DEPARTMENT OF HEALTH AND HUMAN SERVICES

ADVISORY COMMISSION ON CHILDHOOD VACCINES (ACCV)

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P R O C E E D I N G S (9:00 am)

Agenda Item: Welcome & Unfinished Business from Day 1

MS. CASTRO-LEWIS: I would like to call the meeting to order. Good morning everybody. Lovely morning, for those of you who are tired of DC. I bet you feel right under the elements, raining all the time. That's why we're here. It was very nice welcome for you. Okay. Let's just start with the unfinished business from yesterday. I don't think we have anything really pending from yesterday, so we can really get into our agenda. So we're going to start with Dr. Gruber. He's on the phone now. Okay. He's from the Center for Biologic Study Evaluation Research for the Food and Drug Administration Vaccine Activities. Dr. Gruber. Are you there? Operator, is Dr. Gruber on the phone?

OPERATOR: I'm not showing that Dr. Gruber has dialed in yet.

MS. CASTRO-LEWIS: Okay. So it's a little early today. Mr. Malone from the Vaccine Information Center from the CDC. Is he there?

MR. MALONE: Yes, we're here. Skip Wolfe, too.

MS. CASTRO-LEWIS: Okay, wonderful. So I guess we can start with the report on the information statements and the process of the development of these instruments.

MR. MALONE: Okay, and we have a power point presentation. Is it set up up there? Thanks. Are you ready then?

Agenda item: Vaccine Information Statement Process

MR. MALONE: This is Kevin Malone. I'm an attorney with the Center for Disease Control in Atlanta and Skip Wolfe, with the National Center for Immunization and Respiratory Diseases, is here also. And we're going to go over the history and development of the Vaccination Information Statement. Feel free to interrupt us at any time if you have any questions.

The first slide that should be up says background and it references a court decision called Reyes v. Wyeth, which is out of the 5th Circuit and basically it dealt with a situation where the Texas State Health Department was administering vaccine in a public clinic. The court hearing, in a nutshell, is that in a mass immunization setting, in which a learned intermediary does not examine the patient prior to immunization, the vaccine manufacturer

retains the obligation to inform the vaccinee or the parent of the child of the risks related to the particular vaccine.

In general, when you're using a prescription product, the duty to warn obligation of a manufacturer would transfer to the so-called learned intermediary, that is the physician who examines the patient and that person then would then have the obligation to talk about any risks and benefits of the particular product that you're going to be used.

Vaccines are unique then that they're used in these mass immunization clinic settings where you may have a nurse, for example, administer the vaccine. It varies state by state, by the way, whether the term learned intermediary encompasses a nurse. In many states, it only encompasses the physician. And so the end results of that, next page, is that CDC was purchasing quite a lot of vaccine, this was back in the mid '70's, and the manufacturers threatened that they would stop selling vaccine to CDC for use in mass immunization clinics unless the government would assume their duty to warn the ultimate patient.

And so since that time actually, we negotiated a clause in the CDC contracts which has us assuming the manufacturers' duty to warn, in accomplishing that in one

of two ways. One is either to just have the patient examined by a learned intermediary prior to vaccination, which may or may not happen, typically does not happen in a mass clinic setting. And the other then is to provide information to the patient or the parent regarding vaccine risks. And that was really the genesis of what is now called The Vaccine Information Statement.

Those statements were called Important Information Statements. They were drafted by CDC to meet that duty to warn obligation and were distributed with each dose of vaccine that was purchased off of CDC contracts, generally using what are called 317 Grant Funds, of which 317 refers to as section of the Public Health Service Act under which CDC provides grants to states for prevention services kinds of programs. Next slide please.

And so we drafted those Important Information Statements back in the mid ‘70’s and those were used right up until the time that the National Childhood Vaccine Injury Act was passed in 1986. And as noted on this slide, they were only required to be used when they were, when vaccines, that was purchased off of CDC contracts, was being used.

A historical note is that the swine flu episode of ’76, I believe, was the first time that the Important Information Statement was used. Next slide please.

The National Childhood Vaccine Injury Act of 1986, of which you are all very familiar because your own Commission was created by that Act, was a comprehensive act addressing development and use of vaccine in the United States. It set up the Vaccine Injury Compensation Program. It set up the National Vaccine Program Office, the National Vaccine Advisory Committee, and it also provided for limitations on litigation for any lawsuits that happen after going through the Vaccine Injury Compensation Program.

It required record-keeping by providers of immunizations and also it set up what is called the VAERS Program, the Vaccine Adverse Even Reporting System, where providers were required to notify the government of side effects that happened after administration of vaccines that are part of the Vaccine Injury Program are administered. It’s been expanded actually and any vaccine adverse event can be reported to that program. It’s jointly administered by FDA and the CDC. And also it then, that law, the NCVIA also provided for development of the Vaccine Information Materials. Next slide please.

