

DEPARTMENT OF HEALTH AND HUMAN SERVICES
HEALTH RESOURCES AND SERVICES ADMINISTRATION

ADVISORY COMMISSION ON CHILDHOOD VACCINES

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P R O C E E D I N G S

Agenda Item: Welcome and Chair Report

MR. SCONYERS: Good morning, everyone. Thanks for joining us this morning. This is going to be a long, full day of presentations. I appreciate everybody being here and getting started.

This morning we are going to do things a little bit differently than we have done in the past. Usually we start out with a series of fairly regular reports, but this morning we are going to take some time to hear from a variety of perspectives on the program, its origins, its operations. We have a number of people who have made time in their schedules to come in and talk with us. I hope this is going to be interesting for the members. The purpose here is, as everything is going on with the development of the national vaccine plan and as we look at the operation of the program and its goals, this is a chance for us to hear from a variety of voices and make some conclusions about whether there are any recommendations that this commission would like to make for the better functioning of the program, serving the interests of promoting vaccine safety and availability.

That's just a brief overview. Before we move to our business, Dr. Geoff Evans has a few housekeeping

announcements he would like to make.

DR. EVANS: Thank you, Jeff. Actually, very few.

At this point I usually welcome everyone to whatever quarterly meeting it is of the Advisory Commission on Childhood Vaccines. It turns out that this is the 71st quarterly meeting.

As usual, if anyone needs anything, go to Michelle Herzog, staff person for the commission.

In your folders we actually have a couple of things you should be aware of. On the right side there are copies of the presentations later this morning by Dr. Caserta, Kay Cook, from the Altarum Institute, and then the updates in the afternoon that I provided, and Vince Matanoski from the Department of Justice.

On the left side you will see an edited copy of the minutes, a rotavirus notice that was published in the *Federal Register* last month, and a copy of the strategic plan.

That's all I have.

Agenda Item: Approval of September 2008 Minutes

MR. SCONYERS: The first item of business on our agenda is approval of the September 2008 minutes. Tawny?

MS. BUCK: Actually, I would request that we not approve the minutes from the last meeting. I think we need

to do some edits and some revisions. Geoff, I didn't have time to get those to you this week. If we could maybe have some time on that -- my comment about the minutes mostly is that I think most of us are pretty aware that there are things that we can accomplish on this commission, and one of them is to get information that we are seeking on the public record. I strongly believe that the minutes should do a better job of reflecting discussion that is occurring. I think the contractor or whoever is doing the minutes should be able to figure the difference between when we are just having a sort of general philosophical discussion and when somebody is asking a question that they are seeking a response to that probably should be recorded for the record.

Additionally, it was unclear to me until just now which version of the Department of Justice minutes we were approving, because, apparently, the Department of Justice looked at the first version and then wrote their own, to which I also have some changes.

I can get those to Michelle in written form. But what I would suggest is that whenever a commissioner is seeking some sort of clarification or is asking for something -- an example would be, Ms. Hoiberg asked the Department of Justice for a published copy of the DeBazan decision, and the response to that was that they would work

to provide us that. I think that's the kind of comment that should be reflected in the record.

Additionally, there were a whole lot of comments that were made during the meeting that should be reflected.

I have actually taken the transcript and the minutes and gone through and flagged all the things that I think should be included. I would suggest that other commissioners that know that they made comments in the meeting that they would like to see -- and also being identified. There are a lot of folks out there that follow what we do by just reading the minutes on the Internet and on the Web site. We are all here to represent different groups, so it's pretty important, I think, for those people that we represent to understand what our contribution to these meetings is. It's not good enough to say there was discussion regarding this and this and this. I think we need to do a better job of identifying.

I will be happy to provide you with my edits. If it's all right with you, I would just like to postpone the approval of those minutes.

MR. SCONYERS: Is there any discussion about that? I think that sounds like a good suggestion. What I would like to suggest, Tawny, is that if you could -- I know you have taken a lot of time to look at this; we have talked about this a couple of times -- if you could

circulate, when you have the time to do it, your changes. Then I would like to ask everyone else who was at the meeting in September to look at that revision, and if you think there are additional revisions needed, then let's get a set of minutes that everybody is happy with. Then we can approve them next time.

Sherry?

MS. DREW: I have a question. Tawny just mentioned the transcript. I wasn't aware that there was an actual transcript available.

MS. HOIBERG: I have a copy of it, if you want it. I would actually suggest that the transcript be available on the Web site as well, so that folks can just access it. On a lot of the Web sites you can do that. It is helpful to be able to refer back to the transcript.

MS. DREW: I would certainly agree that that would be a very good idea.

PARTICIPANT: We can't hear anything out here.

MS. DREW: We were discussing the fact that the transcripts are available upon request, and perhaps we should post the transcript, as well as the minutes, which would be sort of a miniaturized version of the transcript, on the Web site.

MR. SCONYERS: Let me just check with the members. Is it okay to postpone and circulate the minutes?

I'm not going to do that by a formal motion. We don't have a motion to approve.

Then let's move into our morning's work. I would like to thank Magdalena Castro Lewis and Charlene Gallagher, who worked as the agenda committee this last time, to put together a set of views about the Vaccine Injury Compensation Program, and got some folks who have agreed to come in and speak with us from their various perspectives.

I would like to ask Tawny Buck to introduce our first speaker, from the National Vaccine Information Center.

MS. BUCK: Barbara Loe Fisher -- of course, I think most people are aware of who she is. She has been advocating for families who are raising children who have been injured by vaccines for a very, very long time. She was also one of the people who helped in the initial development of this program. She is a personal friend of mine. I believe that her perspective, from helping develop this program from the start to where it is now, will be very helpful for this commission.

I thank you very much for taking time to talk to us today.

Agenda Item: Stakeholder Views of the VICP

MS. FISHER: Mr. Chairman and members of the

Advisory Commission on Childhood Vaccines:

My name is Barbara Loe Fisher and I'm cofounder and president of the nonprofit National Vaccine Information Center that worked with Congress on the National Childhood Vaccine Injury Act of 1986, which included the Vaccine Injury Compensation Program for which this advisory commission has provided guidance for the last 20 years.

Along with our organization's first president, environmental law attorney Jeff Schwartz, who was a principal co-architect of the act, NVIC cofounder Kathi Williams and I were all parents of DPT vaccine-injured children. We participated in four years of deliberations with congressional staff, representatives from the American Academy of Pediatrics, vaccine manufacturers, and the Departments of Health and Human Services and Justice.

The Vaccine Injury Act included in Public Law 99-660 was historic for several reasons:

It was the first acknowledge by this society that vaccines injuries and deaths are not a myth, but are real, with catastrophic consequences for the lives of the vaccine-injured and their families who take care of them.

The law was passed by Congress at the specific request of pharmaceutical companies, threatening to stop making vaccines without product liability protection, as well as organizations representing pediatricians reluctant

to give childhood vaccines without liability protection. It is a matter of public record that the Departments of Health and Human Services and Justice were strongly opposed to this legislation.

The young parents of vaccine-injured children who came to the table in the early 1980s at the request of congressional staff to fight for the rights for vaccine consumers and the vaccine-injured agreed to work on the act because of promises made by Congress and the AAP that the proposed legislation would provide a fair, expedited, non-adversarial, less traumatic, less expensive, no-fault compensation alternative to civil litigation. We believed we were participating in the development of a law which would give, in the words of the then-AAP chairman, "simple justice to children."

In fact, Congress made it clear that the congressional intent was to create a system that would be expeditious and fair to the vaccine-injured and be unlike a trial, in order to offer an attractive, non-adversarial alternative to a lawsuit against vaccine manufacturers and physicians.

Parents had two conditions for coming to the table: First, there would be no agreement to an exclusive remedy system that would bar a lawsuit if federal compensation was denied or too little was offered to meet

the injured child's lifetime needs, or if it could be demonstrated that a vaccine manufacturer could have made a safer vaccine or had engaged in criminal fraud or gross negligence. Second, the act must contain provisions to make vaccines and policies safer so fewer children would be harmed and need compensation.

We knew then, as we do now, that a law shielding vaccine manufacturers and providers from liability for vaccine harm must also contain strong provisions to ensure that the safest vaccines and policies are in place.

The final act did include important safety provisions requiring doctors to give parents written vaccine benefit and risk information before children are vaccinated, to record serious health problems following vaccination in the child's medical record, to keep a permanent record of all vaccines given, including the manufacturer's name and lot number, and to report serious health problems, hospitalizations, injuries, and deaths that occur within 30 days of vaccination to a new centralized federal vaccine adverse events reporting system.

The act also directed the Institute of Medicine to conduct a review of the medical literature for scientific evidence that vaccines can cause injury and death, which resulted in four major reports by IOM to

Congress in 1991 and 1994 providing that evidence.

All through the act, the words "safety" and "safe" are repeated over and over again. There is language emphasizing prevention of vaccine reactions, such as "to make health practitioners and the public aware of potential adverse reactions and contraindications to vaccines," and "to reduce the risk of any major adverse reactions to the vaccine that may occur." All of the vaccine safety provisions are in the act because parents of vaccine-injured children insisted that any law providing liability protection must also help prevent vaccine harm.

In 1999, I gave congressional testimony outlining the reasons why parents who participated in good faith in creating the act felt betrayed by how it had been implemented. I stated, "There is bitter disappointment and pervasive unhappiness among parents and the plaintiffs bar with the current structure and administration of the Vaccine Injury Compensation Program. Public opposition to forced vaccination with multiple vaccines in the absence of adequate scientific evidence documenting vaccine safety and effectiveness is growing. When parents are unable to obtain financial assistance to care for a severely vaccine-injured child, public faith in the mass vaccination system is further eroded."

I noted that in 1989 amendments, the House of

Representatives redirected the U.S. Court of Claims to "provide for a non-adversarial, expeditious, and informal process for the resolution of petitions filed under the program," a sentiment that was reiterated in the 1989 House and Senate conferee report, which made it clear that Congress was unhappy with the claims process, how it had become complicated, time-consuming, and emotionally draining for petitioners. The report stated, "The reinvention of the adversarial process will serve neither to compensate injured children nor maintain the stability of the immunization program in the U.S."

In preparing to make this statement today, I reviewed the legislative history of the act and spoke with plaintiffs' attorneys and parents who have applied for compensation for their vaccine-injured children, as well as parents being told by pediatricians that their healthy children must get 69 doses of 16 vaccines from birth to age 18 to comply with federal recommendations and, in some states like New Jersey, are mandated to give their children three dozen doses of more than a dozen vaccines in order to attend school.

I sincerely regret having to come here today to reiterate much of what I told Congress in 1999, as well as to provide further evidence that this program is not operating in a way that lives up to the spirit and intent

of what legislators intended when parents with vaccine-injured children agreed to work on this act 25 years ago, believing the vaccine-injured and their attorneys would be treated with fairness, compassion, and goodwill in this program.

What has happened over the past two decades since the act's passage?

Although the vaccine manufacturers and pediatricians may have been primarily concerned with liability protection, while Congress was anxious to protect vaccine supply and delivery, parents in the 1980s were assured that a federal compensation system would even the playing field for vaccine victims and their attorneys. We were assured that, unlike a lawsuit in civil court, the federal compensation system would be based on the presumption that a vaccine or combination of vaccines caused the child's injury or death if no other demonstrated cause could be found. The emphasis was on "presumption," and there was a recognition that this presumption, in the absence of scientific data and certainty, would be in the plaintiff's favor, even if that presumption would result in some children being compensated who were not, in fact, vaccine-injured.

The emphasis on "presumption" was integral to the integrity of a no-fault, expedited vaccine injury

compensation system. There continues to be a lack of scientific understanding of the specific biological mechanisms involved in most vaccine-associated injuries and deaths and an absence of pathological profiles to conclusively prove which health problems following vaccination are, in fact, vaccine-induced and which are not. These gaps in scientific knowledge and uncertainty mean that a no-fault vaccine injury compensation system must err on the side of presumption of causation rather than proof of causation to offer a viable administrative alternative to a lawsuit.

Even so, the architects of the act knew the presumption could not be arbitrary, but had to be predicated on evidence that when certain signs and symptoms were present following vaccination, and those signs and symptoms were followed by permanent injury or death, the vaccine could be presumed to have played a role in the absence of a demonstrated biologically plausible alternative cause.

The mechanism to facilitate presumption agreed upon by all parties participating in the development of the act was a table of compensable events, known as the Vaccine Injury Table. This Vaccine Injury Table, devised after exhaustive review of vaccine medical literature and years of discussion with doctors, vaccine manufacturers, and

parents, was designed to remove much of the burden of proof of cause and effect that exists in an adversarial vaccine injury lawsuit in civil court.

For example, the table was intended to spell out the signs and symptoms associated with DPT vaccine-induced brain inflammation, including seizures, within 72 hours -- a DPT vaccine-induced adverse event which had been acknowledged in more than 60 years of medical literature -- in order to provide a framework to allow for a presumption of causation under the act. Therefore, the table was inserted into the law by congressional sponsors to ensure that the compensation process would remain essentially administration rather than litigious.

The reality of what has occurred during the past two decades is something quite different.

In the 1990s, DHHS chose to wield discretionary authority given under the act to change the rules and eliminate almost all on-table adverse events that would allow for presumption of causation. With the assistance of the Department of Justice, DHHS turned the administrative compensation process into a highly adversarial, lengthy, expensive, traumatic, and unfair imitation of a court trial for vaccine victims and their attorneys. The only difference is that the trial is now conducted in the U.S. Court of Claims in front of one individual who acts as

judge and jury.

Ironically, parents who helped create the act in the 1980s were told that Congress needed to grant the secretary of DHHS broad discretionary authority to alter the Vaccine Injury Table so the secretary could expand the list of presumptions for injuries associated with existing and future vaccines, to make the system more inclusive, not less inclusive. We never imagined that DHHS would take away existing presumptions from the table, because the stated purpose of the act was to err on the side of compensating potential vaccine victims in order to offer an effective alternative to vaccine injury lawsuits.

But DHHS did not just remove signs and symptoms of potential vaccine reactions from the table of compensable events. Federal health officials also used discretionary authority to arbitrarily redefine what constitutes a permanent vaccine injury. For example, DPT vaccine-induced encephalopathy, the first signs of which can be manifested by seizures, has long been recognized by the medical community. In a move to make compensation more difficult to obtain, DHHS redefined the clinical signs that have been used for more than a century to diagnose an encephalopathy.

One attorney representing vaccine-injured children in the program commented that the rewriting of the

medically recognized definition of encephalopathy by DHHS "is so restrictive that it is believed by petitioners' counsels across this country that they will never again see an injury to a child that falls within the definition's narrow confine," for the purpose of awarding uncontested compensation.

The National Vaccine Information Center has repeatedly called for DHHS, under rulemaking authority, as well as Department of Justice and U.S. Court of Claims officials, to make the federal compensation process more fair and humane for petitioners, their families, expert witnesses, and plaintiffs' attorneys. For example, DHHS has the power to add "death within 72 hours" of vaccination to the table as a presumption event.

The Department of Justice can choose to make it less traumatic for vaccine victims and their families by including in compensation awards guardianship costs, fairly calculating lost future income and expenses for housing modifications and special education, and providing mental health counseling for parents coping with their vaccine-injured child's 24-hour needs, instead of fighting most special-needs costs identified by life-care planners and doctors advising families.

The U.S. Court of Claims can make it possible for more attorneys to represent vaccine victims in the program

by awarding interim fees to plaintiffs' attorneys, a discretionary authority affirmed by the U.S. Court of Appeals in the Avera decision.

Both Justice and U.S. Court of Claims officials can refrain from trying to discredit and destroy the reputations of plaintiffs' expert witnesses in what is perceived by parent as an attempt to frighten and discourage doctors from testifying on behalf of vaccine-injured children.

What I heard most often when speaking with parents and plaintiffs' attorneys was that the compensation process is filled with a mean-spiritedness and a growing hostility on the part of DHHS, Justice, and U.S. Court of Claims officials toward plaintiffs, their families, experts, and attorneys. Whether that is true in every case I don't know, but there certainly is a sense that parents feel their children are pawns in a political tug-of-war that compels those in government responsible for administering the compensation program to protect the reputation of the current vaccine system at all costs, even if it means denying compensation to vaccine victims in order to limit the numbers of children acknowledged by government as having been harmed by vaccines being promoted by government.

In retrospect, the fact that Congress made DHHS

and Justice, two government agencies opposed to passage of the act, responsible for making the act work is perhaps its greatest operational flaw.

What are other signs that obtaining federal compensation has become a highly adversarial, time-consuming process and that the act does not do what Congress intended it to do?

In 1986, federal health officials recommended that 23 doses of seven vaccines be given to children from two months to six years of age, and most of these were mandated by states. The act, in fact, was supposed to protect the supply of those seven vaccines for tetanus, diphtheria, pertussis, polio, measles, mumps, and rubella. Since then, 46 doses of nine new vaccines have been added to the CDC-recommended schedule for girls, 43 doses of eight new vaccines for boys, and many state health departments have either mandated most of them or are in the process of mandating them. Today there are twice as many opportunities for vaccine injury or death during childhood than before the act was passed more than two decades ago.

But with this increased vaccine adverse event risk exposure, what has been done to minimize increased vaccine risks and also to fairly compensate those injured by one or more of the new vaccines?

DHHS has recommended every one of the nine new

vaccines for universal use, which allows all nine to be added to the compensation program. This gives automatic liability protection to the drug companies marketing these nine new vaccines, as well as to all doctors administering them.

When parents look at the table of compensable events, what do they see? They see that no signs, symptoms, or injuries have been added to the table for these nine new vaccines, except anaphylaxis within four hours for hepatitis B vaccine. They see that if their child is injured or dies after getting one of these vaccines, they are in for a long, hard fight to obtain federal compensation in the U.S. Court of Claims. When they check out the statistics on the HRSA Web site, they found out that two out of three individuals applying for vaccine injury compensation have been turned away empty-handed, even though to date about \$1.8 billion has been awarded to more than 2,200 plaintiffs out of some 12,000 who have applied. They learn that nearly 5,000 of the vaccine injury claims are sitting in limbo because they represent children who suffered brain and immune system dysfunction after vaccination, but have been diagnosed with regressive autism, which is not listed in the table of compensable events. Yet there is \$2.7 billion sitting unawarded in the trust fund, and people suggesting all

sorts of ways to use that money for all sorts of reasons other than for compensating vaccine victims.

The fact that the compensation program is not working the way parents were promised it would work and that Congress intended it to work is also demonstrated by the fact that parents of vaccine-injured children and their attorneys have been forced to seek justice in the civil courts. In a series of federal court cases beginning with the 1996 U.S. Supreme Court case *Margaret Whitecotton v. Secretary of Health and Human Services*, the judicial system has reminded DHHS, Justice, and the U.S. Court of Claims that Congress intended the compensation program to be an "expeditious, just, and non-adversarial" alternative to a lawsuit.

In the landmark 2005 *Althen* case, the Court of Appeals for the Federal Circuit affirmed that the burden of proof for vaccine victims filing under the act should be lessened. The court made it clear that a person need only show a vaccine was the likely cause of the injury and that experts presenting evidence in favor of compensating the vaccine victim can base their opinions on circumstantial evidence rather than conclusive scientific evidence.

In the 2006 *Capizzano* case, the Federal Court of Appeals held once again that the petitioner does not need to present peer-reviewed scientific literature proving

causation, but need only provide a medical theory linking an injury to the vaccine, a logical sequence of cause and effect, and a temporal relationship between them as evidence by medical records or expert opinion, especially the opinion of doctors who have treated the child.

After two decades, the federal courts are speaking, and importantly, judges are looking back at the legislative history which so clearly affirms the intent of Congress when creating the act. In a Supreme Court of Georgia ruling on October 6, 2008, in *American Home Products v. Ferrari*, the justices unanimously held that the National Childhood Vaccine Injury Act does not give a vaccine manufacturer blanket immunity from vaccine injury lawsuits if it can be proven that the company could have made a safer vaccine.

Georgia Supreme Court Justice George Carley wrote that the 1986 law and "the congressional intent behind it shows that the Vaccine Act did not preempt all design defect claims." He added that Congress did not "use language which indicates that use of the compensation system is mandatory," but only "an appealing alternative" to the courts. He wrote that there is no evidence that "FDA approval alone renders a vaccine unavoidably safe," and said, "We hesitate to hold that a manufacturer is excused from making changes it knows will improve its

product merely because an older, more dangerous version received FDA approval," adding that to do so would have the perverse effect of granting complete immunity from liability to an entire industry. He concluded that "in the absence of any clear and manifest congressional purpose to achieve that result, we must reject such a far-reaching interpretation."

Judge Carley got it exactly right. There was no intent by Congress in 1986 to totally remove all liability from drug companies marketing vaccines for injuries and deaths caused by those vaccines. There was no intent by Congress to put a law in place that would absolve federal agencies from their responsibility to ensure that vaccines and vaccine policies are necessary, safe, and effective. That is because Congress did not just want to protect the vaccine supply. The lawmakers also agreed with parents of vaccine-injured children that everything possible must be done to make vaccines and vaccine policies safer to minimize vaccine injuries and deaths.

In the opening Section 2101 of the act, which established a National Vaccine Program, there is a clear statement of purpose, which is "to achieve optimal prevention of human infectious diseases through immunization and to achieve optimal prevention against adverse reactions to vaccines." Under this section, there

is a subsection entitled "Evaluating the Need for and the Effectiveness and Adverse Effects of Vaccines and Immunization Activities," which acknowledges that there was no *a priori* assumption on the part of lawmakers that every vaccine industry produces is an automatic candidate for a universal-use recommendation by the CDC and inclusion under the act for the purpose of liability protection.

Section 2127 of the act is entitled "Mandate for Safer Childhood Vaccines," and it directs DHHS to "promote the development of childhood vaccines that result in fewer and less serious adverse reactions than those vaccines on the market" and "to make or assure improvement with respect to the licensing, manufacturing, processing, testing, labeling, warning, use instructions, distribution, storage, administration, field surveillance, adverse reaction reporting, and recall of reactogenic lots of batches of vaccines and research on vaccines in order to reduce the risks of adverse reactions to vaccines."

While this language, which was included at the request of parents of vaccine-injured children, does not address responsibilities of this commission in providing oversight on the implementation of the act's compensation mechanism, this commission was charged under the act with advising the secretary, in implementing responsibilities under Sections 2125 and 2127, about the need for childhood

vaccination products that result in fewer or no significant adverse reactions, gathering information on adverse reaction reporting requirements, and obtaining, compiling, publishing, and using credible data related to the frequency and severity of adverse reactions associated with childhood vaccines.

There is enough blame to go around when looking at why the 1986 National Childhood Vaccine Injury Act has not lived up to the spirit and intent that prompted the 99th Congress to work so hard to create and pass it. Congress itself walked away from providing oversight after the 1989 amendments were passed, even though sporadic attempts have been made in the House and Senate, in bills that sought to address substantive issues such as extending the statute of limitations and increasing the \$250,000 death benefit and pain and suffering limit.

There is little that can be done to recapture a dream of justice that has turned into a nightmare for thousands of families with vaccine-injured children who have been denied federal compensation while vaccine manufacturers and doctors have enjoyed unprecedented liability protection for the past two decades. That liability protection has made it easy for four dozen doses of nine new vaccines to be added to the childhood vaccine schedule, some of them fast-tracked, without any studies

being conducted to evaluate the potential long-term adverse health effects of giving children an unprecedented number of vaccines throughout childhood. That liability protection has made it easy for CDC and AAP to narrow contraindications to vaccination so severely that almost no health condition qualifies as a reason not to vaccinate, placing many more vulnerable children at higher risk for suffering vaccine reactions that are often dismissed by pediatricians and government health officials alike as a coincidence. It is no wonder that estimates for reporting of vaccine-associated health problems, hospitalizations, injuries, and deaths by vaccine providers to the VAERS system is only between 1 and 10 percent.

The fact that unprecedented numbers of highly vaccinated children are now suffering from chronic disease and disability compared to a quarter-century ago calls into question the wisdom of the act, which has made it easier for industry to rush to market new vaccines that government officials mandate, while shielding vaccine makers and providers from liability for any harm that is done. The fact that there has been no attention paid by industry and government to minimizing vaccine risks, including no scientific research, as the act called for, into identifying individuals at high risk for suffering vaccine adverse responses so their lives can be spared, speaks

volumes about the disconnect between the intent of Congress to prevent vaccine injuries and deaths and the intent of those operating the federal compensation system to deny they exist.

For this reason, many parents I have spoken with maintain that the vaccine injury compensation system is a failed experiment in tort reform that should be repealed. They believe the vaccine-injured should be able to return to the courts, where discovery is allowed, to sue vaccine manufacturers for design defect and failure to warn, and sue pediatricians who carelessly implement one-size-fits-all vaccine policies rather than adhere to the precautionary principle to, "First, do no harm."

The decision of whether or not the Vaccine Injury Compensation Program is worth saving belongs to the smart, vaccine-educated parents with young children today, who you will be hearing from as they stand up in greater numbers across this country for the legal right to make informed, voluntary vaccine decisions for their children. I promise you, they will not wait another quarter-century for those of you operating this program to do what you were supposed to do a long, long time ago.

The National Vaccine Information Center will continue to inform and educate the public and legislators about the history of the National Childhood Vaccine Injury

Act of 1986 and why safety, not liability protection, must always come first in America's public health programs.

MR. SCONYERS: Thank you very much for taking the time.

Before I see if there are questions for you, would it be possible to get a copy of your remarks?

MS. FISHER: I have 10 copies to give out.

MR. SCONYERS: You obviously spent a great deal of time preparing them. If we could get that, that would be great.

Are there questions for Ms. Fisher?

MS. GALLAGHER: I'm Charlene Gallagher, and I'm the representative of the vaccine manufacturers on the committee. I want to thank you very much for your remarks and for accepting the invitation.

I must say that much of what you said I don't disagree with. I think that ultimately I reach a different conclusion than you do about whether we should continue to try to move forward with this program. I am reaching out to you now to say, what do you think we can do to make the program more effective? If there is a will to really move forward with what we have and do good for parents and children, tell me what you think would be effective.

