Federal Advisory Committee Act (FACA): Conflicts of interest and vaccine development—preserving the integrity of the process

Dan Burton, Chairman
House of Representatives
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Abstract

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This hearing concerning conflicts of interest and vaccine development includes statements of Chairman Dan Burton, Henry A. Waxman, Danny K. Davis, Marilyn Glynn (General Counsel, Office of Government Ethics), James Dean (Director, Office of Government Wide Policy, U.S. General Services Administration), Linda A. Suydam, (D.P.A., Senior Associate, Commissioner, Food and Drug Administration), Dixie Snider, Jr., MD (Executive Secretary, Advisory Committee on Immunization Practices, CDC), and Benjamin A. Gilman.

Keywords: conflicts of interest, vaccines

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The committee met, pursuant to notice, at 1 p.m., in room 2154, Rayburn House Office Building, Hon. Dan Burton (chairman of the committee) presiding.

Present: Representatives Burton, Gilman, Ros-Lehtinen, Waxman, Norton, Kucinich, and Davis of Illinois.

Staff present: Kevin Binger, staff director; James C. Wilson, chief counsel; David A. Kass, deputy counsel and parliamentarian; Mark Corallo, director of communications; S. Elizabeth Clay and Nat Weinecke, professional staff members; Robert Briggs, clerk; John Sare, staff assistant; Robin Butler, office manager; Michael Canty, legislative aide; Toni Lightle, legislative assistant; Leneal Scott, computer systems manager; Lisa Smith Arafune, chief clerk; Corinne Zaccagnini, systems administrator; Phil Barnett, minority chief counsel; Sarah Despres, minority counsel; David McMillen, minority professional staff member; Ellen Rayner, minority chief clerk; and Jean Gosa and Earley Green, minority assistant clerks.

Mr. BURTON. The hearing will come to order. Before we begin, I ask unanimous consent that statements from members of the committee and witnesses before the committee may be included in the record as well as any other materials they may submit.

Mr. WAXMAN. I reserve the right to object. I would certainly withdraw my objection to those particular documents, but I think that I, at this point, have to object to that blanket request, have to object.

Mr. BURTON. So you are reserving your right to object on that?

Mr. WAXMAN. I do object at this point.

Mr. BURTON. Well, all right. I had one more unanimous consent request as well, Mr. Waxman, which I believe you will object to as well, so why don't we get them all together here. I ask unanimous consent that a set of exhibits which have been shared with the minority prior to the hearing be included in the record without objection.

Mr. WAXMAN. I reserve the right to object to that. These are—Mr. Chairman, I'm reserving my right to object and I'd like to be recognized on my reservation.

The reason I do not plan to object is not out of concern that we would in any way fail to disclose conflicts of interest, but because of the Ethics in Government Act. People submitted their own private financial information under a law that said once they make this submission, it will not be made public. And on that basis, those were the rules under which they have volunteered to serve on various Government panels and have given this information to the appropriate agencies.

The reason they give this information is that if there's a conflict of interest, the agency will know about it, because it will be disclosed. If it's a conflict that goes to a narrow point, they may not be able to vote on that point. If it's a broader conflict, they shouldn't be serving on the advisory committee or any other commission at all. That's the Ethics in Government law.

But for us to in any way disclose what was, here today in the Congress, what was given to an agency with the understanding under the Ethics of Government law that it not be made public seems to be an inappropriate thing to do. So I don't think we ought to be making anything public that was given to our committee with the expectation that the Ethics in Government law would have prevented us as it would any other agency of Government from making that information public. So on that basis, I will object to your unanimous consent request.

Mr. BURTON. Well, I have one more unanimous consent request which you may want to object to, too, and then I'll respond. I also ask unanimous consent that a staff report by majority staff be included in the record, and without objection—

Mr. WAXMAN. Mr. Chairman, I do reserve the right to object. The staff report, as I understand it, refers to some of the documents that were part of the financial disclosures that under the Ethics in Government law were not to have been made public by anyone. And on that basis, I don't think the staff report, insofar as it incorporates that kind of information, should be made public, and I wouldn't agree to it. And therefore, wouldn't want to go along with the unanimous consent request.

And I particularly wouldn't want to go along and give a unanimous consent request to a report that we have not even seen. We haven't even seen this report, we who are on this committee. So we don't know what's in it. So until I know what's in it, I'm not going to agree to release it, if it has information that may be improper to release. So I do object.

Mr. BURTON. Well, I understand that in the case of our majority report and your minority reports, we very rarely see yours either. So I disagree, Mr. Waxman, with your interpretation of the law. I've had our lawyers review it. It's clear to us that your interpretation is incorrect. I have a letter that I've sent to you explaining our views, and I think you have that.

It's clear from a reading of the entire section that the provisions refer to the agency in question and particularly their ethics officials. As you know, Congress guards its rights to conduct oversight and make information public very jealously. It doesn't make any sense to suggest that Congress would pass a law that would stop it from making public information about conflicts of interest and undue influence of special interests. Nowhere in this entire section is Congress referred to.

However, I will withdraw my unanimous consent request. I will not issue our staff report today. I believe that every place where we have referred to financial disclosure form information, that information is publicly available. For instance, at the beginning of every advisory committee meeting at the CDC, the Centers for Disease Control, the members go around the table and disclose their conflicts in public.

It is my intention, however, to use documents during the hearing. Under the rules, the committee documents are available for use by all Members during hearings. I think that it's pretty clear that drug companies do have influence on these advisory panels and these committees, and I don't think it's proper. I think the public needs to know about that. They have a right to know about that.

And we will proceed in the proper manner.

Mr. WAXMAN. Mr. Chairman, I'd like to make a point of order.

Mr. BURTON. The gentleman will state his point of order.

Mr. WAXMAN. Under Rule 11(2)(k)(8), which refers to documents that could be disclosed, you already indicated you plan to refer to and therefore in the course of this hearing make public these very same documents that I think should not be made public. And I want you to rule, under the rules of the House, that it would not be pertinent to our hearing to release those documents.

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I want to read the section of the law. The section of the law, the Ethics in Government law, says, any information required to be provided by an individual under this subsection shall be confidential and shall not be disclosed to the public. Now, as I understand your argument, you think the Congress can make the disclosure to the public, even though the law says it shall not be disclosed to the public.

When the Republicans took control of the House of Representatives in January 1995, we adopted rules saying that we will be subject to the same rules that outside groups have imposed upon them, whether it be OSHA rules or civil rights laws or anything else. Under the spirit of that notion that we should be guided by the same rules that apply to others, I think that the Congress of the United States should not be permitted to make available to the public or disclose to the public that which no other agency of Government, no one working for any of those agencies of Government, no one else would be permitted to do without violating the law.

And in fact, I would submit that even this committee would be violating the law should we disclose this information. So I make at this point a point of order that the Chair rule that the information that he appears to be willing to disclose, not be disclosed based on these arguments, and the rules of the House that would prevent disclosure of information under Rule 11(2)(k)(8).

Mr. BURTON. First of all, before I rule on your point of order, there was never any agreement with Health and Human Services that these documents would not be made public. I have a copy of a letter that I sent to Dr. Shalala, and I'll read from that. It says, the documents produced to the committee in response to the October 1st request will be treated as committee documents. Committee rules state that all committee documents shall be available for use by members of the committee during committee meetings.

Beyond this, if there is a determination that committee documents should be made public, it has been the practice of this committee to do so only upon agreement between the chairman and ranking minority member, or by vote of the committee. When and if committee documents are made public, appropriate redactions are made to delete personal information such as home phone numbers and addresses, social security numbers or bank account numbers. It's my intention that these documents referred to above shall be treated in this manner.

Now, the documents, the documents are pertinent to this hearing, and therefore the point of order is overruled.

Mr. WAXMAN. Mr. Chairman, before you make your decision, which I fully expect to be contrary to my argument, I do want to point out in that letter that you wrote to Donna Shalala, the Secretary of HHS, you said when and if committee documents are made public, appropriate redactions are made to delete personal information, such as home phone numbers and addresses, social security numbers or bank account numbers. It's my intention the documents referred to above shall be treated in this manner.

As I understand, what you plan to do today is to refer to financial disclosures. It seems to me that in the spirit of this letter, some of those things could be redacted. But all of the information will be made public about individuals who submitted these financial disclosures with a clear understanding, because the law spells it out for them, that in doing so, when they volunteer then to serve on a committee, that their financial holdings and information about their financial personal situation would not be made public.

So I want to point that out, and I don't know if that will persuade you differently on the ruling on my point of order, but I think it's important to put on the record.

Mr. BURTON. Well, we have said that we're not going to make those documents public today. However, the committee can use all documents that we have in the course of discussion of the hearing and will do so. And your point of order is overruled.

We'll now proceed with, let's see, I have one more thing. I also ask unanimous consent that questioning under this matter proceed under clause 2(j)(2) of House rule 11 and committee rule 14, in which the chairman and the ranking minority member allocate time to members of the committee as they deem appropriate for extended questioning, not to exceed 60 minutes equally divided between the majority and the minority. And without objection, so ordered.

Opening Statement of Chairman Dan Burton

Today we're going to continue our series of hearings on vaccine policy. For the last few months, we've been focusing on two important advisory committees. The Food and Drug Administration and the Centers for Disease Control and Prevention rely on these advisory committees to help them make vaccine policies that affect every child in America. We've looked very carefully at conflicts of interest. We've taken a good, hard look at whether the pharmaceutical industry has too much influence over these committees.

From the evidence we've found, we believe that they do. The first committee is the Food and Drug Administration's Vaccine and Related Biological Products Advisory Committee. This committee makes recommendations on whether new vaccines should be licensed.

The second committee is the CDC's Advisory Committee on Immunization Practices. This committee recommends which vaccines should be included in the childhood immunization schedule.

To make these issues easier to understand, we're going to focus on one issue handled by these two committees, the rotavirus vaccine. There are other vaccines that we may get into later, but today we're going to use this as the primary example.

It was approved for use by the FDA in August 1998. It was recommended for universal use by the CDC in March 1999. Serious problems cropped shortly after it was introduced. Children started developing serious bowel obstructions. The vaccine was pulled from the U.S. market in October 1999.

So the question is, was there evidence to indicate that the vaccine was not safe, and if so, why was it licensed in the first place? How good a job did the advisory committees do?

We reviewed the minutes of the meetings. At the FDA's committee, there were discussions about adverse events. They were aware of potential problems. Five children out of 10,000 developed bowel obstructions. There were also concerns about children failing to thrive and developing high fevers, which as we know from other vaccine hearings, can lead to brain injury.

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Even with all of these concerns, the committee voted unanimously to approve it.

At the CDC's committee, there was a lot of discussion about whether the benefits of the vaccine really justified the cost. Even though the cost benefit ratio was questioned, the committee voted unanimously to approve it.

Were they vigilant enough? Were they influenced by the pharmaceutical industry? Was there appropriate balance of expertise and perspective on vaccine issues?

We've been reviewing their financial disclosure statements. We've interviewed staff from the FDA and the CDC. The staff has prepared a staff report summarizing what we found. At the end of this statement, while I won't ask unanimous consent to enter this report in the record today, I've already agreed not to do that, we've identified a number of problems that need to be brought to light, and we will be discussing those.

Families need to have confidence that the vaccines that their children take are safe, effective and very necessary. Doctors need to feel confident that when the FDA licenses a drug, that it's really safe and that the pharmaceutical industry has not influenced the decision-making process. Doctors place trust in the FDA and assume that if the FDA has licensed a drug, it's safe for use.

Has that trust been violated? How confident in the safety and need of specific vaccines would doctors and parents be if they learned the following: One, that members, including the chair of the FDA and CDC advisory committees who make these decisions own stock in drug companies that make the vaccines. Two, that individuals on both advisory committees own patents for vaccines under consideration, or affected by the decisions of the committees.

Three, that three out of the five of the members of the FDA's advisory committee who voted for the rotavirus vaccine had conflicts of interest that were waived. Four, that 7 individuals of the 15 member FDA advisory committee were not present at the meeting.

Two others were excluded from the vote, and the remaining five were joined by five temporary voting members who all voted to license the product.

Five, that the CDC grants conflict of interest waivers to every member of their advisory committee a year at a time, and allows full participation in the discussions leading up to a vote by every member, whether they have a financial stake in the decision or not.

So they're discussing it, influencing other members possibly, whether they have a financial stake or not.

Sixth, that the CDC's advisory committee has no public members, no parents have a vote in whether or not a vaccine belongs on the childhood immunization schedule. The FDA's committee only has one public member.

These are just a few of the problems we found. Specific examples of this include Dr. John Modlin. He served for 4 years on the CDC advisory committee and became the chair in February 1998. He participated in the FDA's committee as well. He owns stock in Merck, one of the largest manufacturers of the vaccine, valued at $26,000. He also serves on Merck's immunization advisory board.

Dr. Modlin was the chairman of the rotavirus working group. He voted yes on eight different matters pertaining to the ACIP's rotavirus statement, including recommending for routine use and for inclusions in the Vaccines for Children program. It was not until this past year that Dr. Modlin decided to divest himself of his vaccine manufacturer stock.

At our April 6th autism hearing, Dr. Paul Offit disclosed that he holds a patent on a rotavirus vaccine and receives grant money from Merck to develop this vaccine. He also disclosed that he is paid by the pharmaceutical industry to travel around the country and teach doctors that vaccines are safe. Dr. Offit is a member of the CDC's advisory committee and voted on three rotavirus issues, including making the recommendation of adding the rotavirus vaccine to the Vaccines for Children program.

Dr. Patricia Ferrieri, during her tenure as chair of the FDA's advisory committee, owned stock in Merck valued at about $20,000 and was granted a full waiver.

Dr. Neal Halsey, who serves as a liaison member to the CDC committee on behalf of the American Association of Pediatrics, and is a consultant to the FDA's committee, has extensive ties to the pharmaceutical industry, including having solicited and received startup funds from industry for his Vaccine Center. As a liaison member to the CDC committee, Dr. Halsey is there to represent the opinions of the organizations he represents, but was found in the transcripts to be offering his personal opinion.

Dr. Harry Greenberg, who serves as chair of the FDA committee, owns $120,000 of stock in Aviron, a vaccine manufacturer. He also is a paid member of the board of advisors of Chiron, another vaccine manufacturer, and owns $40,000 of stock. This stock ownership was deemed not to be a conflict, and a waiver was granted.

To the FDA's credit, he was excluded from the rotavirus discussion, because he holds the patent on the Rotashield vaccine.

How confident can we be in the process when we learned that most of the work of the CDC advisory committee is done in ''working groups'' that meet behind closed doors, out of the public eye?

Members who can't vote in the full committee because of conflicts of interest are allowed to work on the same issues in working groups, and there is no public scrutiny. I was appalled to learn that at least 6 of the 10 individuals who participated in the working group for the rotavirus vaccine had financial ties to pharmaceutical companies developing rotavirus vaccines.

How confident can we be in the recommendations for the Food and Drug Administration when the chairman and other individuals on their advisory committee own stock in major manufacturers of vaccines?

How confident can we be in a system when the agency seems to feel that the number of experts is so few around the country that everyone has a conflict and thus waivers must be granted? It almost appears that there is an ''old boys network'' of vaccine advisors that rotate between the CDC and FDA, at times serving simultaneously. Some of these individuals served for more than 4 years. We found one instance where an individual served for 16 years continuously on the CDC committee. With over 700,000 physicians in this country, how can one person be so indispensable that they stay on a committee for 16 years?

It's important to determine if the Department of Health and Human Services has become complacent in their implementation of the legal requirements on conflicts of interest and com-

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mittee management. If the law is too loose, we need to change it. If the agencies aren't doing their job, they need to be held accountable. That's the purpose of this hearing, to try to determine what needs to be done.

