cannot be more serious allegations against an institution. I felt that it was imperative that NIH tackle this issue as quickly, transparently and aggressively as possible.

I ordered an immediate review, not only of the allegations in the press, but of all existing outside activities, to ensure that there have not been breaches of current rules, and to determine the entire scope of these activities.

My first and foremost concern was to ascertain whether any patient had been harmed or if decisions had been unduly influenced as a result of such outside relationships. I want to inform you that, thus far, we have not identified any situations where patients were harmed as the result of financial arrangements NIH employees had with outside parties. Nor have we identified any situations where outside activities resulted in undue influence on grant approvals or other decisions. I will, however, reserve final judgment until all internal and external reviews are completed.

Furthermore, press reports have implied that NIH and its employees willfully used alternative federal pay systems to avoid disclosing their outside activities. This is simply not true. Outside activities are internally disclosed to Ethics officers and supervisors. But it is true that federal rules sometimes do not allow public disclosure of that information. I believe that this needs to be revisited as transparency and full disclosure are core requirements of any viable process of oversight of these relationships.

Clearly, even though real conflict may not have occurred, it is obvious that our practices lead to a perception of widespread conflicts that needs to be corrected as soon as possible.

The governing regulations are set by the Office of Government Ethics (OGE), which promulgates rules for the entire executive branch of the Federal Government. In 1993, the OGE promulgated executive branch-wide Standards of Conduct regulations. Agencies were then required to repeal their ethics regulations and follow the new OGE regulation or propose supplemental regulations, jointly promulgated by the agency and OGE.

Until 1995, NIH policies on outside activities were more restrictive than they are today. Employees could earn no more than $25,000 per year from any single outside source, and no more than $50,000 in total annually. Payments from outside sources in the form of stocks or stock options were prohibited. High-level NIH officials were not allowed to accept payments from outside sources.

I was advised that NIH revised its ethics policies in 1995, after the OGE audited NIH's implementation of federal ethics regulations and determined that the Agency's policies were more stringent than the existing executive branch-wide regulations. OGE offered NIH two options at that time: either change the policies to conform to the regulations or seek supplemental regulations from OGE.

Although I was not at NIH at that time, my understanding is that Agency management was concerned that NIH was at a disadvantage in competing with the private sector for the best scientists due to lower salaries, benefits and the reduced ability to supplement incomes with outside activities as compared to scientists in the private sector. In light of these concerns, NIH management elected to change its ethics policies to conform to the OGE regulations and not pursue supplemental rules, thus easing restrictions on many outside activities. Since then, outside activities have been approved by NIH or Department ethics counselors in accordance with federal regulations.

What should be allowed and what should not be allowed?

On one hand, I believe it is essential that NIH retain the ability to recruit and retain the best scientific researchers in the world. In order to do this, we must be able to compete for their services. So, I think it is important that our scientists be allowed to receive bona fide awards for scientific accomplishments. NIH researchers should be allowed to teach, write textbooks, be inventors on NIH-held patents, and collaborate with for-profit and non-profit companies and institutions, but with appropriate limitations. As the German philosopher Goethe said, "knowing is not enough, you must apply what you know."

On the other hand, the research landscape has changed since 1995. Investments in research by pharmaceutical companies have surpassed the current budget of NIH. The biotechnology industry exploded with new companies and resources, as well. There are now many more opportunities for NIH scientists to be asked to collaborate with the private sector to share their knowledge and help apply it for tangible treatments.

Given these events and the passage of time, I have reached the conclusion that it is appropriate for NIH to completely review the 1995 decision and its implementation by NIH.

This is why I have asked that a Blue Ribbon Task Force, as an adjunct to the existing independent Advisory Committee to the Director of NIH, review all NIH ethics practices, ponder what types of collaborations with non-government organizations are necessary and appropriate, and make recommendations to me on reforms of our policies and procedures within 90 days of its formation. This panel will be co-chaired by two prominent individuals and will be composed of members of the highest reputation for independence and competence.

In the meantime, I have ordered that the NIH system for implementing ethics regulations be restructured to ensure consistency and a strict level of review. A new NIH Ethics Advisory Committee will review applications to receive compensation for certain outside activities, including payments from pharmaceutical or biotechnology companies and payments that exceed certain dollar thresholds.

Finally, and most importantly, I have reached the conclusion that NIH must make changes that will appropriately restrict current practices. I will reserve judgment on specific changes until our internal review and the work of the Blue Ribbon Task Force is completed.

I have discussed these steps with all of the NIH Institute and Center directors, who reaffirm that NIH's first and foremost duty is to serve the American people. They are committed to helping me implement all necessary measures to insure that we eliminate real and apparent conflicts of interest. My goal is to erase any doubts that we remain worthy of the trust and confidence you have placed in us.

Thank you for the opportunity to testify. I look forward to working with the Congress as we move forward. I will be pleased to answer any questions you may have.

Senator SPECTER. Thank you, Dr. Zerhouni.

We have a very large attendance here today. We have quite a few chairs on the dais. Those of you who are standing in the rear are welcome to come up and sit on the staff chairs. You may do so without any obligations to do staff work.

After all the staff chairs are filled, you may sit where the Senators sit and you will be subject to all the disadvantages of being a Member of the Senate if you sit in the Senator's chair. But you are all welcome to come up, and I would urge you to do so so that people who are in the hall can gain access and as many people as possible will be able to hear what we are doing in the room.

Dr. Zerhouni, thank you for your testimony.

The funding of NIH has always been difficult. As Senator Harkin has noted, we have more than doubled NIH funding. Since he and I took over the joint operation of this subcommittee, it moved from $12 billion to $28 billion. Last year we did not get as much as we wanted, and when the opponents of additional funding have something to look to or to pick at, it is going to make it very difficult or perhaps impossible, so that we have to answer these questions.

Let me take up with you, without identifying the individuals involved or the companies, some specific cases.

One pharmaceutical company paid an NIH employee in excess of $100,000 when the company was working on a way to produce a cancer drug, and the individual who received the fee in excess of $100,000 helped lead two NIH-funded studies in which the pharmaceutical company played a crucial role.

Now, first of all, under your procedures, how does a pharmaceutical company play a crucial role in an NIH-funded study?

Dr. ZERHOUNI. There are many ways this can happen. In some instances, the pharmaceutical company may have a reagent or compound or drug that needs to be tested. In other cases the disease that is under consideration is a rare disease, a disease that needs to have trials made, and so——

Senator SPECTER. Let me move on to the second part. We have a very limited amount of time and many witnesses.

In that context, is there not an inherent conflict in having the NIH employee paid very substantially by the pharmaceutical company and collaborate with the pharmaceutical company in NIH-funded studies?

Dr. ZERHOUNI. It will be a conflict if anything that the scientist does is related to his or her Government work or any activities

within the NIH. Those activities are forbidden. The only activities that are allowed is when the scientist is giving advice in an area of knowledge that is not part of his official duties.

Senator SPECTER. Well, it would require a very intensive investigation to make a determination as to whether that line was crossed.

Dr. ZERHOUNI. I totally agree.

Senator SPECTER. Your Department nor this oversight committee is in a position to make that kind of an intensive investigation. So what I want you to do is to make a determination as to whether it is realistic to have that kind of activity undertaken.

Let me move to a second example. A certain biotech company was engaged in gene therapy research, and an NIH investigator became a paid consultant receiving in excess of $300,000 in consulting fees and stock options. Now, the individual became a shareholder in the company and for 2 years did not disclose the holding on his annual financial report. There is no question about that being a violation, and it was explained by the individual saying that it was an error.

What is the consequence to an NIH employee who has this kind of a relationship and does not make the required financial disclosure?

Dr. ZERHOUNI. Senator, I am in total agreement with you. I think you are identifying what I personally believe——

Senator SPECTER. No, do not be in full agreement with me. Answer the question.

Dr. ZERHOUNI. No, but I agree.

Senator SPECTER. Answer the question. What is the consequence of not making a financial disclosure?

Dr. ZERHOUNI. The consequence of not making a financial disclosure is a violation of the rules. There is no doubt that we need full transparency and that is why I am going forward——

Senator SPECTER. Do you know the matter that I am referring to?

Dr. ZERHOUNI. I think I do.

Senator SPECTER. What happened to this individual who did not make the appropriate disclosure?

Dr. ZERHOUNI. This is the matter that is being reviewed fully at this time, Senator.

Senator SPECTER. Well, what needs to be reviewed if you have an open and shut case that there was not a disclosure made as required by law? Are you not in a position, knowing that, to impose a sanction if one is appropriate?

Dr. ZERHOUNI. The matter is under review.

Senator SPECTER. My time is up, but yours is not, Dr. Zerhouni.

Dr. ZERHOUNI. This matter is under review and if there is action to be taken, I will. I think we need to have appropriate due diligence and appropriate steps to be taken. They are being taken.

But again, I agree with the statement that you made that we need full transparency in these relationships and full review. It is complex in many cases, and this is why I have empaneled this panel to help us find out what is exactly the procedure that we need to follow that would serve us best.

Senator SPECTER. My time has expired, so I am not going to ask you why there needs to be full review on a matter so conclusive. But I would ask you to submit promptly a written answer to the subcommittee.

Dr. ZERHOUNI. I will, sir.

Senator SPECTER. Senator Harkin.

Senator HARKIN. Thank you very much, Mr. Chairman.

I will not get into specifics of the case that Senator Specter brought up. I think he has made it quite clear.

I am more concerned again about this idea of transparency. I guess for some reason, I think it has come as somewhat a surprise to a lot of people—and correct me if I am wrong on this—that the kinds of financial arrangements that some scientists at NIH have with outside private entities are included in a report that goes to you or included in a filing that they make at NIH, but that is not subject to the Freedom of Information Act. Is that correct?

Dr. ZERHOUNI. That is correct for a certain category of employee. According to our Office of Government Ethics rules, those within certain pay bands file differently and those are disclosed internally and to the supervisors. They are not made publicly available. And the Office of Government Ethics representative is here to answer those questions.

Senator HARKIN. Were those made publicly available prior to 1995?

Dr. ZERHOUNI. No. Prior to 1995, this pay system was not used. So prior to 1995, we had a different set of rules. The rules changed in 1995.

Senator HARKIN. I guess I am asking was there transparency prior to 1995 on what financial arrangements scientists at NIH might have had with outside entities?

Dr. ZERHOUNI. Prior to 1995, the rules limited greatly the ability to interact.

Senator SPECTER. Excuse me for one moment on an interruption.

Senator HARKIN. Yes.

Senator SPECTER. I have to go to the Judiciary Committee for a few moments. So would you continue with Dr. Zerhouni and I will return as soon as I can.

Senator HARKIN. Do you want me to call the next panel up?

Senator SPECTER. I would like you to talk to him, if you can, if you have sufficient questions for Dr. Zerhouni. I should be back in just a few minutes.

Senator HARKIN. Okay, fine. All right. Thanks.

I was trying to figure out prior to 1995 a scientist who had an arrangement with an outside private entity, was that subject to transparency? When I say transparent, like Freedom of Information. Was that changed in 1995? If so, how was that changed?

Dr. ZERHOUNI. What was changed in 1995 was the ability to have interactions with the private sector. The pay system was changed later. There is no connection between the change in the pay system. The pay system was changed to be able to recruit and retain scientists.

Senator HARKIN. I remember it well. Dr. Varmus was here at the time.

Dr. ZERHOUNI. Right. It was independent. There is no connection between the two.

Senator HARKIN. I understand that. Ellen just told me. Okay. Prior to 1995, the change in the pay system. I am under the understanding that NIH scientists had to make public disclosure of all of their financial arrangements with outside entities.

Dr. ZERHOUNI. That is correct.

Senator HARKIN. After 1995, now I understand it is like 94 or 95 percent of them do not have to do that.

Dr. ZERHOUNI. That is correct. With the change in the pay system, unrelated to the conflict of interest issue, the rules obligate disclosure internally of all relationships, but not because of the type of Federal documents they are filing. Those are not available through the FOIA.

Senator SPECTER. Well, how do you feel, Dr. Zerhouni? I thought I heard your testimony and you talked about transparency. I wrote it down here. How do you feel about that?

Dr. ZERHOUNI. I feel that transparency is absolutely critical. It is needed, necessary. I think it needs to be done appropriately. Remember, 94 percent do not file. Only less than 3 percent of our scientists are involved in any one of these relationships. So we need to make sure that we establish rules that are specific to NIH and human subject research. The Federal Government rules at large, which are the ones that we have to follow, in my opinion are not sufficient and they need to be reviewed and improved.

Senator HARKIN. Well, I commend you for appointing this blue ribbon commission. I do not know who all the members are going to be, but you have got the commission. What time frame do they have? What time frame are you trying to give them?

Dr. ZERHOUNI. I have asked them to do this in 90 days, sir.

Senator HARKIN. Are there any other steps being taken?

Dr. ZERHOUNI. Yes. I have established an NIH advisory ethics committee. I have asked the Office of Government Ethics to give us a temporary waiver so that disclosures of all relationships for individuals at NIH with fiduciary responsibilities like directors, deputy directors, so that that can be disclosed.

I would like to also remind everyone that directors, no matter of their pay system, have always publicly disclosed their relationships. There were three institute directors that were involved in any of those. As of this moment, no director at NIH has any outside biotech or PhRMA relationship. Those have been stopped.

Senator HARKIN. Is it possible that private companies benefit simply from being able to tell shareholders and board members that they have got an NIH director or scientist as a consultant? In other words, could NIH scientists be hired or compensated by a private company just to give sort of a sense that the company has the approval of NIH type of thing? I mean, this is a big stamp of approval when you have a director or a assistant director of one of the NIH institutes consulting with a company.

Dr. ZERHOUNI. As I alluded to in my testimony, I think the industry landscape has changed and biotechnology companies are involved in raising investment funds. And that issue is going to be a core issue that I am asking the panel to review because I do be-

lieve that there may be that perception, and that is something we need to tackle.

Senator HARKIN. Do you have any idea how many NIH scientists have received stock as compensation for consulting work?

Dr. ZERHOUNI. Not the exact number, but I can tell you the total number of current NIH scientists is about 200 scientists who are consulting in one way or another.

Senator HARKIN. But we have no idea how many are compensated just monetarily or how many are compensated with stock or stock options.

Dr. ZERHOUNI. We have that information. I do not have it offhand, but I certainly will provide it to you. But it is around 200 scientists, 300 agreements. A very small number of them—I cannot tell. Maybe my staff will bring me the answer before the end of the hearing. But the stock option or stock ownership is limited to maybe 10 or 20. I do not know the number, but it is a small number.

Senator HARKIN. Do you believe that stock ownership in companies with NIH-funded research presents an ongoing conflict of interest that should be looked at differently in a code of ethics, differently from direct compensation?

Dr. ZERHOUNI. Again, I do not want to prejudge what the panel will say, but in my own experience as a dean at a medical school, we believed very strongly that stock ownership should be treated very differently and does present problems different than simple compensation.

Senator HARKIN. Yes. I think that also is a problem because compensation is one thing, but having stock in a company and you are hoping that stock goes up, in other words, goes through the roof, that is quite another thing. And I think that raises some real serious questions.

I have just one other question about the practice of recusals in which scientists recuse themselves from making decisions that involve companies that they have private dealings with. Again, certainly we do not want them making decisions that would cause a conflict of interest, but when they recuse themselves too often from decisions that they ought to be making internally at NIH, if they were not involved with these companies, then I am concerned that they might not be doing their main job, their NIH job. So again, if they are working for a company and they adhere to ethics and say, okay, I am going to recuse myself from this decision making process, are we, the public, not being a little short-changed from having their expertise applied at the institutes?

Dr. ZERHOUNI. I see your point and I agree that this is a point that needs to be looked into. However, as I looked into it, there are details here that we need to make sure we understand. If it is a scientist that has authority, a director, a deputy director, a scientific director, it is one issue. If it is a scientist who has no authority—and remember, scientists at NIH do not have authority over granting decisions—then it is a different matter. So I believe that there should be a differentiation between those who have authority and those who do not.

For example, if you have a scientist who is asked to—he is, let us say, a human genome expert, knows about genomics and genet-

ics—consult with a company that is trying to develop a vaccine against mad cow disease, completely unrelated, would that be allowed or not allowed? Is there any decision that that scientist would make? If the answer is yes, there are decisions that scientists could make that will affect that relationship, that should not be allowed. But if the scientist is in no position to make that decision, we do want to translate that knowledge to fields other than the direct research of the scientist. It is our job. I think Congress wants us to do that.

That is where the tension is. What is the balance between what we need to do in the public's interest to give our information, to get the best scientists to do that, while not tainting the decisional process?

So again, it is an issue that I think needs to be resolved, but I believe that perhaps instead of having a complete one-size-fits-all rule, I think the rules should be different for those who have authority from those who do not.

Senator HARKIN. Well, as I look more into this and having been on this committee now for 18 years I guess, it is a tough problem because you cannot just say here is NIH and then here is the private sector and all the other companies that are translating basic research into lifesaving drugs and therapies and interventions. There is kind of—I do not want to use the word—a gray area sort of in there where what NIH is doing has to be translated in the private sector.

I have said before there is a reason why NIH is called the National Institutes of Health. It is not the National Institute of Basic Research. It is the National Institutes of Health. It is the make people healthier. It is to find interventions. It is for applying, making sure that whatever basic research is done is applied in the field. So there is not this strict wall that you do basic research and then that is the end of it. I think we expect more of NIH than that. We expect NIH to be actively involved in translational research and getting the basic research done, but also how does this apply itself to the public in terms of healthier lives. That has always kind of been the genius of our system. You have the NIH. You do the basic research that the private sector really cannot afford to do because this is basic research. It is asking fundamental basic questions. But built upon that, the findings of that then are translated into further applied research.

Now, where that ends and where the private sector takes up is kind of a funny area there. You cannot just draw a hard and fast line. I say that publicly. You cannot draw a hard and fast line.

So I have long felt that NIH scientists and researchers need to have some sort of crossover, cross-fertilization with that private sector. They need to know what is happening out there and the private sector needs to know what is happening there. There needs to be that kind of a consultative process, for example. But in that consultative process, the people at NIH really need to have absolutely clean hands.

I would not mind at all—I am just speaking personally and having viewed this for 18 years now—NIH researchers going to whatever XYZ corporation or company talking about what is being done at NIH, some of the new research, some of the new findings, hav-

ing them ask questions about where we are headed in this area. I think that is all perfectly fine. But what I get concerned about is when that same NIH scientist then is compensated by a company, by one company to the exclusion of other companies and other entities out there. Then that skews the research towards one entity, not to a number of them. Perhaps maybe that one entity that is getting that benefit of that scientist's knowledge in that consultative process, maybe that is not the best way for that research to be translated. Maybe another company has a better way but they are not getting the benefit of that.

So I guess I am approaching this and saying, well, I want to have scientists be involved in that, but they cannot be compensated by a company. They just cannot be because it skews it.

Now, if a scientist at NIH at some point in his or her life wants to leave NIH and go to the private sector, that happens all the time. That happens with Members of the Senate and staff. So I understand that. While they are in Government service, whether they are here in the legislative end or the administrative end, they just should not be getting compensated from other companies like that. Like I said, if they want to leave NIH and go to a private company and take their expertise, that is life but not while they are working at NIH. So that is just my thoughts on that, and I just wonder if you have any response.

Dr. ZERHOUNI. I think you are addressing the core issue, and NIH has thought about this for years. We should remember we have very, very elaborate systems to prevent one company from benefitting from another when there is a collaboration. We have a process called CRADA, collaborative research and development agreement. This is an open process. It is independent of the scientist who is collaborating actually. Scientists cannot receive compensation when they are collaborating with a research entity or a company outside. The CRADA is competitive. It is a bid process so that we, in fact, select what is the better company to develop, let's say, a vaccine or any other measures. Those have no compensation attached to them. A collaboration between the scientist and his or her work with any outside entity, a private company or a university, that is not allowed.

The only things that are at issue—NIH does not allow compensation for scientific collaborations or cooperative research and development agreements to the scientist involved. Those are the rules as they exist today.