MS. FISHER: I have gone over a lot of the issues in this statement. The 1999 statement I made to Congress

is something I also certainly could make available to the commission to look at.

In addition to what I said here, there were very specific things that we had been asking for, for a long, long time.

I'm glad to hear that you, representing manufacturers, feel this way. I remember about 10 years -- I don't remember exactly; maybe it was seven years ago -- I came to a meeting where the manufacturer representative said, "The way we do business in this country is, we fight about it," and was not supportive in any way of having this program be administered in a non-adversarial way.

I think, as I said in here, of all the comments that struck me the most when I was talking with parents and the plaintiffs' lawyers was the feeling that they were being victimized a second time, the families, and really felt very distressed with the way this process worked.

I don't have young children anymore. My children are grown. It's up to the parents of this country who have young children who are being mandated to take all of these new vaccines to decide whether or not they want this program, or whether they are going to go to their legislators and press for a repeal of this program, so that they can go back to the courts. I felt it was my responsibility, as the head of the National Vaccine

Information Center, because we represent at this point vaccine victims that go from infancy to adulthood, to lay out what our concerns are.

As I said, I would be happy to provide you also with my 1999 statement.

MS. GALLAGHER: Thank you very much. As a commission, we have been exploring ways to improve what is happening under the act. We are very open-minded about hearing from all sides. We thank you for your views. We know there are other views, but we respect everybody's opinion about what we can do moving forward.

MS. FISHER: Thank you.

MR. SCONYERS: Thank you very much.

Our next speaker is Dr. Jackie Noyes. I'm going to ask Dr. Evans to introduce her.

DR. EVANS: It's my pleasure to introduce Jackie Noyes, who is known to many of us. Jackie has been for many years the head of the Washington office of the American Academy of Pediatrics and, just as importantly, was a member of the commission and chair of the Advisory Commission on Childhood Vaccines within the past decade -- so not too long ago. At that time there was a fair amount of legislation that was being introduced, and Jackie was certainly very helpful to the commission in terms of understanding that and having votes on those important

bills.

Jackie, please.

DR. NOYES: Good morning. Happy anniversary. A very landmark time.

Rather than going back and trying to look at the past, I'm going to give you just a little brief history of how we got to where we are, what kinds of bases we need to touch to move forward and some things that we might do in the future. The past is the past and the future is the future. It's kind of a different presentation here.

You all provide a very important public service. You are trying to balance public health with vaccine safety. It's a very precarious tightrope that you walk. But I think this is the body to do it. I think you have the right people around the table to do it. I think you have the right voices around the table. I wish you good luck and goodwill as you move forward in this task.

The academy got interested in vaccine injury compensation 14 years ago. That was a time when there were a lot more producers of vaccine in the market. There were actually seven producers of a DPT vaccine, three producers of oral polio, and six producers of measles.

The prices, just for historical fact: DPT was 19 cents a dose, polio was \$1.16 a dose, and measles was \$6.81. So there you go. Look where we have come.

We had a hard time getting off the ground. We were mostly talking to ourselves. We were talking to government. We were talking to a lot of different people. But there really was not an impetus to do something about this issue until the *Reyes v. Wyeth* case in 1974, which was a polio case where a child contracted polio after receiving polio vaccine. This was really a wakeup call to a lot of people in the country about who was responsible for what. The court did hold that Wyeth had a duty to warn, with the vaccine, that the disease could be contracted from the vaccine. While it was actually found that the child was exposed to a wild poliovirus, the court still held.

So there was a lot of angst in the public health community about where we go from here and how this was going to work.

In 1975, the academy actually called for a vaccine injury compensation system, similar to the ones that the European countries already had. This was not a new idea for America. We were looking at what other people had and tried.

Then came the swine flu epidemic in 1976, where the federal government immediately assumed liability for the administration of swine flu. It kind of became a no-fault compensation system, if you will, on its own. There was lots of angst around that and how that worked.

In 1977, the secretary of health and human services undertook a national immunization initiative. At that time, the immunization rates in this country were about 65 percent, which the medical community felt was unacceptable. There was a lot of pressure on states to enforce having children immunized at school entry. That seemed to be a good point to do that. But this was a time that a strong federal role was established in the administration of vaccines. They did call for the creation of a no-fault compensation system, not yet formed. But again, if the government was going to require, state and federal governments -- these are state laws -- that children be immunized, should there be an untoward action, should the state and federal government have responsibility for that?

But the experience with the swine flu kind of put a damper on trying to build consensus around what to do. It was kind of at odds there.

We kept pressing and pressing and asking and talking and visiting and writing letters, et cetera. Congress called for an Office of Technology report to look at what the elements would be for a vaccine compensation system and actually agreed that we should move forward with something like that.

In 1982, there was a TV documentary, *Vaccine*

Roulette, which focused on the pertussis vaccine and got the public more engaged. Congress got engaged. They wanted to solve this problem and to satisfy parents. That group really came to the fore, I think, in that period, although they had been loosely formed before then. So the academy decided that we needed to work together to get the thing done, and we sat down with the dissatisfied parents' group, working together with industry, at least initially, to agree on bill components for the first billion that was introduced in 1984. It was introduced by Paula Hawkins from Florida and Henry Waxman from California.

We went to the chairman, Chairman Hatch, to see if he would take this on, because we thought it was so important. But Paula Hawkins was a new shining star from Florida and he wanted to give her something important to do and was right behind her the whole way. He's still very supportive of this program.

In the meantime, there were more suits coming against manufacturers. A lot of manufacturers were dropping out of the market. The prices were going up to cover the litigation costs. So the pressure, grassroots up, was beginning to build.

Congress adjourned in 1984 without passing all of our hard work together. And we were really all together on that first bill -- lots of discussions, lots of

negotiations. But we pretty much held together, if you can believe it, everybody kind of on the same page -- it doesn't always happen in Washington, but we were -- to get that bill through.

Well, if it dies in one Congress, you have to start over in the next, which we did. So in the 99th Congress, we were right back, with the same sponsors, out early, to get this bill through -- more hearings, more discussions, more letters, the whole nine yards. It got right to the end of Congress, and we realized during this period that the surcharge that was going to fund the trust fund had not gone through the Ways and Means Committee. They had to add that. It got to the 11th hour and there was no time for a hearing to add the surcharge. So we decided that the best course would be to drop the funding mechanism and just pass the bill, get it through. In fact, it was the last item that passed the 99th Congress, at the 11th hour.

There was a really funny story on this. It was just sitting; it was stalling. There were some concerns at that time, by the manufacturers, by the parents, by others, on some different components of it. Strom Thurmond was sitting on it. He was sitting in the chair. He was ruling the Senate. We couldn't get him to let it go. One person can hold a bill.

Finally, we got to Nancy Thurmond, who sent a note down to her husband in the chair. Somebody walked in and handed it to the senator, saying, "If you expect any loving tonight, you're going to let this bill go."

So this had kind of a sordid history, if you will, but it did pass. It was signed into law by President Ronald Reagan.

In the 100th Congress, we came back to get the surcharge added. At that point, the manufacturers were protected from liability, the no-fault system, in this bill that passed, but vaccine administrators were not. That was left out. So they were added in the second go-round. This was also the time that we added the surcharges to the vaccine. The first surcharges for DPT were \$4.56, MMR was \$4.44, and oral polio was 29 cents.

Geoff, you'll have to tell me how all that came together, those specific amounts. Anyway, that's where we were.

This law also put burdens on -- not burdens, but sometimes they seemed like burdens -- on the vaccine administrators to record the manufacturer and lot number of each dose of vaccine and to report major reactions, which is now into the so-called VAER system, which seems to be working very well from what we can see. It also created the National Vaccine Advisory Committee and this committee.

NVAC was started first; this was started later. Since we didn't have our funding, it really wasn't -- it was approved but funded kind of programs, moving forward.

As Barbara mentioned, our intent all along, by our then-president Dr. Martin Smith from Georgia, was to secure a better and simpler form of justice for children -- We did not think the tort system was serving families well -- as well as to ensure a more secure vaccine supply -- again, that balance between public health and safety.

You go out with a program the first time and you have to get the bugs out. There were a lot of issues we got out with more experience. We were very naïve. We went strictly for a non-adversarial program. We thought that the surcharge on vaccines would just be a couple of pennies and it would fund the trust fund. That didn't seem to work out, as we came to find out. We didn't know that the federal government takes 25 percent off the top of the trust fund. I don't know whether you know that or not. That goes into the general funds. They do that with all trust funds. That was just a little glitch that we did not know. So you are contributing to paying down the debt with the money that you collect in that trust fund.

Then we knew we had to make sure that the trust fund was secure. There had to be enough money in it to

make sure that people did not feel it was going to go dry if a lot of suits came in and they couldn't pay those. So we had to make good on that promise.

1989 was the first time we were successful in getting some amendments to the program. We tried again in 2001 and 2002, as Geoff indicated. A lot more things came to bear that we knew needed to be included in here. We were looking specifically at, one, the table, which was outmoded. All the cases coming into the program were off-table, which made it very complicated. No one really knew the rules. People were gaming the justice system -- "this special master is more lenient; I hope we get that one."

So it was, again, trying to look for some stability, some fairness in the program. But we did not have a new table to bring up. We just had to depend on the Institute of Medicine reports, et cetera, looking into how we could make the table tighter so we would avoid the adversarial system.

We were looking at payment structures for parents. Barbara mentioned those. They hadn't been increased since we started. We were looking at the death benefit, looking at what it cost to set up an annuity. That was a very tedious process, a nice process for families, establishing guardianships, lifetime planning, those kinds of things. We put those costs in.

The amendments did not go through. Senator Frist had that bill, trying to carry that through.

Looking at pain and suffering payment for parents was a new concept that came in. That was not discussed the first time through. There was a flat payment in there for that.

So we had a nice package going through. Frist agreed to carry it. Due to some glitches and some people getting a little greedy about trying to push some amendments out -- since we weren't going to get through Congress, it got pulled back. One of his staffers went to HHS, so we thought we had a good agreement to pick it up and move it again. But because of a whole bunch of other kinds of controversial things on the floor, we just couldn't get the attention of HHS or the Congress to move another package of amendments. As far as I know, they are still sitting waiting to go.

The concepts, things that we discussed -- when I was chair, we were doing a lot of legislative work. We had very detailed meetings. We had good advice from staff on the legality of where we were, what we could do. We had some really good private discussions in between meetings, back and forth, on how we could make this program better.

I think the intent was always to make it work, to make it work for parents, to make it work for vaccine

administrators, to make it work for manufacturers to an extent. It never was the intent to work for lawyers. There was a bill cap on lawyers as it went through. They didn't want this to be a boondoggle for lawyers. But as we came to find out, there were a lot more expenses as this program got more adversarial, and so there were some interim payment provisions in the Frist package that did not pass that we had looked at -- again, trying to balance this out the best we could to look at the things that people were bringing to our attention that made sense that we could work on.

You still have in Congress the champion of this bill, Henry Waxman, who may be chairing the health committee. That's a big fight right now. We'll see how that works. But at any rate, he has some institutional memory. Senator Hatch, on the Senate side, has institutional memory on this issue, what the intent was, where it was going.

I think it is due for a tune-up. I think we need to look at some things that we didn't through before. I'm sure there are more things that have come to the attention of the commission since we had that last detailed look at what we needed to do to the program.

One thing we learned the first time was that there was not a really good media campaign on the program

either. I think a lot of people did not find out that the program existed, even though in our own little worlds we thought, everybody knows about this. Not true. I think we are learning more and more with any piece of legislation that we are trying to move that you really have to have a good media campaign out there to explain what's going on. You have to have a good Web site now to make sure the information -- people have questions, they can find there -- so that the information is pretty much transparent and you can get what you need.

So I would recommend that. We didn't have money for a big media campaign, but there was a lot of information put out in public health clinics, et cetera. But if you didn't happen to be there or there were too many people in there, you didn't get a chance to read it.

There were some brochures that were given out. The academy made up some that we gave to pediatricians to give out. But it was not a concerted effort. I think that's one of the things that we need right now, to look at both the vaccine safety issue and the compensation system and how that works. There has not been a good campaign on that.

There was a lot of confusion, I think, with how the court system was working. I think Gary Golkiewicz has made a good effort to have these meetings or work sessions

that he is having that you all are going to tomorrow, to bring the plaintiffs' lawyers in, to talk about this, how this is working -- how you play the game, really. I think there is a lot of mystery out there on how you do it and where you do it.

I think the academy is as concerned as Barbara is with all the costs of the expert witnesses back and forth and where you are going. It was not the intent to have an adversarial system.

How we fix that is a different question. Again, we wanted a simple system that would be better than the tort system for families. For many families, at least at the time that we started, you could be in court, but it was eight to 10 years before you get a decision. You get one decision, then it would be appealed, and then that would be appealed, and you just kept going up the ladder. So that didn't seem to be the right way to go.

I had a call from someone in Canada who called to get some information on -- they wanted to set up a vaccine compensation system. They don't have one. They were trying to get some information, some history -- what would you suggest to do different, that kind of stuff. We were talking, and I asked her how many adverse cases they had in Canada that they were working on, and she said five. I said, "Five?" And she said, "Yes."

But again, they are looking at the United States. They are looking at the 5,000 autism cases that are being held there. They are concerned that they are going to have the same kind of problem.

But she said, "One of the reasons that I think we don't have as many court cases is that we have universal health care." There are health services out there at no cost or very low cost to families if they need it. We have for families -- it gets expensive cases -- we don't have that kind of stuff. We may in this next administration, but for a lot of families there is nowhere to go if this is the situation you find yourself in.

So again, just a little different balance, back and forth. There may be more in Canada. I haven't talked to them in about four months -- at any rate, going that route.

But I think it's always hard when you are -- I think this is a landmark bill. From the academy's standpoint, it has been a successful bill. Without it, I don't know whether we would have any kind of childhood immunization program in existence today. The needs that we had to meet at that time I think we met. But that doesn't mean that we have a perfect bill. No piece of legislation is perfect. I think what we haven't had in these last few years is an opportunity -- not because we haven't tried,

but we just haven't gotten the secretary, whom you report to, to say, "I want these changes," and send up this package.

I think there needs to be a concerted effort now to educate the new secretary coming in. We have a new slate. We have a new Congress. We have a new secretary. Hopefully, this secretary will be more interested in these kinds of issues. We have a good chance to put these together. There will be more open meetings where we can talk about how we create a system that will fix, or at least try to fix -- ameliorate the concerns that Barbara raised, that people with this program. If they don't trust it, then we have a problem. We have to do something to get that trust. I think that involves a good media campaign, good discussion by people around the table, good discussion at different meetings where you can bring in different people and get that kind of information out there. I think it's past time to get that done, and that's where I would go.

I'm going to stop there and see if you all have any questions. We tried diligently to get these amendments through. We didn't always agree around the table on our decision, but we reported to the secretary what our vote was: It was 4-to-3 that this happened. It was unanimous that this happened. That was due to the good staff I'm

seeing sitting back in the room that kept me on the straight-and-narrow on that, that we reported every decision that we voted on, so they could see that this was on the table. It may not have passed, or maybe did -- so that they would know that. Again, the attempt was made to educate.

Members of Congress received those letters after the secretary did so they would circulate on Capitol Hill, so they knew what we were talking about -- again, just trying to keep the issue in front of folks. Once you lose the issue, it's hard to get it back on the table. I don't think you have any problems now with these kinds of issues on vaccine safety. The issue is out there. What we need to find is a way to do better with answering those questions, getting information out, and have a system that people can trust again.

From the academy's point, we really, as I say, find this a very successful program. It is the only no-fault system in the government, as far as I know. It recognizes -- trying to balance the issues out there, which we balance on the side of public health.

I guess one other thing we thought about, too, doing that we did not establish here -- there were some technicalities to it, but I think we can get around them. The CDC monies on vaccine safety have been drying up over

the last few years. The thought was, if the trust fund was solvent and if we put a stopgap in there -- such as, if it got to such-and-such a level, this would stop -- divert maybe 5 cents or 10 cents into vaccine safety. That seemed to be consistent with the intent of the law. It would be another pot of money where more studies could be done.

That was just a thought. I'll just throw it out for you all to maybe think about it later. I know we have some technicalities, but -- it would require an act of Congress. You couldn't do it yourself. But that would be a diversion to find at least some monies without people sticking their hands in your trust fund, trying to take it and do something else with it, if you had a real reason where you wanted to go.

You are up to, what, \$2 billion in the trust fund?

PARTICIPANT: \$2.9 billion.

DR. NOYES: As I say, again, I don't think the signal should be that we are taking money out of the trust fund, because I think it's a bad signal to parents. But if you had a stopgap -- if we get below \$1 billion or whatever, then we don't take out that nickel or whatever and move it to the other side -- that would generate a lot of lost dollars that the CDC does not have currently for safety studies.

So that's another idea.

MR. SCONYERS: Thank you very much.

Are there questions for Dr. Noyes?

DR. HERR: Thank you, Jackie, for coming to talk to us.

Obviously, we have work for us and future commissions trying to make this program and ensure the public trust. The question, though, is that we probably need to go and work on things that we have already tried to work on in the past. What sorts of efforts do we have planned to try to implement or execute some of the changes we have recommended for the secretary to present and for Congress to effect?

DR. NOYES: I would start with the ones that this commission passed back in 2000-2001. We had three different letters that went up with recommendations. They may not still be relevant. I haven't gone back and really looked at them -- I just kind of scanned them before I came here -- to see if they are relevant. But you all need to look at them again, so that you put your stamp of approval on them, back and forth.

Then there are probably twice as many recommendations that you should also take forward at the same time, since we really haven't looked at it since then and a lot more information is out there and a lot more

concerns have been raised.

So part of it is within your scope; part of it is not within your scope. It doesn't mean you can't write -- your job is to recommend to the secretary different actions. If it doesn't fall within your purview, you can also suggest to the secretary that this pressure be brought on this department or that department or something else.

The beauty of the ACCV is that you do report to the secretary of health and human services. NVAC reports to the assistant secretary. You go right to the top. I don't know how we lucked out in the design here, but that's the right place to go, because sometimes things get lost in the shuffle.

But at least you have a base to start from. Some of those are minor amendments as far as cost goes. We thought they would just breeze through. But at the time when they were getting ready to go to the floor, we were again at crunch time, and somebody tried to move part of the bill without the whole bill, and it failed. Congress just got a sour taste in its mouth for the way that was handled and wouldn't pick it up again.

I can tell you offline how that exactly happened, but I'm not going to go into that kind of detail.

It was a concerted effort to really put some more positive things into the system, and we just didn't get it

through.

DR. HERR: With your legislative experience, do you recommend that we wait until we discuss some of the other things that we would like to add to that, which may take a little bit more time, or get the Congress up and going when they first come back, with what we have already presented?

DR. NOYES: I think maybe at the end of this meeting, with the rest of some of your agenda items, you could write a congratulatory letter to whoever the secretary is going to be. We will know that probably before January. It has to go through a confirmation process. Get something ready to go early, maybe after your next meeting, to flag this for the secretary: "We look forward to working with you. We have some concerns we would like you to send up early for a legislative package. We would like the opportunity to work with you on that" -- just a very brief letter, so you get it on the agenda. Then you can spend more time as you flesh out some of these things.

Or you could attach the letters, if you still feel those are good -- but it doesn't have your stamp on it. That's old. You could say, "We concur with the recommendations," or, "We don't concur. We pick these out," just flag some of this stuff.

Then this can start moving and get on the secretary's agenda early. They start fresh. When the old secretary leaves, all the files leave, everything else. But the guts of HHS stays there with people that probably will be there for transitional stuff.

But I would get it up there early.

MR. SCONYERS: I would like to remind everybody that we distributed at our September meeting -- you should have a CD of all the comment letters that the commission has ever submitted since its origin, including the ones that Jackie is talking about, the ones from the Frist bill. If you want to go back and take a look at that -- I don't know if anybody brought it with you -- you should have it and you can see the comments that have been made.

I also remind you that our next meeting is scheduled for early March, which will be very shortly after the new Congress and new administration take office. So we are in a position to, if the members so choose, move forward very early in the process.

MS. HOIBERG: I just wanted to make a comment. You mentioned testing the safety of vaccines and possibly using part of the trust fund for that. As a parent of a vaccine-injured child, I would have to say, hands off. That's not what that money is for. That money is to compensate. We really shouldn't have that much money in

the trust fund because we should be compensating many, many more children. So I would say, absolutely not. Don't touch that money for that. That's not what it's more.

That's all I have to say about that.

DR. NOYES: We have heard that argument before, which is why it hasn't been touched before. I just throw it out. At CDC, again, we are in a very tight budget crunch right now. If people want the safety studies to be done, we are going to have to find a resource for those to be done, or they are not going to get done to the extent that you want them to.

I appreciate exactly what you are saying. That's why I put the stopgap measure in there. You want to make sure that you have this much money. Congress can always increase the surcharge if they need to build it back up. But it's just looking for the information everybody wants to have. That is just trying to be creative.

Dollars in this budget are very, very, very tight. It's going to be dog-eat-dog out there for extra dollars, and it's not going to be pretty. I think we could be looking at 15 percent across-the-board cuts in most of the programs that we love and care about. One of the things I worry about is the staff for this program and the special masters, et cetera, making sure that we have enough, so that the system doesn't clog because you don't

have enough staff.

Geoff says I'm not supposed to say that, but I have to say that anyway. Nothing runs well without staff behind it. I think in this instance we don't want to lose two or three special masters. We don't want to lose staff, because we can't keep moving forward.

So I think flagging this program early with the secretary -- if you believe it's important. I believe it's important. If you don't believe that, then you can do something else -- so that it gets on the radar screen, so that they are looking for something like this and the new legislative people are attuned to this, so that they can help push this forward on the Congress.

DR. SALMON: Dan Salmon, from the National Vaccine Program Office.

I can just share with you that we briefed Secretary Leavitt on vaccine safety last week, and he made it clear that it's his intent to transmit to the new secretary that vaccine safety is a high priority in his eyes. I think that will, hopefully, be conveyed to the next secretary in the next administration and perhaps open the door for recommendations in that area.

DR. NOYES: Or maybe not. They may just say, "Well, you did it. I'm not going to do it."

Again, if you all want to weigh in and flag it

early, I would suggest doing that, because that is your responsibility, to advise the secretary on that.

MS. GALLAGHER: I just want to thank you personally for coming and sharing your views. I especially appreciate your views on and your insights into how to effectuate the changes that we are looking for. Perhaps we can call on you in the future for some of your insights, because it sounds as though you kind of know your way around Congress and the secretary.

DR. NOYES: That part I know -- no restrictions on me. I'm just in this chair. We're different. But I think I -- but we had some really good discussions. We had some good people come in and some very good discussions. I think that was helpful for all of us. We went through legislation line by line, and good presentations by staff on comparing what we needed, where we have come. We saw how that was moving forward.

I think it's difficult for all of us to get our hands around everything that we want to get done. We have to look at what's practical and start with step one and then step two and step three.

But with the things that you have, most of these things that cost money will be coming out of the comp system, more support for families that will go into the awards. So you don't have to have a fiscal note, exactly,

for that. But if you need 10 more special masters or something like that, that's a whole different ballgame.

Again, as I say, as you sit down and look at those things, staff can give you some really good side-by-sides on how that looks. And they actually put it in English so you understand it, for those of us that aren't lawyers, so you can follow along with what it does.

The rooms were filled with people from the outside, really good public discussions, too. So it was trying to bring all that stuff down, good questions.

But again, at the end, you usually come up with some sort of a compromise that works. That's what we started with initially on the bill. Compromise is really the name of the game. That's why discussion is so important, to keep it moving.

I do see that as a role of this commission, that you need to be active, you need to be advisory to the secretary and get this stuff out there, rather than just, again -- but don't forget the media part. Don't forget the educational part on the outside for the public, because I think that's a key piece that we did not do well on as we started.

The secretary has a huge budget for PR kinds of activities. We just didn't get our stuff out there on the agenda for that. So that's another pot you could put your

hand in and use efficiently, I think, if you have some ideas on how that might go better. There are a lot of questions out there on vaccine safety and we need to get the information out there to people that need it.

MR. SCONYERS: Thank you very much for taking the time to come and talk with us.

DR. NOYES: I wish you good luck. I know you are going to do a fantastic job. If I can be of any help, I would be happy to. Thank you.

MR. SCONYERS: Thank you.

We are going to turn to our own member, Sherry Drew, who is the commission member representing the petitioners bar, for her to speak from the perspective of the petitioners bar on the current operation of the program.

MS. DREW: Good morning. My name is Sherry Drew. I'm a member of this commission. I have been asked to address you from the perspective of an attorney who represents petitioners.

I thought about that, and I think, as a lawyer, I need to start out with a couple of disclaimers.

First, I'm not going to try to generalize about how all of the petitioners' counsels think, because I don't always know how their lawyers think.

Second, there are ethical and practical

considerations with sharing some of my thoughts and experiences with you. So I'm not going to tell you everything that I think.

But what I want to tell you is how I feel about what I do and tell you some of my experiences and to try to make this something more personal than what has been said so far.

I believe this advisory commission has heard through the years, and as recently as a few minutes ago, many of the complaints of petitioners' attorneys, or at least as many as they choose to put on public record. I'm not going to enumerate all of the difficulties and frustrations of working within the system, because this commission has heard that before. Barbara Loe Fisher did an excellent job of enumerating a lot of the problems, so there is not really much point in me running through the various things that I know this commission has made recommendations to correct.

What I would like you to understand, though, is that for my clients, for my petitioners, and for me -- and this is more than just vicarious -- this whole vaccine process is intense, painful, extremely personal, and nothing that any of my clients ever bargained for. I'm sure that the parent representatives on this commission can verify that these are very difficult cases for the

petitioners and for their lawyers.

I know that the Justice Department attorneys take their cases seriously, but I would guess that after a few years they realize, as I did after doing insurance defense work for years, that they win and they lose some, and there is a certain amount of luck involved in any kind of trial. For them, it all averages out for their one single client. But that's not the case for my clients. If my clients lose, they lose, period. Sadly, even before they start, they have already lost something they value. They have lost a child, they have lost a child's health, or they have lost their own health. So they are starting from a very sad underdog sort of position.

