ADVISORY COMMISSION ON CHILDHOOD VACCINES

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P R O C E E D I N G S

MR. SCONYERS: Good morning, everyone. Thanks for joining us this morning, bright and early. We are continuing our session from yesterday.

We are going to go a little bit out of order to accommodate some of our speakers, and partly because we also need to fill in a little time here.

We heard extensively from Dr. Marion Gruber, from the Center for Biologics Evaluation and Research, yesterday. Dr. Gruber has other commitments today and has joined us by phone. I would like to take her report, just her update, on the center out of order so that she can answer any questions and then move on with her day.

Agenda Item: Update on CBER Vaccine Activities

DR. GRUBER: (Via telephone) Good morning. Thank you very much.

I would like to give today a very brief update on the Center for Biologics Evaluation and Research, Food and Drug Administration, vaccine activities.

We have actually approved two additional vaccine products since I reported in June 2008. On June 20, we approved an infant vaccine called Pentacel. This vaccine

is a combination product that is manufactured by Sanofi Pasteur. Its indication is for active immunization against diphtheria, tetanus, pertussis, poliomyelitis, and invasive disease caused by *Haemophilus influenzae*. The vaccine is administered to infants and children 6 weeks to 4 years of age. Again, this vaccine contains diphtheria, tetanus, pertussis, poliovirus, and *Haemophilus* type b vaccine antigens.

That was an approval on June 20.

On June 24, 2008, we licensed an additional vaccine that is also a combination product. It's manufactured by GlaxoSmithKline. This vaccine is indicated for active immunization, again, against diphtheria, tetanus, pertussis, and poliomyelitis, but it's given as a fifth dose in the diphtheria-tetanus-acellular pertussis vaccine series and as a fourth dose in the inactivated poliovirus vaccine series. That's very complicated. So this vaccine is administered to children 4 through 6 years of age who have previously received DTaP in four doses and IPV as three doses.

Those are the two vaccine approvals. Are there any questions on this one?

MS. HOIBERG: Do they contain thimerosal?

DR. GRUBER: No, they do not have thimerosal preservative.

Are there additional questions?

DR. HERR: A question on catch-up immunization in children who haven't received the Hib in the past. Will this be available -- you say through age 4. If you are just under 5, at this point you would still perhaps be at risk for that and recommended to receive that immunization. Could Pentacel be given for that catch-up immunization?

DR. GRUBER: That's a tough question that I can't even answer right offhand without doing some reading. I think that's complicated, because it contains other vaccine antigens --

(Telephone transmission intermittently interrupted)

I would have to follow up on this one. I can perhaps clarify that with you with an email or maybe at the next meeting.

DR. HERR: That would be great. Thank you.

MR. SCONYERS: Any other questions for Marion?

(No response)

Thanks for joining us, Marion. We appreciate that.

DR. GRUBER: I just want to -- one more thing, and that's about the influenza vaccine. As you know, we have, in the meantime, six -- the manufacturers. For five of those, the FDA has started to release influenza vaccine lots that are available for distribution by the manufacturers for the upcoming 2008 and 2009 influenza season.

That's actually all that I have to report today.

MR. SCONYERS: Any questions on influenza vaccine?

(No response)

Thank you very much.

DR. HERR: Jeff, before we get started on things, I know that we are really looking at trying to maintain the safety of the vaccines and to take care of any unfortunate children who have had problems with that. But I think we need to also keep our minds and eyes on the success of the vaccine.

I was in a conversation last night. This time of the year 50 years ago was a very scary time for families.

It was hot, but nobody went to the beach. Nobody went to pools. When your child developed diarrhea, parents were terrified, because this could be an early sign of polio.

I think we have to recognize that, while nobody sees that anymore, nobody worries about it anymore, this is something that is 100 percent because of the immunization practice. We have to recognize that the goal of keeping our children healthy and protecting them and allowing them to have fun is why we are doing this.

But again, we need to make sure that everything is as safe as possible.

MS. BUCK: Yes, and since we are doing that, I would like to remind you all, while we are here, that the reason that I'm not sitting there with you folks this week is because my vaccine-injured child is having such a terrible bout of seizures that are uncontrolled that I'm unable to leave my home and get much further away than just to the city. We should all keep in mind that some of these very severely vaccine-injured children -- and they do occur -- are not just numbers on a page. These are children and these are families whose lives are forever changed, who will need care on a regular basis, and who

generally take people like me and take control out of their lives.

As much as I appreciate -- it is why I work so hard with Dan Salmon and the other groups on vaccine safety, because I appreciate the public health aspects. But it's always very important to personalize the injury and to remind everybody just how devastating they are and why we have to set the bar higher in terms of eliminating adverse events. What we want is 100 percent benefit and no risk. If we could have that, we wouldn't be here right now.

MS. HOIBERG: I would say my main concern with these new vaccines that have just been approved is, you are lumping the ones that are the most dangerous together. I think the reason they do that is that it is -- of course, we don't want to have to stick our babies three or four times at one time. But what they don't understand is -- they are getting how many vaccines at one time? And then let's go ahead and add some more.

Are these vaccines going to be put on the table immediately? Is there any question? Or do we have to wait for children to die and be maimed forever?

That’s my question.

MR. SCONYERS: These are all licensed.

MS. HOIBERG: We have vaccines that are not on the table -- like the particular brand that’s on there, but the other ones that are not. This is one that is lumped together. So how much harder is it going to be for us to prove?

MR. SCONYERS: These are all going to be covered.

DR. EVANS: All vaccines that are routinely administered to children by recommendation by CDC are covered by the program. When different products are licensed that have combinations -- even one of these vaccines -- they are covered.

MR. SCONYERS: Other questions or comments at this point?

(No response)

I’m going to continue to go out of order and take Dr. Dan Salmon and ask him to give us his report from the National Vaccine Program Office, which he has indicated will be a fairly short report, given the other agenda items that we have had or will have today.

Agenda Item: Update form the National Vaccine Program

DR. SALMON: Thank you for letting me go out of order. We have an NVAC Safety Working Group call this afternoon that I need to attend. I appreciate your accommodating my schedule.

Yesterday I updated you on the NVAC Safety Working Group, as well as the public engagement process. This afternoon Dr. Ray Strikas from our office is going to talk to you about the National Vaccine Plan and the work being done to revise that. That really covers much of what my update would be within those three areas, which is why I have only asked for a few minutes.

But there are two other areas that I can briefly mention to you.

First, we have our NVAC meeting on September 16 and 17, in Washington. That’s in just a couple of weeks. Typically, the ACCV and the NVAC meetings are scheduled fairly close together. Fortunately this time they are not back to back, but they are usually right around the same time.

There are probably a couple of items that would be of interest to the ACCV -- one, only tangentially, on

issues of vaccine financing and supply, which I think generally relates to the Injury Compensation Program. Part of this program was intended to ensure an adequate supply of vaccines.

The area which may be of interest to you is a session on vaccine hesitancy. In that session the NVAC is going to hear what we know about the rates of hesitancy and refusal in the U.S., some of the work being done by CDC to address these issues of concern to parents, as well as the views of some other organizations that work with parents in these areas. It's an hour-and-15-minute session. I think this is a general topic that is probably of interest to this committee.

The only other topic that I would update you on is that the secretary has recently formed a federal immunization safety task force. The intent of this task force is to look at what federal assets are involved in immunization safety and to really bring them together and enhance them, where feasible. This is a task force which is chaired by the assistant secretary for health, who is also the director of the National Vaccine Program, Dr. Garcia. It has fairly high-level representatives from all

of the HHS agencies that have assets in vaccine safety, including, as you would suspect, FDA, CDC, NIH, HRSA, as well as AHQR and CMS, a few other HHS agencies that have a more peripheral role in vaccine safety, as well as the DOD and VA. So this is really a federal, not just an HHS, task force.

This task force has four working groups that are focused on research, data coordination, risk communication, and public engagement. They have been working with the assistant secretary for health to look at our immunization safety system and make recommendations in terms of how that infrastructure might be enhanced.

This relates to some of the areas we discussed yesterday, because this is some overlap between this task force and the National Vaccine Plan, which Dr. Strikas will describe to you shortly, as well as the goal of the NVAC Safety Working Group, which, as I mentioned yesterday, is developing a white paper on what the optimal vaccine safety system would look like. We look forward to the opportunity to hear from our advisory group on their views on this issue.

That’s really all that I have to update you on,

in addition to what you heard yesterday and what you are going to hear today.

If anybody has any questions, I would be happy to address them.

MR. SCONYERS: Thanks, Dan. Tom?

DR. HERR: Again, if it's going to be looked at, could somebody -- maybe it's not the purview of that particular group, but as we are looking at some of the alternate schedules that people are coming up with because of their concern, their anxiety, can there be ultimately some discussion on the efficacy of some of these programs, so that we can advise families, as they choose alternate methods, on some of the risks that they may have because of the slower timetable or different timetable and evidence behind that?

DR. SALMON: That's a great question. I thought the dialogue earlier about the benefits of vaccines, as well as the individual-level costs when an adverse event does occur -- it's a fascinating and very moving discussion, and I think much of the value which this advisory committee really offers. Your question, I think, is somewhat related, in that clearly safety and efficacy or

effectiveness are related.

The focus of the work that I have been describing has been and is safety. However, as you point out, when one looks at different schedules of immunizing a child, there are, potentially, impacts on safety, but also on efficacy or protection that is offered to that child.

So I think this is within the domain of our office. If you look at NVPO, our charge is really twofold: To both prevent infectious diseases through vaccines, as well as the prevention of adverse events caused by vaccines. The two are fundamentally linked, and they have to be. Often when studies are done, both are examined. However, it depends on the study. Some studies are designed to look primarily at safety endpoints and some are designed primarily to look at disease endpoints. Sometimes you are able to look at both.

I think, in concept, I and the groups that are working on this hear you and agree with you. Whether or not a specific study can look at both or you need separate studies is an important issue, depending exactly on how it's designed.

MR. SCONYERS: Any other questions for Dr.

Salmon?

(No response)

Thanks, Dan, for joining us.

At this point, we have on our schedule a presentation on the CDC Web site that we have asked for. I just don't know if our presenters from CDC are available for us. Is Michelle Batch on the phone?

(No response)

Hearing no response, I'm going to again go out of order and ask Dr. Ray Strikas if he could give us an update on the National Vaccine Plan.

Agenda Item: Updating the National Vaccine Plan

DR. STRIKAS: Good morning, and thank you for the opportunity to do as Dan suggested -- give you an update of what this National Vaccine Plan was and what we hope it will be.

What I'm going to do in the course of the next 15 minutes or so is:

- Describe the mission of our office, which you are probably pretty familiar with, since Dan sits on this committee.

- Talk about the 1994 National Vaccine Plan a little bit and changes in the vaccine landscape since 1994, which you are probably familiar with.