However, consulting that is considered an outside activity unrelated to the scientist's activity at NIH as reviewed by our current system could be allowed, as in the case of someone giving genomic information to an unrelated field of science that is unrelated to what they do.

So in addressing the point you are making, I think we need to make sure that those rules are well understood, that they accomplish the goal you are seeking, which I think is the same goal. We want to make sure that there is no such gray zone.

So any collaboration, any cooperative research and development agreement, no scientist gets any compensation for that. That is illegal at NIH today. However, a consultation that is unrelated to their research which is qualified as an outside activity, not on Gov-

ernment time, and not using any Government resource or information, that is the point at issue here.

Senator HARKIN. But, Dr. Zerhouni, I understand about the cooperative research agreements that are made. I am getting to the point of a highly placed scientist at NIH intimately involved with the development of a certain therapy or drug or whatever that then consults with a company. Even though there may be a cooperative agreement somewhere else, on the side they are going out on their own time, I am told, and consulting with a company on that very issue. On that very issue. So there is a financial arrangement that could be circuitous, you know, background.

I see Ruth shaking her head no, but I will ask you later about that. But I am concerned about that because of a couple of cases that have come up.

Now, it is not where a scientist at, let's say, Infectious Diseases is consulting on heart, lung, and blood or on something else. They are consulting on what their area of expertise is. Is that not so?

Dr. ZERHOUNI. The situation you describe about a collaborative research agreement and then the scientist taking a consulting relationship, that is not allowed. That is illegal. If that happens, that would be addressed.

Senator HARKIN. Let me figure this one out.

Dr. ZERHOUNI. All right.

Senator SPECTER. Dr. Zerhouni, there is one other specific case which I would like to get your view on, and that is the situation where an individual at NIH received in excess of $1 million in fees over more than a decade and stock options for hundreds of thousands of dollars. And the company formally collaborates on research with his laboratory. With that general description, are you familiar with the situation that I am referring to?

Dr. ZERHOUNI. I am and we are reviewing this case in particular. I am told that the numbers that were reported in the press are somewhat overstated because of the ranges in which the reports are made. That is number one.

Number two, I am very concerned that if, indeed, there was that relationship, that would be a violation of our current rules. However, our review to date does not show that this was the case, that the individual performed research for those consulting entities.

Senator SPECTER. We would like to get into the specifics of that.

With the extra time on this round, may I come back to the point of the failure to have the financial disclosure filed? How long ago was that called to your attention?

Dr. ZERHOUNI. Basically this was called to my attention this summer when the issue of lecture awards came up through Congressman Greenwood's committee for one of our directors.

Senator SPECTER. Have you taken any action in response to the clear-cut violation of not making the financial disclosure report?

Dr. ZERHOUNI. Well, that is the issue that is at issue here because there is no violation of whether or not these reports are disclosed to the public. All scientists at NIH disclose internally, but if they are under a certain pay system, they are not obligated or the Federal Government rules do not allow us to make those records public. The Acting Director of the Office of Government

Ethics is here and can comment at great length on that issue in particular.

But our intent again is to have full transparency, and one of the issues I am asking the blue ribbon panel to look at is to what extent disclosure should be made without undue stress on the system. Again, although the report says 94 percent of our scientists do not disclose, we should remember 3 percent of our scientists are involved in any one relationship of this kind. So we have to be cognizant of the fact that to me what is important is transparency, and we need to be able to do it. The rules do not allow us to do it, not that NIH does not want to do it.

Senator SPECTER. We have been joined by the distinguished chairman of the full committee, Senator Stevens.

STATEMENT OF SENATOR TED STEVENS

Senator STEVENS. Thank you very much, Mr. Chairman. My voice is not exactly what it should be, but I am pleased to be here today with Dr. Zerhouni. I think NIH is in very capable hands under your leadership.

This committee has more than doubled the amount of money that is available to NIH for basic research in the last decade, and I think that the issues involving collaboration between NIH scientists and biotech and pharmaceutical industries are very important issues to all of us. We have been working to get some of the best researchers in the world working at NIH on basic and applied research. Without encouraging them to work together with biotech companies and the pharmaceutical industry, the fruits of their research might not reach the taxpayers who really are basically funding this research.

I am disturbed that some would characterize the very existence of contractual relationships between NIH researchers and biotech companies as somehow or other unethical. As I understand it, these researchers at NIH had sought and received clearance from their superiors and had followed the agency's procedure in entering into these relationships. Now, if that policy of how that clearance is achieved is something that is being criticized, then I would hope that you would review that, and I commend you for your efforts to make this area more transparent.

I also believe we have to encourage collaboration rather than putting some sort of a taint on it as these researchers do enter into such agreements. Since the mid-1980's, it has been the policy of our Government to encourage technology transfer from the laboratory to private companies. This allows the results of medical research to be developed into new treatments and therapies to benefit all Americans at the earliest possible time. We have made this enormous investment that I have mentioned in medical research at NIH, and I think we must continue to press forward. With this baby boomer generation coming at us, we must be able to apply the fruits of this research as quickly as possible. I do not think there would be any disagreement with this. Without collaboration between NIH and its scientists and the biotech community, that would not be possible.

PREPARED STATEMENT

Having been subject lately to a little criticism concerning my own situation, I am a little sensitive to this, as a matter of fact. I am sensitive to the fact that I do not think the newspaper industry has transparency. I do not think they disclose their collaboration or their contracts. We could not mandate that because of the First Amendment. I do not know if you know that, Dr. Zerhouni. But I think voluntarily we ought to see some information forthcoming from the newspaper industry to tell us who in their groups are getting paid by those who they are reporting about. Some way or other, there should be more balance in this society of ours, and people should investigate and determine if the system is working before they taint those who are working under the system.

Thank you very much, Mr. Chairman.

[The statement follows:]

PREPARED STATEMENT OF SENATOR TED STEVENS

Thank you, Mr. Chairman. I'm pleased to welcome Dr. Zerhouni before our panel today. I believe NIH is in excellent hands under your capable leadership.

The issue of collaboration between NIH scientists and the biotech and pharmaceutical industries is an important one. We have some of the best researchers in the world working at NIH on basic and applied research. But without encouraging them to work together with biotech companies, the fruits of their research will not reach the taxpayers who are funding the research.

I am disturbed that some would characterize the very existence of contractual relationships between NIH researchers and biotech companies as somehow tainted and unethical. As I understand these allegations, the researchers at NIH had sought and received clearance from their superiors and had followed agency procedure in entering into these relationships.

I commend Dr. Zerhouni for his efforts to make these relationships more transparent, but I also believe we need to encourage this kind of collaboration rather than putting eminent researchers "on trial."

Since at least the mid-1980's it has been the policy of our government to encourage "technology transfer" from the laboratory to private companies. This allows the results of medical research to be developed into new treatments and therapies to benefit all Americans at the earliest possible time.

We have made an enormous investment in medical research and in NIH—and we must continue to expand that investment. But without the collaboration between NIH, its scientists and the biotech community, we will not be able to translate that investment into treatments for diseases.

I look forward to hearing your testimony and to your continued leadership at NIH.

Senator SPECTER. Thank you, Mr. Chairman, Senator Stevens.

Dr. Zerhouni, at the request of Congressman Tauzin and Congressman Greenwood and myself we have asked for the compilation of the total number of consulting arrangements and have been advised that there are more than 1,500. Short-term arrangements at 579, long-term arrangements of 365, total number of employees of 527, total number of long-term arrangements on another category at 936. And it is obvious that this poses a very, very substantial problem. To deal with them on an individual basis is going to be enormously complicated to investigate each one of these matters and make some determination.

Do you have any plan as to what you are going to do immediately to deal with this issue as you work through the analysis of each one of these arrangements?

Dr. ZERHOUNI. The numbers you mentioned, Senator, are the cumulative numbers over 5 years. The active agreements currently at

NIH are about 365. Of those, some are long-term, some are short-term, 1-day consultations.

So what I did is I established a review process in my office through a central committee that will review every relationship and all relationships that involve any individual with any authority at NIH, directors, deputy directors, scientific directors, anyone who has authority over a decision, and second, every relationship with industry will be reviewed.

Senator SPECTER. Are you taking any action to suspend these arrangements while the investigation goes on?

Dr. ZERHOUNI. Basically we have suspended any approval until this system is in place.

Senator SPECTER. Are you saying that you are suspending these arrangements while the investigation goes on?

Dr. ZERHOUNI. I have to follow the rules and regulations. I can change the process. I cannot change the rules and regulations that govern NIH now. The review process is to change the regulation. My process is to review and evaluate every single relationship as they exist today for every scientist, about 200 scientists.

Senator SPECTER. Are you saying that the current rules and regulations preclude you from suspending these arrangements until the rules and regulations are modified?

Dr. ZERHOUNI. The rules and regulations as they exist—and I would like to have the Acting Director of the Office of Government Ethics report on that, but my understanding is I cannot change the rules without new regulations being promulgated.

Senator SPECTER. How long would you expect it to take to promulgate new rules and regulations?

Dr. ZERHOUNI. I am told by the Office of Government Ethics they will collaborate with us as diligently as they can, including if we need some help from Congress. I want the review to be done within 90 days and the implementation of the changes be done as soon as possible after that.

Senator SPECTER. Are you setting a 90-day time limit?

Dr. ZERHOUNI. I am setting a 90-day time limit for the outside independent review panel to review our policies, procedures, rules, regulations and make firm recommendations.

Senator SPECTER. Well, apparently you are not in the position to say now because I have asked you and you have not responded precisely to the question as to how long it will take to change the rules and regulations. Would you provide the subcommittee with a time line as to how long all of this is going to take so we have some idea as to what is going to be happening in the interim?

Dr. ZERHOUNI. I will do so, Senator, but again, that is not necessarily all under my control, as you well know. It has other entities——

Senator SPECTER. Well, would you specify what is not under your control so that the subcommittee can make an evaluation of that?

Dr. ZERHOUNI. I will do so.

Senator SPECTER. Okay. Thank you very much, Dr. Zerhouni.

Dr. ZERHOUNI. Thank you, Senator.

Senator SPECTER. Now I would like to call the second panel: Ms. Marilyn Glynn, Mr. Edgar Swindell, and Dr. Ruth Kirschstein.

Our first witness on this panel is Dr. Ruth Kirschstein who currently serves as Special Advisor to the Director. Previously Dr. Kirschstein had been acting Director of NIH for more than 2 years between January 2000 and May 2002, and prior to that post, Dr. Kirschstein served as agency ethics official from 1993 to 2003. She has a long-term record of outstanding service to NIH going back to 1956 as a medical officer in clinical pathology, a bachelor's degree magna cum laude from Long Island University and an M.D. from the Tulane University School of Medicine.

Dr. Kirschstein, you have appeared before this subcommittee many, many times. We welcome you back. The floor is yours. In accordance with our practice, the statements will be limited to 5 minutes.

Dr. KIRSCHSTEIN. Thank you, Mr. Chairman. As you said, I am currently the Senior Advisor to the Director of NIH, and I am going to have to get some water, if you will pardon me for a minute.

Senator SPECTER. May I again invite people who are standing in the rear of the room to come up and take the chairs which are behind the bench here, either the staff chairs or the Senators' chairs. You are welcome to sit down. If you come up, you will allow more people. Whoever is the custodian of the door, would you tell people outside who are waiting that they can come up and take chairs that others are reticent to take?

Dr. Kirschstein, you will be glad to know we have not started the clock yet.

Dr. KIRSCHSTEIN. Thank you, sir. I am appearing today before the committee to describe the role of the NIH Deputy Ethics Counselor as part of the duties of the Deputy Director of NIH. I had anticipated that Ms. Glynn and Mr. Swindell would precede me so that they would have described some of the process. However, I should——

Senator SPECTER. Would you prefer that they go first?

Dr. KIRSCHSTEIN. Well, it would perhaps make the process more transparent to you, but it is fine with me if you would like me to go ahead.

Senator SPECTER. Well, if it would be more orderly to proceed the other way. They were listed ahead of you on the schedule.

Dr. KIRSCHSTEIN. That is why I made that assumption, sir.

Senator SPECTER. I immediately saw you number 3 and for me you are number 1.

Dr. KIRSCHSTEIN. Thank you, sir.

STATEMENT OF MARILYN L. GLYNN, ACTING DIRECTOR, OFFICE OF GOVERNMENT ETHICS

Senator SPECTER. Which was the reason I made you number 1. That is the chairman's prerogative, but if it would be more orderly to proceed, we will go to Ms. Marilyn Glynn first, Acting Director of the U.S. Office of Government Ethics. She serves in the Office of General Counsel, a position she has held since 1977. Undergraduate from Emmanuel College in Boston, a law degree from the Washington College of Law, the American University in Washington, D.C. Thank you for joining us, Ms. Glynn, and we look forward to your testimony.

Ms. GLYNN. Good morning. I will try to move up to number 1 now in your estimation.

As you said, I am the Acting Director of the Office of Government Ethics (OGE). Thanks for the opportunity to appear today to discuss the ethics program in the executive branch and at NIH as well. I respectfully request that my written statement go in the record, which is rather lengthy.

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

Ms. GLYNN. OGE is the executive agency responsible for directing policies relating to the prevention of conflict of interest on the part of executive branch employees. As the supervising ethics office for the executive branch, OGE has issued and provides guidance on standards of conduct for executive branch employees, rules relating to financial disclosure and the criminal conflict of interest laws.

While developing and publishing rules is an important part of OGE's role, it is in a sense only the starting point. With an emphasis on education and prevention, OGE works with agencies to implement these rules by assisting agencies in carrying out their responsibilities. The head of each agency has the primary responsibility for the ethics program at his agency and appoints a designated agency ethics official, or DAEO as we call it, to manage the ethics program. OGE works with DAEO's through one-on-one consultation, education, and outreach and periodic program reviews.

A little history is in order to explain the evolution of the ethics rules being looked at today. In 1989, then President Bush created a commission to evaluate the existing ethics program in Government. Based on the commission's recommendations, President Bush directed my office to develop and issue a single comprehensive set of standards of conduct and directed agency heads to develop supplemental rules where necessary to meet unique needs. One of the President's goals—and this is something you touched on earlier, sir—was to balance the need for exacting rules that ensure that employees will act with the utmost integrity against the need to avoid rules that are so restrictive that able people will be discouraged from entering public service. Striking this balance was an important factor in developing the standards of ethical conduct and it continues to inform my office's interpretation of the ethics rules and laws.

In 1993, when the new standards became effective, agency-specific regulations were largely supplanted. Agencies were expected to bring inconsistent policies into compliance with the new standards or to issue supplemental regulations with OGE's concurrence.

As I stated earlier, OGE monitors agency ethics programs through periodic program reviews. In large agencies, OGE may look at specific components rather than the entire agency. These reviews generally focus on program elements rather than the individual cases of misconduct.

In 1995, OGE conducted a program review at NIH looking at three institutes. In general, we found that NIH had a good ethics program. As part of this review, which was the first one at NIH after the new standards came into effect, OGE found that certain NIH policies relating to outside employment were inconsistent with the new standards. As such, we recommended that these policies

be revised to be consistent with the new rules. We also noted that HHS could consider proposing supplemental rules that imposed more stringent rules on employees of NIH if necessary. HHS did issue a supplemental regulation in 1996 that included prohibitions on certain types of outside activities and employment for HHS employees generally, as well as some provisions relating to specific HHS components, but they did not propose any special rules for NIH employees.

In the year 2000, my office conducted another program review, this time looking at three different institutes. Overall, we found the programs at these institutes to be sound.

We have now initiated a 2004 review of the NIH ethics program. This review is being performed at the Office of the Director of the NCI, the National Institute of Allergy and Infectious Diseases and the Clinical Center. Though this review had long been planned for 2004, in light of recent news reports concerning the ethics program at NIH, we moved the start date up and tailored the focus to current concerns.

I have discussed specific rules regarding outside activities and employment and the public financial disclosure system in some detail in my written testimony, so I will not repeat that here.

PREPARED STATEMENT

In closing, I want to say that I want to work with you as well, with NIH and with HHS to address the problems that have been identified and to ensure that the public has the highest confidence in the important work going on at NIH.

[The statement follows:]

PREPARED STATEMENT OF HON. MARILYN L. GLYNN

Mr. Chairman, Senator Harkin, and members of the subcommittee: Thank you for the opportunity to appear today to discuss the policies and procedures in place to avoid conflicts of interest in the executive branch generally and at the National Institutes of Health (NIH) in particular. Mr. Chairman, you requested that the Office of Government Ethics (OGE) "provide an overview of how ethics rules and regulations are determined and implemented throughout the executive branch and the role of the Office of Government Ethics." In addition, you requested that OGE "summarize the results of any ethics audits that the Office of Government Ethics has conducted at the NIH within the last 10 years" and provide documents relating to these audits.

THE EXECUTIVE BRANCH ETHICS PROGRAM AND OGE'S ROLE

Established by the Ethics in Government Act of 1978, OGE is the executive branch agency responsible for directing policies relating to the prevention of conflicts of interest on the part of Federal executive branch officers and employees. As the supervising ethics office, OGE develops rules relating to ethics and conflicts of interests, establishes the framework for the public and confidential financial disclosure systems, develops training and education programs for use by executive branch ethics officials and employees, and supports and reviews individual agency ethics programs to ensure they are functioning properly.

While OGE provides direction and overall leadership to the executive branch ethics program, the head of each agency has primary responsibility for the ethics program at his agency. Each agency head appoints a Designated Agency Ethics Official (DAEO) to manage the ethics program and act as a liaison to OGE. The DAEO and his staff ensure that the required ethics program elements are accomplished. Basic elements and responsibilities of an agency ethics program include effective collection and review of financial disclosure reports; ethics training that meets the requirements of OGE's training regulations; an employee counseling program; and prompt and effective action for violations of the ethics rules. Additionally, an agency that

wishes to supplement the Standards of Ethical Conduct to meet its particular needs may submit a proposed supplement to OGE for concurrence and joint issuance. Through its role to provide direction and leadership to executive branch agencies and departments, OGE supports high ethical standards for employees and strengthens the public's confidence that the Government's business is conducted with impartiality and integrity.

As the supervising ethics office of the executive branch, OGE has developed and issued various executive branch-wide regulations in Title 5 of the Code of Federal Regulations, including the Standards of Ethical Conduct for Employees of the Executive Branch (Part 2635), rules that implement the financial reporting requirements in the Ethics in Government Act (Part 2634), and rules that implement criminal conflict of interest laws (Parts 2635, 2637, 2640, and 2641). Pursuant to the Ethics in Government Act and Executive Order 12674 (as modified by E.O. 12731), these regulations are issued after consultation with the Attorney General and the Office of Personnel Management.

While developing and publishing rules are important and central elements of OGE's role in providing direction and leadership to the executive branch ethics program, it is, in a sense, only the starting point. With an emphasis on education and prevention, OGE works with agencies to implement these rules by assisting agencies in carrying out their responsibilities through training of ethics officials, sponsoring regular national and regional conferences, and communicating with agencies through memoranda to agency ethics officials ("DAEOgrams") and an electronic list service. Additionally, to ensure consistency in the interpretation of its rules, OGE issues redacted versions of important advisory opinions it issues each year.

To ensure that DAEOs receive accurate and timely consultation on ethics issues, OGE also provides one-on-one consultation to agencies through its attorneys and a desk officer system in which each agency is assigned an individual ethics specialist as a primary OGE contact. OGE attorneys and desk officers assist agencies on a wide range of ethics issues, including responding to questions regarding application of specific rules in the Standards of Ethical Conduct, providing assistance in analyzing conflict of interest questions, and responding to questions relating to implementation of the financial disclosure systems.

In addition to these outreach activities with agencies, OGE is responsible for monitoring and evaluating the executive branch ethics program. This function is accomplished through periodic program reviews of the ethics programs at each agency. The purpose of the review is to ensure that agencies have developed effective ethics systems and procedures, in compliance with OGE regulations, to prevent conflicts of interest and other violations of ethics laws and regulations. Individual misconduct by employees is investigated by the Office of Inspector General responsible for each agency. I will discuss our review process in greater depth later in my testimony.