For the most part, I think petitioners learn about the Vaccine Act only after there is an actual injury. Sometimes it's a catastrophic one. The existence of the Vaccine Act, in my opinion, probably played no part in most of their decisions to consent to vaccination. Usually, for instance they doubt vaccine safety, it's not the Vaccine Act that convinces people to let their child be vaccinated. What finally convinces them is that their child is not going to be allowed in school with vaccines. So they consent, and occasionally, unfortunately, there is a catastrophic injury.

As far as I know, none of my particular clients

ever said, "Okay, I'll let my kid be vaccinated," or, "I'll get that flu vaccine myself, because I know for sure that if anything goes wrong with the shot, my government will take care of the problem and make things right for us." Instead, they learn after the fact about the act, even about the existence of vaccine injury. Many of them don't have a clue that there could be any problem, other than maybe a sore arm or a temperature later.

After there is an injury, many of them go to the Internet. They learn about the Vaccine Act. They feel better, and they expect too much from the act. Several times a month, I would say, it is my sad responsibility to take phone calls from hopeful people and tell them that they don't have a case. Frequently, the three-year statute of limitations has already run by the time they call me. My first question to them is, how did this happen? Frankly, if it happened more than three years ago, there is not really a lot of point in my discussing it any further with them. I tell them that their only chance of change is legislative and they should contact their congress people. But there is nothing that can be done for them from a legal perspective unless there is a change in the law.

I want to step back a little and give you a little history.

I have been involved, at least peripherally, with

vaccine injuries since the early 1980s, which was well before the inception of the Vaccine Act. Back then there were lawsuits. Plaintiffs' lawyers were able to engage in discovery with pharmaceutical companies. I think legal discovery with the pharmaceutical companies, and even sometimes with the doctors who administered the vaccine, by the plaintiffs' lawyers was a really valuable service that has been eliminated by the Vaccine Act, sometimes to the detriment of the public. That's an unfortunate compromise. Legal discovery, I believe, back before the act, uncovered hot lots of vaccines, put the term "hot lot" in the public ear, and in one case that I'm aware of, actually put a drug-addicted doctor who gave a child with a past record of seizures more vaccines and contributed to a real sad decline in the child -- it's a good thing that doctor was put out of business, because there were other children whose lives were probably saved by that.

The firm that I worked for on a part-time basis during the 1980s, when my own children were small, was instrumental in the drafting of the Vaccine Act. At the time, we understood, as Barbara Fisher has told you, that this was a compromise and it was designed to both provide a fair and sure path to recovery for injured children and to protect the vaccine supply.

Back in 1991, I joined the firm full-time. I

took on about 100 vaccine cases that were resolved over the next 10 years. Most of the cases were the pre-act cases that allowed only a combined total of \$30,000 for attorney's fees and costs and pain and suffering, and provided no future lost wages for the child.

However, the compromise for that was that up to 1991, there was no statute of limitations for injuries that occurred before 1988. So you could go back to time immemorial, with no statute of limitations, and file a really old case.

The award in death cases back then was the same as it is now, \$250,000. In fact, it was really gratifying for me when one of my clients, a woman whose child had died back in the 1940s from a DPT injury, received the death award. The fact of the award meant that she could finally place fault somewhere, something that she had been looking to do for 50 years. The money, in fact, provided her with some financial security. It was a happy day for me.

In my years before practicing law, before I had vaccine cases, back when I was dealing with some pretty serious injuries as a defense lawyer, I never had a case that made me cry. After acquiring my 100 vaccine cases, that changed. These were and often are heartbreaking situations. By the terms of the act itself, only serious cases can be filed. So I don't have any happy ones. I

represent parents who lose their babies, and worse, I think, I represent little children whose futures are lost. Their parents can no longer look forward to graduations and marriages and grandchildren. Instead, they become afraid to get old and die, because they know no one will be there to take care of their handicapped child when they are gone.

Looking back to another one of my pre-act cases from the 1990s, I remember that I represented elderly grandparents who had custody of a 27-year-old grandchild who had sustained a vaccine injury as a baby. They had raised her, and they were considering taking things into their own hands and euthanizing her as soon as the first one of the two of them died, because it took both of them all day, every day, without fail, to care for her.

The award that those folks received made a real difference. It made a life-or-death difference for the injured child.

But I also remember equally tragic and probably no more meritorious cases where compensation was not awarded. One of my cases was decided on a video of a child, with experts on both sides opining as to whether the child was having seizures or just exhibiting behaviors, as she sat in a highchair. We rewound that tape probably a dozen times. I will never forget the look on the mom's face when she said, "That's a seizure. That's exactly the

same look on her face, the same thing she does, when they do an EEG video and she has seizures."

But I lost that case.

I have other cases that have been decided on one single laboratory result that was different when it was done another time. I have another case, decided in my favor, on one single thermometer reading; other cases decided on random comments in the medical records.

There is no certainty about these cases. These cases are often so 50/50 that I guess I'm glad I'm not deciding them -- although I know which way I would decide if it were my decision.

It is terrifying for a lawyer to try a case that is potentially worth millions of dollars and could change the course of a client's life, and to try it absent the usual rules of evidence that lawyers are taught to rely on and to try it with no legal discovery, other than a report from the respondent's expert doctor and maybe a couple of journal articles. You don't know what the doctor is going to say. You can't pin them down. Experts know how to testify. And I'm not a doctor. I can read journal articles. I can spend days preparing, but I still can't be prepared for everything. I can have my doctor sitting there, but he doesn't have his medical library.

It's extremely difficult. It's extremely

frustrating. It is a responsibility that I think is probably unique to attorneys practicing under the Vaccine Act, and one that I think most sane lawyers would refuse to take.

I don't think it's really fair to either side, by the way. But as I said before, on the average, the government does just fine, because they can look at the big picture. My clients never get the big picture. They only get the little tiny picture of their own case. They don't care about averages.

Which gets us back to the purpose of the act, which was to be sure and fair to petitioners. Sometimes -- frequently, from my perspective -- it is neither. I have seen too many families devastated first by an injury and then devastated again by an adverse ruling.

So what is my point here? It is that petitioners' lawyers relate to the individuals involved in the cases in ways that none of the other stakeholders, other than the parents, can really imagine. They take on very difficult burdens, legally, personally, and emotionally. From my perspective, this practice can be extremely satisfying, but satisfaction is too rare an occurrence.

What would I like? I would like a system that is what the petitioners bargained for back in the old days, in

the 1980s, one that is more sure and that casts a wider net. I would like to see some of that huge excess in the fund go to compensating injuries, even if it means that close cases are decided on entitlement and on damages, whenever there is a doubt, in favor of the petitioners, because, after all, it is the petitioners who took the risk and had the vaccine.

If I could go back in time and choose again, I don't know that I would choose to do these cases. Vaccine cases burned out my former partner, and he left the practice of law. He couldn't stand it anymore. It was just too depressing.

I can say that I have learned a lot over the past 20 years. I literally wore out one edition of a child neurology textbook. More than anything, I have learned just how persistent, dedicated, and courageous my clients can be when confronting the worst problems that people can face.

But it's hard. I feel terrible for them. I really wish we could go back to what we bargained for in the 1980s and could have a do-over.

Thank you.

MR. SCONYERS: Thank you, Sherry, very much. I appreciate you taking the time to put your remarks together.

We have quite a few people on the phone. I'm going to take about a five-minute break at this point. Then I would like to work in an opportunity for public comment after our next presentation, which is by Dr. Caserta, on the evolution of the Vaccine Injury Table. As we have heard already from several folks this morning, the development of the table has an awful lot to do with the resolution of these cases. It's an important component of our evaluation of the current program to understand how the table came into existence and how it has been modified over the years.

At the conclusion of DR. Caserta's remarks on the table, I'm going to take just a few minutes, and if there are public comments on the information that has been presented to us this morning, the views that have been presented this morning, we will hear them. Then we will move on with our regular agenda.

So get water if you need it. Take about five minutes. We are not going to go far from here.

(Brief recess)

MR. SCONYERS: Let's get back under way.

I think it's obvious that we have a lot of meat to chew on. I would like to try to keep us as much on schedule as possible. I have a feeling we are going to have some significant conversations.

Our next agenda item is a review of the evolution of the Vaccine Injury Table. If you look in your blue folders, you will see some slides on the Vaccine Injury Table changes, 1988 to 2008. We have Dr. Vito Caserta to talk with us about that.

Agenda Item: Evolution of the Vaccine Injury

Table

DR. CASERTA: Good morning, everyone.

What I would like to try to do this morning is go through the 20 years of history that we have already amassed with the Vaccine Injury Table, so that we can understand its development and evolution, and hopefully that will give us some insight as to how to make it better and move forward into the future.

What is the table? The table was a central component to the legislation that created the program. It was novel. It was unique. It was something that had never been really tried before. It wasn't clear if it was going to really work. When Congress created the program, there was a sunset provision as part of the law. If things got out of hand, the program could stop. But the table was an important critical piece to this program working.

Why was it important? What did the table do? The intent of Congress was that the table would remove what then was a huge burden. The huge burden on petitioners was

that they had to actually prove in civil courts, in every state in the country, that their child was injured by a vaccine, which at the time was a big feat for anyone to accomplish. It was very expensive, it took a lot of time, and it certainly was not very certain as to what the outcome would be. Petitioners were going against huge pharmaceutical companies that had huge resources. It was not very fair and not very user-friendly, in many ways.

So the table was to remove that burden. It was a compromise solution that wanted to streamline the whole process, in order to create a system that would give us quick decisions and quick recovery for families that had an injured child.

What was Congress really thinking? I guess the best way to figure that out is to go to the congressional committee language.

What the committee said in 1986 -- and I'll read it -- is, "The Committee further recognizes that the deeming of vaccine-relatedness adopted here may provide compensation to some children whose illness is not, in fact, vaccine-related.'

So what are they saying? In 1986 there was a great deal of uncertainty about vaccines and their adverse events and what was related and what wasn't. We didn't have the benefit of the IOM studies. We didn't have the

benefit of a lot of the science that has happened since then. So there was a great deal of controversy.

What Congress wanted to do was cast a wide net, understanding that that wide net would catch folks that may not have been injured, but that was okay, because Congress wanted to try to catch everybody.

If anyone has any questions, just ask.

The next part of that quote is, "The Committee anticipates that the research on vaccine injury and vaccine safety now ongoing and mandated by this legislation will soon provide more definitive information about the incidence of vaccine injury and that, when such information is available, the Secretary or the Advisory Commission on Childhood Vaccines may propose to revise the table."

Key words here, I think, are the fact that Congress recognized that there was a lot of lacking information, a lot of knowledge that we just didn't know. So they mandated that the IOM or a group like the IOM -- and we took their recommendation and used the IOM -- study these very, very complex issues.

In addition, part of the legislation that created the program also created the National Vaccine Advisory Committee, which is a scientific group whose charge is to oversee vaccine safety research and the vaccine agenda in the country in terms of making vaccines better and safer,

and getting children vaccinated.

I think key words that we need to look at -- once we have the research and the research brings us more definitive information, that definitive information can then be used by the ACCV or the secretary to modify the table. What Congress, I think, is saying here is that they wanted the revisions to reflect the state of the research whenever the revisions were being made, and whatever the state of the science was at the time.

In terms of modifying the table, with the original statute, the secretary had the authority to change the table and the qualifications. But he or she didn't have the ability to add new vaccines. Again, I think Congress wanted to make sure that the program was working before they gave the secretary that ability. In 1993, that ability was given to the secretary. So as of 1993, the secretary could not only add and remove injuries, but now he can also add and remove vaccines.

The statute in 1993 was the Omnibus Budget Reconciliation Act of 1993. This laid out two steps that the secretary had to follow in terms of adding new vaccines to the table.

The first step, generally, was that the vaccine would be recommended by CDC for routine administration to children. The way that that was defined was, it would be

published in the MMWR, which is a CDC publication that stands for the Morbidity and Mortality Weekly Report. It's a weekly publication that CDC puts out. Generally, the words "routine" or "recommended for all" would need to be part of that recommendation for it to mean routine administration to children.

So that's step one.

Step two -- and sometimes the order is one way and sometimes it's the other way, but you need both things -- is that Congress needs to impose an excise tax on that vaccine. Congress certainly couldn't give the secretary the right to create new taxes. If this second step wasn't there, then the secretary could add new vaccines and, by doing so, add new taxes, which, I guess, messes up the separation of powers and all that. So Congress retained that.

Once the secretary recommends, through the CDC recommendation, and Congress does the excise tax, then what the secretary does is to publish a notice of coverage, with an effective date, in the *Federal Register*. The effective date is the date that the tax is enacted. Once the vaccine is taxed, that's when it is effective.

In general, what is the process for adding or removing injuries or conditions in the table? Medical information becomes available about a vaccine or about an

injury that causes us to consider that maybe a change might be good. The information is vetted through NVAC, ACCV, and others. Those groups give their recommendations to the secretary. Certainly, the American Academy of Pediatrics and others generally are involved with this sort of information and the giving of their recommendations.

The secretary then would publish a notice of proposed rulemaking in the *Federal Register*, which outlines what is being proposed, what the secretary has sort of digested from all his recommendations as to what he thinks or she thinks should be done.

There is a 180-day comment period once it is published for anyone to provide comments about what is being proposed. Then, once the comments are taken in, digested by the secretary, the final rule is published that lays out what will be done. In that final rule, generally, the secretary will take each of the comments and explain why or why not that comment was incorporated into the new final rule or -- if it was, why; if it wasn't, why.

When the table is revised, it only applies to petitions filed after the table is revised. If the table is revised on Tuesday and someone files on Monday, the Monday filing is the old table. If someone files on Wednesday, then clearly it's the new table that would apply to that filing.

Whenever there is a change in the table, for that change, folks have an eight-year retroactive time when the injury could have occurred to file. If the table, for example, is changed on January 1, 2000, folks can submit petitions with injuries all the way back to 1992, which would be eight years before. In addition, petitioners have two years to file. So, in essence, it gives a 10-year window for when folks can file whenever there is a change, if that filing relates to that change to the table. This could be a change to the injury -- not necessarily a new vaccine -- it could just be an injury that's added or modified, which would now make you eligible. Then you have that larger time period.

MS. HOIBERG: But they would have had to originally file before the statute of limitations has run? Would these be people that were injured by a vaccine, filed, were dismissed?

DR. CASERTA: No, you don't have to have filed.

MS. HOIBERG: These are people who had an injury, but then what happened in the statute?

DR. CASERTA: You are talking about the three-year?

MS. HOIBERG: Yes.

DR. CASERTA: The three-year issue doesn't really apply here. You have the eight years. The eight-year sort

of supersedes the three-year. The three-year doesn't apply. So you could have filed and been dismissed, and then you could file again.

MS. DREW: I don't think so.

DR. CASERTA: What is it you don't think?

MS. DREW: I think if you have filed and been dismissed, you can't file again if there is a change.

DR. CASERTA: If your new filing relates to a change that now gives you a more reasonable case -- Elizabeth, please.

MS. SAINDON: I don't believe so.

DR. CASERTA: Maybe I'm wrong on that.

MS. SAINDON: If you filed already for the same vaccine administration, you can only file once.

DR. CASERTA: Okay, I stand corrected. Even though now the injury pertains to you, whereas before it didn't? That's something I didn't know.

That's why we have all these brains, which is good.

Any other questions?

But if you fall under a different vaccine, though, you could, a different vaccine administration.

MS. SAINDON: Right.

DR. CASERTA: So what were those mandated studies that I mentioned before?

In the statute there are Sections 312 and 313, which, in our jargon, is how we refer to them. There were two IOM studies. The first IOM study looked at pertussis vaccine and rubella vaccine. The secretary promulgated the regulations based on the information provided by that study in 1995. Then the 313 looked at all the other vaccines -- measles, mumps, diphtheria, tetanus, polio. New vaccines that had come into the picture at that time, which were Hib and hepatitis B, were also looked at by IOM. The report came out in 1997.

What happened with the 312, the first IOM report that looked at pertussis and rubella? That report was published in August of 1991. What happened once it was published? PHS put together a task force that looked at the report and made recommendations. The NVAC also had a subcommittee and the whole committee reviewing the IOM report. ACCV was also very involved at the time with this.

Once all these groups looked at it, they provided recommendations to the secretary. The secretary published a notice of proposed rulemaking in 1992. There were six months of public comments, including a public hearing, which was a meeting like this where folks came and were able to speak publicly about their concerns.

In the midst of this, it became clear that the national childhood encephalopathy study, which was the

study done in England in the late 1970s, which was the major piece of evidence that implicated vaccines in encephalopathy and seizures -- it was actually the largest study of its kind, and a very difficult study to do -- that study was getting ready to publish a 10-year follow-up, which was very, very important with regard to how to understand this initial IOM report, because it was dealing with pertussis. Because it became clear that that follow-up study was in the wings, the brakes were put on. A second *Federal Register* notice went out soliciting comments, once the 10-year follow-up study came out. The IOM was also asked to look at this 10-year follow-up study. They issued a new report related to that new NCES study.

With all of this, there were 41 written comments and five oral comments from the public related to these proposed changes.

There was then a second consultation with ACCV in March and June of 1994, and then ACCV voted. There was the endorsement of the AAP and AMA for the recommendations. The final rule was published in 1995.

So it was not a quick process. IOM published their report in 1991 and the final rule was published in 1995.

This was a very difficult one, because it was our first one. The changes that were made had a large impact

on the way the program would move forward, so we wanted to be very, very careful and very deliberate. It took time.

The initial table had seven vaccines, 12 injuries. Listed on the slide are the vaccines that were on the table.

Going to Table II -- what I'm going to ask you to do, to help follow along with this -- there are a couple of handouts. There are handouts that are in color like this. Just put these in three different piles. There is a handout that is a table from a textbook. This handout speaks to the aids to interpretation and how they were changed with the final rule after that first IOM study. This goes through each of the different tables and sort of lays out what the changes were. There is also another table that lays out each of the tables subsequently, so you have what the table looked like with the changes. If you can just kind of make three piles, I think it's easier to follow along with those three piles.

With the second table, the new table after the initial IOM study, what modifications were made to the table? HHE, which is hypotonic-hypo-responsive episode, was removed and residual seizure disorder were removed for the DPT vaccines. Chronic arthritis was added for rubella vaccine. The time intervals were changed for anaphylaxis, residual seizure disorder, and encephalopathy.

The way to see that on this handout that shows all the different tables is, the changes are in bold and, of course, what has been removed is crossed out. If you see something in bold -- "chronic arthritis" is in bold -- that was added. It helps you see that that was added. The "42 days" was new for the chronic arthritis. For encephalopathy, you can see that, with measles, MMR, the "5 to 15 days" is bolded, because that was changed.

That's how you can look at this table to help you read it.

MS. HOIBERG: I have a question. Why was residual seizure disorder removed?

DR. CASERTA: The reason that it was removed was that the IOM in their recommendations -- they, in evaluating the studies, felt that the vaccine was associated with febrile seizures. That was their conclusion, that the pertussis vaccine caused febrile seizures. That was a clear conclusion from the IOM.

The problem is that you need the fact that the vaccine will cause an injury and you also need that the injury would be chronic for it to stay on the table. The problem with the seizures was that the IOM also said that these febrile seizures -- the studies indicate that they are benign and that they don't go on to serious sequelae.

Afebrile seizures are a different story. The IOM

looked at afebrile seizures and found that there was no association with the vaccine in afebrile seizures.

To take a step back, the IOM found that febrile seizures were caused by the vaccine, but they also found that they were benign and self-limited and that you wouldn't have the six-month sequelae. Because it's missing that six-month sequelae piece, the committees that reviewed all of this recommended that it be removed.

I think at the time the ACCV agreed with that recommendation. It was encephalopathy that they didn't agree with. That's my recollection.

You're looking at me like --

MS. HOIBERG: Well, it's criminal. My daughter has residual seizure disorder and she has encephalopathy.

DR. CASERTA: Right, but the basis --

MS. HOIBERG: -- last more than six months. So what if she had seizures every time? She has seizures whether she has a fever or not. If a child is given a vaccine and then suffers from seizures every time he has a fever now, then the government should be responsible for taking care of that. That should not have been taken off.

DR. CASERTA: I understand what you are saying. But it was based on the science. The epidemiology didn't show that there was increased risk. Based on that, it was removed.

MS. HOIBERG: So if I had been lucky enough to have just had my child suffer benign seizures or whatnot or now have -- that's horrible. Is encephalopathy next?

DR. CASERTA: I'll get to that.

So HHE and residual seizure disorder were removed. The reason why HHE was removed -- it was for the same reason. Clearly, the pertussis vaccine did cause an entity called HHE, which is a poorly understood reaction that some children get where they become less responsive after the vaccine. But again, for the same reasons -- there was no evidence that HHE causes long-term sequelae. For that reason, the thinking scientifically was to remove it.

Chronic arthritis was added because the IOM felt that there was good evidence that the vaccine virus does invade the joint and does cause chronic arthritis.

Also the time intervals were changed for anaphylaxis, residual seizure disorder, and encephalopathy. The residual seizure disorder that was removed was removed for DPT, not for MMR at this point. It's still on the table, but only for MMR.

You can see on this table how it was changed by the bolded markings.

Also in the aids, you can see the changes that were made. I certainly don't expect you to digest this

now, but in your leisure, looking this over -- and certainly if any questions arise, please feel free to ask, and we will answer them.

This lays out the changes that that first table did to the aids to interpretation. There's a typo. That shouldn't be "HHS" at the bottom. That should be "HHE."

Any more questions about that first table change? It was a really contentious, difficult table change that the program had to go through.

The next table change was based on the next IOM report that looked at measles, mumps, and the other vaccines in the program, in addition to hepatitis B and Hib. Based on this IOM report, the vaccines of hepatitis B and polysaccharide Hib and Hib conjugate were added, and also varicella was added to the table.

In terms of injuries, brachial neuritis was added for tetanus and encephalopathy was removed for tetanus-containing vaccines, again based on the evidence that the IOM provided. Thrombocytopenic purpura was added for measles and vaccine-strain viral infection was added for measles.

What that means is, if, for example, a child were to have a myocarditis, or an inflammation of the heart, and they were to culture out a measles virus and it was the vaccine strain, clearly the vaccine caused that. That's

what this was intended to capture. Those were possibilities. Those were things that may happen. So it was added to the table, again based on the IOM recommendation.

Vaccine-strain viral infection was added for polio -- the same thing. If the poliovirus caused the myocarditis, then it would be on the table.

Also with this new set of changes, a new category was created. If you look at your latest version of the table, the new category you can see on the latest version is Roman numeral XIII on the bottom. It says, "Any new vaccine recommended by the Centers for Disease Control and Prevention." With this set of table changes, that new category was created. What this does is, it sort of lumps vaccines that are on the table, but haven't gone through the six-month public comment and publication of a final rule, to determine what injuries may be added to the aids to interpretation. It's a way of including something before all the information has been fully vetted. Once all the information gets fully vetted, the vaccine gets its own category, which you can see from categories I through XII on the table.

MS. BUCK: Can I just interrupt you for a moment? I apologize for the simplicity of my question, but I'm getting a little lost in all the medical stuff. For me, at

least, what I really need to know is -- it appears -- and I may be incorrect -- that it's pretty easy to add new vaccines to the table. As soon as they are out and they are recommended for us, they are going on there. Our struggle -- and I think what we have been hearing from folks -- is that initially this program was run by looking at the table to determine whether folks came in or not. But my understanding is that we have taken stuff the injury list, but we haven't added a whole lot to it, particularly with new vaccines.

My understanding from that is that that is a very long process. Is that correct? In your opinion, is there any way to make that quicker? Can we ever go back to using the table to determine whether folks get into the program?

I appreciate what you are doing, but I'm trying to get to the heart of the matter, which is what we are struggling with, which is the idea of the table and updating the injury portion of the table to align with the new vaccines that are going on there.

DR. CASERTA: Part of the problem with new vaccines -- the fact that they have gone through the arduous process that FDA has in place to license new vaccines -- safety is something that they are looking at very, very carefully, more carefully now than in the years before the program, with all the surveillance and all that

they are doing. I think, intrinsically -- also because of better technology -- we have safer vaccines. So the new vaccines that are coming out tend to have fewer issues with regard to adverse events. Of course, there are surprises, like rotavirus and intussusception, which was a real injury that clearly the vaccine caused, no doubt about it, and sort of blinded us. But that's part of the process. You can never do the studies with millions of people that would need to be done in order to completely make sure a vaccine is safe.

MS. BUCK: But our system for picking up on adverse events continues to be very reactive. It is slow. VAERS is underreported. VSD takes a long time to process. It's one of the struggles that I think a lot of us are frustrated with as we look at this idea that the new vaccines that are coming out are much safer, but the process to pick up the adverse events is still very slow and reactive. I believe that all this ties together with the difficulty of families coming to the program and trying to get in.

DR. CASERTA: It can be slow if the adverse event is very rare. That's absolutely true. If the adverse event isn't very rare, like intussusception -- that was picked up very quickly. So it really depends on the type of adverse event.

But you are absolutely right. Something that is very rare is going to take us a long time to figure out.

MS. BUCK: That is a bit of a gray area. If you are looking at, perhaps, Gardasil and hits on VAERS, that does become a little bit gray in terms of what is rare and how many hits are out there and how you wade through that and determine which ones you really want to pursue, and not, which is again getting to our point, which is this idea of trying to make this program back to what it was, which is easier for people to get into. It still seems to be what I hear, which was, when we used the table, it worked better.

DR. CASERTA: Right. I guess, in a nutshell, the intent of Congress that we read was that Congress wanted the initial table to have a wide net, to catch anything that may be vaccine-related. But they also instructed us to revise the table based on science. When we do that, the table becomes more restrictive, because it's not casting as wide a net as it did before.

MS. BUCK: Have all the IOM recommendations for the table been implemented?

DR. CASERTA: No.

MS. BUCK: Can you tell me why?

DR. CASERTA: It depends. There are different recommendations. For example, I'll give you one that we

struggled with.