Why is this review necessary? Vaccines are the only substances that a government mandates a U.S. citizen receive. State governments have the authority to mandate vaccines be given to children prior to admission to day care centers and schools. State governments rely on the recommendations of the CDC and the FDA to determine the type and schedule of vaccines.

I am not alone in my concern about the increasing influence of industry on medicine. Last year, the New England Journal of Medicine learned that 18 individuals who wrote drug therapy review articles had financial ties to the manufacturer of the drugs they were discussing. The Journal, which has the most stringent conflict of interest disclosures of medical journals, had a recent editorial discussing the increasing level of academic research funded by the industry. The editor stated, ''What is at issue is not whether researchers can be 'bought' in the sense of a quid pro quo, is that close and remunerative collaboration with a company naturally creates goodwill on the part of the researchers and the hope that the largesse will continue. This attitude can subtly influence scientific judgment.''

Can the FDA and the CDC really believe that scientists are more immune to self-interest than anybody else?

Maintaining the highest level of integrity over the entire spectrum of vaccine development and implementation is essential. The American people have to have trust in the system. The Department of Health and Human Services has a responsibility to the American public to ensure the integrity of this process by working diligently to appoint individuals that are totally without financial ties to the vaccine industry to serve on these and all vaccine-related panels.

No individual who stands to gain financially from the decisions regarding vaccines that may be mandated for use should be participating in the discussion or policymaking for vaccines. We have repeatedly heard in our hearings that vaccines are safe and needed to be protecting the public. If the panels that have made the decisions on all vaccines on the childhood immunization schedule had as many conflicts as we have found with rotavirus, then the entire process has been polluted and the public trust has been violated. I intend to find out if the individuals who have made these recommendations that affect every child in this country and around the world stood to gain financially and professionally from the decisions of the committees on which they served.

The hearing record will remain open until June 28th for those who would like to submit a statement for the record.

I now recognize the ranking minority member, Mr. Waxman, for his opening statement.

Opening Statement of Henry A. Waxman

Mr. WAXMAN. Thank you very much, Mr. Chairman.

This hearing is about conflicts of interest and vaccine decision-making. This is an issue I take very seriously. I have probably done more than any other member of this committee to identify and oppose genuine conflicts of interest in Federal decision-making.

In 1991, I held a hearing on conflicts of interest in Vice President Quayle's Council on Competitiveness. These hearings revealed that the executive director of the council owned 50 percent of a chemical plant subject to regulation under the Clean Air Act at the same time that he was chairing biweekly interagency meetings on Clean Air Act regulations, including regulations that dealt with toxic substances that may have affected his chemical plant.

In 1998 and 1999, I was the only member to question what role a key NIH official played in selecting Rezulin in a diabetes drug trial when he was consulting for Rezulin's manufacturer, Warner Lambert. My question led directly to an ongoing inspector general review of NIH's management of its conflict of interest policies.

In 1997, when the Supreme Court ruled that the Federal Advisory Committee Act applied to the National Academy of Sciences, some members wanted to exempt the Academy from those requirements. I insisted that we put in place a system to examine conflicts of interest in the membership of those advisory groups. In 1997, when the Republican Congress wanted to privatize medical device approvals and farm out product reviews to for-profit entities, I was one of the members who fought hard to ensure that conflicts of interest were prohibited and that the public interest was protected.

If indeed a real threat to objective decisionmaking by our health agencies is identified during these hearings, I will call for a full investigation, as I have done in the past. I know that conflicts can be dangerous, not only because of the possibility that a financial interest could exert undue influence on critical policy decisions, but also because they can lead to loss of public confidence in the system.

But there's a right way and a wrong way to investigate conflicts of interest. The right way is to investigate first and then reach conclusions later. The wrong way is to accuse first and then investigate later. Unfortunately, our chairman has a propensity to investigate in the wrong way, not just in this issue, but in other issues. He has made unsubstantiated allegations that smear people's reputations but turn out to have no basis in fact.

The chairman made his latest allegation last Sunday on Meet the Press. On national TV, he accused the President, the Vice President and the Attorney General of obstruction of justice and other crimes. But when he was asked to provide evidence to back up these accusations, the chairman refused, stating, ''I can't give you the specifics of it right now.''

My fear is that the chairman has reached a predetermined conclusion that vaccines are dangerous. It is difficult for him to persuade others to agree with his conclusion because it is so far out of the scientific and medical mainstream. But rather than accept the fact that he may be wrong, the chairman has decided that those who disagree with him must be part of a drug company conspiracy.

I intend to keep an open mind as I review the evidence we hear today. The chairman didn't share with us the report that he planned to release today. As a result, I've had no time to review what his staff has written, and cannot comment on the findings.

But from what I've seen, I have my doubts that the chairman will be able to demonstrate that vaccine decisions have been tainted by scandal. CDC and FDA should follow the highest possible standards in applying conflict of interest rules. There

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may be questions about whether these rules have been properly applied in every instance. But lapse in the application of these rules, if there are any, does not mean that vaccine decisions have been made improperly.

Unfortunately, CDC and FDA face a difficult challenge in assembling together expert advisory panels on vaccines. Vaccine decisions have major public health implications. For this reason, it's important, in fact it's essential, that the individuals serving on the vaccine advisory panels be the world's leading experts on vaccine issues.

But some of these experts also have varying ties to the pharmaceutical industry, such as working with the industry to develop new and better vaccines. After all, their field is vaccine research. CDC and FDA have the responsibility of ensuring that the public benefits from the expertise of these individuals, while at the same time ensuring that appropriate precautions are taken against conflicts of interest.

That's why those disclosures were required of all of those people that serve voluntarily on advisory committees, so CDC could see if there's a conflict, FDA could see if there's a conflict. But to get those disclosures, people are promised that their financial holdings are not going to be made public, which is why I objected to the release of this information, which I gather will be made public indirectly today.

Let me give you an example. The chairman referred to Dr. John Modlin and said, he must have a conflict of interest because he owns $60,000, I think it was, maybe $40,000, of shares in Merck Pharmaceutical. Maybe it's $100,000, I don't remember the number. But the point I want to make is that this man served on an advisory committee and approved a drug by another company. It wasn't a Merck rotavirus vaccine that he voted to approve. It was a Wyeth product.

Now, he was later asked, did he know that Merck was also working on a rotavirus vaccine. And he said he didn't even know that they were working on a rotavirus vaccine. Maybe if he knew, he would have voted against the competitor's product because he had a financial interest in Merck.

Well, the fact of the matter is, Merck is involved with many products, as is Wyeth, as is every other pharmaceutical company. If we want to say that anybody who works as an advisor cannot own these stocks, then let's say it. But you know what? We don't say that of Members of Congress. The Roll Call newspaper today has an article about all the Senators that have stocks in high tech. Now, that's not wrong or illegal. And we even vote on issues that affect those industries.

If we're going to have a requirement that no one own stocks in companies that may benefit from our decisions indirectly, then we ought to say it. But we have not said that, and therefore, people have not violated any rule because they simply have financial holdings.

This hearing will serve a useful purpose if it provides an opportunity to explore objectively how good a job CDC and FDA are doing in meeting their obligations. But let's be ready to look at the evidence first, before we reach conclusions that could scare people into thinking that vaccines that are on the market are going to hurt their children, and have them run away from getting their children immunized, when one thing we do know is that those diseases that can be prevented can take an enormous toll on the lives of children.

I also want to point out that rotavirus, which is the example used by the chairman, is not a vaccine that is mandated by the Federal Government to be used by children. As I understand it, the CDC had put it on its list of recommended vaccines for infants. They recommended it. They later took it off that list. But it is not required by law that children be immunized. Some States have laws that require that before children can go to school, they be immunized. This particular product, as I understand it, was never mandated to be used.

But when the Centers for Disease Control says that they recommend a product, it's a very serious matter. If FDA approves a product, they're saying to the American people that this product has undergone scrutiny and is safe and effective. As I also understand in this particular case, FDA asked that they continue to monitor after the approval to be sure that if there are problems, we know about those problems.

Those of us who looked at the FDA issues on the committee that has jurisdiction, the Health and Environment Subcommittee, which I once chaired, know very well that there is pressure from Congress and the American people to get drugs approved as quickly as possible. And when we press to get these products approved as quickly as possible, it means we've got to make sure that we monitor any adverse impacts so we can respond if we learn about problems.

With this particular vaccine, there was an advisory that it be monitored. After it was monitored, they found that there was a problem, because adverse event reporting requirement for vaccines, and they acted to take this vaccine off the market. That appears to me to be appropriate. We wish they would have been able to catch it before it was ever used. But we want to be able to make sure that we catch it after it's being used and the decisions that are made to make a vaccine available be the decisions that are based on the science, by the leading scientists and make sure that if they are acting on these advisory panels that they not have genuine conflicts of interest.

Let's be mindful of the way things work and explore the evidence before we jump to conclusions. I will do that with an open mind today as we hear from various witnesses, and hope that we can reach some conclusions based on the facts.

Thank you, Mr. Chairman.

Mr. BURTON. I would like to add or correct one thing that the gentleman from California said. Merck was listed as an affected company in the documents provided by the FDA to Dr. Modlin. So he was aware of that.

Mr. Davis, do you have a comment you'd like to make, sir?

Statement of Congressman Danny K. Davis

Mr. DAVIS OF ILLINOIS. Yes, Mr. Chairman.

Thank you very much, Mr. Chairman, and I'd like to commend you for holding this oversight hearing to examine the implementation of the Federal Advisory Committee Act and to examine the operation of the Department of Health and Human Services.

Mr. BURTON. Excuse me, Mr. Davis, I don't mean to interrupt you. We have 7 minutes on the clock. Would you like to continue now or—

Mr. DAVIS OF ILLINOIS. I'll be done in 2.

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Mr. BURTON. OK, Mr. Davis.

Mr. DAVIS OF ILLINOIS. And to examine the operation of the Department of Health and Human Services Advisory Committee on Immunization Practices of the Centers for Disease Control and Prevention and the Vaccine Related Biologic Products Advisory Committee of the Food and Drug Administration.

A strong and prosperous America needs healthy people. Healthier people will build a stronger America. It is crucial that we provide the best health care to all Americans. And in order to ensure the health of all Americans, the two advisory committees have critical roles to recommend the kind and dosage of vaccinations that our children and adult populations receive.

There is a tremendous amount of interest in this subject, as is evidenced by the numbers of people who are at this particular hearing, and in my community, especially, Mr. Chairman, there is a great deal of interest. And I note the presence of Barbara Malarkey, a representative of the Illinois Vaccine Awareness Coalition, who happens to live in my neighborhood. She is indeed a fighter, a hard worker, and has raised the level of awareness locally where we live. I simply want to commend her for taking time out to come all the way from Chicago to just simply be here today and participate and hear the information as we discuss this important subject.

Mr. WAXMAN. Would the gentleman yield to me just to use this opportunity?

Mr. DAVIS OF ILLINOIS. Yes.

Mr. WAXMAN. Because you have a minute left. Dr. Modlin was a non-voting member on this panel. If there was a document given about Merck being an affected company, he claims he did not know about it. And the reason I say he claims that is that my staff talked to him and asked him about it. I don't know if Mr. Burton's staff talked to him and asked him that question.

He said that when he served in this advisory capacity, he did not know that Merck was listed as one of the affected companies. He didn't know Merck was working on a rotavirus vaccine as well. He was looking at a Wyeth product, and used his best scientific judgments with regard to that Wyeth product.

Thank you for yielding.

Mr. BURTON. We have a vote on the floor. We will be back very shortly. The Chair stands in recess.

[Recess.]

Mr. BURTON. We will now proceed with the statements of Mr. Dean and Ms. Glynn. Would you please stand and raise your right hands.

[Witnesses sworn.]

Mr. BURTON. Ms. Glynn, would you like to go first with your prepared statement?

Statement of Marilyn Glynn, General Counsel, Office of Government Ethics

Ms. GLYNN. Sure. I'm pleased to be here today to talk briefly about the Federal ethics and conflict of interest statutes and regulations and how they apply to members of Federal advisory committees generally.

The core conflict of interest statute is Section 208 of Title 18 of the U.S. Code. This law prohibits employees from participating personally and substantially in any particular matter which to their knowledge has a direct and predictable effect on their financial interest. It also applies when the matter would affect the financial interests of certain other persons or organizations with whom they have some connection, such as an outside employer.

The law contains waiver and exemption provisions that would permit an employee to participate in a matter notwithstanding a potential conflict of interest. Section 208 applies to regular employees of the executive branch as well as to so-called special Government employees, or SGEs, as we call them. Many members of Federal advisory committees are SGEs, in fact, probably most are.

The SGE category was created by Congress as a way to apply an important but limited set of conflict of interest requirements to a group of individuals who provide important but limited services to the Government. Some members of Federal advisory committees are not employees of the Government at all. These individuals serve as representatives of outside interest groups. It is understood by the Government that they represent a particular bias and they aren't covered by any of the rules that apply to regular employees or to these SGEs.

There is a wavier provision in Section 208 for SGEs who serve on Federal advisory committees within the meaning of the Federal Advisory Committee Act [FACA], I think as it's known. It permits the agency employing the SGE to grant an individual waiver based on a written determination that the need for the individual services outweighs the potential for a conflict of interest created by the financial interests involved.

In contrast, the waiver provision for regular Government employees under Section 208, and these employees typically provide a range of services of course far broader than those provided by SGEs, that other waiver for regular employees focuses on the size of the employee's financial interest, and the likelihood that the financial interest would affect the integrity of the employee's services.

OGE has issued regulations interpreting Section 208. Included in our regulations is guidance concerning the issues of waivers and various procedural criteria required by the statute. OGE has also issued regulations granting general exemptions from the disqualification requirement in Section 208.

Many of these exemptions apply to SGEs as well as to regular employees. For example, there are de minimis exemptions for ownership of publicly traded securities. Some other exemptions apply only to SGEs serving on FACA committees. The most significant of those exemptions exempts certain financial interests arising from the SGEs' outside employment.

Beyond the criminal conflict of interest laws, OGE has promulgated regulations prescribing standards of ethical conduct for employees of the executive branch, including these SGEs. One of those rules provides a mechanism for dealing with potential appearances that an employee make lack impartiality when dealing in certain matters. The rule provides a balance to be struck between concerns about appearances of partiality and the Government's interest in having the employee participate in the particular matter.

Most SGEs serving on advisory committees have to file financial disclosure reports with their agencies. Financial disclosure helps protect the integrity of the advisory committee process by providing the agencies an opportunity to determine

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whether an SGE may have any potential conflicts of interest that must be addressed.

In closing, I want to emphasize, of course, that OGE shares the committee's belief that Government decisions should not be tainted by an employee's conflicts of interest. At the same time, the Government needs the services of SGEs who can contribute relevant outside expertise and perspectives to the work of an advisory committee.

Balancing these two considerations is frequently a difficult task. Nevertheless, we believe that the current statutory and regulatory system that applies to advisory committees provides an appropriate framework for accommodating both objectives.

Thank you, and I'd be happy to answer any questions you may have.

Statement of James Dean, Director, Office of Government Wide Policy, U.S. General Services Administration

Mr. BURTON. Thank you, Ms. Glynn.

Mr. Dean.

Mr. DEAN. Good afternoon, Mr. Chairman, Mr. Ranking Member, members of the committee. Thank you for the opportunity to discuss with you today the important role played by Federal advisory committees in achieving the missions assigned to the executive branch.

The Federal Advisory Committee Act [FACA], operates within the body of statutes that promote access to Federal decisionmaking and information. For example, policy related to the accessibility of Government records was revised in 1966, following the enactment of the Freedom of Information Act. And the two remaining cornerstones of Federal access policy, the Privacy Act, and the Government in the Sunshine Act were enacted by the Congress in 1974 and 1976 respectively.