POLICIES AND PROCEDURES FOR AVOIDING CONFLICTS OF INTEREST

1. New Standards of Ethical Conduct Issued in 1993

The current Standards of Ethical Conduct, at 5 C.F.R. Part 2635, became effective in 1993. Prior to that, ethics rules were located in numerous sources and implemented in a decentralized, sometimes inconsistent, manner largely by individual agencies. In 1989, President George H.W. Bush created the President's Commission on Federal Ethics Law Reform to evaluate the existing ethics program and make recommendations for improvement. One of the Commission's central recommendations was that OGE consolidate all executive branch standards of conduct regulations into a single, uniform set of rules. The Commission found that "the sheer bulk of ethics statutes and rules, inconsistent rules, and varying interpretations have contributed greatly to making compliance difficult. To the extent that rules and interpretations can be standardized, the rules can be more easily understood and compliance will be facilitated." President's Commission on Federal Ethics Law Reform, *To Serve with Honor,* p. 93 (March 1989). In addition to a standardized set of rules, the Commission recognized that some agencies would need to have supplemental regulations specifically tailored to their needs. For example, owning stock in a particular company or industry could pose a problem at one agency but not others.

Shortly after the Commission issued its report in 1989, President Bush announced a comprehensive ethics reform proposal and an executive order that directed OGE to promulgate "regulations that establish a single, comprehensive, and clear set of executive-branch standards of conduct that shall be objective, reasonable, and enforceable." Section 201(a) of Executive Order 12674 of April 12, 1989 (as modified by E.O. 12731). In addition, agency heads were directed to "[s]upplement, as necessary and appropriate the comprehensive executive branch-wide regulations of the Office of Government Ethics, with regulations of special applicability to the par-

ticular functions and activities of that agency." Section 301(a) of E.O. 12674. One of the premises of this package was the recognition of the need to balance the competing interests of having exacting rules that ensure employees will act with the utmost integrity with the need to avoid rules that are so restrictive that able members of the public will be discouraged from entering public service. Striking this balance properly was an important factor in the development of the Standards of Ethical Conduct, and it continues to influence OGE's interpretation of the ethics rules and laws. Indeed, this is a continuous process, and OGE currently has a project focused on considering how to modernize and update the Standards with respect to outside activities, among other issues.

At the time the Standards became effective, agency specific regulations were largely supplanted. To the extent that agency policy was inconsistent with the new rule, agencies were expected to bring those policies into compliance with the executive branch-wide Standards or issue supplemental regulations, with the concurrence of OGE, when a determination was made that doing so was necessary and appropriate in view of that agency's programs and operations. To allow time to issue supplemental regulations, however, agency regulations that had prohibited specific financial interests or specific types of outside employment or that required prior approval for outside activities were allowed to remain in effect, through a series of grandfather provisions, for several years or until the agency had issued a supplement as a replacement. To date over 35 agencies, including the Department of Health and Human Services (HHS), have issued supplemental regulations.

As discussed more fully later in this testimony, through a program review conducted at HHS in 1995—the first program review at that agency after the new Standards became effective in 1993—OGE determined that written guidance NIH provided to employees about criteria for permissible outside activities and employment was inconsistent with provisions in the new Standards. As such, OGE recommended that these policies be revised to be consistent with the new rules and noted that HHS could consider proposing supplemental regulations that addressed, should they determine it was necessary, more stringent criteria for employees at NIH.

HHS did issue a supplemental regulation in 1996 that included prohibitions on certain types of outside activities and employment applicable to all HHS employees, including those employed at NIH. Specifically, HHS employees may not provide compensated professional or consultative services related to the preparation of any grant application, contract proposals, program report, or other document intended for submission to HHS. Additionally, HHS employees may not participate in compensated outside activities with respect to particular activities funded by HHS. This supplemental regulation also contains prohibitions on outside activities and employment applicable to employees of the Food and Drug Administration and the Office of the Chief Counsel, and to the outside practice of law by attorneys in the Office of the General Counsel. HHS did not propose any special standards for NIH employees in its supplemental regulation.

2. Handling Conflicts of Interest Arising From Outside Activities (Including Employment)

One of the major areas that can give rise to conflicts of interest questions is employees' outside activities. Two basic issues must be addressed when an employee proposes to engage in an outside activity: whether the employee may participate in the outside activity and, if permissible, what rules apply to such participation.

a. Conflicting Outside Activities and Judging Appearance Problems

The Standards prohibit an employee from engaging in an outside activity that conflicts with his official duties. An outside activity will conflict with an employee's official duties if it is prohibited by statute or an agency supplemental regulation, or if the disqualification required to avoid a conflict of interest is so central or critical to the performance of the employee's official duties that his ability to perform his job is materially impaired. This provision recognizes that even if an outside activity is not prohibited under this standard, it may nonetheless violate other principles or standards and therefore be prohibited. See 5 C.F.R. § 2625.802. For example, even if a proposed outside activity does not conflict with an employee's duties, it may be prohibited if it creates the appearance that the employee is using public office for private gain.

When an employee wishes to participate in an outside activity for which a disqualification from certain matters is required to avoid a conflict of interest, a determination that the resulting conflict will materially impair that employee's ability to do his job requires a judgment call based on a variety of facts, including the nature of the employee's duties, the needs of the office, and the ability to reassign projects

in the office. However, whether or not a disqualification is required, an agency should consider whether the employee's participation in the outside activity is prohibited by any other provision in the Standards, including if participating in the activity would create the appearance that he is using public office for private gain.

The Standards provide that whether "particular circumstances create an appearance that the law or these standards have been violated shall be determined from the perspective of a reasonable person with knowledge of the relevant facts." 5 C.F.R. § 2635.101(b)(14). Agencies are undoubtedly in the best position to determine if an outside activity is permissible under these Standards generally, and with respect to appearances in particular. Some things that an agency should consider in making a decision about whether participation in an outside activity will create the appearance that an employee is using public office for private gain are the level of the employee's position and the nature of his duties; the subject of the outside work and its relation to agency programs and operations; the identity of the outside employer and its relationship to the agency, including whether it receives grants or contracts; and the timing of the offer of employment.

The Standards do not contemplate direct consultation on ethics issues between OGE and employees of other agencies. Rather, the regulations provide that employees and their supervisors should seek advice from their agency ethics officials and that those ethics officials may consult with OGE as necessary. The reason for this is clear: agencies are in a better position to know or develop the facts necessary to understand how the issue implicates agency programs. This is particularly true with respect to questions regarding appearances, and OGE will generally defer to agency determinations on these questions.

OGE's role in this process is to provide consultation, upon request, to agency ethics officials regarding application of the Standards and applicable laws. Such assistance may be provided through informal consultations over the phone, in meetings, or through the advisory opinion process. When necessary, OGE consults with the U.S. Department of Justice when an agency presents an issue of first impression with respect to one of the criminal conflict of interest statutes. While the final judgment on appearances rests with the agency, OGE has an important role in ensuring that agencies understand the rules and are applying them consistently across the executive branch. OGE may also provide agencies with input on these issues through its periodic program reviews.

b. When an Outside Activity Is Approved

The Standards of Ethical Conduct provide that an employee who is engaged in an outside activity must comply with all applicable provisions set forth in the rules, including rules that prohibit use of position or Government resources, information, and time in connection with outside activities and that relate to providing representational services on behalf of others before the Government. Particularly relevant in the context of the present inquiry are the rules that require employees not to participate in certain Government matters when their own interests, or the interests of others, are affected by such matters.

Non-participation may be required in connection with an outside activity under one of two ethics provisions. Under 18 U.S.C. § 208, a criminal conflict of interest statute, an employee is prohibited from participating personally and substantially in any particular matter that would have a direct and predictable effect upon an employee's own financial interest or upon the financial interests of her or her non-Government employer, among others. Adherence to the statute is accomplished by not participating in the particular matter. Under 5 C.F.R. § 502 of the Standards of Ethical Conduct, an employee is also required to recuse himself when he determines that his impartiality would reasonably be questioned if he were to participate in a particular matter involving specific parties where persons with whom he has certain personal or business relationships are involved.

The obligation to recuse when necessary and to ensure that a disqualification is observed, always remains the personal responsibility of the individual employee subject to the disqualification. An employee should notify his supervisor when he becomes aware of the need to disqualify himself from certain matters because of a potential conflict of interest. Once notified, the employee's supervisor also has a responsibility to facilitate the disqualification by ensuring that the employee is not assigned to work on matters from which he is disqualified. Agency ethics officials obviously have an important role through direct counseling to, and education of, employees to ensure that they understand when a recusal is required and how to effectively implement a required recusal. OGE's role is to ensure that agency ethics officials understand the rules and ensure that they are applied consistently across the executive branch.

It is worth noting that agencies do have discretion with respect to whether a disqualification will be approved as an appropriate remedy for a potential conflict of interest. In other words, the Standards permit a supervisor to disapprove a request for approval of an outside activity if the required disqualification is unworkable because other employees in the office cannot readily be assigned to work on the matter from which the requesting employee would be disqualified if he were permitted to pursue the proposed outside employment. See 5 C.F.R. § 2635.403(b).

3. Financial Disclosure

The financial disclosure systems implemented by OGE for the executive branch are one of the ways that potential conflicts of interest may be identified and handled. The Ethics in Government Act requires senior officials in the executive, legislative and judicial branches to file public reports of their finances as well as other interests outside the Government. The theory of public financial disclosure is rooted in post-Watergate concepts of "Government in the Sunshine," which aims to promote public confidence in the integrity of Government officials. Congress also sought "to strike a careful balance between the rights of individual officials and employees to their privacy and the right of the American people to know that their public officials are free from conflicts of interest." H. Rep. No. 800, 95th Cong., 1st Sess. 18 (1977). OGE has no authority to alter the statutory requirements. OGE's regulation and the public financial disclosure report (SF 278) format reflect the law's mandates and its dual purpose: avoiding conflicts of interest through analysis of disclosures and ensuring public confidence in Government through disclosure as an end in itself.

The statute specifies which officials in the executive branch file a SF 278. Employees in statutorily-specified positions must file the SF 278; neither the employees nor their agencies have the discretion to determine that they may be exempted from this requirement. Among the positions specified as subject to this filing requirement are the President, Vice President, certain commissioned White House appointees, senior postal service employees, Presidential nominees requiring Senate confirmation, other political appointees, and members of the Senior Executive Service. Congress specified that a senior employee paid under an alternative pay systems must file when his position's rate of basic pay is equivalent to or greater than 120 percent of the minimum rate of basic pay for GS–15.

Additionally, the Director of OGE was granted the authority to designate additional positions for filing SF 278s if OGE determines that those positions are equivalent to others that normally require filing, generally referred to as an "equal classification" determination. OGE gives careful consideration to requests that a position be subject to the public financial disclosure requirements based on an "equal classification" argument, paying special attention to Congress' concern that the right balance be struck between the employee's right to privacy and the public's right to know public officials are free of conflicts of interest.

A variety of factors are considered in making equal classification determinations, but it is important to keep in mind that the amount of compensation paid to an employee is not the crucial factor in determining whether an employee is in a position covered by the public reporting requirements. The law contemplates that the quality and level of responsibility must be considered. While the amount of pay may, in many cases, be commensurate with responsibility, in recent years Congress has developed pay plans that provide relatively high levels of compensation to recruit and retain employees who are highly skilled and qualified in their fields, such as doctors.

Concerns have been raised about the positions at NIH for which public disclosure is not required. Specifically, a recent news report asserts that, based on a 1998 OGE opinion, officials at NIH are "allowing" senior employees to avoid public financial disclosure requirements. The article suggests that NIH as an agency, and its employees individually, have improperly exercised discretion in this area. This is simply not true. Indeed, as noted above, neither NIH nor its employees have discretion in this area.

I would like to take this opportunity to explain how certain determinations were made with respect to positions covered by the public financial disclosure system at HHS generally, including NIH. In late 1997, the DAEO at HHS requested OGE's opinion on what was meant by the term "rate of basic pay" when determining, among other things, whether employees under a particular pay system are required to file public financial disclosure reports. At that time, the Secretary of HHS had been empowered to appoint a number of employees in the "Senior Biomedical Research Service" under a new pay system in which pay was determined by the Secretary in an amount not less than the minimum rate payable for a GS–15 and not more than the rate of pay for level I of the Executive Schedule. Under this system there were no steps or grades within the range; it was one broad "pay band."

Under the statutory requirements for filing, employees in "pay band" systems would be subject to the public financial disclosure reporting requirement only if their "rate of basic pay" was equal to or greater than 120 percent of the rate of basic pay for a GS–15. In an opinion issued in early 1998, OGE determined that, based on previous opinions interpreting both the statutory language and legislative history of the Ethics in Government Act, the term "rate of basic pay" means the lowest step authorized for a position's pay grade. For "pay band" systems in which the minimum allowable pay is less than 120 percent of the basic rate of pay for a GS–15, and where there are no intermediate steps or grades, this means that no employee compensated under that "pay band" system is required to file a public financial disclosure report, regardless of the actual amount they are compensated. As a practical matter this mean that some employees at NIH who had been required to file a public financial disclosure report because they had previously been in the Senior Executive Service were no longer required to do so. HHS has recently requested that OGE consider whether a number of positions at NIH meet the criteria for filing a public financial disclosure report under an equal classification analysis.

OGE PROGRAM REVIEWS AT NIH

As I stated earlier, OGE conducts systemic reviews of all executive branch department and agency ethics programs to determine whether agencies have developed effective ethics systems and procedures, in compliance with OGE's regulations, to prevent conflicts of interests. OGE currently conducts reviews of 35 agencies annually, with major agencies being reviewed approximately every 5 to 6 years. Agencies are selected for review based on the length of time since their last review, OGE staff concerns about an agency's program, and news media reports of ethical concerns.

These reviews generally focus on several ethics program elements, including the structure and staffing of the ethics program, the financial disclosure systems, the ethics education and training program, the advice and counseling services, the outside activity approval process, ethics systems for advisory committees, acceptance of travel payments from non-Federal sources under 31 U.S.C. § 1353, ethics staff relations with the Office of Inspector General, and ethics issues unique to that agency. In large agencies or departments, OGE may look at how the ethics program is managed in its individual components rather than the entire agency. The reviews do not typically look at individual employee cases of conflict. On occasion concerns about an individual employee will arise in the course of a review, and OGE will consider the facts giving rise to the concern and make appropriate recommendations.

Once a program review report is issued, the agency is required to report, within 60 days, on any actions it will take to address issues raised in the report. OGE conducts a six-month followup to check on the agency's progress in addressing these issues. In rare cases, where we find programs that are extremely deficient, we will send a Notice of Deficiency to the agency requiring them to correct certain matters, usually within a specified period of time.

Since 1990, OGE has performed three program reviews at NIH and has a fourth review underway. In 1991, we conducted a review focusing on the National Cancer Institute (NCI), the National Heart, Lung and Blood Institute (NHLBI), and the National Institute of Allergy and Infectious Diseases (NIAID). This review focused in part on the NIH outside activity approval process as it related to scientists and doctors. Our recommendations focused on the need to improve the criteria and process for approving outside activities, particularly in the area of teaching, speaking, and writing. Our main concerns were that some activities appeared to be approved without adequate documentation. We also observed that a large proportion of outside activity requests were being considered and approved after the activity had already taken place. It is important to note that the 1991 program review was conducted prior to the issuance of the new executive branch-wide Standards of Ethical Conduct.

Following the 1991 review we met with the Director of NIH and the HHS DAEO to discuss our concerns. We recommended that HHS assist NIH in establishing an Office of Ethics on site at NIH and that clear policies, consistent with OGE regulations, concerning outside activities be developed. We also again recommended that HHS correct its department-wide standards of conduct regulations to reflect the correct standards for outside speaking and writing activities. Following the 1991 review, HHS established a satellite ethics office at NIH and issued interim guidance to NIH on the correct standards for approving teaching, speaking and writing activities.

In 1995, OGE conducted a program review at NIH looking at NCI, NHLBI, and NIAID. While OGE will normally review different components in a large agency like NIH, it was felt that a follow-up at these three institutes was appropriate given the

results of the previous review. We were pleased to find that NIH had put much time and effort into developing its guidance on outside activities, and in implementing a much improved system for approving outside activities.

As noted previously, the new executive branch-wide Standards of Ethical Conduct became effective prior to the 1995 review. After the Standards went into effect some NIH policy guidance on outside activities—though consistent with our 1991 recommendations—was superseded. Following the 1995 review, NIH did rescind its guidance on outside activities, and HHS issued supplemental regulations, though, as previously noted, HHS did not propose any special standards for NIH employees in its supplemental regulation.

In 2000, OGE conducted a program review at NIH of the National Institute of Arthritis and Musculoskeletal and Skin Diseases (NIAMSD), the National Institute of Child Health and Human Development (NICHHD), and the National Institute of Diabetes and Digestive and Kidney Disorders (NIDDKD). Recommendations included ensuring that proper determinations are made before issuing statutory conflict of interest waivers to special Government employees on Federal advisory committees, and recommendations to NIDDKD in particular regarding the procedure for approval to engage in outside activities. The latter recommendation arose primarily from the fact that a new ethics official at NIDDKD could not locate the approvals granted before he took the position. Through our normal follow-up procedures, we concluded that NIH took actions to implement these recommendations.

OGE has initiated a 2004 review of the NIH ethics program. This review will be performed at the Office of the Director, NCI, NIAID, and the Clinical Center, and it will focus on the structure and staffing of NIH's ethics program, the public financial disclosure system, the criteria and process for approving outside activities, the criteria and process for approving the acceptance of awards, and other basic ethics systems.

CONCLUSION

In closing, I would like to emphasize that OGE stands ready to work with you, the Committee, HHS, and NIH to ensure that the public has the highest confidence in the important work of all the components at NIH.

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

STATEMENT OF EDGAR M. SWINDELL, ASSOCIATE GENERAL COUNSEL, ETHICS DIVISION, OFFICE OF THE GENERAL COUNSEL, DEPARTMENT OF HEALTH AND HUMAN SERVICES

Senator SPECTER. Thank you, Ms. Glynn.

We now turn to Mr. Edgar Swindell, Chief Ethics Officer for the Department of Health and Human Services. He has held that position since 1997. He also serves as Associate General Counsel in charge of the Ethics Division of the Office of the General Counsel. Prior to joining HHS in 1983, he was in the private practice of law. Both his degrees, a bachelor's and law degree, come from the University of Tennessee.

Thank you for joining us, Mr. Swindell, and we look forward to your testimony.

Mr. SWINDELL. Thank you, Mr. Chairman. As you have indicated, I am the Associate General Counsel for Ethics at the Department of Health and Human Services and my principal role there is to advise the Secretary and the General Counsel on ethics and political activity issues within the Office of the Secretary.

Concurrently I serve at the designated agency ethics official, or DAEO, for the Department. In this capacity, I am the point of contact with the Office of Government Ethics and I exercise general superintendence over a decentralized departmental ethics program through the appointment of deputy ethics counselors. These are DEC's and they operate in the Food and Drug Administration, the Centers for Disease Control and Prevention, the National Institutes of Health, and other operating divisions of the Department.

The DEC's administer an ethics program within their respective components and are responsible for establishing a system for reviewing public and confidential financial disclosure forms, considering outside activity requests, providing ethics advice to the individual employees, initiating ethics education and training programs, and ensuring that violations of the conflict statutes or the conduct standards are reported to investigatory authorities and, where appropriate, disciplinary action is taken. My office has similar responsibilities within the Office of the Secretary and staff lawyers within my Ethics Division are available to provide guidance to the DEC's.

The DEC's are senior officials within each component and they have staff who assist them in carrying out the ethics functions, either as collateral duties or as members of an ethics program office. Within the NIH, a DEC in the Office of the Director coordinates the ethics program for that operating division. The NIH DEC also serves as the ethics official for senior NIH staff, and in addition, DEC's in each institute and center administer the ethics programs for their respective employees.

The committee has asked that I briefly recount the process and applicable law that governs the approval of outside activities, and it is rather complicated, so I will try to be brief about it.