- Talk about the priorities that we have defined for the revised plan. This plan has a 10-year horizon, from 2010, when we expect it will be issued, to 2020. It will attempt to incorporate the Healthy People 2020 objectives, which will be issued sometime next year.

- Talk about our revision process.

- Lastly, talk about stakeholder input leading into what I see is a discussion about how this committee can offer input to the plan.

As you may know, the National Vaccine Program Office has been around for about 20 years. It was established by congressional statute. The public law is listed here. The office is directed, through the assistant secretary for health, who is its director for the program, to coordinate and provide direction for all these different things in the U.S. vaccine enterprise. I think it's better to say we coordinate; we don't direct. The office is small. We have 10 folks. We do review these issues with

the agencies acting on those within the federal government, from research, development, production, procurement, distribution, use -- all these different things -- sometimes paying more attention to some things, such as vaccine safety and vaccine supply, than research and development, as an example of relative priorities within the office, and resources. But we do pay attention to all of them.

The statute went further, to say that the NVP director shall prepare and issue a plan for implementation of those responsibilities, and it will establish priorities and optimal use of resources to carry out such priorities, how the departments and agencies will do so.

So there was a plan issued in 1994. If you go to hhs.gov/nvpo, our Web site, you can see the National Vaccine Plan from 1994. I did not bring my copy. It's a rather long document.

The major part you need to know about is that there were four goals in the old plan:

- To develop new and improved vaccines, or research and applied research.
- To ensure the optimal safety and effectiveness

of vaccines in immunization.

- Education and communication for both the public and health-care providers.

- Lastly, program issues around better use of existing vaccines to prevent disease, disability, and death. This included one phrase on biodefense. It included three objectives on international health as well.

The footnote at the bottom is a reminder that by statute our office to date deals only with preventive vaccines for infectious diseases. There is a huge amount of work going on with vaccines meant to be therapeutic, be it for cancer or for infectious diseases. We, by statute, are not dealing with those, albeit one can argue -- and people have argued -- that we should develop a companion plan to look at those issues. That has been something discussed, but not yet dealt with.

To be more specific to what you all think about and deal with, regarding vaccine injury compensation, in the 1994 there were three strategies listed. One had to do with ensuring the viability of the Injury Compensation Program through adequate funding. The others stated that the vaccine injury table should be updated periodically to

reflect the latest scientific knowledge and that new vaccines recommended for universal immunization are covered under the program. Basically, these things continue to happen.

I'll jump ahead and say that the additions to these general ideas -- while these general ideas remain in our draft planning process, Dr. Evans and others have suggested that other things need to happen, such as ensuring regular reviews by the Institute of Medicine of the injury table, better communications about the work of this committee in the program. These types of things are envisioned in the new plan at present.

In 1994, some of the major emphases had to do with the childhood immunization initiative. You may have been told in the past or be aware that there were large outbreaks of measles in 1989 and 1990, which led to funding for an immunization initiative, largely through CDC, to improve delivery of services, education, reducing costs, so on and so forth.

Other activities that were important at that time and continue to be were HIV vaccines, emerging infections. The National Institutes of Health had a blue-ribbon panel

and looked at some specific issues -- they are listed there, on pertussis, measles, STD vaccines, and so on -- and policy and program issues. Even in 1994, we were talking about pandemic planning, as we still do now, and addressing unmet needs, which our office has tried to do through some modest funding.

So this plan was completed and published in 1994. We reviewed it three years later at a retreat, to catalogue and see what was being done. There hadn't been, really, a formal evaluation, until very recently the Institute of Medicine did one. There were no revisions since publication, although our statute says we are supposed to revise this thing every year.

Early last year, the assistant secretary for health said that the plan should be updated to reflect current priorities and potential future directions, as well as think about the budget, summarize current priorities, research, development -- basically, to do what the plan was supposed to do in the original statute.

The things we have had to take into account are things, again, you are probably familiar with: disease incidence changes; new vaccines; new schedules; changes in

coverage; implementation of immunization information systems, sometimes called registries; a focus on adolescent immunization; challenges vaccinating adults; and a huge effort around biodefense and pandemic preparedness.

You have seen this table, probably, as many times as I have, in terms of the changes of vaccine-preventable disease incidence from the time vaccines were licensed. These are diseases that we talk about all the time. Twentieth century annual morbidity before vaccines is listed in the second column. There are two numbers in the third column: What was going on in 1994 and where we were in 2005. With the exception of pertussis, there were marked decreases in these diseases' incidence from their peak to 1994, and they continue to drop to 2005, with the exception of pertussis. Pertussis has diminished significantly since 2005, but it still continues to be a problem.

If we look at some other diseases for which vaccines were more recently licensed, such as hepatitis A, hepatitis B, pneumococcal disease, from pre-vaccine estimated morbidity, in the second column, you see significant drops -- not quite as striking as in the

earlier slide -- for all of these diseases. These have continued to drop from 2005 to 2007, for all of them.

Coverage data -- and I should have updated this slide, because CDC actually just published its 2007 National Immunization Survey data yesterday -- coverage stays pretty much where it is now for these commonly recommended childhood vaccines, and substantially better than it was in 1994, if you look at where those colored bars are on that slide and then where they have gone to. For each individual vaccine, coverage is around 90 percent for the commonly recommended ones, and for the series -- depending upon how you define series -- I believe the number CDC issued yesterday was 77 percent for these vaccines and I think on the order of 67 percent for all vaccines recommended for children through the age of 2 years.

We don't do so well, as you probably know, for adults. This is a slide of influenza vaccination uptake, stratified by racial/ethnic group, through 2005. It's not a whole lot different in 2007. We are about 65 to 70 percent, depending on how you look at the data, overall. White persons are better vaccinated than black or Hispanic

people. The vaccination rate is even lower for people less than 65, be it influenza or pneumococcal vaccine. The Healthy People 2010 goal for older persons is 90 percent coverage. We are not going to get there. So there are remaining challenges in dealing with this group.

There have been a lot of new vaccine indications. My colleagues at FDA caution me to say not so much "new vaccines" as "vaccine indications." This is a listing of most of them since 1994, in terms of specific antigens or diseases for which vaccines were licensed. Again, you probably know about all of these. You discuss them all the time. Most of these are in the program that you monitor, with exceptions being zoster vaccine, which is only recommended for adults 60 and older, and H5N1 influenza, which is a vaccine that is licensed, but not being used. Hopefully, we won't use it anytime soon.

But a lot of vaccines have come into play in the last 14 years.

MR. SCONYERS: Can you just state what a vaccine indication is?

DR. STRIKAS: It's a way of me shorthanding by saying, for example, that we have TDaP vaccine for

adolescents and adults. There are two vaccines. I use the word “indication” rather than “vaccine,” because if I listed all the vaccines licensed since 1994, this list would be on two and a half pages. It’s easier to talk about the antigens or the proteins, the products, and call it “indication.”

I was anticipating that human papillomavirus would have two vaccines licensed, and I would have added another one. There is only one.

But it’s a shorthand way of portraying what we have vaccines for, by saying “indication.” For the most part, it’s almost the same as “vaccine,” but not quite the same.

Some of the hot-button issues, if you will, around adolescent immunization that we need to take into account that were not active issues in 1994:

- There are a lot of vaccines recommended for adolescents and preadolescents at this time, as you are aware, such as meningococcal vaccine, TDaP, and HPV.

- We are talking about vaccination in a variety of venues.

- School mandates and laws continue to be issues.

- The role of informed consent is a concern.

These are some things that Dr. Freed, the former chair of the National Vaccine Advisory Committee, listed in a report the committee issued earlier this year.

Biodefense and pandemic preparedness, of course, become very important. Project BioShield authorizes over $5 billion over the next 10 years, not all for infectious diseases, but for a lot of things that are infectious diseases, such as anthrax, botulism, and smallpox. Billions more -- it’s on the order of over $5 billion now -- have been allocated to pandemic preparedness, most of that for vaccines, with the largest lump coming in 2006 for a variety of vaccine approaches.

These things, in any plan we write, have to be taken into account.

Other challenges:

- As you are well aware, vaccine safety issues are prominent.

- Vaccine financing is a great concern among practitioners in terms of amount of reimbursement, timing

of payment, so on and so forth. There has been a large amount of work the NVAC has done around this issue that will find its way into our plan.

- International vaccine and health-protection issues.

- Vaccine supply. There always seem to be a supply issue. If it's not flu this year, it's Hib or something else.

- Influenza, up until recently, has been an annual challenge. The challenge this year is figuring out how to use 146 million doses of vaccine in an appropriate and efficient fashion, which is a challenge preferable to having half your vaccine supply cut, as we had in 2004.

What is in this new plan? We have 13 draft priorities. We have five goals. But we first set out to say, what are the top things that we think need to be represented in the plan?

On this slide and the next one, we have said what must be included. None of these are terribly large surprises. I don't think any of them are surprises.

- Basic and applied research.

- Specific vaccines to pay attention to which have been prominent issues at NIH and elsewhere are HIV, TB, and malaria. Universal influenza -- and I should have added it to this slide -- is another one that we think is very important.

- Maintaining high childhood vaccine coverage, and indeed improving it where we can.

- Achieving 90 percent coverage for adolescents.

- Achieving appropriate coverage targets for adults.

- Reducing or eliminating financial barriers to access for vaccines.

- Enhancing security of vaccine supplies, both globally and in the U.S.

- Vaccine safety infrastructure -- improving it, and all the work that Dan has talked about that they are doing.

- I have highlighted for you the priority that we included on the National Vaccine Injury Compensation Program -- that it continue to do its work -- who have been

injured by vaccines, based on the injury table.

- Advance global disease reduction and eradication goals. These are goals issued primarily by WHO, with CDC and USAID being the U.S. partners.

- Assuring that we can monitor vaccine-preventable diseases and immunization coverage, or just surveillance in general.

- Preparedness, be it for biodefense, pandemic influenza. This is much more prominent than it was 14 years ago.

- Last, but perhaps it should be first, is communication and education -- that we clearly articulate our vision and what we think is important and get information -- it's a two-way street. We get information from folks like you and then we pass it back to those who need to know.

The process for this plan: We have an interagency task force that met twice in 2007. It continues to meet actively in 2008. The steering committee consists of our office, CDC, NIH, HRSA, and FDA. We have regular participation, as need it, from the Department of

Defense, the VA, and USAID, and other parts of the department.

The Institute of Medicine, at our request -- and we funded them -- put a committee together, which I will talk more about in a minute, to evaluate both the impact and -- not so much impact, but the way in which the 1994 plan was written and what they think that plan offers to us in terms of how we think about the next one. Our National Vaccine Advisory Committee will review and comment on the committee's recommendations and the draft priorities, and they will review what the IOM committee comes up with. This IOM committee has met twice, once in open session, to review the program areas on childhood, adolescent, adult immunization, supply, finance, and surveillance. They met on July 24, in a long session that day, and they have a series of meetings that will recommence beginning December 1 to look at the other areas. These are probably focusing on vaccine safety, relationship and development, global health, and communication/education, the other goals that we are going to lump those priorities into.