FACA seeks to accomplish two important objectives. First, to establish the means for providing congressional and executive branch oversight over the number and costs of the advisory committees, and second, to ensure that the advisory committees operate in plain view of the public. Simply stated, the act's purpose is to illuminate how agencies make decisions, based upon advice and recommendations from individuals outside of Government, while also making sure that the costs as reported by the advisory committees are commensurate with the benefits received.

Although advisory committees do not make or implement decisions, they are used by over 60 agencies to provide advice on issues that reflect the complex mandates undertaken by the Government. During fiscal year 2000, almost 50,000 committee members will serve on 1,000 committees and provide advice and recommendations on such matters as the safety of the Nation's blood supply, steps to address the management of natural resources, and the country's national defense strategies.

In our full testimony, Mr. Chairman, we have provided a complete listing of the act's most significant provisions. To summarize, the Secretariat is responsible for issuing policy and providing a framework for Government oversight. Agencies have joint responsibility for implementing the act and for issuing additional guidelines that are needed to address their unique requirements.

At the agency level, committee management officers [CMOs] as we know them, are responsible for implementing FACA on behalf of the agency head. Each committee has a designated Federal officer [DFO], who must work with the CMO to manage the committee's operations day to day. Together, the CMO and DFO are responsible for ensuring compliance with FACA, the agency's internal operating procedures, regulations issued by the Secretariat, and any other applicable statutes or regulations such as those issued by the U.S. Office of Government Ethics, the National Archives and Records Administration, or the Office of Personnel Management, just to name a few.

Mr. Chairman, in your letter inviting us to testify before the committee today, you asked us to address how the Federal Advisory Committee Act deals with issues relating to balancing an advisory committee's membership and conflict of interest issues relating to individual members. The act does not include provisions addressing committee member conflicts of interest. The applicability of conflicts of interest laws and various ethical requirements for members of advisory committees who serve as special Government employees are covered by other laws and regulations issued by OGE.

The act, however, does include two important provisions designed to promote the objectivity of advisory committee deliberations. First, FACA requires that ''the membership of the advisory committee be fairly balanced in terms of the points of view represented and the functions to be performed by the committee.''

Second, the act requires ''provisions to ensure that the advisory recommendations will not be inappropriately influenced by the appointing authority or by any special interest, but will instead be the result of the advisory committee's independent judgment.'' Thus, while the act addresses the importance of assuring an advisory committee's independent judgment, it also requires that at a minimum, the composition of the advisory committees reflect the expertise and interests that are necessary to accomplish a given committee's mission.

The act does not, however, define those factors that should be considered in achieving balance. The Secretariat's regulations provide in part that ''in the selection of members for the committee, the agency will consider a cross section of those directly affected, interested and qualified as appropriate for the nature and function of the committee. Committees requiring technical expertise should include persons with demonstrated professional or personal qualifications and experience relevant to the functions and tasks to be performed.''

In their efforts to balance a committee's membership, agencies focus primarily on the subject matter to be addressed. Nevertheless, other factors may be appropriate in relation to a committee's function, such as geographical representation, racial or ethnic diversity, occupational affiliation or the need to consult with State, local or tribal governments.

Similarly, the act does not outline specific steps that must be taken to ensure that advice or recommendations offered by an advisory committee are free from inappropriate influence by the appointing authority or special interest. Accordingly, each agency is responsible for developing specific operating procedures, consistent with the act and the Secretary's regulations to

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promote the advisory committee's independent judgment and to achieve a balanced committee membership.

Although the act is quite detailed in the specific procedures agencies must follow—I see I have the stop sign.

Mr. BURTON. If you're close to concluding, go ahead.

Mr. DEAN. Probably about a minute and a half.

Mr. BURTON. OK.

Mr. DEAN. Although the act is quite detailed in specific procedures agencies must follow with respect to the establishment of advisory committees, the conduct of meetings and the availability of records, it provides substantial flexibility to agency heads in other areas such as membership selection, tenure and procedural issues such as voting. This is appropriate given the diverse needs of the executive branch and the necessity for agencies to quickly adopt new operating procedures where conditions warrant.

This flexibility is balanced by a variety of procedural safeguards to ensure that the advice or recommendations tendered by an advisory committee are properly obtained by an agency through a public process prior to final agency action. In particular, the act's provisions require opening meetings and a summary of closed or partially closed meetings, the ability of the public to provide written or oral statements to a committee and access to committee minutes and records reinforce the act's goals of maintaining committee independence and freedom from inappropriate influence. These checks and balances, rooted firmly in the principle of Government in the Sunshine, have contributed greatly to the success of advisory committees over the past 28 years.

Mr. Chairman, that concludes my statement.

Mr. BURTON. Thank you very much.

I think the one thing that was significant, or one of the things that was significant about your statement is the Sunshine aspect, that the public and the American people have a right to know where major decisions are being made.

I wish Mr. Waxman was here. I see that his staff has put in his desk there a copy of a document. And so for the record, I'd like to show that Dr. Modlin was aware that Merck was involved in producing a rotavirus. He was a consultant to the FDA, he got this notification on December 12th. And it was voted on December 12th, was it? He got it on November 4th and he voted on December 12th. So he knew about this for over a month.

And so I wanted to correct the record, and correct what Mr. Waxman said. Mr. Modlin did know that Merck, and he had a financial interest in Merck, he did know that Merck was involved in that process.

Mr. Dean, you just said, and Ms. Glynn can comment on this as well, the whole idea we've been talking about behind the advisory committee law is openness. Do either one of you think it's appropriate for an advisory committee to do a lot of their work through working groups behind closed doors?

Mr. DEAN. Mr. Chairman, the act provides that most advisory committees should be open to the public. However, it does provide the opportunity to close meetings that are consistent with Government in the Sunshine Act. Many agencies find that it is necessary from time to time, in particular the agencies such as the Department of Defense, for example, with—

Mr. BURTON. Well, let's confine our remarks to the health agencies.

Mr. DEAN. Oh, sure. Within HHS, then, many meetings are closed where necessary to discuss proprietary information, to protect material that contains information subject to the Privacy Act and other issues that are exempted under the Sunshine Act, sir.

Mr. BURTON. Should advisory committee members who have conflicts and financial interests, and can't vote at public sessions, be allowed to work on or in working groups on the same subject on which they have a conflict of interest?

Mr. DEAN. I think that OGE may want to comment on that as well. But I can address that from a structural standpoint. It is very common, and the act provides that agencies may establish working groups or subcommittees to support parent committees. All working groups and subcommittees must report to the parent, and only the parent may vote on issues before the committee. In other words, the deliberation on matters that are normally prepared at the subcommittee level or working group level are fully vetted, or are to be vetted under FACA in the parent committee.

So the normal way of business is done is that the work done at the lower level will come up to the higher level.

Mr. BURTON. Do you have a comment?

Ms. GLYNN. Yes, I do. As to your question about whether it's appropriate to work sort of behind the scenes when you have a conflict of interest, I would say that it's not necessarily inappropriate if the agency has been made aware of the conflict of interest in advance, has had an opportunity to weigh whether they want that person to work behind the scenes in that capacity and has gone through the necessary procedural steps of issuing a waiver as required under the law.

Mr. BURTON. Let's say you have a child, and there's a new vaccine that's coming on the market. And let's say that there's an advisory committee that's going to be making a decision on whether or not that should be put in the marketplace and into your child's body.

Do you think they should be totally unbiased and without any financial conflicts?

Ms. GLYNN. I have to say that I think, given the breadth of the criminal conflict of interest statute, it might be difficult to find someone who has the requisite expertise, that has absolutely no financial conflict at all.

Mr. BURTON. How many doctors did we say we had in the country? We have 700,000 physicians in America, probably a couple hundred thousand scientists as well. Now, the rotavirus, we found that many of those people that were on the advisory committees that dealt with that were on the committees year after year after year, had financial conflicts of interests and were making decisions on this vaccine knowing full well that the company that they had stock in or had financial interest in was making, was going to make a profit, which in turn would be beneficial to them.

Ms. GLYNN. Yes, sir, I understand.

Mr. BURTON. The vaccine had not been, to our knowledge, thoroughly tested, and yet they went ahead and approved it. Don't you think if you were a parent you'd be a little bit concerned about that?

Ms. GLYNN. Well, I am a parent, and I do have—

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Mr. BURTON. Would you be concerned about that?

Ms. GLYNN. I think with the type of knowledge that I have, having worked for many years in the ethics field and understanding that some of these conflicts of interest could really be characterized as technical. For example, the ownership of stock, I think is a good example. Remember, in evaluating your financial stake in the matter when you own stock, it's not the value of the stock you own.

Let's say you own $40,000 or $50,000 worth of stock, whatever those numbers were that you were discussing earlier. The value of your financial interest in the matter is the potential for gain or loss to you. And when you own stock in a large publicly traded company such as, I think Merck was the example, you really own a billionth of an interest in the company.

So the likelihood that your personal financial interest in the matter is going to be affected I think is pretty remote. So I really don't think it's inappropriate for agencies to issue waivers in those situations.

Mr. BURTON. What if you were getting paid to go around and make speeches for that company and you were on that payroll? Would that be a conflict, do you think?

Ms. GLYNN. You know, it might very well not be a conflict under the criminal conflict of interest statute. It would only really amount to that level if you were actually an employee of the company or if the honorarium or whatever it is you're receiving was dependent on the matter which was under consideration.

But believe me, of course there are certainly appearance concerns in a situation like that. And so that's why my office has issued a regulation which requires the employee to consider whether his impartiality would be questioned in such a situation. And the agency can of course go ahead and make its own determination that they don't want an employee to act in such a situation, if they think the appearance is so great that the benefit of having him participate is outweighed by the appearance of a conflict of interest.

Mr. BURTON. Do you know that there were some serious side effects from the rotavirus and they took it off the market shortly after it was put on the market? And one child, I think, died?

Ms. GLYNN. I don't—

Mr. BURTON. Did you know that?

Ms. GLYNN. No, sir, I'm not—I'm not involved in the details of this.

Mr. BURTON. Well, I guess the point I'm trying to make, and the question I'm trying to make is that, I have a grandchild, I have two grandchildren. One of them almost died from a vaccine, the other one is now autistic, we believe, from vaccines. And I think that I, like most people who have children or grandchildren that are having these things put into these bodies, need to be assured that they've been thoroughly tested and that the people who are making the decisions on whether or not those should be mandated, mandated by law, don't have a conflict of interest.

And so what you're telling me is that the regulations, the updated regulations that you're talking about, still would allow these people, even though there are 700,000 people in this country, other physicians, and probably a couple hundred thousand scientists, that could be taking a look at these things besides a select group that continues to do it over and over again who don't have financial interests?

Ms. GLYNN. Yes, sir, I'm saying the statute that Congress passed gives the discretion to the agency involved to decide whether that particular individual is so important to the process that they should—

Mr. BURTON. Well, do you think that it should be reviewed, the statute?

Ms. GLYNN. I don't think there's ever anything inappropriate about Congress reviewing a statute that they've passed. But I have to say that from the information that OGE gets from agencies that operate advisory committees, we've been led to believe that it's working well and that they feel that the exemption provision in the statute is necessary for them to continue to operate their advisory committees.

Mr. BURTON. Oh, me. The immunization process takes place, a vaccine has not been thoroughly tested, an advisory panel on which people serve that have financial interests in the company, some children are maimed for life or die, and you're saying that you don't think there's a problem with a conflict of interest, where they're mandating, mandating that those vaccinations be given to these children, and these people who are making the decisions do have an interest in the company? And you did say if there's an appearance of impropriety, they should recuse themselves. But you don't see any problem with the current regulations?

Ms. GLYNN. No. I do not. I think the regulations do provide, as our testimony says, an appropriate framework for making those decisions.

Now, I'm certainly not in a position to say whether any individual serving on any particular committee was the right person to be serving, and whether the need for that particular individual was so great that that outweighed a potential conflict of interest. But I think the appropriate framework is in place for making those decisions by the agency.

Mr. BURTON. OK. The Code of Federal Regulations, 5 C.F.R. 2640.202(a), by the Office of Government Ethics, states that stock holdings not exceeding $5,000 on a specifically affected company or $25,000 on an affected company is considered to be a low involvement and thus is generally waived. How did OGE decide the acceptable parameters of what constitutes an acceptable financial interest?

Ms. GLYNN. In the particular regulation at issue, we issued a proposed regulation, proposing that figure. We got comments, I'll tell you truthfully, all over the place. Some commenters thought we should raise the amount to $100,000 I would say generally the comments that we got thought the amount was too low. We took a ballpark guesstimate at what we thought was something that would appear to be acceptable across the board. Remember, that regulation is an exemption for every Government employee, whether they're a regular Government employee or a special Government employee, acting in any type of matter.

Mr. BURTON. How did you arrive at that amount?

Ms. GLYNN. A ballpark guesstimate—

Mr. BURTON. A ballpark guesstimate.

Ms. GLYNN [continuing]. Of what we thought would be appropriate.

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Mr. BURTON. Did you consult with the Department of Health and Human Service officials about this policy?

Ms. GLYNN. I believe they commented on our regulation.

Mr. BURTON. What did they say?

Ms. GLYNN. I don't recall their specific comments.

Mr. BURTON. You don't remember?

Ms. GLYNN. No.

Mr. BURTON. The Food and Drug Administration has a document entitled Waiver Criteria Document 2000 which lists additional classifications for financial interests, mainly medium involvement and high involvement. The standard amounts shown in these categories are quite broad and range, for example, stock holdings in a company directly affected or more than $5,000 but less than $100,000 are deemed to be of medium involvement. Most likely to be waived.

In other words, an advisory committee member could have owned $100,000 worth of stock in Wyeth Lederle, and most likely would be allowed to vote on the Rotashield vaccine, is that correct?

Ms. GLYNN. I don't know. I have not seen the document you're
reading from.

Mr. BURTON. Did the FDA consult with the OGE in setting the policy I just mentioned?

Ms. GLYNN. I don't know if they did or not. I don't personally recall them doing it.

Mr. BURTON. Are you aware of who set the criteria for all of the different classifications listed in the FDA's Waiver Criteria Document 2000?

Ms. GLYNN. At the Department of Health and Human Services, I don't know. I think you would have to ask them.

Mr. BURTON. Does the OGE generally agree with the standard policy set forth in that document?

Ms. GLYNN. Well, sir, as I said, I haven't seen the document. But I don't think it's inappropriate for an agency to set forth general parameters of the type you describe. I guess we could argue about the numbers. But I guess one of the things you have to remember is that there are a lot of employees, regular and special Government employees, who own stock. It's not uncommon, and it's not unusual, I think, for agencies to develop a sort of internal policy in which they say, OK, interests in this sort of ballpark can be waived, interests in another ballpark would typically not be waived, and use that as a sort of standard operating procedure.

I don't think there's anything inappropriate about that.

Mr. BURTON. I understand that the Food and Drug Administration employees cannot own stock in pharmaceutical companies of which they are maybe making determinations on. Is that correct?

Ms. GLYNN. You would have to ask the Food and Drug Administration. I believe that they have a statute prohibiting ownership of stock, and I know they have regulatory provisions related to it.

Mr. BURTON. Why do you think they have that kind of a statute?

Ms. GLYNN. I think you have to ask them.

Mr. BURTON. Well, let me just ask, because they're afraid that there would be a conflict of interest?

Ms. GLYNN. Well, of course they are a regulatory entity, and they deal with all these companies.

Mr. BURTON. What's the difference between FDA and CDC and the other agencies that are involved in the decisionmaking process on vaccines and the advisory panels?

Ms. GLYNN. Sir, I think these questions are more properly addressed to the FDA and to the CDC. We were invited to talk generically this morning. Our letter of invitation asked us to speak generically about the framework for conflict of interest.

