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FACA: CONFLICTS OF INTEREST AND VACCINE DEVELOPMENT—PRESERVING THE INTEGRITY OF THE PROCESS

HEARING

BEFORE THE

COMMITTEE ON GOVERNMENT REFORM

HOUSE OF REPRESENTATIVES

ONE HUNDRED SIXTH CONGRESS

SECOND SESSION

JUNE 15, 2000

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THURSDAY, JUNE 15, 2000

HOUSE OF REPRESENTATIVES,
COMMITTEE ON GOVERNMENT REFORM,
Washington, DC.

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 an 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.

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.

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 Re-

lated 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. 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 decisionmaking 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 committee 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.

[The prepared statement of Hon. Dan Burton follows:]

Opening Statement

Chairman Dan Burton

Committee on Government Reform

"FACA: Conflicts of Interest and Vaccine Development: Preserving the Integrity of the Process"

Thursday, June 15, 2000

1:00 pm

2154 Rayburn House Office Building

Washington, DC 20515

Today, we are 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 (FDA) and the Centers for Disease Control and Prevention (CDC) rely on these advisory committees to help them make vaccine policies that affect every child in this country. 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 found, I think they do.

The first committee is the FDA's Vaccines and Related Biological Products Advisory Committee (VRBPAC). This Committee makes recommendations on whether new vaccines should be licensed. The second committee is the CDC's Advisory Committee on Immunizations Practices (ACIP). This committee recommends which vaccines should be included on 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. 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 up 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've 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. Even with all of these concerns, the committee voted unanimously to approve it.

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How confident in the safety and need for specific vaccines would doctors and parents be if they learned the following:

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2. That individuals on both advisory committees own patents for vaccines under consideration or affected by the decisions of the committee.
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4. That seven 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.
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6. 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:

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naturally creates goodwill on the part of 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 other people?

Maintaining the highest level of integrity over the entire spectrum of vaccine development and implementation is essential. 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 policy making for vaccines. We have repeatedly heard in our hearings that vaccines are safe and needed to protect the public. If the panels that have made the decisions on all vaccines on the Childhood Immunization Schedule had as many conflicts as we 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 effect every child in this country and around the world, stood to gain financially and professionally from the decisions of the committees they served on.

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

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

This hearing is about conflicts of interest and vaccine decisionmaking. 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 decisionmaking.

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 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.

[The prepared statement of Hon. Henry A. Waxman follows:]

Opening Statement of Rep. Henry A. Waxman
Ranking Democratic Member
Committee on Government Reform
Hearing on
FACA: Conflicts of Interest and Vaccine Development - Preserving
the integrity of the Process

June 15, 2000

This hearing is about conflicts of interest in vaccine decision making. This is an issue that 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 hearings on conflicts of interest in Vice President Quayle's Council on Competitiveness. These hearings revealed that the executive director of the Council owned 50% 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.

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 questions 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 the public interest was protected.

If indeed a real threat to objective decision making by our health agencies is identified during this hearing, 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 financial interests could exert undue influence on critical policy decisions, but also because they can lead to loss of public confidence in the system. .

But there is a right way and a wrong way to investigate conflicts of interest. The right way is to investigate first and reach conclusions later. The wrong way is to accuse first and investigate later.

Unfortunately, our Chairman has a propensity to investigate in the wrong way. He regularly makes unsubstantiated allegations that smear people's reputations, but turn out to have no basis in fact. The Chairman made his latest allegations 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 this conclusion because it is so far out of the scientific and medical mainstream. But rather than accept 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 did not share the report he is releasing with me before today. As a result, I have 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 may be questions about whether these rules have been properly applied in every instance. But lapses in the application of these rules, if there are any, do not mean that vaccine decisions have been made improperly.

Unfortunately, CDC and FDA face a difficult challenge in assembling expert advisory panels on vaccines. Vaccine decisions have major public health implications. For this reason, it is 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. CDC and FDA have the responsibility of insuring that the public benefits from the expertise of these individuals, while at the same time insuring that appropriate precautions are taken against conflicts of interest.

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.

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?

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.

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.

[The prepared statement of Hon. Danny K. Davis follows:]

Statement of Congressman Danny K. Davis
Committee on Government Reform
"Federal Advisory Committee Act (FACA): Conflicts of Interest and Vaccine Development- Preserving the Integrity of the Progress."

Mr. Chairman, I would like to commend you for holding this oversight hearing to examine the implementation of the Federal Advisory Committee Act (FACA), and to examine the operation of the Department of Health and Human Services' Advisory Committee on Immunization Practices (ACIP) of the Centers for Disease Control and Prevention (CDC) and the Vaccine and

Related Biologic Products Advisory Committee (VRBPAC) 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. In order to ensure the health of all Americans, the two advisory committees have crucial roles to recommend the kind, and dosage of vaccinations that our children and adult

population receive.

I am interested to hear how the implementation of the Federal Advisory Committee Act affect the functions and operations of the two advisory committees' recommendations and decisions regarding the development and usage of vaccinations. In addition, I am especially interested to hear how the possible conflict of interests of the scientists affect the operation of the two

advisory committees.

I would like to thank the representatives from the Center for Disease Control, the Food and Drug Administration, the General Service Administration, and the Office of the Government Ethics for taking their time to share valuable information with us today. I also would like to recognize the presence of Barbara Mularkey, a representative of the Illinois Vaccine

Awareness Coalition, who happens to be a constituent of mine. She is a fighter and a hard worker: she has really raised the level of awareness of vaccinations in Chicago.

Again, thank you Mr. Chairman for convening this committee hearing and I look forward hearing from all witnesses.

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?

STATEMENTS OF MARILYN GLYNN, GENERAL COUNSEL, OFFICE OF GOVERNMENT ETHICS; AND JAMES DEAN, DIRECTOR, OFFICE OF GOVERNMENTWIDE POLICY, U.S. GENERAL SERVICES ADMINISTRATION

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 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.

[The prepared statement of Ms. Glynn follows:]

STATEMENT OF

MARILYN L. GLYNN
GENERAL COUNSEL, OFFICE OF GOVERNMENT ETHICS

BEFORE THE

COMMITTEE ON GOVERNMENT REFORM

U.S. HOUSE OF REPRESENTATIVES

JUNE 14, 2000

MR. CHAIRMAN, AND MEMBERS OF THE SUBCOMMITTEE:

Thank you for the opportunity to appear today to discuss the subject of conflict of interest and federal advisory committees. In its invitation, the Committee requested that OGE "present testimony outlining the regulations regarding conflicts of interest for Federal Advisory Committees and the importance of preserving the integrity of this process." On behalf of OGE, I am pleased, therefore, to address the general statutory and regulatory framework governing financial conflicts of interest in the context of federal advisory committees.

As a general matter, the framework includes criminal statutes, administrative standards of conduct, and financial disclosure requirements. Because the focus of this hearing, as described in the invitation, is primarily on financial interests and the standards for waiving financial conflicts, I will begin with a discussion of the financial conflict of interest statute.

18 U.S.C. § 208

Chapter 11 of Title 18, United States Code, contains a number of criminal conflict of interest laws that were enacted in 1962 in a general overhaul of federal conflict of interest legislation. Among these laws is section 208 of Title 18, the basic financial conflict of interest statute. This statute is designed to help ensure that the integrity of Governmental operations and decisions will not be compromised by the conflicting financial interests of executive branch employees.

Section 208 is essentially a disqualification statute. It does not prohibit employees from holding any particular financial interest, but rather requires that they recuse themselves from certain matters affecting those interests. Moreover, it should be emphasized that neither section 208 nor any other ethics law or regulation governs the selection of individuals for particular federal positions; thus, for example, section 208 does not govern the selection of individuals for membership on a federal advisory committee, which is a subject governed by laws and regulations outside the jurisdiction of OGE.

Section 208 prohibits employees from participating, personally and substantially, in any particular matter which, to their knowledge, has a direct and predictable effect on their financial interests, or the financial interests of others with whom they have certain relationships. The statute applies if the Government matter would affect the financial interests of: the employee, the employee's spouse, minor child, or general partner; any organization which the employee serves as officer, director, trustee, general partner or employee; and any person or organization with which the employee is negotiating or has an arrangement concerning prospective employment.

Congress recognized, however, that this broad prohibition needed to be accompanied by certain reasonable waiver or exemption provisions. Therefore, the original 1962 act included, among other things, a provision permitting agencies to waive the disqualification requirement on a case-by-case basis. This provision, section 208(b)(1), authorizes agencies to grant a written waiver where they determine, in writing, that the financial interest is not so substantial as to be deemed likely to affect the integrity of the employee's services.

Special Government Employees

Given the subject matter of this hearing, it is important to note that section 208 applies not only to regular employees of the executive branch, but also to "special Government employees." Special Government employees, or SGEs, are defined as any officer or employee who is selected to perform temporary duties for no more than 130 days during any 365 day period. See 18 U.S.C. § 202(a). Many members of federal advisory committees are SGEs, who provide expert advice to the Government on a short-term or intermittent basis. (Not all advisory committee members, however, are SGEs. For example, some members are specifically designated as representatives of certain outside interest groups, and it is understood by the Government that they represent a particular bias. Pursuant to a longstanding interpretation, such representative members are not deemed federal employees at all and are not subject to the conflict of interest statutes, administrative standards of conduct, or financial disclosure regulations. See, e.g., 5 C.F.R. § 2634.904(b).)

SGEs serving on advisory committees provide advice to the Government on a broad range of important matters. According to the Twenty-Seventh Annual Report on Federal Advisory Committees, advisory committee members assist the Government in such diverse areas as national defense, small business, nuclear waste, and juvenile justice, to name but a few of the hundreds of subjects.

By way of background, the SGE category was created by Congress in 1962 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. Commenting on the state of federal conflict of interest legislation prior to the 1962 act, the House Judiciary Committee observed that the restrictions were "excessive" in that they "failed to take into account the role, primarily in the executive branch of our Government, of the part-time or intermittent adviser whose counsel has become essential, but who cannot afford to be deprived of private benefits, or reasonably requested to deprive themselves, in the way now required." H.R. Rep. No 748, 87th Cong., 1st Sess. 4 (1961).

Consequently, Congress created a number of exceptions and exclusions for SGEs under several of the laws in Chapter 11 of Title 18. At that time, Congress did not create any special exceptions for SGEs under section 208. The executive branch, however, almost immediately issued guidance advising agencies that it was appropriate to exercise the waiver authority in section 208(b)(1) to release SGEs from the prohibition where they render "advice of a general nature from which no preference or advantage over others might be gained by any particular person or organization" or, alternatively, "where the financial interests involved are minimal in value." Presidential Memorandum, "Preventing Conflicts of Interest on the Part of Special Government Employees," 28 Federal Register 4539, 4543 (May 2, 1963).

SGEs Serving on Advisory Committees

In 1989, President Bush appointed a bi-partisan commission to review and recommend reforms to the federal conflict of interest statutes, including those applicable to advisory committee members and other SGEs. The commission, chaired by Judge Malcolm Wilkey, included an entire chapter concerning SGEs and federal advisory committees in its final report. The Commission found that the Government needs advisory committee members with very specific outside expertise in the matters being examined, but that often those individuals would be likely to have employment and other financial ties with organizations whose interests would be affected by such matters. The existing waiver authority of section 208(b)(1) was deemed inadequate, because it focused in large measure on the magnitude of the SGE's financial interest, whereas "[f]or many advisory committee members, the financial interest may be quite large, but it may nonetheless be highly desirable to have the benefit of the individual's expertise." Report of the President's Commission on Federal Ethics Law Reform, at 30 (March 1989). While noting that "appropriate ethical constraints" are still needed for SGEs, the report emphasized: "In the absence of particularized provisions for the treatment of special Government employees within the general conflict of interest prohibition of 18 U.S.C. § 208, however, the Commission believes that the Government is needlessly handicapped in obtaining advice and information from individuals with expertise who are located in the private sector." Id. at 29 (March 1989).

Consequently, the Commission recommended, and Congress enacted almost verbatim, a liberalized waiver provision applicable to SGEs who serve on federal advisory committees within the meaning of the Federal Advisory Committee Act (FACA). Under this provision, enacted in 1989 as section 208(b)(3), an agency now has broad discretion to grant an individual waiver based on a written determination that the need for the individual's services outweighs the potential for a conflict of interest created by the financial interest involved. Such a waiver mechanism was deemed appropriate for several reasons: FACA itself includes a fair balance requirement that helps to protect against disproportionate influence by a particular interest group; FACA similarly requires that most advisory committee meetings be open, thus subjecting them to "the most exacting public scrutiny;" and advisory committee members typically are not the ultimate decisionmakers, but only advisors. Id. at 30.

The authority to issue waivers under section 208(b)(3) is vested in the employing agency. OGE does not have the authority to approve or disapprove waivers proposed by other agencies. Such authority properly resides in the agencies themselves, which are in the best position to determine whether the need for any particular individual's services outweighs any conflict of interest concerns.

OGE Regulations Governing the Issuance of Waivers under Section 208(b)(3)

Under Executive Order 12674, however, OGE is responsible for issuing regulations interpreting 18 U.S.C. § 208, including the provisions governing waivers. In 1996, OGE published regulations providing guidance to executive branch agencies concerning the issuance of waivers under section 208(b)(3). Specifically, in 5 C.F.R. § 2640.302(a), OGE explained the basic waiver standard and procedural criteria required by the statute. Furthermore, in section 2640.302(b), OGE provided a non-exclusive list of factors that agencies may consider in making their determination that the need for the individual's services outweighs the potential for a conflict of interest. These include various factors bearing on the nature and size of the conflicting financial interest and the Government's need for an SGE with the particular individual's qualifications, including the difficulty of finding other qualified SGEs who are not also conflicted.

Section 2640.303 sets out procedures for OGE consultation and notification regarding waivers issued under section 208(b)(1) or (3). Consistent with section 301(d) of Executive Order 12674, the rule provides that agencies, "when practicable," shall consult formally or informally with OGE prior to issuing any individual waiver under section 208(b)(1) or (3). In practice, many agencies consult in advance with OGE before issuing waivers. This may not happen, however, in connection with some waivers granted under section 208(b)(3) for advisory committee members. Based on discussions with agency ethics officials, we believe that the scheduling and agenda development for specific advisory committee meetings frequently create timing problems that make prior consultation impracticable. Moreover, at some agencies, ethics officials have developed more or less regular criteria for granting waivers based on past precedents, including past discussions with OGE about analogous situations, thus making prior consultation less crucial, in the view of those agencies, with respect to cases perceived as being routine or nonproblematic.

Exemptions Issued by OGE under Section 208(b)(2)

In addition to the authority of agencies to grant individual waivers, section 208 also authorizes OGE to issue regulations creating general exemptions from the disqualification requirement. Section 208(b)(2) allows OGE to exempt all employees, or certain classes of employees, with respect to those financial interests deemed to be too remote or inconsequential to affect the integrity of the services of those employees. In 1995, 1996 and again this year, OGE issued certain regulatory exemptions under this authority, which are found in Subpart B of 5 C.F.R. Part 2640.

Many of these exemptions apply to SGEs as well as regular employees. These include, for example, including certain *de minimis* exemptions for publicly traded securities and other

exemptions pertaining to mutual funds. However, certain exemptions apply only to SGEs serving on FACA committees. The most significant, section 2640.203(g), exempts certain financial interests arising from the SGE's outside employment. The exemption permits the employee to participate in matters of general applicability – such as general rulemaking or policymaking – provided that the matter does not have a special or distinct effect on either the SGE or the SGE's outside employer other than as part of a class.

Standards of Conduct Regulations

Beyond the criminal conflict of interest laws, OGE has promulgated regulations prescribing standards of ethical conduct for employees of the executive branch, including SGEs. See 5 C.F.R. Part 2635. One of those rules, 5 C.F.R. § 2635.502, provides a mechanism for dealing with potential appearances that an employee may lack impartiality with respect to certain matters. Section 2635.502 requires employees, including SGEs, to consider the need to recuse themselves from any matter involving specific parties where they have a "covered relationship" with a party or a representative of a party to the matter. "Covered relationship" includes, among other things, certain business, financial and contractual relationships that are not already covered by 18 U.S.C. § 208. However, like section 208, section 2635.502 has a waiver or "authorization" provision, which allows the agency to balance any concern about appearances of partiality against the Government's interest in having the individual participate in the matter.

Financial Disclosure

Finally, most SGEs serving on advisory committees are required to file a confidential financial disclosure statement with their agency, and they must do so no later than their first committee meeting. See 5 C.F.R. §§ 2634.904(b); 2634.903(b)(3). The agency then reviews the statements to determine whether the SGE may have any potential conflicts of interest that must be addressed.

Conclusion

In closing, I want to emphasize that it is vitally important to protect the integrity of federal advisory committee processes. It is axiomatic that Government decisions should not be tainted by the conflicting interests of federal employees. At the same time, it is understood that the Government needs the services of SGEs who can contribute relevant outside expertise and perspectives to the work of advisory committees. Balancing these two considerations is not always an easy task. Nevertheless, we believe that the current statutory and regulatory system provides an appropriate framework for accommodating both objectives.

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

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 ad-

dressing 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 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.

[The prepared statement of Mr. Dean follows:]

TESTIMONY OF JAMES L. DEAN

DIRECTOR

COMMITTEE MANAGEMENT SECRETARIAT

OFFICE OF GOVERNMENTWIDE POLICY

U.S. GENERAL SERVICES ADMINISTRATION

BEFORE THE

COMMITTEE ON GOVERNMENT REFORM

U.S. HOUSE OF REPRESENTATIVES

June 14, 2000

TESTIMONY OF JAMES L. DEAN
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Mr. Chairman, Mr. Ranking Member, Members of the Committee, I am pleased to discuss with you today the important role played by Federal advisory committees in achieving the missions assigned to the Executive Branch.

More than a quarter-century before the enactment of the Federal Advisory Committee Act (FACA) in 1972, the Government began to recognize the important role played by advisory committees in developing effective policies. While the use of citizen-advisors has its roots in the earliest efforts of the Nation's leaders to obtain objective and informed advice, it was not until after the end of World War II that advisory committees became institutionalized as a unique tool of democratic government. For example, it was an advisory committee, the Hoover Commission, whose work laid the foundation for the creation of the General Services Administration (GSA) in 1949.

As the influence and number of advisory committees grew, so did concerns within the Executive and Legislative Branches regarding their management, cost, and accountability. In 1962, President Kennedy issued Executive Order 11007 establishing

guidelines for using such groups. These guidelines were expanded in 1964, with the issuance of the original Bureau of the Budget Circular A-63.

Federal information policy relating to the accessibility of government records was revised in 1966, following the enactment of the Freedom of Information Act (FOIA). In 1972, similar openness policies were applied to the use of advisory committees through the enactment of FACA. Later in the 1970's, the two remaining cornerstones of Federal access policy, the Privacy Act (1974) and the Government in the Sunshine Act (1976) were enacted by the Congress.

The Congress enacted the Federal Advisory Committee Act in 1972 to accomplish two important objectives: (1) to establish the means for providing Congressional and Executive Branch oversight over the number and costs of advisory committees; and (2) to ensure that 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 to support advisory committees are commensurate with the benefits received. Since 1972, the Act's coverage has been extended to more than 4,000 advisory committees made up of an estimated 530,000 members.

Today, advisory committees are used by over 60 agencies to address 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

needed to address the management of natural resources and the country's national defense strategies.

OVERVIEW OF GSA RESPONSIBILITIES

Several important governmentwide roles and responsibilities are assigned by the Act to the Committee Management Secretariat which, taken together with those specific functions reserved for the Congress and Executive Branch Departments and agencies, are designed to improve the management and accountability of advisory committees. Among the statutory responsibilities assigned to the Secretariat are:

- Conducting an annual comprehensive review covering the performance of, and need for, existing advisory committees (section 7(b));
- Issuing regulations, guidelines, and management controls of governmentwide applicability (section 7(c));
- Providing for adequate notice to the public regarding committee meetings (section 10(a)(2)(3));
- Issuing guidelines on committee member compensation in conjunction with the Office of Personnel Management (section 7(d));
- Providing for follow-up reports on public recommendations of Presidential advisory committees (section (6(b)); and
- Assuring that advisory committees are established in accordance with the Act's requirements (section 9).

OVERVIEW OF AGENCY RESPONSIBILITIES

Responsibilities assigned to agencies that sponsor advisory committees subject to FACA include:

- Issuing and maintaining uniform administrative guidelines and management controls (section 8(a));
- Appointing a Committee Management Officer (CMO) to provide oversight of the agency's entire committee inventory (section 8(b));
- Consulting with the Secretariat regarding proposals to establish advisory committees (section 9(a)(2));
- Filing Charters with the Congress prior to initiating committee activities (section 9(c));
- Maintaining records, minutes, and reports covering closed meetings (section 10(b)(c)(d));
- Appointing a Designated Federal Officer (DFO) for each committee (section 10(e));
- Maintaining financial records (section 12(a));
- Providing support services (section 12(b)); and
- Terminating advisory committees as appropriate, consistent with FACA (section 14(a)(1)(A)).

FACA PROCEDURES

While FACA is generally recognized for its emphasis on justifying the number and costs of advisory committees, its provisions governing access to committee meetings and records are equally important. FACA's goal is to provide the broadest

possible contemporaneous access to meetings of, and materials generated for or by, Federal advisory committees during their deliberations. In particular, Section 10 of the Act provides that:

- Each meeting of an advisory committee must be open to the public, except for those closed or partially-closed pursuant to specific exemptions contained in the Government in the Sunshine Act (section 10(a)(2));
- Timely notice of each meeting must be published in the Federal Register (section 10(a)(1));
- Interested persons may appear before , or file statements with , an advisory committee, subject to reasonable operating procedures established by an agency (section 10(a)(3));
- Documents prepared for or by, or otherwise made available to, an advisory committee must be accessible for public inspection and copying at a single location, subject to exclusions provided under the FOIA (section 10(b)); and
- Minutes of each open or partially-open meeting must be kept and made available to the public (section 10(c)).

Agency CMOs are responsible for implementing FACA on behalf of the agency head. Each DFO must work with the CMO to implement the Act's requirements at the individual committee level. Together, the CMO and DFO are responsible for ensuring compliance with FACA, the agency's internal operating procedures, regulations issued by GSA, and any other applicable statutes or regulations, such as those issued by the

U.S. Office of Government Ethics (OGE), the National Archives and Records Administration (NARA), or the Office of Personnel Management (OPM).