The IOM recommended that Guillain-Barré syndrome is related to tetanus vaccine. That was their conclusion. Through, again, recommendations by the scientific community, NVAC, the database, and the studies that were done, it was clear that the IOM recommendation was based on the experience of one individual that had rechallenge with the vaccine. That individual developed GBS. But all the epidemiology showed that there was no increased risk.

So the position that the program took was that to include a common condition like GBS under tetanus, the net would catch a lot of people where it's not vaccine-related, clearly not vaccine-related. If someone were to apply to the program and show that they had rechallenge, the program would concede such a case and compensate it, and we have.

That's sort of the thinking that went on. I think what the scientific community was looking at was the epidemiology, and I think the commonness or rareness of a condition is important. It does come into play as to the number of folks that you may compensate who truly, if one really knew the information, were not deserving of compensation because it wasn't related to the vaccine.

MS. BUCK: Thank you. I appreciate your answers.

DR. EVANS: I need to interject a clarification. The IOM did not issue any recommendations.

DR. CASERTA: I think I said that. They said that the vaccine is associated with GBS, based on the Australian --

DR. EVANS: I understand. I want to make clear, though, that the IOM never issued any recommendations. Their task was to put into categories the various causation strengths and weaknesses. One thing that we did not get into detail about was just the general approach that the secretary took in trying to take the results of both the 313 and 312 reports and then apply them, through public comment and consultation and input, in making these changes to both the Vaccine Injury Table and the aids to interpretation.

I just want to be very clear that that was the process. I saw Dr. Stratton's face tightening at various points. The IOM is accused of many things from time to time, but making recommendations on changing the Vaccine Injury Table was not their charge.

MR. SCONYERS: I think the point was that there was a charge to the IOM to develop a scientific study, an assessment, of the association between conditions and vaccines. The program chose not to recognize one of the associations that the IOM identified in revising the table.

I think your point is correct, Geoff, but it's a fairly semantic one and somewhat beside the point in terms

of this commission's concern about the way that the table has not necessarily kept up with things.

Please help me understand. I understand that there is an association between the old rotavirus vaccine and intussusception, but I don't see that that was ever reflected in the table.

DR. CASERTA: What you have is the new table, where that has been removed. I'll get to that.

MS. BUCK: The other point is, I understand the comment, with GBS and tetanus, that it was too wide of a net and that if you want to come back and look at that, then we can concede it, but I believe that this commission has heard over and over again -- we don't understand exactly why cases are not conceded. That goes back to the heart of the matter that we have been hearing all morning, which is, when they go through that process, it is lengthy, it is adversarial, it is difficult.

It's just a comment in terms of sort of a different approach -- saying that the fear of casting the net too wide may be a problem leads to this other approach that we are now struggling with, perhaps, the other way.

But I very much appreciate your comments.

DR. CASERTA: Okay, we are on the changes from the second IOM report, which is Table III.

MR. SCONYERS: [Off-mic]

DR. CASERTA: With encephalopathy, that brings us back to the previous slide, Table II. With encephalopathy, what occurred was that the Public Health Service task force recommended that encephalopathy be removed for DPT vaccine. I'm not sure what NVAC recommended. I don't remember. ACCV recommended that encephalopathy remain. When the final recommendations went forward, encephalopathy stayed on the table for DPT vaccine and for MMR vaccine.

Part of that was that 10-year follow-up. The IOM evaluation showed that if one had the types of illnesses that you needed to have to get into the national childhood encephalopathy study, which was that study from the late 1970s in England that I mentioned before that was very large -- if you, as a patient, had those characteristics and had an adverse event after the vaccine, in those people, the vaccine was likely a causative factor or -- there were three or four possibilities. One was that it was likely a causative factor. One was that it was just a temporal association. But because the IOM couldn't distinguish and it was still cloudy, encephalopathy was not removed from the table at that time, because it wasn't clear.

MS. HOIBERG: That's the leading side effect. Encephalopathy is what you hear. If your child had a reaction to the vaccine, it is an encephalopathy. So the

fact that they would even consider taking it off --

DR. CASERTA: I hear you. But it was based on the epidemiology. That's what they were basing the recommendations on. It is what it is.

I think I can go ahead and not necessarily go through the rest of the table changes. They are laid out very schematically in the handout. You could just take a look at that.

I will stop here and see if there are any other questions, to keep us on time.

MR. SCONYERS: Other questions for Dr. Caserta? We have been asking them as we go along.

DR. CASERTA: And please feel free, as you review the materials, if questions come up, to submit them to us.

MR. SCONYERS: In the changes to the table that were just effective 10 days ago, why has intussusception been removed from the --

DR. CASERTA: The reason why that was removed was that the vaccine that causes intussusception, the rhesus-based vaccine, is no longer given. It has been not given for long enough that the three-year statute of limitations is well past. So there really can't be any claims out there within the three-year window. Because of that, just as a housekeeping thing, it was taken off.

MS. HOIBERG: My question is, are you sure that

they are all off the shelf, that they are not being given, that they are not on doctors' shelves, that they are not still in circulation?

DR. CASERTA: Pretty sure.

MS. HOIBERG: "Pretty sure," that's not a good enough answer.

DR. CASERTA: I can't be sure because I'm not in every doctor's office. But the recommendation has been that that vaccine not be used.

DR. HERR: I don't think the vaccine has been made or sold for at least seven to eight years or more.

DR. CASERTA: Right. Certainly some physician somewhere could have an old stock of it. But no one would ever use it.

DR. HERR: In which case it's expired.

MS. HOIBERG: Talking about expired vaccines, I have been in contact with a mother in Jacksonville whose son was given a vaccine that was nine years old. It happens. Hopefully, in that case, they would be able to still get compensation.

DR. CASERTA: Certainly they could still file, because it's a rotavirus vaccine. That's still on the table. It's just the rhesus-based intussusception that was removed. Rotavirus is still on the table.

MS. HOIBERG: But what if they had

intussusception?

DR. CASERTA: If they had intussusception and they received the rotavirus vaccine, we would not hesitate to compensate, as a compensable case. That's a slam-dunk.

MR. SCONYERS: But again, I think we have expressed concern about the revision of the table to remove injuries when there is a known association between the vaccine and the injury. The things that you are saying you wouldn't hesitate to compensate should be on the table.

DR. CASERTA: Right. But I'm saying that the reason why it's not on the table is that that vaccine is no longer produced or administered.

MS. BUCK: But why not just leave it?

DR. EVANS: Actually, I was going to cover this in my remarks after lunch. The reasoning behind removing the category for live rhesus-based rotavirus vaccine and the specific injury of intussusception is this. When it was added the Vaccine Injury Table in 2002, it became ineffective 30 days after it was published. So it is a category that is no longer effective on the Vaccine Injury Table. It is for a product that is no longer given. The potential for confusion, for example -- because we have two newly licensed rotavirus products that do not have any proven association or any suggestion that there is an association with intussusception, based on clinical trials.

Because it is not effective any longer and there's a potential for confusion, this was a technical change that was done by the secretary, and it was done as an interim final rule, which I'll explain a little further.

MS. BUCK: My only comment to that is that, working on the vaccine safety issue with the NVAC, I have heard personally that there is concern about administrative errors with vaccines. I understand what you are saying. That is a piece that makes me just a wee bit uncomfortable, because some expired vaccines are out there. There are some errors that are made. I understand that you are saying that the program would pick that up, and that's a good thing.

I guess, for me, it just plays to a bigger issue. But I understand what you are saying.

MR. SCONYERS: If there are no more questions for Dr. Caserta, thank you preparing it.

We are scheduled for a break now, but we are not going to move to a break. We are going to take the opportunity to see if there are any public comments at this point. After we have done that, we will evaluate where we are in our agenda.

Operator, if you could see if there are any people on the phone who would like to make public comments, and, of course, anyone who is here is welcome to do that as

well.

OPERATOR: One moment.

Terry Poling (phonetic), you may ask your question.

Agenda Item: Public Comments

MS. POLING: I noticed that you were just talking about the rotavirus vaccine. I was noting that in the United Kingdom they have not put that in their recommended schedule yet because of a possible sixfold increase in intussusception. That being the case, I'm not clear why we would take that off of the injury table. Considering the fact that it is on the recommended schedule here, how are we ever going to know that the child has intussusception from the vaccine or would have gotten it another way?

MR. SCONYERS: Thanks for that comment.

Are there any others?

OPERATOR: At this time, I show no further comments.

MR. SCONYERS: Anyone?

(No response)

We are a little bit past our time. Let me ask the preference of the group. Would you prefer to go ahead at this point without a break? We have Kay Cook to speak to us about the program's strategic plan and performance measures and then we have a presentation on the Petitioner

Satisfaction Survey. We could push straight through. I'm seeing an indication to push straight through.

So let's do that. Those who may have a need to take a brief respite from the festivities here can just go down the hall.

While I'm in the transition mode, let me just remind anyone who is here as a visitor to sign in. There's a sheet on the table there. Just make sure that you have signed in so that we have a record.

With that, Kay, if you could come up and give us a few minutes on the VICP strategic plan and performance measures.

Members, you will recall that this was distributed to us several weeks ago. We thought, in evaluating where we are with the program, it would be important to hear how the program looks at itself and measures itself.

Agenda Item: VICP Strategic Plan and Performance Measures

MS. COOK: Good morning. My name is Kay Cook. I'm the chief of the Policy Analysis Branch in the Division of Vaccine Injury Compensation.

For those of you that aren't aware, I have only been there for three months, so bear with me.

The branch is responsible for the National

Vaccine Injury Compensation Program strategic plan and performance measures.

In 2002, a workgroup of eight members representing key stakeholders with interest in the Vaccine Injury Compensation Program, the VICP, was formed. The workgroup gathered data and developed draft documents. These data and documents were discussed at the planning retreat held in October of 2002. The retreat included a large representative sample of stakeholders with interest in the VICP. The draft strategic plan was presented to the participants at the retreat for their review and comments. The strategic plan was completed in June of 2004 and published in April of 2006.

A dramatic shift in claims from nearly all alleging a Vaccine Injury Table condition to a majority now alleging an off-table condition, which creates a more difficult burden for petitioners and raises questions as to how the current causation standard is applied to VICP, is one of the key factors facing the VICP from 2005 to the projection of 2010. Also the claims process is difficult for stakeholders to understand, and many parents, general public, attorneys, and health professionals are not aware of the existence of the VICP, thus creating the strategic plan to get our word out.

The VICP developed a five-year strategic plan

which consists of four themes.

One is to examine the alternative approaches for adjudication of off-table claims, a showing that the VICP is responsive for evaluating science, medicine, and policy actions, assessing and streamlining the claims process to make it quicker and fair to all parties, and increasing the knowledge about the VICP amongst all stakeholders.

The plan objectives include reviewing the possible vaccination adverse events and more recommendations, updating the revised table based on these events and research, evaluating the recommendations for a possibility of covering additional vaccines, evaluating the current claims process, obtaining feedback from petitioners and their attorneys, making improvements to the claims process, ensuring that the claims process requirements of the act are implemented and followed, considering additional proposals for making improvements, evaluating the VICP communications and outreach materials, developing and implementing a marketing plan, and creating communication materials that are easily understood.

Our outcomes for the plan so far have been: HRSA has recently awarded a contract to the Institute of Medicine, IOM, to study adverse events associated with certain childhood vaccines. We are conducting the Petitioner Satisfaction Survey, which is expected to be

completed in May of 2009. We established a HRSA Information Center. We have established printed materials on the program, and we are currently establishing a VICP outreach plan.

MS. BUCK: A quick clarification. You said you have a contract with the IOM to study certain vaccines? Or did you mean all childhood vaccines?

MS. COOK: No --

MS. BUCK: Oh, I'm sorry. You are going to take about it later again?

DR. EVANS: Yes.

MS. BUCK: But the thing is, there are people that might not stick around. Can you answer that real quick?

DR. EVANS: Certainly. Again, this happened because we flipped around the presentations. Usually these updates are in the morning, for those who are so curious.

This is why Dr. Stratton, Kathleen Stratton, from the Institute of Medicine, is here this afternoon to go into further detail about the project. This will be studying four vaccines. It will be varicella, influenza vaccines, hepatitis B, and the human papillomavirus vaccine.

MS. BUCK: Thank you.

MS. COOK: Shifting gears into assessing program

performance, the program performance rating tool, otherwise known as PART, was developed by the Office of management and Budget to assess and improve program performance so that the federal government can achieve better results. The VICP performance measures focus on timely adjudication of vaccine injury claims and monetary awards, and the extent that the VICP serves as an alternative the traditional tort system by ensuring that no compensated claim is rejected.

The first measure tracks the number of individuals who pursue civil litigation following a determination that they are eligible for compensation. Our target for this was zero. From 2005 to 2007, we have met our target.

The second measure is the average length of time from the date that the claim is filed until payment is authorized, for compensated claims, and the date of the filing to judgment for dismissed claims. The VICP has met its targets for 2005, 2006, and 2008. In 2007, the program did not meet its target. The target was not met due to the unanticipated additional petitioner- and court-driven delays in adjudicating the claims.

The third performance rating tracks how the efficiency of the VICP is at filing Rule 4(b) reports for the cases that have been filed with adequate medical

documentation. The filing of these reports is the first step in the process of adjudicating cases. A Rule 4(b) report is similar to a government's answer in a traditional civil lawsuit. Since 2005, the VICP has exceeded its targets. Data for fiscal year 2008 is not yet available.

MR. SCONYERS: Can I just ask a question there? Why is the target not 100 percent?

DR. EVANS: There can be various reasons. It could be the sufficiency of records, the ability to go forward and make a definitive recommendation one way or the other. We try as much as possible to produce an answer, but sometimes we don't have enough information to do so. That's one common reason why.

MR. SCONYERS: I thought this was measured from when the case was deemed complete.

MS. COOK: It measures from how efficient --

DR. EVANS: Clearly in the past, when there have been staffing difficulties, we have not been able to keep up with a surge. For example, doing influenza claims, we had to really work very hard to make sure that we made the 90-day deadlines in those cases that were sufficient.

MR. SCONYERS: That's an answer to why actual isn't 100 percent, but that's not an answer to why the target is not 100 percent.

DR. EVANS: I guess because it gives us the

allowance to be able to -- in the situations where we cannot meet it, there has to be some --

MR. SCONYERS: Why would you set your targets --

DR. EVANS: Why don't we have one of our DOJ colleagues help with this answer?

MS. MCINERNEY: I'm Julia McInerney, for the Department of Justice. I'm a trial attorney.

I don't have the Department of Justice -- we are also PARTed on certain issues as well. These are not our statistics. But I can speak with respect to when a case has been deemed complete. That has many factors that come into play, not the least of which is the special master, who may or may not suspend the court deadline for filing a Rule 4, because the records are not complete, the petitioner is in the process of getting an expert report, and therefore the Rule 4 report can't be performed because the information isn't there to complete it.

So each case is dependent on whether or not it has been filed in compliance with Section 11 of the act. So it really is dependent on the court.

MS. HOIBERG: But we're not asking -- you're still not answering the question. We want to know why you are not striving -- we understand the actual. That's obvious, that it's not going to be 100 percent. But why would your target not be 100 percent?

DR. EVANS: Because for various reasons, it's unachievable. These figures were from a process of negotiation with the Office of Management and Budget staff, who, after eliciting input from the Department of Justice, the Court of Claims, the special masters, and so on, understanding the process, realized that 100 percent was not a viable or practical figure. These are the realities of the adjudication process. We strive to do as many as possible, but 100 percent is not something that can be achieved.

MS. HOIBERG: That's like, I'm going to work for a B. I'm not going to try hard enough to get an A. I just want a B or a C. It's really kind of sad.

MR. SCONYERS: I think we have made the point. Let's let Kay move on.

MS. COOK: Performance measure number four measures the -- the purpose of this is to measure the average time that the settlement payments are approved. The VICP has met its targets in reducing the average time to approve settlements. For 2009, the increase in target reflects the maximum efficiency possible, in view of delays in the process.

The fifth performance measure -- the purpose of this measure is to track the average time that the lump-sum awards with required documentation to issue payments are

made. The VICP has met its targets in reducing the average time to pay a lump-sum award.

We have one output measure. This measure is to track the percentage of cases in which settlements are processed within 15 weeks from the date of tentative agreement between the parties and the settlement for the proposal is submitted to the petitioner for his or her review. The VICP has surpassed its target for the output measure.

Basically, if you want more information on the strategic plan, you can get it on HRSA's Web site, which is provided. Also in your blue folders is the complete strategic plan. For more PART information, that can be found on OMB's Web site, which is also listed.

MR. SCONYERS: Thanks for putting these slides together, Kay.

Other questions for Kay?

MS. CASTRO LEWIS: I just want to go a couple of slides back in the outreach. You said the plan is under preparation at this point. Could you explain a little bit what that means? What exactly are you doing in that plan? Who is involved in the plan?

MS. COOK: Basically, what we are doing in that area is, I have a staff member who is going back to review to see what we did in the past, what we are currently

doing, and what we propose to do in the future. Once we get that information together, I will be more than happy to provide it to the ACCV members for comments and suggestions. That's pretty much where it is right now.

MS. CASTRO LEWIS: What is the anticipated date for that plan to be ready?

MS. BUCK: Can we get an update by March, do you think? Is that reasonable?

MR. SCONYERS: I think we are expecting, actually, to have the outreach plan at our March meeting.

MS. BUCK: Your measures are based sort of on the system that works right now. It's just going to be a continuing comment of mine during the day. I really think the program's success should be measured by its accessibility to people who are injured by vaccines. You are measuring how you are doing and what you are doing, and that's good, but I think we have heard it a lot. I know that's not a measurable performance standard, but it's certainly one to consider.

MR. SCONYERS: Other comments or questions?

I would like to go back to slide 4, which is where you outlined the strategic goals you have. I'm unclear what you are doing in your strategic theme 1, which is examining alternative approaches for adjudication of off-table claims.

DR. EVANS: Jeff, you picked the most difficult to answer of the four. It's also one of the most difficult issues, if not the most difficult, facing the program. The program began with a table. It was table-centric. The table guided most of the compensation claims in the program that went through the system, either through concessions or through court findings. Now we find ourselves with most claims alleging non-table injuries.

The fact of the matter is that while there have been discussions ongoing in the department from time to time, nothing substantively has happened in that area. It's a very difficult challenge. It is one that will require legislative changes. It's something that hopefully we will be able to take up once again.

But the last definitive effort at looking at alternative approaches was when the American Academy of Pediatrics presented to the commission in, I believe, December 2001, and there was so little consensus about what they were proposing that there wasn't even a vote taken at that point.

So that's where we find ourselves now. It's something that will hopefully be taken up by policymakers in the future, with input from the commission, if it deems to do so.

MR. SCONYERS: I guess my comment would be, if

it's theme 1 for this program, I would expect to see it on your work plan. And if it's not on your work plan, it must not be theme 1.

Other questions or comments?

(No response)

Our last agenda item before we break for lunch is a presentation on the Petitioner Satisfaction Survey, something that we have talked about several times. We have a report from Namratha Swamy and Kara Rudolph.

Thank you very much.

Agenda Item: Petitioner Satisfaction Survey

DR. SWAMY: Good morning, everyone. It's a pleasure to be here with you. My name is Namratha Swamy. My colleague Kara Rudolph is in the audience. We are here today to talk to you about some preliminary findings that we have regarding the Petitioner Satisfaction Survey on the Vaccine Injury Compensation Program.

I want to first give you a little bit of background on the project itself. Back in September 2005, the Altarum Institute was contracted to conduct an evaluation feasibility study to determine whether certain components necessary to conduct an evaluation actually existed, such as whether there was data available, whether there were program measures in place, common program goals, and what evaluation projects we could possibly take on to

address some of these issues.

In March 2007, the evaluation feasibility study was submitted to the HRSA Division of Vaccine Injury Compensation Program, and a few months later, the decision was made to move forward with a petitioner satisfaction survey, which was an evaluation option that was given in the feasibility study.

The purpose of the evaluation was to determine the extent to which petitioners who have completed the claims process were satisfied with the process and their outcomes. With this information, the hope was that specific recommendations could be made for improving the day-to-day functioning of the program.

Some specific questions that were of interest: Do petitioners feel capable of navigating the legal process? Do petitioners feel that the decision on their claim was reached in a timely manner? Do petitioners who receive awards believe that the award was adequate?

Our population was petitioners who filed a claim and whose claims were resolved, either through compensation or dismissed and closed, within the last five years. However, the sample does not include petitioners who voluntarily dropped out of the process. We used the program's database, the DVIC database, to determine who should be included. We extracted information about the

claim resolution date, the decision status, the petitioner's attorney's name and their contact address, and for those that did not have an attorney, the petitioner's name and their actual contact address.

Our data-collection method was through anonymous, self-administered paper surveys, in addition to Web-based surveys, and English and Spanish versions were distributed.

Our survey was developed in collaboration with DVIC and all of you. The domains that we covered in the survey had to do with:

- Pre-claim filing awareness and information.

How did petitioners first learn about the program?

- The claims process. How satisfied were they with filing a claim and the hearing process?

- Compensation decision and payment of the award. How satisfied were they with the process, the adequacy of the award amount.

- The overall process and communications, which essentially was the satisfaction with the length of time it took to complete the entire process.

- Lastly, demographics -- the age, race, ethnicity, education, et cetera, of the petitioners.

The surveys were sent to the petitioners through their attorneys to ensure confidentiality. Petitioners received a package that included a cover letter with the

survey instructions, an informed-consent form, a hard copy of there survey, and a return envelope to return the survey. For over two months, we distributed thank-you/reminder letters to encourage a higher response rate.

The evaluation questions that we are going to cover today are the following: How did petitioners learn about the program? To what extent are petitioners satisfied with the information they received from the program on filing a claim? With the clarity, ease, and navigation of the process? With the length of the process? With the decision regarding receipt of compensation and adequacy of compensation? With the program's negotiation with Medicaid to reduce and/or eliminate their lien, when applicable?

Our data-collection period is over a six-month period. It started in June 2008 and will end in December 2008. We just sent out this month the final thank-you/reminder letters, to again encourage a higher response rate. To date, we have 93 returned surveys out of a possible 518 surveys distributed. That is equivalent to an 18 percent response rate. There are a couple of reasons for this lower response rate.

The primary reason is that we are working with an attorney intermediary. We are not in complete control of the data-collection process. For instance, attorneys, if

they encounter an incorrect address, may not be notifying us of that incorrect address. We can't take that into account. They may not be tracking those undeliverable surveys.

Also this is a very sensitive issue. Petitioners may not be willing to revisit this issue, it's such a sensitive one. So I think it's the very nature of the subject matter that is contributing to a low response rate. It is a contributing factor.

MR. SCONYERS: You said this is a lower response rate. Is this lower than you expected?

DR. SWAMY: It actually is. There were two other studies that were done regarding this issue, the survey study, where I believe they did not work through an attorney intermediary. The response rate was about 48 percent. We were expecting a higher response rate, perhaps 25 to 35 percent -- maybe not as high as 48 percent. That's what we were hoping for. But we are at 18 percent at this point.

To give you a sense of what our findings are looking like, the first one is respondent characteristics. As you can see, 56 percent of the respondents are parents of the injured party and 42 percent are the injured parties themselves.

The majority of the respondents are in the 36-to-

49-year age range. The majority are white. We have 7 percent that are Hispanic.

The majority of respondents are of a college graduate or graduate degree level, following by some college or technical or trade school, and also living in a four-person household.

As far as household income goes, 41 percent have a household income of over \$80,000 and 24 percent have a household income level of \$40,000-\$59,000.

Now we will get into some of the petitioner survey results.

How did petitioners learn about the program? How did they first learn about the program? Survey results showed that a Web site other than the VICP site was actually the likely source of information for petitioners, followed by 16 percent that used the program Web site itself, followed by parents or adults involved in the program, health-care providers who provided the vaccine, and other health-care providers. You see the other breakdowns there. The lowest percentage, 2.1 percent, was a flyer or brochure from the National Vaccine Program.

DR. HERR: Do you know what the primary site was? Do you know what the most common site was?

DR. SWAMY: We did not ask.

How easy was it to get information about the

program? You will see that 38 percent said very difficult or somewhat difficult and 34 percent said somewhat easy or very easy. We didn't specifically ask for explanation about what the source of the difficulty was. However, we did ask about other suggested sources of information. From that question, we received a couple of responses that we categorize into several categories. One was to make doctors more aware of the program, so that they will be the source of information to the injured party, and also to give information to patients when they first receive the vaccine. Those were the two most prevalent sources of information that were suggested when asked the question.

MS. BUCK: Just to clarify, I noticed that on the previous screen, the vaccine information statements were rated pretty low as a source of information. I assume they are talking about something -- they are not using the VIS, is what it's telling me.

DR. SWAMY: I would assume not. Again, we didn't ask for clarification, but I would assume that's the case.

We also asked about the helpfulness of the information about filing a claim. We specifically asked, how helpful was the information provided when filing a claim with the program? Thirty-three percent said very unhelpful or somewhat unhelpful, 37 percent said somewhat helpful or very helpful.

The majority of respondents were petitioners who hired an attorney, at 84 percent. Sixteen percent did not hire an attorney. We asked about the ease with which they had the experience of finding an attorney. Forty percent said it was a very difficult or somewhat difficult process, whereas 41 percent said it was somewhat easy or very easy. We asked about suggestions for making the process of finding and hiring an attorney easier. One suggestion was to publish a list of attorneys who specialized in vaccine injury cases, and potentially include that list in the package of initial information that is sent out and also include it on a Web site.

MS. HOIBERG: When I filed my claim, with the information that was sent to me, they did specify that they would provide you a lawyer. You could call a firm in Boston, I believe. But it would be nice to say, "Okay, you're in Florida, so here's a list of attorneys in Florida." I found that in being in close proximity with my attorney, I was able to -- there is a relationship that you have with the person and you can talk regularly, and there are no long-distance phone calls or anything like that. I think it would be wonderful if they could actually get a list of petitioner's attorneys.

DR. EVANS: I want to clarify something, Sarah. The program is not allowed to send out a list of attorneys.

What we do is refer to the court. The U.S. Court of Federal Claims keeps a list of attorneys that practice before the bar. There are other Web sites that also have lists of attorneys. But we cannot do that.