Mr. BURTON. OK.

Ms. GLYNN. I have given a cursory review to waivers issued by CDC and FDA in preparation for this hearing, and we received an invitation only 1 week ago. So we haven't had much time to prepare.

Mr. BURTON. Well, is it your interpretation of the (b)(3) waiver under 18 U.S.C.A. Section 208 that any kind of financial interest, no matter how great, could potentially be waived if the agency determines that the need for the individual is so unique and so important to the agency that it outweighs the potential conflict of interest? In other words, Wyeth Lederle CEO could potentially be allowed to participate in the decisionmaking process, if it was deemed by the agency that he had some expertise that no one else in the United States has?

Ms. GLYNN. Yes.

Mr. BURTON. And can you think of a situation where this could actually happen?

Ms. GLYNN. Yes, I think theoretically, your reading of it is correct that that could happen. In practice, I think that agencies do not issue waivers where they really think there is the potential the person will be actually biased in the advice that they give.

Mr. BURTON. Can liaison members be considered de facto SGEs if they contribute substantially in the decisionmaking process of an advisory committee?

Ms. GLYNN. I think not, sir. They're actually called there to provide a kind of biased opinion. It's understood that their point of view is going to be representing an industry view or an organization view, and presumably, people involved in the decisionmaking process know how to weigh that in. They understand that it's not going to be an objective point of view. In fact, that's why they're there, to provide that. I don't think they would become SGEs because they're involved in the discussion.

It's important, though, I mean, you're making a good point,
which is that it's important to determine in advance whether the person serving is in fact an employee or not. The agency should determine, in advance whether they want that person there to represent the biased industry view, so to speak, or to provide a service to the Government as an employee.

Mr. BURTON. It's my understanding if those people have a role in the decisionmaking process in these private meetings, that the public doesn't have any access to it, is that correct?

Ms. GLYNN. I don't know, sir.

Mr. BURTON. So you're not familiar with that in your capacity?

Ms. GLYNN. No, sir.

Mr. BURTON. So I'd have to ask the FDA or CDC or those people about that. OK.

Mr. Waxman.

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Mr. WAXMAN. Ms. Glynn, I know you're going to answer some questions generically about the ethics of Government law and how it applies across the board, and we'll have a chance to ask FDA and CDC about their specifics. But has the Office of Government Ethics reviewed CDC and FDA conflict of interest policies recently?

Ms. GLYNN. Our office has a component that does agency reviews, reviews of agency programs. And we do them on a 4-year cycle. I believe the last time we reviewed the FDA was about 3 years ago. We recently reviewed CDC; perhaps we've just issued a report in this past year.

Mr. WAXMAN. Can you tell us what you found with regards to these two agencies?

Ms. GLYNN. I can. In preparation for this, I did a cursory review of documents relating to these specific agencies. And we'd be happy to provide copies of those reports for the record, if you'd like them. As to the FDA, generally I can say we gave it what you might call a clean bill of health. We found that their ethics program, which examines things such as financial disclosure, counseling and advice, ethics training and so on, we found that they had a very good program and that it was operating quite well.

As to CDC, we found that they had what we call a sound ethics program. But we frankly found that they were somewhat understaffed and we recommended that they devote more staff resources to their ethics program.

Mr. WAXMAN. What's the standard for determining whether there's been a violation of the conflict of interest law?

Ms. GLYNN. The law prohibits an employee from acting in a matter that affects as financial interest. The standard is very broad. And so arguably, using the stock case as an example, again, if you own one share of stock in a company and the matter affects that company, you have violated, in the absence of a waiver or exemption of course, you have violated the conflict of interest clause.

The Congress created a law, as we see it, Congress created a law that was very broad that sweeps in a lot of interests. And they tempered that broad law by creating these exemption and waiver provisions—so that the agency would have the opportunity to examine the potential conflict of interest either across the board for groups of people, or on a case by case basis in individual waivers, and make its own determination about whether they want the employee involved.

Mr. WAXMAN. Isn't the standard to determine whether an advisory committee member is acting in a particular matter that will have a direct and predictable effect on the financial interest of that employee, his spouse, his children, or an organization which he serves as an officer, director or general partner and so on? Isn't that the standard, whether there's a direct and predictable conflict?

Ms. GLYNN. There has to be a direct and predictable effect on the financial interest for the statute to be violated.

Mr. WAXMAN. So the financial interest that would arise in a conflict, can't be speculative?

Ms. GLYNN. That's right.

Mr. WAXMAN. It has to be an actual conflict of interest?

Ms. GLYNN. That's right.

Mr. WAXMAN. So if somebody owns stock in Merck and they're voting on another company's drug?

Ms. GLYNN. There may or may not be a violation of the statute, depending on the facts of a particular case. You can theorize about situations where you act in a matter involving a competitor and it has the effect of virtually driving the other company out of business. It would be probably easy in a situation like that to establish the direct and predictable effect on the competitor. But oftentimes, it's a little bit more difficult.

Mr. WAXMAN. It seems to me there are two goals that agencies should have when they put together an advisory committee. First, they should try to have the best possible experts, and second, they should try to have individuals on the committee who are without conflicts of interest. Now, if you're trying to achieve those two goals, those two goals may be in conflict at times.

For example, in the case of vaccines, often the best researchers, those people with the most expertise, have had some relationship with a vaccine manufacturer, such as a research funding or honoraria from participation in a conference. Do you find that this is often the case with advisory committees?

Ms. GLYNN. From the copies of the waivers—remember, we don't issue the waivers at our office, the waivers are issued by the individual agencies and copies are provided to our office—from the copies of the waivers we have seen, that seems to be the typical kind of conflict of interest that is waived. I can't really say how many members of advisory committees receive waivers. We just don't keep that kind of information.

Mr. WAXMAN. Well, the chairman said that there are 700,000 physicians in America. I presume by that statement he means, why should we rely on these people who know the most about vaccines, when we can get just another physician. I don't know that any of us would want to have brain surgery done by a physician who's licensed and his general practice is podiatry.

Ms. GLYNN. I believe that's why Congress gave discretion to the agencies involved in deciding which particular individuals are those that are so needed that it's reasonable to issue a waiver under the conflict of interest statute. Only the agency really is in that position to decide whether the qualifications the individual possesses are so special that a waiver is appropriate.

Mr. WAXMAN. Mr. Dean, do you agree with the comments on these questions?

Mr. DEAN. Yes, I do. I would just add, Mr. Waxman, that the process that's established by the Federal Advisory Committee Act provides yet another level of protection potentially in that much of what an advisory committee does, and certainly the final recommendations issued by a parent committee, are subject to, I think, to a very public process, and at times a very intense public review by any number of people, whether it be the general public, the media, interest groups and so forth and so on. The Federal Advisory Committee Act provides a great deal of access to what advisory committees do.

Mr. WAXMAN. And is it, in your experience, uncommon for agencies to seek waivers for its advisory committee members so they can participate in committee meetings?

Mr. DEAN. Mr. Waxman, I don't have any experience with the waiver process at all. I do know anecdotally that our customers do talk about the difficulty in finding qualified people to serve on advisory committees. And you alluded earlier to our hearing regarding the National Academy of Sciences, and that's certainly one of the issues that we discussed then.

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And I just might note that the NAS and similar organizations I think by and large use procedures that are very similar to those used in the executive branch in terms of screening for conflicts of interest, balancing advisory committees, providing access to committee deliberations and so forth.

So it's not a problem that's unique to Government. I would point out that it's a problem that is, I think that we face, that universities face, that the NAS faces, that any organization that does research I think faces that very same problem.

Mr. WAXMAN. Ms. Glynn, what's your experience? Is it uncommon for an agency to seek waivers for its advisory committee members? And do you think waivers are inappropriate if there's apparent conflict of interest?

Ms. GLYNN. To answer your second question first, no, I don't think it's inappropriate to seek waivers. And whether it's uncommon or not is a little hard for us to judge from OGE. We are told anecdotally by agencies, I have to support what Mr. Dean said, we are told anecdotally by agencies that they have difficulty obtaining the services of expert advisors for advisory committees, in that they would be unable to obtain the services they need in the absence of some type of waiver provision.

Provided that the process is not actually tainted by bias, I don't think it's inappropriate to issue waivers at all. And I tend to think that some of these conflicts of interest tend to be more technical and it's reasonable to waive them.

Mr. WAXMAN. Well, let me go back to Dr. Modlin. I have his CV. It's extensive. He's clearly one of the leading experts in his field. Just to cite a little bit about him, he was the medical director of the Clinical Virology Laboratory of the Mary Hitchcock Memorial Hospital in Lebanon, NH. He sat on several editorial boards. He's been a reviewer for over 20 medical journals. He's participated in numerous conferences and workshops on various vaccine issues.

He's an expert. He knows more than the other 700,000 physicians in the country. So he's an expert. And he owns, as I understand it, 600 shares of Merck stock.

Now, he doesn't remember getting a notice that when he looked at a Wyeth Lederle vaccine product, that another company that might have been affected by his decision might have been Merck. He doesn't recall. Mr. Burton put in the record that he was given some notice that one of the affected companies was Merck, affected products, all investigational, Merck, Virus Research Institute, NIAID, Wyeth, obviously Wyeth. So he was given that information.

Is that an apparent conflict, if a man owns 600 shares of Merck? How important is a decision on this one issue going to affect the bottom line of Merck and therefore his stock price? How should we evaluate that conflict?

Ms. GLYNN. I'm not in a position to comment on the facts of an individual case. And I think we made clear before the hearing that I wouldn't be commenting on individual—

Mr. WAXMAN. Well, let me ask you a generic question. If a man owns stock in a drug company, let's say he was voting on that company's product. Would that be a conflict?

Ms. GLYNN. If he owns stock in a company, I'm speaking hypothetically now, if he owns stock in a company and he was voting on that company's product, yes, that would be a conflict of interest. He couldn't vote, in the absence of a waiver or some exemption applying.

Mr. WAXMAN. Now, he's voting on another company's product, and that company may be in a competition with a company where he owns some stock. Is that an actual conflict of interest?

Ms. GLYNN. That may potentially be a conflict of interest, depending on whether the matter would have some sort of effect on the competitor in which he owns stock.

Mr. WAXMAN. So just those facts alone wouldn't leap out as saying that people throughout this country should be wary that vaccines are not safe, because they're being approved by people like that example?

Ms. GLYNN. I certainly wouldn't be in a position to say that. But I think it's important in situations such as you described for the agency to examine these potential conflicts of interest in advance and make a determination whether they think the person should go forward acting or should be issued a waiver to permit them to go forward and act.

Mr. WAXMAN. I presume that Dr. Modlin had to file a form or disclosure about his own financial holdings. Isn't that required of people who want to serve on these advisory committees?

Ms. GLYNN. Our regulations require that members of advisory committees—or I should say require that the so-called special government employees—file confidential financial disclosure forms.

Mr. WAXMAN. And on that confidential financial disclosure, would a person have to list stock holdings?

Ms. GLYNN. Yes.

Mr. WAXMAN. How about if they received compensation from that company?

Ms. GLYNN. Yes.

Mr. WAXMAN. For whatever purpose?

Ms. GLYNN. Yes. They have to list all their assets, outside employment, typically outside consulting arrangements of any type, honoraria received or other forms of income of that type, liabilities, membership in certain organizations. It's relatively extensive.

Mr. WAXMAN. Why isn't this public? Why can't the American people or the press go and look at all these disclosures, the way they can look at our disclosures?

Ms. GLYNN. Certain people in the executive branch, of course, do file public financial disclosure forms. They're the higher level employees or people who have political appointments. For the vast majority of other employees, a balance is struck that you don't want to put too many roadblocks in luring them into Government service.

And for people who serve on advisory committees, they don't serve in the kind of positions that Congress has deemed appropriate for filing public forms. The criteria for filing public forms is set out in statute. And they just don't meet those criteria unless they're so highly paid by the Government and they work a certain number of days, then they would file a public form.

Mr. WAXMAN. So the law is that that is not made public?

Ms. GLYNN. That's right.

Mr. WAXMAN. Furthermore isn't the law that it can't be made public by anyone?

Ms. GLYNN. The law is that they may not be made public, that they're meant to be held as confidential.

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Mr. WAXMAN. Do you think that applies to the FDA?

Ms. GLYNN. Yes, sir.

Mr. WAXMAN. HHS?

Ms. GLYNN. Yes.

Mr. WAXMAN. CDC? How about the Congress of the United States?

Ms. GLYNN. I'm not in a position to comment on that. I think you would have to go to your own Ethics Committee.

Mr. WAXMAN. But the spirit of the law that Congress passed was that that information is not to be made public. It doesn't say not to be made public only by FDA, CDC, HHS, and everybody else at Congress is—it doesn't say one way or the other. It just says shall not be made public.

Ms. GLYNN. The provision does not—it says it shall not be made public. When we provide confidential financial disclosure forms to Congress, for example, occasionally as part of financial disclosure review of people being nominated to certain positions, we alert Congress to the fact that they are confidential, that we're not making any public release of the form, and that Congress in effect has to make its own decision about whether they think they should.

Mr. WAXMAN. Now, let me ask both of you, if Congress through its investigative committee started making public all these disclosures, what impact would that have on people's desire or willingness to serve in advisory committees?

Ms. GLYNN. My own view is I think it would have a chilling effect. What I understand from agencies is they have difficulty attracting people to these advisory positions to begin with, because they're typically low paying. And for the type of people they're trying to attract—very expert, well-known people—they're at a point in their careers where maybe isn't that much in it for them to be serving on these committees any more. And if they thought that they were giving their forms to the Government with a pledge of confidentiality, only to discover that wasn't being honored, I think it could have a chilling effect.

Mr. WAXMAN. Mr. Dean, what do you think?

Mr. DEAN. I would tend to agree with that, Mr. Waxman.

Mr. WAXMAN. So Congress ought to be very careful if we're going to start making public information that people were told was not going to be made public, not just because we're maybe violating the rights of those individuals, but we could have a chilling effect on people being willing to come in and serve on these advisory committees.

Mr. DEAN. I think it ought to be looked at very carefully before we make them public.

Mr. WAXMAN. Mr. Chairman, I'm going to yield back the balance of my time.

Mr. BURTON. I'll just take a couple of minutes to make a couple of comments. We're talking about, what's the gentleman's name, Dr. Modlin, is that how you pronounce his name? He was a paid consultant for Merck. When the rotavirus was approved, it had a positive impact on other companies who were producing the rotavirus, because it showed that it has been approved for one company, and if it was a similar product, it would be approved for the other company.

So Merck was going to be the beneficiary of that. Not only that, he was a paid consultant for Merck. Now, we don't know how much he was paid by Merck, but we know he was a paid consultant in addition to owning stock in Merck.

Now, I don't know how the bureaucracy in Washington feels, but I think I can speak for an awful lot of parents around the country who want to have confidence that the vaccinations their kids are getting have been tested, and that there's been an unbiased judgment made as to whether or not they're going to be safe as well as effective.

And the problem with the bureaucracy is, you keep saying, well, we can't do this because we might not be able to attract people to these advisory committees. Look, there are 700,000 doctors. There must be somebody else out there in that vast mass of humanity that has the expertise to be able to be on these advisory boards.

And if a parent knew that there was a financial interest, possible conflict of interest from the person making the decisions on the vaccination, especially if we find out after the fact that kids died or are ruined for life, then I think the parents would say, you know, maybe we ought to make absolutely sure there's no conflict before we allow these people to be on these advisory panels making these decisions.