The statute itself confers that obligation on the Secretary of the Department of Health and Human Services. It delegated development of the Vaccine Information Material to CDC. The key difference here between the Important Information Statement and Vaccine Information Materials is that it now required that this information be given to every person receiving any vaccine purchased in the United States, whether it was purchased under a public contract or through private means.

Again, though, it only applied to vaccines covered by the Vaccine Injury Compensation Program. However, since then, we have developed other vaccine information materials for voluntary distribution by providers. Next slide please.

The initial law was a very complicated, had a very complicated list of requirements and it also required that the Vaccine Information Materials be developed through rule-making. You may be familiar with rule-making. Rule-making is the process by which the government takes a statute and administratively expands on it to provide information of the more practical sense of how you implement a particular law.

And in this case, it dealt with the fact that under the Administrative Procedure Act, when you do a rule-

making, you basically notify the public of what the content of the rule is going to be and kind of an overview of the sense of where you're moving with that. And you provide an opportunity for members of the public to comment on that. And the statute then required us to go through rule-making.

It typically requires some publication of a notice of a proposed rule-making in the Federal Register, which is kind of the federal newspaper of actions of the United States government. And it also required ninety days of comment therein.

In the first round of this rule-making, since it was a brand new event, it was a brand new event, but development I would say, we decided to go slow, frankly, and to make sure that we did a comprehensive job and find a way to best implement this law in a way that satisfies all the groups.

So although the law required, for example, that we have ninety days of comment, when it appeared that people had additional comment, we actually extended it to one hundred and eighty days. The entire process lasted approximately three years and from the date of the MPRN to the date of the final publication was over two and a half years.

Things that happened in between then is CDC, in drafting the initial version to be considered by the public, consulted with the National Institutes of Health and also the Food and Drug Administration and drafted vaccine information materials for publication in that MPRN.

Later, there was a public hearing held in Atlanta for members of the public to present. As you all are aware, the Advisory Commission on Childhood Vaccines has been specifically given a role in the development of the Vaccine Information Materials and CDC was required to consult with them. In that initial instance, actually the very first meeting of the ACCV dealt with the development of the Vaccine Information Materials. It tended to focus on the DTP vaccine at that time because that was the controversial vaccine because of the whole cell pertussis that existed in the vaccine at that time.

So over the course of the next two years, CDC met with the ACCV to discuss the Vaccine Information Materials over four times. In addition, CDC held a three-day work group meeting in Atlanta where a variety of people were invited. As the law requires, in addition to consulting with the ACCV and the FDA, CDC is also required to consult with provider organizations and parent organizations.

So a large number of people representing those various groups, the American Academy of Pediatrics, for example, the Organization of Dissatisfied Parents Together, which was the predecessor of what's now called the National Vaccine Information Center, and was one of the very first vocal organizations in getting information passed to parents. In fact, I think in many ways, that organization could be credited with getting passage of this provision of the NCVIA requiring that parents be notified about the risks associated with vaccines.

And the ACCV also sent representatives to that three-day workshop. So we had numerous meetings. We also had a separate meeting directly with the Organization of Dissatisfied Parents Together and also with the National Parents and Teachers Association.

I'll just quickly go over the list of requirements that were required for the first round and of the VIM and the law that was passed in l986. It says this material shall be presented in understandable terms and shall include, 1) the frequency, severity, and potential long-term effects of the disease to be prevented by the vaccine, 2) that symptoms or reactions to the vaccine, which if they occur, to be brought to the immediate attention of the health care provider, 3) precautionary

measures legal representatives should take to reduce the risk of any major adverse reactions to the vaccine that may occur, 4) early warning signs or symptoms to which legal representatives should be alert, possible precursors to such major adverse reaction, 5) a description of the manner in which legal representatives should monitor such major adverse reactions, including a form on which reactions can be recorded to assist legal representatives in reporting information to appropriate authority, 6) a specification of when, how, and to whom legal representatives should report any major adverse reactions, 7) the contraindications to and basis for delay of administration of the vaccine, 8) an identification of the groups, categories, or characteristics of potential recipients of the vaccine who may be at significantly higher risk of major adverse reaction to the vaccine than the general population, 9) a summary of relevant state and federal laws concerning the vaccine, including information on the number of vaccinations required for school attendance and the schedule recommended for such vaccinations and the availability of the Vaccine Injury Compensation Program, and 10) such other relevant information as may be determined by the Secretary.

So basically, the first version of these materials effectively went through that list, point by point, and ended up being approximately ten pages in length. You can go on to the next page. One other point I might make is that the law also allowed providers, though, to develop their own materials that were comparable to those.

As I had mentioned earlier, it took several years to develop the initial Vaccine Information Materials. They were published in the Federal Register in 1991 and were required then to be administered six months later, which was April 15th, I believe, of 1992. The end result, then, was very lengthy pamphlets.