We have planned a series of citizens-at-large, or public engagement, meetings. The slide says 2008-09. They

probably won't start until 2009 -- to do four meetings and conclude those by March, and have a report that we can sure with whoever is interested, in particular the IOM and our constituents.

The IOM is having open meetings to get stakeholder input. That is, anyone who is interested -- they will invite people, but their meetings are open, and anyone who wishes to come may come and offer comment.

We hope to complete this plan by the end of 2009. The IOM will give us their report on what the plan should look like by latter 2009, and our vision is to take that into consideration with the public engagement, with input from other stakeholders, and complete it by that time.

We have to get an interim draft to the IOM by November 1. We are working on that now. We have a retreat on Monday with our various agencies to try to get the federal part of that done and move it along.

This is a listing of the IOM committee members. Some of these folks are familiar to you. They have probably talked to you or you have worked with them in the past. Probably the most important thing is the Web site at the bottom of the slide. It lists all the activities of

the IOM committee, all the slide sets presented at the two meetings they have had so far. Their letter report to us, with six recommendations on what the new plan should do, is available at this Web site.

The recommendations deal with, not surprisingly:

- Identify what is a priority and what isn't, and how you made those decisions.
- Identify short-, near-, and long-term goals.
- Identify how you are going to include innovation in this thing.
- Identify how you are going involve stakeholders in the process, in addition to the IOM -- stakeholder meetings that they are convening.
- Vaccine supply was identified as a particular concern.

That's not all the recommendations, but those are some of the more prominent ones.

So far our National Vaccine Advisory Committee has provided comment and input on the priorities that I listed for you. They will review the final IOM report and comment on it. We will share our near-final version of the

plan in 2009 with the committee.

We think this iterative process, in addition to the agency's work, will offer some additional involvement. It's a moving target. How do we involve all the many different players who are interested in the vaccine enterprise in the United States? There's the IOM process; there's NVAC; there is this committee. We are talking to members of the Advisory Committee on Immunization Practices. We are still open to suggestion on how to involve other stakeholders, beyond what I have described.

Possible roles that you all may want to suggest: We would be happy to send the draft plan to you, as we send it to the IOM, which we hope will be available the end of October. It will largely reflect the federal point of view, because we have had limited time to collect stakeholder input to date. You are welcome to comment on this, of course, now and on the plan when you receive it.

You are welcome to participate in the IOM meetings, most of which will be in Washington, D.C., though the next one is in California, on December 1. But after that they are scheduled to be in Washington.

Of course, you can comment on the IOM committee

final report, both to them and to us.

So those are just some examples of opportunities for this committee to participate in this process.

That's all my slides. I thank you for your attention. I'm happy to take questions.

DR. FISHER: We had the IOM letter among the things that we were provided. Reading over it, it looks like their biggest note about the 1994 plan was not so much the plan or anything about it, but the fact that it couldn't be measured.

I have been involved in several strategic planning groups for a variety of things. It does seem important that when you make a plan, you delegate the responsibility to a certain group. I think that's really going to be essential.

One of the things I have been most impressed with on this committee is, there are a whole lot of different departments of the government doing a whole lot of things, and we don't always get the feeling that you are all talking to each other.

To have a plan like this, where individual things were assigned to different groups, seems like a way to

ensure that it actually might happen. It's taken you two years to make a plan that you are supposed to revise yearly.

DR. STRIKAS: You are right. There's not much for me to add. That's a clear message the IOM gave us. You have repeated it, and that's appropriate. We are struggling with that, in terms of how to put down numbers. For example -- and it's not an excuse, but it's a circumstance that we have to figure out how to deal with -- Healthy People 2020 won't issue their framework until February or March of next year. That has, as you know, for Healthy People 2010, targets for vaccine coverage, for disease reduction. My sense is, though they are not saying it, that they will have similar things in there for 2020.

It makes no sense for us to make up some numbers as targets, because they are going to do it in a large and reasonable fashion, with a lot of stakeholders. So we kind of have to put that one on hold.

But that's only a small piece of the puzzle. A challenge, for example, is getting colleagues who do research, who hate to be pinned into corners, to say we

will develop a new HIV vaccine by 2015. A certain secretary of health and human services said they would have an HIV vaccine in three years in 1984. I commend her optimism, but it didn't work out. Dr. Fauci has written in the *New England Journal* this week or last week that we have a lot of work to do; we have to go back to square one on that one.

So getting targets in research is really a tough one.

On the other hand, Dan Salmon, who left, is actively involved in editing the safety component of the plan. One of the challenges there -- but it's eminently doable -- is writing down targets for how to improve surveillance, how to get to certain points on increasing populations in different systems, what studies to conduct by when. A lot of these things, as you know, perhaps better than I, are eminently doable, and it's already defined which agency is doing what. It's a matter of putting it down on paper in one place.

It's our responsibility to execute what you said. It's not easy, but that's what we need to do. Again, part of this vision is to get this down, identify the

stakeholders both within and without government, and at least for the federal part, when we get this thing done, talk to whoever is in the corner office of the Humphrey Building on the sixth floor next year and say, here's our vision. This is what it's going to take us to get there, beyond usual resources. What can you do for us?

That's part of the purpose of this thing. And it won't work unless we say, this agency is going to do it and they hope to do it by this time.

Again, you are right. That's what we need to do.

MS. BUCK: I'm a participant on the Vaccine Safety Working Group with Dan Salmon for NVAC. When we are working on the white paper and we are reviewing the ISO scientific agenda, it has often been suggested to us to not be concerned about funding mechanisms, that what they want from us is sort of a perfect plan, regardless of funding -- to not hold our thoughts and our suggestions, based on funding restrictions.

How are you being affected by that on this project?

DR. STRIKAS: You identify the challenge of having different moving parts going on. We have an

obligation to get an interim plan, interim draft -- capital “I” and capital “D” -- to the IOM for their consideration in a couple of months. Your process with the National Vaccine Advisory Committee working group and others won’t be done by then, nor was it planned to be, nor need it be hurried up, because that process can feed into the final plan, which is latter 2009. My understanding from Dan -- and correct me if I’m wrong -- is that you are supposed to finish up your process early or middle of the next year. That certainly is adequate time to take into consideration the vision that you have had the luxury of taking more time in developing than we have had to get a hurried draft together.

We have an interim draft coming, but the final document is a year away. We are obliged to take into account a variety of NVAC documents -- the one you are working on is one of those -- both on the research agenda and the white paper vision for the safety system. The NVAC has a group that has worked on vaccine financing for over a year. They are not quite done yet. Parts of what they have recommended in draft are showing up in the plan, but the final work will have to show up later.

So there are two examples where we will have a lot of caveats around this draft that goes to the Institute of Medicine and gets posted, and say, there are further coming attractions, because certain work isn't done yet.

MS. BUCK: So the work you are doing on this draft is based on funding mechanisms as they are right now.

DR. STRIKAS: Based on what they are right now. My interpretation -- you can say, Ray said this -- cautious optimism on what else we can do. What can we aspire to? We may have to change that, based on input from your working group and others.

MS. BUCK: I think one of the things that has been fairly obvious in our working group is that a lot of the ideas that are being floated for vaccine safety are very different than the current structure and the current way of doing business. It's almost like a reform approach to looking at the systems as they operate now and saying maybe we need to make some really significant changes.

Of course, we have the liberty of doing that, because they are asking us to come up with sort of a grand vision, without worrying about funding.

When I look at your objectives 2.4 that relate to

our program, I'm struck by the fact that we have often tried to tackle almost these same things. For example, ensure that the vaccine injury table is updated periodically -- those of us who have been on the commission for a while understand that the process to update the vaccine injury table is apparently very slow. I'm still having a hard time understanding why suggestions that we have made to change the table have not been implemented. Most of the time, the answer is that it's a very long and slow process that can take years and years.

So when you are looking at some of these plans, particularly under objective 2.4, I'm struck by the fact that I think there may have to actually be some real reform in the way the systems run in order to actually achieve some of these goals that you have.

I was curious to know if those are the kinds of things that you think you are coming up with. Or are you suggestions pretty much just defined by the way the programs currently run and operate?

DR. STRIKAS: I think there is incremental change in what we have proposed so far. We will talk about it more on our retreat Monday and as we work along. But, as I

said, we look forward to your vision. The document we come up with in the next two months is an interim draft. It has lots of room for comment and improvement. I for one look forward to -- the hackneyed phrase -- people who think outside the box and the things you come up with.

MR. SCONYERS: Other questions or comments?

(No response)

It was a great presentation. Thank you very much.

I believe we have our friends from the CDC -- Michelle Batch, are you on the phone?

MS. BATCH:: Yes, we are.

MR. SCONYERS: This is a request that the commission made a couple of meetings ago. We are able now to schedule a demonstration of the CDC Web site, where there is a huge amount of information. Michelle Batch and, I think, others are going to walk us through what's available and how to access it.

Agenda Item: CDC Web Site Demonstration

MS. BATCH: (Via telephone) I just want to confirm that the participants there have a PowerPoint slide set.

MR. SCONYERS: Yes.

MS. BATCH: And we also have the actual PowerPoint slides available on overhead?

MR. SCONYERS: Yes.

MS. BATCH: Okay, great.

Good morning, everybody, and thank you for the opportunity to provide this tour of the CDC Web site. We are specifically going to focus on how to find information related to vaccine-preventable diseases, vaccines, and vaccine safety on CDC's Web site today.

Just quickly, there will be three parts to this presentation. The first presentation will be from the National Center for Immunization and Respiratory Diseases, NCIRD, which has the responsibility of managing information related to vaccine-preventable diseases and vaccines on the CDC Web site. I will be walking you through this section of the Web. My goal today is to give you just a general overview of the site, as well as to highlight a few of the many features that are available.

I also at this time would like to acknowledge Cathy Hogan, who is NCIRD's webmaster, and Cindy Fowler, who has been assisting in preparing this presentation for

you today.

The second part of the presentation will cover the vaccine safety information on the CDC Web site. As you know, in 2005, the Immunization Safety Office was relocated to CDC's Office of the Director. The Immunization Safety Office, ISO, has the responsibility for vaccine safety information on CDC's Web site. So we also today have PerStephanie Thompson, who will be walking you through the immunization portion of the CDC Web site in the second half of this presentation.

Lastly, we will have time to answer questions that you may have on the site.

This is the home site of the CDC Web site. The bottom black bar of the presentation set will give you the direct URLs -- in this case, www.cdc.gov -- to the pages we are discussing today during the presentation.

Specifically, what I want to highlight on this slide is that there are numerous ways to find vaccine information on the CDC home page. The search feature is in the upper right-hand corner of the slide and of the actual Web page. I have highlighted two red ovals. They actually identify two quick ways you can find disease-related

vaccine information.