Now, you know, you may disagree because you serve in a position in the bureaucracy where these decisions are made, and you think that that's the way it ought to be. I speak from a little bit of experience. I have two grandchildren, two. One got a hepatitis B shot and within 3 hours she was dying. She wasn't breathing any longer. They had to rush her to the hospital and she survived. Now, there's a lot of parents who have had that kind of problem with other drugs and other vaccinations. My grandson got nine shots in 1 day. He was a perfectly normal child. And within about 3 or 4 or 5 days, a week, he became autistic. Now, it may be a coincidence. A lot of people say that's coincidental.

But the one thing I want to make sure of as a grandparent or as a parent is that the guys making these decisions or the ladies making these decisions, these doctors, these experts, don't have some kind of a conflict of interest that skews their judgment in one direction or the other. And the American people, well, you can say, we shouldn't be making this stuff public. Let me tell you something. Everybody in American who has a child who's had this kind of a problem wants this stuff made public, because they want to know if the people making these decisions do have a conflict of interest.

We go to the doctors and we get these shots for our kids, and we do it believing that the health agencies are above reproach, that there's no danger to our children, or at least it's minimal. And we put great confidence in CDC and FDA and all of our health agencies. And if we find out after the fact that our child has had a terrible, serious problem, and then we find out after the fact that people on that advisory committee that made those decisions did have a conflict of interest, it will weigh on us very heavily, because we'll wonder, always wonder, if that conflict of interest led to the problem that we have in our family.

And that's why the people on these advisory committees need to be above reproach. They need to be above reproach. If they have a conflict of interest, if they're a paid consultant for a company that has an interest in that product, if they have a large amount of stock in that company, and they're going to benefit from that product, or if they have some other reason to be tied to that company, they're getting grants from that company for scientific research, whatever it might be, they should not be on

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those advisory committees. And if they are, it should be made known at the outset so that people can make a decision based upon information, total information.

And I just think it's wrong. You may shade this one way or the other, based upon what you feel is being with the Department of Ethics in this country. But if that's the way it is right now, I think the law should be reviewed and changed. There's got to be people out there that can serve on these advisory panels that don't have conflicts, who may have their judgment skewed in one direction or another. And there's got to be people out there that are going to make decisions based upon what's best for the people of this country and the kids of this country without any bias whatsoever.

And that's what the American people, I believe, want. And I know as one who's been affected by this, that's what I want.

Mr. WAXMAN. Mr. Chairman, my heart goes out to you, for your personal family tragedy. I don't know whether it was connected to the immunization or not. I just don't know the answer to that. I think you feel that it was connected, and I understand your strong feelings about it.

But I don't think we ought to pick on Ms. Glynn and say that she believes something because she's part of the bureaucracy. After all, we're talking about laws that were adopted by the Congress. She didn't vote on these laws, we did. And under the law that we voted there is a whole mechanism to try to avoid against conflicts of interest. The disclosure had to be made by each of these people who wanted to be on an advisory committee, or we tried to get on advisory committees, and we told them, we want you on, you have to make a disclosure.

So they made a disclosure, the agencies had the information. We'll find out when we hear from the next panel whether they had disclosures. But I presume they had disclosures about everybody on the advisory committee.

Second, they may or may not have had waivers if they thought that it was important to allow these people to continue to serve, notwithstanding the fact that they may have had a conflict, such as owning shares. But what would gall me the most, as a parent and as a grandparent, was to think they got people who didn't have expertise in the science and started having them sit on these committees and approve drugs or vaccines that later turn out to be a problem. Now, it turned out there was a problem with this particular rotavirus vaccine. The fact that there was a problem with the rotavirus vaccine, and I don't know why they didn't foresee it, but it seems like from what I understand, they had some concerns about it and they were watching to see if this problem might develop that they feared might result from this vaccine. I have not heard any evidence that anybody, even if they had no conflict of interest to even talk about, made any decision that wasn't completely proper, scientifically and otherwise proper in terms of their evaluation of this particular vaccine.

So, to say that because there's an apparent conflict with some of the people on the advisory committee, that that apparent conflict meant that the vaccine might have had a problem, is a huge leap. It is a huge leap, and we ought to have a lot more evidence before we make that kind of a statement publicly, because it does tend to scare people into thinking that decisions are made at FDA on drugs and vaccines or at the CDC on public health issues, by people who are sitting there thinking about how they're going to enrich themselves, and they're not evaluating the science. If they've evaluated the science, that's the first thing that's important. And we have no evidence that they didn't do that which was necessary.

I don't want people who are beyond reproach. I don't want saints. I want people who know what they're doing and if there's a problem or a possible conflict, I want that disclosed and dealt with. And as I understand it, in the case of each and every one of these people who served on these advisory committees, their holdings, their income, were all disclosed to the people who were having them serve on the committee.

So I don't think, notwithstanding the frustration that you and others may feel, that we ought to leap to conclusions based on what we have heard so far about some of the individuals that served on the advisory committee. Look at how Members of Congress are dealt with. We disclose our information and we assume therefore there's no conflict. Look how we handle our campaign finance laws. We disclose—we thought, except for some loophole that's now come up in the form of these nonprofit organizations that are now being used to subvert the disclosure laws—but we worked under the assumption that we disclosed from whom we get the campaign money and therefore we've done what's necessary to show that if we act, people can judge whether we've acted in a conflict.

These people who serve on advisory committees had to make that disclosure, and therefore for those who work in the agencies and handle the ethical questions, they can evaluate whether there was a breach of ethics. From Ms. Glynn's testimony, FDA seems to have a good record in ethics. CDC apparently has a good record in ethics. You're not talking about agencies that have a bad record on how they handle their ethics. And I think we need to get more information before you reach some of those conclusions that you've mentioned.

Mr. BURTON. I'd like to just ask my colleague one question, because I don't want to prolong this. The rotavirus that we're talking about, before the advisory committee made its recommendation, they already knew that there were adverse events, 1 out of 2,000 children had severe side effects. And yet they went ahead and approved this rotavirus anyhow. And it was put on the market and then withdrawn in less than a year because of severe side effects and problems.

That's the thing I have concerns about.

Mr. WAXMAN. I understand, and I share that concern as well. But without knowing more, it could well have been a judgment that was a mistaken judgment on the scientific evaluation of whether they thought that this was a likely result and therefore they should have foreseen it, or whether it was an unlikely result and they didn't know about it in the instance in which they reviewed it, and thought maybe these were isolated cases, and let the vaccine go forward.

After all, vaccines can prevent a virus that is a killer all around the world of children and of infants. And you have to evaluate, with all products, the risk benefit calculation.

Mr. BURTON. I want to thank this panel for being here.

We'll now go to our next panel. Our next panel consists of Linda Suydam, Dixie Snider, Kevin Malone, Jennie Slaughter, Bill Freas, and Nancy Cherry. Would you please come forward. Would you please stand. As I understand it, one person from each agency is going to be the principal spokesman, and the

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others will be there to help you, to assist you. So I guess you don't need to come forward, as long as you're sworn in.
[Witnesses sworn.]

Mr. BURTON. Please be seated.

Ms. Suydam, do you have an opening statement?

Ms. SUYDAM. I do, Mr. Chairman.

Mr. BURTON. You're recognized.

Statement of Linda A. Suydam, D.P.A., Senior Associate, Commissioner, Food and Drug Administration

Ms. SUYDAM. Thank you. Mr. Chairman, members of the Committee, I'm Linda Suydam, Senior Associate Commissioner of the Food and Drug Administration.

I'm pleased to have the opportunity to be here today to discuss with you FDA's advisory committees. FDA is committed to selecting the most qualified members for our advisory committees, and to rigorously complying with the statutes and regulations governing those committees. FDA is a science based regulatory agency with regulatory responsibility for approximately 25 percent of the gross national product, including food, drugs and medical devices.

FDA's mission is to protect and promote the public health by promptly and efficiently reviewing clinical research and taking appropriate action on the marketing of regulated products in a timely manner. FDA's advisory committees play a critical role in this public health mission. FDA's decisions must be based on the highest clinical and scientific standards. To provide this critical scientific base, FDA has over 1,500 outside experts who provide FDA with essential expertise in highly specialized areas.

Many of these experts serve as members on or consultants to our advisory committees. These members are public servants in every sense of the word. While they are compensated for their time at meetings, the amount of time and effort these members and consultants put into the public health needs of this Nation is a true public service.

Currently, FDA is administratively responsible for a total of 32 advisory committees. Each has a core membership identified with each committee's charter. This membership is developed based on the complexity of the issues to be considered and the assessment of the issues by the agency as to the types and degrees of expertise needed.

FDA's advisory committee system assists FDA's mission in the following seven ways: by providing independent expertise and technical assistance related to the development and evaluation of products regulated by FDA; by lending credibility to the product review process; by speeding the review of products by providing visible sharing of the responsibility for the evaluation and judgment of these products; by providing a forum for public discussion on matters of significant public interest; by allowing sponsors and consumers to stay abreast of trends in product development by reviewing process and changes in regulations and guidelines related to FDA-regulated industries; and providing external review of FDA's internal research projects.

Committee members with voting status vote on substantive scientific and policy matters. It is extremely important to note, however, that these advisory committee recommendations are not binding and that panel members are not asked approval or disapproval questions. The agency retains all final decisionmaking authority. Thus, FDA alone decides to approve a product for marketing as safe and effective.

The standing membership of advisory committees includes academicians, clinicians, consumers, and in some cases industry reps and patient or patient caregivers. In addition to the standing membership, temporary voting members and consultants may be needed to provide specific expertise.

FACA requires that committee memberships be fairly balanced in terms of points of view represented to the committee function, and DHHS policy requires that the committee membership be composed of as equitably as possible of geographic, ethnic and gender representation. In screening nominations for prospective standing committee members, FDA has a thorough and consistently applied process. This ensures that we obtain qualified members who are able to provide the agency sound advice. Final appointment of all advisory committee members is done by me, the senior associate commissioner.

If permitted by a committee's charter, the committee's standing voter membership will be supplemented by the appointment of temporary voting members. These members are important, as they have specialized expertise often necessary for the consideration of particular issues.

While FDA has a great need for scientific advice, it is critical that that advice be as free as possible from conflict of interest and potential bias. If the advice FDA receives is biased or perceived as biased, it is of little value to the agency and only diminishes the credibility of agency decisions.

Studies have shown that academic and biomedical research is increasingly supported by industry. For that reason, outside experts in research centers where they work frequently have research grants from and contracts with regulated industry. Thus, most active researchers in the private sector have some ongoing or past relationship with the regulated industry.

This by itself does not preclude them from becoming SGEs. If this were the case, FDA would not have the top scientists in the field and the recommendations of the committees would not be of the highest scientific nature, with a likely impact on public health.

Prior to each advisory committee meeting, each SGE completes an FDA conflict of interest disclosure form. Types of interests that are screened are stocks, investments, primary employment, consultant work, contracts, patents, grants, trademarks, expert witnesses activity, speaking engagements and other information. FDA has the authority to allow an advisory committee member to participate in the review of a new therapy, even if there is a potential conflict, as long as FDA applies with applicable legal standards. And FDA may provide for this by granting a waiver.

In the 1990's, the Institute of Medicine recommended to FDA that it formulate a written guidance document. And an FDA task force with DHHS did create that waiver criteria document. And in 1997, the Office of Government Ethics audited the FDA ethics program, including the advisory committee programming, concluded that it was impressed with FDA's program for protecting SGEs from conflict of interest, and that it was a model for other agencies to use in developing their own systems and procedures.

In conclusion, Mr. Chairman, let me assure that the agency has met every effort to rigorously comply with the applicable statutes and regulations in appointing outside members to the FDA advisory committees. Multiple, independent and sometimes redundant views, taken together ensure FDA, the medical community, industry, consumer and patient groups and most importantly, the American public, that advisory committee recommendations are based on the best possible science and are free from bias.

Thank you. I'll be happy to answer any questions.

Mr. BURTON. Thank you, Ms. Suydam.

Dr. Snider, do you have an opening statement?

Dr. SNIDER. Yes, sir, I do.

Statement of Dixie Snider, Jr., MD, Executive Secretary, Advisory Committee on Immunization Practices, CDC

Dr. SNIDER. Thank you, Mr. Chairman, and good afternoon. I'm Dr. Dixie Snider, Jr., Associate Director for Science at the Centers for Disease Control and Prevention. As executive secretary for CDC's Advisory Committee on Immunization Practices, I'm pleased to be here to discuss the policies and proce-

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dures of the committee and its role in developing recommendations for vaccine use.

The ACIP develops written recommendations subject to the approval of the Director of CDC for routine administration of vaccines for the pediatric and adult populations, along with schedules regarding the appropriate periodicity, dose and contraindications applicable to the vaccines. In addition, as provided by statute, the ACIP designates vaccines for administration in the Vaccines for Children program.

The overall goal of the ACIP is to provide advice that assists CDC, HHS, and indeed the whole Nation, in reducing the incidence of vaccine preventable diseases and increasing the safe usage of vaccines and related biological products. The ACIP consists of 12 regular voting members, many of them parents, selected by the Secretary of the Department, from authorities who are knowledgeable in the field of immunization practices, have multidisciplinary expertise in public health, and have expertise in the use of vaccines and immunologic agents in both clinical and preventive medicine.

In addition to required technical expertise, consideration for ACIP membership is given to representation from diverse geographic areas, both genders, ethnic and minority groups and the disabled. In addition to regular voting members, the ACIP has ex officio members from other Federal agencies who are involved in vaccine issues. And we have non-voting liaison representatives from professional societies and organizations responsible for the development and execution of immunization programs for children and adults. These people do not vote.

The representation of these ex officio members and liaison representatives does contribute toward a better understanding of the position and views of their sponsoring organizations and results in better informed decisions, in our view. Open public ACIP meetings are held three times a year with meeting dates announced 6 to 12 months in advance. Notices of each meeting are published in the Federal Register in accordance with the requirements of the Federal Advisory Committee Act. ACIP meetings are open to the public, as I said, and public comments are solicited during the ACIP meetings.

Federal advisory committees inherently have members who may have potential financial conflicts of interest. Experts in the field frequently have affiliations with or may be engaged in research conducted by academic institutions or other institutions which may receive funding by vaccine manufacturers. The situations which produce immunization expertise also may result in potential conflicts of interest.

And Congress has recognized the need for service on Federal advisory committees by these experts by providing the authority to issue waivers of conflicts of interest when the need for the individual's services outweighs the potential for a conflict of interest created by the financial interest involved. The work of the ACIP necessitates significant immunization expertise.

One of the purposes of this advisory committee is to provide additional scientific expertise beyond what may be known and presented to the committee. Experts are more likely to be familiar with the published scientific literature, with its strengths and weaknesses, than non-experts. But in addition, experts are more likely to know cutting edge research information, including unpublished information, that may not be generally available. And if this expertise were not available to us, members would be limited to decisionmaking based solely on selected information presented at the ACIP meetings.

So consistent with these provisions of law, limited waivers are issued to ACIP members who have potential conflicts of interest, so that the Government may benefit from the scientific and public health expertise of each member. And under these waivers, each member with a potential or actual financial conflict of interest is granted a limited waiver to allow participation in all committee discussions, with the conditions that the member publicly discloses relevant interests at the beginning of every ACIP meeting and abstains on votes involving entities with which the member has a current direct financial interest when that vote could potentially result in a significant financial impact on the entities.

This public disclosure, which is fairly unique to the ACIP, ensures that the agency, their fellow members and the public are aware of each member's interests, which then can be weighed in the deliberations of the committee.

CDC is continuing to review its policies related to its advisory committees to achieve the highest level of scientific integrity in obtaining external expertise. We welcome any suggestions to improve the process. And I'd be happy to respond to any questions you may have, Mr. Chairman.

Mr. BURTON. Dr. Snider, when a person decides that they may have a conflict of interest and they decide not to vote, does anybody vote in their stead at these advisory committee meetings?