DR. HERR: Is there a link that we can have to the Court of Federal Claims, so that they can get that information, not directly from our Web site, but through a link to the court?

DR. EVANS: I will look into that, Tom.

DR. FISHER: I have a question on the one before that, petitioners who hired an attorney. Sixteen percent didn't hire an attorney. My question is, how did they get the survey? The survey came from their attorney.

It only makes me wonder -- 16 percent of the people were giving you bad information.

DR. SWAMY: Or they discontinued the process altogether. They did have an attorney and then they didn't follow through.

MR. SCONYERS: As we are listening to this presentation, I would ask the members to think about what this implies for us as we consider recommendations. Dr. Evans has responded that the program can't provide a list of attorneys. Whatever the source of that prohibition is, perhaps that should be addressed.

This is just an update on where we are with the

survey.

DR. SWAMY: I appreciate the questions, though. To the extent that I can offer any clarification, I'm happy to do that.

We also asked about the satisfaction with the claim-filing process. Fifty percent said that they were very dissatisfied or somewhat dissatisfied. Thirty-four percent said they were somewhat satisfied or very satisfied.

As far as the ease of obtaining additional information after filing a claim, 61 percent thought it would be very difficult or somewhat difficult to obtain that information. Only 21 percent said it was somewhat easy or very easy. We asked about what changes they would make to the claim-filing process. The respondents reported back that they would encourage a shorter process -- it's fairly lengthy one as it is, and they would appreciate a shorter process -- and to make the request easier to understand and perhaps offer assistance for interpreting the forms themselves. That would be beneficial.

Satisfaction with the hearing process, with the special master: We have 49 percent reporting very dissatisfied or somewhat dissatisfied, and 35 percent reporting somewhat satisfied or very satisfied.

Respondents who received a monetary award: We

have 57 percent who received an award. Forty-three percent did not receive any award. Of the 42 people who were denied an award, 24 percent appealed the decision, 4 percent pursued civil action, 17 percent withdrew after 240 days, 7 percent withdrew after 420 days, and 48 percent did none of the above.

MS. HOIBERG: So they just gave up altogether.

DR. SWAMY: That's what I would assume, yes. We didn't ask for clarification on that.

Satisfaction with the award process: Forty-seven percent were either very dissatisfied or somewhat dissatisfied with the award process. Twenty-eight percent were somewhat satisfied or very satisfied with the process.

How helpful was the program in working with Medicaid to reduce or forgive their lien? Twenty-six percent said it was very unhelpful or somewhat unhelpful, whereas 38 percent said it was very helpful.

Adequacy of award to cover past and future medical expenses for the injured party: Fifty-six percent said it was very inadequate or somewhat inadequate. Thirty-three percent, however, said it was somewhat inadequate or very adequate.

Sixty-five percent were very dissatisfied or somewhat dissatisfied with the length of the claims process, and 18 percent were somewhat satisfied or very

satisfied with the length of the claims process.

How satisfied were they with the way they currently received award payments? Twenty percent were very dissatisfied or somewhat dissatisfied, whereas 52 percent were somewhat satisfied or very satisfied. We asked how petitioners would improve the way the award was paid. They would reduce lag time between the award and payment. Another suggestion was to provide payment in one lump sum, if that's an option.

One of our final questions was, how would petitioners improve the program? We received a number of responses. One was, again, to make it a shorter process. They would also appreciate more respectful communication regarding this issue; make it a simpler process; more streamlined communication and information sharing; finally, outreach, to advertise to the public, to put more resources into that outreach strategy and effort.

So that's basically our preliminary analysis. I just want to share with you how we are going to move forward.

Our data collection is going to end in December 2008. Hopefully we will receive more surveys that we can actually add to our survey pool to conduct analysis on. We are going to complete analysis by exploring our survey results by the demographic characteristics and also by

whether or not they received an award, seeing if there is any difference in opinion there. We will also analyze the survey results on satisfaction with the VICP stakeholders and analyze the data from open-ended questions. I mentioned several of those responses to you. We are going to cull the data further and analyze the results, in a multitude of ways, to make sure that we use the data and maximize the data that we have collected so far.

All of this will be reported in a final report due to HRSA at the end of May.

MS. DREW: Will you provide a copy of the questions that you asked? Some of these responses don't seem to make any sense to me. You talk about the people who had their cases denied, but then we are talking about 25 percent of those people withdrew their petition. So their petition wasn't denied; it was withdrawn. Some of these things, just based on the headings, don't really make sense to me.

DR. SWAMY: Okay.

MR. SCONYERS: We will get Michelle to distribute the questionnaire so that everybody has it.

MS. CASTRO LEWIS: I would like to emphasize the importance of the open-ended questions, the analysis of them. The statistics are fine, to give us an indication of what's going on, but I think the open-ended questions are

really going to guide us better in terms of what we need to do next. So I recommend that you take a good look at that.

DR. SWAMY: Sure.

MR. SCONYERS: Other comments or questions?

MS. HOIBERG: I just think it speaks loud and clear to the failure that is this program at this point. We have a lot of work to do -- a lot.

MR. SCONYERS: Can you go back to the last slide? Your third point, I'm not sure what that means.

DR. SWAMY: In the survey we asked a number of questions about the respondent satisfaction with DOJ, a number of other stakeholders. So that's what we are going to actually analyze as well, in terms of the level of satisfaction they had with each stakeholder.

MR. SCONYERS: I misunderstood what your bullet was saying.

You have some data on some of the open-ended questions. Will that be reported in the final report, the narrative comments?

DR. SWAMY: Yes. What we will do is categorize the responses into main themes. But if the actual data is requested, that's actually HRSA's decision on whether to share that data with you.

MR. SCONYERS: I think it would be our sense that we would like to have that data shared with us. Am I

correct on that?

MS. CASTRO LEWIS: Yes. I have one more question. What will be the due date for receiving more questionnaires from petitioners? Is there a way that we can make an effort to increase the number of responses?

DR. SWAMY: We are ending data collection in December, just for contractual purposes. At this point, because we are working through an attorney, we have sent two follow-ups at this point. If the recommendation by HRSA is to continue sending follow-up reminders -- I actually don't know what the likelihood of our actually increasing our response rate will be. I don't think it will be significant. Time will go on, and as time goes on, the likelihood of our increasing our response rate is actually minimal.

Originally, it was a three-month data-collection window. In order for us to increase our response rate, we have extended it beyond that, so now it's a six-month window.

MS. CASTRO LEWIS: Thank you.

MR. SCONYERS: Thank you very much.

Having skipped our break, we are now right on schedule. In order to get us out of here on time this afternoon -- I know a lot of people are interested in attending the reception tonight -- I would like for us to

take a lunch break until 1:15, when we will recommence. You know me; I will start us again at 1:15. I hope to see everybody sitting at their places. We will get started at 1:15.

With that, we will adjourn for lunch. Thank you very much.

(Whereupon, at 12:00 noon, the meeting was adjourned for lunch.)

AFTERNOON SESSION

MR. SCONYERS: Thank you all for being on time. We're going to begin the afternoon portion of our meeting. We're going to start with Dr. Evans and his report from the Division of Vaccine Injury Compensation. You have slides in your blue folders.

Before I start, everyone should have received a copy of Barbara Loe Fisher's remarks. If you didn't, Michelle has some extra copies.

Also at your place you have the Petitioner Satisfaction Survey. Michelle made copies of the actual survey itself. That should go with your slides on the survey interim results.

Then you have some slides that were not in your packet earlier that will go with our presentation from the Institute of Medicine.

That's our housekeeping for this afternoon, and I will left Dr. Evans move on with his report.

Agenda Item: Report from the Division of Vaccine Injury Compensation

DR. EVANS: Thank you, Jeff.

As usual, I will start with the claims filed -- this is for the post-1988 program -- as of November 5. This will be in your meeting books and handouts in the table.

The trend that you see for the non-autism program -- it is increased for fiscal year 2007 because of the two-year deadline for getting in flu vaccines, just as a reminder -- has now dropped down to more of a steady state. We have been receiving on average about 167 claims per year. This has remained fairly steady.

You will notice in the autism column, however, that the downward trend that was present up until fiscal year 2007 has begun to go in the other direction. We think that's primarily because of the publicity, the fact that the National Vaccine Injury Compensation Program has received a lot of media interest since the autism hearings began. Certainly, our claims have increased as a result.

I would also mention -- and this becomes an issue for the commission to keep in the back of their mind -- that a process was begun to begin doing jurisdictional reviews approximately a year ago. The chief special master, in his visit here last time, advised that the court was assigning approximately 200 autism claims per month and the petitioners bar was beginning to get records for these cases. It's also a fact that after the Cedillo hearing in June 2007, claims that were newly filed with the program, either with medical records at that point or when they did receive medical records, would then assume the normal posture of having a 90-day turnaround time for review of

these medical records.

What I'm saying, just to be clear, is that up until June 2007, the short-form petition autism claims that were being filed, literally in the thousands, were basically put on a shelf and are now undergoing this jurisdictional review. The ones that have come in since June 2007, depending on their status and medical records, become subject to the 90-day review timeframe that is present for non-autism claims.

This is increasingly becoming a workload problem for our office and something that we are going to keep an eye on and let you know about as things go on. Obviously, you see a little bit of a trend increase here, but as the claims that are found to be jurisdictionally sound -- one would think it's only a matter of time before the court would begin to order them for medical review also. So it's something that we certainly anticipate as a workload issue, a staff issue, in the future.

Turning to the next slide, average annual award amounts paid represented here: \$59 million for petitioner's awards, \$4 million for attorneys' fees and costs. You will see that there was a peak outlay in 2007, and since then it has dropped. We believe that's because there has been a significant increase in the number of settlements. The settlements have an average award value

of less versus the ones that were compensated and went on to damages determinations previous to 2007. So as the percentage of claims that are settled increases, the average value for each one decreases as a result. You will see that, actually, in 2008, there was less compensation paid, and that trend may continue into 2009.

These are fairly subtle variations, but one may wonder why there was suddenly an increase and now it begins to go down again. Still, a lot of claims were adjudicated during 2008 and were paid.

Another interesting data point that people are always asking about is the current balance of the trust fund. This is now over \$2.9 billion. Just in the past couple of years, since influenza vaccine was added to the program, this has begun to increase significantly. It's not surprising, because there are more than 100 million doses of influenza vaccine distributed annually. If you are receiving 75 cents per dose for more than 100 million doses, you can see that this would significantly increase revenues coming in. According to my calculations, we are now probably netting somewhere on the order of \$260 million annually. So gross receipts minus what we are paying out, the trust fund is growing approximately \$250 million a year at this point, both with gross receipts coming in and the interest, which is approximately a third.

In terms of significant activities, continuing on with the views and some of the information that we received this morning, as you know, October 1, 1988 was the beginning of the program and October 1, 2008 marks the 20-year anniversary. Since the program began, over 12,000 claims have been filed and nearly 7,000 have been adjudicated, with compensation to more than 2,200 families and, as has been mentioned before, over \$1.8 billion.

In addition to compensation, the program has served as a successful alternative to the tort system. Back in 1985-86, DTP vaccine lawsuits peaked 255 and have been going down ever since. The way this is tracked, for non-autism claims -- because there are hundreds of autism claims in the civil courts these days -- for non-autism claims, for all 16 vaccines that are covered by the program, according to an informal survey that we were able to do among vaccine companies, there are fewer than two dozen claims now filed annually. But that's data that is back to 2005 that needs to be updated, too. But I have no indication that there has been a significant increase in the number of suits for non-autism claims.

So clearly the program is functioning very well that way.

I would like to also take this opportunity to salute the dedicated professional staff and support staff

that have worked for Health and Human Services, worked for the Department of Justice these 20 years, and also for the Office of Special Masters for the court. It's a program that has an extremely important mission in helping children and families and individuals who have been harmed by vaccines. I look forward to an even more successful program over the next 20 years.

In terms of activities, on September 16-17, I represented HRSA at the National Vaccine Advisory Committee. I was joined by Tammy Tempfer, who is the ACCV representative to NVAC. The topics included adolescent and adult immunization, vaccine financing was one of the key votes that was taken that day, and there was an update on the process for the updating of the National Vaccine Plan. Ray Strikas came the last time and told about the process for trying to get the vaccine plan updated through using an Institute of Medicine process.

Tammy and I gave an update on the program. Tammy talked about the commission. There were a couple of questions about the survey.

Tammy is going to be revolving off the commission, and Magdalena is going to be taking her place. So we don't have to have those Buffalo fly-ins in the morning.

Next, the Institute of Medicine contract, which

you referred to: I'll simply say that this was a contract awarded at the end of September, right before the end of the fiscal year, for \$1.7 million. The commission has certainly expressed an interest in having independent studies of the Vaccine Injury Table vaccines, as well as vaccine adverse events possibly associated with them, something we are very excited about. This is new, just getting off the ground right now. We look forward to Dr. Stratton filling us in on some further details.

Dr. Rosemary Johann-Liang is going to be the project officer on the HHS side for this contract. Rosemary is in the audience.

Next, the interim final rule, which I would like to say a couple more things about. Sarah brought up a point about whether there are possibly products that may still be out there. I thought I would take a couple of minutes to explain a little further about what actually took place in putting this on.

Rotavirus vaccine was licensed in 1998 and the excise tax was put into place four months later. It was put on the table as a general category of rotavirus vaccines at that time. It was officially put on the table, actually, in July 1999 -- we finally got the notice published, at least. But about that same time, the CDC recommended that its use be suspended. Three or four

months later, Wyeth did a national recall of the product. As well, the ACIP withdrew their recommendation.

This all took place toward the end of 1999. In 2002, through formal rulemaking, public comment, hearing, et cetera, the final rule established a separate category for the RotaShield live oral rhesus-based vaccine, with intussusception with as the injury, with an onset of zero to 30 days.

That stayed on there, and subsequently there were about three dozen RotaShield claims filed, the last of which was filed in 2004. Given that the vaccine was no longer administered, given the fact that when this was put on in 2002, as I explained earlier, there is a very short effective period, because the vaccine had now been taken off the market and was not being given in this country for more than three years.

So those were the circumstances in 2002, when it was added, the thinking being now in 2008 that since there is very little chance anyone could file a claim at this point, it simply was something that had no further function on the Vaccine Injury Table, and if anything, would imply that the two currently licensed vaccines, Rotateq and Rotarix, have this injury that has been associated with them and should receive that presumption, and that is not the case at this point -- not to mention the fact that

legally it was not effective any longer.

That's the reason why the secretary moved to remove from the table at this point, and did so in a little bit of a different mechanism -- not formal rulemaking, but not just a notice. Since it was technical in nature, but had the potential for, maybe, some questions being raised, it was done as an interim final rule. Therefore, once it was put in the *Federal Register* on October 9, there was a 30-day comment period for individuals to submit any comments or questions they had. I'm aware of only one comment that was filed, and it was not specific to the removal itself. It had more general kinds of comments.

So that's the basis for the interim final rule. The very unexciting text that is laid out in most *Federal Register* notices also is in your book for you to read.

Finally, Dr. Rosemary Johann-Liang and I attended the ACIP meeting in Atlanta. I believe the only news that hit the media for that meeting was that adults smokers were now being recommended to have the pneumococcal polysaccharide vaccine, which is the pneumococcal vaccine that is not covered by our program. We cover the conjugate, which is recommended for children. I, of course, gave a brief update, as is customary, at that meeting.

I think that's the end of my update.

MR. SCONYERS: Any questions or comments for Dr. Evans?

I do have -- I don't know whether it's one or two or several.

I think the dates of our last meeting and the publication of the interim final rule are close enough together that I think, as a matter of courtesy, this committee should have received some greater information about the proposed withdrawal. I assume that it wasn't decided on October 8 and published on October 9.

I looked at our charter, as we were learning for the first time this morning that the table had been updated. I do see that it's not within our charter that changes to the table come before us. But it's my understanding that historically that has certainly been the case.

I think, as a matter of courtesy and appropriate use of this commission, it would have been much better to, if nothing else, let us all know by email or by mail that this change was pending and let us all give some input on it, because I think there may be views on the part of the members here as to whether this is a change that is warranted or not.

As I say, I looked at the charter and I don't see that it's required that this change come to us in the first

place. But as a matter of courtesy, I think several of us would have appreciated that.

DR. EVANS: I apologize for any oversight that is perceived. I guess the thinking at the time was that this was a purely technical change, one that in most circumstances would simply be a notice and something that did not require -- and Elizabeth may have a different opinion, but we did not feel it required insight or feedback or comment by the commission, since it was a technical change.

But certainly the courtesy of knowing in advance is a well-regarded comment.

MR. SCONYERS: I'm unclear about -- is RotaShield still an approved product?

MS. GALLAGHER: I can check, but I don't think so. I think the license has been withdrawn. I can get back to you on that.

MR. SCONYERS: That would have been a question that I would have raised prior to publication.

DR. EVANS: I don't think the license was withdrawn as far as an FDA --

MS. GALLAGHER: I meant withdrawn by the company. You can file to have your license withdrawn. I don't think the license exists anymore. But I will check on that and get back to you.

DR. EVANS: This was an appendage on the table. This was a category that had no legal meaning whatsoever because it had been ineffective years previously.

MR. SCONYERS: One way of looking at it is that. Another is that if it's an approved product, it can be marketed again. To leave it on the table is to address the risk of intussusception if this product were ever, for some reason, to come back on the market.

I know that seems unlikely, but it's within the bounds of possibility. Whether that would have had a change to whether you would make the alteration to the table or not I don't know. But having now not had an opportunity to provide that insight -- if it is an insight -- that opportunity is lost, right? Thirty days has passed since October 9.

DR. EVANS: The 30-day comment period has passed. If there is comment that the ACCV would like to provide the secretary, I would encourage you to put it together and provide it. We will then evaluate it and make a determination.

MR. SCONYERS: I simply was surprised to hear about this this morning for the first time.

Comments?

(No response)

Next on our agenda is our regular report from the

Department of Justice. We appreciate Vince Matanoski being here from the Torts Branch.

Thanks, Vince, for coming in.

Agenda Item: Report from the Department of Justice

MR. MATANOSKI: Thank you. Good afternoon, everyone. I'm pleased to be back to address you. I'm sorry, again, that I'm back here because Mr. Rogers is still in Iraq. I'm sure he is sorrier than I am about that. I'll do the best I can here.

This is a little bit new for me, because I'm not used to doing PowerPoint presentations. We had a name for those years ago when they first came out. In DOD, a lot of people seemed to grab onto PowerPoint and use it, and you couldn't go to a meeting without having it at that time. And at that time in currency amongst little kids were Power Rangers. Those groups of people who would use PowerPoint were known in DOD as PowerPoint Rangers.

I hope not to become one. But in putting this together, I realized that this actually is a pretty useful tool. I have to confess, other people put it together for me. But I found that it could be a useful tool in explaining things.

I remember when I was here in September, my oral presentations raised more questions than it answered.

Hopefully, by combining my oral comments here with this PowerPoint, it will be a little clearer for everyone.

The first one has our fancy seal. I think we can go right past that.

This one -- I think you already understand that.

The cast -- the reason I have this on is -- Tom Powers is going to be coming up next. I had to settle an issue, and we decided we would arm-wrestle over it, and I lost. Nothing good was accomplished out of breaking my wrist, not even that.

The statistics we have. This was a shorter reporting period than last time. It's more like a two-month or two-and-a-half-month window here. We had a total of 86 cases filed during that period. As you can see, the breakdown was 55 non-autism and 31 autism.

Just kind of a rough feeling I was getting as I saw these cases come in the non-autism area was that it seemed like an uptick in flu cases coming in -- it shouldn't say flu cases, but cases that alleged injuries due to the influenza vaccine. I didn't see any particular trend in the type of injury alleged, but it seemed to me -- and this is just kind of an intuition -- that there were more flu cases coming in.

DR. HERR: Any specification of what particular vaccine, whether it's the injected, the live vaccine?

MR. MATANOSKI: Since most of the cases were individuals over 50 years old, it probably was the injected vaccine, since the live vaccine is recommended over age 50.

As the nurse told me when she was going to give me the live vaccine, "How old are you?"

I said, "Do I look that old? Do I look like I'm over 50 now?"

DR. HERR: That would be an important differentiation as we look at the years coming down through: Is it the injected or is it the oral?

MR. MATANOSKI: It was the injected, I think, in every case that I looked at. Some of the cases don't have the records with them, but they would have the age of the individual. With the age of the individual being in the 60s and 70s, it would be the injected vaccine.

Any other questions on that?

(No response)

This is where I think things got a little confusing last time. I hope to go through this particular slide and then there is a glossary of terms that everyone had, which I think might make this a little clearer.

In this last period, we had 20 cases adjudicated. I usually contrast that with the number of cases coming in. You can see we had a lot more cases coming in than adjudicated. Of those cases that are adjudicated, there is

a breakdown here that tells you compensable and non-compensable: How many of those were found compensable? How many were found non-compensable? Thirteen were compensable and seven were non-compensable.

Within the category of compensable, we broke them down a little bit more so you can get a little bit more information about them. Of those 13, six of them were conceded by Health and Human Services. Seven of those that were found compensable were not conceded, but were settled by the parties without a decision of the court.

So that's the basic breakdown of what happened with those 20 cases. Later on I have a kind of flow chart that shows how we get to those points, which I think might make things a little clearer, in terms of the questions I got last time.

MR. SCONYERS: Vince, could I just ask one question about that before you move on? I'm assuming that none of those cases were table injury cases?

MR. MATANOSKI: The conceded cases I'm not certain about. The conceded cases may have been table injury cases. It would be either table injury or causation and fact conceded by the Division of Vaccine Injury Compensation. I don't have the breakdown of whether, of those six, they were all table or whether they were a mix of table and actual causation.

MR. SCONYERS: I had someone ask me at lunch about the settled cases, and whether those settlements are subject to FOIA requests. It was my impression that they were not, but this is not my area. I didn't know how to answer that.

MR. MATANOSKI: I'm not sure, since I didn't hear the conversation -- the stipulation settling the case itself, the court publishes that. The court gives the parties a chance -- primarily, the petitioner a chance -- to have their name removed, but the court will publish the stipulation itself settling the case.

Documents that the petitioners have -- obviously, they are not going to be subject to the Freedom of Information Act. But within the Department of Justice, pre-decisional documents would be, under FOIA, exempt from --

MR. SCONYERS: That was my impression. I just wanted to confirm that. Thank you.

MR. MATANOSKI: This is the glossary. In coming up with these definitions, we tried to make them -- when we first put them together, they had a lot of the legal terms in there, and we tried to get that out and make it a little more understandable, I think, for a non-lawyer. The glossary should be helpful in understanding the statistics that I just gave you.

There was one area that I think might be a little confusing from that previous slide. It was about "decision." As reflected on this slide, "decision" was only talking about compensable cases, where there had been a decision on a case that had not been conceded by HHS, but, the quote went on, "and decided it and gave compensation." As you can see, in this last period, no cases came up in that category. All the non-compensable cases in that category were decisions by the court finding that the petitioner was not entitled to compensation.

I'm not going to read the glossary of terms for you. I know you have had a chance to take a look at this. If you have any questions about the definitions there, I will try to explain them.

MR. SCONYERS: I appreciate your putting this together. It was our request last time, and I appreciate your being responsive to it.

MR. MATANOSKI: Thanks. Like I said, I can't take the credit for the actual technical aspect of it, but I am hopeful that this is going to make my presentation a little clearer.

DR. FISHER: I have a question on the conceded. The definition of "conceded" is that the department determines that the petition should be compensated.

MR. MATANOSKI: Yes.

DR. FISHER: So it really doesn't say cause, but it says it fits the compensation.

MR. MATANOSKI: Right. And there are two reasons that it could be compensated. One could be that it fits the presumptive injuries on the table and the other could be that it does not fit the presumptive injuries on the table, but there is sufficient proof of actual causation.

Now I'll go to the flow chart. This, I thought, might help explain how we get to the endpoint of compensated/not compensated, what happens with a petition once it's filed.

MS. BUCK: A quick question. Are the conceded cases public? Are those published for people to read?

MR. MATANOSKI: I believe when the court enters a decision on the case, the final decision, it will be a public decision, a public document. It will explain the procedural history of the case. It's probably going to be a very short decision. In those instances, the longer part of that decision will be talking about damages. Often the damages parts of those decisions are series of charts that explain what compensation is going out over the years for the various categories of compensable item -- neurologist care or something like that.

MR. SCONYERS: But again, the division's analysis of the grounds for conceding -- is that part of the pre-

decisional materials?

MR. MATANOSKI: The analysis, as far as it was reflected in a pleading that was filed, would be part of the court file that would be filed in that case. There is statutory provision that essentially says that all the information filed in the case is not disclosable without the written consent of the party that provided it. It's disclosed to the parties in the court, but it's not disclosed to the public in general.

Court decisions, on the other hand, by statute are. What will be reflected in a decision on a conceded case is that there was a case that was alleging a certain injury after the vaccination and it was conceded as a table case or actual causation.

With this chart, we tried to think through what happens with a case after it is filed, the steps along the way, to try to give a sense of what the process is, in visual form at least.

You have a petition that is filed. After the record is complete in that petition, HHS reviews the case. That initial review of the case can result in one of two things: either HHS recommending that the case be conceded or HHS recommending that it not be conceded.

To think about those 20 cases where we know what happened in this last period, HHS essentially said, "We

don't believe 14 of those 20 should be conceded. Six of them we believe should be conceded."

Now, what happens with those six that were conceded? They are going to go on to damages. You can see that from the diagram there. They go on and then there is a determination of damages.

The ones that are not conceded -- in this example, the 14 that were not conceded -- those are essentially on track to go to court for a hearing and have the court determine whether or not the case should be compensated.

On that track, or as the case is developed, the parties may come to a resolution of the case short of a court decision. That's what we have there on the chart in "Settled." That happened to those 14. Seven of those cases were settled by agreement of the parties. The other seven went on to be decided by the special master. In this particular example, in all seven of those cases the special master found that the case shouldn't be compensated.