HHS employees are required by our supplemental ethics regulation to get prior approval for professional or consultative activities, teaching, speaking, and writing, and board service. They submit an HHS Form 520 that solicits detailed information about the proposed activity and each operating division may specify various levels of review which may start with the supervisor and end with the DEC.

Approval requires an assessment of whether the proposed outside activity violates any statute or regulation, including the OGE standards for ethical conduct of employees of the executive branch or the HHS supplemental ethics regulation. Included in those OGE standards is the requirement that the proposed activity cannot create an actual or apparent conflict that would result in recusals that would materially impair an employee's ability to do his job.

In evaluating conflicts, the reviewer must address two provisions that form the core of Federal ethics law. A criminal statute, 18 U.S.C., section 208, deals with an actual conflict due to the employee's own or imputed financial interest in the resolution of a Government matter. And a regulatory provision in the OGE standards principally addresses disqualifications called for when an appearance of a conflict arises from a covered relationship.

Under section 208 of the criminal code, to avoid a conflict of interest that results, for example, from stock ownership or outside employment, a Federal employee must not participate personally and substantially in a particular matter that, to his knowledge, directly and predictably affects his own financial interest or that of his outside employer.

To prevent an appearance of a conflict that results from serving in a role short of employment, for example, as an advisor, consultant, or other type of independent contractor compensated with fees and expenses, a different rule applies. Under section 502 of the regulations, if a reasonable person with knowledge of the relevant

facts would question the Federal employee's impartiality, he must recuse, but only from particular matters involving specific parties. These are things like grants, contracts, audits, lawsuits, clinical trials, new drug applications that involve the very company to which he is providing consulting services as a party or representative of a party.

It is key to point out that both sections are disqualification provisions in that they do not prohibit the acquisition of an asset or relationship. Rather, they bar actual participation in a potentially conflicting matter, either personally or through the direct and active supervision of the participation of a subordinate. However, neither section is triggered by the mere knowledge of or official responsibility for a particular matter. In short, if an employee can recuse appropriately and still be able to do his job, then an outside activity shall be approved under the regulations, provided there are no other statutory or regulatory impediments. And there are quite a few that have to be reviewed.

PREPARED STATEMENT

I must finish my statement here. What I would like to add, just to let you know, is that the FDA within our Department does have a regulation that prohibits certain outside activities and the ownership of certain types of stock. This perhaps might serve as a model for NIH. However, of course, FDA is a regulatory agency and NIH has a different function, but my office is committed to providing legal assistance to Dr. Zerhouni's body that will be reviewing these policy issues and to the NIH as it deals with these matters. If supplemental regulations prove the best option, my office is available to assist them in promptly drafting regulations for submission to OGE.

[The statement follows:]

PREPARED STATEMENT OF EDGAR M. SWINDELL

Mr. Chairman, Senator Harkin, and members of the subcommittee: I am Ed Swindell, Associate General Counsel for Ethics at the Department of Health of Human Services (HHS). My principal role is to advise the Secretary and the General Counsel on ethics and political activity issues within the Office of the Secretary. Concurrently, I serve as the Designated Agency Ethics Official (DAEO) for the Department. In this capacity, I am the point of contact for liaison with the Office of Government Ethics (OGE) and exercise general superintendence over a decentralized Departmental ethics program through the appointment of Deputy Ethics Counselors (DECs) chosen by each operating division, such as the Food and Drug Administration (FDA), the Centers for Disease Control and Prevention (CDC), and the National Institutes of Health (NIH).

The DECs administer an ethics program within their respective components and are responsible for establishing a system for reviewing public and confidential financial disclosure forms, considering outside activity requests, providing ethics advice to individual employees, initiating ethics education and training programs, and ensuring that violations of the conflicts statutes or the conduct standards are reported to investigatory authorities and where appropriate, disciplinary action is taken. My office has similar responsibilities within the Office of the Secretary, and staff lawyers within the Ethics Division are available to provide guidance to the DECs. The DECs are senior officials within each component, and they have staff who assist them in carrying out the ethics functions, either as collateral duties or as members of an ethics program office. Within the NIH, a DEC in the Office of the Director coordinates the ethics program for that operating division. The NIH DEC also serves as the ethics official for senior NIH staff. In addition, DECs in each NIH Institute and Center administer the ethics program for their respective employees.

The committee has asked that I briefly recount the process and applicable law that govern the approval of outside activities. HHS employees are required by an agency supplemental regulation to seek prior approval for professional or consultative activities, teaching, speaking, or writing, and board service. They submit an HHS Form 520 that solicits detailed information about the proposed activity, and each operating division may specify various levels of review, which may start with the supervisor and end with the DEC.

Approval requires an assessment of whether the proposed outside activity violates any statute or regulation, including the OGE Standards of Ethical Conduct for Employees of the Executive Branch or the HHS supplemental ethics regulation. Included in the OGE Standards is the requirement that the proposed activity cannot create an actual or apparent conflict that would result in recusals that would materially impair an employee's ability to do his job.

In evaluating conflicts, the reviewer must address two provisions that form the core of Federal ethics law. A criminal statute, 18 U.S.C. § 208, deals with an "actual conflict" due to the employee's own or imputed financial interest in the resolution of a government matter. A regulatory provision in the OGE Standards, 5 C.F.R. § 2635.502, principally addresses disqualifications called for when an "appearance of a conflict" arises from a "covered relationship."

Under section 208 of the criminal code, to avoid a conflict of interest that results, for example, from stock ownership or outside employment, a federal employee must not participate personally and substantially in a particular matter that, to his knowledge, directly and predictably affects his own financial interest or that of his outside employer. To prevent an "appearance of a conflict" that results from serving in a role short of employment, for example, as an advisor, consultant, or other type of independent contractor compensated with fees and expenses, a different rule applies. Under section 502 of the regulations, if a reasonable person with knowledge of the relevant facts would question the federal employee's impartiality, he must recuse, but only from "particular matters involving specific parties," such as grants, contracts, audits, lawsuits, clinical trials, or new drug applications, that involve the company to which he is providing consulting services as a party or representative of a party.

Both sections are disqualification provisions in that they do not prohibit the acquisition of an asset or relationship, rather they bar actual "participation" in a potentially conflicting matter, either personally or through the direct and active supervision of the participation of a subordinate. However, neither section is triggered by mere knowledge of, or official responsibility for, a particular matter. In short, if an employee can recuse appropriately and still be able to do his job, then an outside activity shall be approved, provided there are no other statutory or regulatory impediments.

In addition, a number of statutes and regulations do preclude certain outside activities. For example, if an employee sought approval to be a lobbyist, the anti-representation statutes, 18 U.S.C. §§ 203 and 205, would be implicated. If the activity were clearly one that should be done as an official duty, then approval would be denied, under 18 U.S.C. § 209, as an improper salary supplementation. If the circumstances would create an appearance that the employee has used his official position to obtain an outside compensated business opportunity or would create the further appearance of using his public office for the private gain of the outside company, then under the principles in the OGE Standards, 5 C.F.R. § 2635.101(b), and the rules governing misuse of position, 5 C.F.R. § 2635.702, the outside activity may be denied. An example would be where an employee was recently instrumental in formulating industry standards and would again be so involved. If an affected company offers a consulting contract to the employee to render advice to the company about how it can restructure its operations to comply with the very industry standards that the employee has just drafted, the consulting arrangement should not be approved even though the employee lacks any current assignments affecting the industry, and even though the outside consulting can be finished before he again works on such matters.

Another regulation, 5 C.F.R. § 2635.807, precludes compensation, subject to certain exceptions, if an employee wants to teach a course, deliver a speech, or write a book that relates to his official duties. (Consulting, technically, is not covered by this section, but the analysis does provide guidance in evaluating many outside activities.) The "relatedness" test evaluates, among other factors, the subject matter of the activity. For career employees, compensation is precluded if the teaching, speaking, or writing deals in significant part with any current assignment (or one completed within the last year) or any ongoing policy, program, or operation of the agency. However, the provision has an important exception. A career employee may receive compensation for "teaching, speaking, or writing on a subject within the em-

ployee's discipline or inherent area of expertise based on his educational background or experience even though the [activity] deals generally with a subject within the agency's areas of responsibility."

As noted earlier, outside activities must also comply with applicable provisions governing the avoidance of actions creating an appearance of violating the ethical standards, including the prohibition against use of official position for an employee's private gain or for the private gain of any person with whom the employee has employment or business relations or is otherwise affiliated in a nongovernmental capacity.

As can readily be seen, supervisors, ethics program officers, and the DECs, in particular, have difficult assessments to make when reviewing outside activity requests. Even when the activities are approved, individual employees remain personally responsible for abiding by their recusal obligations and avoiding violations of any other applicable provisions. These responsibilities are exacerbated by mergers, acquisitions, joint ventures, partnerships, and even name changes, within industry that, on any given day, may make it difficult to know whether one has a conflict to avoid.

One HHS component, the Food and Drug Administration (FDA), has dealt with these difficult issues by regulation for over two decades. When the OGE Standards became effective in 1993, FDA had prohibited holdings and outside activity regulations that were "grandfathered" for a certain period. The OGE Standards allow agencies to promulgate, with OGE concurrence, supplemental ethics regulations deemed "necessary and appropriate" to address issues unique to an agency's programs and operations. FDA requested that the Department seek to preserve FDA's pre-existing rules. Accordingly, the HHS supplemental ethics regulation issued in 1996 prohibits FDA employees from holding financial interests in significantly regulated companies, subject to limited exceptions for lower level employees. In addition, FDA employees whose positions require them to file public or confidential financial disclosure forms are barred, subject to certain exceptions, from engaging in employment or consulting with a significantly regulated company or "any self-employed business activity for which the sale or promotion of FDA-regulated products is expected to constitute 10 percent or more of annual gross sales or revenues."

FDA, of course, is a regulatory agency that, according to some estimates, directly affects 25 percent of the American economy. FDA's supplemental prohibitions may or may not provide the best model for non-regulatory agencies. NIH clearly interacts with universities and medical research organizations, as well as the health, biotechnology, and pharmaceutical industries, but primarily through intramural research and clinical trials and extramural funding of similar pursuits. Individual assessment of an employee's proposed outside activity under the extant, albeit recondite, standards may remain the appropriate course. NIH Director Elias Zerhouni will be forming a Blue Ribbon Panel to consider these policy options. My office is committed to providing legal assistance to that body and to NIH as it deals with these difficult issues. If supplemental regulations prove the best option, we will work with NIH in drafting regulations for Departmental approval and submission to OGE. Our collective goal is to ensure public confidence in agency programs and operations through whatever means will best accomplish that objective.

Thank you for the opportunity to speak with you today. I would be pleased to answer any questions that you may have.

STATEMENT OF RUTH KIRSCHSTEIN, M.D., SENIOR ADVISOR TO THE DIRECTOR, NATIONAL INSTITUTES OF HEALTH, DEPARTMENT OF HEALTH AND HUMAN SERVICES

Senator SPECTER. Thank you very much, Mr. Swindell.

We now turn to Dr. Kirschstein. With that preliminary definition as to some of the rules and regulations and legal procedures, the floor is yours, Dr. Kirschstein.

Dr. KIRSCHSTEIN. Yes, sir. Thank you for allowing them to go first. I think you understand now why I suggested that.

I do explain in my written statement also the evolution of the programs at NIH since the inception of these rules in 1978. At that time, I was the Director of the National Institute of General Medical Sciences and immediately became the Deputy Ethics Counselor of that institute. So I have been doing this kind of activity for many, many years.

There has been an evolution. Over the years, during the times of the audits, NIH has taken the statements and the reports very seriously and has amended and changed its manual issuance on the conductance of outside activities accordingly after each of the three audits. There have been four, but we have not changed anything after the fourth.

I do want to tell you about the duties of a deputy ethics counselor. They are to provide assurances that the activities of, in the case of the deputy ethics counselor for NIH, in the case of the institute and center directors, as well as the senior staff in the Office of the Director, that these were performed properly both in regard to their official duties that involve outside organizations, as well as and even more importantly any outside activity such as lecturing, editing, and consulting, and no activities can be undertaken without the approval of the Deputy Ethics Counselor. In addition, the Deputy Ethics Counselor does the final review and certification of the financial disclosure reports filed by these employees. It is also the responsibility of the Deputy Ethics Counselor to assure that each official receives the appropriate annual ethics training.

In regard to activities related to outside organizations, the procedure has been as follows, that the official's request for outside activity was first reviewed by the Office of Human Resources Management and in consultation with the DHHS Special Counsel for Ethics to ensure that all the documents met the applicable executive branch standards of conduct and the regulations and applicable standards of the NIH and DHHS. The Deputy Ethics Counselor then performs the final review.

In general, I approved activities that were recommended, but if necessary, I discussed the activity with the individual involved and on occasion did not give my approval. However, based on the consultation, the majority were approved.

When I became Deputy Ethics Counselor of NIH in 1993, outside work by high-level officials was significantly limited and consulting with outside activities was prohibited by the most senior people.

However, the decision by Dr. Varmus, based on the 1995 audit, to change the context of everything that was done because it allowed high-level officials, defined as NIH deputy directors, associate directors, institute and center directors, deputy directors, to perform exactly the same type of outside activities as all other NIH employees and provided that any outside activity requests submitted should be reviewed for any conflict of interest based on the employee's job rather than the position of the individual. Monetary limits were no longer allowed, nor was the time spent prohibited.

Now, the Deputy Ethics Counselor has another important task which goes with being the senior official, and that is to have an in-depth knowledge of the duties of these high-level officials so that one can make a determination whether, by the need for a recusal or disqualification because of the person's relationship with an outside entity, the individual involved can still perform his duties. And if the time imposed and the recusals are of such significance that the person cannot perform his duties, it is the Deputy Ethics Counselor's duty to prevent those activities and not approve them.

PREPARED STATEMENT

Mr. Chairman, I believe that the NIH ethics program has followed the principles set forth by the executive branch Office of Government Ethics as they have evolved over the past 25 years, but I also believe that like all activities, there is a need for greater oversight of the entire NIH program. In that, like many activities, there is room for improvement. I completely and strongly endorse the proposals made by Dr. Zerhouni, and I would be pleased to answer any questions.

[The statement follows:]

PREPARED STATEMENT OF DR. RUTH KIRSCHSTEIN

Mr. Chairman, members of the Committee, I am Ruth Kirschstein. I am currently the Senior Advisor to the Director of the National Institutes of Health (NIH). Today, I am appearing before this committee to describe the role of the NIH Deputy Ethics Counselor, as part of the duties of the Deputy Director of NIH. I will also discuss the evolution of the ethics program at NIH.

HISTORY

In 1978, the Ethics in Government Act established the U.S. Office of Government Ethics (OGE) as part of the Office of Personnel Management. Each department or agency of the Executive Branch of the Government was given the responsibility for its own ethics program. The Department (at that time) of Health, Education and Welfare, in turn, delegated much of the responsibility for ethics program activities to its agency heads. In turn, the Director of NIH delegated the individual responsibility for ethics activities to the heads of the various institutes, centers and divisions.

And so, in 1978, as Director of the National Institute of General Medical Sciences (NIGMS), one of my responsibilities was to serve as the Deputy Ethics Counselor of that Institute. In the early days of the new ethics laws, the Deputy Ethics Counselors of the Institutes worked closely with the ethics officials of the Department and the OGE to establish the applicable rules and regulations. We also received considerable training about the new law and its implementations.

For fifteen years, from 1978 until 1993, as Director of NIGMS, I personally reviewed all the financial disclosure forms that were filed by Institute staff. I ensured that annual ethics training was given to all such employees and participated, with the other Deputy Ethics Counselors (the Directors of the other Institutes and Centers) and with Department officials, in the evolution of the ethics activities both at NIH and in the executive branch generally.

OFFICE OF GOVERNMENT ETHICS (OGE) AUDITS

Over the years, the ethics program at NIH has evolved, based on the experiences of NIH and the Department staff in its operation, and more recently, on periodic audit reports by the Office of Government Ethics. This evolution resulted in a number of revisions and reissuances of the NIH Policy Manual Chapter 2300–735–4, which sets out NIH policies on activities involving outside entities. Since 1987, there have been four OGE Audit Reports submitted and each has had a different perspective. Three have resulted in a careful revision of the NIH Policy Manual Issuance Chapter cited above.

1991 Audit

The 1991 Audit Report recommended that NIH establish an Office of Ethics. In response, the Office of the Special Counsel for Ethics, within the Office of General Counsel, Department of Health and Human Services (HHS), established a satellite office on the campus of NIH. This individual reported to the Ethics Division but worked very closely with NIH ethics staff.

ROLE OF THE NIH DEPUTY ETHICS COUNSELOR

In 1993, when I was appointed the Deputy Director of NIH by Harold Varmus, then NIH Director, both he and the HHS Designated Agency Ethics Official at that time appointed me as Deputy Ethics Counselor for NIH.

As I said previously, responsibilities for the ethics programs for the various Institutes and Centers were, and still are, delegated to those organizations. The NIH

Deputy Director/Deputy Ethics Counselor provided assurance that the activities of the Institute and Center Directors as well as the senior staff in the Office of the Director were performed properly, both in regard to their official duties that involved outside organizations, as well as, and even more importantly, any other outside activities such as lecturing, editing and consulting. No activities could be undertaken by these senior level officials without the approval of the Deputy Ethics Counselor. In addition, the final review and certification of the financial disclosure reports filed by these employees was performed and certified by the Deputy Ethics Counselor. The procedure that was followed regarding outside activities is outlined in the NIH Policy Manual Chapter as follows:

—The employee (in this case, the IC Director or senior staff member) submitted a request of approval for either an official duty or on outside activity to the Office of Human Resources Management (OHRM). For an outside activity a special form (520) is submitted. Each form was reviewed by OHRM and forwarded to the HHS Office of Special Counsel for Ethics for consultation as needed. (It became standard practice to forward all requests relating to Institute and Center Directors to this office.)

—The HHS Office of Special Counsel for Ethics reviewed the paperwork and additional information provided to ensure that all required information was supplied, and, at times, alerted the Deputy Ethics Counselor to potential issues related to the request. If this review presented no problems, the material was sent back through the OHRM Office to the NIH Deputy Ethics Counselor for final review and recommendation.

In general, I approved activities that were recommended, but, if necessary, I discussed the activity with the individual involved. Based on legal advice provided and knowledge of the surrounding facts and underlying science, the majority of such requests were approved. In 1993, outside work by high-level NIH officials was significantly limited, and consulting with outside entities that had been, or were likely to be, recipients of NIH grants or contracts was prohibited. Besides formal requests, the Deputy Ethics Counselor discussed many requests informally with officials and provided advice, which often led to decisions not to make formal requests.

In addition, the Deputy Ethics Counselor had to ensure that each employee received annual training in ethics and, when required, disqualified (recused) him/herself from issues in which there is a conflict of interest.

Recusals

A Deputy Ethics Counselor also must assess the information provided in the financial disclosure form or in the Request for Approval of Outside Activity (form 520) as to the application of the conflict of interest statutes and regulations and must attempt to resolve actual or potential conflicts or the appearance of a loss of impartiality. In regard to a proposed outside activity, a determination must be made as to whether it conflicts with official duties and whether the recusals that would ensue in the Federal workplace as a result of the particular outside activity would require the employee's disqualification from matters so central or critical to the performance of his or her official duties that the employee's ability to perform the duties of the Federal position would be materially impaired. If conflicts are of such magnitude that official duties would be impaired, the outside activity must be denied.

If a disqualification can resolve the conflict, then a written memorial of the promise to recuse is prepared and signed by the employee and the Deputy Ethics Counselor and sent to the official at the next highest level, who can act instead of the employee. All other employees in the official chain of command must be informed of the fact that, as long as the agreement or need to recuse pertains, the official must disqualify him/herself from any actions covered by the promise.

1995 Audit

The June 1995 report of the audit review of the NIH ethics program was transmitted to the then HHS Designated Agency Ethics Official and the NIH. The report stated that, "[t]he ethics program demonstrates a commitment to ensuring that violations of ethics statutes and regulations do not occur. OGE's recommendations are made with a view toward further refining an already estimable program."