COMMITTEE COMPOSITION AND RELATIONSHIP TO AN AGENCY

Mr. Chairman, in your letter inviting GSA to testify before the Committee today, you asked that we address how FACA 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 covering individual committee member conflicts of interest. The applicability of conflict of interest laws and various ethical requirements for members of advisory committees who serve as Special Government Employees (SGEs), are covered by other laws and regulations issued by the U.S. Office of Government Ethics.

The Act, however, does include two important provisions designed to promote the objectivity of advisory committee deliberations. First, sections 5(b)(2) and (c) require 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, sections 5(b)(3) and (c) require "provisions to assure that the advice and 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 stresses the importance of assuring an advisory committee's independent judgement, it also requires that the composition of

advisory committees reflect the expertise and interests that are necessary to accomplish the committee's mission.

The Act does not define those factors that should be considered in achieving "balance." However, the Secretariat's regulations provide 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 to the nature and functions 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."* (41 CFR 101-6.1007(b)(2)(iii)) In their efforts to balance a committee's membership, agencies focus primarily on the subject matter to be addressed by the committee; 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, FACA does not outline specific steps that must be taken to ensure that advice and recommendations offered by an advisory committee are free from inappropriate influence by the appointing authority or special interests. Accordingly, each agency is responsible for developing specific operating procedures, consistent with the Act and GSA's regulations to ensure an advisory committee's independence, and to promote a balanced committee membership.

FACA'S SYSTEM OF CHECKS AND BALANCES

Although the Act is quite detailed in the 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 and tenure. GSA believes 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.

FACA also includes a variety of procedural safeguards to ensure that advice and 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 requiring open meetings and summaries 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 of special interests. These "checks and balances," rooted firmly in the principle of government in the sunshine, have contributed to the success of advisory committees over the past twenty-eight years.

Mr. Chairman, Members of the Committee, that concludes my prepared statement. I would be pleased to answer any questions you may have.

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——

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.

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.

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.

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.

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 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 non-profit 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 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.

STATEMENTS OF LINDA A. SUYDAM, D.P.A., SENIOR ASSOCIATE COMMISSIONER, FOOD AND DRUG ADMINISTRATION; AND DR. DIXIE SNIDER, JR., M.D., EXECUTIVE SECRETARY, ADVISORY COMMITTEE ON IMMUNIZATION PRACTICES, CENTERS FOR DISEASE CONTROL, ACCOMPANIED BY KEVIN MALONE, JENNIE SLAUGHTER, BILL FREAS, AND NANCY CHERRY

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 review-

ing 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.

[The prepared statement of Ms. Suydam follows:]

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville MD 20857

STATEMENT OF

LINDA A. SUYDAM, D.P.A.

SENIOR ASSOCIATE COMMISSIONER

FOOD AND DRUG ADMINISTRATION

DEPARTMENT OF HEALTH AND HUMAN SERVICES

BEFORE THE

COMMITTEE ON GOVERNMENT REFORM

U.S. HOUSE OF REPRESENTATIVES

JUNE 14, 2000

RELEASE ONLY UPON DELIVERY

Introduction

Mr. Chairman and Members of the Committee, I am Linda A. Suydam, Senior Associate Commissioner, of the Food and Drug Administration (FDA or the Agency). I am pleased to have the opportunity to be here before the Committee today to discuss with you FDA's advisory committees. As I will discuss, FDA has made a strong commitment, and given high priority, to selecting the most qualified clinical and scientific experts for its advisory committees and to rigorously complying with the statutes and regulations governing these advisory committees.

FDA is a science-based regulatory agency with responsibility for regulating approximately 25 percent of the gross national product. 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 oversees foods, drugs, biologics, and medical devices that the American public uses every day.

To carry out that mission, FDA's decisions need to be based on the highest clinical and scientific standards. As science

becomes more specialized, it becomes more difficult for general scientists and medical personnel to keep up with the scientific advances in the many areas that FDA regulates. To provide this critical science base, FDA has over 1500 outside experts who provide FDA with essential expertise in highly specialized areas. Many of these experts serve as members on, or consultants to, FDA advisory committees.

Federal Advisory Committee Act (FACA)

The Federal Advisory Committee Act (FACA)(5 U.S.C. App. II) sets forth standards and procedures to govern the establishment, operations, and administration of advisory committees. As defined in FACA, a public advisory committee is any committee, board, commission, council, conference, panel, task force, or other similar group, or any subcommittee or other subgroup thereof, established or utilized by a department or agency of the Federal Government in the interest of obtaining advice or recommendations, and that is not composed wholly of full-time officers or employees of the Federal Government.

The General Services Administration (GSA) has oversight in the management and control of all Federal advisory committees under

their Federal Advisory Committee Management regulations in 41 CFR Subpart 101-6.10. FDA's implementing regulations under FACA are found at 21 CFR Part 14. FDA carefully follows the process established under these regulations. The Department of Health and Human Services (DHHS or Department), in concert with GSA, sets policy for components of DHHS with advisory committees, such as FDA, the Centers for Disease Control and Prevention, the National Institutes of Health, and the Substance Abuse and Mental Health Services Administration.

Currently, FDA is administratively responsible for a total of 32 advisory committees, which operate within the legal framework noted above. Each advisory committee has a core membership identified within each committee's charter. The charters for the committees are in existence for a two-year period unless the duration is otherwise provided by law. The authorized core is developed based on the complexity of the issues to be considered and assessment of the issues by the Agency as to the degree of expertise needed. The charters are standardized and formally developed in accordance with the requirements of section 9 of FACA.

Impact of the Food and Drug Administration Modernization Act (FDAMA) of 1997

Section 120 of FDAMA (P.L. 105-115) mandated additional requirements applicable to some FDA advisory committees. The requirements in section 120 provide that FDA may not grant a waiver for an advisory committee member to review his or her own work; there must be at least two members on the advisory committee who are knowledgeable about the disease that the product is intended to treat; and advisory committee members shall be trained in the committee meeting process.

What Does an Advisory Committee Do?

The FDA Advisory Committee system was established:

1. to provide independent expertise and technical assistance related to the development and evaluation of products regulated by FDA;
2. to lend credibility to the product review process;
3. to speed the review of products by providing a visible sharing of the responsibility for evaluation and judgment;
4. to provide a forum for public discussion on matters of significant public interest;
5. to allow sponsors and consumers to stay current with trends in the product development and review process and changes

in regulations and guidelines related to FDA-regulated industries; and

6. to provide external review of FDA intramural research programs.

Advisory committees review many issues, including cutting edge technology, safety and efficacy issues, adverse event problems, labeling issues, guidance documents and peer review of intramural research.

Advisory committees also advise the Agency on general criteria for evaluation, of broad regulatory and scientific issues that are not related to a specific product. Committee members, who have voting status, vote on substantive scientific or policy matters, which impact on FDA's regulatory role. It is very important to note, however, that advisory committee recommendations are not binding. The Agency retains all final decision making authority.

Who Comprises the Membership of an Advisory Committee?

The standing membership of advisory committees includes academicians, clinicians, consumers, and in some instances

industry representatives and patients and/or patient caregivers. In addition to the standing membership, temporary voting members and consultants, who may provide needed expertise, may be appointed to participate in an individual advisory committee meeting. FACA requires that committee membership be fairly balanced in terms of the points of view represented to perform the committee's functions. DHHS policy requires that the committee's membership be composed of as equitable a geographic area and ethnic and gender representation as possible so long as the effectiveness of the committee is not impaired. Members should also be selected without discrimination on the basis of race, gender, sexual orientation, HIV status, and cultural, religious, socioeconomic or physical status.

Who Can Recommend a Prospective Member?

In order to recruit new members for its advisory committees, FDA publishes announcements at least once per year in the Federal Register soliciting nominations for current or upcoming vacancies on its advisory committees. All nominations in response to the Federal Register notice must be submitted to the appropriate Center, Office or Division specified in the notice.

Each FDA Center is responsible for identifying and seeking prospective candidates from additional individuals and organizations. The responsible office seeks nominations and referrals from FDA's stakeholders including former and current advisory committee members, FDA scientists, professional societies and journals, academic institutions, consumer groups, patient advocacy groups, self-nominations, and industry.

Selection Process

In screening nominations for prospective standing committee members for scientific and technical expertise and competence, FDA has a thorough, and consistently applied, process. This ensures that we obtain qualified members who are able to provide the Agency advice. The Policy and Guidance Handbook for FDA Advisory Committees states that:

- Candidates should be carefully screened to ensure that they possess expertise relevant to the particular subject matter on which their advice will be sought.
- Attention also should be paid to reputation and leadership qualities.
- Whenever possible, nominees should be acknowledged experts in their fields whose credibility is beyond question.
- All nominees should have both demonstrated skills in the

critical evaluation of data and, to the extent feasible, the communications skills necessary to promote efficient and effective committee deliberation.

- The responsible office is expected to seek diligently, and document external evaluation of, the credentials of the nominee.
- The process of obtaining external evaluation and endorsement is essential.
- Appropriate sources of external evaluation include current advisory committee members, senior officials in the individual's primary institution, and relevant professional society boards.

Nominations received are referred to the executive secretary of the appropriate advisory committee who makes the first cut and then forwards the information to the appropriate product review office for consideration. Selection of nominees is based upon: the areas of expertise presently required on the committee; the qualifications of the applicants; potential conflicts of interest; and the need for fair balance. FACA requires advisory committee membership to be fairly balanced in the points of view, and the Agency is committed to diligent pursuit of ethnic, gender, and geographic diversity.

For the consumer representative, recruitment efforts are made through FDA's Consumer Consortium, which is a body composed of members of leading consumer organizations. Consumer representatives must be technically and scientifically qualified in the appropriate field and must represent the consumer interests.

For the industry representative, FDA compiles a list of nominees from responses to the Federal Register notice, self-nominations, previous members, and other sources. The list is then sent to all organizations who nominated individuals with the instructions that they should select a representative candidate.

Once the selection process is completed within the Center a formal package containing the list of candidates and their background information is prepared by the Center, signed by the Center Director and forwarded to the Senior Associate Commissioner. The Senior Associate Commissioner appoints all advisory committee members. Each candidate is invited to serve for a set term of office. The candidate is provided an "Acknowledgement of Invitation" to return to FDA either accepting or rejecting the appointment. Most "standing"

members become Special Government Employees (SGEs) and are subject to conflict of interest screening. The appointment process is handled uniformly Agency wide.

Temporary Voting Members

If permitted by a committee's charter, the committee's standing voting membership may be supplemented by the appointment of temporary voting members (TVMs) drawn from the present members of other FDA committees as well as from SGE consultants to FDA. Consultants with specialized expertise appointed as SGEs may be granted voting privileges for a particular advisory committee meeting. Such temporary appointments cover a single meeting only and all appointments are subject to the same conflict of interest review as any standing member of an advisory committee. The Commissioner or her designee may appoint temporary voting members to a committee when expertise is required that is not available among the current voting standing members of the committee or to make up a quorum when, because of unforeseen circumstances, a quorum is or will be lacking.

Unless otherwise established in the charter of the committee, a quorum shall consist of a majority of the committee's

authorized membership, including TVMs. An advisory committee's charter allows FDA in certain cases to specify a quorum that is less than a majority of the current voting members. For example the VRBPAC Charter states:

> Because of the size of the committee and the variety in the types of issues that it will consider, FDA may, in connection with a particular committee meeting, specify a quorum that is less than a majority of the current voting members.

The Agency's regulations authorize committee charters to specify quorum requirements (21 CFR 14.22 (d)).

The need for the Agency to ensure that a meeting takes place is critical to its role as a regulatory Agency. Without the ability to hold scheduled advisory committee meetings, products could be delayed in getting to market.

Terms of Advisory Committee Members

It is DHHS policy to avoid excessive individual service on advisory committees and multiple committee memberships. Specifically, this policy provides that a Federal advisory committee member will not:

- serve continuously as a member of any single advisory committee for more than four years;
- serve for more than eight combined years within a period of

12 years on one or more committees within an agency;

- serve on more than one committee within an agency at the same time; or,
- serve on the same committee at the same time with another individual who is affiliated with a particular non-Federal organization or institution in the same city.

If any of the above criteria apply to a candidate's appointment/reappointment, an Exception to Department Policy must be prepared to waive the appropriate criteria(ion). All Exceptions to Department Policy, i.e., appointment waivers, must be approved by the FDA Senior Associate Commissioner and is part of the official nomination process. In concert with DHHS, a strong justification to waive the criteria to avoid excessive service is required.

Potential for Conflict of Interest

While FDA has a great need for outside scientific advice, it is critical that the advice be free from conflict of interest and potential bias. If the advice FDA receives is biased or is perceived as biased, it is of little value to the Agency and only diminishes the credibility of Agency decisions. The outside experts who serve FDA are often pre-eminent scientists

in their field such as Stan Prusiner, M.D., recipient of the Nobel Prize, and Douglas Norman, M.D., past president of the American Society for Transplantation. They are typically active researchers on the cutting edge of science. As such, they and their organizations are often sought out by regulated industry to assist in product development. Indeed, studies have shown that academic biomedical research in the United States increasingly is supported by industry. For that reason, outside experts and the 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 regulated industry. This, by itself, does not preclude them from serving as SGEs. If this were the case, FDA would not get the top scientists in the field and the recommendations of the advisory committees would not be of the highest scientific nature, with a likely impact on public health.

Conflict of Interest Rule

Federal statute and the implementing regulations contain conflict of interest standards applicable to all Federal employees, including SGEs serving on advisory committees. Regulations issued by the Office of Government Ethics (OGE) and

DHHS create additional standards of ethical conduct and provide interpretive guidance concerning the Federal conflict of interest statutes. The Designated Agency Ethics Official (DAEO) of DHHS has been designated by the Secretary of DHHS to coordinate and manage the DHHS' ethics program. The DAEO and the DAEO's staff in the Office of the General Counsel (OGC)/Ethics Division provide legal guidance concerning the Federal conflict of interest statutes and regulations and provide guidance, as needed, regarding the application of those legal authorities in specific cases. The DAEO has delegated to the FDA Deputy Ethics Counselor and the FDA Ethics Staff the authority to perform many of the functions of administering the FDA ethics program.

Within FDA, the Commissioner of Food and Drugs has the final authority, to make determinations in conflict of interest matters such as the issuing of conflict of interest waivers, where Federal law accords the Agency authority to exercise discretion regarding an employee's participation in official matters.

Criminal Conflict of Interest Statute (Title 18 U.S.C. 208)

For years, the Federal Government has balanced the need for outside expertise in advisory committees with the need to protect against potential conflicts of interest. A Federal employee, which includes all SGEs, is prohibited from participating personally and substantially in an official capacity in any particular matter in which he has a financial interest if the particular matter will have a direct and predictable effect on that interest (18 U.S.C. 208(a)). The interests of the spouse, minor child, and employer are imputed to the employee. In addition, the interests of the general partner, organization in which he is serving as an officer, director, trustee, general partner or employee or any person or organization with whom he is negotiating or has any arrangement concerning prospective employment are also imputed.

Assessing Conflict of Interest Concerns - The Form 3410

Prior to each FDA Advisory Committee meeting an SGE must complete an FDA Form 3410 - "Conflict of Interest Disclosure Report for SGEs." The Form 3410 relates and is accompanied by a list of sponsors, affected firms, competitors, parent firms, and other information, for each topic to be covered at the upcoming meeting. Financial interest is defined in the

regulations as the potential for gain or loss as a result of government action on the particular matter (18 U.S.C.208 and 5 CFR part 2640). The types of interests screened are stocks and investments, primary employment, consultant work, contracts, patents, grants, trademarks, expert witness activities, speaking engagements, and other information.

Steps for Conflict of Interest Clearance

The process for determining the eligibility of outside experts (which can include standing members, TVMs, and consultants) to participate in advisory committee meetings is a labor-intensive task that involves multiple levels of review.

The agenda of the advisory committee meeting or individual assignment (such as consultants providing expertise but not voting) is reviewed to assess the types of matters to be addressed. This assessment is critical because the eligibility and waiver rules vary depending on the type of meeting or assignment (5 CFR part 2640). In considering an assignment for an SGE for a meeting related to a product approval, entities with a financial interest may include the sponsor and firms who will manufacture or market the product being reviewed, products

that would be used in manufacture or market conjunction with the one being reviewed, and products that would compete with the one being reviewed.

FDA staff reviews the responses to the confidential financial disclosure questionnaire (Form FDA 3410) and focus on whether a conflict of interest exists. Based solely on the reported information it is often possible to determine that: there is no conflict of interest; there is a conflict of interest and a waiver can be justified; or there is a conflict of interest that is so great, recusal is the only course of action. When clarification is needed, FDA staff may ask the SGE to respond to additional questions.

Advisory committee meetings are scheduled to provide advice to the FDA official making the regulatory decision on products. Typically, the FDA official is an Office or Division Director. The official is notified of any significant conflicts of interest that are reported to enable a determination of the extent to which the member's expertise is important to the meeting. If the reported interest is significant and the need for the member's services is not great, recusal is appropriate. If the member's services are important to the meeting because

nobody else with the expertise can be obtained for the meeting, a waiver may be appropriate. In making this determination, the review office and division take into account the requirements of FDAMA.

FDA's Ethics staff conducts an independent review of all conflict of interest waivers and makes a recommendation to the Senior Associate Commissioner concerning the waiver. If questions arise about the justification for the waiver, the Ethics staff may ask the recommending office for additional information. The Ethics staff may also consult with the OGC in DHHS or OGE.

A proposed waiver and justification for the waiver will have received eight levels of review before reaching the Senior Associate Commissioner for final approval. As the final step, the appointing official makes the decision based on the information provided. The conflict of interest determination may indicate that: no action is needed; a waiver to participate as a full voting member is granted; a waiver to participate with nonvoting status is granted; an appearance authorization is granted; or the SGE is excluded from participating in the meeting.

What is an appearance determination (502) and who gets one?

The OGE "Standards of Ethical Conduct" for employees of the Executive Branch provide criteria by which to judge the appearance of lack of impartiality where actual conflicts of interest, as defined by 18 U.S.C. 208, do not exist. Federal regulations, 5 CFR 2635.502, provide a procedure for "waiving" certain appearance problems. Similarly, even where 5 CFR 2635.502 is not technically applicable, FDA may decide to reassign a matter when there is a concern about appearances.

Waivers

In the 1990s the Institute of Medicine (IOM) recommended to FDA that it formulate a written guidance for granting waivers. An FDA Taskforce, in collaboration with the DHHS Ethics Division, created the "Waiver Criteria Document" (WCD). In 1997, the OGE audited the FDA Ethics Program, including the Advisory Committee Program, and 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. . ." The WCD is an evolving document which provides guidance for FDA staff, Advisory Committee Members and other SGEs about the Agency's policies and procedures for handling conflicts of

interest. The WCD 2000 describes changes to the original document, including an updated format, revisions to existing categories, and the creation of new categories to clarify waiver criteria practices that have been in existence for some time. The concepts and underlying principles of the WCD remain unchanged.

FDA has authority to allow an advisory committee member (standing and temporary) to participate in the review of a new therapy even if there is a potential conflict of interest, as long as FDA complies with applicable legal standards. FDA may provide for this participation by granting a waiver under 18 U.S.C. 208 for the SGE.

Whether a waiver should be sought or granted is subject to scrutiny and review by more than eight different parties, which include:

- the Committee Members;
- the Executive Secretary;
- the Committee Management Specialist;
- the Program Officer;
- the Chief of Scientific Advisers and Consultants Staff;

- the Ethics Specialist;
- the Director of Advisory Committee Oversight; and,
- the Senior Associate Commissioner.

These seven evaluations occur before the final evaluation by the deciding official in FDA, the Senior Associate Commissioner. In some situations, legal counsel at DHHS and OGE also may be consulted prior to a decision. At any level of review a waiver can be removed from consideration and the SGE excluded from participation. This review allows for an in-depth assessment of the waiver request.

Who is Granted a 208(b)(3) waiver?

Under section 18 U.S.C. 208(b)(3), an SGE, who may be a standing or temporary member, may participate in an advisory committee meeting despite a potential conflict of interest. After reviewing the SGE's financial disclosure statements, the Senior Associate Commissioner may determine that the need for the employee's services outweighs the potential conflict of interest created by the financial interest involved. A waiver may be indicated if, for example, the SGE will provide expertise that is necessary to the issues on the agenda that would otherwise be considered unavailable. Another example

would be if the product in question is widely studied, it would be difficult to find a qualified SGE who was not at least involved, either personally, or indirectly through his or her institution, with that product or a competing product. After a review of the reported interests, the Senior Associate Commissioner either certifies in writing that the need for the individual's services outweighs the potential conflict of interest created by the financial interest involved or denies the waiver.

Vaccines and Related Biological Products Advisory Committee (VRBPAC)

One of FDA's advisory committees of particular interest to the Committee is the VRBPAC. The VRBPAC is composed primarily of non-government experts in fields related to vaccines, such as infectious diseases, immunology, virology, bacteriology, molecular biology, pediatrics, and biostatistics. The last selection for committee vacancies occurred in September 1998. Fifty-seven candidates were reviewed for five slots. While VRBPAC provides advisory opinions to FDA on a wide range of vaccine-related issues it does not specifically recommend for or against licensure of a vaccine. VRBPAC provides

recommendations on the adequacy of safety and efficacy data. FDA is not required to follow the recommendations of advisory committees, but often does. In addition, FDA has no mandate to present all vaccine products before the committee prior to licensure. There have been a few instances where a vaccine has been approved without VRBPAC review.

The committee's role is to provide recommendations on safety and efficacy, but these are not the sole issues considered by the Agency in approving a product. There have been instances when VRBPAC unanimously voted that the data presented was adequate to support the safety and effectiveness of the product, however, FDA delayed approval of the vaccine until all product manufacturing issues were resolved.

Conclusion

Mr. Chairman, let me assure you that the Agency has made every effort to rigorously comply with the applicable statutes and regulations in appointing outside experts to the FDA Advisory Committees. Multiple, independent and sometimes redundant reviews, taken together, ensure FDA, the medical community, industry, consumer and patient groups and the American public that advisory committee recommendations are based on the best

possible science and are free from bias.

Thank you, and I would 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.

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 procedures 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.

[The prepared statement of Dr. Snider follows:]

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Centers for Disease Control
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STATEMENT OF

DIXIE E. SNIDER, M.D., M.P.H.