The first is through health and safety topics. If you click on this section and go to the topic list, you will find vaccines and immunizations there, which leads you to the home page. Probably the easiest way to find this is to look on the right-hand side, where it says “CDC.gov Top 10.” You will find vaccines and immunizations on that particular list. That highlights the most viewed sections of the CDC Web site.

If you click directly on vaccines and immunizations, that will come to the home page of vaccines and immunizations. You will see the direct URL there, which is cdc.gov/vaccines.

A few things, in general, on the Web site. The CDC Web site is arranged by topic. All information on the site is updated daily. It’s reviewed by subject-matter experts. On the bottom of each of the contact pages of the Web, you will find when the page was last modified, reviewed, and the content source.

Just quickly, on the left side of our home page, I want to point out that you can find additional resources and contact information, both telephone and email, for CDC.

There is also a contact webmaster link, which will get you to Cathy, where you can report a bad link, an error, or a problem with the Web site, if you are having a problem with the Web site.

The area highlighted in the red box, “In the Spotlight,” if you click on any of these topics, you will be directly linked to information on that topic. So the spotlight highlights new studies. For example, the first hyperlink features the 2007 National Immunization Survey information, which Ray alluded to, which was released yesterday. That reports on immunization coverage for children 19 to 35 months.

Also drawing your attention to the sixth bullet, there is information in the spotlight on vaccine safety information, like the sixth bullet, which is information from the CDC and FDA on safety. Again, that particular sixth bullet links directly to the vaccine safety site.

There are many different areas on the vaccine immunization home page. The areas that are highlighted in red are the ones we are going to be covering today. That, specifically, is the immunization schedule, the recommendation on guidelines, a little bit about vaccine

and preventable diseases, the publication section, the statistics surveillance, parent education, an area for specific groups, health-care professionals, and education and training.

The highlighted area in purple, the box, addresses vaccine side effects, which looks at the possible side effects and risks of vaccines, as well as vaccine safety. This vaccine safety area of the Web site is hyperlinked to the ISO site, which will be covered later on by PerStephanie Thompson.

From the home page, clicking on the immunization schedule, you will find a page that will actually have the childhood schedule, from birth to 6, the adolescent schedule, from 7 to 18, and the adult schedule for the recommended vaccinations for those age groups. There is also a red oval and a highlighted box here, which highlights the catch-up schedule. Parents and providers can actually download this interactive resource. What they do is, they put their child’s vaccination to date, as well as the date of birth of the child, and they find out what vaccines the child needs. This is a really useful resource for seeing what vaccines are missed or skipped according to

the recommended immunization schedule.

The next slide looks at the recommendation and guidelines area. The information on this particular slide looks at the Advisory Committee on Immunization Practice, the ACIP, as well as guidelines on vaccine storage and handling, vaccine administration, and recalled vaccines. Also it highlights areas for strategies in increasing vaccination rates.

Today we are going to focus, because of time, on the ACIP in the big red oval area, highlighted. That contains information on ACIP meetings, which, I'm sure you are aware, is open to the public. You will find agendas and registration, as well as the presentations at the ACIP meetings. You will also see the ACIP recommendations, provisional recommendations, and VFC resolutions in this particular area.

Clicking on the smaller oval, with immunization recommendations, if you turn to the next slide, you will find documents that summarize the science base for the recommendations, both comprehensive recommendations that apply to multiple or all vaccines, like the general recommendations on immunization, and those that apply to a

single vaccine or disease, such as influenza.

A couple additional points to make on this slide. The ACIP recommendations can also be found in the *Morbidity and Mortality Weekly Report*, the MMWR site, which is published weekly. That's highlighted in the top box. It gives you the direct URL to MMWR.

We also want to point out a special feature. There's a "Get email update" feature. When you see this icon on any part of the Web site, you can actually click on it and subscribe to receive email alerts. Whenever the page is updated with new information, you will get an email. When you subscribe, all you need to do is give an email address, as well as decide how frequently you would like updates. You can get it immediately when the page is updated or on a daily, weekly, or monthly basis.

In the vaccine-preventable disease area, this gives Web users vaccine-preventable disease and vaccine-specific information. In the vaccine-preventable disease area, if you click on measles, using measles as an example, what you will get is -- each individual vaccine or disease page is divided into three sections. In the first section, "What You Should Know" is highlighted with the yellow oval

or the top oval. It covers information about diseases, like signs and symptoms, common Q&As about the disease, also information about the vaccine. This includes risks and benefits, side effects, vaccine safety, as well as contraindications -- who should not be vaccinated -- and Q&A, too.

The second oval, the blue oval, addresses clinical resources for providers. That includes technical information about the disease and vaccine, the recommendations, additional references and resources, related MMWRs, and other materials for providers, as well as materials that providers can give to their patients.

The last oval that we have highlighted in green is for the media. That covers recent press events or briefings. An example in this case is, it highlights a CDC August 21 press release on measles.

I want to show you the publication portion of the Web site. There are a variety of resources for providers and the public. I want to make sure that you see the right side of the screen. That oval shows you how to electronically order materials. All materials are free of charge and can be copied or reproduced. Some materials

have an order limit, but most materials are available in bulk. You can fill out the form and make note of how many you need.

Also there are CDs available, so you can print files locally if you wish to print mass copies of any of the CDC materials.

Many of these materials can also be downloaded. You can download them directly from the Web site. One example of this is on the next slide, which is the vaccine information statements.

You can download these. These VISs are sheets produced by CDC that explain to vaccine recipients, their parents, or their legal representatives both the benefits and risks of vaccines. Folks can get these via direct download off the Web site.

You will see that the “Get email updates” is an option on this page. You can be alerted when new vaccine information statements are available. You will also see a link to the IAC Web site, which offers information statements in multiple languages.

I want to also cover the statistics and surveillance. When you click that from the main home page,

it will lead you to information on data and definitions. It highlights the common surveillance data definitions that CDC uses. It also highlights the methodology and results of various immunization surveys.

The example highlighted here is the immunization coverage in the U.S. for children. It's the largest ongoing survey of immunization amongst preschool kids. This is where you will find surveillance information, as well as other data sources.

The next section that we want to focus on is, when you click on the "For Parents" section of the page, it has information on vaccines that is targeted towards parents. One resource I want to quickly highlight is in the red oval in the yellow box, the "Parent's Guide to Immunizations." It's a booklet that can be ordered or downloaded, giving parents information on how the vaccine works, an overview of the disease, risks and benefits and known side effects of each vaccine, as well as common questions parents have, including vaccine ingredients.

Clicking on "For Specific Groups of People," that's where you see highlights for adult immunization, infant and toddler immunization, preteens, for college

students and young adults, parents, health-care providers, pregnant women, some information on international adoptions and what vaccines are needed in that case. Also they can get to our Spanish language resources from that particular site.

There are a couple things on health-care professionals that I want to highlight. On the health-care professional section, this particular piece is targeted towards health-care professionals. It includes resources and publications, as well as recommendations, as well as immunizations that are needed for health-care professionals. You will find the schedules there, which we have already discussed, and also vaccine administration and storage and handling guidelines.

In the spotlight in the red box is the same one as we discussed on the vaccine home page. The arrows are also ways that they can get to some of the earlier resources that we discussed.

I also want to share with you that the highlighted yellow box is a section that is on all of our Web sites as well, and it talks about related pages. There are links to immunization safety offices, vaccine safety

sites for providers, as well as a link to the Vaccines for Children Program. That features information for parents and providers on VFCs, which provide vaccines at no cost to kids who might not otherwise be vaccinated.

The pullout yellow highlighted box under the resource section is a great resource for health-care providers. That is the 10th edition of *The Pink Book*, which is a book on epidemiology and prevention of vaccine-preventable diseases. It's published annually by CDC. The target is physicians, nurses, nurse practitioners, physician assistants, pharmacists, and others. It gives them comprehensive information on vaccine-preventable diseases and health-care workers, with current recommendations and disease information. That can be ordered from the publication page or downloaded online.

The next section is education and training. This section provides health-care workers with continuing education opportunities. You will see webcasts there that are upcoming, as well as past webcasts and related broadcasts. It also gives information on how to register for these, what the objectives are, and the faculty providing these webcasts, as well as continuing education

credit.

There are also net conferences. These are one-hour live presentations which both online visuals and audio tapes and audio via teleconference calls, as well as live Q&A sessions. These can also be looked at after the fact.

You will see some other things, like self-study. Again, most of these are offered in several formats, including DVD, CD-ROM, Web-based. All of these are free of charge. Most of them do offer continuing education credit for health-care providers.

With the next three slides, I want to give you URLs that you can access quickly some of the top hit sites on the CDC site.

This slide shows the seasonal flu site, which is at www.cdc.gov/flu. This site is updated throughout the flu season. There is a variety of information that you might find helpful to your work.

The next piece is traveler’s health. If you look at the highlighted oval area there, that leads you to the vaccination requirements for travelers.

The next slide is a direct link to MMWR. We have highlighted four ways to reach MMWRs and recommendations

off of NCIRG's Web site. But if you would like to go directly to MMWR, this URL gives you the direct link to that particular resource.

Finally, some contact information, both phone and email. You can get us at the CDC contact number, as well as email us at NIPINFO.

At this time, I would like to turn it over to PerStephanie, who is going to talk more about the vaccine safety site.

MS. BUCK: Can I ask a quick question before you do that? You were flying, and I was trying to keep up.

Is the only place that there is information about our program, the Vaccine Injury Compensation Program, that people could find is if they went to the VISs or was there another spot and I just missed it?

MS. BATCH: I believe there are other spots. We will check on that and we will let you know. I think it's covered in a few other areas. We will come back with a couple additional URLs after PerStephanie's presentation.

MS. BUCK: Okay. I'm not doing it in real time with you either. I'm just doing it with the handouts, so I can go and check for myself. I wanted to mention that.

MS. BATCH: Thanks.

MS. THOMPSON: Good morning. I'm PerStephanie Thompson. I'm the senior health communications specialist with CDC's Immunization Safety Office.

I want to give you a brief overview of our vaccine safety Web page.

Our communications mission is simple: To communicate our work in a clear and transparent manner that allows our partners to incorporate vaccine safety findings into public health policy decisions, that allows the public to be well-informed about vaccine risks, as well as their benefits, and allows the public to make informed vaccination decisions with confidence.

Just to give you some background on the vaccine safety Web page, what you are looking at now is the new and improved page. In February of this year, we launched this new look and feel that I like to call the three-column home page. This format provides richer navigation and greater visual appeal.

Our home page is divided into five functional areas. I will speak briefly on each area.

The first functional area is located on the far

left side of the page, titled “Vaccine Safety Basics.” It should be highlighted in a red box. This section is what I like to call the “We, the People” page. What you will find here is information for parents, doctors, students, and the general public, information such as who we are, what we do, and how we do it, the history of vaccine safety, information for parents, vaccine safety concerns and frequently asked questions, and how vaccines are monitored.