In terms of financial disclosure systems, the report further stated:

"NIH has effectively implemented practices and procedures to ensure that financial disclosure reports are filed and reviewed according to applicable statutes and regulations. NIH's accomplishment of administering sound financial disclosure systems demonstrates its commitment to ensuring that violations of ethics statutes and regulations do not occur."

Regarding approval of outside activities, the report stated:

"NIH has documented its internal guidance on the policies and procedures governing outside activities in the NIH Policy Manual Chapter 2300–735–4, 'Outside Work, Financial Interest and Related Activities' (the Manual). The Manual, which was reissued on August 30, 1993, reflects changes implemented by the new executive branch standards, NIH Policy, and recommendations made in OGE's 1991 ethics program review report.

"It is evident that much skill, time, and effort were devoted to developing the Manual. While the Manual accomplishes its purpose to explain the executive branch standards (and HHS' preserved standards), *we identified several restrictions and limitations that are broader in scope than provided by the executive branch standards, including those sections on prohibited source criteria for outside activities, outside activity compensation and service limitations, and outside activities performed by high-level officials. If NIH wished to continue these prohibitions and limitations, HHS should consider including them in the agency's proposed supplemental regulation and obtaining concurrence from OGE.* (emphasis added).

"(1) NIH's prohibited source criteria for outside activities are broader in scope than the executive branch standards in two aspects. First, NIH's criteria for outside activities by intramural employees (scientists who perform research in-house at NIH) and extramural employees (scientists who administer grants and contracts with outside sources who perform research outside of NIH) generally states that intramural employees are prohibited from engaging in outside activities with outside entities that do business with the employees laboratory/branch; and extramural employees are prohibited from engaging in outside activities the employee's ICD.

"(2) NIH provides two outside activity compensation and service limitations, which are more restrictive than the executive branch standards. First, the Manual provides that total compensation from any one outside organization is limited to $25,000 per year, with some exceptions. It also states that total service time for all compensated activities is limited to 500 hours per year. *However, there is no dollar limit on the amount of outside employment income from all sources, except for certain Presidential appointees. There is also no limitation of service time for compensated outside activities, per se. Therefore, if HHS wished to restrict outside activity and service time, the limitations would also require inclusion in HHS' supplemental regulations.* (emphasis added).

"Second, the Manual states that employees may not consult as an outside activity with companies in which they (or their spouses or dependent children) own stock and may not accept stock or stock options as compensation. The executive branch standards also do not contain this restriction.

"(3) The Manual is also broader in scope than the executive branch standards regarding outside activities performed by high-level officials. The Manual states that because of their national prominence and professional achievement, the NIH Director and certain other high-level officials are limited to performing only certain outside activities such as editing and writing. However, absent a specific regulation that is being violated, we do not recommend that NIH subjectively restrict certain outside activities."

1995 NIH POLICY

Based on the OGE 1995 Audit Report, NIH management undertook to consider and analyze the pros and cons of seeking supplemental regulations versus implementing the government-wide Standards of Ethical Conduct in light of the nature of the work done at the NIH. On November 3, 1995, Dr. Varmus notified the Directors and OD Staff that:

—High-Level Officials—defined as NIH Deputy Directors and Associate Directors, and ICD Directors and Deputy Directors—may perform the same type of outside activities as all other NIH employees, but any outside activity request submitted by any employee should be reviewed for any conflict based on the employee's actual job duties and not on the position of the employee.

—Intramural employees may now engage in activities for any outside organization except those with whom they have direct official business dealings as government employees.

—Extramural employees may engage in activities with outside organizations provided they do not manage a portfolio that includes grants or contracts from one or more of these outside organizations.

—Employees may accept stock as payment for approved outside activities.

—There is no longer a dollar limit on the amount of income that can be received from activities performed for one or more outside activities.

—Employees may no longer be limited in the amount of time they devote to activities performed for outside organizations. If it is determined that the amount of work for outside entities will impinge on the performance of NIH duties, the request should be denied.

As of the issuance of that memorandum for all outside activities, the sequential procedures for approving outside activity requests were as follows:

1. The outside activity request must be approved by the supervisor.
2. Analysis of the proposed activity must be performed by the NIH OHRM.
3. As necessary, consultation was sought with the lawyers in the Office of Special Counsel for Ethics of the OGC.
4. Based on the information provided by 1–3 above, I, as the Deputy Ethics Counselor, in turn, reviewed the activity and in general, would approve. However, on occasion, there was a need for further discussion and an activity would be disapproved, even though no issues warranting disapproval were raised by the previous reviewers.
5. A recusal, if needed, was prepared and provided to the appropriate official so that a required action could be referred to the next subordinate level of authority. (Recusals for activities with which the official has a "covered relationship" (i.e., is a Director, Officer, consultant or employee or spouse of an employee of the outside organization) last for a year beyond the end of the relationship.)

Mr. Chairman, I believe that the NIH Ethics Program has followed the principles set forth by the Executive Branch Office of Government Ethics as they have evolved over the past 25 years. I also believe that there is need for greater oversight of the entire program and, like many activities, room for improvement. I completely and strongly endorse the proposals made by Dr. Elias Zerhouni, the NIH Director. I would be pleased to answer any questions that you may have.

Senator SPECTER. Thank you very much, Dr. Kirschstein.

Ms. Glynn, is there present authority or could there be a suspension of consulting arrangements at this time until there is inquiry into all of the specific matters to see if there is a conflict of interest?

Ms. GLYNN. It might be difficult to do that in many cases. Presumably these arrangements——

Senator SPECTER. I am not talking about many cases. I am talking about a blanket suspension of consulting arrangements until there can be an inquiry as to all the pending matters to see if there is an actual conflict of interest.

Ms. GLYNN. The permission to engage in those outside activities was done under the standards in effect right now. Presumably if the standards were applied correctly, the NIH found that there was no actual or apparent conflict of interest in performing those activities. I would be loathe to say that there could be a blanket suspension based on——

Senator SPECTER. There could be?

Ms. GLYNN. I would be loathe to say there could be a blanket suspension.

Senator SPECTER. As a matter of law, there could not be a blanket suspension.

Ms. GLYNN. Yes, sir, as a matter of reading the regulation and applying it correctly. If they are correctly applying the regulation as it is written now, it would be rather counter-intuitive to withdraw that approval now. However, I think they could look at individual cases and say maybe we should have looked at this factor or that factor and not given approval in the first place.

Senator SPECTER. Obviously, there can be an inquiry into each individual case to see, on the facts of that individual case, whether there is a violation of the rules and regulations. But on the surface on the cases which we have looked at, I would say it is more than

questionable as prima facie conflict, but if they have to be examined one by one, so be it.

Mr. Swindell, do you think there ought to be any change in the statute?

Mr. SWINDELL. Well, actually what we could do is do it by regulation as they do at FDA. They could——

Senator SPECTER. So you are saying there need not be a change in the statute? That was my question.

Mr. SWINDELL. The statute itself?

Senator SPECTER. That is my question.

Mr. SWINDELL. There would be no need to deal with the statute because the agency would have the power to submit to the Office of Government Ethics a regulation that is more focused on the problems at NIH, depending upon——

Senator SPECTER. The agency would have the authority to do so?

Mr. SWINDELL. Yes. It would have the authority to submit a regulation to the Office of Government Ethics and then the Office of Government Ethics has to concur before it can be put into effect.

So the FDA has one of these types of regulations. In FDA, for example, employees are not permitted to hold stock in significantly regulated organizations.

Senator SPECTER. How long would it take to have a change in regulation?

Mr. SWINDELL. Well, it is the usual issue with time of drafting. We do have a model from FDA, obviously, which would indicate that we could proceed more quickly.

Senator SPECTER. How long would it take?

Mr. SWINDELL. Well, I would think that Dr. Zerhouni would want us to wait to hear the results from the blue ribbon panel as to what the recommendations would be about——

Senator SPECTER. Suppose this subcommittee did not want you to wait. How long would it take you to draft a regulation?

Mr. SWINDELL. We would move as expeditiously as we could and put it through the process. Of course, some things——

Senator SPECTER. Well, it is apparent I am not going to get an answer. So will you think about it and submit an answer in writing please?

Mr. SWINDELL. Yes, sir. I will be happy to do that.

Senator SPECTER. Ms. Glynn, in 1996 NIH requested that all members of the Senior Biomedical Research Service be required to file the public financial disclosure form. At the time the Office of Government Ethics ruled that NIH could not require those employees to fill out the public financial disclosure form. This was because the bottom of the pay scale fell below a certain threshold. However, the top of that pay scale is $200,000. Is there any reason why a governmental employee making as much as the Vice President should not be required to fill out a public financial disclosure form?

Ms. GLYNN. Yes, there is, and that reason is that the basis for filing the public financial disclosure form is not how much you make but rather the level of the responsibility that you have in Government. Public financial disclosure is really for people who have broad responsibilities.

But there are people in that pay band that do have those broad responsibilities and it is possible that those folks should be re-

quired to file. HHS can and actually has submitted to us already a request for——

Senator SPECTER. How do you define those broad responsibilities? Congress appropriates $28 billion to NIH. It seems to me that the NIH employees have those broad responsibilities.

Ms. GLYNN. The statute, which is the Ethics in Government Act, that requires public financial disclosure for high-level people actually specifies certain positions like the President, the Vice President, and so on. Members of the Senior Executive Service are another example of people who have to file.

Senator SPECTER. The statute makes those determinations?

Ms. GLYNN. Yes, sir.

Senator SPECTER. So you think we might need a statutory change?

Ms. GLYNN. No, I do not think we do because I think if NIH would like to specify which positions are essentially equivalent, for example, to the SES positions, those people can be ordered, in effect, to file after a determination by my office that it is an appropriate place to draw the line for those folks.

Senator SPECTER. Where you have a record of NIH employees owning stock and taking consulting fees and doing research which directly relates to the specific company and not filing financial disclosures, why should those employees, who are paid more than Members of the Senate, not be required to make a public disclosure as Senators are?

Ms. GLYNN. Well, first, I cannot say for that fact that my office has any information that folks at NIH are receiving fees for consulting on work that is directly related to the work that they do——

Senator SPECTER. If you accept the facts as I have stated them, would people in that category not be fairly asked to file public financial disclosure forms?

Ms. GLYNN. I really think they have to be treated as two separate issues. One is the issue of whether they should be permitted to do that consulting work to begin with. The second issue is public financial disclosure.

Remember, folks that do not file publicly are required to file confidential financial disclosure forms. So that information should be disclosed to the agency so that they can determine some potential conflict of interest.

Really, once again, it is the level of responsibility of the position that dictates whether you file a public financial disclosure form.

Senator SPECTER. Well, the agencies do not appear to be moving with much dispatch on it.

Mr. Swindell, in 1998 you requested a ruling regarding the Senior Biomedical Research Service. The Office of Government Ethics ruled that they could not be required to file public financial disclosure forms. Was there any attempt made to appeal that decision?

Mr. SWINDELL. I am not sure what appeal process there would be. The Office of Government Ethics is the interpreter of those regulations.

Senator SPECTER. Is there no appeal process from what the Office of Government Ethics rules?

Mr. SWINDELL. I am not aware of any, Senator.

Senator SPECTER. Ms. Glynn, on January 12 of this year, Mr. Swindell wrote to you requesting that NIH institute directors, deputy directors, and scientific and clinical directors be classified so that they would have to file public financial disclosure forms. Would not at minimum those individuals fit into the category of the kind of responsibilities which would warrant public disclosures?

Ms. GLYNN. I am assuming the answer to that is yes, sir. We are seeking additional information from NIH specifying exactly what positions are being asked for. At OGE, we are not as familiar with the terminology used in Mr. Swindell's letter as perhaps your committee is. But yes, I think the answer is yes. I think at a minimum those people would fall within the criteria.

Senator SPECTER. Mr. Swindell, would you take a look at the positions generally and make a determination from your point of view as to whether that is adequate or how far down you could go in meeting the standards which Ms. Glynn identifies?

The Congress really does not want to get into this, if we do not have to, to micro-manage what you are doing, but I think that there are really major problems here. The first line is to have transparency with a public disclosure so that people can see what is going on.

You have got an enormous job taking up several hundred cases of individual investigations, and this subcommittee is prepared to do it if you do not and we are prepared to get into the changes of law if you do not come up with something which is adequate.

Dr. Kirschstein, after the Office of Government Ethics issued its audit report in 1995 and found that the NIH outside activities compensation guidelines were "broader in scope" than provided by the executive branch standards, what role, if any, did you play in setting new NIH policies regarding consulting arrangements?

Dr. KIRSCHSTEIN. Mr. Chairman, at the time there were two deputy ethics counselors in the Office of the Director. One was the Director of the Office of Human Resources Management and the other one was I. The report went to the Director of the Office of Human Resources Management who worked with Dr. Varmus and presented to him some options and some decision points as to whether or not the NIH could ask for some supplemental regulations or enforce what the Office of Government Ethics requested. And Dr. Varmus made the decision to go forward. I was not involved in that decision.

Senator SPECTER. Have you completed your answer, Dr. Kirschstein?

Dr. KIRSCHSTEIN. Yes.

Senator SPECTER. Thank you.

Well, thank you very much. There are many, many more questions. We may submit more inquiries in writing. We have another panel and we are about to have a vote on the cloture on the omnibus appropriations bill at noon. So that will conclude panel two. Thank you all very much.

We now call panel three: Dr. Stephen Katz, Dr. John Gallin.

STATEMENT OF STEPHEN KATZ, M.D., Ph.D., DIRECTOR, NATIONAL INSTITUTE OF ARTHRITIS AND MUSCULOSKELETAL AND SKIN DISEASES, NATIONAL INSTITUTES OF HEALTH, DEPARTMENT OF HEALTH AND HUMAN SERVICES

Senator SPECTER. Dr. Katz was appointed Director of the NIH Arthritis and Musculoskeletal and Skin Diseases in 1995. He joined NIH in 1974 as a senior investigator at the Dermatology Branch. A bachelor's degree from the University of Maryland, M.D. from Tulane University Medical School, and Ph.D. in immunology from the University of London in England. Dr. Katz, we welcome you here and look forward to your testimony.

Dr. KATZ. Thank you very much, Mr. Chairman. As you said, I am the Director of the National Institute of Arthritis and Musculoskeletal and Skin Diseases and a senior investigator in the Dermatology Branch of the National Cancer Institute. I am a dermatologist, an immunologist, and a research scientist.

I have devoted almost 32 years, my entire medical and scientific career, to public service and believe that I have done so in a manner that reflects the highest integrity.

The issue of the relationship of the NIH and its senior—indeed, all of its scientists to private industry is important for public reflection and discussion. I share Dr. Zerhouni's view that the NIH must uphold the highest standards for scientific excellence and ethical practices.

I have prepared a written statement that addresses specifically and in detail the allegations and insinuations that were contained in the LA Times story and request that it go into the record.

I want to emphasize that I have always conducted myself in full compliance with NIH's rules and regulations, that I have always sought and received official Government permission to undertake these consultations, that I properly and in writing recused myself from contacts with the companies with which I consulted, that as an NIH employee, I made no decisions affecting any company for which I consulted, that I fully and publicly reported all income earned from outside consulting, and that Government-supported research was not influenced as a consequence of my consulting agreements.

It is in this context that the allegations presented in the LA Times article must be considered. These allegations of misconduct on my part are misleading, grossly inaccurate, and filled with false innuendo. The manner in which the story misrepresented my actions deliberately led the reader to an entirely false impression about my conduct. Indeed, the Associated Press, as well as other news media, were misled by the manner in which the article described my actions. They issued apologies, corrections, and/or letters in response to my identifying the misleading nature of the LA Times story.

With respect to my consultation with Schering AG's Center of Dermatology in Berlin, Germany, the LA Times story identified a gap in the NIH recusal process. Although I had recused myself from all matters relating the Schering AG, NIH had no mechanism in place to identify subsidiaries or affiliated entities to the companies from which NIH staff had recused themselves.

Then, when a drug supplied by Berlex, a U.S. subsidiary of Schering AG, was used in the lupus study, no one at NIH, including myself, linked U.S.-based Berlex to its German parent, Schering AG, for purposes of applying the recusal process. As a consequence, the usual procedures which prevented anything identified as a matter related to Schering AG from reaching me failed to operate with respect to issues related to Berlex.

As I said earlier, I have discussed the three instances in which I had contact with this lupus trial in my written testimony.

PREPARED STATEMENT

Notwithstanding this gap in the recusal system and despite the sensational and wholly inaccurate impression the LA Times sought to create, I did not make any substantive decisions which affected the Berlex company or the lupus trial conducted under its sponsorship.

I do appreciate the opportunity to appear before this committee to set the record straight, and I am happy to answer any of your questions.

[The statement follows:]

PREPARED STATEMENT OF DR. STEPHEN I. KATZ

Mr. Chairman, Senator Harkin, and Members of the Committee: I am Stephen I. Katz, M.D., Ph.D., Director of the National Institute of Arthritis and Musculoskeletal and Skin Diseases (NIAMS) and Senior Investigator in the Dermatology Branch of the National Cancer Institute (NCI). I am a dermatologist, an immunologist and a research scientist. My research has been focused on basic and clinical studies related to the skin and the immune system.

I have devoted my entire medical and scientific career to public service and have done so, I believe, in a manner that reflects the highest integrity, first in the U.S. Army and, for almost the last 30 years, at the NIH. For 24 of these years, I was Chief of the Dermatology Branch of NCI and for six of these years, I served as both Dermatology Branch Chief and Director, NIAMS. During 12 of these years (1983–1995), I also served as the Marion Sulzberger Professor and Acting Chair of Dermatology at the Uniformed Services University of the Health Sciences.

During my nearly 32 years of public service, I have focused my research efforts on enhancing our understanding of how skin functions as an immunologic and inflammatory organ system and how it becomes a target for autoimmune diseases. I have trained more than 60 research dermatologists, almost half of whom now serve as Deans of medical schools or Professors and Chairs of Dermatology Departments in leading centers in the United States, Europe, and Asia. I have received many awards and honors from both governmental and non-governmental organizations, including the President's Distinguished Executive Award of the Senior Executive Service.

In my role as a physician, scientist and leader at the NIH, I have had numerous interactions with scientists in the private and public sectors, including those in industry, and have always abided by governmental rules regarding such contacts. I have consulted with industry at various times beginning in 1986, when such interactions between government and industry were encouraged by then President Reagan to promote technology transfer from government to the private sector.

When I became Director of the NIAMS in 1995, I conferred with NIH ethics officials and, on their advice, stopped all of my consulting activities. In late 1995, I was informed that a new policy had been adopted by the NIH, initiated by then Director Harold Varmus, which again permitted such consulting arrangements. Thereafter, I began to accept consulting relationships on a limited basis. However, recently, in response to Dr. Zerhouni's outside activity approvals memo of November 20, 2003, and in keeping with the spirit in which it was written, I elected to terminate my one remaining outside consulting agreement.

These consultations utilized my global knowledge as both a dermatologist and a basic scientist and, as required, were conducted outside of my government work schedule. The consultations dealt with a broad range of subjects, but were most often focused on my critiquing the activities that the company was undertaking to

address a given clinical or basic science issue and suggesting new or varied approaches. In no instance did I ever discuss, with any company for which I was consulting, any research that it might be conducting with the NIH or any application it had submitted to the NIH for funding. Although I had many opportunities for consulting, I undertook such consultations only if the issues were of intellectual interest to me, I felt that I could contribute scientifically and the agreements would not create unavoidable conflicts of interest that might interfere with my duties at NIH. These consultations provided me with an in-depth knowledge of how industry functions knowledge that has helped me in carrying out my responsibilities at the NIH and especially as NIAMS Director.

I wish to emphasize that I have always conducted myself in full compliance with NIH's rules and regulations; that I have always sought and received official government permission to undertake these consultations; that I properly and, in writing, recused myself from contacts with the companies with which I consulted; that, as an NIH employee, I made no decisions affecting any company for which I consulted; that I fully and publicly reported all income earned from outside consulting; and that government-supported research was not influenced as a consequence of my consulting agreements.