Dr. SNIDER. In most cases, they do not. We do have a provision that if we do not have a quorum, which is six members, available, that is not conflicted, that is able to vote, then in the most recent charter, I have the authority to appoint the ex officio members as voting members.

Mr. BURTON. And who are those ex officio members?

Dr. SNIDER. The ex officio members are representatives from other Federal agencies.

Mr. BURTON. So you appoint somebody to go in and take the place of the people who aren't there or who have disqualified themselves on that issue?

Dr. SNIDER. I'm able to appoint ex officio members as voting members under certain circumstances, yes, sir. On some committees, ex officio members are routine voting members.

Mr. BURTON. Now, these people that you appoint to go in, do they discuss the issue at hand with the people who are in the meeting, including the person who may have said they have a potential conflict of interest before they vote?

Dr. SNIDER. I'm sorry, I don't quite understand the question.

Mr. BURTON. Well, let me explain it again. You've got a meeting, you've got say six or eight people there, and a couple of them say, you know, that I have a financial interest in this company. And they say to you that in order to make sure we have a vote today, because we've come a long way, can you send a couple of people in to vote in our stead. Now, when they go in there, do those people discuss the issue with the people in the meeting?

Dr. SNIDER. All right, Mr. Chairman, let me explain the process. I understand the question now.

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In the meetings, as I mentioned, there are these potential conflicts of interest that are disclosed at the beginning of the meeting. When we arrive at a point in the meeting at which a vote needs to be taken, we do another ascertainment to determine who is able to vote and who is not able to vote among the regular voting members.

Also in the room during the whole meeting are the ex officio members. And so they have been participating and listening to the discussions. Therefore, they are well equipped to participate in the vote.

Mr. BURTON. So the people who have a financial interest who have disqualified themselves, do they participate in the discussion about the vaccination or the product at hand?

Dr. SNIDER. As was indicated earlier, Mr. Chairman, these individuals have been granted waivers. Of course, we could allow them to vote on the issue if we wanted, under those waivers.

Mr. BURTON. I know, but let's get—

Dr. SNIDER. But we have decided, to answer your question, sir, we have decided that because of their expertise, we would like them to participate in the discussion.

Mr. BURTON. So they participate in the discussion.

Dr. SNIDER. But they do not vote.

Mr. BURTON. But they do not vote. But the people that you have appointed to come into the room hear all of the arguments, and they are persuaded to vote either for or against it, based on the discussion in the room, correct?

Dr. SNIDER. The individuals who are ex officio members participate throughout the meeting.

Mr. BURTON. I understand.

Dr. SNIDER. They are active participants. They are representatives from FDA, a representative from NIH and so forth. They understand these issues on their own.

Mr. BURTON. OK, I don't understand. We don't need a long dissertation.

Dr. SNIDER. They're vaccine experts.

Mr. BURTON. The question I asked is this. They sit in the room, the people who are not going to vote, in whose place these people from your agency are going to vote, they hear the discussion. And after they hear the discussion, which includes the people who are not going to vote, then they vote in their stead, is that correct?

Dr. SNIDER. It's not—we don't view it as in their stead. But they do vote, yes, sir.

Mr. BURTON. OK, but they have heard the discussion, which includes the people who do have a potential conflict of interest, they participate in the discussion and then they don't vote after they participate in the discussion?

Dr. SNIDER. That's correct. The other people do vote after hearing those people who are conflicted, and also knowing that those people are conflicted.

Mr. BURTON. Do you think that the people who are conflicted expressing their opinion and how they feel about the potential product, do you think that they have any persuasiveness to them? Obviously they're there to tell how they feel about the product.

Dr. SNIDER. People vary in their persuasiveness. And just because individuals have conflicts of interest does not necessarily mean that you can predict what position they will take. And individuals may or may not be very persuasive.

Mr. BURTON. Would you say that they're in a de facto, they are de facto participants in the decisionmaking process, because they're actually giving their views to the people who are going to vote in their stead?

Dr. SNIDER. As are members of the public and as are representatives from professional societies.

Mr. BURTON. How many members of the public do you have in there?

Dr. SNIDER. In many meetings we have maybe 60, 70, 80 people present at the meeting. And we'll have 10, 15, 20 members of the public.

Mr. BURTON. How many of those people vote?

Dr. SNIDER. I'm not suggesting they vote. My point was that there are many people who are recognized by the chairman who are able to comment on these issues throughout the discussions. If a member of the general public gets up to the microphone, Dr. Modlin, our current chair, will recognize that individual and allow them to influence the committee as much as anyone else can.

Mr. BURTON. As much as the person who has the conflict of interest who's on the committee who's not voting?

Dr. SNIDER. To the extent that they have those persuasive powers.

Mr. BURTON. How many recommendations by advisory committees are not followed? How often does that occur, by the FDA?

Ms. SUYDAM. It's very rare when, the recommendations are generally related to specific questions that the advisory committee is asked. For example, they're asked, is there enough data to support the safety of this product, is there enough data to support the efficacy of this product. So when you say follow, the decision that whether the product is allowed on the market is FDA's alone.

Mr. BURTON. I understand that. But how often does a recommendation by an advisory panel of this type, how often is that rejected?

Ms. SUYDAM. It is very rare.

Mr. BURTON. Very rare. I mean, can you give me a number in the last 2 or 3 years how many times it's happened?

Ms. SUYDAM. I don't believe I can, Mr. Chairman. I'll be glad to provide that for the record.

Mr. BURTON. Can you list all the instances where the FDA has not licensed a vaccine product recommended for licensure by the VRBPAC on the basis that it did not agree with the findings of the committee from January 1990 to the present? Can you give me some examples?

Ms. SUYDAM. Mr. Chairman, I don't believe there are any.

Mr. BURTON. So for the past 10 years, the recommendations of the advisory panels have pretty much been followed 100 percent?

Ms. SUYDAM. With some delay in some cases. For example, it may be 5 years before a product is brought onto the market.

Mr. BURTON. The Supreme Court, when they were talking about additions to 18 U.S.C. 208, said ''The statute is thus directed not only at dishonor, but also at conduct that tempts dishonor. This broad proscription embodies a recognition of the fact that an impairment of impartial judgment can occur in even

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the most well-meaning men or women when their personal economic interests are affected by the business they transact on behalf of the Government.''

Now, I want you to bear that in mind, because I have some questions that bear upon that. The committee, one of these committees, VRBPAC, for the VRBPAC meeting where Rotashield was approved for recommendation, an advisory committee member, Dr. Mary Estes, her employer had received a $75,000 grant from American Home Products, the parent company of the sponsor, Wyeth Lederle. In addition, the member herself was the principal investigator on a grant from Merck, an affected company, for the development of its rotavirus vaccine. This member was given a waiver and fully participated and voted on the recommendation.

Another member, Dr. Catherine Edwards, was receiving a grant for research on another vaccine of $163,000 from Wyeth Lederle. And yet another member, in fact the chairwoman of the committee, Dr. Patricia Ferrieri, owned close to $20,000 worth of stock in Merck, an affected company whose rotavirus vaccine was already in the pipeline. This person as chair leads and conducts a discussion on the approval recommendation of a vaccine that, by the FDA's own admission, will make it easier for other similar rotavirus vaccines in the pipeline to be approved.

Now, I know you can't comment on specific cases. But generally speaking, should a person who is getting large grants of money from a company that makes the vaccine under consideration be able to get a waiver and vote for its approval?

Ms. SUYDAM. Mr. Chairman, as you know, the Government Ethics Act and the Privacy Act prohibit me from talking about specifics.

Mr. BURTON. I'm not asking about specifics.

Ms. SUYDAM. I would suggest that—

Mr. BURTON. Generally speaking.

Ms. SUYDAM. We have a procedure in place whereby we have eight levels of review that looks at the financial disclosure statements for every member of our advisory committees, including temporary members. And those eight levels of review would weigh whether the benefit of having a particular expert is necessary for that committee in order to have them on the committee, if they had and did own some stock.

Mr. BURTON. Generally speaking, generally speaking now, you have one that got a $75,000 grant from American Home Products, and was the principal investigator on a grant from Merck, which was an affected company. And this person was given a waiver. Another member received a grant for research for a vaccine from the company in question, Wyeth Lederle, for $163,000. Another who was the chairwoman had $20,000 worth of stock in Merck, an affected company. And she led and conducted the discussion on the approval of the recommendation of the vaccine that by the FDA's own admission will make it easier for other similar rotavirus vaccines in the pipeline to be approved.

Now, generally speaking, don't you think the American public would consider these to be a possible conflict of interest, if they saw that?

Ms. SUYDAM. Mr. Chairman, they are considered a conflict of interest, but they were waived after considerable thought and review. And we've gone back and reviewed all of the members of those committees. So I won't speak about each one individually. But I will tell you that we believe that the decision was made in a way that made the committee the most effective for the American public.

Mr. BURTON. So if a decision was made like that, then obviously you would not consider that to be a real conflict of interest problem.

Ms. SUYDAM. We consider it a conflict of interest that could be waived based on the needed expertise of those particular individuals.

Mr. BURTON. And this rotavirus that went on the market, even though there had been 1 in 2,000 adverse events, which was withdrawn after substantial problems by people who took the vaccine, within a year, so would you say that maybe there was a mistake made? And what about those people who suffered as a result of that mistake? Do you think they might think there was the possibility that there might have been a conflict of interest by these people that had a financial interest, even though you folks didn't?

Ms. SUYDAM. Mr. Chairman, I think the injuries that were suffered are a great tragedy for the people and for the parents of those children. I do believe that those kinds of injuries happen when you bring a product onto the market. I think we put protections in place so that we could pull off that product as quickly as possible.

And when we saw that the incident rate was higher than we had anticipated, we did take action and the product was withdrawn.

Mr. BURTON. They knew at the outset that there were adverse events. They knew at the outset. And yet it was a unanimous decision, I guess, by the advisory panel, to go ahead and put that product on the market. And people did have conflicts of interest, it was very, very clear, substantial conflicts of interest. And you felt that their expertise was substantial enough that you waived.

Ms. SUYDAM. Yes, sir, we did.

Mr. BURTON. At the very least, don't you think that a person who's receiving substantial amounts of money, either for his or her research or as a consultant is likely to be biased toward that company?

Ms. SUYDAM. I believe that the bias is one that has to be weighed in terms of what is the person's scientific abilities and whether that person can participate in a way that is unbiased. Clearly, if the person had an interest that was specifically related to the product that was being reviewed, they would not be granted a waiver. And in fact, that was the case in the Rotashield meeting. We excluded a number of people from those meetings.

Mr. BURTON. Well, you have waived a lot of people who have these conflicts. And we have a lot of cases. We've been doing a lot of research. So I won't go into all those, we just took this one example today.

But let me go back to what the U.S. Supreme Court said. And I want you to listen to this, and think maybe you're waiving these things too often. It says, the statute is thus directed not only at dishonor, where a person intentionally does it, but also at conduct that tempts, tempts dishonor. This broad proscription embodies a recognition of the fact that an impairment of impartial judgment can occur in even the most well-meaning men and

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women when their personal economic interests are affected by the business they transact on behalf of the Government.

Now, the reason I bring that up again is the Supreme Court said that even the best of us, when put in that position, may have our judgment tainted because in the back of our minds, they know we have a financial interest. And yet you waive continually on these products people who have substantial financial interests.

And in the case of the rotavirus, even though there were 1 in 2,000 side effects that were substantial, they voted to put that on the market, and in less than a year, it was taken off. They knew there were side effects. They knew they had a conflict of interest. You waived on it and people suffered and it went out into the marketplace.

You don't see that as a problem?

Ms. SUYDAM. It certainly is a problem when people suffer from products that cause harm. I understand that. But Mr. Chairman, I waive conflict of interest when we feel and the scientists in FDA feel that they need the expertise of those particular people to make the decisions that they have to make.

Mr. BURTON. Dr. Snider, for the VRBPAC meeting on Rotashield on December 12, 1997, only seven advisory committee members were in attendance. Two of them had strong financial conflicts of interest that prevented them from even participating in the proceedings. That meant that only five members were available for the meeting, and five people were brought in as temporary voting members.

Why wasn't this meeting postponed when it became evident that there would not be a quorum of advisory committee members?

Ms. SUYDAM. That's my question, I think.

Mr. BURTON. Yes, that's a question for you, go ahead.

Ms. SUYDAM. It is my question. At the time, we had two other topics on the committee agenda as well. And we felt it was important to go forward with the meeting as such. And we have used and have authority to use temporary members and bring those in as temporary voting members. And we did that in this case.

Mr. BURTON. Well, wasn't it inappropriate, and this is when the rotavirus was approved, wasn't it inappropriate not to say against the Department policy that states that a meeting will generally not have more than four temporary voting members? I guess in your charter it says that you have to have, you can't have 50 percent of the voting members being temporary members. So why would you have more?

Ms. SUYDAM. I think the operative word, Mr. Chairman, is generally. And we felt that it was important in this case, the meeting for other issues we had individuals at that meeting and we went ahead with the meeting and had the rotavirus discussion.

Mr. BURTON. That was because there was a deadline coming up?

Ms. SUYDAM. We felt it was important to have the advisory committee at the time when we set it up, there were more people attending, we had hoped there would be more people attending.

Mr. BURTON. If the concerns were related to deadlines or getting this job done that the FDA had to comply with, why didn't the FDA get an extension to make sure that the members were there? Didn't feel like you needed to do that?

Ms. SUYDAM. No, Mr. Chairman, I think we initially thought there would be more members at the meeting, and then at the last minute, some people had things that came up and they were not able to attend.

Mr. BURTON. After reading, and we read the VRBPAC Rotashield approval transcript, it became obvious that members voted unanimously to recommend the approval of the vaccine, even though many expressed serious concerns about the efficacy and the safety of the vaccine. I mean, they expressed concern about the safety of the vaccine at the hearing.

For example, one of the temporary members asked, and as a result, I would ask the FDA to work with the sponsor to further quantify what these serious side effects are, specifically the adverse effects driven in particular by febrile illness is inducing hospitalizations, and what is that level of access. I still don't feel like I have a good grasp of that at this point.

And yet, even though he had serious concerns, he worked for the agency, he voted, along with everybody else, for the approval of this vaccine that was jerked off the market.

Now, doesn't it concern you that these members are voting unanimously to approve a product that they have serious concerns about, like this person from the agency?

Ms. SUYDAM. I think you're quoting from the transcript, is a scientist who is speaking out and talking about some of the issues that he still thinks need to be resolved, because they know that FDA makes the final decision and that FDA will in fact be able to followup with the company. So they're giving us a signal, they're sending us a signal that says, FDA, go ahead and talk to the company about this particular issue. And I assume that the FDA did.

Mr. BURTON. But you said in the last 10 years, there hasn't been one time that the advice of these committees has been rejected by the FDA, in 10 years. Isn't that correct?

Ms. SUYDAM. In the case of the VRBPAC, yes.

Mr. BURTON. So in 10 years, they haven't rejected it. And yet this gentleman or gentlelady that made this comment who had reservations, went ahead and voted for it, I presume because he was persuaded by everybody else, or maybe because he worked for the agency, and nothing was done. They went ahead and approved it and put it on the market.

Ms. SUYDAM. Well, I can assume, Mr. Chairman, that the agency, if they also take the advice of the committee, would also go ahead and followup with the company and resolve that issue, resolve that question that the scientist was raising in the transcript.

Mr. BURTON. Does anybody know if that was resolved? Do you,

Ms. Suydam? Do you know if it was resolved?

Ms. SUYDAM. I believe it was. Otherwise the product would not be on the market.

Mr. BURTON. Well, it wasn't on there very long.

As I understand it, the very concerns that were expressed here were the reason they pulled it from the market. So maybe it wasn't addressed.

Are most of the votes of the VRBPAC unanimous votes?