One of the questions that came up through the process for developing them was the readability of them. In addressing the points that the law required, a lot of detail was put in, including technical information. And one of the reasons that these materials ended up so lengthy was that if a technical term was used, then that term would be defined. And there was a lot of criticism about that. And in fact, the criticism went to the point that can you actually give somebody too much information. That if you give them so much information, that they actually don't have time to read it or they end up glossing over the

information. You can go to the next page, which is evolution of Vaccine Information Materials.

And also I might note that providers also complained that the length of time that parents would have to read that in their waiting rooms might be disruptive to medical practices, might lead to lengthening the amount of time that each encounter with a physician took, which could ultimately result in increased costs for immunizations.

And so as the process developed and we held all of these hearings, it became very clear that the initial concept was somewhat flawed. And so while publishing those, we noted in the 1991 final rule that we intended to do an analysis of them and determine whether or not it made sense to go to Congress to seek to have the requirements amended.

And so in 1993, in fact, CDC did go to Congress and there were revisions that were passed. If you go to the slide, next generation, that lays out the entire list of requirements in the current statute. It says that the information of such material shall be based on available data and information shall be presented in understandable terms and shall include a concise description of the benefits of the vaccine and a concise description of the risks associated with the vaccine, a statement of the

availability of the VICP, and such other information as may be determined by the Secretary.

One significant change, based again on comment that we received, is the law removed the ability of providers to develop their own materials and said that they had to use the CDC developed materials. However, the law also said that providers should supplement those materials with visual presentations or oral explanations as needed. And obviously, that would be particularly relevant if you were speaking with a non-native English speaker.

I might note that CDC initially did develop vaccination information material that covered several languages. I believe it was Spanish, Chinese, Vietnamese, and French. And then later, a grantee of CDC, the Information Action Coalition, is that it's name?

MR. WOLFE: They distribute, they post the translations. The translations are actually done by two state health departments with grant money, in California and Minnesota.

MR. MALONE: Okay, and there's how many different languages are in there now?

MR. WOLFE: Twenty, twenty-some now, I'm not sure how many exactly. Twenty-four, twenty-five, something like that.

MR. MALONE: And so, that's been another development. Another point about to change in the law is the original statute only required that these materials be given to children, or to the parents of children. And, of course as you know, the Vaccine Injury Compensation Program covers vaccines that are recommended for administration to children. So once a vaccine is covered by the Compensation Program, any person who receives that vaccine, the classic vaccine would be Hepatitis B, where it's given to adults in addition to children, that they qualify for compensation under the Program too.

So it obviously made sense to fully inform patients, adult patients, about the risks associated with vaccines. And so we had that added to the law to require that any provider in the United States, whether public or private, whether using vaccines purchased off of a federal contract or off a private contract, and whether administered to a child or an adult, would need to use the Vaccine Information Materials. Next slide please.

And so, in addition to getting, to stopping the requirement that it be done through rule-making, the law allowed us to go through a little more concise process, if you will. It still involves the Federal Register. There still is a notice of the draft materials that's published

in the Federal Register. However, rather than a ninety days of comment, it requires only sixty days of comment. There's no longer a requirement for a public hearing, however, members of the public are invited to provide information to the public.

The requirement for consultation would be ACCV, and health care providers and parent organizations remain. And CDC, to this day, as we develop new information materials, will come up and consult with the ACCV and will also hold a meeting with various parent and provider organizations. That somewhat evolved early in the process. It generally would be done in an in-person consultation. It's generally done now, as we've gotten more efficient, by phone consultation. However, there is still, extensive consultation occurs. Next page please, which should say development process.

And I'm going to go ahead and defer to Skip for the rest of this presentation.

MR. WOLFE: Thanks, Kevin. The development process, there are a number of steps that don't have to be followed in any specific sequence. But this is the way it usually, this is the way a particular VIS usually develops.

First of all, we'll do a draft of it here at CDC. Have it reviewed by CDC. Subject matter experts revise it.

And once the subject matter experts here are happy with it, then we will go to you at ACCV for a review. We'll send it to FDA for a review. It will be published in the Federal Register, as Kevin was just saying, for sixty days of public comment. And we'll have that consultation meeting that he mentioned, where we will invite members of different public organizations and professional organizations to discuss it.

Once we've gotten the comments from all of these reviews, we will bring it back to CDC, revise it again, show it the subject matter experts again. Once they are happy with the final result, we will send it through final CDC clearance. When it's cleared, we will publish it for a final notice in the Federal Register. This isn't for comment, but just for notification that it's been done. And then publish it.

MR. MALONE: And I might note that the statute itself says, that the effective date has to be no more than six months from that. So the notice itself will tell providers the date after which they need to be using it.

MR. WOLFE: Yes. In the next slide, this is just sort of bringing you up to date on where we stand today with Vaccine Information Statements. This is the slide that says current vaccine information materials. They're

called Vaccine Information Statements now. They're generally two pages, one page front and back. As Kevin mentioned, we now have them for all vaccines, not just vaccines that are covered by the Compensation Program, the one exception being PCG.