We use our home page sort of like a traffic cop to direct people in different areas. So the five functional areas will direct the visitor to where they want to go.

The second functional area is located on the left, at the very bottom. It should be highlighted in a red box, titled “Vaccine Safety Activities.” This section lists our six priority vaccine safety public health activities. Each button in this area will provide you with an overview of that program. This section is geared more to frontline public health providers, scientists, and academia. In this section, the reading load tends to be a little bit higher, due to using more scientific terms.

By clicking on one of the buttons in this

section, you will find out more about the different programs ISO is working on. Each page is content-driven and uniquely different. Oftentimes you will find a summary of findings, reference materials, and links as well.

The middle section, the third functional area, is where we feature new content. The content feature here will either take you to functional area number 1 or functional area number 2.

Here's where I wanted to spend some time. I'm not sure whether it's going to work or not, but we'll try it.

Michelle, can you click on the first picture where the little baby is, the MMR vaccine safety icon?

When you click on the first square in the center, it will send you to the most recent postings for that particular one, MMR vaccine. Because of the public interest in MMR vaccine content, it is up in the "We, the People" section, under a button labeled "Vaccine Safety Concerns." On this page you will find an overview of the vaccine, a summary of highlighted studies, and related links.

While you are on this page, if I can draw your

attention back to functional area 1, the “We, the People” section, if you look under the “Concerns” button, you will see a list of all other known concerns that we have done work on. This feature allows the visitor to see the level and the different content that we offer that people are concerned with. It also allows them to have a better grasp of some of the work that we are doing as well.

If you can click on the “Escape,” it will take you back into the presentation.

Functional area number 4: This area primarily links you to -- the first half of that area links you to our VAERS page. I’m going to come back and talk about that in detail. The middle area, “Health Topics,” links you off of the ISO Web page, but in other areas that are health topic-driven. At the bottom of the page, the “Government Agencies” links you to other federal agencies that are doing vaccine safety work, outside of our Web site.

Michelle, if you can click on “Report a Suspected Vaccine Reaction.” This is the VAERS button. It will take you to the CDC VAERS page. The CDC VAERS page is just a general overview of the vaccine adverse events reporting. It gives you an overview of the page. If you look at the

left navigation at the very bottom, where the VAERS button is, you will also see other work that we have done using VAERS content.

If you go to the second hyperlink on the VAERS page and click on that, that will take you to the HHS VAERS page. This is where you can report an adverse event. This is where you can query the system to find out like adverse events that have been reported. It gives you more detail about the program, a public use data set, how to report. This is the site where you actually do the reporting.

That particular site is not housed by the Immunization Safety Office. But it is housed with the CDC VAERS team in the Immunization Safety Office.

If you can hit “Escape,” it should take you back to either the CDC site or back to the presentation.

Finally, the fifth functional area: This is where visitors can contact us with a concern, they can contact us and provide us feedback on the site, or any information that they would like to share with us. Everything in the navigation on the left side is found on every page in the site.

Some of the challenges: You hate to bring up the

“funding” word, but most of our challenges are around that. We lack the technology to understand and study our visitors. We lack resources for usability testing. We lack current software and hardware updates. Our Web only covers a small percentage of the work that is done in ISO.

However, what we have been able to do in seven to 12 months is amazing. In February of this year, we launched a new site, what you are looking at, the new look and feel. In April of this year, we were able to change our URL name to something that was easier for most people to remember, which is www.cdc.gov/vaccinesafety.

In the last 12 months, we have been to procure primetime Web real estate on the cdc.gov home page. What you have listed there are four features of vaccine safety information that were featured on the cdc.gov page.

We have also been able to have more timely postings of relevant vaccine safety data within an hour of release of a study.

Up until October of 2007, we did not have a dedicated Web developer for vaccine safety activities. Now we do have a full-time Web developer. When we release content and content is published in various scientific

journals, simultaneously we can make easy-to-understand, easy-to-read Web content available for our visitors.

Additionally, we have been able to encourage and influence others to link to our pages. You look at visibility and you look at the look and feel, and you think, eye candy. But most people are attracted to pictures, and so we try to have our pictures tell the story. Even Web developers have increased links to our site. Our partners link to our site more. That was probably one of the ways we were able to procure the cdc.gov features, because of the look and feel, the navigation, and the utility of the Web site in itself.

In preparing for this particular talk, I went back to a Web proposal that I wrote back in November 2007. In that proposal, one of the things that I did was, I went Googling and I also used the Yahoo search engine to see, if I Googled “vaccine safety,” where CDC’s Immunization Safety Office fall on the list. At that time, in November 2007, on Yahoo we placed seventh and on Google we placed fifth.

On Wednesday, I went in and did the same exercise. We placed first on Yahoo; we placed first on Google.

I went in today and did the same exercise. We placed first on Yahoo and we placed third on Google.

To me this is a major accomplishment. I was ecstatic. We haven't done any campaigns. We haven't done any Web campaigns, any banner ads. We haven't paid for anything. It tells me several things that are happening here.

One is that there is an interest in vaccine safety. Secondly, we are becoming an authority in the public's eye. They come to us for information. Our links are well placed, not only on government pages, but they have to be somewhere else, for less than 12 months. Our site did not launch until February. So within eight months, we have changed our place.

That's it. Thank you.

MR. SCONYERS: Thank you very much. We really appreciate it. There is a lot of information in a hurry. I think given the nature and the eyes looking at the extremes I think we are going to want to go back and look at home. Are there questions, comments?

DR. FISHER: I just want to tell you both that just this summer the safety insights were absolutely

invaluable, absolutely easy to navigate and an article that would have taken me weeks previously was down to hours to get the same information. But to get that information and be able to write it was phenomenal. My compliments to an extremely easy to navigate page with all the links that you wanted.

DR. SCONYERS: Other comments, questions for our CDC presenters? Geoff?

DR. EVANS: This is to either of you. When you do a search -- I did notice that there was at least one search field, is the search limited to the vaccines web site, or does it go out to the CDC web site?

MS. THOMPSON: If you are doing the search on the CDC search engine it is powered by Google and it will only say under the CDC umbrella at cdc.gov. But it is not just going to stay in immunization or vaccine safety; it all depends on what you are searching for.

MS. HOGAN: This is Cathy Hogan. I am the webmaster of the vaccine site. If you are on the vaccine site and you do a search your results will be specifically on the vaccine site. But if you notice the box at the very top of the search results page, it will allow you to go

anywhere else on the CDC site to also make a more expanded search. But it will only stay in the CDC.

DR. EVANS: That is exactly what I was going to say. When you go into CDC you are getting all kinds of different material. If you are just in the vaccine site then you have a very rich entrance into all those materials that they have. If you are a health professional you are able to -- the average person that is trying to get it, because hardly a day goes by that I don't click on to the immunization web site one way or the other, and if we have a search engine that would be much more helpful to get people to where they need to be.

MS. GALLAGHER: This is Charlene Gallagher and I just wanted to give you my sincere thanks for this presentation. I think it has been excellent and the Committee appreciates it because we had asked for it some time ago. This was really excellent. Thank you very much.

MR. SCONYERS: Other comments or questions? Thank you very much for the presentations. We are a little bit behind schedule in terms of when we were going to take our break, but on the other hand I think we are well ahead of our schedule in terms of our agenda items. SO let's

take about a ten-minute break.

(Brief recess)

MR. SCONYERS: We are going to get started again. Tawny, are you there?

MS. BUCK: I am.

MR. SCONYERS: Thanks very much for everybody's attention. We had some good presentations this morning and some good conversations about them.

I want to turn your attention to an agenda item called "Issues and Process for ACCV Input into the National Vaccine Plan."

Agenda Item: Issues and Process for ACCV Input into the National Vaccine Plan

I'm going to give you a few introductory remarks. As Tawny and I discussed this as an agenda item, we were hoping that the members can have an active conversation about what we want to do as far as the development of the National Vaccine Plan is concerned.

First, I want to acknowledge and thank Michelle for pulling out and putting together all of the comment

letters that this commission has submitted since it came into existence, and also preparing what I think is an excellent summary of all of those letters, so that if you didn't want to spend the time going through them, you could just look at the summary.

The letters are all there. I don't know to what extent you have had an opportunity to look at them. I think you will see as you go through either the summary or the letters that there have been a variety of concerns and issues that have been before this commission over the years, but there are some recurrent themes, as you will note. Some of them, most recently, are being expressed in the Burton bill that is currently pending. I think Dr. Evans mentioned yesterday that this commission could take some pride in having an actual effect on potential legislative change by seeing many of those recommendations that we have talked about get into proposed legislation -- coverage of counseling and guardianship expenses, interim payment of costs and fees, changes in membership of the commission, and some other things.

Some of those have been recurring. Some of the issues, as you read the letters, have come and gone. Some

of that is because of changes to the program over the years. Geoff and I were just talking during the break. In 1994, there was a funding crisis because there wasn't money. There needed to be a change to the way the excise tax was assessed and collected. As you know, now, at least on an ongoing basis, year to year, this program has the funds it needs to satisfy claims. That's always with the caveat that we don't know what's going to happen with the 5,000 pending autism cases.

There was added a mechanism as well for adding vaccines to the table and to coverage under the program. Initially only those that had been in the legislation had been covered. As science advances and as we get more vaccines available to us, we now have a way to add those on.

I was privileged with our new members on Wednesday as they received an orientation to the program and to the commission. We have heard this several times. I just want to go back and mention that the purpose of the Vaccine Injury Compensation Program was initially, and is, to ensure that individuals injured by childhood vaccines are provided with fair and efficient compensation. That's

one of the primary goals that we have. I would add to that that it's consistent as well, so that like cases are treated in a like way. I think that's a goal of the program. That was a goal of the creation of the table.

Of course, another key goal, growing out of what was a perceived crisis in the mid-1980s, was to ensure a stable vaccine supply by controlling and limiting liability for manufacturers and administrators.

Hiding behind that goal is one that I think we have already discussed this morning, that Dr. Herr brought up, that we all know: A goal of this program is to promote vaccination as a public health benefit. We were having a discussion again in the hallway. It is a tragedy that anyone is injured by a vaccine. This program needs to exist to compensate people who are injured. But it is also true that we are not dealing with seasonal outbreaks of poliomyelitis these days. We are dealing with rare outbreaks of measles and pertussis, rather than the issues that I think most people of a certain age grew up with.

Just as a side note, I work in an academic medical center, and we now have a lot of residents who come never having had chickenpox. We need to make sure that

they are vaccinated, because we have chickenpox in my hospital, and it's a bad disease if you are an adult.

So we have made substantial progress.

I want to go to a couple of other documents and just draw your attention to them. We heard today from Dr. Strikas that one of the draft priorities coming out of the National Vaccine Program Office is to assure that the National Vaccine Injury Compensation Program continues to compensate people possibly injured by vaccines. It's my understanding -- and Geoff can correct me if I'm wrong -- that that priority item is not currently assigned to a particular organization, agency, or workgroup. It's an issue, it's a priority, it's something that needs to be dealt with, but I don't believe it's on anybody's work plan right now.