ASSOCIATE DIRECTOR FOR SCIENCE

CENTERS FOR DISEASE CONTROL AND PREVENTION

BEFORE THE

COMMITTEE ON GOVERNMENT REFORM

U.S. HOUSE OF REPRESENTATIVES

June 14, 2000

Good morning. I am Dr. Dixie Snider, Associate Director for Science at the Centers for Disease Control and Prevention (CDC). As Executive Secretary for CDC's Advisory Committee on Immunization Practices (ACIP), I am pleased to be here to discuss the policies and procedures of the Committee and its role in developing recommendations for vaccine use.

The ACIP provides advice and guidance to the Secretary, Department of Health and Human Services (HHS), the Assistant Secretary for Health, and the CDC Director on the most effective means to prevent vaccine-preventable diseases. The ACIP develops written recommendations, subject to the approval of the CDC Director, for the routine administration of vaccines for the pediatric and adult populations, along with schedules regarding the appropriate periodicity, dosage, and contraindications applicable to the vaccines. In addition, as provided by statute, the ACIP designates vaccines for administration in the Vaccines for Children Program (VFC). The ACIP makes such recommendations taking into account available information about a vaccine and placing that information in the larger context of the various health care delivery systems in the U.S., the current disease epidemiology, implementation issues, ethical and legal constraints, and other factors. The overall goal of the ACIP is to provide advice that assists CDC, HHS and the Nation in reducing new cases of vaccine preventable diseases and increasing the safe usage of vaccines and related biological products that provide active and passive immunoprophylaxis.

The ACIP consists of twelve regular voting members, selected by the Secretary, HHS, from authorities who are knowledgeable in the field of immunization practices, have multi-disciplinary expertise in public health, and have expertise in the use of vaccines and immunologic agents in both clinical and preventive medicine. It is crucial that these varied

areas of expertise are represented by the Committee membership. One of the purposes of an advisory committee is to provide additional scientific expertise to add to the body of special knowledge and information, beyond what may be selected for presentation at committee meetings. Experts are more likely to be familiar with the published scientific literature with its strengths and weaknesses than non-experts. In addition, experts are more likely to know cutting-edge research information, including unpublished information, that may not be available to non-experts. If this expertise were not available, members would be limited to decision-making based solely on selected information presented at ACIP meetings. In addition to required technical expertise, consideration for ACIP membership is given to representation from diverse geographic areas, both genders, racial and ethnic groups, and the disabled.

In addition to the regular voting members, the ACIP has ex-officio members from other Federal agencies involved with vaccine issues, and non-voting liaison representatives from professional societies and organizations responsible for the development and execution of immunization programs for children and adults. The participation of these ex-officio members and liaison representatives provides a better understanding of the position and views of their sponsoring organizations resulting in better informed decisions.

ACIP regularly scheduled meetings are held three times a year, with meeting dates announced 6-12 months in advance. Notices of each meeting, along with agenda items that may be discussed, are published in the Federal Register in accordance with the requirements of the Federal Advisory Committee Act (FACA). Notices of these meetings are issued at least 15 days in advance of the meeting, to allow adequate time for all interested parties to make arrangements to attend. ACIP meetings are open to the public, who are welcome to attend and present their

views. Public comments are solicited during the ACIP meetings and are included in the decision making process prior to voting on recommendations.

To ensure a thorough review of available information, the ACIP often appoints working groups to assist in the development of drafts of recommendations. Working groups generally consist of ACIP members and CDC staff and may include ex-officio members, liaison representatives and other consultants with immunization expertise. Working groups present these drafts for deliberation by the full Committee at regularly scheduled meetings of the ACIP. Only the full committee of the ACIP may issue ACIP recommendations, after a vote approving those recommendations is taken. A vote may be taken when a quorum of at least seven eligible ACIP members are present. Eligible voters are those members who do not have a conflict of interest. If there are not seven eligible voting members present, the Executive Secretary of the Committee can appoint the ex officio members as voting members, as provided in the Charter for this Committee.

Federal advisory committees inherently have members who may have potential financial conflicts of interest because, as I've mentioned, the members are chosen for service based on their expertise in the areas in which advice is sought by the government. Experts in the vaccine field frequently have affiliations with, or may be engaged in research conducted by, academic institutions or other institutions which may receive funding from vaccine manufacturers. Physicians in private practice who are considered experts often do consultancies, work for managed care organizations involved in clinical trials, and/or accept honoraria for lectures given at scientific meetings sponsored by manufacturers. This professional experience which contributes toward the development of their immunization expertise also may result in potential

conflicts of interest. Congress has recognized the need for service on federal advisory committees by these experts and has provided for waivers of the conflict of interest prohibitions under 18 U.S.C. § 208 when the need for the individual's services outweighs the potential for a conflict of interest created by the financial interest involved. CDC is sensitive to any perception regarding potential conflicts of interest of members serving on the ACIP and is committed to taking steps to ensure not only that there is technical compliance with the provisions of 18 U.S.C. § 208, but that the spirit of those provisions is also fulfilled.

Consistent with these provisions of law, limited waivers may be issued to individual ACIP members who have potential conflicts of interest so that the government may benefit from the scientific and public health expertise of each member. Under these waivers, each member with a potential or actual financial conflict of interest may be granted a limited waiver to allow participation in all committee discussions, with the conditions that (a) the member publicly discloses relevant interests at the beginning of each ACIP meeting and (b) the member 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.

All ACIP members are required to disclose financial interests they have had within the past 12 months, as well as the financial interests of their spouse and minor children. This information is collected using the Office of Government Ethics (OGE) 450 Confidential Financial Disclosure Form. Financial interests which are reported include: 1) stock-ownership; 2) honoraria; 3) employment; 4) general partnership interests; 5) contracts; and, 6) receipt of grant funds. Consistent with OGE guidance, the OGE 450 forms of ACIP members are reviewed for vaccine-related interests by CDC's Committee Management Office, the ACIP's Executive

Secretary and Administrative Assistant, and CDC's Office of General Counsel. In addition, members' curricula vitae are reviewed to determine whether additions need to be made to the OGE 450 forms. Members revise/update their OGE 450 forms on an annual basis.

As noted, in addition to disclosing financial interests by submitting a Confidential Financial Disclosure Report, members are required to publicly disclose all relevant financial interests at the beginning of each ACIP meeting. This public disclosure, which is fairly unique to ACIP, ensures that the agency, their fellow members, and the public are aware of each member's interests which can be weighed in the deliberations of the committee.

ACIP maintains the highest scientific standards in developing recommendations for the use of vaccines. Their process includes (1) a review of the labeling/package inserts for each vaccine; (2) a thorough review of the scientific literature (both published and unpublished, when available) on the safety, efficacy, acceptability, and effectiveness of the immunizing agent, with consideration of the relevance, quality, and quantity of published and unpublished data; (3) an assessment of cost effectiveness; (4) a review of the morbidity and mortality associated with the disease in the population in general and in specific risk groups; (5) a review of the recommendations of other groups; and (6) a consideration of the feasibility of vaccine use in existing child and adult immunization programs. Feasibility issues include (but are not limited to) acceptability to the community, parents, and patients; vaccine distribution and storage; access to vaccine and vaccine administration; impact on the various health care delivery systems; population distribution effects; and social, legal and ethical concerns.

ACIP recommendations are extremely useful to CDC and others engaged in developing vaccine use recommendations and policies. Once the ACIP recommendations are submitted to CDC, they are reviewed and a determination is made whether or not to accept them. When approved by CDC, the ACIP recommendations are published in the *Morbidity and Mortality Weekly Report Recommendations and Reports* series, and occasionally reprinted in other publications.

CDC is continuously reviewing 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 this process which will also provide this necessary expertise which is so essential to an advisory committee.

In closing, I'd like to note how immunization recommendations such as those developed by the ACIP have benefitted this nation. Immunization is recognized as one of the greatest public health achievements of the 20th century, based on its impact on preventing death, illness, and disability. Immunizations have resulted in the eradication of smallpox; elimination of poliomyelitis in the Americas; and control of measles, rubella, tetanus, diphtheria, Haemophilus influenzae type b, and other infectious diseases in the U.S. and other parts of the world. Vaccine-preventable diseases are at an all time low in the U.S. Still, there are challenges which face us. CDC is committed to meeting those challenges to improve the health of children and the nation as a whole.

I'll be happy to respond to any questions you may have.

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.

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 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 discus-

sion 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 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.

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.

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.

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.

[The prepared statement of Hon. Benjamin A. Gilman follows:]

Opening Statement for Government Reform Hearing on Vaccine Development
Rep. Benjamin Gilman
June 15, 2000
CHAIRMAN BURTON,

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industry and the Federal Drug Administration (FDA) and Center for Disease Control (CDC) advisory committee members results in more than an ethical question, it results in personal injury and death for innocent children and adults.

Previous investigations have revealed that: the conflict of interest rules employed by the FDA and CDC are weak and not strictly enforced, advisory committee members with 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.

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The FDA and its advisory board who approved the vaccine in 1999 overlooked a 1989 test of a similar

vaccine in China, in which a number of babies suffered identical bowl 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 the China test is now working at the CDC and 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 died.

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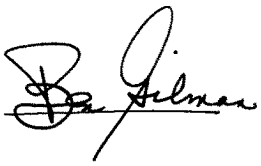

Rep. Benjamin Gilman
Additional Opening Statement Remarks
June 14, 2000 hearing on Vaccine Development

Mr. Chairman. I would like to include the following information regarding the hearing that took place on June 14, 2000 regarding vaccine development. Since the date of the hearing, information about the development of the rotavirus RotaShield vaccine has been brought to my attention, and accordingly I would like to clarify my remarks and have them included with my opening statement.

As the transcripts of the proceedings at both the Federal Drug Administration (FDA) and the Center for Disease Control and Prevention (CDC) show, there was extensive discussion about intussusception. Based on the expected background rate (those cases that would have occurred normally in the population), it was anticipated that the trial population would show 4 cases of intussusception. Five cases were actually identified. This is not a statistically significant difference. It is not possible to conclude that the vaccine caused intussusception based on one additional case just as it would not be possible to conclude that the vaccine prevented intussusception if only 3 cases had occurred instead of the anticipated 4. However, because there was the one unsuspected case, concern was raised about whether or not this represented a real problem or not. Due to this concern, a warning was placed on the vaccine's label to alert physicians to this possible side affect.

The CDC conducted a trial in China using a virus strain that was a combination of human rotavirus mixed with bovine components which was given to infants at birth. RotaShield is a human virus strain mixed with rhesus components and was given at 2, 4, and 6 months of age. In other words, these were two completely different schedules - they were in no way the same vaccine. More importantly, there were actually no deaths associated with the China trial and in fact there were no hospitalizations associated with the trial. There were some reported instances of gastrointestinal distress, a common malady found in infants, which were not able to be attributed to the vaccine or control group.

Intussusception is a condition in which the bowel telescopes upon itself. In most cases, this condition is corrected during the diagnostic procedure - a barium enema which causes the bowel to unfold. In slightly less than half the cases, surgery is required and in the vast majority of surgeries, the physician simply manually separates the telescoped bowel. While no one knows the causes of intussusception, it is thought that the condition occurs in about one in every 2500 infants.

One infant died from intussusception after receiving the RotaShield vaccine. His parents had sought medical attention, but the problem was misdiagnosed at the hospital and the infant was sent home. The other cases of intussusception attributed to vaccine administration were restored to normal status through the barium enema used to diagnose the condition or with a simple surgical procedure.

In contrast, rotavirus disease kills about 40 babies in the U.S. each year (globally 2000 children die EVERY DAY from rotavirus disease) - deaths that would be prevented with a rotavirus vaccine. In addition to deaths, rotavirus infection causes over 100,000 hospitalizations in children under age 5 in the U.S. The reality is that American babies suffer and die as a result of this disease, not from the vaccine that prevented the disease. There were and continue to be members of the scientific and medical community who argue that even with the known side effect of extra cases of intussusception, the vaccine should still be used because its benefits - the deaths and hospitalizations prevented - still outweigh the increased incidence of intussusception.

We must not forget the importance that vaccines and the vaccine industry have played in recent history - vaccines are in fact the most effective way in which to combat a number of serious diseases. Accordingly, I am hopeful that these additional facts will be considered by the committee if and when it continues to look into this issue in the future.

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

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

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 Rotashield 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 rotavirus 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 cur-

sory 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 members, 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 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.

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.]

[The prepared statement of Hon. Helen Chenoweth-Hage and additional information submitted for the hearing record follow:]

Statement of Congressman Helen Chenoweth-Hage
Committee on Government Reform and Oversight
2154 Rayburn House Office Building
June 15, 2000

Thank you, Mr. Chairman. I would like to take the opportunity to thank both the Chairman and the Committee for holding today's hearing, "*FACA: Conflicts of Interest and Vaccine Development - Preserving the Integrity of the Process*". I look forward to hearing from our two panels of witnesses today and hearing about the ethics rules and guidelines that cover the approval process for vaccines.

Mr. Chairman, you know as does the rest of the committee, that I have very real concerns about the current vaccination programs and the way they are administered. Over the past year, this committee has held a series of hearings regarding vaccines and their effect on the populace. However, today's hearing is about conflict of interest in the development of vaccines on the part of federal health policy decision makers. This is not the same type of hearing, but the subject is disturbing nonetheless.

Today, we'll be focusing on the Rotavirus vaccine and the possible conflicts of interest that developed during its approval process. This discussion should be informative because of the troubling history of the Rotavirus vaccine. Somehow, this vaccine was able to make it through our 'rigorous' approval process and yet still result in a number of severe adverse health events when it was brought to market.

Could this be due to the fact that its approval was expedited by members who had conflicts of interest in seeing it approved? I do not know the answer to this question. However, it is one that must be explored. It is especially important to explore this possibility considering that vaccines are the only type of 'medicine' that the government regularly forces anyone to receive.

I look forward to this discussion over why waivers for conflict of interest are routinely distributed by the Centers for Disease Control (CDC), why financial disclosure statements are not always completed, and why those employees with conflicts of interest can still participate in the approval process.

Mr. Chairman, vaccines are an important, but troubling, course of pre-treatment for many diseases. In the past year we've discussed their possible links to both autism and Gulf War Disease. I appreciate the committee taking the time to now explore the problems that may exist within the approval process.

Thank you, Mr. Chairman.

MEDICAL DECISION-MAKERS COMMITTED TO PROTECTING U.S. CHILDREN AGAINST SERIOUS INFECTIOUS DISEASES

National Parent Organization Supports Recommendations for Universal Protection Against Vaccine-Preventable Diseases

June 15, 2000, Washington, D.C. - The national parent advocacy organization, PKIDs (Parents of Kids with Infectious Diseases), is committed to protecting our nation's children against diseases that have life-long effects on their health and development. In response to a U.S. House Government Reform Committee hearing regarding conflicts of interest surrounding childhood immunization recommendations, PKIDs voices its strong support of the medical community in protecting our children against serious, yet easily preventable diseases.

"Universal childhood immunization is the only way to protect our children against highly contagious and potentially debilitating diseases, such as hepatitis B, measles and diphtheria," said Dr. Elizabeth Fagan, medical advisor to PKIDs and Professor of Pediatrics and Medicine, Rush Presbyterian St. Lukes Medical Center, Chicago, IL. "A frightening fact supporting the need for immunization programs is that even in the U.S., where immunization rates are among the highest in the world, approximately one million pre-school children are not adequately protected against potentially disabling and fatal diseases."

Immunization Recommendations: Critical to Keeping Infectious Diseases at Bay

Childhood immunization recommendations are made by the Advisory Committee on Immunization Practices (ACIP), an advisory body to the Centers for Disease Control and Prevention (CDC), and by the American Academy of Pediatrics (AAP) and the American Academy of Family Physicians (AAFP). These leading medical organizations carefully examine the safety and effectiveness of all new vaccines as the vaccines undergo the arduous approval process of the Food and Drug Administration (FDA), they make recommendations for use through a deliberative process and they focus on improving the safety of childhood vaccines.

A recent example of the prudent decisions made concerning the use and safety of childhood vaccination is the expedient withdrawal of the rotavirus vaccine. After receiving only 15 reports of infants developing intussusception (bowel obstructions) following administration of the rotavirus vaccine, the CDC temporarily suspended the vaccine and, following subsequent studies, the vaccine was withdrawn from the market.

"Vaccine advisory groups such as the Advisory Committee on Immunization Practices are made up of national experts who are carefully selected to serve on these committees based on their vast knowledge in the fields of public health, vaccine research and usage, and preventive and clinical medicine," said Dr. Deborah Wexler, Executive Director of the Immunization Action Coalition, a national nonprofit organization based in St. Paul,

PROVE Parents Requesting Open Vaccine Education

Dawn Richardson, President
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Re: June 15th 2000 Hearing on Conflicts of Interest and Vaccine Development:

The Vaccine Machine Plagues State Vaccine Policy with Conflicts of Interest Too

June 27, 2000

To the members of the U.S. Congressional Committee on Government Reform,

Regarding your recent committee hearing on the on the "Conflicts of Interest and Vaccine Development" on June 15, 2000, please accept the following comments as written testimony to become a part of public record and considered in your investigation. My name is Dawn Richardson. I am a mother, a citizen of the United States, and the president and founder of the Texas-based grassroots support organization Parents Requesting Open Vaccine Education (PROVE). I commend the chairman, Congressman Burton, and all committee members for investigating this serious problem of conflicts of interest in the area of vaccines. Through our grassroots experience of attempting restore parental rights by inserting informed consent provisions and a conscientious exemption to vaccines in the Texas statutes, I have concluded that the charges being investigated by your committee only represent the tip of the iceberg as conflicts of interest in the vaccine arena are so pervasive that they permeate and corrupt vaccine policy right down to the state and local level.

Since the committee focused a lot of its efforts on the controversy surrounding the rotavirus vaccine and the manufacturers of vaccines ties to policy makers, we will do the same. The first example was the attempt of some Texas physician and pharmaceutical lobbyists to push through legislation during the 76th legislative session in the state of Texas to require the Texas Board of Health to automatically adopt the recommendations of ACIP, AAP, and AAFP as law. HB 3036, if passed in it's introduced version, would have amended Chapter 161.004(f) of the Health and Safety Code to read as follows: "The board shall adopt an immunization schedule that complies with the guidelines for immunization schedules developed by the Advisory Committee on Immunization Practices, the American Academy of Pediatrics, and the American Academy of Family Practice." HB 3036 would have translated into a statewide legal mandate for every child in the state for all vaccines RECOMMENDED by the above organizations regardless of the severity of the disease in the U.S. and lingering safety questions.

This proposed piece of legislation, sponsored by Representative John Smithee and pushed by the lobbyist who simultaneously represented Wyeth-Ayerst and the state chapter of the AAP, would have removed the public's ability to have any impact on the immunization schedule for our children since the Board of Health would have been

legally required to adopt their schedule regardless of any public debate around the new recommendation. Because there is no parental rights exemption in this state, this would have amounted to forcing vaccines without any public representation by elected officials. This proposed piece of legislation would have additionally automatically required all HMOs to pay for the vaccines regardless of the cost set up by the pharmaceutical company. (See Appendix A for full text of the introduced version of HB 3036.)

At the time this bill was introduced, there were two vaccines that were on the nationally recommended schedule that were not yet on the state schedule – Varicella and Rotavirus. This bill also represented a backhanded attempt to legally mandate a vaccine for these diseases. With all the children in Texas, and no legal way for a parent to just object to the administration of the vaccine to their child, this would have been a windfall of profits for pediatricians and pharmaceutical companies.

Where the gross example of conflict of interest comes in is where the lobbyist who was responsible for convincing Representative Smithee to file this, Marc Samuels, promoted this bill as something that the "doctors want." While this may have been true as Mr. Samuels was the lobbyist for the Texas chapter of the American Academy of Pediatrics – The Texas Pediatric Society, what was not openly represented or disclosed was that Mr. Samuels also got paid that year up to $200,000 to represent the sole manufacturer of the rotavirus vaccine - American Home Products/Wyeth. We learned this after checking later with the Texas Ethics Commission. What also concerns me greatly is that the state chapter of the American Academy of Pediatrics would have as their lobbyist someone who also represented a vaccine manufacturer. While this is not illegal, I consider it a highly unethical choice of the Texas Pediatric Society and a prime example of conflict of interest. (see Appendix B for the Texas Ethics Commission listing of Mr. Samuels interests.)

Luckily, HB 3036 never got passed. However, at the end of the legislative session, the interests that wanted rotavirus paid for by insurance got the provision amended in an unrelated bill, HB 2748 going through the Senate Economic Development committee. We couldn't help but notice the irony in the fact that what this amendment really represented was economic development for pediatricians and the sole manufacturer of the vaccine – Wyeth-Ayerst. (see Appendix C for HB 2748)

The rotavirus and blank coverage requirement for vaccines by HMOs was supported by the Texas Medical Association, the Texas Pediatric Society and the Texas Academy of Family Physicians all through representation by lobbyist Marc Samuels. (see Appendix D for witness list for HB 2748) Again, his relationship with the manufacturer of the vaccine was not disclosed or represented. We attempted to stop this bill on the grounds that the vaccine was extremely expensive, it was not required so insurance shouldn't be forced to pay for it, and bottom line it was for diarrhea. (see Appendix E for PROVE's opposition letter to HB 2748) Unfortunately, we were not successful. It is ironic now that Texas has a law requiring HMOs to pay for a vaccine that was later proven unsafe for some children and has been removed from the market.

Finally, I would like to illustrate a more recent example of how the vaccine manufacturers, specifically Wyeth-Ayerst, continue to work with doctors to try to influence state legislators and vaccine policy. Here is a quote from the June 26th, 2000 15th issue of SnapShots, a publication funded by the Robert Woods Johnson

Foundation under a project entitled All Kids Count. "In June, Wyeth-Ayerst hosted a meeting at its Pearl River, NY, facility to increase Texas state legislators' understanding of the debate around safe vaccines. Discussions on vaccine policy and safety were led by Cyndee Long from Global Public Policy, Wyeth-Ayerst; Candie Phipps, Texas Pediatrics Society; and Paul Offit, Children's Hospital of Philadelphia. Laurie Carmody, All Kids Count, addressed the role of registries in increasing vaccine safety."

The Texas Pediatric Society has already demonstrated a close relationship with Wyeth-Ayerst through their common lobbyist Marc Samuels. When state legislators hear that a doctor wants vaccine legislation, they are assuming as the public does that the vaccine is safe, effective, and necessary in the doctor's opinion and that the doctors have made this decision in the best interest of their patients. As demonstrated here by the coordination efforts by Wyeth-Ayerst, that is not what has occurred in Texas.