And we don't have them for non-routine combination vaccines. In other words, what we're calling a routine combination vaccine would be MMR, DTAP, ones that, they are routinely given in that formulation. For other combinations, we ask providers to use the individual VIS's for the components.

One innovation that we've made over the years, we noticed that the more vaccines we have, the more often the recommendations might change. And because of the length of time it takes to develop them, there would always be a period of time between the time when the recommendation changed and we were able to get a new VIS out. So we started producing what we call interim VIS's, which is a version that we can publish with the new recommendations in it but has not completely gone through the process yet. So that it gives providers something they can use in the meantime to make sure that patients get the most up to date information.

Another recent innovation, which you're familiar with because you reviewed them, are the multi-vaccine VIS's, which cut down on paperwork by allowing providers to use one VIS that covers a number of different vaccines and can just check off which ones they get.

The final slide, I wanted to talk just a bit about distribution of the Vaccine Information Statements, which has evolved over the years. Initially, when they first came out, we printed, we printed lots and lots of copies. We would basically print one copy of a VIS for every dose of vaccine purchased through federal contract. So providers who were giving federally purchased vaccines would basically get all the Information Statements printed by us as they needed. In addition, we would print camera-ready copies and ship them to the states, who could, if they wanted to, reproduce on their own and ship them out to providers within the state. Or, providers could ask for their own camera-ready copy.

Once the internet became more prevalent, we decided to go to, now where providers can actually download the VIS's from their computers and print their own out or get them printed, which has the benefit that when a change is made, we can distribute it virtually instantaneously.

We've gotten complaints over the years from both providers and parents about the amount of paper that's used. And so a lot of providers were asking us if they could print out office copies, basically have them laminated and have the patients read them in the office as opposed to actually giving them a separate paper that they said a lot of times they threw away. And we determined that they could do that as long as each patient was offered a paper copy to take away with them because we believe it's important for people to take away a copy because there's some information on there that could be useful to them after they leave the office.

So as long as a patient is offered a copy of the VIS to take away, which they can refuse if they want to, we do allow providers to use office copies. And a more recent development, which we're just working on now, is to allow patients to download their own copies on their blackberries or iphone or any kind of internet accessible device. Rather than carry away a paper copy with them, they will be able to download a copy onto their device and take it away that way. Again, helping to save more paper, and we're just working on that web page to allow them to do that now.

That basically concludes the presentation. So we're open to questions.

MS. CASTRO-LEWIS: Thank you so much. We have been a part of the process on reviewing the Vaccine Information Statements, but I think it was very helpful to know that there is a process for the development and the revision and distribution of the Statements.

I do have a couple of questions, but I'm going to leave it there for the Commissioners to ask questions, if any?

MS. BUCK: I have two questions and a comment. This is Tawny Buck. First, you mentioned the original VIS Statement, and, I think we've talked about this in the past. Some of us have been curious to just know if that's, if there's any of those copies still around that we could look at. Do you happen, do you think you have one that we could see?

MR. WOLFE: The ten page pamphlets you're talking about?

MS. BUCK: Yes.

MR. WOLFE: Yes, I've got actually copies of every VIS that's ever been produced.

MS. BUCK: I would love to have a copy of the original one if that's possible.

MR. WOLFE: Yes, I can. I won't be able to give you a pamphlet, but I can copy it and send you a copy. The original ones were for three vaccines, DPP, OPV and MMR.

MS. BUCK: Thank you. Okay. Also, my other question was is there, do you know when you anticipate your next public comment period on these? Is there one upcoming?

MR. WOLFE: Are you talking about the Federal Register publication?

MS. BUCK: Which allows for public comment.

MR. WOLFE: There are. There are several that we've, there are none in the Federal Register right now, but there are several vaccines that we need to do that for and we don't have a specific date yet, but it will be soon.

MR. MALONE: And so we will consult with the ACCV also.

MR. WOLFE: Yes.

MS. BUCK: Thank you. And then my only comment was you mentioned that one of the purposes of these was a statement of availability of the Program. And I think this has probably come up before, but at least in my opinion, a piece of this availability of the Program is to include the three year statute of limitations language, since that it's pretty critical in terms of the Program being available to people. So I know you're always sort of battling for space

on these, but I think that's a big issue in terms of people understanding what they need to do in order for this Program to be available to them if they do indeed suspect that their child's been injured by a vaccine.

MR. WOLFE: Good point.

MS. BUCK: Thank you.

MS. CASTRO-LEWIS: Any other questions? Dr. Herr.

DR. HERR: Yes. This is Tom Herr. I have a question. Last meeting, we reviewed some of the vaccine information sheets. Will we have any opportunity to see what changes you've made prior to it's further publication?

MR. WOLFE: Generally, we don't. Once we've gotten comments, we incorporate them but don't go back to the agencies who've reviewed them to let them review them yet again. It's more, it's kind of a, yes, yes.