The final document I want to mention before I shift a little bit is the charter. I'm pleased that Michelle included it in our materials. We have a stated set of functions. This grows out of the legislation. I just want to remind you about what they are. They are:

- To advise the secretary on implementation of the program, the program being the Vaccine Injury

Compensation Program.

- On our own initiative or as a result of filing a petition, to recommend changes to the vaccine injury table. We have had a little bit of discussion about that already today.

- Advise the secretary in implementing responsibilities for the need for vaccination products that result in fewer or no significant adverse reactions.

- Survey programs for gathering information.

- Recommend to the director of the National Vaccine Program research related to vaccine injuries which should be conducted to carry out the program.

- Consult regarding the development or revision of vaccine information material.

Those of you who have been on the commission for a while know that we see the vaccine injury statements whenever they are being revised. I think we have a well-functioning process for getting input on those. Those of you who are new to the commission, I think you can anticipate that you will be seeing those as they come along.

As we had our discussion the other day and as you have heard from a variety of sources through the course of this meeting, the things that are listed in the charter as items 3, 4, and 5 -- that is, to deal with vaccines and information about adverse events and research related to vaccines and vaccine safety -- I think there are other agencies and bodies that are primarily dealing with those issues. We have had an opportunity, as you can see through the letters over the years, to express views about that from time to time.

You will recall, those of you who participated in the discussion about the last workgroup's output, that we had a very difficult time finding any kind of recommendation to make as far as funding for vaccine safety research. I think everyone here understands and believes that there is a need to advance vaccine safety research, to promote it, and to assure that we are doing everything that we can do assure the safety of the vaccine supply. But beyond having expressed those views, I think it hasn't been clear that this commission has much significant to say about exactly what the agenda for that vaccine safety research could be. I don't think, at least, that I'm

qualified to have an opinion about that.

Tawny, I'll defer to you about whether you think you are. You are certainly participating to some extent in that.

Which leads me to focus on the first two items on our charter.

DR. FISHER: Jeff, before you leave that part, while I think it's very true that we haven't had, and probably don't need, a particular say in that agenda, I think we have been incredibly clear in saying that the funding should not come out of this fund. I think we have made ourselves loud and clear on that.

MS. BUCK: I would like to make a comment about that as well. I have, actually, a couple of comments before you go much further, Jeff.

One is that the issue brought before this commission tends to be identifying the trust fund as a mechanism for funding vaccine safety activities. And Meg is correct. As the new members should know, this commission has come out strongly against that idea of identifying the trust fund as a funding mechanism. That issue will come before this commission and will continue

to, and it's something that the new members would want to get up to speed on.

The other comment that I have is that this commission has done a lot of work and made recommendations, and our workgroup did as well in the last letter. However, it's not quite accurate to imply that the Burton bill has used our letter. In fact, we used an earlier version of the Burton bill when our workgroup came up with our recommendations. In conversation with Congressman Burton's office this summer, they weren't even aware of our letter to the secretary. If you compare our letter and our recommendations to the Burton bill, you will see that, although some things are the same, the specific recommendations aren't at all.

Unfortunately for us, I don't think we had much impact at all on the Burton bill. It's a bill that's been out there for a long time. It's a bill we used as a basis for our recommendations in some part. It continues to be floated out there.

MR. SCONYERS: Thanks, Tawny. To some extent, I'm trying to be as optimistic as I can.

MS. BUCK: I was disappointed to hear from his

office that they were not aware of our letter when they drafted their next version of the bill.

MR. SCONYERS: But you are quite right. In the process of developing our recommendation letter, we are looking at bills that had been before Congress that we liked and that this commission had commented on in the past. You can see that there were a large number of comments on pending legislation in the past.

Not to put too fine a point on it, as you look through the correspondence that has gone out from this commission, you also have in almost every case the response to those letters. There is a certain predictability to the response letters that come back, which is to say, “Thank you very much. We appreciate hearing from you. We’ll let you know if anything comes up.”

That may be a little bit too severe a characterization.

MS. BUCK: I agree.

DR. FISHER: Are the response letters on the disk and not in the thing? I actually was pretty impressed that there was no response to most everything.

MS. HERZOG: They are on the disk.

DR. FISHER: Okay.

MR. SCONYERS: So some people did not read the disk. That's, of course, very disappointing to me. (Laughter)

But they are all there, and there will be a quiz. The response letters that we had are included in there. If anybody wants to look, I have a set of papers that Michelle made for me.

You weren't in the room to hear me thank you, and I want to thank you for all the hard work that you do in putting this together.

So with that kind of background and with a history of a number of letters, a stack of paper an inch thick, and the sense that, first of all, it's very important to make sure that we have a well-functioning system for compensating people who suffer vaccine injury, second, that the current status of the development of the vaccine plan offers an opportunity for comment about that, and third, that, just based on conversations I have had with several of you during the course of the last couple of days, there is some concern about the relevance of the work that we do here, I want to tee up this issue of the role

that the commission wants to play in commenting on and making recommendations about any potential changes to the Vaccine Injury Compensation Program, as part of the development of the National Vaccine Plan, as you heard today from Dr. Strikas, with an anticipated rollout over the next 12 to 18 months.

That would give us time, if there is interest here, to work on issues and make recommendations for adoption by the commission for forwarding on for conclusion. Another alternative is to say that's not something we want to work on, that we want to continue to do most of the things that we have done over the last period of time. Dr. Strikas had some suggestions for ways that we could participate in the development of the plan -- to review the draft plan, provide comments to the NVPO, participate, either as individuals or as members of the commission, in IOM meetings. That's another alternative.

Finally, just as a personal comment, I had a realization this summer -- I have been sitting here for a couple of years -- that I finally begin to feel like I understand a little bit about the way this program works, and I realized that I'm not going to be sitting here this

time next year. I have the sense that I want to make some kind of contribution personally to advance the interest of people who have been injured by vaccines and the general public in assuring that vaccinations occur and are as safe as they possibly can be.

That's all that I have by way of comments. First of all, I would like to let Tawny give her comments and thoughts about this topic and then open it up for general conversation.

MS. BUCK: Most of my comments will be based on the kind of work that we are struggling through on the Vaccine Safety Workgroup for NVAC, for the white paper. This is a very complex issue, and this program is a very important part of the public's overall perception and trust issues with vaccine safety.

One of the charges that we are working on is improving the public trust. There is definitely a problem there. Understanding and demonstrating that this program helps -- as long as we continue to be willing to sacrifice some for the good of the whole, then this program has to step in and care for those that have been injured.

In addition to that, there are issues of efficacy

of the vaccines themselves and there are also concerns that we are working on in terms of reducing the overall number of severe events. This isn't 100 years ago; this isn't 50 years ago. All due respect to those who saw how it was then, this is a different time, with different technologies and different ages. As we have advanced in medicine and science, we should also be able to advance in making our vaccines safer, reducing adverse events or anticipating them before they even begin, looking at genomics and that, to give us answers to our questions in terms of our children before we ever begin this process with them, so that we can increase overall vaccination rates while decreasing the number of adverse events.

Tied into that, this program still has to work and the public has to believe that it works and has to see that it is actually working quickly and efficiently to compensate those, in addition to providing liability protection.

Those are just my general comments in terms of the work that we are doing and the work that we are struggling through.

My questions to Dr. Strikas in terms of funding

mechanisms and also reform of the overall program are really important for us to look at. We have made recommendations for the table, and it's taking an incredibly long amount of time to see any changes to the table. Until some of that kind of stuff can be addressed and maybe some programmatic reform, these are going to be continuing problems that the new members and the members that continue on are going to have to face.

MR. SCONYERS: Thanks, Tawny.

One of the things that this commission has done in the past with issues that it felt were important enough to warrant a concentrated amount of attention is to create a workgroup that would then make recommendations to the whole commission. It's hard to function as a committee as a whole. It's not impossible, but it is hard. These are complicated questions and issues.

So that's an option that is available to us.

But before we even consider a process, my question is, what is the will of the members about what role you want to play? This is potentially an important point in consideration of this program and the National Vaccine Plan. Let me just ask you for comments.

MS. GALLAGHER: I was just thinking about what was discussed. I'm looking at the functions of the commission in our charter, number 1 and number 2. I think there might be a role for us in trying to look at why it takes so long to add the injuries to the table and suggest some sort of changes to implement a better system or process. I'm not clear on what the problem is, so I can't describe the solution. But we could seek ways to understand what's happening and see if it can be done more efficiently and more quickly.

DR. FISHER: I think that's right-on. To me, probably the best goal that this commission could do is to talk about the compensation and concentrate on the compensation. I think one of the things we don't know is -- we haven't even seen what the changes in the table are, other than the addition of the vaccines to the table. That has clearly happened and we can see that. But I think we need some basic information that we get little pieces of, but we don't quite have.

That would be the table as it looked in whatever year it started and what the changes in that table have been, if any, number one; number two, a line listing -- and

I hate to make somebody work, but I think we really need it -- of the cases that have been conceded and a line listing of the ones that have been settled, with an idea of which vaccine it was -- what Tawny has been asking for for the last three meetings, as far as I can remember, which is just more information on what is actually happening, not just the raw number -- there were 16 cases settled -- but what those cases were about.

I understand that you don't want to go back and look at each individual case, but at least going forward, I think that information would be very easy to have, and I don't know how the commission can work without it.

MS. HOIBERG: Going through the blue folder here, it actually says that, yes, 16 cases were settled, but only four of those were compensated to the families.

DR. FISHER: Four were entitled. The settlements, I thought, included compensation.

MS. BUCK: Yes.

MS. HOIBERG: Yes?

DR. FISHER: Yes.

MS. HOIBERG: Thirty-three cases resolved, 20 were compensated, 16 settled, 4 entitlement decisions

against the government.

DR. FISHER: The settled ones were compensated.

MR. SCONYERS: Twenty were compensated.

MS. BUCK: It’s a difference in how the decision was made.

MR. SCONYERS: The four entitlement decisions were made by special masters.

MS. HOIBERG: Okay.

DR. FISHER: But all those 20 were compensated.

MR. SCONYERS: To pick up on what Meg just said, I think what many of us have a sense about is that there are rules at work here, that cases are being settled on the basis of an understanding of what kinds of cases get settled, but those are not on the table. If that’s in fact what’s happening, I think, first of all, this commission deserves to know about it, and second, to understand why that doesn’t then translate into table changes, if those are the rules by which cases are being settled.

But I should say less and listen more. Who else has a comment?

MS. CASTRO-LEWIS: I actually agree with the issue that we really need more information, and probably

presented in a clearer way. It is very hard to understand the report that we get from the Department of Justice. It was hard for me to understand. I don't know if the rest of you got everything. At a point, I thought it was a language issue, but I think the way that it's presented, we are not able to get all the information that we need.