It is in this context that the allegations presented in the LA Times December 7, 2003, article must be considered. These allegations of misconduct on my part are misleading, grossly inaccurate, and filled with false innuendo. The manner in which the story misrepresented my actions deliberately led the reader to an entirely false impression about my conduct. Buried within the innuendos are the facts—that I always conducted myself in accordance with government regulations; that I recused myself where appropriate; that I made no decisions regarding the companies for which I consulted; and that I reported all outside income. However, the carefully crafted story paints a very different and entirely inaccurate picture.

Within days of the article's publication, Slate Magazine took the LA Times to task for "choosing to furtively prod the reader" to conclusions about my conduct that were not justified by the facts. Even as sophisticated a reader as The Associated Press was misled by the way the article described my actions and was required to issue a formal correction of its story on the article. In addition, other newspapers, such as the Charleston, W. Va. Gazette and the Pittsburgh Post Gazette, picked up the LA Times story, were also misled by the way it was written, and they issued apologies, corrections or letters in response to my identifying the misleading nature of the LA Times story.

The LA Times story raised questions about my relationship with two companies, Advanced Tissue Sciences and Schering AG.

On the matter relating to Advanced Tissue Sciences, I had recused myself and made no decisions regarding their application or grant. In keeping with NIH policies, the recusal was sent to the Deputy Director for Extramural Research at NIH, who had responsibility for making decisions regarding this company.

With respect to my consultation with Schering AG, the LA Times story identified a gap in the NIH recusal process. Although I had recused myself from all matters relating to "Schering AG," NIH had no mechanism in place to identify subsidiaries or affiliated entities to the companies from which NIH staff had recused themselves. Then, when Berlex, a U.S. subsidiary of Schering AG, undertook to help support a lupus study, no one at NIH linked U.S.-based Berlex to its German parent company Schering AG for purposes of applying the recusal policies. As a consequence, the usual procedures which prevented anything identified as a matter related to Schering AG from reaching my desk, failed to operate with respect to issues related to Berlex.

Notwithstanding this gap in the system, and despite the sensational and wholly innacurate impression the LA Times sought to create, I did not make any substantive decisions which affected Berlex or the lupus trial conducted with its drug.

Because of the misleading emphasis given by the LA Times to my three contacts with the lupus trial, I will review these in detail for the record:

1. I signed a form letter acknowledging a gift to the NIAMS from Berlex: As Director, I routinely sign such thank you notes drafted by others. This gift was negotiated by another NIAMS employee without my knowledge or involvement, and followed the usual administrative clearance procedures through the NIH technology transfer experts. Significantly, at the time I signed the letter, neither I nor any NIH staff handling my recusal were aware that the thank you note was addressed to a subsidiary of a company for which I was consulting. I was consulting for Schering AG's Center of Dermatology in Berlin, Germany—the subsidiary company had a different name (Berlex) and, at that time, did not have anything to do with dermatology or products related to the skin. In fact, I did not become aware that it was

a Schering AG subsidiary that had supplied one of the drugs used in the lupus trial until the LA Times made inquiries to me about these issues.

2. With regard to the lupus nephritis trial, I had no role in conceiving, initiating or overseeing the trial. I made no decisions about how the results were to be reported or what the NIH's response should be to the patient's death. When the patient died, as Director, I was notified by the NIAMS Clinical Director, Dr. Jack Klippel, who told me that actions were being taken to determine the cause(s) of death. Standard NIAMS procedure following an adverse event required the Clinical Director, not the Institute Director, to make all necessary decisions and take any actions required subsequent to the event. As the most knowledgeable person about the trial, Dr. Klippel was the appropriate person to take action. Of importance for our purposes here, is the fact that at that time, neither he nor I discussed or focused upon who had manufactured the drug utilized in the trial, let alone whether it was provided by a subsidiary of a company for which I was consulting. Consistent with NIH procedures, no decisions were made by me during that conversation. The author of the LA Times article knew this and that is why he included only that "Steve Katz was notified almost immediately," without expanding on what he (the author) learned in his conversation with Dr. Klippel. In fact, and also known to the LA Times, studies using the drug in question for lupus nephritis had been undertaken at the NIH, and by the NIAMS in particular, long before I ever became Director of the NIAMS.

3. In April 2000, Dr. Peter Lipsky (the NIAMS Scientific Director) told me that there was going to be a newspaper report on the death of the patient in the lupus nephritis trial, and that in his opinion, possible litigation might follow. We thereupon met with Dr. Ruth Kirschstein, then Acting Director of NIH, who told us to refer all calls to the Office of General Counsel. At that meeting, none of us discussed the company that had manufactured the drug in question, and certainly not that it bore any relationship to a company for which I was consulting. Most importantly, no decisions were made by either Dr. Lipsky or myself at that meeting.

Thus, notwithstanding that the recusal process failed to exclude me from three contacts with a matter related to Berlex, most important to this hearing, is that no substantive decisions related to this lupus trial were made by me, despite the misleading insinuations contained in the LA Times story.

In sum, in my three brief contacts with this trial, I was unaware that it bore any relationship to a company with which I was consulting. I had no role in the conception or initiation of the lupus nephritis study, was not advised that it was ongoing, and had no role in overseeing its conduct or in how the results were reported or in what the NIH's response should be to the patient's death. All decisions were made in accordance with established procedures by people other than me.

Of note, in preparing my response to the LA Times article, I learned that Dr. Michael Gottesman, NIH Deputy Director for Intramural Research, was informed by the NIH Office of Human Subjects Research that the death of the patient in the lupus trial was properly reported to regulatory authorities by the NIAMS and promptly reported to the Food and Drug Administration and to the National Institute of Allergy and Infectious Diseases (NIAID) Institutional Review Board, the review group that was overseeing this study. Decisions regarding the notification of other patients in the study and whether the study should be continued or not were solely those of the principal investigators and the NIAID Institutional Review Board. In addition, the DHHS Office for Human Research Protections (OHRP), on February 27, 2002, reported that, upon examination of this study, it found no evidence that the investigators and the NIAID Institutional Review Board failed to ensure the safety of the research subjects, as required by DHHS regulations.

I share Dr. Zerhouni's view that the NIH must uphold the highest standards for scientific excellence and ethical practices, and believe that my career in government service has been exemplary in this regard.

While the issue of the relationship of the NIH and its senior scientists to private industry is an important topic for public reflection and discussion and while this is a legitimate and appropriate issue for debate in the media, I believe that it is entirely improper and unfair of the LA Times to have maligned my character and misrepresented my actions in focusing attention on this topic.

I am pleased to have had the opportunity to appear before the Committee to publicly set this record straight and will be happy to answer any questions you may have.

STATEMENT OF JOHN GALLIN, M.D., DIRECTOR, CLINICAL CENTER, NATIONAL INSTITUTES OF HEALTH, DEPARTMENT OF HEALTH AND HUMAN SERVICES

Senator SPECTER. Thank you very much, Dr. Katz.

We now turn to Dr. John Gallin, Clinical Center Director, and NIH Associate Director for Clinical Research in 1994. Prior to his appointment, he served as Director of the Division of Intramural Research at the National Institute of Allergy and Infectious Disease. A graduate of Amherst College, M.D. from Cornell University Medical School.

I am advised that we have present with us today Dr. Ronald Germain and Dr. Jeffrey Schlom. While they were not originally listed as witnesses, if they care to speak, they will be welcome to do so at the conclusion of Dr. Gallin's testimony. Since there had not been any prior notice, there is no requirement that they speak, but if they want an opportunity to testify, the subcommittee would be glad to hear them.

Dr. Gallin, thank you for joining us, and we look forward to your testimony.

Dr. GALLIN. Thank you, Mr. Chairman.

As you said, I am a physician and it has been my privilege to be an employee at the NIH for now over 31 years, and as you said, I am currently the Director of the Clinical Center.

I have submitted my full statement for the record, if that is okay with you.

Senator SPECTER. That will be made a part of the record in full.

Dr. GALLIN. Thank you. I would like to briefly summarize it.

As Director of the Clinical Center, my job is to ensure that the Clinical Center provides a safe environment for patients volunteering to serve in our clinical research studies. My personal research has focused on children and adults with inherited abnormalities of the white blood cells. Our work has included developing new therapies for our patients. One therapeutic approach of our laboratory is gene therapy, to put a normal gene in our patients' cells and correct the defect.

The December 7, 2003 LA Times article by David Willman included a side bar about me. Unfortunately, a key aspect of this side bar showed a fundamental misunderstanding of the relevant facts. In his article, Mr. Willman claims a conflict of interest existed between my laboratory activities related to a gene therapy study and a company called Cell Genesys. Mr. Willman ignored important historical and chronological information that I provided to him on two occasions. Let me briefly review the historical facts.

In October 1994, we initiated a contract with a company called Somatix to develop a viral vector to carry a normal gene into our patients' cells. The vector was made and the last patient received the treatment in December 1995. The patients were then followed for a year.

A manuscript describing our findings was completed in June 1997 and submitted for publication on July 1997, ending our relationship with Somatix.

In June 1997, 18 months after we administered gene therapy to our last patient and after our manuscript was ready for submission for publication, Somatix was bought by Cell Genesys. Cell Genesys'

leadership insisted that we recognize their company in our manuscript even though the research project was completed before they acquired Somatix. Because we were informed that we were obligated legally to honor their request, Cell Genesys was recognized in the front of the paper. In protest, however, we added a footnote at the end of the paper which stated that the industrial collaborator in the project was Somatix Therapy Corporation.

The committee should know that these facts were shared with Mr. Willman before he wrote his December 2003 research article.

In September 1997, I was asked to join the scientific advisory board of a new company, Abgenix, a spinoff of Cell Genesys. I should emphasize again that Somatix and Cell Genesys were not affiliated at any time during our gene therapy study. Therefore, there was no conflict between my consulting work for Abgenix and my laboratory's clinical research study done with Somatix.

My consulting for Abgenix was the first and only time during my 31 years at NIH that I agreed to serve on a scientific advisory board for a company. Importantly, all my activities were approved by the senior NIH leadership as compatible with NIH policy.

PREPARED STATEMENT

To conclude, Mr. Chairman, I am proud of my service at NIH. I am proud of the progress we are making at the Clinical Center. The December 2003 LA Times article strongly implied that my consulting relationship with Abgenix was a conflict with Cell Genesys because of my laboratory's relationship with a third company Somatix. As I have explained above, I want the committee to know that Somatix was acquired by Cell Genesys well after my laboratory completed studies using the Somatix viral vector. There was simply no connection between my membership on the scientific advisory board of Abgenix and the gene therapy study.

Thank you for the opportunity to testify today and to clarify the facts.

[The statement follows:]

PREPARED STATEMENT OF DR. JOHN I. GALLIN

Mr. Chairman and Members of the Committee: I am Dr. John I. Gallin. I am a physician and it has been my privilege to be employed by the National Institutes of Health for over 31 years. Thank you for inviting me here today to discuss important issues related to NIH.

During my career at NIH I have served 8 years as Scientific Director of the National Institute of Allergy and Infectious Diseases (NIAID) and ten years as Chief of the Laboratory of Host Defenses of NIAID.

In 1994, I was invited by the then Director of NIH to be Director of the Warren G. Magnuson Clinical Center. As Director of the NIH Clinical Center my job is to assure that the NIH Clinical Center provides a safe environment for patients volunteering for our research studies and that the necessary resources are available for the NIH institutes to carry out their intramural clinical research programs. Let me emphasize, I have no responsibility for the awarding or oversight of grants to the extramural community, including industry.

My research has focused on children with inherited abnormalities of the white blood cells called phagocytes. In addition to my administrative and research activities, I continue to care for children and adults with these rare diseases. Our work has ranged from the description of newly discovered diseases to defining their genetic basis and recently to developing new therapies. One therapeutic approach of our laboratory is gene therapy that attempts to correct the inherited defects in the patients' white blood cells.

On December 7, 2003 the Los Angeles Times published an article "Stealth Merger: Drug Companies and Government Medical Research" by David Willman that included a sidebar about me. Unfortunately, a key aspect of this sidebar showed a fundamental misunderstanding of the relevant facts. In his article Mr. Willman claims a conflict of interest existed between my laboratory activities related to a gene therapy study and a company called Cell Genesys. Mr. Willman ignored important historical and chronological information that I provided to him on two occasions.

A brief review of the historical facts follows.

In October 1994, my Deputy Laboratory Chief established a cooperative research and development agreement with a company called Somatix Therapy Corporation. This new biotechnology company specialized in designing viral vectors; we needed a viral vector to carry a normal gene into the adult stem cells of our patients. Specifically, the cooperative research and development agreement with Somatix Therapy Corporation was required to implement a protocol designed to correct the defect in children with a rare and devastating disease called Chronic Granulomatous Disease of Childhood. In early 1995, a vector prepared by Somatix Therapy Corporation was ready to give to patients and in spring 1995 the first patient with Chronic Granulomatous Disease was given gene therapy. In December 1995, the last patient in our study received gene therapy. The patients were followed for over a year to evaluate the response to the gene therapy.

In February 1997, my laboratory Deputy drafted the manuscript describing the findings. I was the last author of that paper. Like all NIH manuscripts, the draft paper went through intense internal review at NIH and was completed in June 1997. The manuscript was submitted for publication in the Proceedings of the National Academy of Sciences, USA early July 1997. In June 1997, eighteen months after we administered gene therapy to our last patient and after our manuscript was ready for submission for publication, Somatix Therapy Corporation was purchased by Cell Genesys. Following the purchase of Somatix Therapy Corporation, Cell Genesys leadership insisted that we recognize their company in our manuscript even though the research project was completed before Cell Genesys had acquired Somatix Therapy Corporation. Because we were informed that we were obligated legally to honor their request, Cell Genesys was recognized in the front of the paper. In protest, however, we added a footnote at the end of the paper, which stated the industrial collaborator in the project was Somatix Therapy Corporation. Again, the Committee should know that these facts were shared with Mr. Willman before he wrote his December 2003 article.

In September 1997, because of my general expertise in immunology and inflammation, I was asked to join the Scientific Advisory Board of a new company called Abgenix Inc., a spin off of Cell Gensys. At the time I was asked to consult for Abgenix Inc. I was not aware that there was some degree of ownership by Cell Genesys. But, I should note again that Somatix Therapy Corporation and Cell Genesys were not affiliated at any time during our gene therapy study. Therefore, there was no conflict between my consulting work for Abgenix Inc. and the clinical research study that my laboratory did with Somatix Therapy Corporation.

This was the first and only time during my career at NIH that I agreed to serve on a Scientific Advisory Board for a company. I agreed to serve on the Abgenix Inc. Scientific Advisory Board for several reasons: I thought Abgenix Inc. had an exciting vision; I was very impressed by the outstanding quality of the other scientists from the extramural community invited to serve on the Board; and, I thought serving on the Board would broaden my perspective in my area of scientific expertise and enrich and enhance my service to the NIH. Participating on the Abgenix Inc. Scientific Advisory Board did not represent a conflict of interest and I believed that it was consistent with other outside activities I participated in during my career at NIH. These other activities have included serving on the Scientific Advisory Board of the Rockefeller Brothers/Culpepper Foundation to select young medical scientist investigator awardees, volunteer service on the Medical Center Operating Board of the University of Virginia Hospital, serving as a co-editor of three editions of a text book Inflammation,or editing the text Principles and Practice of Clinical Research. Importantly, all my outside activities, including serving on the Scientific Advisory Board for Abgenix Inc., were reviewed by senior NIH leadership and approved as compatible with NIH Policy.

To conclude Mr. Chairman, I am proud of my service at NIH. I am proud of the progress we are making at the Clinical Center. The Los Angeles Times article, strongly implied that my consulting relationship with Abgenix Inc. was a conflict with Cell Genesys because of my laboratory's relationship with Somatix Therapy Corporation. As I have explained above, I want the Committee to know that Somatix Therapy Corporation was acquired by Cell Genesys well after my labora-

tory completed studies using the Somatix Therapy Corporation's viral vector. There was simply no connection between my membership on the Scientific Advisory Board of Abgenix Inc. and the gene therapy study.

Thank you for the opportunity to testify today about this important topic. I would be pleased to answer your questions.

Senator SPECTER. Thank you very much, Dr. Gallin.

We have asked Dr. Germain and Dr. Schlom if they would care to testify and both have responded in the affirmative. Would you gentlemen come forward?

STATEMENT OF JEFFREY SCHLOM, M.D., CHIEF OF THE LABORATORY OF TUMOR, IMMUNOLOGY, AND BIOLOGY, CENTER FOR CANCER RESEARCH, NATIONAL CANCER INSTITUTE, NATIONAL INSTITUTES OF HEALTH, DEPARTMENT OF HEALTH AND HUMAN SERVICES

Senator SPECTER. We will start with Dr. Schlom. Thank you for joining us. Staff had contacted both of you gentlemen yesterday asking for statements, and we had them. It seemed to me appropriate, since you were here, to give you an opportunity to speak, if you wish to do so. There are two other doctors who were not available when staff made efforts to contact, so of course, they cannot be included.

But we will turn now to you, Dr. Jeffrey Schlom, Chief of the Laboratory of Tumor, Immunology, and Biology at the Center for Cancer Research at the National Cancer Institute.

Dr. Schlom.

Dr. SCHLOM. Thank you. I just found out at 5 o'clock last night that I would be asked to be here, and I had not prepared any statement. I prepared something last night and early this morning at 6 a.m.

Senator SPECTER. When we saw exactly what was happening, it seemed to me appropriate to give you an opportunity. Again, I repeat, we are not asking you to. We are just making it a matter for your discretion.

Dr. SCHLOM. Fine.

I did prepare a detailed response to the allegations in the LA Times, which I had given to the NIH and NCI ethics officers. I do not know whether this has been forwarded to the committee. I have many copies here.

Senator SPECTER. We would be glad to make those a part of the record, if you request it.

Dr. SCHLOM. Yes.

I would just like to say that the allegations were misleading, grossly inaccurate, and there were many, many false innuendoes in the LA Times article. I have addressed each of these in this document which I can give you for the record.

[The information follows:]

RESPONSE TO THE INFORMATION IN THE L.A. TIMES ARTICLE CONCERNING J. SCHLOM

This is in response to allegations of "potential conflict of interest" made against me by Mr. Willman of the L.A. Times in his sidebar article of December 7, 2003. I provide below details of the inaccuracies in the article, as well as corroborating information from individuals involved in this matter which substantiates that I was wrongfully accused of a real, or even perceived, conflict of interest involving the use of the drug Taxol.

1. I was a consultant for Cytoclonal from June 1992 to March 2002. I filed all the appropriate NIH Outside Activity forms and subsequent disclosure information as

a then member of the SES and now a Title 42 employee. The approved HHS 520 Form stated, "Cytoclonal Pharmaceuticals Inc. is interested in becoming involved in the area of biotechnology and the use of monoclonal antibodies for the diagnosis and therapy of a range of human cancers. Dr. Schlom is being asked for advice and to evaluate their present and proposed programs in these areas." That is exactly what I did.

2. There were never any discussions concerning the drug Taxol, or the recombinant microbial form that I believe they were trying to develop at Cytoclonal. Personnel at Cytoclonal knew that that was not my expertise and it never once came up in all the years of my consulting for Cytoclonal.

3. In his e-mail to me of November 27, 2003, Mr. Willman states, "As a member of the SAB, you were privy to Cytoclonal's research and development program." He obviously drew his incorrect conclusions before I had a chance to respond. I immediately responded to Mr. Willman that I never attended a meeting of the Scientific Advisory Board and had absolutely nothing to do with their drug development program. He chose to ignore that in his article.

4. My only involvement with Cytoclonal was to give advice on immunotherapy reagents such as monoclonal antibodies, spending on average one-half day every 2 years working from my home on annual leave. Thus my contact with Cytoclonal was minimal.