DR. HERR: I guess I'm kind of looking, or trying to avoid the "you guys missed the boat" comment in the sense that we had an overwhelming or an overlying comment and it got lost in the technology or some of the translation so that it came out just as bad as it was before. I hate to say it that way, but the purpose of the, we look at, just to make sure, okay, yes, the things that we were concerned about, you guys dealt with adequately. Fine.

MR. MALONE: You know, I think that one way to address that is, it would be, sometimes just getting comments doesn't end up with the result that you're looking for. And that working on the actual language for the Vaccine Information Statement, I would just suggest that at future meetings with the ACCV, if you have particular concerns, that you try, to the extent possible, to articulate actual language to insert in that. And then I think you're going to find it's much more likely that you'll know what's coming down the pike.

PARTICIPANT: I think we've done that.

DR. HERR: I do think we did that. And the other question, comment on that is okay, fine, you come out with a new set of information sheets, and when is the process to when they would be revised again so that any comments that we would have, critical comments or critically constructive comments on the new sheets, when would they be, you know, effective?

MR. MALONE: Well, I think that the ACCV, having a role in the development of these materials, that we're certainly always open to input from the Commission on, there's a need right now to revise this statement, or that even that you didn't get it right. If we have a flaw in a statement that we put out there, especially now that the

technology allows for this kind of updated dissemination and we don't end up with people ending up with ten thousand copies that they printed, anticipating they would be able to use something for three years.

I think that we're in a better position to change these over time and update them on a more timely basis. And we're very open to comments that the ACCV may have in trying to get us to initiate a new process or a particular one.

MR. WOLFE: And occasionally what happens is that recommendations that are made, once the subject matter experts review them, they might over rule a comment for some reason. They might believe it's misleading or it might, or for any other reason, so occasionally, suggestions do not get incorporated for those reasons. And we don't always go back and, you know, again for efficiency reasons, go back and justify every suggestion that has been incorporated or not incorporated.

DR. HERR: I know, but in some ways it would be nice.

MS. CASTRO-LEWIS: We have another question.

MR. SCONYERS: I was just going to suggest that perhaps the Commission could get the final versions once

they're published and then that would give everybody an opportunity to comment if there was an issue.

MS. CASTRO-LEWIS: Yes, thank you.

MS. SAINDON: I think, I'm not clear on whether the, from your process, it seemed that the comments from the ACCV are received and then it's put in the Federal Register for public comment. At that point, are the comments from ACCV already incorporated, and if so, if you could notify the Commission when it's put in the Federal Register for pubic comment, then they could have that second opportunity to look at it.

MR. WOLFE: That's a good idea. We haven't been doing that, but we certainly can. That is a good idea.

MS. CASTRO-LEWIS: Yes, that's very good. I do have another question also regarding the Spanish language materials and other languages. Do they actually go through this rigorous process of revision to ensure that the translations or adaptations are accurately and they are culturally competent?

MR. WOLFE: We here at CDC headquarters don't really have a role in the translations. As I said, they're done by two states who contract them out to translation services.

MS. CASTRO-LEWIS: But you said the CDC role to ensure that the materials are accurate and, you know, you can commission somebody to translate them, but who is in charge of ensuring that the materials are correct and that the appropriate language is used?

MR. MALONE: Yes, I think you're correct that ultimately CDC is responsible for the content of the vaccine materials, whatever language they're in. And we'll take your comment under advisement.

MS. CASTRO-LEWIS: What can we do to, I don't know, other than the translators, to look at them and to ensure that the materials are done correctly because just the fact that you're saying that they're correct doesn't mean that they're correct unless you're really proficient in the language to, and there are several languages that are translated to. What can the CDC do? Is there any mechanisms there that we can come up with, anything? Obviously, it's a challenge.

MR. MALONE: Right, and it is a challenge, but it's a reasonable challenge and we'll look into it.

MS. CASTRO-LEWIS: Well, thank you and please let us know what conclusion to you come or let us know what mechanisms are you going to use to ensure that. The other question that I have is you have a distribution process, a

mechanism for the providers to gather the information in many ways. Is there any follow up to, with the health care providers, to be sure that they're actually using it? Is there any kind of research to see if they really pass on the materials to the parents and in different ways?

MR. WOLFE: There have been some studies, I don't have any data, we don't, there's not, even though they're required by law, there's no enforcement mechanisms.

MR. MALONE: But it, what I think you allude to, it has been frustrating. I know that a lot of us, just in our personal experience, has, going in with our pediatricians over the years, have had either where we're not getting the materials or we're only getting the materials one time and not for follow up doses. And we've discussed various mechanisms over the years for getting out reminders to providers. I believe that JAMA has occasionally published a reminder notice and one of our more recent discussions was approaching the medical boards of each state to ask that they put out a notice to providers on some kind of schedule.