So I really would like to get a presentation that includes some charts, maybe, and some graphs and some explanation of vocabulary. Give us a glossary of the terminology. Until we are able to understand clearly that the process is and what is happening at that level, I think it's difficult for us to really make some kind of a contribution as to how we need to improve this.

The one thing that I got yesterday -- yes, definitely we need more lawyers to speed up this process and get the families out of this long period of waiting -- what is happening with my inquiry, or whatever.

So in addition to the way that the information is presented, I think the content needs to be specific and clearer to us, because it's difficult, really, to understand it.

MS. GALLAGHER: I don't mean to put Julia on the

spot, but I was wondering if she could comment on whether the information we are seeking would be tied up in privacy issues or whether it would be possible to get such information.

MS. MCENERNEY: Julia McEnerney from the Department of Justice. This is an issue that Vince Matanoski and I talked about yesterday, hearing the comments. Definitely there has been confusion on definitions. I'm going to be working with Ward Sorenson (phonetic) to see how the statistics are kept. It's not just from the Department of Justice. We work related to HHS and their statistics and their database. It all depends on how the searches are run.

We hear the comments. I'm not sure that I can answer your question, Charlene, as I sit here today. But we will endeavor to get the information to you in a legible form, a PowerPoint presentation. This committee is more interested in these statistics than it has been in the past. We want to be able to answer your questions and make sure that you are all able to understand the data so that you can make informed choices.

So we'll be working with HHS to provide more

complete data, along with definitions and terminology, so that we can address these issues and you guys can do your job.

So I can't answer the question today, but I hear it.

MS. GALLAGHER: Thank you very much. We really appreciate your commitment to come back to us later with more information.

MS. BUCK: As we work through these issues -- and I apologize for putting Sherry on the spot a little bit -- I'm wondering if at our next meeting Sherry can perhaps talk to her contacts on the petitioner's side and give us -- I'm always very interested in hearing their perspective on the same issue, as much as they can provide. I can certainly talk to my contacts, or maybe Sherry and I could work together to see if we can perhaps hear from the petitioner's bar and their feelings about that.

MS. DREW: Tawny, I was going to comment shortly. The petitioner's bar is attempting to put together a meeting outside of the upcoming judicial conference, but in roughly the same time, either before or after. I'm not sure when it's going to be scheduled. I will certainly be

happy to address this issue and any others that anyone may want to bring up today or email to me prior to that time.

DR. FISHER: Can you explain to us what the petitioner's bar is?

MS. DREW: It's an informal group of attorneys that handle cases in the Vaccine Program.

MR. SCONYERS: On behalf of petitioners, obviously.

MS. DREW: It's not a formal group. We pretty much know each other's names. We email each other.

MR. SCONYERS: It's the correlate to the Department of Justice lawyers.

DR. FISHER: Except that you are all private and you are not organized.

MS. DREW: Right.

MS. BUCK: We have presentations from Tom Powers. Because he's doing the Omnibus Proceeding, he focuses a lot on that. It's him and Sherry and all the folks who are working for families.

MR. SCONYERS: And I think this is of particular concern to us because every time we hear about cases, we hear that essentially there are no table changes, that they

are all causation of fact cases. Then we get an indication about how many cases are resolved and in what way. But it's not very much information. That goes directly to the first point of our charter, which is to advise the secretary on the administration of the program.

MS. BUCK: Jeff, the other piece that's important -- and I tried to line it up for this meeting and couldn't. I have had phone conversations with Barbara Lowe Fisher, who is one of the founders of this program, and have invited her to come in November and talk to the group and just sort of give an overall perspective about what it was when it started and what she sees now. She has watched it very closely over the years. So just an FYI that she or somebody who works with her is kind of queued up for November to do that and discuss this with us.

MR. SCONYERS: What other thoughts do people have?

Geoff, do you have anything that you want to comment about?

DR. EVANS: A couple of things. I think there is a variety of good issues here. This is part of your oversight of the program.

In terms of updating the table, I think we have said this before and I'll say it again. The secretary has used before independent studies by the Institute of Medicine when it has made broad, sweeping changes to the vaccine injury table. That is the first step. It has to happen. At least these studies by the Institute of Medicine or some other independent body have to take place. There has to be an evaluation of the literature. Until that's done, there cannot be the kinds of changes in the vaccine injury table that took place through rulemaking, which also, by statute, takes two to three years, because you are required to have six months of public comment, including a hearing, during that time. So it is an extensive process of notice of proposed rulemaking, the public comment period, a hearing, and then publication of the final rule.

So nothing happens quickly. Step one is getting the independent studies done. Step two is going through this rulemaking procedure, with ACCV input at various points.

I just want to remind the commission that this is what is part of updating the table. It's a lot easier said

than done.

It's good to understand why we haven't been able to do it, and to the extent that we can help with, we certainly will try.

MS. GALLAGHER: Will you just remind me of the last time you had the independent review? I know you have said this a million times, but I can't remember it as we are speaking now -- the date of the last review.

DR. EVANS: The last extensive studies of vaccines that are in the table were published by the IOM in 1991 and 1994. It has been 14 years. Those committees each took the better part of three years in order to form and produce reports.

So this does not happen quickly.

MS. GALLAGHER: Perhaps we could urge that process to begin, since it has been such a long time. Maybe our voice would be heard. I want to understand it more. I'm not prepared to do a motion today or anything. But this would be a place where perhaps we could be heard.

MR. SCONYERS: I refer you to the March 22, 2006 letter from the ACCV to the secretary, that a standing scientific panel of recognized medical and scientific

experts review and recommend changes, if any, to the table. I'm looking for whether that was in the 2007 letter. We certainly talked about it.

MS. BUCK: We are talking about our input, maybe, into the National Vaccine Plan. Again, this was one of their objectives. This is where I keep saying that perhaps we need to look a little deeper than using the systems that are currently in place. An overall review of the whole system -- why on earth it's taking long -- I understand what Dr. Evans is saying, and it is moving as fast as he can make it move with the systems that are in place. The problem lies in the systems themselves. You can't just tell them to make it go faster if the systems only work as fast as they work.

MR. SCONYERS: Good point.

DR. EVANS: So issue number one, updating the vaccine injury table. I heard an issue of process and delays in the process. I also heard an issue of what seems to be causation, the way that the program is now adjudicating claims which are mostly off-table. In some ways, that's a very simple one to look at, because these claims are being filed that are mostly off-table, the

reason being that we have more than doubled the number of vaccines on the table, with relatively few injuries that have been put at the same time, because vaccines, when they are licensed by FDA, do not have serious adverse events associated with them, or else they wouldn't be licensed. It's only time, with postmarketing experience, that we can identify these kinds of adverse events, and then we will go forward with rulemaking, again, though, with some kind of an objective assessment that there is causation.

The exception to that was just rotavirus. That was a very compelling circumstance, in which there were epidemiologic studies that were quickly put together. It was causation; an association was shown. The secretary then put the injury of intussusception on the table within a year or so. But that really was the exception.

What we are talking about here is actually a much broader look at numerous vaccines.

In terms of causation, I think that what is happening -- stepping back for a second, our database records what is alleged in each claim. We do not record the medical diagnosis per se after our evaluation, nor do we actually have specific wording of the court. But

certainly we have an extensive database on what is alleged when the claim is filed.

For the off-table claims, that could be a fairly accurate representation, because they will probably say, hepatitis B vaccine and Guillain-Barré syndrome or a rheumatoid condition or something. So that would be illuminating to you. We can certainly identify which ones of those claims were settled and which ones were dismissed and so on. So I think we can provide some insight into that.

But why a particular case was settled or not settled gets really to the specifics of the litigation. That’s something that we are not going to be in a position to be able to share.

MS. HOIBERG: My question to you is, how can you say that the vaccines don’t cause a substantial injury when you have two parents, one who is not here because her daughter is suffering, and another one that -- that’s the part that makes me feel angry. These vaccines -- yes, they save lives, but they also maim and kill. And that needs to be addressed. They “allegedly” cause an injury? No. They cause the injury. My daughter was perfect. She had her

shots. She is no longer perfect and suffers every day. Tawny's daughter is the same way.

For us to just keep going over and over, oh, well, they allegedly cause it -- no, they didn't. They caused it.

Have they helped? Yes, for many people. But it just angers me so much that we can just sit here and go around and around and around and around and around. They cause injury. So let's fix that. It's not just a handful of people who are affected. There are so many more out there that don't know about the program. I didn't know about the program, and I read a lot. There are plenty of people out there whose children have autism that don't know that there is this Omnibus Proceeding. They don't know that they even have an option to have help.

This program needs to be more visible and it needs to be more effective.

MS. BUCK: One of the problems that we are identifying in our work in other groups is that the system is designed to be reactive. That's very difficult. It is why what Geoff is saying is the case. Once the vaccines are out there, the adverse events -- they watch for them.

What we are talking about is trying to prevent them or having systems in place to catch them before they are out there -- to not have them be an experiment on our children, once they are out there, to determine what the adverse events are, but to try to come up with these answers ahead of time.

It's a bigger issue than what's involved in this program, but it does go to the same frustration point that Sarah and I share, which is that it's designed to be backwards and reactive in terms of responding to them after they have happened, responding to the carnage afterwards.

MS. HOIBERG: I was going to say, these new vaccines that have been released, how long were they tested? Who were they tested on for their safety?

MR. SCONYERS: I think it is important for us to concentrate on our role, which is advising about the Vaccine Injury Compensation Program. That has implications beyond just adjudication of the cases, but that is our role.

I understand, Sarah, what you are saying about the need for safer vaccines. Tawny, I thought, said it perfectly this morning. We want to have 100 percent

effectiveness and a zero percent complication rate with vaccines. That absolutely, I think, is everybody's goal. I think as we hear the description about current activities, that's a shared goal by the agencies that are involved.

But our role is to deal with the compensation program. I think you just made a great point. Part of the administration of the program -- we have talked about this from time to time -- is to make sure that the program is known to parents and to practitioners who may be looking at a potential patient who has been affected by a vaccine. So it certainly is within our role to talk about how better to get this information out there.

We look at the vaccine information statements and we have made sure that there is information on the program on each one of them. You heard Tawny asking -- and you saw it today on the CDC Web site -- that the program is actually listed on the CDC site. But there is a question about whether there is additional information or promotion that could be done.

MS. HOIBERG: Maybe there should be a poster in every doctor's office. The vaccines are everywhere -- "I

want my child to be one less," and the children saying, "We want to be one less." There need to be posters out there, and commercials. That's just what needs to happen.

Even with the petitioner's bar, if there could be some way to create a public service announcement -- injury trial lawyers do it all the time: Have you been injured by asbestos? Call this number.

There needs to be a commercial out there for the Vaccine Injury Compensation Program.

MR. SCONYERS: Meg, you have a comment.