If, however, the special master were to have found one or more of those cases to be compensated, what would happen with that case is that it would go on to damages, just like you saw with the conceded cases. Then the parties either manage to determine what the damages are, working cooperatively together, or if they aren't able

to figure out what the compensation should be between themselves -- usually, they have actually agreed on some of the compensation and they leave a couple of issues for the court to resolve.

MS. BUCK: So "Decision," that box is something that's done with the special master. Tell me the difference between your "Conceded" box, then, and your "Settled" box, in terms of making a determination there. What's different about those two?

MR. MATANOSKI: The "Conceded" means that the secretary believes that --

MS. BUCK: It's his decision. And "Settled" is a decision between the parties and Justice? Is that the difference?

MR. MATANOSKI: No. It's between the parties, the parties being the secretary and the petitioner.

MS. BUCK: So what is the difference?

MR. MATANOSKI: The "Conceded" means that the secretary's review has indicated that the case qualifies under the statute for table injury or under the regulation for table injury or under the statute requirements and existing case law, actual causation --

MS. BUCK: I get that. So is "Settled" just that he rethought it?

MR. MATANOSKI: No.

MS. BUCK: How does it differ, then?

MR. MATANOSKI: "Settled" means the secretary still maintains that the case is not compensable under the table or as a matter of actual causation. But the parties have managed to -- nevertheless, they continue to maintain their positions. They have worked out an arrangement that some compensation goes to the petitioner, short of having the case decided by the court. There is a meeting of the minds between the parties that, while they maintain their separate positions, an amount of money should be paid to settle the case.

MS. BUCK: And those decisions are made not looking at the table or causation? What kinds of pieces come into that?

MR. MATANOSKI: Actually, the secretary has already made the determination, at least in the secretary's view, of whether the table or actual causation has been met. There are varied considerations.

MS. BUCK: Can you give me some examples?

MR. MATANOSKI: Yes. Say the other side has an expert witness. The relative strength of that expert. It may be weaker or stronger. Both parties may be thinking of that. The petitioner may say, "I have a weak expert, and so I'm probably going to lose if I go to trial, so I want to settle." The respondent may say, "The petitioner has a

strong expert, and we may lose if we go to trial, so we may want to settle this case."

That's just one kind of factor. Another kind of consideration may be the cost of continuing the litigation. With the program paying attorneys' fees in the case, one might conclude that the litigation costs of continuing on are going to exceed an amount that the petitioner finds acceptable to settle their case. I think in that instance the general public would say, better to enrich the petitioner than lawyers --

MS. BUCK: I notice you don't have a line from "Settle" to "Damages." When you settle a case, are damages done the same way, Vince, with a life-care plan and all that? Or is it just a single lump-sum payment?

MR. MATANOSKI: That's a really good observation. It can go either way. It might be that the parties, without using life-care planners, end up deciding on an amount. Many of the cases go that way that are settled. However, in some instances, the parties engage life-care planners and determine how much the ultimate damages would be if the case were to go, in kind of an all-or-nothing proposition. Then there may be a settlement based on the assessment of what the damages are, but with the recognition that this is not a finding of compensation in the case. So you may not get all of what the life-care

planner says.

MS. BUCK: Are those settlements paid the same way, like into the reversionary trusts, or in the same general way? Are they distributed like the other type?

MR. MATANOSKI: As far as I know, there is no difference in the way they are paid out.

MS. BUCK: Thanks.

MR. MATANOSKI: Sure.

I think that explains the chart. Are there other questions?

MS. CASTRO LEWIS: I continue looking at the chart and I see that it is like a circle. The "Damages" is the end, but what I'm seeing is that you can read it from left to right and from right to left. The end is if you are not compensated or compensated, right?

PARTICIPANT: It can end various ways.

MR. MATANOSKI: Damages would be the endpoint. I'm looking at it now and I can see how one could say, then we get to damages and then we come back around to compensated -- it's linear. It moves left to right, and when you get to damages, that's an endpoint.

MS. TEMPFER: I just have a clarification also. Where do the special masters come in? Is that the "Decision" box? What about Court of Appeals? Is that outside this?

MR. MATANOSKI: All really good questions. The special masters actually are involved in the process all the way along. They are issuing orders. They are having status conferences. Where they are actually doing something as far as this chart is concerned is where it says "Decision." They also could be doing something where it says "Damages," because they could be issuing a decision at that point, too. But they are involved in the process all the way along.

Where does the Court of Appeals come in? Where it says "Not compensated," that could be appealed. That's a final decision. Where it says "Damages," there could be an appeal out of that.

I don't recall very many appeals in the last decade where a petitioner has objected to the amount of damages that they have received. There were some earlier cases where the law concerning certain things like lost wages was being settled and petitioners may have appealed a decision giving them damages.

Generally, if a case has gone to damages, they are not being appealed, unless the secretary is appealing it. I can't recall a situation, other than, I guess, the death benefit situation, in recent memory where the secretary appealed an award of damages. If the secretary was appealing, it was the finding of entitlement in the

first place, the finding that the person was entitled to compensation, rather than the amount of compensation a person got.

So it's in those two places where you could see an appeal coming out, not compensated and after damages.

We have actually been through the autism -- I think you are up to date on the next couple slides. What I will tell you about, though, is that the interim fees have been filed in both the *Cedillo* case and by the Petitioners' Steering Committee, and that's under consideration by the court in both instances. They are moving forward on that -- or the interim fees are moving forward.

The other matter that -- the post-hearing briefs for the second theory are now scheduled. I believe the PSC, the Petitioners' Steering Committee, brief is due February 6, 2009, and respondent's brief, I believe, is due April 9, 2009.

MR. SCONYERS: I'm sorry, what's that --

MR. MATANOSKI: The second theory of causation in the autism cases is now -- the transcripts have been reviewed and the PSC is working on their post-hearing brief and we will be responding to their post-hearing brief thereafter.

DR. FISHER: So that means no decision before April or before May.

MR. MATANOSKI: That's correct. I would imagine the court is going to take some time after the briefing is closed before the court will issue a decision.

The briefing is done on the first theory. Actually, it has been done for quite a while. A decision may be coming out sooner.

DR. FISHER: So they may decide one theory, but not the other.

MR. MATANOSKI: That's right. I think everybody anticipated that theory one would be decided before theory two, and it may be decided well before theory two.

The next thing is, we had some appellate activity. Actually, we had a lot of appellate activity. I'll try to move along here, because I think I'm running behind.

DeBazan and *Mojica*, which are up there, we talked about last time. But one that just came out was *Kay*. That was mentioned at the last meeting of the ACCV. It was a case that was found to be time-barred. That is, the statute of limitations prevented it from being heard. The petitioner's counsel sought attorneys' fees. The court denied them attorneys' fees. That denial has been affirmed by the Federal Circuit, November 10. It was just last week that it was affirmed.

There was no written decision with that. It was

a per curiam affirmance -- what we call in the law "per curiam," which means that the court didn't issue a decision. It's just a summary affirmance in the case.

The other two that are recently filed that are pending, *Nordwall* and *Andreu*, are pretty much fact-specific. I'm not sure you are going to see tremendous development in the law there, although the Federal Circuit, if they decide to write on it, may give us some new law to work with. They may make things a little clearer for us. That's what we always hope for, at least.

At the Court of Federal Claims, we have been really, really busy. I didn't count these up, but I think I have two pages of appeals that were decided or are pending since the last time I spoke to you. I won't go through each of these cases.

The *Hopkins* cases that were affirmed recently were companion cases. They had been remanded to the special master to do some more fact finding. He did. He came back and said that the petitioners were not entitled to compensation. That was affirmed by Judge Horn after it went back up to her following remand.

The *Savin* case was an attorneys'-fee case brought. The different issue there for the court was, the respondent had objected to some parts of the request for attorneys' fees. The court had accepted some of those

objections and not all of them, but the court had also found some other areas that the respondent hadn't objected to where the court reduced the fees. The appeal was taken up on the complaint that the court overstepped its bounds. Our argument to the Court of Federal Claims was that the special masters, as the statute is written, have an independent duty to decide what they think is reasonable compensation in a case, regardless of what the parties say. The Court of Federal Claims agreed that that is an independent duty that the special masters have.

We do have a couple of other cases here that are pending that are also fees cases, which is kind of interesting. *Carrington*, I know, is one of them. That is on the second page of the appeals. That has been argued. We may be getting some more decisions out of the court with regard to attorneys' fees.

Again, just intuition: It seems like we are seeing more appellate activity on the attorneys'-fee issues coming up.

Four of the cases that you see pending were all decided by one decision by a special master. They are all autoimmune hepatitis cases. Those are the *Myers* case, *Porter*, *Rotoli*, and *Torbett*. We will probably have one decision come out deciding all those.

There were actually five cases decided. It was a

very exhaustive decision by the special master, looking at the common issue of whether autoimmune hepatitis could be related to the hepatitis B vaccine. There is one more out there that is being appealed as well, so there are five. We anticipate that there will be one decision that will resolve all of those cases.

That is it for my comments. I would welcome any further questions that you might have.

MR. SCONYERS: Any questions for Vince?

MS. CASTRO LEWIS: I just have a comment. It's just to thank you for preparing this PowerPoint. It actually made it much easier to understand and to see the process. Thank you.

MR. MATANOSKI: You're very welcome. I'm becoming a PowerPoint Ranger, then.

MS. BUCK: Vince, have there been interim attorneys' fees paid? I know you worked with the steering committee to establish break points. Has there been some success with that?

MR. MATANOSKI: Yes, there has. As a matter of fact, I think I figured the last time that there had been about 15 payments. They continue to be paid.

The break points, for the most part -- the firms that had the vast majority of the cases seemed to be okay with the break points. Where we are seeing a little bit of

concern for us and the DOJ end is, we are seeing requests for multiple interim fees. That has the possibility of slowing things down quite a bit.

In our view, what the court was trying to do was -- it understood that you could get a situation where there is fairly extensive litigation, it's going on for a long period of time, there are a lot of fees and costs invested in the case, and the case is going to go on for a long time more. The paradigm example is a case where entitlement was not conceded. There was a long, involved hearing on entitlement. Experts were used. A decision comes out on entitlement and says, in fact, the petitioners are entitled to compensation. So now you are going to go into the damages, which can take a while. Even though they tend not to be as contentious in the sense of hearings, they tend to take a long time to get the damages assessed. So now you might be looking at another full year before you get to the end of the case.

That was what was the court was directing interim fees to address, that kind of instance where there is going to be a long time and there has already been a lot --

MS. BUCK: And you were thinking a single payment, not multiple?

MR. MATANOSKI: Exactly. Not multiple because --

MS. BUCK: When you say break points, you are just talking about places where they could submit for their one singular request, not all these places along the line that they can submit requests for?

MR. MATANOSKI: That's right. What we were thinking was that what might trigger it would be that a decision comes out and we're going to damages, so there is going to be extended litigation further on, high costs. Those were the kinds of things we were thinking about in terms of break points.

What we are concerned about, about multiple interim fees -- if we see this every month in a case -- is that a lot of the resources will then be relegated to a series of decisions and review of these, and frankly, to the detriment of getting to the resolution of the case. We only have a limited amount of resources in terms of the people and the time that they have to devote to these cases. We are limited in terms of staff at DOJ, and obviously the court is limited. They are actually limited by statute as to how many special masters can be there deciding cases. So if they are deciding multiple interim fees and issuing decisions multiple times, then that could slow down their ability to issue decisions resolving cases.

DR. HERR: I appreciate the time looking at the appeals, the precedent-setting appeals, but you guys are

going to mention some of these cases time and time again in the future. I don't think you need to go over the old ones each time. But on the other hand, could you sort of have an updating list of precedent-setting cases and what they actually meant, so that when you refer to a particular case -- we would go, "I know they talked about that six months ago, but what was it?" -- we can just refer to it, rather than bother you with the question? Then just discuss the new updates.

MR. MATANOSKI: That's a great suggestion. We will try to identify those cases that look like they may have some impact and give you a little description of those. Then we can follow those on through and see what happens with them. Then you will have more than just the one line here of the cases that were filed.

MR. SCONYERS: I think especially for cases that are at the Circuit Court, because those are precedent-setting.

MR. MATANOSKI: Right.

MR. SCONYERS: Remind us what *DeBazan* is about.

MR. MATANOSKI: Right, right.

DR. HERR: Or *Avera* and all of those.

MR. SCONYERS: To have it just be in the materials would be helpful. I think that's what Tom is suggesting.

MR. MATANOSKI: I'll do that.

MS. TEMPFER: I just wanted to thank you also for the glossary of terms. That is so helpful -- and the flow chart. I would really recommend using that for the orientation for the new ACCV commissioners, especially us non-attorney ones. This finally sort of solidified for me what was going on with all the different cases.

MR. MATANOSKI: That's another great suggestion. I'll do that.

I'm sitting here taking all the praise and I'm looking at the people who did all the work. Julia worked hard on this, and there were some other folks in our office, some of our paralegals. I shouldn't be sitting here basking in this praise. Thanks.

MR. SCONYERS: Take it when you can get it.

MR. MATANOSKI: But I have to work with those folks, and they know.

MR. SCONYERS: Any other comments for Vince?

(No response)

Thank you very much. It's really very helpful to have it organized and presented in this way.

We are very pleased to have Tom Powers here to talk with us from the Petitioners' Steering Committee and the petitioners bar standpoint. Tom, as you know, has joined us several times by phone. He has been very

stalwart in participating and providing very helpful input to the commission. Here he is in person. He is not just a disembodied voice.

Thank you for coming.

Agenda Item: Report on Autism Hearing from the Petitioners' Steering Committee

MR. POWERS: I appreciate the invitation and the opportunity to come here.

I don't have a PowerPoint, so I won't have praise to bask in. But I can at least try to organize my thoughts in a PowerPoint-esque way, so that you can track what I have to say in providing an update on what's going on with the Omnibus Proceedings.

In particular, I want to focus on some issues, based on feedback from members of the ACCV coming out of the last couple of telephonic updates that I have given and that Vince has given, some fundamental questions about the omnibus proceeding itself, and make clear just with a little overview what the Omnibus Proceeding is all about and what the PSC's role is.

In PowerPoint form, I will talk about the Omnibus Autism Proceeding, a very brief summary of its history and its current status. Secondly, I'll talk about the Petitioners' Steering Committee, its history and current status, how it came about and how it fits into the role of

adjudicating the autism cases within the Omnibus Proceeding. I will talk a little bit about the test cases that we have been providing updates about and that Vince mentioned. I will talk about the timeliness hearings and the statute-of-limitation issues that are raised in those timeliness hearings that are going on. I will talk very briefly about interim fees and then talk even more briefly about civil cases, technically outside, obviously, the purview of the Vaccine Compensation Program, but given the intersection of the vaccine program, the vaccine statute, and the civil justice system, something that might be of interest to folks on the ACCV.

I should preface it by saying that my role as an attorney here -- unlike Sherry, the only cases that I have ever done in the program are these autism cases. So I had not had any vaccine injury cases that I had prosecuted in the Vaccine Compensation Program until I got involved with the autism cases back in 2002.

I'm an attorney in private practice in Portland, Oregon. It's a four-lawyer law firm. We do plaintiff-side civil litigation, mainly involving pharmaceuticals, which is why we got involved in these cases to begin with.

So I just want to make that clear. I am not the person to talk to about the overall history of the program or about litigating individual vaccine cases, aside from

the Omnibus Autism Proceeding. That's my experience exclusively in the program.

The OAP was set up by the chief special master, Gary Golkiewicz in 2002, when it became clear to everybody -- to the petitioners' bar, to HHS, to DOJ, to the Office of Special Masters -- that in 2001 and 2002, there was a train coming down the tracks. There were a significant number of autism cases that were being filed in the program. Folks were aware that there were a number of autism cases that likely would end up in the program, because people knew that they were being filed in the civil system. So in anticipation of handling what really would be an unprecedented caseload -- potentially, many thousands of cases -- the chief special master and the stakeholders in the program sat down and talked about how to manage those. The Omnibus Autism Proceeding, at its heart, is a case-management tool.

The idea was that there would likely be very common issues of science and medicine that would underlie all of the autism claims. Now that we are sitting here with about 5,000 of those claims, the thinking was that rather than having to handle 5,000 claims one at a time, which would just cripple the system, if there were common issues of science and medicine, we could resolve those general causation issues in an aggregate way, and do it in

a way that could then be applied to the individual cases to resolve those.

So as case management and economy of scale, judicial efficiency, and, frankly, resource efficiency, it's a way of managing this huge caseload.

So that's where the OAP came from. Since July 1, 2002, which I think is when the general order was signed creating the Omnibus -- from then until now, there has been a huge amount of activity, many thousands of hours of work by attorneys from the respondent's side and the petitioners' side, developing the scientific evidence, the medical evidence, putting on the testimony, and conducting hearings, all designed to establish principles of general causation, under the legal standards in the program, that might then help resolve individual cases in the Omnibus Proceeding.

Something else that happened, in addition to developing all that evidence and conducting the hearings -- and the hearings were in the test cases that I will talk about in just a second -- in addition to that, there was discovery that went forward under the Omnibus Autism Proceeding. As we heard earlier, discovery is typically not available as a matter of right to parties in the vaccine program. But through arguing and litigating, and sometimes even agreeing, within the OAP, the DOJ

lawyers and petitioners' lawyers developed a pretty extensive set of discovery requests and responses -- tens of thousands of pages from FDA, from CDC, even some depositions of HHS employees and scientists.

That is pretty unusual. There was discovery that went on in OAP.

The OAP ultimately conducted the test-case hearings. The petitioners in this whole process -- 5,000 petitioners, with 180-plus lawyers, some lawyers with one or two cases, other lawyers with many hundreds of cases -- again as a matter of efficiency, rather than the special masters -- at the onset, Special Master Hastings, singular -- having one special master having to deal with 180 petitioners' lawyers, you can instantly see that that might be a bit unwieldy, to say the least. So the petitioners within the OAP got together and essentially selected a steering committee, a group of lawyers who made a decision to commit resource and time and money to spearhead the effort on general causation and pursuing the test cases in the program.

Technically, the PSC is every single one of those individual lawyers that has anywhere from one to 1,200 autism cases in the OAP. That, technically, is the entire PSC. But there is a group of perhaps a dozen law firms that in the last six years have been most active in

pursuing these claims. That's the executive committee of the PSC, or the steering committee. It's not a technical organizational flow chart. It's a bit more vernacular than that. But that's essentially what it is.

That has been my role and my law firm's role, helping to guide the steering committee of the PSC, and so, in a sense, the responsibility for pursuing the general causation issues on behalf of all the claimants and all the individual attorneys with cases in the OAP.

All of that work culminated in two significant series of events. We have talked about them extensively, so I'll just very quickly hit them now. Those are the test-case hearings.

As Vince explained, the three MMR-thimerosal-combined exposure theory cases were heard back in 2007. The *Cedillo* case was in May, the *Hazelhurst* case was in October, and the *Snyder* case was in November of 2007.

As Vince also mentioned, decisions in those cases are, we believe, imminent. There is no clock set on that. There is no timeline on that.

I should say that it does get frustrating for everybody to be waiting and waiting and waiting. If you start peeking out into the blogosphere, there are a gazillion theories about some conspiracy about why it is taking so long. From having spent all these years in

contact with respondent's counsel and with the special masters, I am 100 percent confident that the reason the decisions are taking as long as they are taking is that the special masters understand that they are significant, they understand that there is a huge body of evidence that they need to look at, there are a lot of arguments to consider, and they know that the stakes are high. I'm confident that they are taking the time they need to get it right. If it takes a long time, I would rather wait a little longer -- and certainly my clients would rather wait a little bit longer -- knowing that the record was considered thoroughly and that the import and the impact of those decisions was taken into account.

So I think that's why it is taking so long. They have a huge amount of very important work to do.

After those cases were heard in 2007, the next round of test cases, on the thimerosal exposure theory, were heard this past year. The *King* and *Mead* cases -- those happen to be clients of mine -- were heard in a three-week hearing in May of 2008 here in D.C. In July of 2008, the third and final test case, the *Dwyer* case, was heard in D.C.

The briefing on those is in progress. As I am acutely aware, the petitioner goes first on the briefing, so I know that the respondent's counsel -- it's not as if

they put everything on the shelf and are not looking at it. But I'm certainly plunging into the record, going through three weeks of transcripts and hundreds and hundreds of science journal articles to develop the post-hearing brief.

"Post-hearing brief" is a legal term. It's essentially arguing on paper the evidence that was into the record at the hearings. At the hearings, there were expert reports submitted by both sides, ahead of the hearings. The medical records of the children were submitted to the special masters well in advance of the hearings. At the hearings themselves, the expert witnesses and fact witnesses -- essentially, the parents as fact witnesses -- appeared and testified live, very much like a court you would see on the *Law and Order* shows on TV, the big difference being that there is no jury, obviously. The special masters are hearing them. With no rules of evidence, you don't get the drama of the TV objections -- banging the table on hearsay and relevance and all that kind of stuff.

It's an opportunity for those witnesses to testify live and for the special masters to ask questions directly of the witnesses.

After doing all of that, both parties then look at that record and, as I said, in written form, summarize and reargue the case on paper and submit it to the special

masters.

Questions have come up to me about what special master is doing what in which case. I have had people say, so each special master is going to write his or her own opinion in each of the six cases, so there could be 18 different opinions. Other people have said, isn't it true that the three special masters are getting together and writing one opinion on each theory, so there are only going to be two opinions?

Let me try to answer some of those questions.

Each of these test cases was individually assigned to one of the three special masters, Special Master Hastings, Campbell-Smith, or Vowell. Each of those special masters will write an opinion in one case under theory one and in one case under theory two. That's it. So of the six test cases, there will be six opinions and six decisions.

In the first round of cases, Special Master Hastings has *Cedillo*, Special Master Campbell-Smith has *Hazelhurst*, and Special Master Vowell has the *Snyder* case. You will see three individual decisions, one from each of the special masters, in that first round of cases. In the second round, Special Master Hastings has Jordan King's case, Special Master Vowell has Colin Dwyer's case, and Special Master Campbell-Smith has William Mead's case.

So there will be six test-case decisions that come out, when they do come out -- not one, not two, and certainly not 18.

Having six cases could create its own interesting set of appellate issues that I'm not even going to attempt to get into here. At some later date, once these decisions are out, there may be updates on appeals. But the short description is that there could be six appeals -- that is, an appeal in each of those test cases by whichever side doesn't like the result that they got. So the appellate process could itself be a long and winding road.

But none of that is going to kick in -- it's all speculation at this point -- until we see the decisions and the parties have a chance to evaluate the decisions.

So that's it on the test cases.

Any questions at this point on sort of the overview of the OAP, the PSC, and the test cases?

DR. HERR: On the issue of time, recognizing that we still haven't gotten yet on what happened last year and then we have this year -- then I guess I would probably assume that there are going to be appeals on all of them -- how long are we talking about before we are going to start seeing some action? Just a ballpark idea of when something is going to start being decided, one way or another, on the Omnibus plan.

MR. POWERS: There are, I think, two answers right off the top of my head to that question. The first, sort of an easier one, gets into the statute-of-limitations issues. Within the Omnibus Proceeding -- I'll go into the details in a second -- there is substantive activity on a large number of omnibus cases, where those cases, at least on the timeliness issue, are being resolved.

Put that aside and focus more on cases that we assume are timely, and what I think is going to happen on causation and resolving cases on the merits of causation and the proof. That's a tough question to answer. Until we see what the decisions are, it's just impossible to say. I can just picture certain decisions that might persuade some petitioners to dismiss their claims entirely -- worst case, from the petitioners' perspective. I cannot speak for respondent, but I would like to think that if decisions go dramatically the other way, the respondent might be interested in discussing settling -- not conceding, but settling -- some of those cases, again based on applying what these test-case decisions give us in terms of guidance.

It's just hard to say. I'm not trying to hem and haw, but it's just so hard to say because we haven't seen what those decisions look like. But I do know that there would be reasons for people to very quickly make decisions

about whether they are going to continue to pursue cases or not. I would hope that's something that goes back and forth on both sides.

MS. HOIBERG: Tom, when the decisions come out on the test cases, are they going to then take those cases and then lump all of the other autism cases that are there and say, "This child falls under this test case. Therefore we're going to rule in their favor"? Is that what's going to happen or are they going to take each of the 5,000-plus cases?

MR. POWERS: I think it's going to be a combination. Again, this is somewhat guesswork. I know with Vince and his cohorts, we have gone back and forth on this issue for five years: Whatever gets decided in the test cases, how will they be, as a practical matter, applied to the 4,800 other cases out there to resolve those cases?

As I said, I think that in some cases, if you have a decision that, for some reason, is just bright-line one way or the other and it's written in a way that you could very readily look to the facts of another of the 4,800 cases and say, "We have 100 other cases where the child got the exact same number of shots in the exact same sequence and had the same" -- you could make an argument that there should be a presumption to resolve those cases

in favor of the petitioner.

The worst case, from my perspective and my clients' perspective, is exactly the opposite: You read a decision and you go, "Mrs. Smith, there's just no way, even with this favorable decision, that your case on the facts fits that and you should dismiss your case."

Other questions on where we are?

(No response)

Okay, I will move on to what would be the fifth topic, which is the timeliness issue. I don't want to be redundant with Vince. His description of what's going on is accurate, but I want to give you a little of the petitioners' perspective of it. Every lawyer who has cases in the Omnibus Proceeding is now receiving orders, sort of on a rolling basis. Our firm has 140 cases. I'll use my firm as an example. About nine or 10 months ago, we started getting orders saying, "Produce your medical records, so that there can be this timeliness review." Out of our 140 cases, we have received those orders directing us to file medical records in about 60 of those cases right now. So for 60 of our individual claimants, the medical records are with HHS and with DOJ. In about half of those, DOJ has looked at those records. We get a very straightforward letter back saying, "We've had a chance to review the records, and based on what we see here, it

appears that your petition is timely" -- very straightforward.

In the larger group of cases, we haven't heard back yet, and understandably, because they are getting a couple of hundred of these a month. But in some cases we get a letter back saying, "We don't see enough here for us to really answer the question on timeliness. We just don't see enough information in the medical records or the medical records are obviously incomplete. Give us more information." We respond by going back out and really beating the bushes to get medical records from doctors. If you have ever tried to get medical records that are eight, nine years old in some cases from physicians and you tell them you are a law office calling, it can be a long, slow process. But we are getting those.