We haven't completed a decision on whether or not to do that, but I agree with you that there are a lot of providers who, over the years, I believe that many more providers have become aware of these materials and that

they are being more routinely used. There's still a significant population of providers not using them, although the law requires them to.

DR. HERR: This is Dr. Herr. I want to let you know and interject here that many insurance companies, as part of their quality assurance programs, will check charts and ensure that there's signatures that indicate that the vaccine information sheets have been distributed. So there are processes out there that check for compliance with this part of the law. Yes, there are.

MR. MALONE: And by the way, although the statute itself doesn't provide any kind of compliance mechanism, it doesn't even require record-keeping, in the rules, in the, what we call the instruction sheet that we put out for the materials, it does require providers to make a notation in the medical record. The original Important Information Statement, the Department of Justice insisted that we have an actual acknowledgment by the parent of receipt, and in fact, understanding of those materials. Got a lot of criticism during the development of the initial Vaccination Information Materials about that and we decided that a more efficient mechanism, and one that would actually put the burden back on the provider, would be to require a contemporaneous notation in the medical record that the

materials have been provided to the parent, that they have been provided a version of the particular materials that have been provided. So that's probably what these insurance companies are relying on.

MR. SCONYERS: The other thing that happens is for hospital-based clinics, where the hospital is accredited, this is something that the accrediting agencies audit and check.

MR. WOLFE: A couple more observations, in all of the training that we do at the Immunization Program at CDC, our satellite courses, our on-line courses, and our live courses that Bill Adkins and others put on, they always stress VIS use in those. So that's another way of getting out the word that people need to use them. And just from my own observations, from my own contacts, I know within the last several years, I've been astounded that for awhile, a lot of providers were pretty much ignoring VIS's.

Now, it seems to have gone just the opposite way, that if there's a change in recommendations, before we even get a chance to start working on a draft, we're getting calls from providers saying when are we going to have a new VIS. So that's kind of encouraging news.

MS. CASTRO-LEWIS: One last question.

DR. EVANS: Skip, one last question. I know the Academy of Pediatrics had had at least one Fellow's survey looking at the compliance rate of VIS's and how well they're being distributed to patients. Have you all done any surveys since then that gives us some idea of how effectively these are being communicated and distributed to patients and parents?

MR. WOLFE: No.

MR. MALONE: One of the points I think that's made here is that just as parents, there's always new parents coming down the pike, and that's why we can't just assume that everybody knows about the need to get vaccinated. The same thing with using these materials, that there's new providers and there are parents who don't know that these materials exist. And so it is an ongoing challenge to make sure that CDC fulfills it's obligation to get these out there.

MS. CASTRO-LEWIS: Okay.

MS. BUCK: What happens if they're not used? I mean, what if there's a case where, you know, there's been an injury and there's no evidence that the VIS was distributed or an outdated one was given or, I mean.

MR. MALONE: Well, that's an interesting question. As you know, the Vaccine Injury Compensation Program is

required to provide, requires anybody who's injured, to go through the Program first. But even after you go through the Program, I don't have a copy, actually Geoff probably know this better than I do, I believe that providers, well you have to go through the Program before you can sue a provider. And there's nothing in the statute that has a sanction if a provider does not use these materials.

However, I would argue that the standard of care in the practice of medicine would be that you should use these materials because they're required by law. And therefore, I guess theoretically, a provider could be sued for malpractice for failure to use the materials or to use the accurate materials, if someone would end up rejecting the conclusion of the Injury Compensation Program and decide to go directly after the provider.

By the way, I might mention one other thing from the statute, that what started the whole development of these materials in the first place, the old Important Information Statement, was this Reyes v. Wyeth decision. The National Childhood Vaccine Injury Act waives any kind of requirement for manufacturers anymore to provide information directly to parents. So they actually wouldn't have liability in any scenario that we can see. So it's purely on the providers and on CDC in developing these

materials and make sure that parents get that information now.

DR. EVANS: Kevin, the only thing I would add is, as you know, that there's a duty to warn that was part of litigation prior to the Program Act. That was one of the things that was addressed through the law that was passed. Whether, the VIS's, whether furnishing VIS's or not furnishing VIS's makes someone liable if there is an injury or not, has not, to our knowledge, been tested in a civil case. But that's certainly an open question.

MS. CASTRO-LEWIS: Okay, thank you. I believe there are no more comments and we are surely went over our time, but, thank you so much for the presentation and for responding to questions. I think we can move on and thank you again.

MR. MALONE: Thank you.

MR. WOLFE: Okay, thanks. I want, before we go, Tawny, I said I was going to send you one of the, would you like copies of all the original vaccine pamphlets, or just one of them as an example?

MS. BUCK: Dr. Evans says I only need one. But I would wade through, if you, if it's not a big deal, you can send me whatever you have. Sometimes I have a hard time sleeping when I'm back here, so that might help.

MR. WOLFE: Okay.