Resentment and anger is building in parents around the country toward health officials who presume to care more for their children than the parents while it is becoming painfully obvious that conflicts of interest in the name of increased profits to physicians and vaccine manufacturers plague how vaccine policy is made at the state level. This is even more concerning in states like Texas, of which there are 35, where a parent can't legally exercise their inherent right to choose which vaccines are given to their child. It is tragic that children's health is ostensibly used to funnel money into industry because it is the child, as clearly demonstrated in the case of the rotavirus vaccine fiasco, who ultimately suffers. I have submitted this testimony in hopes that the Government Reform Committee would have a better understanding of how pervasive the conflict of interest problem is regarding vaccines. I urge you to do whatever you can to encourage the adoption of informed consent and conscientious exemption provisions in all state laws and to raise the bar at the federal level to prevent these conflicts of interest from influencing state vaccine policy.

Sincerely,
Dawn Richardson

APPENDIX A

Introduced Version of HB 3036

Taken from:
http://www.capitol.state.tx.us/tlo/billnbr.htm

By Smithee H.B. No. 3036
76R8134 MCK-D

A BILL TO BE ENTITLED
AN ACT

relating to immunizations of children.

BE IT ENACTED BY THE LEGISLATURE OF THE STATE OF TEXAS:

SECTION 1. Chapter 161.004(f), Health and Safety Code, is amended to read as follows:

(f) The board shall adopt rules that are necessary to administer this section. **The board shall adopt an immunization schedule that complies with the guidelines for immunization schedules developed by the Advisory Committee on Immunization Practices, the American Academy of Pediatrics, and the American Academy of Family Practice.**

SECTION 2. Section 3(a), Article 21.53F, Insurance Code, as added by Chapter 683, Acts of the 75th Legislature, Regular Session, 1997, is amended to read as follows:

(a) **A health benefit plan that provides benefits for a family member of the insured shall provide coverage for each covered child described by Subsection (b) of this section, from birth through the date the child is six years of age, for:**

(1) immunization against:

(A) diphtheria;
(B) haemophilus influenzae type b;
(C) hepatitis B;
(D) measles;
(E) mumps;
(F) pertussis;
(G) polio;
(H) rubella;
(I) tetanus; [~~and~~]
(J) varicella; and
(K) rotavirus; and

(2) any other immunization that is required by statute or rule [~~law~~] for the child.

SECTION 3. (a) This Act takes effect September 1, 1999.

(b) The change in law made by Section 2 of this Act applies only to an insurance policy that is delivered, issued for delivery, or renewed on or after the effective date of this Act. A policy that is delivered, issued for delivery, or renewed before the effective date of this Act is governed by the law as it existed on the date the insurance policy was delivered, issued for delivery, or renewed, and that law is continued in effect for that purpose.

SECTION 4. The importance of this legislation and the crowded condition of the calendars in both houses create an emergency and an imperative public necessity that the constitutional rule requiring bills to be read on three several days in each house be suspended, and this rule is hereby suspended.

APPENDIX B
Texas Ethics Commission listing of Mr. Samuels' interests

Lobby Report Information Provided by:

Texas Ethics Commission
201 East 14th St., 10th Floor
P.O. Box 12070
Austin, TX 78711-2070
(512) 463-5800
1-800/325-8506
FAX: (512) 463-5777
Disclosure Filing FAX: (512) 463-8808
http://www.ethics.state.tx.us

Samuels, Marc B.
(512) 236-0252
400 West 15th Suite 600
Austin, TX 78701-
Lobbyist Termination Date: 12/31/99

American Home Products Corp.
Five Giralda Farms Madison, NJ 07940-
Concern Termination Date: 12/31/99
Type of Compensation: Prospective
Amount of Compensation: $ 50,000.00 - 99,999.99

Baylor Health Care System/Health Texas Inc.
3500 Gaston Ave Dallas, TX 75246-
Concern Termination Date: 12/31/99
Type of Compensation: Prospective
Amount of Compensation: $ 50,000.00 - 99,999.99

Brown Schools Rehabilitation Centers
Concern Termination Date: 12/31/99
Type of Compensation: Prospective
Amount of Compensation: $ 25,000.00 - 49,999.99

East Texas Regional Healthcare System
100 S Beckham Tyler, TX 75711-
Concern Termination Date: 12/31/99
Type of Compensation: Prospective
Amount of Compensation: $ 50,000.00 - 99,999.99

Girling Healthcare
4902 Grover Austin, TX 78756-
Concern Termination Date: 12/31/99
Type of Compensation: Prospective
Amount of Compensation: $ 50,000.00 - 99,999.99

Pfizer, Inc.
235 East 42d St New York, NY 10017-
Concern Termination Date: 12/31/99
Type of Compensation:
Paid Amount of Compensation: $ 0.01 - 9,999.99

Physicians Reliance Network Inc.
Concern Termination Date: 12/31/99
Type of Compensation: Prospective
Amount of Compensation: $ 25,000.00 - 49,999.99

Rural Community Health System of Texas
P.O. Box 289 Rush, TX 75785-
Concern Termination Date: 12/31/99Type of Compensation: Prospective
Amount of Compensation: $ 25,000.00 - 49,999.99

Southwest Texas Rural Hospital Alliance
Concern Termination Date: 12/31/99
Type of Compensation: Prospective
Amount of Compensation: $ 0.01 - 9,999.99

Superion, Inc.
701 Capital of Texas South Suite C-1282 Austin, TX 78746-
Concern Termination Date: 12/31/99
Type of Compensation: Paid
Amount of Compensation: $ 0.01 - 9,999.99

Tenet Healthcare Corp.
14001 N. Dallas Pkwy Dallas, TX 75038-
Concern Termination Date: 12/31/99Type of Compensation: Prospective
Amount of Compensation: $ 50,000.00 - 99,999.99

Texas Academy of Internal Medicine Services
401 West 15th Street Suite 700 Austin, TX 78701-
Concern Termination Date: 12/31/99
Type of Compensation: Prospective
Amount of Compensation: $ 25,000.00 - 49,999.99

Texas Genetics Network/TexGene
7703 Floyd Curl Drive San Antonio, TX 78284-7802
Concern Termination Date: 12/31/99
Type of Compensation: Prospective
Amount of Compensation: $ 25,000.00 - 49,999.99

Texas Medical Foundation
901 Mopac Expwy S Suite 200 Austin, TX 78746-5799
Concern Termination Date: 12/31/99
Type of Compensation: Prospective
Amount of Compensation: $ 25,000.00 - 49,999.99

Texas Pediatric Society
401 West 15th St Suite 600 Austin, TX 78701-
Concern Termination Date: 12/31/99
Type of Compensation: Prospective
Amount of Compensation: $ 25,000.00 - 49,999.99

United HealthCare Corporation
1620 L St NW Suite 800 Washington, DC 20036-
Concern Termination Date: 12/31/99Type of Compensation: Prospective
Amount of Compensation: $ 50,000.00 - 99,999.99

Whitehall - Robins Healthcare Division
P.O. Box 8616 Philadelphia, PA 19101-
Concern Termination Date: 12/31/99Type of Compensation: Prospective
Amount of Compensation: $ 0.00 - 0.00

Wyeth Ayerst Pharmaceuticals
A Div.Of American Home Products
P. O. Box 8616 Philadelphia, PA 19101-
Concern Termination Date: 12/31/99
Type of Compensation: Prospective
Amount of Compensation: $ 50,000.00 - 99,999.99

APPENDIX C
Enrolled Version of HB 2748

AN ACT

relating to coverage for certain care for children provided through certain health benefit plans.

BE IT ENACTED BY THE LEGISLATURE OF THE STATE OF TEXAS:

SECTION 1. The Texas Health Maintenance Organization Act (Chapter 20A, Vernon's Texas Insurance Code) is amended by adding Sections 9E and 9F to read as follows:

Sec. 9E. WELL-CHILD CARE FROM BIRTH. (a) In this Act, "well-child care from birth" has the meaning used under Section 1302, Public Health Service Act (42 U.S.C. Section 300e-1), and its subsequent amendments, and includes newborn screening required by the Texas Department of Health.

(b) Each health maintenance organization shall ensure that each health care plan provided by the organization includes well-child care from birth that complies with the federal requirements adopted under Chapter XI, Public Health Service Act (42 U.S.C. Section 300e et seq.), and its subsequent amendments, and the rules adopted by the Texas Department of Health to implement those requirements.

Sec. 9F. IMMUNIZATIONS OF CHILDREN. In addition to an immunization required under Section 3(a), Article 21.53F, Insurance Code, each health maintenance organization shall include in each health care plan provided by the organization coverage for immunization against rotovirus and any other immunization required for a child by statute or rule.

SECTION 2. Except as provided by Section 3 of this Act, this Act takes effect immediately.

SECTION 3. Section 9F, Texas Health Maintenance Organization Act (Chapter 20A, Vernon's Texas Insurance Code), as added by this Act, takes effect September 1, 1999, and applies only to an evidence of coverage that is delivered, issued for delivery, or renewed on or after January 1, 2000. An evidence of coverage that is delivered, issued for delivery, or renewed before January 1, 2000, is governed by the law as it existed on the date the evidence of coverage was delivered, issued for delivery, or renewed, and that law is continued in effect for that purpose.

SECTION 4. The importance of this legislation and the crowded condition of the calendars in both houses create an emergency and an imperative public necessity that the constitutional rule requiring bills to be read on three several days in each house be suspended, and this rule is hereby suspended, and that this Act take effect and be in force according to its terms, and it is so enacted.

President of the Senate Speaker of the House

I certify that H.B. No. 2748 was passed by the House on May 5, 1999, by a non-record vote; that the House refused to concur in Senate amendments to H.B. No. 2748 on May 26, 1999, and requested the appointment of a conference committee to consider the differences between the two houses; and that the House adopted the conference committee report on H.B. No. 2748 on May 30, 1999, by a non-record vote.

Chief Clerk of the House

I certify that H.B. No. 2748 was passed by the Senate, with amendments, on May 24, 1999, by the following vote: Yeas 30, Nays 0; at the request of the House, the Senate appointed a conference committee to consider the differences between the two houses; and

that the Senate adopted the conference committee report on H.B. No. 2748 on May 30, 1999, by the following vote: Yeas 30, Nays 0.

_____
Secretary of the Senate

APPROVED: _____
Date

_____
Governor

APPENDIX D

Witness list for HB 2748

Taken from http://www.capitol.state.tx.us/tlo/76R/witbill/HB02748S.HTM

HB 2748
SENATE COMMITTEE REPORT
Economic Development Committee

May 11, 1999 - 8:00A
Registering, but not testifying:

For: Barron, Connie (Texas Medical Assn.), Austin

Patterson, Jerry (Self), Austin

Samuels, Marc (TMA,Tx. Pediatric Society, Tx. Academy Family Physicians), Austin

On: Myron, Rhonda (Tx. Dept. of Insurance), Austin

APPENDIX E
PROVE's opposition letter to HB 2748

Please VOICE OPPOSITION IN DEBATE TODAY and VOTE AGAINST the conferenced version of HB 2748

The original bill that was passed in the House had to do with insurance coverage for baby checkups. An unrelated amendment was added in the Senate Economic Development Committee that requires insurance companies to pay for the Rotavirus (diarrhea) Vaccine. Rotavirus Vaccine is NOT REQUIRED IN TEXAS OR ANY OTHER STATE so insurance coverage should not be mandated. Texas law already provides for mandated coverage of mandated vaccines. That is sufficient. Why should diarrhea and the sole manufacturer for the vaccine, Wyeth Lederlee, get special exceptions to common practice in Texas?

Rotavirus Vaccine is Outrageously Expensive

A physician survey shows that the average price charged by a pediatrician in the Austin area is $65 per dose with and extra $15 nurse administration fee for a total of $80/dose or $240 for the full series. The manufacturer charges the doctors $38 per dose; it doesn't take an investment banker to figure out why the doctors want this covered by insurance. This will increase physician profits at the expense of higher insurance rates for everyone.

Implementation Cost Grossly Exceeds Benefit in the U.S.

The manufacturer states on its package insert that Rotavirus only causes 5% of all diarrheal diseases and has told the media that the vaccine only cuts the cases of Rotavirus in half. Wyeth also states that since "good health care has limited rotavirus caused deaths in this country to no more than 40/year" the drug's benefit will be preventing $400 million in medical bills. However, if one takes into consideration that there are well over 3.3 million babies born in the U.S. every year and you multiply that times the $240 it costs to be fully vaccinated for a total cost of $792 million, you will see that the vaccine costs more to administer than medical costs saved in the United States. This is probably because Wyeth has stated in a press release that they want to use the "profits from rich countries to subsidize poor ones." Wyeth, the exclusive manufacturer, will make millions of dollars in Texas if this vaccine is mandated to be covered by insurance because doctors will just start to give this to the babies when they are already having other vaccines.

Rotavirus Vaccine Exposes Children to Monkey DNA and Monkey Diarrhea Viruses

The manufacturer's vaccine product insert states "The vaccine contains four live viruses, a rhesus rotavirus and three rhesus-human reassortment viruses." Why would anyone condone or support contaminating a 2, 4, or 6 month old baby with animal viruses? None of the other vaccines do this. There is a movement in this country to stop animal organ transplants into people because of the spread of animal viruses into the human population. It contaminates our DNA with foreign sequences. Here, a drug

company and some physicians want to do this on purpose to babies. Before monkey diarrhea viruses are unleashed into babies in Texas by an amendment that will pave the way for every new baby to get the vaccine because "it's covered," shouldn't some studies be done and we have a public debate and hearing about this? At the 2 month visit to their doctor, babies are already required to take vaccines for 6 different illnesses. Rotavirus Vaccine was just licensed this past fall so there are no long term safety studies done on the effects of combining this vaccine with the others on a baby's developing immune system or what these animal viruses will do to babies long term. Also, since it is a live virus, people who come into contact with a recently vaccinated baby may become infected with the vaccine virus. Dr. Diane Simpson from Texas Department of Health recently testified that the main side effects of the vaccine are diarrhea and fever which happen to be the same as the symptoms of the illness.

I hope that you have found this information useful in you consideration to fully oppose HB 2748 because of the Rotavirus/Diarrhea vaccine amendment. If you have any questions, please call me at home this weekend or on my cell phone (512) 426-0870. Thank you for all that you and your staff have done for Texas.

Sincerely,
Dawn Richardson, President
Parents Requesting Open Vaccine Education (PROVE)

New England Patients' Rights Group, Inc.

P. O. Box 141
Norwood, MA 02062-0002
(781) 769-5720

"Quality Health Care is a Right"

attention Beth Clay June 27, 2000

Linda DeBenedictis
President

Chairman Daniel Burton
2157 Rayburn House Office Building
Washington, DC20515
(202) 226-1274
Contact: Beth Clay

"Vaccine Conflict of Interest Testimony-June 15, 2000" To be included in the official record

I am deeply concerned with the lack of accurate, unbiased information that medical consumers receive about the safety and efficacy of drugs. All too often, side effects are not recognized or reported. The consequences lead to "serious" injuries and/or death. On April 15, 1998 the Journal of the American Medical Association published a report that properly prescribed and administered drugs were a leading cause of death and adverse reactions in the U.S.

With that said there seems to be an "epidemic of silence" when it comes to the possible link between vaccines and serious consequences that can occur. This is not an issue that is well known or discussed in the main stream public. This is mind boggling when we consider the number and doses of vaccinations that are mandated before children are allowed entry in daycare and school.

In view of this it's inconceivable that those "entrusted" with a decision of such magnitude should have any "conflict" with financial rewards for the licensing of a new vaccine. At the very least parents must have more information about the process and understand the benefits versus risk. It's an outrage that a "few" people with ties to the pharmaceutical industry should bear responsibility for decisions of such magnitude. The recent recall of the rotavirus vaccine one year after approval because of severe bowel obstructions and death should be a wake-up call. There is nothing left to say....the facts speak for themselves. As. Rep. Dan Burton said in reply to Rep. Waxman's position, "There is none so blind as those who will not see."

Thank you for the opportunity to speak, and I hope that your efforts will not be in vain.

Sincerely,
Linda DeBenedictis
Linda DeBenedictis
President

Lightle, TJ

From: David Kosh [dkosh@earthlink.net]
Sent: Monday, June 19, 2000 11:33 PM
To: Lightle, TJ
Subject: FW: Vaccine Conflict of Interest Testimony-June 15,2000

From: David Kosh <dkosh@earthlink.net>
Date: Mon, 19 Jun 2000 23:21:22 -0400
To: <beth.clay@mail.house.gov>
Subject: Vaccine Conflict of Interest Testimony-June 15,2000

Dear Ms. Clay,

Please include my following testimony.

These are the urgent matters I feel the committee must address:

1. The public, including parents, should be allowed to participate as voting members of the ACIP and VRBAC. (If the science is sound any person will understand. Furthermore, it is the public who is forced to live with these committee's decisions.)

2. Voting members on the advisory committees should have NO financial ties to the vaccine manufacturers.

3. No voting committee members should be allowed to own stock in any vaccine manufacturing companies.

4. Individuals who are developing a vaccine or who hold a patent to a vaccine should NOT be allowed to even participate in the discussion at the advisory committee meetings.

5. Temporary voting members should NOT be used to get a vote passed. If the voting members of the committee are not present then the meeting should be postponed.

6. If voting members participated in legal cases then this should also be identified as part of their financial disclosures.

7. The ACIP should NOT be allowed to make a recommendation for use of a vaccine until the FDA approves its use on the public.

8. Liaison members should be required to disclose all ties to pharmaceutical companies when attending committee meetings.

9. Request more hearings into vaccines, conflict of interest, and the influence of the CDC, FDA, and HHS with regard to state vaccine legal mandates.

Children's lives depend on this.

Thank you very much,

David Kosh

DAN BURTON, INDIANA
CHAIRMAN

BENJAMIN A. GILMAN, NEW YORK
CONSTANCE A. MORELLA, MARYLAND
CHRISTOPHER SHAYS, CONNECTICUT
ILEANA ROS-LEHTINEN, FLORIDA
JOHN M. McHUGH, NEW YORK
STEPHEN HORN, CALIFORNIA
JOHN L. MICA, FLORIDA
THOMAS M. DAVIS, VIRGINIA
DAVID M. McINTOSH, INDIANA
MARK E. SOUDER, INDIANA
JOE SCARBOROUGH, FLORIDA
STEVEN C. LaTOURETTE, OHIO
MARSHALL "MARK" SANFORD, SOUTH CAROLINA
BOB BARR, GEORGIA
DAN MILLER, FLORIDA
ASA HUTCHINSON, ARKANSAS
LEE TERRY, NEBRASKA
JUDY BIGGERT, ILLINOIS
GREG WALDEN, OREGON
DOUG OSE, CALIFORNIA
PAUL RYAN, WISCONSIN
HELLEN CHENOWETH-HAGE, IDAHO
DAVID VITTER, LOUISIANA

ONE HUNDRED SIXTH CONGRESS

Congress of the United States
House of Representatives

COMMITTEE ON GOVERNMENT REFORM
2157 RAYBURN HOUSE OFFICE BUILDING
WASHINGTON, DC 20515–6143

MAJORITY (202) 225-5074
MINORITY (202) 225-5051
TTY (202) 225-6852

HENRY A. WAXMAN, CALIFORNIA
RANKING MINORITY MEMBER

TOM LANTOS, CALIFORNIA
ROBERT E. WISE, Jr., WEST VIRGINIA
MAJOR R. OWENS, NEW YORK
EDOLPHUS TOWNS, NEW YORK
PAUL E. KANJORSKI, PENNSYLVANIA
PATSY T. MINK, HAWAII
CAROLYN B. MALONEY, NEW YORK
ELEANOR HOLMES NORTON,
DISTRICT OF COLUMBIA
CHAKA FATTAH, PENNSYLVANIA
ELIJAH E. CUMMINGS, MARYLAND
DENNIS J. KUCINICH, OHIO
ROD R. BLAGOJEVICH, ILLINOIS
DANNY K. DAVIS, ILLINOIS
JOHN F. TIERNEY, MASSACHUSETTS
JIM TURNER, TEXAS
THOMAS H. ALLEN, MAINE
HAROLD E. FORD, Jr., TENNESSEE
JANICE D. SCHAKOWSKY, ILLINOIS

BERNARD SANDERS, VERMONT,
INDEPENDENT

June 26, 2000

Lisa

The Honorable Donna E. Shalala, MD
Secretary of Health and Human Services
Department of Health and Human Services
200 Independence Avenue, South
Washington, DC 20201

Dear Honorable Shalala:

On June 15, 2000, Drs. Linda A. Suydam, of the Food and Drug Administration and Dixie Snider, of the Centers for Disease Control and Prevention testified to the Committee's hearing entitled "FACA: Conflicts of Interest and Vaccine Development – Preserving the Integrity of the Process?"

At the conclusion of the hearing, I asked Dr. Suydam and Dr. Snider to respond to written questions submitted by the committee for the record. I informed them that the answers to these questions would be made public and reminded the doctors that they are still considered under oath for the purposes of answering these questions. Attached, you will find these questions. I hope the witnesses will answer them to their fullest extent possible.

Please return the responses to my professional staff member, S. Elizabeth Clay by June 28. Please have your staff contact Ms. Clay at 202-225-5074 should you have any questions. Again, thank you for your cooperation.

Sincerely,

Dan Burton

Dan Burton
Chairman

Cc: Henry Waxman, Ranking Minority Member
Linda A. Suydam
Dixie Snider
Kevin Malone
Jennie Slaughter
Bill Freas
Nancy Cherry

Attachments

Questions for the Food and Drug Administration

1. At the time of the VRBPAC meeting for the approval of RotaShield (12/12/97), Dr. Caroline Hall's employer, the University of Rochester, had a $9,586,000 contract with the NIAID for work related to a rotavirus vaccine. According to the disclosure form used by the FDA, it is not known whether the rotavirus vaccine licensed to Wyeth by the NIAID, was the rotavirus vaccine that Dr. Hall's employer had worked on. Was the rotavirus vaccine licensed to Wyeth-Lederle initially developed at the University of Rochester? Why was Dr. Hall granted a waiver for participation in this meeting?

2. Another member of the VRBPAC, Ms. Rebecca Cole, the committee's consumer representative and an ardent advocate for the increased use of vaccines, had received travel expenses and honoraria from Merck, an affected company at the 12/12/97 meeting. Did Ms. Cole require a waiver for participation?