5. The above items 2, 3, and 4 can be corroborated by Dr. Arthur Bollon, who was CEO of Cytoclonal for virtually the entire time I was a consultant. His e-mail address is arthurb@flash.net <mailto:arthurb@flash.net> and his telephone number is 469–585–7613. In a phone conversation with Dr. Bollon after the appearance of the L.A. Times article, he informed me that I was never under a confidentiality agreement concerning their recombinant "Taxol" development program, and therefore could not have had any conversations regarding it. This is corroborated by Dr. Bollon in an accompanying e-mail of December 15, 2003.

6. I never had stock in Cytoclonal, so the failure or success of any drug developed by the company would not have been of benefit to me.

The following involves the clinical trials side of the story.

7. My lab at NCI, NIH and I have had a long-standing and fruitful collaboration with one of the premier oncologists and Cancer Center Directors in the United States—Dr. Albert LoBuglio, Director of the University of Alabama at Birmingham Comprehensive Cancer Center. We have published 19 papers together from 1991 to 2003 involving monoclonal antibodies developed in my lab and experimental and clinical studies conducted at the University of Alabama at Birmingham Comprehensive Cancer Center. As a research immunologist, my input in these studies involved the development of the antibodies. The clinical research designs and conduct of the trials were done by Dr. LoBuglio and his colleagues at the University of Alabama at Birmingham Comprehensive Cancer Center.

8. Taxol is an FDA-approved drug that is widely used throughout the world as a therapeutic for many different kinds of cancers. I had nothing to do with the clinical design of the studies whose results were published in the two papers cited by Mr. Willman in his L.A. Times article. These two studies used two different forms of a radiolabeled monoclonal antibody developed in my laboratory and various combinations of Paclitaxel/Carboplatin and Interferon [Clin. Cancer Res. 8:2806–2811, 2002] and Interferon/Taxol [Cancer Biother. Radiopharm. 16:305315, 2001]. In his L.A. Times article, Mr. Willman stated, "Schlom helped lead two NIH funded studies in which Taxol played a crucial role." This is another inaccuracy. I was not the Principal Investigator on either of these studies and I was neither the first author nor the last author on the publications involving either of these studies. I informed Mr. Willman that my role was minimal, as stated above, yet Mr. Willman chose to ignore it and indeed reported on it inaccurately. Dr. LoBuglio can be contacted to corroborate the above; his e-mail address is al.lobuglio@ccc.uab.edu <mailto:al.lobuglio@ccc.uab.edu> and his telephone number is 205–934–5077. Also see the accompanying e-mail of December 15, 2003, from Dr. LoBuglio.

9. Mr. Willman, in his L.A. Times article, neglected to mention the clinical benefit to patients reported in the papers cited. I wish I could take credit for this, but it goes to Dr. LoBuglio and his colleagues at the University of Alabama at Birmingham Comprehensive Cancer Center. Mr. Willman also chose to ignore the fact that I am an intramural NCI scientist, and I am not involved in any extramural policy decisions.

10. In the opening sentence of his article, Mr. Willman states, "Jeffrey Schlom has built a busy outside career as a consultant." The inference here is that I am spending a lot of time as a consultant. This is also inaccurate. My consulting for all companies usually totals no more than 2 to 4 days per year, during which I take annual leave. I always have many days and sometimes weeks of unused annual leave at

the end of the year. I work 10–12 hours per day and at home evenings and weekends on my NIH duties. Any inference that I am not an extremely dedicated NIH employee is thus also unfounded.

11. Another point for consideration: The "Taxol" agent that was being developed by Cytoclonal was in some sort of microbial vector (I am still not clear what they were actually doing). However, if this agent was ever to be a drug, it would have to be analyzed as a different form of "Taxol" in terms of toxicity, pharmacology, and clinical activity. That drug would then actually be a competitor with "Taxol" as it is now known. Thus, the drug that would be developed by Cytoclonal would actually be a competitor with the drug(s) used in the University of Alabama at Birmingham Comprehensive Cancer Center study. How Mr. Willman conjured an even perceived conflict of interest here thus defies logic, unless there is a predefined agenda.

12. Finally, I welcome a complete review of this matter and a report of its conclusions. I will be happy to meet with any NIH official regarding this matter at any time. I feel it is extremely important to clarify the inaccuracies and innuendos in the Willman article, which is all over the Internet. Where do I go to get my reputation back?

JEFFREY SCHLOM, PH.D.
December 15, 2003.

From: Arthur Bollon [abollon@hemobiotech.com]
Sent: Monday, December 15, 2003 3:54 P.M.
To: Schlom, Jeffrey (NIH/NCI)
Subject: Bollon

JEFFREY SCHLOM: I received your e-mail concerning the LA times article. To clarify, I can confirm without any question that your consultation with Cytoclonal was for advice on immunology and monoclonal antibodies since we had several monoclonal antibodies under development for diagnosis and/or treatment of cancer. You were not involved in the Taxol program of the company which was focused on an improved way to make it and was not related to your expertise. Furthermore we had a confidential relationship with a phrmaceutical company for this program and you were not included. You did not receive options for your services and you consulted by phone conversations or individual meetings. You did not participate in group advisor meetings.

ARTHUR P. BOLLON, PH.D.,
Former President & CEO, Cytoclonal Pharmaceutics, Inc.

From: Lobuglio, Albert
Sent: Monday, December 15, 2003 5:11 PM
To: Schlom, Jeffrey (NIH/NCI)
Subject: Jeffrey Schlom/UAB Collaborations

TO WHOM IT MAY CONCERN: The Targeted Immunotherapy Program, which I direct at the University of Alabama at Birmingham Comprehensive Cancer Center, has had a longstanding collaboration with Dr. Jeffrey Schlom of the National Cancer Institute. This collaboration has involved studies relevant to the use of monoclonal antibodies as therapeutic agents in patients with cancer. Dr. Schlom has originated a variety of antibodies that we have been able to take into phase I and phase II clinical trials.

Regarding the recent *LA Times* article regarding potential conflict of interest, the clinical trials referred to involve phase I/II trials in patients with ovarian cancer at our Cancer Center. These trials, as well as preceding clinical protocols, have involved the therapy of patients with recurrent ovarian cancer using the intraperitoneal administration of radiolabeled CC49 monoclonal antibody. This antibody was derived by Dr. Schlom's laboratory at the National Cancer Institute, and he has played a pivotal role in our development of this antibody through his knowledge of the pre-clinical and molecular studies carried out in his laboratory. Because of his interaction with us regarding this antibody, we have routinely included him as a co-investigator on our clinical protocols, as well as co-author on manuscripts utilizing the reagent.

As indicated in the *LA Times* article, our most recent two protocols utilized a single administration of Taxol in addition to the radiolabeled antibody to take advantage of its well known radiation sensitizing effects. The decision to embark on this additional component of the therapeutic regimen was derived from discussions with-

in our own research group and did not involve Dr. Schlom. Dr. Schlom did not provide any leadership regarding these two funded studies and had no role in our internal discussions regarding the choice of a radio-sensitizing drug. His inclusion as a co-author reflected his long-term participation in our CC49 studies.

I have no insight or knowledge of Dr. Schlom being a consultant to Cytoclonal Pharmaceutics Inc or the same company under other names and have never heard any discussion from Dr. Schlom regarding either the company or its products. I do not believe that there is any credibility to the proposition that Dr. Schlom influenced our clinical trials to use Taxol for the purpose of enhancing any company's business plan or commercial development. My longstanding interaction with Dr. Schlom has reflected a highly professional and ethical approach to laboratory and clinical research.

ALBERT F. LOBUGLIO, M.D.,
Director, Comprehensive Cancer Center.

STATEMENT OF RONALD N. GERMAIN, M.D., CHIEF, IMMUNOLOGY LABORATORY, INSTITUTE OF ALLERGY AND INFECTIOUS DISEASES, NATIONAL INSTITUTES OF HEALTH, DEPARTMENT OF HEALTH AND HUMAN SERVICES

Senator SPECTER. Dr. Germain, Chief of Immunology Laboratory at the NIH Institute of Allergy and Infectious Diseases. Dr. Germain, we would be pleased to hear from you, but again, it is a matter of your choice as to whether you would like to say some things about the allegations.

Dr. GERMAIN. Thank you for the opportunity, Mr. Chairman. I will not take much of the committee's time. I concur with all of my colleagues about the level of inaccuracies and innuendoes, and I will provide a written document for the committee and for the record.

But since you also specifically mentioned earlier a particular matter having to do with my case, I think I do want to address that very briefly here.

The LA Times article indicated that I accepted funds for the research of my laboratory at NIH from companies with whom I had a consulting and paid arrangement. That is absolutely false. Those monies went to other independent tenured investigators in the larger department in which I work. I had no connection to the receipt of those funds, and they had nothing to do with my NIH activities.

[The statement follows:]

PREPARED STATEMENT OF DR. RONALD N. GERMAIN

In response to the opportunity afforded me by the Chairman of the Committee on Appropriations, Subcommittee on Labor, Health and Human Services, Education, and Related Agencies, I am submitting this document for the record in connection with the Committee's questions arising from the December 7, 2003 article in the LA Times regarding consulting activities by NIH employees.

For the past 21 years I have been a scientist at the National Institute of Allergy and Infectious Diseases (NIAID), leading a research team investigating the basic functioning of the immune system at the cellular and biochemical levels. During this time I was appointed Chief of the Lymphocyte Biology Section within the Laboratory of Immunology (LI) of the NIAID and in 1994, also took on the role of Deputy Chief of the LI. During my time at NIH, I have received the NIH Directors Award (1986), the PHS Superior Service Award (1989), the DHHS Distinguished Service Award (1994), and the Meritorious Rank Award, Senior Executive Service (2000). These were received in recognition of both the substantial fundamental research accomplishments of my laboratory and the larger institutional contributions I have made in support of the NIH and DHHS mission.

In addition to the direct contribution to biomedical knowledge arising from the research program I lead at NIH, other mechanisms permit me to use my scientific insight to help improve human health. As I wrote in response to the initial reporter

inquiry leading to the LA Times article at issue here, outside consulting ". . . allows me to use my overall/general scientific expertise [not the specific findings of my lab at NIH] to further biomedical progress in ways that I cannot do within my own laboratory. I conduct only basic research using mouse model systems, which is what my training and experience best equips me to do . . . my general insight into immunology and related biomedical sciences can be used to help develop new drugs and treatments for Americans through the work of private biotechnology companies for whose R and D programs I provide advice. It [also] allows me to gain insight into the practical issues involved in clinical research and drug development, matters that I would know nothing about if my only frame of reference were my NIH laboratory . . . This perspective is different from that of either purely basic investigators or of clinical investigators—the former lack the first-hand knowledge of how development proceeds that I acquire when I consult and the latter have a vested interest in the process that I do not, allowing me a more objective position during discussions."

Based on this rationale, I have engaged in outside consulting activities with drug companies and biotechnology firms as permitted by existing NIH and Federal rules and regulations, providing review of and guidance for translational research programs that seek to create new treatments for human disease, in a manner that will not tarnish the well-deserved reputation of NIH.

It is in this context that the article published in the LA Times on December 7, 2003 is especially disturbing. The section of the article dealing with my conduct in inaccurate, misleading, and makes charges or contains implications that are completely false. The author was well aware of the true circumstances related to the issues raised in the article, but either ignored these facts or presented them in a manner that leads the reader to draw highly erroneous conclusions. Beyond the information available to the author from public records, I also provided detailed answers to his questions that pointed out how NIH and other applicable regulations had been followed in all my activities, and I also volunteered to vet the draft article for accuracy, an offer that was declined. The result was a set of allegations of improper behavior that were not based on the true facts of the relevant matters and a report containing a number of substantial inaccuracies about my income from these activities.

The most serious of the allegations state that I have ". . . taken fees from a company collaborating formally on research with his laboratory. In 2001, Genetics Institute and Germain's lab entered a formal collaboration called a cooperative research and development agreement, or CRADA, to study the effect that genes have on the immune system." It also states that "Alexion collaborated with Germain's lab from 1993 to 1997 under a CRADA. Germain became a paid consultant to Alexion in 1998, about a year after his lab finished collaborating with the company." These charges that I received both support for research conducted at NIH and personal consulting fees from the same outside entity are false and specifically crafted to be misleading. In both of these cases, the indicated research agreements (CRADAs) were with other scientists who headed independent research programs within the Laboratory of Immunology at the NIAID. The article similarly disguises the reality that other cited "relationships" between my Institute (NIAID) and various companies for which I consulted involved either independent investigators in different departments or the award of extramural funding, which is completely separate from the activities of intramural researchers such as me.

The article also leaves the impression that I recently chose to remove my consulting activities from public view. In fact, the change in my financial reporting automatically accompanied a shift in my employment position between Government pay systems, and I learned of this change only after the reassignment. The implication that I took direct action to hide my finances from public scrutiny is thus a clear misrepresentation, as I made the change without consideration of whether or not public reporting of my finances continued. I have never objected to, nor do I now object to the appropriate public disclosure of my outside activities or associated income.

Finally, while it is correct that I have earned a substantial amount in aggregate over many years through consulting (always done in accord with NIH regulations and with what I believe are benefits for U.S. public health), the numbers cited in the article for this income are inaccurate and inflated. In the interest of full financial disclosure (which the article quite wrongly implies NIH and its scientists seek to avoid), I was instructed by the NIAID Deputy Ethics Officer to report not just the previous calendar year's income, but all income earned up the time of filing, typically late May of the subsequent year. The latter amount was of course included again on the following year's form as part of the preceding calendar year's income. Because this contemporaneous reporting is not strictly required by the instructions

accompanying the 278 disclosure form, and because the author of the article failed to accept my offer to check the accuracy of the article, the putative cash compensation reported in the story is based on counting a substantial fraction of my income twice for the 11 years examined. The result is the inflation of the correct amount by hundreds of thousands of dollars. These same errors affect the specific claims made in the article about income in any given year or in aggregate from a particular company. Furthermore, the amount suggested as the value of stock options is also inaccurate, apparently arising from the assumption that all such options were fully vested and sold at the market peak for each stock. This is far from the truth, and in this case, the actual amount realized to date from the exercise of such options is only about one-fourth of the figure cited. By these two routes the article exaggerated my total realized outside compensation by nearly $1 million, a serious matter when the headline for my section of the article is intended to get the reader's attention specifically because of the dollar amount involved.

It is one thing to legitimately raise concerns about possible conflicts of interest in the outside activities of some NIH employees, sharing as I do with Dr. Zerhouni the view that the conduct of all NIH employees much be of the highest standard and visible for public scrutiny. It is another to use sensationalism at the expense of truth. I have worked hard for over 30 years to help medical science gain a deeper understanding of the immune system, earning during this time what I believe is a well-justified reputation for scientific as well as personal honesty and integrity. It is difficult to understand how a newspaper like the LA Times did not feel compelled to better vet the factual elements in its stories and prevent the unjustified tarnishing of something as valuable as a reputation. A similar concern also extends to the unwarranted general disparagement of NIH and its employees that such misleading reporting engenders. I note that my attempts to get the LA Times to correct the inaccuracies in its reporting were rebuffed.

I thank the Chairman and the Committee for the opportunity to comment on this important matter and to correct the substantial misinformation contained in the newspaper article about my conduct as a Federal employee at the NIH.

Senator SPECTER. Thank you, Dr. Germain.

Dr. Gallin, where there is an arrangement for consultation with a company and there are payments made for being a consultant and the interests of the company touch on research which a doctor does at NIH and the doctor, further, is a shareholder, which I believe you were of Cell Genesys, how do you structure the arrangement to avoid either a conflict of interest or the appearance of a conflict of interest on those facts?

Dr. GALLIN. Let me try to respond to that.

Senator SPECTER. I am going to ask the same question for each of you gentlemen.

Dr. GALLIN. In my case I did not think there was a conflict of interest because, as my written statement shows, my serving as a consultant to Abgenix was unrelated to Cell Genesys. I never had a relationship with Cell Genesys. The Somatix project on gene therapy occurred before Cell Genesys bought Somatix.

Senator SPECTER. Did any of the research which you had done touch on work which the company was interested in?

Dr. GALLIN. Not to my knowledge. Only in the broad sense of my expertise in immunology and inflammation, not in my individual laboratory's activities.

Senator SPECTER. So there was nothing you did for NIH which was of value to the company for which you were paid as a consultant?

Dr. GALLIN. Not to my knowledge.

Senator SPECTER. Dr. Katz, in a context of being a consultant where NIH pays a doctor, a research specialist, how can you avoid the issue of conflict or at least the issue of appearance of conflict?

Dr. KATZ. So my commitment, in terms of consulting, has always been to provide advice. I have never done any research, never been

engaged in research with any of the companies that I have consulted for, and that advice is based on my global knowledge of dermatology and basic science.

Now, it is incumbent upon each of us not to provide companies any knowledge that is of a privileged nature. So that knowledge has to be gleaned from the public domain, and basically whatever is in the public domain is permissible to use as an assessment of what a company is doing or as a critique of what their laboratory programs are or of an assessment of whether something may relate to a clinical problem or not. So it was the global knowledge and advice that I provided to these companies. That you could say is quite different than my specific job, particularly my job in the NCI laboratory dealing with specific research endeavors that dealt with a cell called the Langerhans' cell and how it interacts with the immune system.

Senator SPECTER. Dr. Germain, here again, since you did not have a notice in advance, I am not pressing you to respond, but giving you an opportunity to respond if you choose to do so. What is your view of how you avoid a conflict or at least the appearance of conflict from the—or how do you put the wall between your fiduciary duties at NIH and what you may be asked by a company for whom you are a paid consultant?

Dr. GERMAIN. To reiterate what Dr. Katz just said, NIH has made it very clear to all its employees that we are forbidden from transmitting any private information coming from our own laboratory work to any of these companies, and all companies with whom I have any relationships are made very well aware of that not only in writing, but directly by me repeatedly. And it is very clear that those are not topics for conversation.

My interactions with them are very similar to Dr. Katz. I provide general advice often in areas that are very unrelated to the specific work of my very basic science laboratory. I do not conduct any clinical research. I do not do any drug research. My work has to do with cell biology and biochemistry in mice and not in humans, but I do help these companies with advice about moving the basic findings that exist in immunology into the clinic in exactly the ways that Dr. Zerhouni has pointed out, as a benefit to U.S. public health.

Senator SPECTER. We will give an opportunity to others who were identified publicly to submit statements and be included in this record.

Now, Dr. Germain, how do you view this issue of conflict and appearance of conflict? Dr. Schlom? Here again, your response is purely up to you.

Dr. SCHLOM. Well, my wife told me before I came here not to say anything I did not have to.

I just feel compelled to say the following things.

Senator SPECTER. In that event, Dr. Schlom, I withdraw the question.

Dr. SCHLOM. Are you serious?

Senator SPECTER. Was your wife serious?

Dr. SCHLOM. Yes, she was.

Senator SPECTER. Then so am I.

Dr. SCHLOM. Okay.

Senator SPECTER. Go ahead, Dr. Schlom.

Dr. SCHLOM. I think it is really important to emphasize that the consulting that I have done—and by the way, I have never held stock in any company. It's just been a fee for services—has really taken only two forms, and it is to evaluate the scientific program of a given company or to evaluate a given technology that they are interested in. So I just give them advice on these issues.

This does not interfere in any way or overlap in any way with my official duties at the NIH, and I do not disclose to the organization any work or data that is conducted in my laboratory until it has been public for 1 year because that is the regulation. And the industrial organization has no proprietary interest in any of the work that I have ever done, and my laboratory has never ever worked on any agents developed by any organization that I have consulted with. I have been very, very careful in being very diligent in following these regulations.

Again, I probably should not say this, but I will say it anyway. Perhaps we should not believe everything we read in the newspapers.

Senator SPECTER. Dr. Gallin, do you think it would be appropriate to ask a man in your position to file a public financial disclosure statement?

Dr. GALLIN. Absolutely.

Senator SPECTER. Dr. Katz, would you think it appropriate for a person in your position to have a public disclosure of a financial statement?

Dr. KATZ. I have always disclosed publicly my income from all sources, including when my children were dependents, I have always disclosed their incomes as well.

Senator SPECTER. Do you think, Dr. Katz, it would be appropriate to ask researchers in the NIH who are paid consultants or hold stock in companies to have public financial disclosure statements?