Then, in a couple of cases, the record review by respondent, in their mind, raises an issue where they see that it's not a timely claim. In those instances, they file a motion to dismiss. We are then on a litigation track on litigating the issue of whether the claim can stay in the program under the statute of limitations or not.

I know respondent has a huge workload to do on that. Now that more and more lawyers and more and more cases are getting these orders and responding, it's really the focus of the petitioners' bar and the OAP right now,

responding to these medical record orders, but also on the motions to dismiss.

Vince mentioned the *Kay* case. It's important to understand from the petitioners' perspective how absolutely critical, and ultimately problematic -- not just for the petitioners' bar, but for, I think, the ability of the program to fulfill its congressional mandate on getting people in -- just in the program. As an attorney, when I get a phone call, if I have that conversation that Sherry described and the claim is way old, I just have to tell them, "Yes, unless there is a statutory change, your claim from an injury that clearly occurred 10 years ago is time-barred, and I just can't help you."

But if I get a call from somebody and it sounds like a close call -- it sounds like a really close call -- and I look at those medical records and I think it looks right on the cusp, I have a dilemma. My obligation is to that client and to the statute's direction -- the statute specifically puts a duty on attorneys to steer people to the program, make people aware of the program. So if I'm getting this call and it looks like there is at least reasonable, straight-faced, good-faith basis in the facts to think that claim is timely, I am going to file that claim.

Then, when I get challenged -- and this is not at

all pejorative; this is just the way the system works -- I'm then challenged to prove, often through expert testimony, that that claim is timely, based on a motion to dismiss because respondent thinks it's untimely. I have to litigate that issue, often hiring an expert, perhaps having a hearing -- thousands and thousands of dollars just in costs, out-of-pocket costs, that are not compensable under the current law.

Now the *Kay* case -- the Federal Circuit has spoken. I can tell you, it's already a tough decision to make on the phone or sitting and meeting with a potential client. After reviewing their medical records, it's a really uncomfortable position, as a petitioners' attorney, a plaintiff lawyer, to have to say, "You know, I think you have a decent shot at a claim, but financially it's not viable to even file it, because you might lose on that threshold issue."

Again, I'm not going to try to argue the merits of the statute. It is what it is. But with the *Kay* decision, it seems to put the ball back into Congress' side of the net, if there is to be an adjustment there, whether it's expanding the statute of limitations, putting discovery rule language into the statute of limitations, making it date of diagnosis instead of date of onset, or having the petitioners' costs at least -- perhaps their

fees, but at least their costs -- compensable in a contested timeliness hearing where there is a reasonable, good-faith basis for bringing the claim.

I highlight that because that's something that creates practical problems in how petitioners' attorneys manage their cases, but very serious ethical issues that we confront as lawyers -- do I literally second-mortgage my house to come up with the costs, to move these cases, to get them into the program?

MS. DREW: Tom, could you just mention that many of the cases now on trial were brought when the case law was different than it is now?

MR. POWERS: The question is, is the case law different now than when some of these cases were filed?

Technically, the law is the same that it has always been, because it's by statute, the language of the statute. Then you have case law that interprets the statutory language.

I think the big thing that has come up is in the autism cases in particular, where you have to litigate the issue of, what is a symptom of autism? If you have a multi-symptom injury, you have to start debating at what point in the medical record, is there a particular note of something going on with the child, at what point does that constitute a symptom of autism or the onset of autism or

the manifestation.

So you have all of those issues that get litigated in these motions to dismiss.

But again, I just want to emphasize sort of the public policy issue. When you take that public policy of encouraging people to file in the program and having an open-door alternative to the tort system, but you have a facially tougher limitations period than you would ever face in civil law in any of the 50 states. You then combine that now with a litigation burden to prove that you are even allowed to be there. It's something that the program and public policy folks that care about the program are going to have to grapple with. It's not about lawyers getting rich. It's about bottom-line, out-of-pocket costs to get those people with reasonable-looking claims into the program in the first place.

So that's where we are with the statute-of-limitations and timeliness issues.

Interim fees, really quickly: Yes, we have filed the interim fee petition.

One of the things about lawyering is that it is very much sort of the-ball's-in-somebody-else's-court/tennis-match type of thing.

The ball was in my court, the petitioners' court, to get this huge interim fee petition over to respondent's

counsel. We have hit that over the net. They have to work on returning that, but there's no rest, because as soon as that is off my desk, the briefing schedule for the thimerosal test cases is up.

But we have filed the interim fee petition for the PSC's work through the end of the *King* and *Mead* test-case hearing. In those test cases, that was three weeks of hearings, almost, 13½ actual court days. A lot of that evidence is the general causation evidence, so that when the *Dwyer* case was heard, it was only a day and a half. Neither side had to redo everything they had already put on. But the attorney time and the costs and expenses of litigating those cases, beginning way back in late 2001, when the discussions began about forming the OAP -- starting way back then and going up through the end of this summer this past year, so you have about six and a half or seven years' worth of out-of-pocket expenses, costs, lawyer time from a couple of dozen attorneys in over a dozen law firms, all over the country.

Respondent has that now, and they are conducting their review. We look forward to seeing what their response is and ultimately working with them and the special masters to resolve the interim fee petition issues.

Finally, on the civil cases, Barbara Loe Fisher mentioned a case in Georgia. There was a Georgia Supreme

Court decision that said Section 22 of the Vaccine Act did not as a matter of law bar a design defect claim. If the petitioner alleged and indicated that they would be able to obtain discovery to prove that there was a safer and effective alternative design to a particular vaccine, that case would at least survive summary judgment. That is a decision of the Georgia Supreme Court.

One of the anxieties people have had is that large numbers of these cases would suddenly leave the program and end up back in the civil courts. I can't speak for other attorneys, but what we have seen on the record so far is that the vast, vast, vast majority of people who have claims in the OAP are leaving their claims in the OAP. I haven't seen anything indicating that a large number of people are looking to withdraw their claims during the pendency of these test-case decisions and pursuing remedies in the civil system. I haven't seen that happen yet. I haven't seen any movement towards doing that at this point.

But it certainly raises the issue that, at least in Georgia, one could pursue a civil case against the vaccine manufacturer. It's important to note, that was for thimerosal-only cases, not vaccines generally. The argument that the court recognized was that since thimerosal-free vaccines are available now and the plaintiffs alleged that they were equally available back

when that child was injured, that's pretty good proof that there was a safe alternative design, because it's currently being used. So the supreme court decision, while intriguing, is somewhat limited in its application to non-thimerosal cases. That was a critical linchpin of the decision.

It was a unanimous court that considered that issue thoroughly and, I believe, got it right, obviously.

I think that is it for my update.

Actually, I do have, Vince, one question for you. I thought of it after I came up. It's from one of your slides.

In cases right now, the new filings for autism claims, do you have a sense of how many of those are pro se versus represented?

DR. HERR: Definition, please.

MR. POWERS: More lawyer Latin. "Pro se" is without representation, where the family is essentially pursuing the case on their own. In the slides on the satisfaction survey, there was a pro se thing in there. That's where you don't have a lawyer.

MR. MATANOSKI: A pro se petitioner brings it themselves. Sometimes there may be an attorney in the background. They may not be a member of the bar. For some reason, they choose not to come forward.

I think, Tom, at one point we saw a lot more than we are now. Now the autism claims that are filed -- of that last group, where we had about 31, maybe six to 10 of them were pro se. At one point it seemed like they were going to about half pro se. The reason why I believe that was true -- we were seeing more of the cases -- they probably were looking time-barred, which would be a reason why an attorney wouldn't bring the case, if it looked pretty clearly time-barred.

MR. POWERS: Those are all the questions I had. Anything else for me?

MS. TEMPFER: I just have a quick question. I'm trying to understand the financial burden. If the family wants to hire a lawyer, do they have to come up with a significant retainer fee to do that? How does that work?

MR. POWERS: In our practice, as a plaintiffs' firm, if we were not in the program, we would do a contingency fee. The clients never get monthly bills. They are not billed by the hour. There is no retainer. There is none of that.

In the program, our law firm made the decision as soon as we got into these cases that we were not going to have retainer fees or anything like that. At our firm, it's me -- a little bit of Mike Williams, but primarily me on these cases. My time is something that the client never

sees a bill for. We don't bill the clients. We carry the costs and we carry the expenses.

Particularly in the autism cases, and in any of these serious vaccine injury cases -- you have heard people talk about this -- these folks are spending thousands of dollars a month in uncompensated, uninsured medical care and treatment for their children. The last thing, as an attorney, that I want to do is send them another bill, knowing that it could break them or they simply couldn't pay it.

We are fortunate in that we have a practice outside of the program that allows us to carry some of those costs. But our firm and other firms have to -- whether it's lines of credit or borrowing money, to help these families get through the program from beginning to end.

MR. SCONYERS: Any other questions or comments for Tom?

(No response)

We really appreciate you being here and taking the time.

We are going to move to our next agenda item. Dr. Kathleen Stratton is here. You have some slides that came in at the lunch break.

As Dr. Evans mentioned, the Institute of Medicine

has been engaged to form some studies. Kathleen is going to talk to us about this project on vaccines and adverse events.

Agenda Item: Institute of Medicine Project on Vaccines and Adverse Events

DR. STRATTON: Thank you for inviting me. It has been quite some time since I was here at ACCV. It's nice to see a lot of familiar faces. But there are a lot of new faces around the table since the last time IOM came to talk to ACCV, so I thought maybe I would do the two-minute version of who or what the IOM is and just a few little facts about us. Certainly it's not always clear to the outside world.

I should say that I had the honor, actually, of being the staff director for the committee that produced the 1994 report for the compensation program, the 313 study, which is when I started getting involved in the vaccine issue. That was really quite an experience, and when I met many of you for the first time. Fourteen years later, here we are again.

The Institute of Medicine is part of the National Academy of Sciences. We are not part of government. We are not part of the NIH. We are not part of the National Science Foundation. We are a nonprofit, nongovernmental organization.

That said, we were established by Congress and President Lincoln in 1863 for the stated purpose of providing scientific advice to the government.

The Institute of Medicine became a distinct entity of the National Academy of Sciences in 1970, as the medical or health arm of the National Academy of Sciences.

We do our work through committees of experts. There is a staff person, such as me, who provides technical and managerial support. The experts and the authors of the reports that we produce come from all over the country, people who are very esteemed scientists and researchers and clinicians.

It's important for you to know that they are not compensated for the work that they do and the time that they spend on this. They do this in service to the nation. We pay for their travel to come to Washington for the meetings that we hold over the course of time, and we pay for their breakfast and their lunch and their dinner and their airfare and their hotel room. But they are not paid for their time. They donate that time.

That is actually a pretty impressive thing. If any of you have ever read one of our reports, they are big, they are thick, they are dense, and committee members write those and spend a great deal of time on it. So we thank them for all the work that they do.

The Institute of Medicine works under the processes of the National Academy of Sciences, which have developed over the years to protect the scientific integrity of the work. That has to do with the peer-review process and it has to do with some of the exemptions that we have by Congress from the Federal Advisory Committee Act to allow committees to deliberate, as well as our processes for how we select the committee members. We can talk about some of that.

As Jeff mentioned, the contract was signed on September 25. We have agreed to review literature -- and we will talk about it in a second -- related to four vaccines. In a sense, there are really five, since there are two very different influenza vaccines, live attenuated, as well as killed. So it's really five separate kinds of vaccines. The vaccines are varicella, the two influenza vaccines, hepatitis B vaccine, and human papillomavirus vaccine.

The hepatitis B vaccine was, in fact, reviewed in the 1994 report, but it was very, very new. There is a lot more information out now about that vaccine, and a lot of claims, I suppose, and that is why we are looking at that again.

Influenza vaccine was covered by a different series of vaccine work, but not for the express purposes of

the compensation program. The IOM has never looked at varicella or human papillomavirus vaccine for any reason -- the safety of those.

There is the possibility, should resources be found, whether from the government or from private sources -- and we are talking to some nonprofit foundations -- of getting additional funds to be able to include in the review other vaccines of importance to the program. Should that money become available within some reasonable period of time, they can be added to the task of the committee. I believe the order in which the program feels they have needs is meningococcal, hepatitis A, DTaP and others -- what that really means is currently administered tetanus toxoid-containing vaccines, DTaP being one of vaccines of great interest. The last time we worked, the whole-cell vaccine was what was being used. So it would be DTaP, Tdap, DT, and tetanus toxoid. So that "and others" means any tetanus toxoid-containing vaccine -- as well as MMR. The other vaccines covered by the program would be added at some future date, should resources become available and the program feel the need for a review of the literature.

The main charge to the committee, as was the case with the committees that did the reports that came out in 1991 and 1994, is to look at evidence bearing on the causal

relationship between a specific vaccine and specific adverse events, as well as a discussion of the quality and quantity and meaning of the evidence, the literature about the biologic mechanisms that might be operative if a vaccine were to cause an adverse event.

The specific adverse events that the committee will review have not yet been determined. That will be determined -- and Geoff or Rosemary would have to answer the process questions about this -- those will be decided by HRSA or the compensation program, with advice from the Advisory Commission on Childhood Vaccines. Obviously, they are to be adverse events that are of importance to the program, determined by the nature of the claims that you have in front of you.

As was the case in the 313 study, the IOM reserves the right to add adverse events to the list that the compensation program asks us to look at. In fact, in the 313 study, thrombocytopenia purpura was originally not on the list and not originally in the series of things that we were to look at. At an open meeting, a compelling case was made by one or two speakers that it was an adverse event that was likely to be real and needed to be looked at. We took it upon ourselves to add it and, in fact, found for a causal relationship between the measles-containing vaccines and thrombocytopenia purpura. So the

IOM wanted to reserve the right to add adverse events if we feel that there is sufficient reason to do that.

We are very early in the process of this. What we are doing now is seeking nominations for the committee. Anyone who would like to propose people to be considered for service on the committee can send information to me. I will have on the very final slide how you can do that.

The expertise that are need on the committee: obviously, pediatrics, internal medicine, neurology, immunology, rheumatology, epidemiology, physiology, pathophysiology.

The committee will probably be between 12 and 15 people. That seems a manageable size for a task of this nature. But there is no magic number for how many people will be on the committee, until we see everyone's qualifications and decide, finally, who we will have on the committee.

We are partway through that. It is not too late if anyone wishes to suggest experts to serve on the committee.

The first meeting will be held early in 2009, after the committee is approved by the president of the National Academy of Sciences and we can get all these busy people's calendars together and they can come to Washington for the first meeting. The first meeting will be very

organizational: What is the charge? What are the vaccines? What are the adverse events? How are they going to work? Do they understand how the process has worked in the past?

After that, we start diving into, in the second and subsequent meetings, very substantive scientific meetings. This is the way committees generally work. The first meeting is very process-oriented and organizational in nature.

The first large-scale public meeting will be a workshop to discuss a framework for reviewing and categorizing the evidence on biologic mechanisms. From my experience with working on the 313 study and seeing how that has been read, used, interpreted, I think the causality-argument side of what these committees do is, compared to the biologic mechanisms, fairly straightforward. I think the committees understand what literature is important to think about causality. The field of epidemiology and biostatistics has a long history of the kinds of things one has to think about as you analyze these studies, what is important to assess the quality of the evidence and how to kind of put them together in some package.

One can argue around the edges, of course, whether or not any one study has been interpreted the way

everyone else in the world would interpret it. But it's a fairly straightforward process.

The biologic mechanisms, which was part of the charge to the 312 and the 313 committees -- I think there is a lot of work to be done to make that part of the report clearer. The process for identifying the literature and how it's weighed and how it is reviewed -- we could be more transparent about that. After 1994, when the 2001 and 2004 immunization safety review series began, I think that committee became more transparent in terms of the words they used to describe biologic mechanisms. But it could definitely be improved upon -- the language that we use, the way we describe how that literature is collected and reviewed, and what is considered to be important in understanding the theory.

There is not a history -- it surprises me every time I go back and look at this -- in science and medicine for -- there is not the framework for how one thinks about evidence bearing on the biologic mechanisms. I think that is not true for causality. That's a fairly established and well-accepted way of thinking and analyzing.

So I hope that the new committee can make a real contribution in terms of pulling together some of the best biologists around who think about: Here's an exposure. Here's an outcome. What do we need to understand how this

leads to that? What evidence is relevant? What evidence might not be relevant?

That's just a really hard thing. I think it has been the less successful part of the efforts that we have done throughout the years. So there is a major commitment to improve that.

It will be a large public workshop. People will be invited. I would expect that that would be late winter, early spring. That will be the first major substantive effort.

Then we will move on to starting to accumulate the literature and evaluating it, the way the committees usually do. There will be open public meetings. There will be other scientific meetings. But the committee needs to plan exactly how and when they are going to go about those pieces of the study process.

I know that we have agreed -- and I think it makes sense -- to do this kind of framework around biologic mechanisms very, very early on. We will welcome people's input on that.

In particular, not only for the members of the commission, but also for members in the audience who have been readers of our work, it will be helpful for us to think about, in these public workshops, what has been most difficult for the users of the reports to understand, so

that the reports can be as clear as possible, so that they are most helpful to the program, to the petitioners, to the Department of Justice, and to parents. It is a scientific report, but that doesn't mean that it can't be understandable by everybody. That's something that we need, obviously, to work on. I see often where things that were written were not understood in the way that I think the committee had intended them to be understood. We want to try to do a much better job on that. I think that's one of the reasons why this is going to be so difficult, and hopefully also so important.

There is a project email address. If you want to send suggestions about the committee, you can send them to vaccinesafety@nas.edu. [Nas.edu](http://nas.edu) is the suffix for all of our email addresses at the Academies. We have a phone number, 202-334-2077, if anyone needs to call to talk about the project. We will be establishing, once the committee is set up, a listserv that will let people know about the open meetings and the public workshops and important events. There will be a project Web site so that the materials that are presented and reviewed at the public meetings can be accessible for people after the fact.

A lot of the next steps and the details about how the committee will operate will be decided by them. There is a lot to be forthcoming after that committee actually

gets established.

But the charge to the committee is very, very similar to that of the committees that did the 1991 and 1994 reports, which is to produce conclusions on the scientific evidence bearing on causality and biologic mechanisms.

Thank you.

MR. SCONYERS: Thank you very much for coming and talking with us.

Are there questions or comments for Kathleen?

Is there a due date, an anticipated date?

DR. STRATTON: For the final report? If I remember, it's 26 months from the start. Is that right, Rosemary? Okay, 24 months. It's only confusing because we had a lot of options for how many vaccines were going to be covered and how long it was going to take. I had forgotten.

So two years, which is about typical. I think the 1991 and 1994 reports took about the same. Each one took about a two-year period of time.

If more vaccines are added, it is possible that it will take more time, but not proportional, because there are economies of scale in terms of how committees operate and the material that you consider and the things that committees have to consider. Should we be fortunate that

resources, for example, were found to do another four vaccines, it wouldn't double the time that it takes. It doesn't take twice as long to do eight as it does four, but it is more than just four.

MR. SCONYERS: Is it going to be possible for us to get updates as this process moves forward? I think we would be interested in following the progress of it. Some of us won't understand the science, but we would be interested to know how it's going.

DR. STRATTON: I certainly am more than happy to come and talk to you whenever you wish. I will tell you, as many of you who have followed us throughout the years know and find frustrating, at some point there is going to be very little that I can tell you, other than process steps. We don't put out draft findings. I can't tell you where the committee is going or where I think they are going. I'm happy to keep you informed about workshops and even some of the discussions at those things, because those are public events. But it will likely be frustrating. There are things that I won't be able to talk to you or anyone about, because that is our process.

MR. SCONYERS: That kind of process information, I think, would be useful to the commission.

DR. STRATTON: Sure.

MS. CASTRO LEWIS: How are the committee members

going to be recruited? I'm just thinking of having nice representation from different -- not only the medical expertise, but --

DR. STRATTON: Your question is, how do we get the names sent into us? We have done the first phase, which is a very typical way we do things. We ask members of the Institute of Medicine and the National Academy of Sciences, some of the best scientists in the country, to nominate themselves or other people, other colleagues, who they think would like to serve. We contact people who served on previous committees who know what these questions are like and what the work burden is like and what it is like to do this, for suggestions of colleagues who they think would be interested in serving in this way.

But doing that, I have 100 names already suggested. People respond.

This is the first time telling people such as you that we are soliciting nominations. I will similarly send out a request to other advisory groups or national stakeholder groups to suggest people for the committee.

Those names come into us. Then, ultimately, the president of the Institute of Medicine and the president of the National Academy of Sciences decide who is to be invited and then appointed to the committee.

DR. EVANS: Two things, Kathleen. Has there been

a decision made in terms of conflict of interest, whether the approach is going to be, as it was in the 1990s -- you know where I'm going with the question. That's one thing.

The other thing is, recognizing that the next time that the commission is going to meet will not be until March, a lot will have developed in the interim. I know you will be seeking input on vaccine adverse events. We will be seeking input from the commission. So that's something that we will work out in the interim also, to be able to assist you all.

DR. STRATTON: The National Academies has a policy -- it's on their Web site, which is actually nationacademies.org -- that you can find on bias and conflict of interest. In general, the conflict-of-interest considerations for the Academies' committees are current financial interests. For the 312 committee, for the 313 committee, and for the Immunization Safety Review Committee -- which was not, again, directly related to the compensation program, but a similar effort that we undertook -- we also considered people's past relationships. The Academies' official policy is that only current affiliations matter. Because this was such a controversial and sensitive issue, the Academies looked at past relationships and considered them.

We will do that again. We will have a slightly

different view of people's past activities. So it is highly unlikely that someone who has served as an expert witness, for example, for either side in a compensation program would be considered a viable member of the committee. It's a very complicated process. In general, that has been our policy. It has not always made people happy. But we believe it has served us well and that it is the right direction to go. So we will be looking at past activities, as well as current activities.

With regard to the input about adverse events, I think we have the general nature of the types of claims that are in front of the program and the types of adverse events that are of concern to the program and to parents and to vaccine recipients. So I think that we can put together a committee with the proper scientific, medical, and technical expertise, without knowing every single adverse event that is going to be in front of us.

Our first work will be general in nature, which is this general framework for thinking about biologic mechanisms. So, although just to be settled I wish I knew now what those adverse events were that the committee was going to ask to be reviewing, it's not stopping us from moving forward as we need to.

March is around the time that we are going to really need to have a better feel for what adverse events

we are going to be looking at. That said, should the program, for whatever reason, ask us to look at some adverse events that we don't believe the committee has the proper expertise to evaluate, we would add people to the committee to meet that need. So we have some flexibility there. But, obviously, the sooner we on the committee, as well as all of you with an interest in this topic, know which adverse events are going to be reviewed, the better. But it's never a perfect world, and it was more important to get the project started without knowing what they were than to wait until that all got resolved.

MS. GALLAGHER: I have a question about timing, actually. I just wonder if there is an opportunity, if you start on the first four vaccines, to have a report come out on a rolling basis, without having it delay the entire report. Or is that where you lose economies of scale? I know you said you weren't sure whether there would be additional time because there might be additional vaccines.

DR. STRATTON: Do you mean within the first four or do you mean between the first four and any subsequent ones?

MS. GALLAGHER: I didn't mean that, but that's an excellent revision to my question.

DR. STRATTON: I'm not sure which one you meant. There are economies of scale. Before reports are

released by the National Academy of Sciences, we have a rather elaborate, extensive, and important external peer-review process. That takes a lot of time. If we had to do it multiple times, that takes resources.

If you do it on a rolling basis, it does take more time, for other reasons. You also like to have a set number at a time so there is consistency, so that the committee is consistent in terms of how they view those things. We like to think that there was a great deal of consistency in the way committees thought about causation in the 312 committee and the 313 committee. I was not involved in the 312 committee. I only joined at the beginning of the 313, so I can't swear to this. I believe it to be true, that those committees evaluated evidence with the same kinds of criteria. But one never knows.

I see Barbara nodding her head. We talked about this briefly.

One superficial level was, we kept the meaning of the five categories of causation, but we, I believe, greatly improved in 313 on the wording to make it more obvious what the committee meant.

It's not efficient to do too many reports. It's more efficient to do fewer reports. That doesn't mean that it's not possible, as time went on. Chances are, if the next two, next four, next eight -- however many there could

be -- came too late to be properly wrapped into this committee's work, a second committee could be formed, and there are ways to think about consistency. But ideally we would know relatively soon.

MS. GALLAGHER: Thank you.

DR. STRATTON: Our job, as put forth by Congress, is to be responsive to the needs of government in scientific and technical issues. If the government all of a sudden found more money at some point, it's incumbent upon us to do our best to meet that request. Exactly how we do it is another story.

DR. EVANS: Just an additional comment. I think it's extraordinary that HRSA has now come up with the money, the \$1.7 million, to be able to fund this contract. It's the first time they have done this. NIH was the contractor in the 1990s. I'm certainly going to do whatever I can to cajole and try to convince my colleagues in the various PHS agencies to donate some money. So maybe within a fairly short period of time, we can get some additional funding so that Kathleen can continue to add more vaccines -- the thinking being that if we can actually do the eight vaccines, that represents about 80 to 85 percent of the workload of the program. The difference in cost for the four additional vaccines is a third of what we will have spent already. So we are talking about something

that may be able to be worked out. We are certainly going to try.

MR. SCONYERS: Anything else?

(No response)

I think it's excellent that this project is under way. I look forward to the results of it.

DR. STRATTON: And I'm happy to come back whenever you would like.

MR. SCONYERS: Thank you for being here.

If you are following in the program, Dr. Salmon is not with us. We are not going to be getting his update. He had to leave. So we are just going to continue on through our agenda and hope to have a little bit of time at the end for some discussion among the members about our next steps.

Next up is our update from the Immunization Safety Office at CDC. Is PerStephanie on the phone?

OPERATOR: If she would like to press star zero, I will open up her line.

(No response)

I'm not showing that pressing star zero.

MR. SCONYERS: All right. Barbara, we now have your update from the National Institute of Allergy and Infectious Diseases.