3. Two of the three consultants who participated at the VRBPAC RotaShield meeting on 12/12/97 had extensive ties with the pharmaceutical industry:

a.) Dr. Neal Halsey has been one of the leading advocates for the use of vaccines. He has received frequent reimbursements for travel expenses and honoraria from companies such as Merck. In addition, at the time of the RotaShield meeting, Dr. Halsey was seeking start-up funds from most of the leading vaccine manufactures for the establishment of an institute for vaccine safety at Johns Hopkins University. At the time, he had already received $50,000 from Merck and was awaiting funds from Wyeth Lederle. After participating in the morning session of the VRBPAC meeting, Dr. Halsey was found to have conflicts of interests that impeded his participation in the afternoon session. Was Dr. Halsey originally granted a waiver to participate as a consultant to VRBPAC? Why was the fact that he was seeking start-up funds (Merck, Wyeth Lederle, and other vaccine manufacturers) not considered a conflict of interest?

b.) The second consultant with considerable conflicts of interest, Dr. John Modlin, at the time owned approximately $600 shares in Merck stock, an affected company. At the time, he was also serving on Merck's Immunization Advisory Board. Was Dr. Modlin granted a waiver to participate in the 12/12/97 VRBPAC meeting?

Questions for the Centers for Disease Control and Prevention

1. Examination of ACIP members' financial disclosure forms reveals that many members do not fill them out completely. CDC ethics officials conceded to Committee staff that they have been lax in compelling the ACIP members to provide complete and thorough information. Problems have been identified on the following members' financial disclosure documents:

a. **Dr. Mary (Mimi) Glodé** - Dr. Glodé lists reviews of medical legal cases on her OGE 450 for 1996, 1997, 1998, and 1999. She estimates that she performs 5 reviews per year, as does her spouse. However, she does not detail the law firms or clients for whom they do the legal work. She only discloses that the maximum income allowed by the University of Colorado is $10,000 per year.
   1. Is she required to disclose which law firms she worked for?
   2. Is she required to disclose the clients the firms were representing?
   3. Is she required to disclose the dates that she performed these law reviews?

   Dr. Glodé and her spouse have attended numerous conferences and received honoraria for their attendance. However, she does not list who the sponsors were in 1995, 1996, 1997, 1998, and 1999. She states only that the honoraria given was from $500-$750 per occurrence and were limited to five per year; her spouse does 5-10 per year as well.
   4. Is she required to disclose the sponsors?
   5. Is she required to disclose the dates of the conferences?

   On her 1996 FDA financial disclosure form she lists that she was a co-principal investigator on an $84,500 grant from Chiron to study the MGNIN C Vaccine, $10,000 of which was a part of her salary. The study lasted for fifteen months from 10/96-3/98. But on her CDC financial disclosure forms for 1997, 1998, and 1999, this funding was not mentioned as required. Furthermore, the conflict was not mentioned on the waivers granted to her by the CDC for the same years. According to the Federal conflict of interest statutes, she would not be able to participate in any deliberations regarding Chiron before the ACIP absent a waiver.
   6. Did Dr. Glodé participate in any reviews of Chiron products during her tenure on the ACIP?
   7. Did the CDC know about her work with Chiron?

b. **Dr. Marie Griffin** - Dr. Griffin doesn't fill out a new form each year. She refers to previous year's forms instead and adds any new items to the current year's form.
   1. Is this an acceptable practice for filling out disclosure forms?

She also lists "publicly traded stock," but not the specific companies on her 10/6/94, 2/95, 6/9/96, and 10/20/97 OGE form 450.
   2. Is she required to disclose the specific "publicly traded stock" that she owns?
   3. Is she required to disclose the amount of numbers of shares of the stock?

c. **Dr. Paul Offit** - Dr. Offit lists that he is a consultant to Merck on an attachment to his OGE 450, but does not disclose whether or not he received any remuneration for his services.
   1. Is he required to disclose the amount of the fees that he has received?

d. **Dr. Richard Clover** - Dr. Clover lists legal fees paid by the law firm of O'Bryan, Brown, and Toner, but not their client or the amount he was paid.
   1. Is he required to disclose the clients the law firm was representing or the amount he was paid?

2. What steps, if any, did the CDC take to get the information noted above that was not included on the financial disclosure forms?

3. How many members of the ACIP have a waiver?

4. Why doesn't the CDC grant waivers on a meeting-by-meeting, issue-by-issue basis, as does the FDA?

5. Why are liaison representatives not required to file a financial disclosure report?

6. Why are the ACIP's working group meetings held in private?

7. On how many occasions have ex officio members voted no at ACIP meetings in the last five years?

8. Why did the ACIP vote to recommend routine use of Rotavirus vaccine for universal use when it was not yet licensed by the FDA?

In the case of rotavirus vaccine, the vaccine before the advisory committee was developed by Wyeth-Lederle. However, Merck and Smithkline-Beecham had rotavirus vaccines under development. While ACIP members with ties to Wyeth-Lederle were not allowed to vote on recommendations for the rotavirus vaccine, those with ties to Merck and Smithkline-Beecham were allowed to vote.

11. Why are ACIP Members allowed to vote on vaccine recommendations, even when they have financial ties to drug companies developing related or similar vaccines?

12. At ACIP meetings from February 11, 1998, through June 17, 1999, there were numerous votes related to the their recommendation of the rotavirus vaccine for routine use. The following members voted on issues relating to the rotavirus vaccines despite their conflicts of interest. For each example, please provide an explanation as to why each member was allowed to vote on specific issues.

a. Dr. John Modlin – Dr. Modlin owned 600 shares of Merck

b. Dr. Paul Offit - Dr. Offit shares the patent on the Rotavirus vaccine in development by Merck and lists a $350,000 grant from Merck for Rotavirus vaccine development. Also, he lists that he is a consultant to Merck.

c. Dr. Fernando Guerra - Dr. Guerra lists a contract with Merck Vaccine Division from 2/99-8/99 on his OGE 450, and a donation of $25,000 by Merck, Pasteur Merieux Connaught, and Medimmune (5/11/99 supplement to OGE 450). Also, he has a Contract with Smithkline-Beecham as a Principal Investigator (pending 7/99).

d. Dr. Marie Griffin - Dr. Griffin lists consultant fees (3/21/97) and a salary from Merck relating to her position as Chair of Merck's Endpoint Monitoring Committee on her OGE 450 (5/12/98 & 1/22/98). She also lists consulting fees and travel expenses paid by Merck. Moreover, her spouse is a consultant for American Cyanamid (5/12/98 disclosure). American Cyanamid and Wyeth-Lederle are Subsidiaries/divisions of American Home Products Corporation.

e. Dr. T. Chinh Le - Dr. Le's employer, Kaiser Permanente, is participating in vaccine studies with Merck, Wyeth-Lederle, and Smithkline-Beecham. Additionally, Dr. Le owns stock in Merck as reported on his OGE 450.

f. Dr. Richard Clover - Dr. Clover lists educational Grants from Merck and Smithkline-Beecham on his OGE 450.

1 And if anyone has any ideas about that I'd
2 particularly be interested in learning about that.
3 Thank you.
4 CHAIRPERSON FERRIERI: Thank you, Mary Lou.
5 Other members of the audience? Dr. Santosham, would
6 you like to make any comments? I saw you in the
7 audience.
8 DR. SANTOSHAM: Thank you for the
9 opportunity. One question that's often been raised
10 with me because I've done a lot of work on oral
11 rehydration, is do you really need a rotavirus
12 vaccine? Because all you need to do is treat them
13 with oral rehydration. Why both with the vaccine?
14 Having worked on oral rehydration for over
15 15 years and trying to push that concept in this
16 country, I think we have had some degree of success as
17 you see from Roger's data. The deaths have come down
18 but then in the last seven to ten years they've
19 plateaued out. And educating physicians is much more
20 expensive than giving immunizations.
21 (Laughter.)
22 And the same is true in developing
23 countries. They came down -- after the introduction
24 of oral rehydration in the '70s it came down very
25 rapidly and then it plateaued out. So I don't think

1 we will not have a panel left, we will not be voting
2 on the issues. The meeting will come to a close
3 without any resolution.
4 MS. CHERRY: I'd like to move right into the
5 open public hearing session. At this time members of
6 the audience are given the opportunity if they wish,
7 to make a statement. Is there anyone that wishes to
8 make a statement?
9 CHAIRPERSON FERRIERI: Dr. Halsey.
10 MS. CHERRY: Dr. Halsey will speak.
11 CHAIRPERSON FERRIERI: And the rules of the
12 game Nancy, are what?
13 MS. CHERRY: He will now speak during open
14 public hearing. I'm afraid he was excluded from the
15 meeting.
16 CHAIRPERSON FERRIERI: And so the rules are
17 that he can speak but cannot ask questions of people
18 who have spoken? Is that what it is?
19 MS. CHERRY: That's true.
20 CHAIRPERSON FERRIERI: And so this may seem
21 unnecessarily cruel but these are the FDA rules, Neal.
22 And I'm told also that what you say is independent of
23 the rest of the meeting.
24 DR. HALSEY: Thank you for the opportunity
25 to speak.

1 (Laughter.)

2 Briefly, I can't vote and sit at the table

3 because of conflicts that faculty who work underneath

4 me -- just for the rest of the public to know that --

5 who do have more significant conflicts.

6 I'm going to speak on behalf of the American

7 Academy of Pediatrics and as Chair of the Committee on

8 Infectious Diseases who will be writing guidelines for

9 the use of this vaccine.

10 And I only make it a plea in an effort to

11 try to avoid additional, potential conflict between

12 the package labeling and the guidelines that would

13 come out, that at least have permissive language with

14 regard to the upper age cutoff for the use of this

15 vaccine. I think it will create confusion and

16 difficulty if there's a stringent rule saying you

17 cannot administer the vaccine beyond 30 weeks of age.

18 As I think most people appreciate, children

19 do not all get immunized exactly at two, four, and six

20 months of age. If we have a recommendation to give

21 this vaccine at two, four, and six months of age,

22 unfortunately many children fall behind the schedule

23 and that third dose will not be given prior to exactly

24 the end of six months of age.

25 And we need to have flexibility in terms of

1 administering that. From everything I've seen here
2 today I don't see any reason that those children
3 should not be allowed to complete the immunization
4 schedule, and we do have a substantial burden of
5 disease beyond six months of age, as was pointed out
6 by Roger Glass.
7 Thank you.
8 CHAIRPERSON FERRIERI: Thank you very much,
9 Dr. Halsey. A member of our committee was also
10 excluded today. Dr. Clements-Mann, do you have
11 anything that you wanted to say during open public
12 hearing?
13 DR. CLEMENTS-MANN: I just want to say that
14 it's not for lack of looking for correlates of
15 immunity, but I would like to clarify something, that
16 in human populations it's been exceedingly difficult
17 to acquire meaningful data from intestinal IgA without
18 actually doing intubation and getting upper GI-type
19 fluid, because there's a rapid degradation in the
20 stool of the IgA.
21 I know that, particularly working with other
22 vaccines where the University of Alabama group has
23 been working very hard with us, we have not yet solved
24 the problem with how to get meaningful data from
25 intestinal IgA measurements.

1 was performed for the 30-day post-vaccine period as
2 well as for the entire study period, and the results
3 are concordant -- and I will show you only the 30-day
4 data.
5 The most common events are not surprising.
6 These are inter-current childhood illnesses: otitis,
7 conjunctivitis, cough, bronchitis, eczema, rhinitis,
8 etc. None of these are observed more frequently in
9 the RotaShield™ versus placebo group. All of these
10 are not significant.
11 Fevers: two percent in the RotaShield™
12 group versus 1.1 percent in the placebo group. This
13 difference is statistically significant. We already
14 know from the reactogenicity data which I showed you,
15 that fever is more frequent in the post-dose period in
16 the vaccinated group.
17 Now, these data were not to include the
18 post-dose fevers but in some cases they were included;
19 therefore this difference in fever appears to be
20 explained by the increased incidence of fever in the
21 post-dose period. Nevertheless, we reviewed the case
22 records for all of these fevers in the RotaShield™
23 group to confirm that none of them were associated
24 with concurrent serious illness.
25 There were seven infants who died in the

1 RotaShield™ studies: two of these were in the
2 placebo group and five were in the vaccinated group.
3 The difference in numbers is not statistically
4 significant. For all of the seven infants death
5 occurred more than one month after the vaccine was
6 administered. The proximate cause of death could not
7 plausibly be attributed to vaccination.
8 This slide shows the causes of death in the
9 time after vaccination. There were three deaths from
10 sudden infant death syndrome: one in placebo, two in
11 the RotaShield™ group. An infant died of meningitis,
12 an infant died of respiratory arrest, there was an
13 accidental injury in the U.S. studies, and in the
14 placebo group in Finland there was an accident injury.
15 All of these as I said, one month or more after
16 vaccination.
17 On the report of the U.S. study, the
18 multicenter study by Dr. Rennels, who told you that
19 there were two infants who were hospitalized in the
20 post-dose period with diarrhea and a rotavirus
21 positive stool. Based on this study alone we cannot
22 be sure whether this represents a true risk of
23 vaccination or a chance association.
24 The rotavirus vaccine strains shed in the
25 stool may or may not be the cause of the diarrhea.

1 the protocols.

2 Infants had to be in good health and live in
3 a household with a telephone. This last criterion did
4 not apply in the American Indian study. Infants were
5 excluded for recent illness, including diarrhea or
6 vomiting within three days of the dose. Infants were
7 also excluded if an immediate family member was
8 immunocompromised or if a family member had diarrhea
9 or vomiting within the previous three days.

10 Premature infants who were otherwise healthy
11 at the time of the first dose were not excluded and a
12 small number were enrolled in the various studies.
13 Surveillance for gastroenteritis of any cause began
14 with the first dose and continued until the end of the
15 rotavirus season, with the most intense surveillance
16 during the immediate post-dose period and during the
17 seasonal rotavirus epidemic.

18 The post-dose period comprised the day of
19 vaccination through day-5, post-vaccination. An
20 interdose period began with day-6 and continued till
21 the next dose. This was repeated for doses 2 and 3.

22 After dose 3, the interdose period continued
23 until the efficacy surveillance period began. This
24 period of efficacy surveillance began two weeks after
25 the last dosing and continued until the end of the

1 placebo-controlled, large-scale studies.

2 There are three non-placebo-controlled

3 studied as well, a total of 6,948 infants received at

4 least one dose of RotaShield™, and 6,229 received all

5 three recommended doses. And 2,222 infants received

6 placebo.

7 The three efficacy studies are the U.S.

8 multicenter study of RotaShield™ placebo in the

9 monovalent vaccine in which approximately 1,300

10 infants participated. The American Indian study which

11 has a similar design and included just under 1200

12 infants, and the Finnish study which includes only

13 RotaShield™ and placebo in about 2400 infants.

14 There are additional studies including a

15 large-scale study of safety and immunogenicity, a

16 study of vaccine shedding, a placebo-controlled study

17 to rule out interference of RotaShield™ with DTP-Hib,

18 and a study to demonstrate the consistent

19 immunogenicity and safety of five large-scale

20 manufacturing lots.

21 There's one recently completed study for

22 which data are not yet available. This is the study

23 in Finland to demonstrate that RotaShield™ does not

24 interfere with Hepatitis B vaccine and IPV.

25 I plan to spend only a few minutes

1 use the immunogenicity data to demonstrate that large-
2 scale lots of RotaShield™ can be manufactured to
3 specifications defined by the efficacy trials.
4 The development program comprises 27
5 clinical trials of the different generations of this
6 vaccine in more than 17,000 infants, neonate, and
7 adults. Two of these studies were performed by the
8 National Institutes of Health under a separate IND.
9 These 27 studies were done in the United
10 States, Finland, Peru, Israel, Brazil, Myonmar,
11 Thailand, Turkey, and Venezuela; in different
12 populations, in different conditions, and in different
13 epidemic years.
14 These studies included doses ranging from
15 10^3 plaque-forming units of the monovalents, up to 4
16 X 10^6 plaque-forming units of the tetravalents. But
17 during the presentation, unless specifically stated,
18 RotaShield™ means the tetravalent vaccine at 4 X 10^5,
19 which is the dose for which the application was
20 submitted.
21 Of the 25 studies of the different doses and
22 formulations sponsored by Wyeth, eight clinical
23 studies comprised the RotaShield™ database pertinent
24 to our discussion today. There are five placebo-
25 controlled studies and three of these are randomized,

FIGURE 1. Recommended childhood immunization schedule* — United States, January–December 1999

Vaccine	Age										
	Birth	1 mo	2 mos	4 mos	6 mos	12 mos	15 mos	18 mos	4–6 yrs	11–12 yrs	14–16 yrs
Hepatitis B†	Hep B										
		Hep B			Hep B					Hep B	
Diphtheria and tetanus toxoids and pertussis§			DTaP	DTaP	DTaP		DTaP		DTaP	Td	
H. influenzae type b¶			Hib	Hib	Hib	Hib					
Poliovirus**			IPV	IPV	Polio				Polio		
Rotavirus††			*Rv*	*Rv*	*Rv*						
Measles-mumps-rubella§§						MMR			MMR	MMR	
Varicella¶¶						Var				Var	

Range of Acceptable Ages for vaccination

Vaccines to be Assessed and Administered if Necessary

Incorporation of this new vaccine into clinical practice may require additional time and resources from health-care providers.

PENGAD-Bayonne, N. J.
EXHIBIT
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Memorandum June 6, 2000

SUBJECT : **Conflicts of Interest and the Disqualification of Federal Advisory Committee Members**

FROM : Jack Maskell
Legislative Attorney
American Law Division

Summary/Background

The Federal Advisory Committee Act [FACA] provides a structure and mechanism for federal officials and agencies to seek and receive "expert advice, ideas and diverse opinions" on public policy matters from a various and wide range of private sources and individuals.[1] When persons from certain private professions, backgrounds, disciplines, organizations and industries provide advice to the Federal Government in a formalized structure, however, issues and questions of the influencing nature of the personal financial and professional stake in the matters under consideration, that is, the"conflicts of interest," of those individuals advising the Government, have been raised.

Balancing the "conflict of interest" issue with the need to receive expert and sometimes very technical information and advice from those most closely involved in and affected by the subject of certain public policy concerns, federal law and regulation has sought to accommodate both the Government's need for that information and advice, and its need to trust that the information and advice received are not unduly tainted by personal or institutional financial interests. Within the advisory committee structures there are, generally, two types of members appointed to these committees: industry or other group "representatives" to represent the interests and viewpoint of a particular group, industry or other such entity; and those members who are to provide the Government with more independent information, advice and opinions.

[1] 5 U.S.C. , appendix § 2; *see* generally, P.L. 92-463, as amended, the Federal Advisory Committee Act.

This memorandum was prepared by the American Law Division to enable distribution to more than one congressional client.

Persons appointed to serve on a Federal advisory committee to provide independent information and advice to the Government, whether compensated or not, may in many instances because of that service be considered "employees" of the Federal Government, and, if they serve on a part-time or intermittent basis, as "special Government employees."[2] With such a designation as either a regular or "special" Government employee comes coverage under several federal conflict of interest laws and regulations, including one that requires disqualification or recusal by the individual employee from participating in any particular governmental matter which may affect the financial interests of that individual, or the financial interests of other persons, entities or businesses connected to that individual.[3] Conflicts of interest of persons appointed to federal advisory committees who are considered Government employees or "special Government employees," are handled generally in two ways: disclosure and disqualification. When the disqualification requirement is "waived" by an appointing official for an individual advisory committee member who has a conflicting interest,[4] then the importance and reliance on the Federal Advisory Committee Act's structures and procedures requiring open meetings and "balance" on advisory committees would arguably be increased to monitor and regulate potential and existing conflicts of interest.

Industry or other "representatives" on advisory committees who are not compensated from the Federal Government for their opinions or advice, are generally not considered "employees" of the Government, nor "special Government employees," and are therefore not subject to the conflict of interest laws. It is understood that information, opinions, and advice from "industry representatives" could be information that is one-sided and/or "tainted" by personal or institutional economic and financial interests, and not necessarily provided independently with the interests of the general public in mind.[5] Since these individuals are intended to represent outside interests, there is by definition no "conflict" of interest in their role in providing opinions and information to the Government. The statutory structure of the Federal Advisory Committee Act is important to the integrity of the system of advisory committees, particularly in regard to such outside representatives and advisors, as the FACA would allow public scrutiny of advisory committee activities by requiring, for the most part, open meetings; by providing that advice or recommendations from an advisory committee is advisory only, and not binding; and by requiring that the make-up of advisory committees is to be "fairly balanced."

Federal Employees or Industry Representatives

For conflicts of interest purposes, the threshold determination as to any particular advisory committee member is whether such member is an "employee" of the Federal

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[2] *See* definition of "special Government employee" at 18 U.S.C. § 202.

[3] 18 U.S.C. § 208.

[4] 18 U.S.C. § 208(b)(3).

[5] As explained by the Office of Government Ethics: "[U]nlike SGEs and other Federal employees, representatives are not expected to render disinterested advice to the Government. Rather, they are expected to represent a particular bias." Office of Government Ethics, DO-00-003, at 3, February 15, 2000, citing OGE Informal Advisory Letter 93 x 14.

Government or not. As a general matter, members of advisory committees who are appointed by a federal official because of their general expertise or knowledge in a particular field, and who are expected to independently provide the Government with advice and assistance in those areas of expertise, may be considered "officers or employees" of the United States Government.[6] Members of advisory committees who are appointed on the advisory committee to "represent" a particular private interest or entity, and to give the views of those non-governmental groups, however, might not be considered officers or employees of the United States. As quoted by the Office of Government Ethics, citing an earlier memorandum from the President:

> A consultant or adviser whose advice is obtained by a department or agency from time to time because of his individual qualifications and who serves in an independent capacity is an officer or employee of the Government. On the other hand, one who is requested to appear before a Government department or agency to present the views of a non-governmental organization or group which he represents, or for which he is in a position to speak, does not act as a servant of the Government and is not its officer or employee. He is therefore not subject to the conflict of interest laws ....[7]

The Office of Government Ethics has noted that the terms "officer" or "employee" of the Government are not expressly defined for purposes of the conflict of interest laws. However, guidance on classifying persons on advisory committees as either "employees" of the Government or private "representatives" is gleaned from statutory definitions in other contexts, such as 5 U.S.C. §§ 2104 and 2105, which include the considerations of (1) appointment in the civil service, (2) performance of a federal function, and (3) the supervision by a Federal official.[8] Previously, the Office of Government Ethics had discussed several factors and indications in determining whether one is a "employee" or "special" Government employee, or whether one is, rather, a private "representative," including: compensation from the Government (but not necessarily expenses or per diem) as indicative of Government employment; acting alone rather than part of a committee or group as indicative of employment, but noting that not all persons on an advisory committee are "representatives"; appointment on the recommendation of an outside group as an indication that one is a representative of that group; whether a person is a "spokesman" for an outside group (and not whether he can legally bind that group) as an indication of a representational status; and whether the advisor/consultant can speak for the federal agency, as an indication that such person is a federal employee.[9]

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[6] *See* discussion in "Memorandum dated July 9, 1982 from J. Jackson Walter Director of the Office of Government Ethics to Heads of Departments and Agencies of the Executive Branch regarding Members of Federal Advisory Committees and the Conflict-of-Interest Statutes" [hereinafter: July 1982 OGE Memo], Office of Government Ethics, Advisory Opinion 82 x 22, printed in *The Informal Advisory Letters and Memoranda and Formal Opinions of the United States Office of Government Ethics, 1979-1988*, at 325. *See* also OGE Advisory Opinion 93 x 14, June 24, 1993.