Dr. KATZ. Sir, I believe in openness and transparency. I could not agree more with Dr. Zerhouni. Of course, one does not want to anticipate what the blue ribbon panel would come up with, but if you are asking for my personal opinion, I think that if one makes outside income, it should be transparent, and if you do not want to make it transparent, you should not do it in the first place.

Senator SPECTER. Dr. Germain, do you think it would be appropriate to ask researchers at NIH who are consultants who own stock in pharmaceutical companies to make public financial disclosure statements?

Dr. GERMAIN. I would just reiterate what Dr. Katz and Dr. Gallin have already said. All of us, to my knowledge, have always done that. I always have until very recently when the regulations changed, and I would be perfectly happy to do it again. I think that is true across the board.

Senator SPECTER. Dr. Schlom.

Dr. SCHLOM. The same.

Senator SPECTER. Dr. Gallin, do you think there would be a significant loss of researchers at NIH if there was a blanket prohibition against consulting fees or owning stock in a pharmaceutical company?

Dr. GALLIN. That is a very difficult question to answer. In my opinion, it would not be a favorable decision. But I believe that there should be some parity between the investigators who work at the NIH and investigators who work under NIH grants and the universities. I think the blue ribbon committee will have to think long and hard about that.

Could I just make a response to your previous question?

Senator SPECTER. Sure.

Dr. GALLIN. In your case reports, you were referring to me I believe about an example of a failure to disclose for 2 years on a stock, and I just would like, if it is okay, to tell you about that.

Senator SPECTER. Well, I did not so identify, but if you would care to comment, you are welcome to do so.

Dr. GALLIN. Thank you.

This referred to my wife's ownership of the Cell Genesys stock, and as I told Mr. Willman, the failure to disclose it—and as you pointed out—was in error. I just want to point out that the stock was purchased for my wife through a separate management account that was managed by a financial advisor who bought and sold stocks in her name. I did not realize back in 1999 that this stock was in her portfolio. When it became clear to me that it was in the portfolio, I disclosed it. That was in 2001. And it was an error and I totally apologize for it, but that's the facts.

Senator SPECTER. Thank you, Dr. Gallin, for that clarification.

Dr. Germain, do you think it appropriate to have somebody in your position or everybody at NIH—the issue which I want your opinion on is not that one now, but whether if there was a requirement for a prohibition against consulting fees or owning stock, would that cause NIH to lose their research scientists in a significant way?

Dr. GERMAIN. I do not think it is possible for me to predict how many people would leave, but I will comment on the fact that I think psychologically it will make many NIH scientists feel, in the way that Dr. Gallin has pointed out, second class citizens to some of their academic colleagues. And also more importantly, I believe it will deprive many NIH employees of the ability to participate in a productive way in furthering health care development in the ways that Dr. Zerhouni has outlined previously.

Senator SPECTER. Dr. Schlom, what is your view on that?

Dr. SCHLOM. I agree with what Dr. Germain said. I also think it would inhibit recruitment of new scientists because they have the ability to work at universities, obtain Government grants, and do consulting, and I think they would look at this as one more reason not to come to the NIH. I think these rules need transparency, need strengthening, et cetera, but I think it would be a mistake for a complete prohibition.

Senator SPECTER. Well, I think the hearing has been very productive. I believe that there has been a concurrence on the basic point about financial disclosures, which would be much broader than are currently required.

Dr. Katz, do you want to make another comment?

Dr. KATZ. Well, I did not know whether it was significant that you skipped over me in terms of providing an opinion about what

would happen at NIH if we were not allowed to consult in terms of scientists.

Senator SPECTER. I just wanted to see how anxious you were to weigh in on that.

Dr. KATZ. I think it is really important to understand——

Senator SPECTER. It is not easy to run all these hearings without a scorecard, and we do not work on a text.

Dr. KATZ. Betty Lou and I had some eye contact.

Senator SPECTER. I noticed that.

So every now and then we give you a break by not asking a question, but since you do not want a break, go ahead.

Dr. KATZ. So I just wanted to weigh in on that issue because it does get to the crux of what passion that many of the NIH scientists have, whether they are M.D.'s or whether they are Ph.D.'s. There are many Ph.D. scientists who have a passion to see what they are doing come to fruition for the betterment of humankind, and one of the ways that that actually happens is through some of these consultant agreements.

To draw a barrier, a Chinese wall, between Government and industry would, in my view, not be a good thing even forgetting about the consultant fees, but thinking about the importance of that translation and all of the brain power we have at NIH to provide some impetus for moving clinical medicine along in the translation of basic science into the betterment of humankind.

Senator SPECTER. Well, I am very much interested in your views on that as an evaluation which we are going to have to go into greater depth on as to the public policy advantages of having that kind of collaboration and interaction, also the factor of losing scientists. We will have to structure a system which maintains the wall of separation, fiduciary responsibility for the compensation.

But as I had started to say, I think the hearing has been very useful in covering the consensus on public disclosure without any complex definitions by the Office of Government Ethics, which I think has had too constrained a view.

Now we have the job of making individual inquiries, and we are a society which believes in individual rights and every individual has to be protected with a unique inquiry as to what has gone on. That is going to be a painstaking process.

But NIH has a very high level of respect in the United States and in the world, and we have shown you our high regard for you by financing, which is different for you than any other governmental agency. You have gotten more money because you are on the cutting edge of discoveries in Alzheimer's and Parkinson's and heart disease and cancer and all the other serious maladies. But these allegations will give fuel to people who want to cut back on your funding. So all of these questions have to be answered, and the subcommittee will be pursuing the matter further.

We are glad to hear what Dr. Zerhouni has said, and I am pleased to see that Dr. Zerhouni, unlike some lead professionals, has stayed through the hearing to be able to digest what we have worked on. But we will work hard to see to it that whatever conflicts exist or appearances exist we rectify to maintain public confidence in NIH so you can continue to do your outstanding work.

Thank you all very much.

ADDITIONAL PREPARED STATEMENTS

We have received the statements of Senator Mary L. Landrieu and Dr. Harold Varmus, president, Memorial Sloan-Kettering Cancer Center. They will be made part of the record at this time.

[The statements follow:]

PREPARED STATEMENT OF SENATOR MARY L. LANDRIEU

Mr. Chairman, I would like to take this opportunity to thank you for holding this important hearing. I have been proud to support this Committee's goal of doubling the NIH budget over the last five years because, like you, I recognize the great need for continued innovation in medical treatment that the NIH's scientific research facilitates. However, some questionable practices have come to Congress' attention that must be addressed to ensure the continued success of the NIH and its programs. It is important that we do all that we can as a Committee to ensure that individuals' own interests do not taint the NIH research and that it is founded solely on the soundest, most accurate science.

I appreciate Dr. Zerhouni's cooperation with this Committee and the House Committee on Energy and Commerce throughout this investigation and commend his ongoing efforts to address unethical behaviors in the NIH. By taking steps to make NIH scientists' outside work more transparent, Dr. Zerhouni has begun to take the first steps in addressing this important issue. The Ethics Advisory Committee that Dr. Zerhouni has initiated at the NIH is a strong step towards implementing a system of peer review that will promote more accountability among NIH scientists. I support greater oversight both internally and by Congress to create a process that will not allow the integrity of the NIH clinical research to be compromised, while avoiding over-regulation that will impose unintended costs and limit the ability of scientists to perform innovative research.

It is important to note that clinical research is not the only source of NIH funding that is apparently open for compromise based on outside influence or financial considerations. The competitive grant process has also been found to be at risk. The former Director of the National Cancer Institute is alleged to have participated in the decision to award funding to a grantee while he was being considered for employment by an institution affiliated with this grantee. Clearly, something must be done to be sure that the outcomes of these competitive grant processes are based solely on the competitiveness of the grants themselves.

Sadly enough, the opportunity for favoritism in the competitive grant process is not limited to the NIH. Although the details of the competitive grant process differ between federal agencies and between grants within one agency, my experience has shown me that as the competition for federal funding becomes tighter, the awarding of federal grants is becoming less competitive and more open to outside influences.

The competitive grant process is intended to award funding to states and organizations that meet defined criteria, sometimes defined by legislation and sometimes defined by the federal agency awarding the grant. This process was developed to be a fair and consistent way to provide federal funding to states and organizations. If we allow these competitions to be left open to inappropriate influences, we are thereby discrediting the very purposes and people for which these funding streams exist. As we are requesting greater transparency of the NIH practices, we should also consider the need for greater transparency in the competitive grants process of all federal agencies to ensure that this process is fair.

I have personally witnessed some of the breakdowns in the competitive grants process when assisting some of my constituents in their pursuit for federal assistance. As you all know, most grant proposals are scored based on certain criteria through a peer review process. Yet as the competition for funding in certain areas increases, many grant proposals receive a perfect score of 100 and do not receive funding. Often this is because there are more meritorious, well planned proposals than there is funding. In speaking with staff of some of the federal agencies, I have found that the criteria for choosing between proposals that receive a peer review score of 100 are often undefined, leaving room for the discretion and bias of a few individuals to decide the final award.

Our greatest attention must be given to whether the process employed by all of our federal agencies currently is allowing money to get to those that demonstrate the greatest need or the greatest promise. This hearing is an important step in that direction. It is my hope that we will conduct future hearings on exploring the factors that influence grant awards at NIH and other federal agencies. I look forward to the testimony of our distinguished panelists. Thank you.

PREPARED STATEMENT OF DR. HAROLD VARMUS, PRESIDENT, MEMORIAL SLOAN-KETTERING CANCER CENTER

Mr. Chairman and Subcommittee Members: I am grateful for the opportunity to offer my views about the relationships between not-for-profit and for-profit research organizations in the conduct of contemporary biomedical research and about the conflicts of interest those relationships can present for individuals and institutions, especially at the National Institutes of Health (NIH).

I have encountered these issues from different perspectives in three phases of my career—as a faculty member at the University of California, San Francisco from the early 1970's to the early 1990's, during the birth and growth of the biotechnology industry; as Director of the National Institutes of Health, from November 1993 to December 1999; and now as the President of Memorial Sloan-Kettering Cancer Center in New York City. Over the past thirty years, the interactions between scientists in the non-profit sector (academic and governmental institutions) and for-profit organizations (mainly pharmaceutical and biotechnology companies) have become increasingly numerous and complex, influenced by at least three factors: (i) expanding opportunities to transform biological discoveries into practical benefits (such as devices, diagnostic tools, drugs, vaccines, and other health care products); (ii) the prospects of financial returns to industry (through product development) and to non-profit institutions and individuals (through patenting and licensing of intellectual property in exchange for royalties, consulting with industry for honoraria, and equity holding by not-for-profit scientists or their institutions); and (iii) Federal legislation, passed in the 1980's, that encourages academic and government laboratories to pursue commercialization of their research findings through the private sector, with the goals of advancing public health and transferring knowledge more effectively to the U.S. business community.

There are many positive aspects to interactions between the industrial and the non-profit research sectors. The exchanges can provide important practical perspectives to scientists engaged in basic research, they can bring supplemental funding to academic and government institutions through sponsored research agreements and from royalties paid on licensed technologies, and they can help assure the public that the expertise and scientific knowledge that scientists in the not-for-profit sector possess is being transformed effectively into products that can prevent and treat disease.

We have also come to recognize that these relationships are not without risks. Some of these risks arise from conflicts of interests—situations in which the objective pursuit of new knowledge by individuals or institutions in the not-for-profit sector may be influenced by financial interests in a commercial entity. Such conflicts are especially worrisome when they involve the conduct of clinical research, since they have the potential to influence decisions that affect the health of human subjects.

In the most widely discussed instance of a conflict of interest—the circumstances surrounding the death of Jesse Gelsinger, a young man participating in a clinical trial at the University of Pennsylvania—it was reported that the investigator responsible for the clinical trial, as well as the institution in which the research was conducted, held equity in a company that stood to benefit from the treatment being tested. This raised questions about whether the investigators involved or the institution itself could be completely unbiased in running and interpreting the study. It also raised questions about the safety of people participating in the trial. Under such circumstances, even the appearance of a conflict of interest can have a detrimental effect on public confidence in the conduct of research.

As a result of what has been learned from this case and a few others, many leading academic institutions that conduct medical research now regularly review and revise the rules and mechanisms that guide the behavior of their investigators and those who represent the institutions. Extensive recent deliberations about the management of conflicts of interest affecting research on human subjects can be found in an article appearing in *The New England Journal of Medicine* (Volume 347, pages 1371–1375) and committee reports distributed by the American Association of Medical Colleges (http://www.aamc.org/members/coitf/start.htm).

Although most of the attention given to conflicts of interest has been focused on academic institutions, where funding from the for-profit sector is becoming an increasingly large fraction of research support, such conflicts are also an important issue at Federal agencies, such as the NIH, that conduct extensive laboratory and clinical research programs, nearly exclusively with Federal funds.

Government scientists, like their counterparts in academia, possess scientific expertise that is valuable to the commercial sector, and agencies like the NIH often hold intellectual property that can be turned into benefits for the public. Over the

past twenty years, Congress and the Executive Branch have recognized the importance of closer interactions between government scientists and their colleagues in industry. In fact, legislation such as the Federal Technology Transfer Act specifically encourages agencies like the NIH to protect and license intellectual property so that it can be turned into benefits for the public, much as the Bayh-Dole Act has guided academic institutions that receive Federal funding. (A few examples of the many technologies licensed from the NIH as a result of these actions include HIV test kits marketed by several companies; Videx or ddI, a drug marketed by Bristol-Myers Squibb for the treatment of HIV/AIDS; and Fludara, manufactured by Berlex as a treatment for chronic lymphocytic leukemia.) The law allows government scientists to pursue some of the opportunities available in the academic community, including rights to receive royalty payments, albeit capped, for intellectual property patented and licensed by the Federal agency, to work in collaboration with industrial partners that provide research support under Collaborative Research and Development Agreements, and to serve as consultants to industry and receive honoraria for that service. These measures are especially important because the intellectual vigor of government science agencies like the NIH requires an environment that can attract and retain excellent scientists, and such people are likely to demand a stimulating atmosphere that encourages innovation and exchange of information with colleagues around the world, including those employed in the commercial sector.

Many of the concerns about conflicts of interest in the academic sector, especially with regard to research with human subjects, also apply to government agencies, such as the NIH, that conduct both laboratory and clinical research. For that reason, in conjunction with the Office of Government Ethics and the Department of HHS, the NIH has rules governing the ethical conduct of research, and ethics officers are charged to oversee the adherence of NIH personnel to those rules.

Unlike many other government agencies (such as the FDA), the NIH is not a regulatory agency; nevertheless, it has characteristics that differentiate it from academic institutions. For example, the Institutes and Centers of the NIH make grants and contracts to thousands of institutions across the country, including some private companies; leading scientists and scientific administrators are often involved in the formulation of public health policies and the development of research programs; the directors of NIH Institutes and Centers bear the responsibility for distribution of appropriated funds for intramural and extramural research programs; and the salaries and most of the research support for NIH employees comes directly from the Federal budget. For these reasons, it is appropriate to expect an especially high level of integrity and openness in any dealings between NIH personnel and the private sector.

Concerns that such standards may not be universally applied at the NIH were raised recently by articles in the Los Angeles Times, alleging that consultation fees paid to some senior NIH scientists may have interfered with objectivity in making decisions about particular clinical studies. The article did not provide direct evidence that there was any wrongdoing, that rules were purposely broken, or that harm was done to any patient or volunteer in a clinical study as a consequence of conflicts of interest. Nevertheless, it did raise some important questions, particularly about how industry-NIH interactions are approved and monitored and about whether financial arrangements between NIH scientists and the private sector, albeit within regulatory guidelines, should be more open to public scrutiny.

The NIH Director, Elias Zerhouni, has initiated a sensible response to these allegations by convening a panel of members of his Advisory Committee, augmented by other outside experts, to review the existing NIH system for oversight of outside relationships and to make recommendations for improvements. He has also started a review of all outside activities of NIH investigators since January 1999 to ensure that appropriate procedures were followed in the approval of these activities. In academia, where there is more extensive experience with the commercial sector, a few unfortunate cases of real or apparent conflicts of interest have resulted in communal study of the issues and generated improved policies, including a commitment to periodic re-evaluation of the rules and procedures for oversight and management of such conflicts The NIH and other government science agencies should be able to take advantage of that experience.

Without prejudging the outcome of Dr. Zerhouni's timely review of outside activities and conflicts of interest at the NIH, I would like to recommend that special attention be given to three topics:

(i) *Consider the use of multi-disciplinary committees to review selected cases of possible conflicts of interest*.—In the past few years, many academic institutions have established committees composed of faculty members, administrators, public representatives, lawyers, and other individual experienced in ethical decision-making

to review the outside activities of professional staff members whose disclosure statements reveal potential for conflicts. This mechanism removes the responsibility for making very difficult decisions from the shoulders of a single administrative officer, such as an ethics officer, and transfers it to a group with a varied set of experiences, views, and loyalties. Although the number of cases requiring referral usually constitutes a very small proportion of the academic staff, the problems are often complex, and the group evaluation process helps to make fair decisions and to guide the evolution of institutional policy.

(ii) *Consider exempting some senior staff from the opportunity to perform outside activities with for-profit entities*.—Under current regulations, virtually all senior managers at the NIH save the two Presidential appointees (the NIH Director and the Director of the National Cancer Institute), may obtain approval to receive compensation for work with a variety of outside entities, including biotechnology and pharmaceutical companies. These individuals are not regulatory officials and may even be considered of relatively low rank in the Federal system, one or a few grades below the least prominent Presidential appointees (such as Deputy Assistant Secretaries of Departments). Nevertheless, they may have important roles in formulating health policy, developing scientific programs, and awarding Federal grants—ctivities that can present significant conflicts of interest, even when they do not directly affect an institution or business concern with which the individuals have a financial relationship.

Sometimes an effort is made to avoid such conflicts by use of a recusal. (A recusal is essentially a pledge from the individual that he or she will not be informed about or make decisions about government matters involving a potential conflict of interest, such as a program involving a company with which he or she has financial ties.) But recusals may not be fully honored or implemented and are difficult to monitor.

For these reasons, the forthcoming review of NIH policies should include an assessment of whether directors of NIH Institutes and Centers and perhaps a few other high-ranking officials, such as those responsible for development of extramural research programs, should be excluded de facto from certain outside activities.

(iii) *Consider changes to existing rules to guarantee public access to information about outside activities of all NIH scientific staff*.—Under current government rules, many senior staff at the NIH are directed to file financial disclosure reports (known as OGE–450 forms) that are reviewed only by selected administrative staff and released, upon request, only to Chairs of congressional committees, but not available to the public through the Freedom of Information Act. It is difficult to understand the basis on which the reporting requirements for these individuals are distinguished from others—not just from NIH Institute Directors but also from many in comparable positions with similar or even lower salaries. The review of current policies and regulations and their implementation at the NIH should evaluate the options for normalizing access to financial disclosure forms, so that the public can be confident that relationships that might create conflicts for government scientists are not hidden from public view.

To restate my views in summary: I believe that interactions between the not-for-profit and for-profit scientific sectors are important for achieving the maximum health benefits from research performed by government scientists, as well as by academic scientists using government funds. Such interactions have the potential to create conflicts of interest that can distort scientific judgment, or give the appearance of doing so, and thereby undermine public trust in science. Effective, if still imperfect, methods for oversight and management of real and perceived conflicts have been developed over the past decade or two. The NIH has responded to recent criticisms of its management of outside activities by initiating a thorough review. That review should consider, among other things, the advantages of supplementing the activities of NIH ethics officers with conflict of interest committees, exempting some senior staff from certain outside activities, and insuring public access to the financial disclosure forms of all scientific staff.

I want to thank the Subcommittee for the opportunity to express these views.

CONCLUSION OF HEARING

Senator SPECTER. Thank you all very much for being here. That concludes our hearing.

[Whereupon, at 11:32 a.m., Thursday, January 22, the hearing was concluded, and the subcommittee was recessed, to reconvene subject to the call of the Chair.]

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