DR. EVANS: Skip, I would just add that's one of the anecdotes that I certainly remember was my wife was scared about getting MMR after reading the ten page MMR pamphlet.

MS. CASTRO-LEWIS: Yes. Okay. Thank you so much.

MR. WOLFE: Thanks.

MS. CASTRO-LEWIS: Have a good day. Operator, do we have Dr. Gruber on the phone, on the line?

OPERATOR: We do.

MS. CASTRO-LEWIS: Okay, thank you. Good morning Dr. Gruber. Would you please talk to us about the, actually, give us your report, please? Thank you.

Agenda Item: Update on the Center for Biologics and Evaluation Research (CBER), FDA

DR. GRUBER: Yes, I will. And thank you for accommodating my schedule. I can talk to you about the H1N1 virus and I will talk to you a little about this, but I am sure that you went over it perhaps yesterday in the CDC NIH update. Is that true? Did you have some information on AH1N1, epidemiology background, and, because, hello?

MS. CASTRO-LEWIS: Yes, we did. We did have some presentation on that, an update. And then she wanted you

to be here yesterday, wanted your presentation, but didn't work out that way.

DR. GRUBER: Okay. That would spare me the background. I would, on the FDA activities, in terms of H1N1, but I would like to actually report to you, since I gave my last update at ACCV on vaccines approved by Office of Vaccines. We have had one approval and that took place on March 30th when we approved IXIRO, that is a vaccine to prevent Japanese encephalitis, a mosquito transmitted virus thought maybe in Asia. This is merely a traveler vaccine and it is indicated for active immunization for the prevention of disease caused by this virus in persons seventeen years of age and older.

However, we have been very busy reviewing several biologic applications.

MS. CASTRO-LEWIS: Dr. Gruber, are you on a speaker phone? Can you please use the handset because we're not having a good connection.

DR. GRUBER: Is this better?

MS. CASTRO-LEWIS: Yes.

DR. GRUBER: Okay, I am sorry. So, I'm going to speak directly into the phone here, so again I just mentioned the approval of a Japanese encephalitis vaccine on March 30th, 2009. And I went on to say that we have

several other licensed applications currently under review that include human papillomavirus vaccine, thimerosal preservative-free flu vaccine for adults eighteen years and over. We have meningococcal conjugate vaccine under review and a new pneumococcal conjugate vaccine under review. And I hope that I can talk a little bit more about this perhaps at the next update in a couple of months.

Regarding the H1N1 activities, the Office of Vaccine, is working to facilitate the availability of a safe and effective vaccine to protect the public from this H1N1 2009 flu virus. And we have a lot of parallel activities ongoing. For instance, our office has been engaged and is currently engaged in growing and engineering a 2009 H1N1 flu virus in the laboratory for possible use of this vaccine, and this work is also carried out, of course, by other entities such as the CDC, the NIVSC. And actually reference strains for production and growing of the vaccine virus has been sent out to the manufacturers.

We also engaged in discussions with BARDA, that is the Biomedical Advanced Research and Development Authority. We are engaged in discussions with the National Institutes of Health and as well as manufacturers regarding the initiation of clinical trials to evaluate the immune

response to vaccines that would be devised from this H1N1 flu virus.

And I have been just informed in the telecom this morning that it's believed that at least several vaccine manufacturers would be ready to initiate clinical trials to look at the immunogenicity of such new vaccines as early as, end of June or even of July. So that depends a little bit on the vaccine manufacturer, but that actually is good news because the worry has always been that we may not have the time to initiate at least some clinical data with the new H1N1 vaccine to make informed recommendations in terms of how such vaccine would be used.

So in terms of these activities, we have been in close collaboration with vaccine manufacturers. They have submitted their clinical trial proposal to us. We have reviewed all these proposals. In terms of what this vaccine would look like, everybody goes by the assumption or that this should be a monovalent H1N1 inactivated Vaccine, composed only of one strain of virus because this is likely to be more straightforward than trying to combine it with current seasonal vaccine or anything else.

And so we are trying to design the clinical trials so that they can be done in a relatively short time after vaccine is going to be available because nobody

really knows how this circulating wild-type strain will further behave, if its going to, you know, come back and when it will come back. So the goal is to really generate these clinical trial data as soon as possible.

The purpose of these trials is really to get immunogenicity data and to get some information about doses that should be used in a dose in the elderly, as well as in the pediatric population. We assume that the world population, especially the younger population, is probably naïve to this virus and therefore we think that we have to administer two doses to the population. We also will study vaccine antigen that is formulated with investigation of antigen to see or to look at the potential utility of this antigen for dose bearing and enhanced immunogenicity.

And again, as I was saying, the start dates of these clinical studies really depend on the availability of clinical trial lots that are, you know, made available by the vaccine manufacturers. And as I stated, the news were rather good in that some can already start the end of June. And data would be available then for analysis, perhaps from mid September and onwards to make some decision in terms of how this vaccine could be used.