DR. FISHER: It was getting back to your comments on the new vaccines and how long and how widely they have been tested. The fact is that all the vaccines are extensively tested before they are released. I guess my question to you would be, how many people would you allow to get cervical cancer while you are holding up the vaccine to make sure that there is not a 1-in-a-million chance of a bad event?

I think you do have to look at the other side of it. I'm not to any extent minimizing your child or Tawny's child. But there are also the people who have been infected and damaged and died from the diseases we are

trying to prevent.

MS. HOIBERG: Right, and cervical cancer -- it's funny that you bring that up, because the Gardasil vaccine does not guard against -- if you are going to get cervical cancer, you are going to get cervical cancer. That is for an STD. It's to stop the possibility of getting cervical cancer from the human papillomavirus.

DR. FISHER: Fine. I'll switch to the pneumococcal vaccine. How many people would you like to die of pneumococcal meningitis before the vaccine was released in 2000?

I can stay away from HPV if you don't want to do that one. The vaccine is a good vaccine, and I'm glad we have it.

It's the same concept. The diseases that we are trying to prevent are serious diseases, which damage people and kill people. I don't think we want to hold up new vaccines so that we can't protect people from additional diseases because -- of course they have to be safe and they have to be effective. But I don't know of anything in medicine that's 100 percent safe, unfortunately.

MS. BUCK: There is a big issue of public trust.

It is a giant problem.

DR. FISHER: You bet.

MS. BUCK: Part of that comes with, I believe -- what I have been understanding even from the CDC focus groups this summer -- the public's threshold for injury from vaccines is really, really different than it used to be. The herd immunity, one-size-fits all, let's sacrifice a few for the good of the whole -- a lot of those processes that were once in place back when there was a lot more diseases and there were a lot more injuries because of infectious disease happening -- it's a very different world right now.

Again, this sort of steps away from our role in the program. There is really a lot more focus and a lot more idea, which is going to continue to butt heads, unless there is a whole different approach entirely to the development of vaccines and the development of tools that can tell us more about our children before we start giving them vaccines, to prevent the injuries to begin with. Clearly, nobody wants anybody's children to die. But children are dying on both sides of the fence right now. The system as it is isn't working. Although we may be in

the minority, our minority is growing large enough that the confidence and public trust is at a critical stage. It's affecting overall immunization rates. That's a huge problem, too.

It still, though, I believe, is outside the purview of our work here, but it definitely is an overview on the general idea that programmatic change -- really big change to the way the whole system works -- is probably the only way to really address both sides of the fence.

MS. HOIBERG: And here's my last question. The combination vaccines -- that's what I have a problem with, when you sit there and you lump together all these diseases at once. Wouldn't it be even easier for, say, even the Department of Justice to sit there and argue a case if they strictly got, at that one point in time, the diphtheria and then at another visit they got the tetanus and at another one they got the pertussis and then it was the polio. But we are lumping all of these together, so it makes it even more complicated to even determine which one it was.

MR. SCONYERS: I want to jump in and get us back to talking about the compensation program. I think we could ask somebody from FDA or from other agencies to talk

about the development of the combination vaccines, which mostly came about from parents who didn't want their kids stuck as many times.

But I'm not sure that it's within our purview to really spend much time about --

MS. HOIBERG: I know, but I would say it is, because in order for the program to work better, there needs to be a clear line drawn in the sand as far as the effects that each one of these vaccines has and the side effects that each one of these vaccines possibly can cause.

MR. SCONYERS: Geoff, you have a comment.

DR. EVANS: I just want to finish up what I was saying about causation. That is this: I think it's an important issue. We heard Tim Westmoreland a couple of years ago at a judicial conference. He worked with Waxman's staff back in 1986, writing this legislation, saying that they never really envisioned an off-table program. That's one of the biggest challenges -- it's not the biggest challenge -- you all face, and that's part of what the conversation is.

My comment is this. Ray Strikas, in discussing the IOM process and the National Vaccine Plan -- my

understanding is that they are going to have a public meeting in December or February. I think December is going to be the main one. Our program would be part of a huge group of programs and issues facing the National Vaccine Plan as it's updated. We are just a small part of it. But that is the opportunity -- and that's going to be too soon for us really to have much in the way of any articulated and thoughtful input, because what we are talking about now is going to take a great deal of time to begin to really understand and go forward with some legislative proposals.

So I think we are talking about two different processes here.

MR. SCONYERS: Can you get us the specific meeting times and places?

I'm not hearing a groundswell for a particular process that you all want to create today. Here's what I'm going to do with this conversation.

As you know, we have had an agenda committee that has met to develop the agenda for our next meeting. I would like to refer this as an item to that committee for consideration for our November meeting.

Remember, in November, we are going to meet

starting at probably 9:00 in the morning on the Tuesday before the judicial conference. We are going to meet all day. We are not going to do a half-day and a half-day. We are going to meet all day. You should plan to meet until 5:00 in the afternoon at least. We will see what we can do about maybe arranging a dinner.

I would like to have our agenda committee look at and consider what should come forward to this group at our November to further the conversation about our appropriate role in the development of the National Vaccine Plan.

In keeping with the pattern that I have been trying to establish, where we have one new member and one continuing member on that agenda committee, I have asked Charlene if she would continue to function as she and Meg -- and I should have thanked you guys at the start of the meeting for doing the work to put this together. Thank you for serving as the agenda committee this last time.

I'm going to ask Charlene to continue and I'm going to ask Magdalena to join her. So Magdalena and Charlene and Tawny and I will develop the agenda for our November meeting. Then Magda will get stuck being the continuing member for the March meeting, and we will get

one of our new members to suffer through that process for the March meeting.

I didn't think it was totally fair to subject you guys to it at your first meeting. I thought about it. Tawny actually talked me out of it.

We will get to future agenda items in a minute, but I wanted to let you know that that's a process that we are going to follow.

I don't want to cut off this conversation, except that I want to have it be a meaningful conversation based on something that we can do. I think we will do better to take these comments that we have had today, feed them back through, see who we want to have come and address this committee, and what further conversations we want to have and what role we want to play. So I don't want you to think that this is the last we are going to talk about it, but I don't want us to just talk; I want us to produce.

MS. BUCK: Jeff, along those lines -- I was going to ask this anyway -- will we have information from the survey by November? Michelle said she was going to give us the status update on the survey, if we would have it by November. I don't know. That might be early.

MR. SCONYERS: Great question, Tawny.

Michelle?

MS. HERZOG: We just had a meeting with the contractors a couple of weeks ago. The surveys are slowly coming in. We have another meeting on the 19th, and we are going to reevaluate where we are in terms of numbers of surveys, to determine if we need to spread out the response so we can get more than what we have. But we will definitely have some numbers and some information for you in November.

MS. BUCK: Do you know how many we have gotten in?

MS. HERZOG: We only have about 16 percent.

MR. SCONYERS: Sixteen percent is not that bad.

MS. BUCK: Sixteen percent of how many that were sent out? I can't remember.

MS. HERZOG: We had roughly 380, I think, but I'll check on that number for you.

For the new members -- we talked a little bit about it at the new member orientation -- we have a petitioners' satisfaction survey that went out to the petitioners who completed the program within the last five

years. We did one wave in June. The first set of letters went out to the five highest attorneys who have the most number of cases. The second wave just went out the first week in August to the lower-volume attorneys.

MR. SCONYERS: So the surveys will be compiled and we will get a report back here.

MS. HERZOG: You had to have completed the whole program before you got a survey.

MR. SCONYERS: Does that answer the question, Tawny?

MS. BUCK: Yes, thank you.

MR. SCONYERS: Operator, before we move on to our next agenda item, I'd like to pause now and see if there are any public comments or questions.

OPERATOR: Thank you. At this time, if you would like to ask a question or make a comment, please press *1. Once again, if you would like to make a comment or ask a question, please press *1.

One moment.

(No response)

At this time, we have no participants in queue.

MR. SCONYERS: Thank you very much.

This is the last thing I want to do before we head out of here. If there are particular things that you know you want to have on the agenda for next time, let's say that now. You also know who we are going to have on the committee, so you can feel free to communicate with any one of us, Tawny, me, Magdalena, or Charlene.

Are there things in particular that people would like to see addressed? I think we have identified a few already. We are going to talk about the survey next time, for sure. What else?

MS. TEMPFER: I think we already clarified, too, that we are going to talk about Legal Issues 101 and terminology. We are going to get the primer on all the legal-medical terms.

MR. SCONYERS: Yes. We have made several requests, in several different ways, for a breakout of information on cases that have been resolved, whether through litigation or through settlement or otherwise. We are going to see if can't have a glossary that goes along with that.

I would like to make sure that maybe Tawny and I, at least the two of us, look at that before it goes out.

It would be good if we could get that prepared ahead of time. I want to make sure it actually answers the questions that we are asking. Functioning within a system that has specialized terminology, it's easy to get wrapped up in it.

So we will make sure that we make progress on that.

DR. HERR: There will be an update on IOM, if they do anything, as well as the National Vaccine Plan agenda.

MR. SCONYERS: We will have our regular updates, yes.

MS. TEMPFER: Maybe an update, too -- Sarah brought up the point, and I know a lot has been done in terms of public awareness and advertising for the VICP. Maybe a review of what has worked and what hasn't worked. I know Geoff has been real active. He goes to medical conferences. He does different outreach in that way. Last year we talked about that in our workgroup, outreach. Maybe we can look at that again and get some new feedback. Maybe new ideas have come out on that. We could see what has been done, what has been effective, and maybe what

direction we could go.

MS. BUCK: This isn't actually an agenda item, but I wanted to follow up with Michelle. She was going to talk to the webmaster about putting a link on the meeting dates, a more user-friendly link, for meeting information, call-in, and all of that. Was that possible?

MR. SCONYERS: She's nodding.

MS. BUCK: Okay, good, because I still think the one spot that it's out, which is on your home page, is still pretty hard for people to use and figure out. I think it's the link straight to the *Federal Register*, and then you have to figure out where it is in there, read through it before you find it. So if we could get it a little bit simpler on the page where we do meeting dates, I think that would be very helpful.

MR. SCONYERS: What else?

MS. HOIBERG: Will we receive all the information that we need for the next meeting, like we did this last time? Maybe we could get the glossary of terms and stuff like that before the meeting.

MR. SCONYERS: That's what I'm hoping we can do. We need to ask our colleagues at Justice to produce it.

And I would like for at least Tawny and me to take a look at it before it goes out, so that you are not frustrated when you get it, in the first instance.

Julia is nodding.

Anything else?

(No response)

Are there any further matters for discussion?

(No response)

Hearing none, I would like to entertain a motion to adjourn.

(A motion to adjourn the meeting was moved and seconded.)

Those in favor, say “Aye.”

(Chorus of “Ayes”)

Any opposed?

(No response)

I’ll declare us adjourned. Thank you very much.

(Whereupon, at 11:36 a.m., the meeting was adjourned.)