[7] July 1982 OGE Memo, *supra* at 330.

[8] Office of Government Ethics, DO-00-003, at p. 2, February 15, 2000.

[9] July 1982 OGE Memo, *supra* at 330-331.

If advisory committee members who are considered to be Government employees are to consult with and advise the Government only on a part-time or intermittent basis, then they may fall into the category of a "special Government employee."[10] "Special Government employees" of the executive or legislative branches are covered in some conflict of interest laws to a lesser extent than their full-time counterparts to allow the Government to avail itself of the expertise and talents of private sector personnel on a part-time or intermittent basis without overly complex or burdensome conflict of interest regulations, which had proven a severe obstacle in the past to recruiting such outside experts.[11] Members of advisory committees who are *not* officers or employees of the Government are, however, generally not subject to the federal conflict of interest rules, statutes, or regulations.[12]

Financial Disclosure

There are two categories of financial disclosure requirements under federal law and regulation which apply generally to persons in the employ of the Federal Government: (1) the *public* (and detailed) financial disclosures which must be made by certain specified federal employees and officers under the provisions of the Ethics in Government Act of 1978, as amended,[13] and (2) the *confidential* (and often less detailed) disclosures which may be required from certain officers and employees who are not required to file public disclosure statements.[14] Both the public and confidential disclosure requirements apply, however, only to persons who are (or who have been nominated to be) officers or employees of the Federal Government, — either regular Government employees or "special Government employees."

There is not, under the Federal Advisory Committee Act, a separate requirement for personal, *public* financial disclosure for all persons who are appointed to federal advisory committees in the executive branch. Rather, under federal law and regulation one appointed to be a member of a federal advisory committee is required to file a financial disclosure form by virtue of his or her being either a regular federal employee or a "special Government employee," as opposed to requiring a financial disclosure merely by virtue of his or her membership on an advisory committee. That is, a person who is appointed to an advisory committee and who is *not* acting as a regular federal employee or a special Government employee, but rather is "a representative of an industry or other outside entity," would not

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[10] 18 U.S.C. § 202. A "special Government employee" is "an officer or employee of the executive or legislative branch of the United States Government, [or] of any independent agency ... who is retained, designated, appointed, or employed to perform, with or without compensation, for not to exceed one hundred and thirty days during any period of three hundred and sixty-five consecutive days, temporary duties either on a full-time or intermittent basis ...."

[11] See H. Rpt. No. 748, 87th Cong., 1st Sess.4-5, 13-14 (1961); S. Rpt. No. 2213, 87th Cong., 2d Sess. at 6-7 (1962).

[12] The applicable statutes and regulations generally apply by their express language only to one who is an "officer or employee of the United States," see specifically 18 U.S.C. §§ 203, 205, 207, 208, and 209; *note* discussion in OGE Advisory Opinion 93 x 30.

[13] P.L. 95-521, as amended; *see* now 5 U.S.C.A., Appendix 4, §§ 101 *et seq.*

[14] 5 U.S.C.A., Appendix 4, § 107(a); Executive Order 12674, as modified by Executive Order 12731, Section 201(d); *see* now 5 C.F.R. §§ 2634.901 - 2634.909.

appear to be required by any law or regulation of general applicability to file a financial disclosure form.[15]

Whether an employee of the Federal Government (either a regular, or part-time or intermittent special Government employee) is required to file financial disclosure statements is determined, in the first instance, by the rate of compensation that the employee receives from the Federal Government for his or her services to the Government. If the officer or employee "occupies a position classified above GS-15," or, if not on the General Schedule, is in a position compensated at a "rate of basic pay ... equal to or greater than 120 percent of the minimum rate of basic pay payable for GS-15," then the officer or employee is generally subject to the public disclosure provisions.[16] As an additional qualification, those employees compensated at the rate of pay described above will be required to file public disclosure statements if the individual works for the Government for more than 60 days in the calendar year.[17]

The confidential reporting requirements are intended to complement the public disclosure system, and would apply generally to those employees who do not have to file under the public reporting provisions of the Ethics in Government Act.[18] Generally speaking, the confidential reporting requirements apply to those officers or employees who are compensated below the threshold rate of pay for public disclosures (that is, GS-15 or below, or less than 120% of the basic rate of a GS-15), *and* who are determined by the employee's agency to perform duties or exercise responsibilities in regard to Government contracting or procurement, Government grants, Government subsidies or licensing, Government auditing, or other governmental duties which may particularly require the employee to avoid financial conflicts of interest.[19] Such a person may be required to file a confidential report if he or she performs the duties of such a position "for a period in excess of 60 days during the 12 month period ending September 30."[20]

Additionally, unless required to file public reports, confidential reports are required from all "special Government employees" in the executive branch, including specifically "those who serve on advisory committees."[21] As noted earlier, however, the disclosure provisions apply only to persons who are officers or employees of the Federal Government,

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[15] 5 C.F.R. § 2634.904(b), as to *confidential* disclosures; 5 U.S.C.A., Appendix 4, § 101(f)(3), as to *public* disclosure of "each officer or employee in the executive branch, including a special Government employee" compensated over a particular amount.

[16] 5 U.S.C.A., Appendix 4, § 101(f)(3).

[17] 5 U.S.C.A., Appendix 4, § 101(d). Certain exemptions and waivers may be permitted upon particular findings and determinations regarding special Government employees. *See* 5 U.S.C.A., Appendix 4, § 101(i).

[18] 5 C.F.R. § 2634.901(a), although supplemental information may be requested by an agency even from employees filing public disclosures. 5 C.F.R. §2634.901(c).

[19] 5 C.F.R. § 2634.904(a).

[20] 5 C.F.R. § 2634.903(a).

[21] 5 C.F.R. § 2634.904(b).

and thus do not apply to so-called "representatives" of outside entities appointed to advisory committees:

> The term special Government employees does not include an advisory committee member who serves only as a representative of an industry or other outside entity or who is already a federal employee.[22]

In certain unusual circumstances the public availability of the public financial disclosure statement filed by a "special Government employee" may be restricted by the Director of the Office of Government Ethics.[23] Additionally, the confidential reporting required of those not filing the public reports may be waived by an agency head where the possibility of conflict of interest is remote, and where the duties or responsibilities of the employee are at such a low level that reporting is not necessary.[24]

Conflict of Interest Disqualification Requirement

The principal financial conflict of interest law for executive branch personnel is codified at 18 U.S.C. § 208, and prohibits both regular and "special Government employees" in the executive branch and independent agencies from participating as a Government employee in any official matter in which the employee has a personal financial interest, or which affects the financial interests of the employee's spouse, minor children, business associates, or connected firms or organizations. This conflict of interest law as now constructed was enacted as part of a substantial amendment and recodification of the ethics and conflict of interest laws in 1962. The intent of the modern conflict of interest statute and the underlying principles behind it were expressed in the House Report from the House Judiciary Committee on that 1962 legislation. That report noted that the statute was meant to embody the principles "that a public servant owes undivided loyalty to the Government,"[25] and that advice and recommendations given to the Government by its employees and officials be made in the public interest and not be tainted, even unintentionally, with influence from private or personal financial interests.[26] The Judiciary Committee explained further that:

> The proper operation of a democratic government requires that officials be independent and impartial; that Government decisions and policy be made in the proper channels of the governmental structure; ... and that the public have confidence in the integrity of its government. The attainment of one or more of these ends is impaired whenever there exists, or appears to exist an actual or

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[22] *Id.*

[23] 5 C.F.R. § 2634.205(a).

[24] 5C.F.R. § 2634.905

[25] H. Rpt. No. 748, *supra* at 3.

[26] H. Rpt. No. 748, *supra* at 4-5; see also *United States v. Mississippi Valley Generating Co.*, 364 U.S. 520, 549 (1960); *Conflict of Interest and Federal Service*, Association of the Bar of the City of New York, at 3-4 (Cambridge 1960).

> potential conflict between the private interests of a Government employee and his duties as an official.[27]

The statutory language at 18 U.S.C. § 208 is directed not only at conduct which is improper, but rather is preventative in nature, and is directed at situations which merely have the potential to tempt or subtly influence an official in the performance of official public duties. The ownership of certain private economic or financial interests alone, without any improper conduct, thus raises the disqualification requirement as to governmental matters which affect those interests. As explained by the Supreme Court with regard to the predecessor statute to § 208 (see 18 U.S.C. § 434, 1960 Code ed.):

> 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 the most well-meaning men when their personal economic interests are affected by the business they transact on behalf of the Government.[28]

The elements of the statute prohibit the participation of a federal employee, or a special Government employee, on behalf of the Government in any "particular" matter that has a "direct and predictable effect"[29] on a financial interest of the employee, or on a financial interest imputed to the employee. A "particular matter" is a matter that focuses "upon the interests of specific persons, or a discreet or identifiable class of persons."[30] It may involve general rule making that is "narrowly focused on the interests of such a discreet and identifiable class," but does not include the "consideration or adoption of broad policy options that are directed to a large and diverse group of persons."[31]

The "participation" that is prohibited in such particular matters is described in the statute as a personal and substantial participation through "decision, approval, disapproval, recommendation, the rendering of advice, investigation or otherwise...." It is clear that one need not have to possess decision making or final authority on a particular matter to come within the law, but rather, one needs only to participate personally in the activity and have that participation be "of significance to the matter."[32] It has been noted that some agencies, in granting waivers to employees or special Government employees, have given what are called "limited waivers" which allow a special Government employee, for example, to participate fully in the "discussion" of a particular matter, including advice, persuasion, and arguments for or against a particular position or recommendation, but that the employee or special Government employee is still barred from participating in a final vote on the particular recommendation. Such limited waivers are a policy matter that are apparently within the discretion of the agency official involved. It should be noted that, under the

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[27] H. Rpt. No. 748, *supra* at 5-6.

[28] *United States v. Mississippi Valley Generating Co.*, *supra* at 549.

[29] 5 C.F.R. § 2635.402(a), (b)(1).

[30] 5 C.F.R. § 2635.402(b)(3).

[31] *Id.*

[32] 5 C.F.R. 2635.402(b)(4).

statute, it is apparent that the participation in a "discussion" concerning a covered particular matter would most likely be barred by the statute, absent that waiver, because that activity would raise equally applicable and cognizable conflict of interest issues as a vote or final decision. As noted in a law review article by Roswell Perkins, who was the staff director of the Bar Association study that led to the adoption of the conflict of interest law in 1962:

> The effect of the orientation is to bring the self-dealing prohibition to bear irrespective of the character of the functions the official performs in relation to the governmental proceeding — so long as his participation meets the test of substantiality. The behind the scenes advisor may be just as guilty of violating section 208 as the government representative who assumes the front-line negotiating function for the Government.[33]

Clearly, the influence on Government policy from advice and persuasion during a "discussion" of a particular recommendation, immediately proceeding a vote on that recommendation, is significant and is equal, under the law, to participating in a particular recommendation by way of voting for or against that recommendation.

General Exemptions

The statute requires disqualification and recusal of an employee regardless of the size or substantiality of the personal or imputed financial interest involved. There is no *de minimis* rule expressly stated in the statute. The statute does allow, however, at § 208(b)(2), for the promulgation of regulations by the Office of Government Ethics setting out general exemptions to the disqualification requirement for interests of employees, or special Government employees, that are deemed "too remote or too inconsequential" to raise serious conflict of interests problems, and several categories of financial interests, instruments, or relationships have been exempt under the general § 208(b)(2) waiver authority.[34] There are also general waivers promulgated under § 208(b)(2) specifically for special Government employees serving on an advisory committee allowing the participation of such employees in a matter of "general applicability" when that matter will not have a "special or distinct effect" on the employee or his or her private employer, but rather will affect such interests only as part of a class.[35] Other general exemptions promulgated by regulations allow special Government employees on advisory committees to participate in matters concerning "medical products" if the otherwise disqualifying financial interest arises from one's employment in a hospital or other medical facility using that product for patients, or from the "use or prescription of medical products for patients."[36]

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[33] Perkins, Roswell, "The New Federal Conflict- of -Interest Law," 76 *Harvard Law Review* 1113, 1130 (April 1963).

[34] *See*, 5 C.F.R. §2640, Subpart B (§§ 2640.201 - 2640.206).

[35] 5 C.F.R. § 2640.203(g). This does not apply to participation in particular matters involving specific parties, such as drug applications, nor to financial interests in the form of stock ownership in a company by the special Government employee.

[36] 5 C.F.R. § 2640.203(i).

Disqualification and Advisory Committee Members/ Specific Exemptions

After 1962, although the category of "special Government employee" was created in the conflict of interest law revision to lessen some of the burdens on consultants, part time or intermittent employees,[37] those part-time or intermittent employees, including advisory committee members, were actually treated the same as full-time employees for purposes of 18 U.S.C. § 208, the principal conflict of interest statute requiring disqualification. That is, unlike some other conflict of interest laws, 18 U.S.C. § 208 applies to both regular and "special Government employees" in the same manner.

The personal or specific exemption allowed within the statute for employees to participate in matters despite a conflict of interest (known as the § 208(b)(1) waiver) required, and still requires, a written finding by the appointing official that the financial interest of the employee or consultant is "not so substantial" as to affect the integrity of the services one expects from the employee.[38] It is apparent from the legislative history of the provision, as well as from subsequent administrative interpretations of the Department of Justice and the Office of Government Ethics, that only minor or "insubstantial" financial interests of an officer or an employee were intended to be exempted by the appointing official under § 208(b)(1). The apparent intent of the statute was not to allow exemption from the prohibition of an employee who has a substantial financial interest which has a greater potential to subtly influence, or to appear to influence, the employee's recommendations, advice or other service to the United States Government.

As noted, the statutory revision and this exemption were adopted in criminal code and conflict of interest revisions by the Congress in 1962.[39] The model legislation from which the conflict of interest and bribery law revisions were drafted was originally prepared by the Bar Association of the City of New York, Special Committee on the Federal Conflict of Interest Laws, and explained in the Association's treatise *Conflict of Interest and Federal Service.*[40] The exemption to the disqualification provision recommended by the Bar Association would have been an unqualified exemption given by the President for any financial interest, without regard to the substantial nature of the interest, whenever the President found it to be in the "national interest" for the government to have the services of the individual in question, regardless of his or her personal financial interests.[41] This unqualified "national interest" exemption was, however, rejected by the Congress which substituted instead the current 208(b)(1) exemption based on the "substantiality" test, and the general 208(b)(2) waivers (for all employees) for interests considered "too remote or too inconsequential."

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[37] Perkins, "Federal Conflict-of-Interest Law," *supra* at 1123-1124.

[38] *See* 5 C.F.R. 2640.301.

[39] P.L.87-849, 76 Stat. 1124 (1962).

[40] *Conflict of Interest and Federal Service*, Harvard University Press (Cambridge 1960); see H. R. Report No. 748, *supra* at 8.

[41] *Conflict of Interest and Federal Service, supra* at 204-205, 282; see Section 3(e) of model bill.

As indicated in the House Report on the legislative changes in 1962, the intent of the legislation was not to exempt employees from the operation of the statute who have substantial financial interests which may at some time pose conflicts with their official duties, but rather to protect employees from criminal penalties when they have "trivial" or minor financial interests which could be affected by the performance of those official duties:

> However, because it is unfair to require the Government employee to act at his peril in drawing the line between substantial and *trivial* interests, the bill further provides that the prohibition shall not apply if the officer or employee first advises the official responsible for appointments to his position of the nature and circumstances of the matter and makes full disclosure of his interest in it and receives in advance a written determination that the interest is too insubstantial to be likely to affect the integrity of the service, or if by general rule or regulation published in the Federal Register, the financial interest has been exempted from the prohibition as too remote or inconsequential.[42]

A procedure was established therefore which permitted an agency to use the services of an official or employee who would otherwise have been disqualified from participating in a matter because of a "de minimis" financial interest in the governmental matter under consideration:

> Subsection (b) affords the Government ample protection, yet provides a system whereby the Government may utilize the services of its employees in situations in which under the present law a *de minimis* financial interest in a matter may either (1) compel disqualification under criminal penalties, resulting in obvious detriment to the Government, or (2) result in disregard for the law.[43]

Interpretations of the 208(b)(1) exemption have also comported to the notion that the exemption is for insubstantial financial interests. In a Presidential Memorandum of May 2, 1963, it was explained that: "The power of exemption may of course be exercised also where the financial interests involved are minimal in value."[44] This Memorandum was cited in an opinion from the Department of Justice's Office of Legal Council which looked at financial interests of a government consultant to determine questions as to whether those interests are "'insubstantial' in an absolute sense."[45]

The Office of Government Ethics has also stressed that in granting § 208(b)(1) waivers: (1) the "substantial," or the "insubstantial" or *de minimis* nature of the financial interest, and (2) the actual duties of the employee on a particular matter, are the two elements

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[42] H.R. Report No. 748, *supra* at 13. Emphasis added.

[43] *Id.* at 24. Emphasis added.

[44] 28 Fed. Reg. 4539, 4543 (1963).

[45] 2 Op. O.L.C. 151, 156 (June 29, 1978). The O.L.C. explained in this opinion that a further gloss on the "insubstantiality" test was applied in the Presidential Memoraadum in the case of "special Government employees," who may receive an exemption if their advice and recommendations do not impact their company solely, or disproportionately to other companies in the industry. *Id.* at 156-157. *See* now 5 C.F.R. § 2640.203(g).

to consider in deciding the appropriateness of the waiver. The threshold inquiry concerns the substantial nature of the financial interest. In an opinion of the Office of Government Ethics, the agency criticized a waiver granted by the White House to an official, because it was "inappropriate to disregard the substantial dollar value of [the official's and the official's spouse's] holdings of [the company's] stocks".[46]

The Office of Government Ethics noted in earlier opinions that an exemption under this statute was to be based on the more objective substantiality standard, and was not to be based upon the "personal integrity" of the official involved, since that is too subjective a factor in the test of a waiver, and would allow significant financial interests to be retained in contravention of congressional intent.[47] The waiver is *not* a character voucher on behalf of the particular official involved in the potential conflict, but rather is a measurement of the financial interest as to its potential impact on an individual in the official's position who must exercise the official governmental duties involved. The Office of Government Ethics explained:

> [Congress] recognized that there were going to be some situations where the size of the interest in relation to the action being taken was going to be so insubstantial that it would not affect the services of the employee. This decision, too, was to rest on *the size of the interest* and the specific kind of action to be taken, *and not on the personal integrity of the employee.*[48]

The Office of Government Ethics has found that where there is a substantial financial interest which creates a potential conflict because of one's official duties, although a waiver under § 208(b)(1) would work to "protect the individual from prosecution" under the criminal statute, the substantial dollar interest of the official in a company affected by his official actions creates a real conflict of interest in fact, which would "raise an appearance of impropriety that cannot be overcome simply by using the waiver authority of 18 U.S.C. § 208(b)."[49]

In 1989, however, the waivers that may be granted to special Government employees on federal advisory committees were changed. In a report and study from an ethics task force appointed by President Bush, the § 208(b)(1) waivers for "not so substantial" interests were deemed to be too strict for advisory committee members, such that "the government is needlessly handicapped in obtaining advice and information from individuals with expertise

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[46] OGE Advisory Opinion No. 88 X 17, November 23, 1988; *see* also 87 X 6, April 1, 1987.

[47] See, for example, OGE Advisory Opinions 87 X 6, April 1, 1987; 87 X 7, May 5, 1987.

[48] Office of Government Ethics Advisory Opinion 87 X 7, May 5, 1987. Emphasis added. The OGE opinion repudiated the notion that the exemption was merely a subjective character evaluation of the individual official, as had been theorized by some commentators. See, e.g. Perkins, "The New Federal Conflict of Interest Law", 76 *Harvard Law Review* 1113, 1136 (April 1963).

[49] OGE Advisory Opinion No. 88 X 17, November 23, 1988; see also Advisory Opinion No. 83 X 20, December 30, 1983; and 84 X 6, May 1, 1984.

who are located in the private sector."[50] A waiver was suggested which would allow the appointing authority to waive the application of the conflict of interest law at § 208 at any time the appointing official deemed to need the services of the advisory committee member, *regardless* of the substantiality of a conflicting financial interest. The Commission report explained:

> Section 208 ordinarily requires waivers, recusal, divestiture or another special measure when an individual (including a special government employee serving on an advisory committee), has a financial interest that could be affected by actions taken or advice given. In selecting the members of an advisory committee, however, the appointing official will typically want to select individuals with expertise in the matter being studied. It will often be the case that many such individuals are employed by (or have other financial ties with) companies or organizations whose interests will be affected by the recommendations of the advisory opinion. ...
>
> In the case of advisory committees, the usual remedies for potential conflict of interest fall short. Few individuals will choose to divest themselves of assets, much less jobs, to assume a temporary, often unpaid, position on an advisory committee. And, as a general matter, recusal will be an unworkable remedy, because it would deprive the committee of the conflicted individual's expertise. Waiver also is not a solution, since under current interpretations of the waiver standards ... , officials with the authority to grant waivers are required to look in large measure at the magnitude of the financial interest in question. For many advisory commission members, the financial interest may be quite large, but it may nonetheless be highly desirable to have the benefit of the individual's expertise. Thus, existing requirements for disqualification or waiver may have the effect of eliminating a class of talented and skilled individuals from providing advice to the government.[51]

The suggestion for special waivers for advisory committee members was adopted by Congress in amending the conflict of interest laws in the Ethics Reform Act of 1989. Persons who are special Government employees by virtue of their service on advisory committees may now have the restrictions of 18 U.S.C. § 208 waived by the official who appoints that advisory committee member if, after a review of the financial disclosure report of the advisory committee member, the appointing official determines that the "potential" conflicts of interest raised by the financial interests of the individual, or by those imputed to him, are "outweigh[ed]" by the "need for the individual's services ...."[52] This waiver may apply to even substantial economic or financial interests of the employee/advisor, which had troubled the Office of Government Ethics in the past.