Ms. SUYDAM. I believe most of them area. The majority are.

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Mr. BURTON. Can you give me an idea of how many aren't unanimous?

Ms. SUYDAM. Well, occasionally, they will be seven to one or something like that on some issues.

Mr. BURTON. Can you give me a number that have not been unanimous?

Ms. SUYDAM. I don't believe I can, no.

Mr. BURTON. Is there anybody that's with you that can give us a number of the recommendations that have not been unanimous in the last 5 to 10 years? Do you know of any that have not been unanimous?

Ms. SUYDAM. I do. I do know of some.

Mr. BURTON. How many do you know of?

Ms. SUYDAM. I know that even on some of the questions we have asked for the Rotashield, for example, they were not unanimous.

Mr. BURTON. So you know of some vaccines where they were not unanimous?

Ms. SUYDAM. Yes.

Mr. BURTON. But it's rare?

Ms. SUYDAM. It's probably in the range of 20 percent.

Mr. BURTON. Now, if you have somebody that doesn't agree, let's say you have four, do you normally have more than one or two or how many?

Ms. SUYDAM. It's hard for me to say. The numbers of the committee members that are voting changes. Sometimes it could be two, sometimes it could be three, sometimes it could be one.

Mr. BURTON. According to the time line of the approval and recommendation of the Rotashield vaccine, the ACIP committee voted on a recommendation before the vaccine had been approved by the FDA. Do you feel that it's appropriate for the ACIP committee to vote on a recommendation of a vaccine when that vaccine has not even been approved by the FDA?

Ms. SUYDAM. I would not be able to speak for the ACIP.

Mr. BURTON. Doctor.

Dr. SNIDER. I think it's appropriate for the committee to give the working group some guidance on how they would foresee the recommendation going. The recommendation is not an established recommendation until it's published in the Morbidity and Mortality Weekly Report. But there's a lot of scientific work that goes into developing these recommendations. So votes have been taken prior to licensure to give guidance. I think some people have misunderstood the purpose of those votes, and have mistook those votes as being final votes. But a recommendation is not final until it's accepted by the Director of CDC.

Mr. BURTON. So you think it's appropriate for the ACIP committee to vote on a recommendation when a vaccine has not even been approved by the FDA?

Dr. SNIDER. I think it's appropriate, again, to give their opinions about what populations it should be used in and give general guidance to the working group that's working on the recommendations. And that is what we attempt to do in our policies and in our procedures. To the extent that others have been misled about any votes, we apologize and will take steps to try to ensure that never happens in the future.

Mr. BURTON. At the ACIP meeting on February 18th, 1999, Dr. Modlin stated, ''Just when everybody thought we were finished with rotavirus, in fact, we were really almost there. The statement was approved in June of last year and in fact the statement is very close to going to the printers.'' And it was approved on June 25th, prior to it going to the FDA, is that correct? That's—

Dr. SNIDER. And then subject to licensure, there was more discussion at the ACIP meeting and further revisions were made.

Mr. BURTON. But it was already approved, though, was it not?

Dr. SNIDER. That was my point, that the recommendations remain fluid and dynamic until they are published in the MMWR. I think if you'll check the record of the ACIP meeting, you'll find that I made statements to that effect to the committee in 1999.

Mr. BURTON. Are you aware of any other instances when this has happened?

Dr. SNIDER. I think there are other instances where people have gotten the impression that because the committee has expressed a preference for a particular policy option, let's say it has to do with what age children should be recommended for this vaccine, that that's a final decision. But again, the decisions are not final until CDC accepts them and publishes them in the MMWR.

They may go back to working groups for further revision. After some people may have thought their work was over, it wasn't.

Mr. BURTON. Can you give us specifically another instance when this has happened, specifically?

Dr. SNIDER. I'd have to look through the minutes, Mr. Chairman.

Mr. BURTON. I thought you just said that it happened quite frequently. If it happened frequently, can't you just think of one?

Dr. SNIDER. In which we have had numerous drafts of the recommendations?

Mr. BURTON. Votes on a vaccine that had not yet been licensed. Can you think of another instance when that happened?

Dr. SNIDER. Again, I think there were perceptions that we had votes on other vaccines in which there were not final votes.

Mr. BURTON. I think the answer's no, you can't think of any, is that correct, right now?

Dr. SNIDER. I can't think of any that I want to say to the chairman that I'm certain about.

Mr. BURTON. If you would just wait 1 minute, Mr. Gilman, I'll be through with my questioning, and if Mr. Waxman doesn't mind, we'll let you make your statement. Because he has to leave, is that all right with you?

Mr. WAXMAN. When your time is up, I'm taking my time.

Mr. BURTON. Mr. Gilman, Mr. Waxman has said that he will not yield to you for your statement until he takes 30 minutes.

Mr. GILMAN. I have to get back to the floor.

Mr. WAXMAN. I've been sitting here a whole half hour waiting for my turn. I'm not going to yield my time.

Mr. BURTON. OK, Mr. Gilman, we'll submit it for the record.

Mr. WAXMAN. Ben, I'm going to let you do it.

Mr. GILMAN. Thank you very much.

Mr. BURTON. Just 1 second, Ben, we'll be finished here.

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The VRBPAC is the advisory committee that reviews the vaccine efficacy and safety data and then makes recommendations to the FDA as to the approval of the vaccine. Can and does the FDA license a vaccine without a VRBPAC recommendation?

Ms. SUYDAM. Yes, Mr. Chairman, it can and it does.

Mr. BURTON. How does the FDA decide when vaccine data should be reviewed by the VRBPAC?

Ms. SUYDAM. Well, for the most part, if it's a new or novel product, if it's the first of a kind of a particular kind of vaccine, if it's a combination vaccine that hasn't been seen before. So I would say that the examples of those that are not are those that are more second time.

Mr. BURTON. OK, my time has expired. Mr. Gilman, you're recognized for your statement and we'll go to Mr. Waxman.

Statement by Benjamin A. Gilman

Mr. GILMAN. Thank you very much. I want to thank Mr. Waxman for yielding. I'd like to welcome the panel and thank our chairman of the committee for investigating Federal vaccine policy and any conflicts of interest on the part of Federal policymakers that may exist.

This committee has encountered many aspects of Government in need of reform due to weak enforcement of Federal policy. However, the committee's current investigation attracts particular attention, for not only is our Federal vaccine policy a governmental issue but a humanitarian issue that affects every American family. Any possible links between industry and Federal policy enforcers inevitably results in a question of ethics.

However, the apparent ties between the pharmaceutical industry and the Federal Drug Administration and Centers for Disease Control advisory committee members results in more than an ethical question. It results in personal injury and possible death for innocent children and adults. Previous investigations have revealed that the conflict of interest rules employed by the FDA and the CDC are weak and are not strictly enforced. Advisory committee members who have personal or financial ties to pharmaceutical companies have been granted waivers to participate in committee deliberations and many committee members have incomplete financial disclosure statements which may conceal their financial ties to a pharmaceutical company.

The breach of integrity in vaccine development has culminated in the serious need for reform. The urgency for reform can be exemplified by the unethical development of the Rotashield rotavirus vaccine and its subsequent removal from the U.S. market. Rotashield was developed to combat rotavirus, which symptoms are vomiting, diarrhea, low grade fever. However, it was pulled from the market following reports of serious illness in over 100 babies. The Rotashield vaccine intended to cure these symptoms, instead, caused 2 deaths, 53 cases of surgery and 47 cases of required medical care, all in babies.

The FDA and its advisory committee approved the vaccine in 1999, overlooked the 1989 tests of a similar vaccine in China in which a number of babies suffered identical bowel problems to those caused by rotashield known as intussusception, a bowel obstruction so severe that the intestine swallows itself. Moreover, at least one of the researchers involved in that China test is now working at the CDC, was also involved in Rotashield.

Therefore, the data from the earlier China test was available to the advisory committee members who approved the Rotashield vaccine but was overlooked or ignored. Regardless of the reason why this information was disregarded, American babies suffered, underwent surgery and some even died. The FDA and CDC advisory committee members do have the responsibility of abiding by all regulations to ensure the safety of our public health.

Human life should not be undermined or compromised for personal or financial ties that advisory members may have to the pharmaceutical industry. It's essential to uphold the integrity of the vaccine development process and to ensure that the Federal Advisory Committee Act requirements are strictly enforced. And it's for that reason that I commend our chairman for pursuing this issue with both the FDA and the advisory committee administrator.

Mr. Chairman, of recent date, in the last 2 days, it's come to my attention that our whole anthrax vaccine program is in severe problems. And I would hope that the FDA would take another look at that program. The GAO has given us some very serious information that requires, I think, further review. And I hope, Mr. Chairman, that our committee would take a further look at that.

And I thank you for permitting me to make this statement at this time, and I thank Mr. Waxman again.

Mr. BURTON. Thank you, Chairman Gilman. And we will look at that.

Mr. Waxman, you're recognized for 30 minutes.

Statement by Mr. Waxman

Mr. WAXMAN. Thank you, Mr. Chairman. I want to commend Mr. Gilman on his statement. I thought that was a good addition to this hearing. It could have been permitted to be reported by Mr. Gilman a half hour ago, and I was frustrated by the minority having to wait 30 minutes before we could even pursue questions.

Mr. Gilman raised an interesting point. He talked about, the first time I've heard about it, some Chinese study of this rotavirus. Dr. Snider, are you familiar with that Chinese study?

Dr. SNIDER. Mr. Waxman, I'm not an expert in rotavirus. I do know that there were other studies done. There are different rotavirus vaccines. And they may have different properties. But one thing I would want to say is that having observed the process and to a certain extent participated in the process, the issue of whether or not there was an association between intussusception and Rotashield was something of great concern and long debate, both in the FDA advisory committee meeting and at the ACIP meeting. And I think the best scientists were brought in to look at the situation. I think that they were quite objective in the way they looked at this.

And the pros and cons of whether there was an association or was not an association was not a no-brainer call. There was not a statistical difference between those who received vaccine and those who received placebo in terms of the incidence of intussusception. And in contrast to what we observed once Ro-

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tashield went on the market, the rotavirus vaccine studies observed intussusception occurring after the second and third doses. There were none after the first dose.

So I guess the bottom line is that it was not an issue that was passed over, swept under the rug or was not of great concern. But at the same time, although there perhaps are only 20 deaths from rotavirus in the United States, there are approximately 50,000 hospitalizations, parents who are very concerned about that, lots of money is spent on that. And an estimated half a million kids who get rotavirus each year who are sick enough that often their parents have to stay home and take care of them. And that's, as someone has said, not a trivial issue.

So again, the risk-benefit was considered. Human judgment, as you know, is not entirely perfect. But I believe people made the best judgments they could under those circumstances. And as you know, we put measures in place to monitor, because of our concern, that there just might be something there. We caught it very, very early and reacted quite rapidly to it and quite vigorously, as you know, using all of our EIS officers at CDC to gather this information, to assess whether there was a true risk.

In fact, there are some people who still don't think there is a risk from Rotashield vaccine, although we are convinced of it, and as you know, we're so convinced that we withdrew the recommendation.

Mr. WAXMAN. I'm pleased you went through that discussion, that at the time the vaccine was being considered by scientists, both at FDA and at CDC, there was a discussion about this issue.

Dr. SNIDER. Many discussions.

Mr. WAXMAN. Because I think the most telling point I've heard in this hearing as I waited for my 30 minutes, to get a chance to ask some questions, which is frustrating for those of us in Congress as we like to do the talking, but those are the rules, was the chairman saying to you, Ms. Suydam, people suffered as a result of conflict of interest. I don't get it. We know that some people had a conflict of interest who had enormous expertise, and they disclosed that. And waivers were given because their expertise outweighed in some cases a very minor conflict of interest.

And then they used their best scientific judgment and came to a conclusion that a year later was reversed. But it seems to me that, I've heard no evidence, and you were there, both at CDC and at FDA, that those who might have had a conflict of interest tried to sweep it under the rug or tried to get this product out there, even though they knew there was a side effect from it. Is there any evidence of that?

Dr. SNIDER. No, sir, I know of no evidence.

Mr. WAXMAN. As I understand the record, there was a Dr. Rennels who was paid by Wyeth to study this vaccine and she presented data at the VRBPAC, what would that stand for?

Ms. SUYDAM. That's the VRBPAC, that's FDA's advisory committee.

Mr. WAXMAN. OK, that she went to that meeting and despite the source of her funding, she presented this advisory committee data on the intussusception as a possible adverse event associated with the vaccine. Is that your understanding as well?

Ms. SUYDAM. Yes, that's correct.

Mr. WAXMAN. Now, if we believe people only act in their own self-interest, you would think that as a representative of the company, she wouldn't have pointed that out. The other issue is Dr. Modlin who had some interest in stock at Merck. So you would think that if he knew that Merck was working on a rival vaccine, if he were going to vote in his financial interest, he would have voted no on a product that was going to get to market before Merck's vaccine. That would seem to me the conclusion, if you think people only operate on the basis of conflicts of interest.

But people also operate on the basis of integrity and professionalism and based on science and using their expertise and not wanting their reputations in any way tarnished by trying to do something that might potentially improve the stock potentially that they might own of a company, a drug company.

The committee felt there was no data, as I understand it, that definitively showed a connection between the vaccine and intussusception. Is that the situation in the advisory committees?

Ms. SUYDAM. Yes, that's correct.

Mr. WAXMAN. Nonetheless, isn't it true that the committee agreed that it would be necessary to include this information about the possibility of intussusception in the package insert?

Ms. SUYDAM. Yes, that's correct.

Mr. WAXMAN. And the committee agreed that careful post-marketing monitoring was necessary once the vaccine was introduced into the general population, isn't that correct?

Ms. SUYDAM. Yes.

Mr. WAXMAN. Now, why wouldn't those people with a conflict, if they're driving this thing forward, try to not put some label warning? Why wouldn't they say we shouldn't monitor it in the future? After all, if we monitored it in the future, we might find that there's a problem with it, and that might hurt their stock.

And the FDA did carefully monitor Vaccine Adverse Events Reporting System to look for possible side effects. And after about 15 cases of intussusception that were identified in the VAERS, the FDA and the CDC moved quickly to remove this rotavirus vaccine. Is that a correct statement for the record?

Ms. SUYDAM. Yes, sir, that's correct.

Dr. SNIDER. Yes, sir.

Mr. WAXMAN. How do you deal with conflicts of interest, because people are concerned about it. Dr. Snider, I understand that in 1998, ACIP voted to recommend that the rotavirus vaccine be added to the immunization schedule for infants. This was after several meetings, but you voted to add it to the schedule for infants?

Dr. SNIDER. Yes, sir.

Mr. WAXMAN. Why was that decision taken?

Dr. SNIDER. Why?

Mr. WAXMAN. Yes. Why did you decide to do that? Why did you recommend that for parents to have that for their infants vaccinated against rotavirus?

Dr. SNIDER. First of all, I should say that the committee considered a whole range of options, from no recommendation to a recommendation for high risk groups all the way to a universal recommendation. And I think there were several reasons why a universal recommendation was made. One is that rotavirus does not respect socioeconomic or race—ethnic or any other boundaries. So that virtually every child is infected with rotavi-

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rus some time before their 7th birthday and usually much earlier.

So it seemed that every child in the country was susceptible to this potentially.

Mr. WAXMAN. And this vaccine could prevent that?

Dr. SNIDER. This vaccine can prevent at least 50 to 70 percent of episodes. But most importantly, 80 to 95 percent of severe cases, which are the ones that can lead to dehydration and death.

Mr. WAXMAN. So the decision was based on scientific judgment by all the people involved that it ought to be on this recommended list. If it's on the recommended list, is it mandated that rotavirus vaccine be used?