Agenda Item: Update on the National Institute

of Allergy and Infectious Diseases, NIH

DR. MULACH: Great. Thank you for giving me a few minutes.

I was unable to attend the September, but my colleague Jessica Bernstein gave you guys a few quick updates, and I just wanted to follow up on some of those items.

One is the Vaccine Safety Program announcement that came out in August of 2008. Basically, that is just an opportunity to encourage researchers to submit applications to address scientific questions and topics in vaccine safety research. While I don't have anything official to tell you about where we are with that, my name is one of the contacts on the announcement. I would just say, sort of on an informal basis, we are very encouraged by the number of questions and inquiries we are getting. We are enthusiastic to see what applications are coming in. Just stay tuned. If you know of any particular research area that needs to be expanded, this is a great opportunity for researchers to do that work. So we are very encouraged by that.

The second topic -- I think Jessica mentioned to you that there was a series of requests for information concerning the Interagency Autism Coordinating Committee, which is a group that has been formed in various iterations

for several years now. However, with the most recent autism legislation, it has become a formal federal advisory committee. Basically, they are taking this opportunity to make sure they have the right membership and to talk about their strategic plan. The request for information asked for input on the strategic plan. There is a meeting this Friday, November 21. It's a public meeting in the Ronald Reagan Building downtown. If anyone is interested, I will be glad to give you more information about how to access that.

Basically, they are going to be talking about the strategic plan and what areas need to be incorporated. They are also going to be talking about services and support for children and adult populations with autism spectrum disorder. It should be an interesting meeting and we are looking forward to the outcomes of that.

That's it for me.

MR. SCONYERS: Any questions for Barbara?

What's the award date for the grant applications?

DR. MULACH: Basically, it's three receipt dates a year over the course of three years. The first receipt date was in October. But you have to keep in mind that people didn't have very much time from when it was announced. We have gotten some response, but we are really looking forward to the next receipt date in February and

next summer. I think people will have time to pull together their applications. The awards are about seven to nine months after applications. So stay tuned.

MR. SCONYERS: Thanks.

Do we know if we have Dr. Gruber on the phone?

Hello, Marion. You're on the phone. Go ahead.

Agenda Item: Update on the Center for Biologics and Evaluation Research, FDA

DR. GRUBER: Thank you for giving me the opportunity to update ACCV on the FDA's Office of Vaccines and vaccine-related activities.

Since I gave the last update in September of 2008, there has been one new approval, and that was on September 12, when the FDA approved the vaccine Gardasil, the human papillomavirus vaccine, for the prevention of vaginal and vulvar cancer. So this vaccine has now an additional two indications. It is, again, in girls and women ages 9 to 26 years of age.

As you know, we originally approved the vaccine in 2006 for girls and women ages 9 to 26 years of age for the prevention of cervical cancer caused by the serotypes contained in the vaccine, as well as precancerous genital lesions. The new approval presents basically a new indication, vaginal and vulvar cancer as additional indications.

So that was one approval. We have several biologics license applications under review for preventive vaccines.

One is for a further human papillomavirus vaccine.

Another one is for a Japanese encephalitis virus vaccine that will be for active immunization against Japanese encephalitis virus. It will be what we call a traveler vaccine.

There's another vaccine currently under review, and that is an adenovirus vaccine for active immunization against acute respiratory diseases caused by certain adenovirus types. That vaccine will be indicated for a restricted population, such as the military.

Then we have a vaccine under review which is a thimerosal preservative-free influenza vaccine. That's an additional flu vaccine for active immunization of persons 18 years of age or older.

Last but not least, we are reviewing a meningococcal conjugate vaccine for immunization of persons 11 to 55 years of age for the prevention of disease that is caused by *Neisseria meningitides*.

So lots of activity in terms of reviewing license applications for new and additional vaccines.

That is all that I wanted to present today.

MR. SCONYERS: Thank you very much for being on the phone with us. Are there questions for Dr. Gruber?

(No response)

Thank you, Marion. We appreciate you joining us.

OPERATOR: PerStephanie is on the line now.

MR. SCONYERS: Outstanding. PerStephanie, we are looking forward to your update on the Immunization Safety Office at CDC.

Agenda Item: Update on the Immunization Safety Office, CDC

MS. THOMPSON: Okay, great.

As you know, Dr. John Skander (phonetic) asked me to give the update for the Immunization Safety Office. I want to thank you guys for pulling this together and allowing us to give our update.

Currently ISO is in a transition process. On October 14, Dr. Melinda Wharton agreed to serve as the temporary acting director of ISO. Dr. Wharton will provide overall leadership for the office and help guide the ISO transition to the Division of Health Care Quality and Promotion.

On October 22 and 23, ISO updated ACIP members on vaccine safety activities around HPV and MMRV vaccines. The HPV presentation summarized the experience of 20 million doses under passive surveillance and over 375,000

doses under active surveillance. The passive surveillance reporting was to VAERS, the vaccine adverse event reporting system.

We have experienced an increase in reporting. This is expected from -- publicity and a general increase in adverse event reporting.

Ninety-four percent of the reports were non-serious, and most commonly reported events are consistent with pre-license or trial data, such as pain at the injection site, fainting, headaches, and fever.

Active surveillance reporting shows no evidence of elevated risk for syncope or fainting following HPV, but does support increased and post-vaccination syncope across adolescent vaccines first identified through VAERS. Additionally, control data from VSD does not support causal associations between HPV vaccine and GBS or other targeted conditions.

ISO also updated ACIP attendees on the MMRV vaccine. As a reminder, in February 2008, preliminary data from the Vaccine Safety Datalink Project and Merck post-licensure studies were presented to ACIP suggesting increased risk of febrile seizures during the first and second week after the first dose of measles, mumps, rubella, and varicella vaccines among children ages 12 to 23 months.

ACIP recommended removing the preference for MMRV vaccine over separate administration of MMR and varicella vaccines. ACIP recommended forming an ACIP MMRV vaccine safety workgroup. These recommendations were published in the CDC Morbidity and Mortality Weekly Report in March of 2008.

In October 2008, the MMRV working group heard presentations on the risk of febrile seizures after MMRV. Presentation covered a review of the preliminary data from the vaccine safety working group findings and Merck findings; in addition to the working group presentation, an interim summary of the evidence for febrile seizure risk after MMRV dose one.

No new votes were taken for MMRV during the October meeting. The ACIP working group will continue to review the safety data. It will also develop policy options for ACIP regarding MMRV use. A vote is anticipated in June of 2009, at that particular ACIP meeting.

For additional information on ACIP's MMRV working group, you may contact Karen Broder (phonetic) -- she is the co-lead for the working group -- as well as Dr. Mona Marian (phonetic), who handles policy questions with MMRV. I'll be providing that information to you with the final minutes.

Thank you. That's all.

MR. SCONYERS: Thank you for joining us. We do have a question from Dr. Fisher.

DR. FISHER: The MMRV has been -- the company hasn't been supplying it lately. Is there any information on which it might get back online, or is it expected that that won't be until after the final recommendations?

MS. THOMPSON: Actually, at this time I don't know. We do know, as you said, that they are not producing it because of production problems. But I have not heard any specific startup date, or even if they will do it.

MR. SCONYERS: Any other questions?

Is there just a single manufacturer of MMRV?

DR. FISHER: Yes.

DR. EVANS: Yes. As I recall the discussion at ACIP, it didn't seem as though there was going to be product anytime soon. So the recommendation to use them in a split way is going to continue.

For those that want to see the data that was discussed, the ACIP, I believe, has a 30-day turnaround time for getting their minutes on the Web site.

MS. THOMPSON: They are up now. If you want, I can send that link as well, and the final notes from the meeting.

DR. EVANS: I think there will be more detail, PerStephanie, in terms of the VSD data and the VAERS data

that you were talking about. It was a little difficult to hear you in the room.

MS. THOMPSON: Oh, I'm sorry.

DR. EVANS: We didn't know that you needed the screen. It's okay. But those that want more specific information can consult the ACIP Web site.

MR. SCONYERS: Thanks for joining us.

MS. THOMPSON: No problem.

MR. SCONYERS: Elizabeth?

MS. SAINDON: I just wanted to correct the record. Dr. Caserta was absolutely correct and I was mistaken when I corrected him. If the Vaccine Injury Table is changed and it gives you a greater likelihood of prevailing on a claim, you are allowed to refile, even if you had a claim dismissed.

I do apologize for that. I just wanted to clarify that.

MR. SCONYERS: Thanks, Elizabeth.

We are a bit ahead of schedule. I would like to go ahead and see if there are any public comments at this time. Then we'll move to our future agenda items.

Operator, if you could see if there are any people on the line who would like to make public comments? Certainly if there is anyone here who would like to make public comments to the commission.

OPERATOR: Anyone on the phone that would like to make a comment, please press star one on your touchtone telephone.

(No response)

MR. SCONYERS: Thank you very much.

Barbara?

Agenda Item: Public Comment

MS. FISHER: I'd just like to say for the record that I'm very encouraged that the Institute of Medicine has been asked to do what they did in 1994 and 1991 -- but particularly 1994 -- in evaluating the biological mechanisms of vaccine injury and death. This is extremely important. I'm glad that you have been funded, and I hope there is more funding coming.

But I do want to say that the National Vaccine Information Center is absolutely opposed to the use of any money in the trust fund for anything other than paying the people who have been injured, awarding compensation to the victims. This was something that we were told when we came to the table, that this money would only be used for compensating children, and also to administer the program, but certainly not for any other reason. Once you set that precedent, it is open game.

DR. STRATTON: [Off-mic]

MS. FISHER: I'm saying, I'm really glad you got

the money, because it can be gotten another way. There is a lot of money given to HHS every year. That money certainly should be used, whether it's from NIH, whether it's from CDC -- wherever it has to come from. Vaccine safety was supposed to be a priority, always. But the money in the trust fund is supposed to be for the children.

DR. FISHER: Just for us to go on record, as Sarah said earlier, this committee has already made it loud and clear that we would oppose --

MS. FISHER: I'm really glad for that. I know there are a lot of people who are suggesting that it be gone into. Even though, obviously, we support scientific research, we just don't support that kind of -- thank you so much.

MR. SCONYERS: Any other comments?

DR. DEBOLD: My name is Vicky Debold. I'm affiliated with NVIC, but I'm here today as a private citizen. I have two remarks, possibly questions that I would like to ask.

One has to do with the performance measures for the Vaccine Injury Compensation Program. Honestly, I found it a bit odd that the measures didn't include an item that would reflect the number of claims that were dismissed because of timeliness, that they did not meet the statute of limitations. From my perspective, it seems like this

is, in part, a failure on not just the program, but the entire system, all the way through the direct care delivery mechanisms, to let people know that this program is available so that they can submit timely claims and get the help that they need. It just seems to me that that would be one kind of quality improvement measure that would be really helpful to people and would go some distance toward giving people the confidence to know that, in fact, there is a program available to help them should they suffer a rare adverse event.

The second item I want to comment on has to do with table injuries, particularly for new vaccines. I was struck by what I saw on the handout as it relates to what is or is not there, particularly for new vaccines. I say this, in part, as a brand-new member, a consumer rep, on the FDA's VRBAC committee. I'm not speaking for the FDA right now; I'm just speaking for myself.

I was involved with the decision to review and vote on the Rotarix vaccine. Although it is true that at the time of licensure the committee votes and a determination is made that, all things considered, they are safe to administer, that does not mean that for each individual who may take that vaccine, there is virtually no risk of a serious adverse event. In fact, with the Rotarix vaccine, when we reviewed the clinical data provided by the

manufacturer, there was a statistically significant difference in pneumonia-related deaths between the vaccinated and non-vaccinated groups. There was also a statistically significant difference in seizures. None of these were able to be explained.

It just seems to me that if those kinds of clinical data are available in the record at the time of licensure, they ought to be considered for inclusion on the table of injuries, should these events occur and result in substantial morbidity and mortality.

Additionally, something else that is a bit puzzling to me is why the serious adverse events that are listed on the manufacturer's description of the product wouldn't also be considered for inclusion on the table. This is particularly important in light of the fact that early on, Phase IV of the clinical trials and the postmarketing surveillance period is when we are getting information about those rare adverse events that can occur on a population basis. This is our health-outcomes and effectiveness research. We have talked a lot about how the passive surveillance system that we have has limitations.

But to the extent that we can discern usable information and translate that into data that can be included on the table and really help people who suffer an injury, I think it would be helpful to the program, in

terms of supporting and enhancing public trust.

Thanks.

MR. SCONYERS: Thank you.

Any other comments?

MR. MOODY: Good afternoon. Jim Moody,
representing SafeMinds.

Three brief comments.

One, at the close of one of the test cases in vaccine court, the government, in its closing argument, made a remark that in the event the court were to award compensation in the omnibus autism cases, that would discourage parents from getting their children vaccinated and raise the specter of a return of measles epidemics.

I would challenge the commission -- I understand that one of your roles is to advise your client, the secretary -- to urge your lawyers to make very clear that compensation in the program is consistent with the goals of encouraging public health and support for the vaccination program. To say to parents and prospective parents, "We don't want people compensated for vaccine injuries," discourages parents from getting vaccines. Public confidence in the vaccine program is certainly an important issue right now.

The second matter is, one of your colleagues mentioned the autism research agenda that's coming up for

consideration on Friday. One of the issues that's important in the strategic plan for autism research is whether or not vaccines should be investigated as a potential cause for autism. Congress called for that to be in the strategic plan in the Combating Autism Act. Lots of public comments called for that.

However, one of the drafters of the plan, one of the key drafters, was a witness for the government against compensation in the program. In the spirit of removing conflicts of interest, I would also challenge the commission to make a recommendation to its client that it keep more of an arm's length between witnesses against compensation and those who would draft the research that would look into safety of vaccines, particularly as it relates to autism.

Along will come the IOM, when it does its study and looks at the literature. Lo and behold, there won't be any studies looking at adverse events and autism, precisely because the client didn't want those kinds of studies to be funded. The absence would be explained.

The third thing -- I think I mentioned this in a comment last spring -- I would challenge the commission to strongly urge its client to support a comprehensive study of the health outcomes of unvaccinated children versus vaccinated children, to look at the top level, to get an

understanding of whether or not all the vaccine schedule is safe compared to, in a sort of retrospective placebo-controlled trial using a natural experiment, all the unvaccinated children out there who get religious and philosophical waivers.

As far as I know, there are no studies in animals or in people that have compared the health of completely unvaccinated children or animals to those who are vaccinated. It's only through such a study that public confidence in the vaccine schedule as a whole will either be verified or challenged, and if there are problems, they can be fixed.

Thank you very much.

MR. SCONYERS: Thank you.

Anybody else?

(No response)

Agenda Item: Future Agenda Items

I'd like to turn to the final item on our agenda, which is future agenda items. I want to use this as an opportunity to do several things:

First of all, to solicit your thoughts about items for the March meeting.

Second, to talk more generally about what we have been hearing all day long today. In my mind, this has been a day with some pretty significant themes all the way

through it. I appreciate all the time and effort that our various presenters have put in to bringing information and their viewpoints to us. I think it has highlighted and sort of consolidated a number of thoughts and issues that many of us have had.

So I would like for us as a group to talk about what, if anything, we want to do with what has been presented here today.

The third thing that I want to mention, as we launch into this, is that, as has been our practice for several meetings, we are going to have a small committee to work on the agenda for the March meeting. Magdalena has agreed to continue on. She and Charlene put together the agenda for this meeting. Sherry Drew has agreed to be the new member of the committee. Sherry basically is agreeing to two meetings' worth of service, because she will do March and also our next meeting.

Let me take those in whatever order the members would like. If there are specific agenda items that you know now you would like to have covered, let me just jot them down. One of the things I know that we will have on our agenda that we have already mentioned today is an update from the program on outreach activities. That plan is not yet ready, but in preparing the agenda for this meeting, we did hear that we should have information about

outreach at the March meeting. I think that actually goes to address some of the concerns that some of our comments have raised about knowledge of the program and about the program.

I am pleased to inform you that also on the agenda for March will be the election of the chair and vice chair of the commission for next year. That will be good news for at least a couple of us.

We will have our normal updates. I'm hopeful that by March we will actually have some decisions in *Cedillo* and the related initial round of cases in the Omnibus Autism Proceeding. I think we already heard today that the briefing won't be completed for the second theory, so we definitely won't have anything for those. But perhaps we will have something from the first theory.

What other specific agenda items or, if you are not prepared to talk about them yet, what follow-up steps from this meeting do you want to have? Meg?

DR. FISHER: An update on the National Vaccine Plan.

MR. SCONYERS: Yes.

DR. FISHER: Then, if there is a new secretary, it certainly would be wonderful to have that person introduce himself -- or if there isn't, for whoever is the secretary to introduce himself.

MR. SCONYERS: I was saying at lunch that there is one name that I have mentioned that Tom was somewhat incredulous about. If that person were to move forward -- and I won't say what that name is, although I'd be happy to talk with you after the meeting is over -- I'm not sure that we would have time enough on our agenda, in a two-day meeting, to have that person address us. But we'll see.

Sarah?

MS. HOIBERG: I would say, let's get some work done. Let's go ahead and work on the drafts of recommendations that we think we want to change. I think that's really important.

MR. SCONYERS: Great. Barbara?

DR. MULACH: I just want to make a quick comment. Meg mentioned interest in the National Vaccine Plan. For those who are interested, there is a public meeting on December 1 in Irvine, California, where the IOM is going to be discussing the goal one, which is the research goal, of the National Vaccine Plan. So they are ongoing activities, and hopefully you guys will follow the discussion.

MS. BUCK: The NVAC Vaccine Safety Working Group is putting together a series of public engagement meetings that will be occurring in December and January. You can go to the NVPO Web site. I believe there is information there that tells you the locations and the dates of those

meetings, as well as a stakeholder meeting that is to occur in late January. Then the Vaccine Safety Working Group, I believe, is scheduled to meet the day before the NVAC meeting in February, February 4.

That information is all on the NVPO Web site as well. We'll send it to you. Michelle will send it to you.

MR. SCONYERS: "We" in the sense of Michelle.

Tom?

DR. HERR: I would like to have more discussion on what we would like to present to the secretary as far as changes on the act, whether following through with some of the old recommendations or adding new ones. I think we need to get on that early.

MR. SCONYERS: If I may take the liberty of suggesting a couple of different approaches here, I would like to do that and get your reaction to them, so that we can frame a way to proceed.

We have heard a lot of comments about a lot of different aspects about the program, and really beyond that, to vaccination and vaccine-related injuries in general. This commission has in the past constituted workgroups to take a fairly global approach, and there has been certainly a lot of discussion as a result of those workgroups. I don't know if people who participated on them would think that they were uniformly productive.

So that's one very global approach. A much more limited approach -- and let me suggest it -- is, as we distributed last meeting, to take the historical record of this commission and its advice to the secretaries over the years and work to produce something for a presentation at our March meeting that would then be -- with good luck and fingers crossed -- adopted at our March meeting to go on to the new secretary for consideration very early on in the new administration and in the new Congress.

Those are two different approaches. I wonder what you think about them.

MS. GALLAGHER: I don't think I fully understand the second approach. Would we do that individually? Would we do that by conference call? I'm not clear on how it gets accomplished.

MR. SCONYERS: The mechanism that I would contemplate is that we would create a workgroup that would take the prior comment letters of this commission, and understand the basis for them and what issues remain alive and what issues may have already been addressed or are no longer issues that need to be considered, put together a consolidated comment letter to the secretary with advice about the ways to improve the functioning of the program and present that to the commission for consideration and action at the March meeting.

So the work would be a workgroup. I would anticipate that most of that work would be done either by email or perhaps in conference calls. We haven't talked with Dr. Evans about this. There may be an opportunity, perhaps, to have that workgroup meet the day before the commission meeting in March in order to hammer through whatever remaining issues there are. I don't know if that would be a process that we could follow or not. We would have to work that out, partly as a budget issue, partly as an availability issue.

But the general concept would be a smaller subset of this commission to bring something forward.

DR. FISHER: I love the idea of looking at that stuff, getting an action plan, getting something that we want to say. My concern is that if the first time we are seeing it is in March, I think I'll have trouble being convinced that that's what we want to send out. It seems that in an hour meeting or a day meeting -- these are things that I think they have taken years to hammer out. I don't want to make it too -- I realize there is urgency to tell the new administration what we are concerned about, but at the same time I don't want to give them half-baked thoughts.

MR. SCONYERS: I understand the concern. I think that's a very valid concern. A couple of points.

One is, there was a reason that we gave you the letters in September, anticipating that this might be an outcome. There is a lot of work that has gone on. I think, if you looked at those letters and you heard the comments today, you will hear some repeated themes. So that's one issue.

Another is, you are quite right. The contrast between trying to repurpose or repackage work that has already been done to move it forward, as again expressing the thoughts of this commission, and coming up with a brand-new set of recommendations -- those seem like two very different work processes. I wonder whether we could actually accomplish the first.

The third point that I would make is, even though we would not have the entire commission involved in the workgroup, I bet we could find a way to engage anybody who actually had an interest in the forthcoming work effort so that the first time you saw it wasn't, in fact, the morning of the 5th.

DR. FISHER: In that case, I'm very supportive.

MS. GALLAGHER: I endorse that view that we need time to see it in advance and digest it before the meeting.

MR. SCONYERS: I'm sorry, Charlene?

MS. GALLAGHER: I just endorse that idea that we have to see it in advance, have time to read it, digest it,

then go back and look at what the letters said. I think doing it as you are reading it at a meeting is not a productive way.

MR. SCONYERS: I agree. When Tawny and I were talking about this at lunch, our experience a while ago was that some of the most productive time that we have had in a very active workgroup was when we were actually physically present with each other and could interact in that way. It's a different quality of interaction.

But this all just argues for getting you people on the workgroup. So I think you just assigned yourself as well.

We need to have a workgroup that is smaller than the composition of the commission. From what I know, Tawny is so busy with vaccine safety work that she is not available to participate. Having offered a proxy method of proceeding, I'm interested in how many of the members would be interested in working on that workgroup and how many would like to be involved in perhaps looking at drafts or otherwise being kept in the loop for the progress of the recommendation letter.

DR. HERR: You asked two questions. Which one do you want an answer to first?

MS. BUCK: The first question: Who wants to be on the workgroup?

DR. HERR: I'd be happy to.

MR. SCONYERS: I have Sarah, Charlene, Tom,
Tammy.

I want to know who wants to work on it, and from there we will see what we do in terms of appointing.

DR. FISHER: I would be happy to be the first alternative. How's that? If someone else can't make it --

MS. HOIBERG: You're in already.

DR. FISHER: Unfortunately, my time is a little overcommitted.

MS. CASTRO LEWIS: I would like to be in the loop, the second question, for now.

MR. SCONYERS: That was meant to be one question.

MS. BUCK: I'd like to be in the loop.

MR. SCONYERS: All right. So I'm not hearing that anybody wants to be out of the loop. That would be my role.

Tawny and I will consult with Geoff and we will figure out how we can move this forward logistically. If this sounds like a way to proceed, I would encourage you to get out that set of letters. Everybody should have a copy of Barbara's remarks today. We will also get the remarks that we had from Jackie and from Sherry, so that they are available to you, and all the other information that has come out today.

As I say, I think there has been a set of themes that have sounded over and over during the course of the day. I'm hopeful that, as you look back at those letters and think about what we have heard today, it won't be completely unplowed territory that we are traveling through. I do think we have an opportunity here to affect the way this program is considered and operated that, frankly, is a result of the new administration.

MS. CASTRO LEWIS: I think, looking at the letters and the history, it would be wonderful to put it all together into one piece. However -- I'm guilty; I didn't look at the letters since September -- I hear, not only today from the presentations, but ever since I have been in the commission about the inefficiency of the process and the cumbersome process, the length of the process, et cetera. I wonder, if the letters do not totally address that issue, what steps do we need to take in order to ensure that this commission will do something that will help the parents and the families to move this process forward a little more efficiently?

As I said, I'm not sure the letters will have anything related to that, but I think it's an issue that we really need to address. So there might be something else that we need to do.

MR. SCONYERS: Let me say a couple of things.

One is, I think you will find when you look through them that there are a number of procedural issues that are addressed in the series of letters that are meant to either expedite or simplify the process. I think you will see that there are a number of those things.

Second, I don't mean to suggest, by taking this more limited approach in the short term, that it will foreclose the potential that this commission will choose to do other things in the longer term. I'm just mindful of our timing now and advice that we received today that it's a good time to renew some of the comments that have been made, as the new administration gets under way.

So I don't think at all that we need to say there aren't other opportunities to improve the way the program works.

Third, I think, basically with each meeting, as I observe the questions that you all are asking and the presentations that we get, we are getting closer to understanding the way the system currently works. I think Vince and the Department of Justice have been very responsive in terms of explaining what their system is. Until we understand that well enough, we can't make any reasonable comments about it. But I'm encouraged. I think, as a commission, we seem to be moving along in that understanding and trying to look at accountability factors

more.

MS. CASTRO LEWIS: Definitely, with the presentations today, we have a better idea. Again, we were reminded of how inefficient it is. Yes, I agree with what you just said.

MR. SCONYERS: One of the things we have already identified is that we need to understand what the outreach plan is. I think that's a very significant role for this commission to play, having a response on that. If you don't know about the program, you can't access it.

MS. TEMPFER: I think that's why the petitioner survey was -- being involved in that whole process, I think that's what we wanted, to get that kind of feedback where we could find some of the weaknesses and where the loopholes were. I think it's great that that has moved forward.

MR. SCONYERS: It doesn't play to my chronically gloomy personality, because I think things are actually progressing a little bit. I don't know. I don't know how to make sense of that. I have a mug that says, "This mug is now half-empty," with a line.

Any other agenda items you would like to make sure are addressed next time?

(No response)

Those of you who have signed up for this I think

will have plenty to do between now and then. I would encourage all of you to look at those letters, especially those of you who have said you just want to be in the loop, so that as you see something come forward, you have context for it.

If there is nothing else to come before us, I would be willing to entertain a motion to adjourn.

(A motion to adjourn was made and seconded.)

All in favor?

(Chorus of "Ayes")

Oppose?

(No response)

We are adjourned. Thank you very much.