What might be considered the more lenient treatment of conflicting financial interests of federal advisory committee members, as compared to other special Government

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[50] "To Serve With Honor," Report of the President's Commission on Federal Ethics Law Reform, at p. 29 (March 1989).

[51] Report of the President's Commission on Federal Ethics Law Reform, *supra* at 29-30.

[52] 18 U.S.C. § 208(b)(3).

employees, was recommended by the study commission expressly because of the other statutory requirements and "safeguards" in the Federal Advisory Committee Act. The study commission explained:

> The Commission believes that advisory committees covered by the Federal Advisory Committee Act (FACA) warrant a different approach. ... FACA itself includes alternative safeguards that help protect the public's interest in the integrity of the deliberations of advisory committees. First, FACA includes a requirement that the membership of advisory committees be fairly balanced with respect to the issues under consideration. Even more important, FACA requires advisory committees to hold public meetings, except in unusual circumstances. As such, deliberations of a FACA advisory committee are open to the most exacting public scrutiny. Finally, the recommendations of an advisory committee are not, in themselves, binding, but rather are presented publicly to another government official who can judge independently the degree to which recommendations were biased by the personal interests of the members.
>
> The effectiveness of these alternative means of assuring the integrity of advisory committee deliberations depends on the availability of information about the financial holdings of advisory committee members. ... At present, however, public filings are required only of advisory committee members who serve for more than 60 days or who are paid at or above the GS-16/1 level.[53]

Statutory Standards for Federal Advisory Committees - Conclusion

Under the President's Commission's analysis of the more lenient conflict of interest waivers for advisory committee members (§ 208(b)(3) waivers), it may be argued that *without* significant adherence to the statutory standards in the Federal Advisory Committee Act of openness of meetings, "balance" of interests on the advisory panel, and independent review by agency officials for bias in advisory committee recommendations, such statutory "safeguards" (as characterized by the President's Commission) on the integrity of the FACA process would not exist, and the more lenient treatment of advisory committee members' conflicts of interest would not be justified.

The open meeting requirement of section 10 of the Federal Advisory Committee Act, as well as the public access and accountability provisions, have as their objectives, for example, public scrutiny of the operation of an advisory committee to ensure that it is not a secretive, or hidden vehicle for special-interest influence, a goal directly related to issues of the private interests and the potential "conflict of interest" of the advisory committee members. As explained in a law review article by an authority on the provision:

> Passed in 1972, the FACA seeks in large part to promote good-government values such as openness, accountability, and balance of viewpoints. These goals reflect previous worries that advisory committees had become a hidden vehicle for special-interest access to agency decision makers.

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[53] Report of the President's Commission on Federal Ethics Law Reform, *supra* at 30.

> .... These openness requirements facilitate public monitoring of advisory committees, thereby reducing the likelihood that advisory committees can serve as secretive channels for special interest access to agencies.[54]

Similarly, the requirement that a committee be "fairly balanced" in section 5 of FACA was directed at the same concerns that the private and personal financial and economic interests of certain members of advisory committees, particularly those connected to or funded by a private industry, would dominate in the committee and be an undue influence on the agency using the advisory committee. The legislative history of FACA illustrates that concern:

> One of the great dangers in the unregulated use of advisory committees is that special interest groups may use their membership on such bodies to promote their private concerns. Testimony received at hearings ... pointed out the danger of allowing special interest groups to exercise undue influence upon the Government through the dominance of advisory committees which deal with matters in which they have vested interests.
>
> In its report on "The Establishment of a National Industrial Wastes Inventory" this committee commented on the operations of the Advisory Council on Federal Reports, which was organized by several national business organizations at the request of the Office of Management and Budget. When Council members met with government officials to consider a proposed national industrial wastes inventory questionnaire, only representatives of industry were present. No representatives of conservation, environment, clean water, consumer, or other public interest group were present. This lack of balanced representation of different points of view and the heavy representation of parties whose private interests could influence their recommendations would be prohibited by the provisions contained in section 4 of the bill.[55]

Although there is a requirement stated in the statute for advisory committees to be "fairly balanced," there is no specific explication of what that "balance" requires in the statute.[56] Furthermore, the courts, despite the legislative history language quoted above, have not attempted to set any particular formula for public involvement, and have rejected the notion that the "balance" language requires advisory committees to have members from "public interest" groups, such as from "consumer groups," or other end-users of a particular product. The courts, rather, have given a very broad interpretation of "balance," and have allowed the agencies great discretion in choosing the viewpoint "balance" on an advisory committee:

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[54] Croley, Steven P., "Practical Guidance on the Applicability of the Federal Advisory Committee Act," 10 *Admin. L.J. Am. U.* 111,117 (Spring 1996).

[55] H.R. Rpt. No. 1017, 92d Cong, 2d Sess. 6 (1972), reprinted in 1972 *U.S. Code Cong. & Admin. News* 3491,3496; *see Public Citizen v. National Advisory Committee on Microbiological Criteria for Foods*, 886 F.2d 419, 423 (D.C.Cir. 1989).

[56] GSA regulations on advisory committees note also the "fairly balanced" requirement and provide that the agency will "consider a cross-section of those directly affected, interested and qualified, as appropriate to the nature and functions of the committee." 41 C.F.R. § 101-6.1007(b)(2)(iii), *see* also 41 C.F.R. § 101-6.1015.

> The statutory directive that membership of the Committee be "fairly balanced" does not mean that such balance can be provided only by individuals who work for, or are associated with, a consumer or public health organization. The Act does not require that "consumer organizations" be directly represented on the Committee. Section 5(b)(2) is a general provision requiring only that the membership of an advisory committee be "fairly balanced" it does not specify how the "fairly balanced" membership is to be achieved in terms of either the types of representatives or their number. ...
>
> The determination of the "fairly balanced" membership of an advisory committee, in terms of the points of view represented and the functions the committee is to perform, is to be achieved, necessarily lies largely within the discretion of the official who appoints the committee.[57]

Given the breadth of discretion of the agency to choose the "balanced" representation on the advisory committees, and given the *change* in the law concerning individual conflict of interest waivers subsequently adopted in 1989, after the passage of the original Federal Advisory Committee Act, Congress might wish to re-examine the policy and statutory requirements and obligations in the advisory committee statute. It is clear that as a matter of current law the "balance" of an advisory committee is mostly within the discretion of the agency official making the appointments, as is the decision to grant broad conflict of interest waivers to advisory committee members even for substantial conflicting interests. Furthermore, although open meetings are the general rule stated in the current law, important discussions and meetings of advisory committees may be, and apparently often are closed under the statutory criteria allowed.[58]

As a policy matter, however, for conflict of interest purposes and analysis, when an agency constitutes an advisory committee and then grants 208(b)(3) waivers for even *substantial* and direct conflicts of interest to allow members to participate in discussions and state opinions on a matter directly impacting their personal or imputed financial interests (which it is permitted to do), there may arguably be a greater need and obligation for an advisory committee not to regularly close meetings (under the criteria of the Sunshine Act and the Freedom of Information Act standards), but rather to assure even more openness and public oversight.[59] This might include limiting by statute the criteria for closing meetings currently provided.[60] Similarly, under such circumstances of § 208(b)(3) waivers for substantial interests and the allowance of full participation in discussions, it may arguably be of particular importance in terms of conflict of interest policy, resolution and control, to

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[57] *Public Citizen v. National Advisory Committee on Microbiological Criteria for Foods, supra* at 422-423.

[58] Croley, Steven P., "Practical Guidance on the Applicability of the Federal Advisory Committee Act," *supra* at 503-506.

[59] Report of the President's Commission on Federal Ethics Law Reform, *supra* at 30: One of the reasons the President's Ethics Commission recommended more lenient conflict of interest waivers for advisory committee members was that "deliberations of a FACA advisory committee are open to the most exacting public scrutiny."

[60] *See* discussion of pros and cons of more openness public accessability in advisory committee meetings, in Croley, Steven P., "Practical Guidance on the Applicability of the Federal Advisory Committee Act," *supra* at 503-506.

have a broader range of viewpoints, even on expert advisory committees, and possibly including end-users, such as consumer interests, practitioners or institutional or other end-users of subject products or services, as full voting and participating members on the committee. This may require more definite and express statutory language and guidance on public interest group participation and membership, limiting the discretion that the courts have recognized under current law in agency officials to determine the "balance" required.

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EXHIBIT
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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Centers for Disease Control
and Prevention (CDC)
Atlanta GA 30333

C H A R T E R

ADVISORY COMMITTEE ON IMMUNIZATION PRACTICES

Purpose

The Secretary, the Assistant Secretary for Health, and by delegation the Director, Centers for Disease Control and Prevention, are authorized under Section 311 and Section 317 of the Public Health Service Act, as amended, 42 U.S.C. 243 and 42 U.S.C. 247b, to assist States and their political subdivisions in the prevention and suppression of communicable diseases, to advise the several States on matters relating to the preservation and improvement of the public health, and to make grants to States and, in consultation with the State health authorities, to agencies and political subdivisions of States to assist in meeting the costs of communicable disease control programs.

Authority

42 U.S.C. 217a, Section 222 of the Public Health Service Act, as amended. The Committee is governed by the provisions of Public Law 92-463, as amended (5 U.S.C. App. 2), which sets forth standards for the formation and use of advisory committees.

The Advisory Committee on Immunization Practices has been given a statutory role under Section 13631 of the Omnibus Budget Reconciliation Act of 1993, Public Law 103-66 (42 U.S.C. 1396s (c)(2)(B)(i) and (e), subsections 1928(c)(2)(B)(i) and 1928(e) of the Social Security Act).

Function

The Advisory Committee on Immunization Practices shall provide advice and guidance to the Secretary, the Assistant Secretary for Health, and the Director of the Centers for Disease Control and Prevention, regarding the most appropriate application of antigens and related agents (e.g., vaccines, antisera, immune globulins) for effective communicable disease control in the civilian population. The Committee shall review and report regularly on immunization practices and recommend improvements in the national immunization efforts.

EXHIBIT
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In accordance with Section 1928 of the Social Security Act, the Committee shall also establish and periodically review and, as appropriate, revise a list of vaccines for administration to children eligible to receive vaccines through the Vaccines for Children Program, along with schedules regarding the appropriate periodicity, dosage, and contraindications applicable to the pediatric vaccines. The Secretary shall use, for the purpose of the purchase, delivery, and administration of pediatric vaccines in the Vaccines for Children Program, the list established by the Committee.

Structure

The Committee shall consist of twelve members, including the Chair. Members and the Chair shall be selected by the Secretary from authorities who are knowledgeable in the field of immunization practices and have multidisciplinary expertise in public health, or have expertise in the use of vaccines and immunologic agents in clinical practice or preventive medicine.

The Committee shall also consist of seven non-voting, ex officio members: the Deputy Director, Division of Vaccine Injury Compensation, Bureau of Health Professions, Health Resources and Services Administration; the Deputy Director for Scientific Activities, Office of the Assistant Secretary of Defense for Health Affairs, Department of Defense; Under Secretary for Health, Department of Veterans Affairs; the Director, National Center for Drugs and Biologics, Food and Drug Administration; the Medical Advisor, Medicaid Bureau, Health Care Financing Administration; the Director, Microbiology and Infectious Diseases Program, National Institute of Allergy and Infectious Diseases, National Institutes of Health; and the Director, National Vaccine Program Office, Centers for Disease Control and Prevention; or their designees.

The Committee shall not take a vote unless at least seven public members qualified to vote (i.e., not disqualified by reason of financial conflict of interest) are present. Whenever such a quorum is not present, the Executive Secretary, or designee, shall have the authority to temporarily designate the ex officio members as voting members.

There shall also be non-voting liaison representatives from the American Academy of Family Physicians; the American Academy of Pediatrics; the American Association of Health Plans; the American College of Obstetricians and Gynecologists; the American College of Physicians; the American Hospital Association; the American Medical Association; the Association of Teachers of Preventive Medicine; the Canadian National Advisory Committee on Immunization; the Hospital Infection Control Practices Advisory

Committee, Centers for Disease Control and Prevention; the Infectious Diseases Society of America; the National Medical Association; the Pharmaceutical Research and Manufacturers of America; the Secretario de Prevencion y Control de Enfermedades, Mexico; and such other non-voting liaison representatives as the Secretary deems necessary to effectively carry out the functions of the Committee.

Members shall be invited to serve for overlapping four-year terms; terms of more than two years are contingent upon the renewal of the Committee by appropriate action prior to its termination. Members shall serve after the expiration of their terms until their successors have taken office.

A member's term of office may be terminated by the Committee's Executive Secretary should the member fail to attend two consecutive meetings. In such case, a new member shall be appointed by the Secretary to fill the remaining term of office.

Subcommittees composed of members of the parent committee may be established from time to time. The Department Committee Management Officer will be notified upon establishment of each subcommittee, and will be provided information on its name, membership, function, and estimated frequency of meetings.

Management and support services shall be provided by the Office of the Director, Centers for Disease Control and Prevention.

Meetings

Meetings shall be held approximately three times annually at the call of the Chair with the advance approval of a government official, who shall also approve the agenda. A government official shall be present at all meetings.

Meetings shall be open to the public except as determined otherwise by the Secretary or other official to whom the authority has been delegated; notice of all meetings shall be given to the public.

Meetings shall be conducted, and records of the proceedings kept, as required by applicable laws and Departmental regulations.

Compensation

Members who are not full-time Federal employees shall be paid at the rate of $188 per day, plus per diem and travel expenses in accordance with Standard Government Travel Regulations.

Annual Cost Estimate

Estimated annual cost for operating the Committee, including compensation and travel expenses for members but excluding staff support, is $69,596. Estimate of annual person-years of staff support required is 2.0 at an estimated annual cost of $99,762.

Reports

Working group.

In the event a portion of a meeting is closed to the public, a report shall be prepared annually, which shall contain at a minimum, a list of members and their business addresses; the Committee's functions, dates and places of meetings; and a summary of committee activities and recommendations made during the fiscal year. A copy of the report shall be provided to the Department Committee Management Officer.

Termination Date

Unless renewed by appropriate action prior to its expiration, the Advisory Committee on Immunization Practices will terminate on April 1, 2000.

APPROVED:

3/19/98
Date

Acting Director
Centers for Disease Control
and Prevention

THE ADVISORY COMMITTEE

ON

IMMUNIZATION PRACTICES (ACIP)

POLICIES AND PROCEDURES

FOR DEVELOPMENT OF RECOMMENDATIONS

FOR VACCINE USE

AND FOR THE

VACCINES FOR CHILDREN

January, 2000

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THE ADVISORY COMMITTEE ON IMMUNIZATION PRACTICES (ACIP)
POLICIES AND PROCEDURES FOR DEVELOPMENT OF
RECOMMENDATIONS FOR VACCINE USE AND FOR VACCINES FOR CHILDREN

I. Development of ACIP Recommendations for Use of Vaccine and Related Biological Products

A. Purpose

The ACIP provides advice and guidance to the Secretary, the Assistant Secretary for Health, and the Director, Centers for Disease Control and Prevention (CDC) on the most effective means to prevent vaccine-preventable diseases. According to its current charter, the ACIP provides advice and guidance regarding the most appropriate application of antigens and related agents (e.g., vaccines, antisera, immune globulins) for effective disease control in the civilian population. We are proposing that the ACIP charter be modified to acknowledge the broader scope of ACIP recommendations (e.g., use of antivirals, chemotherapy or prophylaxis). The ACIP develops written recommendations, subject to the approval of the Director, CDC, for the routine administration of vaccines to the pediatric and adult populations, along with schedules regarding the appropriate periodicity, dosage, and contraindications applicable to the vaccines. The ACIP is the only entity in the federal government which makes such recommendations taking into account all available information (published or unpublished, submitted under an IND or not) about a vaccine and placing that information in the larger context of the various health care delivery systems in the U.S., the current epidemiology of the disease, implementation issues, ethical and legal constraints, and other factors. The overall goals of the ACIP are to provide advice which will assist the Department and the Nation in reducing the incidence of vaccine preventable diseases and to increase the safe usage of vaccines and related biological products, including active and passive immunoprophylaxis.

The target populations for ACIP recommendations are public and private health care providers who administer vaccines, public and private officials who make vaccine policy, and the general public.

B. Membership

The Committee charter was amended on May 8, 1997 to authorize twelve regular voting members, selected by the Secretary, Department of Health and Human Services, from authorities who are knowledgeable in the field of immunization practices, have multi disciplinary expertise in public health, and have expertise in the use of vaccines and immunologic agents in both clinical and preventive medicine.

ACIP members are selected based on their expertise to contribute to the Committee's responsibilities. Departmental policy provides that committee membership be fairly balanced in terms of points of view represented and the committee's function. Consideration is given to

representation from diverse geographic areas, both genders, ethnic and minority groups, and the disabled. Nominees must be U.S. citizens.

Each year, suggestions for regular voting members to serve a 4-year term are sought from a variety of sources including current and former ACIP members, professional societies, vaccine manufacturers, and the general public. These individuals are encouraged to contact members of their institutions, professional organizations, and peers to develop a broad slate of candidates. In addition, suggestions for membership to the Committee are received from various sources during the year, and compiled for consideration at the appropriate time.

Nomination

Once an individual is submitted for possible nomination to the Committee, the name and information received on the candidate is held and reconsidered each time a member needs to be replaced. The candidate remains on the list until withdrawn or nominated to the Committee.

A listing of possible nominees to the Committee is updated and submitted to the Chair, ACIP; Executive Secretary, ACIP; Director, National Immunization Program (NIP); Director, Epidemiology and Surveillance Division, NIP; and representatives from the National Center for Infectious Diseases and the National Center for HIV, STD and TB Prevention. These individuals then discuss the candidates for nomination to the Committee, and develop a slate of possible nominees. These candidates are then contacted to determine their willingness to serve on the Committee. With concurrence of the candidate, the slate of nominees is submitted to the Director, CDC for permission to prepare the nomination package.

Upon endorsement of the Director, CDC, the nomination package is prepared for the Secretary, HHS. If approved, the new members are appointed to a term of four years. A member who is unable to fill the full four year appointment to the Committee may resign by submitting a letter of resignation. When this occurs, a new candidate is nominated to fill the remainder of the unexpired term of the member who has resigned.

Process

In addition to the regular voting members, the Committee has ex-officio members from other Federal agencies (who may be designated to vote in specific circumstances by the Executive Secretary) and non-voting liaison representatives from professional societies and organizations responsible for the development and execution of immunization programs for children and adults. The function of ex-officio members and non-voting liaison representatives is not clearly delineated in federal regulations or in the Committee charter. However, in contrast to regular voting members who are expected to express their personal opinions on all substantive issues before the committee, ex officio and liaison members comments are expected, to the extent possible, to represent the position and views of their sponsoring organizations. Ex officio and liaison members are expected to contribute to committee discussions when issues of importance to their organizations are being discussed and when they possess information important to the discussion which has not been contributed by another member. These members and others can serve as appointed consultants to working groups and subcommittees to provide expert advice and apprise the working group of the position their organization endorses.

The Committee shall not take a vote unless at least seven members qualified to vote are present. Whenever six or more members are not eligible to vote by reason of financial conflict of interest, the Executive Secretary, or designee, shall have the authority to temporarily designate the ex officio members as voting members.

C. Meetings

Regularly scheduled meetings are usually held three times a year, at the discretion of CDC, with meeting dates announced 6-12 months in advance. Notices of each meeting, along with agenda items that may be discussed, are published in the Federal Register in accordance with the requirements of the FACA. Meetings have traditionally been held in Atlanta either at a CDC conference room or at a local hotel.

If there is a need to consult ACIP members on an urgent or emergency basis, the Executive Secretary may request that the Chair establish and convene an "emergency consultation workgroup" consisting of ACIP members, to discuss the nature of the emergency and possible responses to it. The workgroup will report its findings and recommendations to the Full committee.

In exceptional circumstances, either in follow-up to the workgroup consultation or as an initial response to the emergency, the Director, CDC may call an emergency meeting of the ACIP without prior notice in the Federal Register or with less than the usual 15 day notice. If the notice can not be published at least 15 days prior to the meeting, the Federal Register announcement shall include the reasons for providing less than 15 days notice, as provided under GSA regulations at 41 CFR 101-6.1015(b)(2). If exigent circumstances make publication of the Federal Register notice prior to the meeting impossible, the notice shall be published in the Federal Register as soon as possible after the meeting. In addition, under such circumstances, the agency shall utilize other appropriate mechanisms for providing notice of the meeting prior to its occurrence.

D. Member Responsibilities

1. Attendance at Meetings

The ACIP meeting dates are published a year in advance. Except in the event of an emergency, regular voting members of the ACIP assume the responsibility of attending all meetings. When a member does not attend a meeting or attends a portion of a meeting, the member is provided background material on the issues discussed, and is expected to be prepared for the next meeting. If a regular voting member finds it difficult to attend meetings, he/she has the responsibility to resign from the Committee. This will allow for a new member to be appointed to carry out the term.

2. ACIP Related Contacts

ACIP members may be solicited to participate in interviews or surveys on vaccine issues that are addressed by ACIP. ACIP members should not participate in such surveys if they must reveal their personal identity or if their ACIP membership status is known or revealed.

The Department's Standards of conduct prohibit "speaking" on matters related to an ACIP member's official duties outside committee or working group meetings. ACIP members are prohibited from receiving compensation for any speech or publication in which the purpose is to report on the member's work on the ACIP. Also, the regular voting member should be concerned with, and report to the Executive Secretary, any solicitation of information about the committee's activities by persons not officially affiliated with the committee.

3. Media Interaction

As a public agency, CDC's meetings are open to the public and the media. Therefore, committee members may be approached by the press for an unscheduled interview.