Dr. SNIDER. CDC does not mandate vaccines for anyone. The States make their own determinations about what vaccines will be required. As was pointed out, this is not one of those vaccines that would be on the list of required vaccines for school entry, because it's given at 2, 4 and 6 months of age, although some States may have elected to require it for child care.

But that again would not have been a Federal decision. That would have been a State decision.

Mr. WAXMAN. Now, Chairman Burton issued a press release yesterday about this hearing. And in this press release he said four out of the eight advisory committee members who voted on the Wyeth rotavirus vaccine had financial ties to the pharmaceutical companies that were developing different versions of the vaccine.

My staff has gone through these documents and has identified those four members. One of them is Dr. Modlin, and we talked a lot about him. He owns 600 shares of Merck stock. Because Merck does not have a licensed rotavirus vaccine, this did not constitute a conflict, is that correct?

Dr. SNIDER. That is our interpretation, our view and practice, as I understand it, since the mid-1960's, when the ACIP was created, is that conflicts of interest are determined based on licensed vaccines, not on vaccines that might be in the pipeline and may or may not ever be marketed.

Mr. WAXMAN. Ms. Glynn testified earlier that if you own a stock in a huge company, you really own only an infinitesimal amount of that company. Do you agree with that?

Dr. SNIDER. It's my understanding that for the pharmaceutical industry in general, the figure I heard at a meeting earlier last month was that vaccines account for approximately 1.3 percent of the revenues of pharmaceutical companies. So that for a large firm like Merck, one would anticipate that a decision one way or another about a single vaccine wouldn't have much impact on the stock price one way or the other.

Mr. WAXMAN. The chairman made mention of Dr. Modlin's membership on a Merck advisory board. Are you aware that while he does serve on that board, he no longer takes any honoraria for that service?

Dr. SNIDER. Yes, sir.

Mr. WAXMAN. So he doesn't have a financial interest in that service. He owns some stock.

Dr. SNIDER. He did own. My understanding is that he has divested himself.

Mr. WAXMAN. Well, there are two other members of the ACIP, there's a Dr. Griffin and Dr. Clover, who had relationships with Merck in the form of consulting fees, honoraria and educational grants. It is possible that these two members were unaware of Merck's work on a rotavirus vaccine. Is there any evidence that either of these members knew about Merck's rotavirus vaccine that you know of?

Dr. SNIDER. Not that I am aware of.

Mr. WAXMAN. Mr. Chairman, do you have any evidence that either Dr. Griffin or Dr. Clover knew about Merck's rotavirus vaccine? They had consulting fees, honoraria, educational grants from Merck.

Mr. BURTON. You can proceed. I'll get you an answer to that.

Mr. WAXMAN. I'd be interested in that. If there is no evidence, then I think it would be wrong to accuse them of a conflict without actually knowing whether or not they knew that Merck was working on this vaccine. And let's assume they did know. Would that be considered a conflict for purposes of the ACIP's vote on the Wyeth rotavirus vaccine?

Dr. SNIDER. No, sir.

Mr. WAXMAN. Why does the CDC tolerate a certain level of conflicts, both actual and perceived, on its advisory committees?

Dr. SNIDER. I think for some of the same reasons that have already been expressed. It's extremely important that people who serve on advisory committees understand more than just the cursory science that might be presented to them during the course of the meeting. They need to have an in-depth knowledge of some area that is pertinent to vaccination, whether it has to do with the delivery side, how do you deliver vaccines in the public sector, or how to do research properly, the immunology of vaccines and so forth.

Mr. WAXMAN. Well, there are 700,000 physicians the chairman has told us. Why couldn't we pick somebody else who didn't have any possible conflict of interest?

Dr. SNIDER. Well, we do have members, we've talked so much about conflicts, Mr. Waxman, that we haven't had an opportunity to say that we do have members on the ACIP who do not have conflicts. And of course, on any given issue, we may have several members who have no conflicts with a particular matter that's under consideration.

Just because someone fills out a 450 and indicates a conflict does not mean that they have a conflict with the issue at hand. So that most of the time, we have a large number of members who are eligible to vote.

Mr. WAXMAN. And just because they have no conflict doesn't mean they always make the right decisions?

Dr. SNIDER. Well, I guess that's true of all of us.

Mr. WAXMAN. But I know for myself, if I'm having FDA make a decision or the CDC make a decision on a vaccine or FDA make a decision on a drug, I want people on the advisory committee that know the science, that have an expertise, that understand when these drug companies come in, and they present their reams of documents, on why FDA should approve a drug, I want them to be able to scrutinize it pretty carefully. Not somebody who happens to be a physician educated at a medical school.

Dr. SNIDER. We attempt to get the best scientific expertise we can, Mr. Chairman. It requires a broad range of expertise. And there are a limited number of people. We do rotate mem-

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bers, we don't just recycle people who have always been on the ACIP. But the expertise is difficult to find, and as was mentioned earlier, even when you find it, people are not always willing to serve.

Mr. WAXMAN. Ms. Suydam, when FDA has an advisory committee, they're making a recommendation to FDA, which is usually accepted by the FDA. And they vote to determine whether the application a company submitted for licensure supports the safety and efficacy of the product. But their recommendation is non-binding. They don't vote to license or not to license. There are other issues FDA considers in addition to what the advisory committee tells them as they go about approving a product, isn't that correct?

Ms. SUYDAM. Yes, that's correct, Mr. Waxman.

Mr. WAXMAN. I must say, I've had a lot to do with FDA, as a Member of Congress. And I get reports that scare me more about the conflicts of interest by the companies who want to give the best appearance of their drug. And they sometimes don't want to present the possible side effects. And they may have it buried in the documents supporting their up-front top page documents with the hope that maybe an advisory committee won't read all the way through it. You obviously have busy people. Their conflict is that sometimes they're busy.

Ms. SUYDAM. That's why it takes a very thorough review on the part of the FDA to make sure that all the information that's provided is reviewed.

Mr. WAXMAN. So when you're trying to select advisory committee members, what are you looking for?

Ms. SUYDAM. Well, Mr. Waxman, in the VRBPAC alone, we look for expertise in infectious diseases, immunology, virology, bacteriology, molecular biology, pediatrics and biostatistics. We look for people who understand the research in those areas, people who have been researchers themselves. We try to find the very best scientific experts.

And in fact, in the VRBPAC itself for the last 5 years, we've used 82 different experts, either as members, temporary voting members or consultants. And we think that's a fairly representative sample of the experts available to the FDA, when a vaccine expert is not a typical physician. A vaccine expert is one who has had a lot of experience in the research of vaccines.

When you go to an international vaccine meeting, you don't have thousands of people there like you do at the chemistry meetings or the microbiology meetings. You may have 500 at the most. And that's an international meeting. So we're talking about a very limited pool of people that we can actually attract to our committee in this particular area.

Mr. WAXMAN. You try to reach out and get people who are geographically and ethnically diverse?

Ms. SUYDAM. We have a process, and in fact, we do have people on our committee who are not conflicted or do not have any conflicts. Every year we publish in the Federal Register a notice of vacancies for our committees. We advertise in the Academic Physician, which is the document that most physicians read, all the members of the teaching hospitals across the country are members of the AAMC, and that's their magazine.

We go out to our experts on the committee and ask for other recommendations. We ask for public input, and we usually have a pool of about 50 people that we can select 3 or 4 people from for a membership on the committee.

Mr. WAXMAN. Is there a difference in the conflict of interest screening between agency employees and the special Government employees that serve on these committees?

Ms. SUYDAM. The same statute applies, but the standards are different, the waivers are not granted to FDA employees. FDA employees meet the statutory standards. We have waivers for FDA employees but they're very, very limited. And those are done on an ad hoc, individual basis.

In this case, we look for scientific advisors who have had expertise in a particular area. And they may have, as I mentioned in my testimony, they may in fact be people who have worked in the industry. And so we have to make the decision that the expertise they provide is important enough for us to actually waive that potential conflict.

Mr. WAXMAN. The majority of this committee issued a press release yesterday and they claimed three voting members of the advisory committee for FDA had some kind of relationship with ''affected companies.'' I'd like to walk through each of these situations with you. Let's begin with Dr. Patricia Ferrieri, the committee chair, who owned about $17,000 in Merck stock. Under FDA criteria, this constitutes a low involvement with an affected company, isn't that correct?

Ms. SUYDAM. That's correct, Mr. Waxman.

Mr. WAXMAN. Can you explain how the determination that $17,000 in stock is low involvement?

Ms. SUYDAM. We have a waiver criteria document which has been, was established in 1994 and has been updated, was updated once in 1997 and then again this year. The waiver criteria document was established to provide to all of our committee executive secretaries a guidance document and to all our committee management staff on how you could look at an individual's conflicts of interest. And it was decided that less than $25,000 was in fact a low involvement.

Mr. WAXMAN. I have the memorandum of the Department of Health and Human Services dated November 18, 1997, from Diana Widener, SGE programs officer about this subject. And they go into this document, I hope that's the right document, but I have some FDA document I'll make part of the record, probably the chairman already has it, where these issues of conflict came up.

And for example, they talked about Dr. Ferrieri. This was a letter signed by David Kessler, who was the Commissioner of the Food and Drug Administration. It says, as a member of the Vaccines and Related Biological Products Advisory Committee on the temporary voting member of another FDA committee, Dr. Ferrieri could potentially become involved in matters that could affect her or her employer's financial interests. And they go through the code section and they say, first, although Dr. Ferrieri has a financial interest in a competing firm, she is not involved with the specific products at issue. Further, the financial interest is insubstantial in that it represents only a small percentage of her total income.

Second, the Federal Advisory Committee Act requires that committee members be fairly balanced in terms of point of view. It's intended purpose would be significantly impaired, the committee's intended purpose would be significantly impaired, if they couldn't call on experts that become eminent in their field, notwithstanding the financial interest. Dr. Ferrieri is board certified in pediatrics, she's got both extensive experience in

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pediatric infectious disease, both in research and clinical practice. And on and on and on.

Ms. SUYDAM. That's the waiver document, yes.

Mr. WAXMAN. A very well qualified person.

So far, these situations have not been particularly troubling. There are a couple members whose involvement at least on the surface raise some questions, specifically I'd like to ask you about Dr. Estes, and why, given her level of involvement with NIAID, Merck and Wyeth, you went ahead to give her a waiver to participate in this meeting.

At the time of the FDA advisory committee meeting, Dr. Estes was a principal investigator on several grants associated with Wyeth and NIAID to study rotavirus, and she was in negotiations with Merck for a grant to study the rotavirus vaccine. These connections seem to be a little close to the issue at hand, Wyeth's rotavirus vaccine.

Can you explain to us why you gave her a waiver?

Ms. SUYDAM. We actually went, and I was personally not involved, but the Office of Committee Management went to Dr. Estes. And I would suggest that I probably have to deal with this in the hypothetical as well, since her conflict of interest, I mean, since her financial disclosure statement is something I have to deal with in terms of the Privacy Act.

But we went to her and asked about the specifics of her expertise and her involvement. And they are very different than the issue that was being discussed. So there was a difference in terms of the kind of research she was doing.

And if I could, Dr. Estes' expertise is in bacteriology, immunology and virology. She has experience with reovirus, with gastroenteritis virus, with viral pathogenesis. She is in fact an expert in all of the areas that we needed of that committee.

Mr. WAXMAN. Mr. Chairman, I wouldn't want people to think that if their children are going to get immunized that in some way the CDC or the FDA has not been as attentive as they need to be and we expect them to be on the merits of whether a vaccine ought be made available. After all, we're talking about diseases that can cause death, disability, and disease from which many children do suffer.

And if we can prevent these, we hope we can do it without side effects. But sometimes we find out, as we did in this case, there are side effects. I just don't want people to be scared. I don't think we've shown here, because of some conflicts of interest which were all disclosed and for which their supervisors under the law made a decision to allow them to serve, should in any way discredit the immunizations that are available.

And I want to say that I speak from the point of view of someone who at times has been very critical of FDA. I recently criticized NIH and FDA for the gene therapy patients. Here's a headline that says ''Waxman; FDA has done little to merit confidence in this particular area.'' I will criticize FDA or CDC or NIH if I think there's a reason for it.

But I think that it doesn't appear to me that a case has been made to criticize either agency. It appears that they acted reasonably, in the public interest, to try to protect our children. And it's unfortunate that the result was one that meant that the vaccine was taken off the market within a year, because we found out the problems.

But I was glad we found out about those problems and that everybody acted in the best way possible. It would have been better if we'd known about it before, but sometimes science doesn't allow us to know in advance with certainty what the results are going to be.

My time is expiring. I want to thank the two witnesses for your testimony and to assure people, from my point of view, that we always have to monitor vaccines and drugs and make sure that they're safe. I would hope we would monitor a lot of these other products that are on the market that get no scrutiny at all from FDA. People use them and think they are going to improve their health but they can do damage. From this hearing, I've seen no evidence to change my view that you've acted responsibly and under the best expectations of the Congress and from the American people.

Mr. BURTON. Well, I have a little different opinion, and I'll take a little bit of my time now and say there's none so blind as those who will not see. If you look at Dr. Modlin, Mr. Waxman mentioned that he had some stock, but he failed to mention that he was a consultant for Merck and got paid consultant's fees, and that was not in his financial disclosure form. So we don't know how much money Merck was paying him. And he was the chairman of the panel. I mean, come on, unbiased? Give me a break.

And he was talking about the recommendations by the advisory committee, I think you said, Ms. Suydam, that they haven't rejected the advisory committee's recommendations in 10 years. So it's a fait accompli. If they say it's OK, it's OK, it's going to be done. He mentioned Mary Estes. Gee, this is all going to be public eventually, it's going to be out there. Her employer had grants of $75,000 from American Home Products for rotavirus, $404,000 from NIAID, a number of grants for rotavirus, NIH, $355,000 for rotavirus, $55,560 fee from Merck for rotavirus vaccine, Wyeth Lederle, $10,420 fee for rotavirus, and $5,400 for Norwalk virus vaccine. Come on.

And the Supreme Court said it's not just people knowingly doing something wrong. It's having this in the back of their mind that there's a financial interest to what they do.

I have a number of questions. We have votes on the floor and I don't want to keep you here all night. I think basically I've made my points and Mr. Waxman has made his. There's a lot of other questions I have. I'd like to submit to you both questions for the record. Bear in mind when you answer the questions they will be made public. But we want complete and accurate answers, because you were sworn in and the documents that you send us will be considered under oath.

With that, anything else I need to go into?

I'd like to read Dr. Chen Lee, he was one of those who couldn't vote, he said during the discussions, deliberations when he was talking to the people who you had appointed evidently to come in and vote in his stead and others' stead, he said at one point, he would vote for routine immunization if he was eligible to vote, and he went on to encourage a two dose regimen for the vaccine. Moreover, at the June 1998 ACIP meeting during which they approved the statement for routine use of the rotavirus vaccine, he said he feels very privileged to be able to participate in a discussion that he cannot vote on. Hopefully, that perhaps what I will say will influence the people who can vote for me if I cannot vote.

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Now, that makes the point. He's there saying to the people, you know, you're voting in my stead, I'd vote for it and I hope I'm influencing you to vote for it. That isn't right, folks. We have to be above reproach or even the appearance of impropriety. And I hope that CDC and FDA and the other agencies will take into consideration what we've said today.

You probably don't like me for what I've done, and I understand that. But I want you to know we're going to be watching, we're going to be having more hearings on this. And if people are appointed to these advisory panels, it's going to be made public and if there's a conflict, it's going to be made public. And I think it would be better to err on the side of safety, so that the agencies which you represent will not get a black eye. Because I'd rather you didn't get a black eye and everybody would feel a little bit safer.

And with that, thank you very much. We stand adjourned.

[Whereupon, at 4:52 p.m., the committee was adjourned.]

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