While members are certainly free to give interviews and express their opinions, they are not obligated to give an interview to the press either at the time they are approached or at a later time. If they choose to be interviewed, CDC offers the following guidance:

- ACIP members may choose to do interviews with other ACIP members or CDC staff.
- Or they may feel more comfortable referring the interviewer to the CDC Office of Health Communications representative.
- CDC discourages members from speaking with the press about the likely outcome of an ACIP vote in a manner that would indicate they have already decided the issue prior to presentation of the issue and relevant data at the meeting. Views of a member may change during the course of a meeting, and it could be premature and misleading to make public statements prior to the end of the meeting.
- Members may discuss the public meeting and their views, but should be careful not to disclose any proprietary information.
- Consider whether an issue could come before the advisory committee in the future. Members should be aware that any strong public statements following one meeting could affect their future participation in related meetings because of the need to avoid the appearance of bias.

- Members speaking to the press must remember not to speak as representatives of either the committee or the CDC, unless the agency designates a member to speak for the committee (e.g., the Chair).

- Regarding closed portions of committee meetings, only the topic of discussion may be made public. Prior to discussing any matter, the member should consult with the Executive Secretary or a knowledgeable CDC staff member.

E. Electronic Recording by Public Media

It is CDC policy that advisory committee meetings are open to the public to the extent allowed by law and physical environment. The Chair and the Executive Secretary have the authority to regulate all aspects of the meetings, including electronic coverage. In order to ensure that a meeting is conducted in a fair and expeditious manner, the Chair may restrict or deny use of electronic recording equipment. Any member finding lights or recording equipment disruptive to the conduct of business at the meeting should inform the Chair or Executive Secretary. Factors to guide the Chair in this determination include the potential for significant disruption, prejudicial impact on the meeting, fairness, and impairment of a participant's ability to make a presentation.

F. Financial Interests

Financial Conflicts of Interest and 208 (b)(3) Waivers

1. **Prohibition.** Federal law (18 U.S.C. § 208) prohibits Federal executive branch employees, including special government employees (i.e. members of Federal advisory committees such as ACIP), from participating in matters in which, to his/her knowledge, he/she, his/her spouse, minor child, or organization has a financial interest.

2. **Inherent Potential.** Federal advisory committees usually have members who may have potential financial conflicts of interest because members are chosen for

   service based on their expertise in the areas in which advice is sought by the government.

3. **Waivers.** Congress has recognized the need for service by these experts on Federal advisory committees, despite the potential for conflicts of interest, by providing for waivers of the conflict of interest prohibitions under 18 U.S.C. § 208 (b)(3) when "the need for the individual's services outweighs the potential for a conflict of interest created by the financial interest involved."

4. **Integrity of Committee.** Nevertheless, CDC is sensitive to concerns about

potential conflicts of interest by members serving on the ACIP, particularly given the ACIP's role under OBRA '93, which involves decision making with substantial financial implications (i.e. VFC resolutions). The agency, therefore, has taken steps to assure that there is not only technical compliance with the provisions of 18 U.S.C. § 208, but that the spirit of those provisions is also fulfilled as follows -

a. **Scope of Waivers.** 208 (b)(3) limited waivers are being issued to ACIP members who have potential conflicts of interest so that the Department may benefit from the scientific and public health expertise of each member. Under these waivers: Each member with a potential or actual financial conflict of interest is granted a **waiver to participate in all committee discussions**, but only **if** (a) the **member publicly discloses** all relevant interests at the beginning of each ACIP meeting **and** (b) **abstains on votes** involving entities with which the member has a current direct financial interest (except as noted below under "De Minimus Interest").

b. **Current Financial Interest.** Financial relationships within the past 12 months

c. **Direct Financial Interest** (applicable to member, spouse & minor children) - examples
(1) stock-ownership
(2) employment
(3) contract
(4) receipt of grant funds, directly or as part of salary, when the member also works on the grant from which the funds come. (The member does not have to be the principal investigator on the grant for this to apply.)

5. **Financial Disclosures by Members.** Members will be requested to disclose relevant financial interests at the beginning of each meeting.

6. **Disclosure Not Required - Uncontrolled Interests.**
The member's institution may have financial interests which provide income to the member (e.g. grant funds deposited into a common account), but which interests are outside the member's area of work. Such interests are considered outside the member's control, as are the university's financial interests which do not provide income to the member. Given the lack of control, those interests are not required to be disclosed and there are no restrictions on committee activities based on such interests.

7. **De Minimus Financial Interests - Honoraria and Travel Support for Scientific Interchange.**

Support for expenses associated with attendance at scientific meetings is considered a de minimus financial interest. Honoraria received for presentations at scientific meetings is also considered de minimus to the extent that the total honoraria received in each calendar year does not exceed $1,000 per manufacturer or other entity. (Travel expenses included in honoraria payments are excluded from the cap, to the extent that the travel expenses can be segregated from the honoraria.) The restriction on voting does not apply regarding these de minimus interests if all relevant reimbursing entities within the past 12 months are disclosed at each ACIP meeting.

8. **Voting Restrictions**
Where a direct financial interest exists with a particular manufacturer, the member should recuse himself or herself from voting (i.e. abstain) on matters affecting any vaccine of that manufacturer. (It is the relationship with the manufacturer that creates the financial conflict, not just work on a particular vaccine; thus, the prohibition is on votes affecting any vaccine that is a product of the manufacturer.) However, the scope of the voting restriction is limited to issues that could potentially result in a significant financial impact on the affected manufacturer. For example, votes to recommend additional doses of a vaccine or to recommend administration of a vaccine to additional (or fewer) birth cohorts would be subject to the recusal restriction. On the other hand, no restriction would exist on votes pertaining to the list of contraindications to administration of a vaccine.

G. Selection of topics

Potential topics for ACIP consideration can be suggested by anyone, but are most often proposed by CDC program staff, ACIP members, and vaccine manufacturers.

Approximately ten weeks prior to an upcoming meeting, a memorandum requesting potential agenda items is sent to ACIP members, CDC staff, and vaccine manufacturers. A list of topics based on action or follow-up items from the last meeting or previously suggested is included in the memorandum. Also attached is an information sheet to be completed by the person suggesting the topic (See attachment A). The person suggesting an agenda item is asked to specify the topic to be on the agenda, issues of concern, and specific questions to be addressed by ACIP. Those proposing topics from outside CDC should identify one or more possible CDC staff members to coordinate the presentation; however, the final selection of the appropriate CDC staff member will be done by the program director.

Agenda items are accepted for presentation by the Executive Secretary in consultation with the Chair, and representatives from the National Immunization Program, the National Center for Infectious Diseases, and the National Center for HIV, STD, and TB Prevention. The Executive Secretary has the authority to approve, disapprove, or hold over to another meeting any agenda item submitted for the agenda. The priority of a topic for ACIP consideration will be

based on a variety of factors including the burden of illness (mortality, morbidity, disability); cost of the illness; cost of the intervention; availability of data on the efficacy, safety, cost effectiveness or economic impact, of the intervention; acceptability of a vaccine in the target populations and the quality of these data; availability of vaccine supplies; current utilization patterns of the vaccine and variations in practice; the feasibility of implementing effective vaccination programs; and the perceived potential of a change in the recommendations to improve health outcomes or improve safe usage of vaccines and biologicals.

The ACIP will review every major vaccine preventable disease at least once every five years to consider whether a revised recommendation is needed. The committee management specialist will maintain a tickler system to facilitate this process. A file containing ACIP recommendations including title and date of publication is maintained on the Internet.

For minor revisions, ACIP may choose not to revise the entire statement but instead issue a short update in the MMWR and on the Internet.

H. Process for Developing Recommendations

All recommendations are subject to extensive review by staff of the CDC, ACIP members, and outside expert consultants.

1. **Technical Aspects**

Working groups are formed to develop recommendations and extensively analyze the research data for presentation to the full Committee. These working groups 1) must include one or more regular voting members, 2) must include CDC staff members and 3) may include ex-officio and liaison representatives and other consultants.

Vaccine manufacturer's representatives may not serve on working group but, at the

discretion of the chair, may be consultants to a working group.

Either CDC staff from the relevant programs or ACIP members may take the lead for drafting recommendations for the working group, but the decision about who has lead responsibility for drafting must be made early and reported to the Committee Management Specialist. The process of developing ACIP recommendations includes (1) a review of the labeling/package inserts for each vaccine; (2) a thorough review of the scientific literature (both published and unpublished, when available) on the safety, efficacy, acceptability, and effectiveness of the immunizing agent, with consideration of the relevance, quality, and quantity of published and unpublished data; (3) an assessment of cost effectiveness; (4) a review of the morbidity and mortality associated with the disease in the population in general and in specific risk groups; (5) a review of the recommendations of other groups; and (6) a consideration of the feasibility of vaccine use in existing child and adult immunization programs. Feasibility issues include (but are not limited to) acceptability to the community, parents, and patients; vaccine distribution and

storage; access to vaccine and vaccine administration; impact on the various health care delivery systems; population distribution effects; and social, legal and ethical concerns.

ACIP recommendations may be developed and issued jointly with nongovernmental professional organizations or other PHS advisory committees. When this is done, the composition of the working group is modified to include members of the other organization(s).

Whenever the data permit, specific rules of evidence, such as those followed by the U.S. Preventive Services Task Force[1], will be used by the ACIP to judge the quality of data and make decisions regarding the nature and strength of the recommendations. When requested by the ACIP members, evidence tables will be developed for the vaccine or other prophylactic agent. In the absence of data or when data are inadequate, the expert opinions of voting members and other experts will be used to make recommendations. Depending upon the relative importance of the issue, either formal (e.g., Delphi, nominal group techniques) or informal methods for soliciting expert opinions will be used. The methods used for developing recommendations will be made explicit in the published recommendations.

When necessary for adequate decision making and when requested by the ACIP, a systematic review (meta-analysis) of the literature will be done. Such analyses should adhere to CDC recommendations[2] and those on *Cost Effectiveness in Health and Medicine.*[3]

Published and unpublished economic analyses (e.g., cost-effectiveness) relevant to vaccine issues will be routinely reviewed. If no such studies have been done, the ACIP may request that they be done, either prior to or subsequent to issuing a recommendation. Issues of both general cost, effectiveness, and the cost effectiveness of specific components of the recommendations will be considered.

Published recommendations will explicitly state the basis upon which the recommendations were made, i.e., what inputs there were such as controlled trials, case-control studies, case series, expert opinion, meta-analysis, Delphi surveys, focus groups, cost effectiveness analysis, and other inputs.

2. Policy Analysis

Many of the issues addressed by the Committee are not technical but policy issues. In such cases, a simple but formal policy analysis should be considered and may be requested and/or performed by the ACIP. Although other methods of analysis may be proposed and accepted, the usual (default) approach that should be used by the Committee is the process outlined by Carl Patton and David Sawicki in *Basic Methods of Policy Analysis and Planning.*[4]

This process is:

a. **Verify, define, and detail the problem**
Do not accept the initial statement of the problem without questioning whether it is framed correctly. Verify that the problem actually exists and is an important problem. Be sure the problem is relevant to the objectives of the ACIP and CDC. Determine the magnitude, nature, and extent of the problem. Determine who is concerned about the problem and why.

b. **Establish evaluation criteria**
Determine which criteria will be used to evaluate proposed solutions. Some common measures include cost, benefits, cost-benefit ratios, relative or marginal cost-effectiveness, effectiveness, efficiency, equity, administrative ease, legality, and distributive effects. Those criteria central to the problem must be selected and the relative importance of each measure must be determined.

c. **Identify alternative policies**
Alternatives can be identified through a variety of means such as literature searches, brainstorming, public comment, and others. The no-action or no change option should always be considered.

d. **Evaluate alternative policies**
The expected impact of each alternative policy should be projected and the extent to which it satisfies the evaluation criteria should be determined. A variety of techniques can be used such as risk-benefit or cost-benefit analysis, cost-effectiveness analysis, and linear programming. The method(s) chosen should be appropriate for the problem and the proposed alternative policy; no one method is appropriate for every problem or every alternative.

e. **Display and distinguish among alternative policies**
This can be done in a number of ways, e.g., through matrices, pros and cons, value-comparisons, scenarios, and others. Ranking or weighting schemes can be used. As the Committee assesses the policy options, input should be sought from a wide variety of stakeholders.

3. Resources

Adequate resources must be available to carry out the analyses outlined above. CDC should place a high priority on identifying these resources so that the high quality of ACIP recommendations can be maintained and enhanced.

4. Developing the Recommendations

Recommendations are subject to extensive review by staff of the Centers for

Disease Control and Prevention (CDC), ACIP members, outside expert consultants and vaccine manufacturers.

Working groups are often formed to extensively analyze the research data for presentation to the full Committee. They should first seek additional data which have been overlooked, corrections in data content, appropriateness of the interpretation of data, and critique and challenge expert opinions. Public comments are solicited during the Committee meetings, and are also considered during the decision making process.

Program staff compile and organize comments received and discuss them with the appropriate working group while redrafting recommendations. The chair of the working group is responsible for the final review of the draft recommendations submitted for deliberation and approval by the full voting Committee. Controversial issues will always be brought to the attention of the full Committee during an open Committee meeting.

Areas in need of additional research or data should be clearly identified and each statement should include a specific delineation of data gaps.

Documents and data which will be discussed at the meeting must be disseminated to the Committee in a timely manner for the members to have the time to analyse the information and prepare for productive discussions. It is the responsibility of the presenters/authors to meet the timelines set by the committee management specialist. These timelines are set ten weeks in advance of the meeting. Materials are routinely scheduled to be express mailed to the Committee members fourteen days prior to the meeting dates.

I. Publication of Recommendations

ACIP recommendations are one of the most valuable products of CDC. Although the recommendations are those of the Committee, they may or may not be accepted by the agency.

After agency acceptance, ACIP recommendations are published in the *Morbidity and Mortality Weekly Report Recommendations and Reports* series, and occasionally reprinted in other publications. CDC must ensure that a high priority is placed on providing adequate resources to prepare ACIP recommendations for publication in a timely manner.

The format of the recommendations for specific vaccines will generally follow that shown in attachment B. The final document will indicate the strength and quality of the evidence supporting each of the major recommendations.

J. Implementation and Evaluation of the Recommendations

Implementation and evaluation of the impact of the recommendations is the responsibility of the relevant CDC program, and not the ACIP. However, CDC programs will develop an implementation and evaluation plan for each set of recommendations and periodically report information relevant to these activities to the ACIP, and others who may be involved in implementing the recommendation (e.g., managed care, private practitioners).

K. Other issues

For other issues relevant to guideline development which are not mentioned in this document, the ACIP will consult **CDC Guidelines: Improving the Quality**.[5]

II. ACIP Recommendations for the Vaccines for Children (VFC) Program

ACIP recommendations for the VFC Program are developed and voted upon as a distinct process, separate from other ACIP functions. This process is based upon the unique statutory authority for the VFC program established by the Omnibus Budget Reconciliation Act of 1993 (42 U.S.C. 1396s) [see attachment C]. This legislation gave the ACIP the responsibility and authority to determine the vaccines, number of doses, schedule and contraindications for the VFC Program.

The ACIP applies a systematic and rational approach to developing VFC recommendations. The process for selection of vaccines, schedules, doses, and contraindications for VFC begins with a review of ACIP recommendations for use of each vaccine currently recommended for all or some groups of children or of other available information, and of recommendations by other groups such as the American Academy of Pediatrics. In addition to the considerations which go into the process of issuing general ACIP recommendations, this process also includes a more intensive consideration of (1) the programmatic feasibility of implementing the recommendation in the public and private sectors, (2) implementation strategies which are most likely to be successful, (3) the speed with which implementation can be achieved, (4) the availability of adequate quantities of vaccine, and (5) the cost-effectiveness of using the vaccine in various relevant groups. For each of these issues, background information is discussed, sometimes initially by a working group of ACIP members, and subsequently by the full Committee. Draft VFC resolutions are discussed at full Committee meetings, which are open to the public, before a formal ACIP vote is held.

For each vaccine considered for inclusion in the VFC program, written resolutions on the vaccine, schedule, dose, contraindications, and other issues relevant to appropriate uses of vaccines are reviewed by the Committee and are adopted or rejected through votes by voting ACIP members only. A record of issues voted on is maintained at CDC by the Executive Secretary, ACIP.

REFERENCES

1. U.S. Preventive Services Task Force. Guide to clinical preventive services, 2nd ed. Baltimore: Williams & Wilkins, 1996.

2. Haddix AC, Teutsch S, Shafer PA, et al. Prevention Effectiveness: A Guide to Decision Analysis an Economic Evaluation. New York: Oxford University Press, 1996.

3. Gold M, Siegal J. Cost-Effectiveness Analysis in Health and Medicine. New York: Oxford Univeristy Press, 1996.

4. Carl Patton and David Sawicki. Basic Methods of Policy Analysis and Planning. 2nd ed. Englewood Cliffs, NJ:Prentice Hall, 1993.

5. Centers for Disease Control and Prevention. CDC GUIDELINES: Improving the Quality. Atlanta: Centers for Disease Control and Prevention, 1996.

THIS FORM MUST BE FILLED OUT FOR YOUR ITEM TO BE CONSIDERED FOR THE FEBRUARY ACIP MEETING

ACIP AGENDA PROPOSAL
Meeting Date: Month 00, 0000

Due: 00/00/00 to Gloria Kovach, MS E61 404-639-8096(FAX:404-639-8520)

Topic: _____

Presenter(s) and Address	PHONE #	MS
_____	____	____
_____	____	____
_____	____	____

Time Required: Presentation _____ min.

Discussion _____ min.

Total _____ min.

Questions to be Addressed by ACIP

1. _____
2. _____
3. _____
4. _____

Please circle all that apply: Discussion Information

Decision VFC Vote

*Background Materials to be Provided	Yes	No
*Draft Statement to be Distributed	Yes	No
Visual Aids Required If yes, circle all applicable	Yes	No

Slides Overheads Handouts Other _____

* Due to Gloria Kovach, E61 no later than 14 working days before the meeting. Otherwise, BRING 125 COPIES to the meeting and give directly to Gloria. We appreciate your input in planning an interesting and productive meeting, and we appreciate you providing background materials and draft statements well in advance so the Committee has time to review them before the discussion.

Attachment D

FORMAT FOR RECOMMENDATION(S)

Summary

Purpose of Recommendation(s)

Clinical Description of Disease

Diagnosis and Treatment

Epidemiology of Disease

1.) Route(s) of transmission
2.) Morbidity, Mortality, Disability
3.) Cost Association with Illness
4.) Risk Groups

Efficacy, Effectiveness, and Cost Effectiveness of Intervention(s)

Precautions and Contraindications

Adverse Events

Recommendation(s) of ACIP with summary score for evidence and strength of recommendation

Recommendation(s) of Other Groups

Discussion of Rationale for ACIP Recommendation(s)

Recommended Surveillance, Research, Education, and Program Evaluation Activities

Attachment C

To be inserted.

Conflict of Interest of ACIP Liaison Representatives

a. American Academy of Family Pediatrics
Abbott Laboratories, American Home Products Corporation, Aventis, Bayer Corporation, bioMerieux, Boehringer Ingelheim Chemicals Co., Bristol-Myers Squibb Company, Eli Lilly and Company, Forest Laboratories, G.D. Searle & Co., Glaxo Wellcome plc, Janssen Pharmaceutica, Lederle Laboratories, Merck & Co., Muro Pharmaceuticals, Novartis, Novo Nordisk A/S, Ortho-McNeil Pharmaceuticals, Otsuka America Pharmaceutical, Inc., Pasteur Merieux Connaught, Pfizer, Inc., Pharmacia, Schering AG, Schwarz Pharma, Inc., SmithKline Beecham, Solvay S.A., Warner-Lambert Company, and Wyeth-Ayerst Laboratories .

b. American Academy of Pediatrics
Abbott Laboratories, Astra, Merck & Co., Pasteur Merieux Connaught, Pfizer, Inc., and SmithKline Beecham.

c. American College of Obstetricians and Gynecologists
Berlex Laboratories, Eli Lilly and Company, Novartis, Ortho McNeil Pharmaceutical, Pharmacia, Schering AG, and Wyeth-Ayerst.

d. American Medical Association
Aventis, Glaxo Wellcome plc, Merck & Co., Pfizer, and Shering AG.

e. Infectious Disease Society of America
Aventis and Bristol-Myers Squibb Company.

f. Biotechnology Industry Organization
Merck & Co., Wyeth-Ayerst and many other pharmaceutical companies.

g. Pharmaceutical Research and Manufacturers of America

good news. Let me reiterate Dixie's admonition for everyone to speak directly into the microphone, including those making comments from the back of the room. Let me also reiterate that I intend to keep things as much to schedule as I possibly can. It's in the interest of everyone here that we stay on schedule and finish on schedule. So I will again apologize in advance to anyone who I get a little bit short with for running over time. With that, I'd like to start with introductions by members of the Committee, by the *ex officio* members and the liaisons. I think we'll start with Dr. Le, go around the blue table first, and then we'll ask the liaison members to introduce themselves. When you introduce yourselves, I wonder if you would also go ahead and make your disclosures with respect to potential conflicts of interest. Chinh?

LE: Yeah. I'm Chinh Le, the Chair of the Infectious Disease Subspeciality for Kaiser Permanente, Northern California region. In terms of disclosure, Kaiser Permanente has some vaccine studies with Merck, Wyeth Lederle and SmithKline Beecham. I do own some stock with Merck and used to own some stock with Aviron, but no longer.

GRIFFIN: Marie Griffin, Vanderbilt University. I'm currently on an Endpoint Monitoring Committee for Merck.

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CLOVER: I'm Richard Clover from the University of Louisville. I receive grants from Merck and SmithKline. I've received honorariums from Connaught and Merck.

HELMS: Chuck Helms from the University of Iowa. I have no conflicts.

LIVENGOOD: John Livengood, National Immunization Program, CDC.

CORDERO: Jose Cordero, National Immunization Program at CDC.

MAWLE: Alician Mawle, National Centers for Infectious Diseases, CDC.

FLEMING: I'm David Fleming, the State Epidemiologist of the Oregon Health Division, and I have no conflicts.

GLODE: Mimi Glode from the University of Colorado and I have no conflicts.

GUERRA: Fernando Guerra from the Department of Health in San Antonio. We've done some work for SmithKline Beecham, for Merck, for MetImmune and North American Vaccine—either vaccine field trials and/or some consulting work and received honorariums from both SmithKline Beecham and MetImmune.

SNIDER: Dixie Snider, Associate Director for Science, CDC.

MODLIN: Okay. John Modlin from Dartmouth Medical School. I own a small number of shares of stock in Merck and I have participated in educational programs supported by Pasteur-Mérieux Connaught. Why don't we begin with Dr. Santos?