And that would conclude my update. I would be happy to answer questions if there are any.

MS. CASTRO-LEWIS: Thank you so much, Dr. Gruber. Any questions from Commissioners? No? There are no questions at this time and I would like to thank you, again, for your presentation and we're looking forward to hear more, to gain more, about this vaccine coming up. So, thank you so much.

DR. GRUBER: Okay. Thank you.

MS. CASTRO-LEWIS: I kind of missed, this morning, in the introduction, to let you know that we were doing a little switch in the agenda. We are going to do next a presentation from the Outreach Work Group and moving after that the IOM report. So my apologies for the last minute notice. So this group was very busy the last three months and Sarah is going to give us a report of what we have accomplished.

Agenda Item: ACCV Outreach Workgroup Report

MS. HOIBERG: Okay. Thank you Magda. The group was comprised of myself, Magdalena, Sherry, and Dr. Tom. And we met a total of three times, twice on the phone and once before yesterday's meeting. And we actually had the opportunity to meet with, over the phone, the, she's not the Director of the CDC Communications but someone that works for the CDC's Communications.

And I had a pipe dream and my pipe dream was a public service announcement and we found out that public service announcements are very expensive and that even though you do spend the money to actually create a public service announcement, you have to then pay someone to possibly run it and then you don't know what time they're going to run it or even if they are going to run it. So that went out the window for now. It's on the back burner.

The one thing that I felt that we did learn from the survey, the Petitioners Satisfaction Survey, was that the providers need to be educated on vaccine injury and on the availability of the Program. But we have to figure out how to educate the providers. One of the options was a poster, which again, I thought was a simple way to promote the Program, but that also is going to be something that we're going to be looking into, but not available at this time.

So we moved on to the Internet and we're looking at a possibility of a WebMD ad for the, and that would prove, a educational, for an educational prop for the patients, the customers out there, the Petitioners. But we also wanted to look into having Google or Yahoo or one of those, when you query vaccine injury, for it to pop up immediately. And when I queried it on my search engine, it

did, the HRSA website does pop quite, it's number one. But then again, I didn't, I only had my phone and I go there very often, so I don't know if it programs itself to go to where you go most often. But Dr. Tom, I wanted him to talk about the prep.

DR. HERR: There was some discussion on our work group of trying to educate, or trying to pass the word, to practicing pediatricians as a reminder about vaccine injury as a possible etiology of a child's illness after a vaccine. And the fact that these don't come up that often, so that it's not really always one of their high priority items, is recognizing the fact that when a child's critically ill, you're thinking about things that you can actually do something about that may make the child recover as opposed to making a diagnosis that, okay, this is an injury, things are going to happen, and we don't need to worry about anything else.

But, with that discussion, I did discuss with people, with Bob Pearlman, who's the Head of Continuing Education at the Academy of Pediatrics, and what he suggested is that we can set up and write an article that will be published in the AAP News that will be distributed to all practicing pediatricians and certainly can act as a

guideline for communications with some of the other specialty groups.

And in that article, we can certainly talk about not only the occurrence of vaccine injuries and what to look for, but also reference the Table and where to go look for it. Many people may not know where to go find it. And then certainly recommend the, mention the Compensation Program and also try to set up a periodicity of getting this back in AAP News so that every few years, whether it's every year or every two years, every three years, it's something that's set out there, will continue to spur the attention of practicing physicians so that they can be proper resources for their patients.

MS. HOIBERG: Thank you. So really, we are still in the very beginning stages and I welcome any comment that you may have, any ideas. We had also talked about piggybacking on CDC's information. They're going to be doing a mass mailing. They offered to, the next time they do a mass mailing, to possibly include information from our Program in their mailing. So that would be great.

I would like to find out how to get hold of Pharma because Pharma was the, they have a lot of advertising monies and they put out ads all the time now for them and actors on television all the time and just ads

in children's magazines and in the regular magazines for vaccinations, just to have, just a little blurb at the bottom of the Program and about how it could help in case of adverse events because adverse events do have to be listed. So let's give them a solution for it. Go ahead.

DR. FISHER: A couple other possibilities, since pediatricians give, first of all, usually only children, and since lots of children get their vaccines from other than pediatricians, I mean I think it's great to hit pediatricians. Remember also, probably less than half of pediatricians are members of the AAP. So I think that's a great start, but we should also hit the American Academy of Family Physicians and the internal medicine people and the ob-gyn, ACOB, the Association of OB-GYN, because both of those groups also do primary care and presumably should be giving immunizations.

And then, since we're talking about something that happens after, that may or may not be recognized by that pediatrician, or they may go to someone else, or whatever. There's also a huge body of school nurses that are very well organized and they kind of pay attention to things like this that I think could be a great resource. So the School Nurses Association. And then there was one other, I'll think of it and then I'll throw that in too.

PARTICIPANT: PA's.

DR. FISHER: Yes, PA's, sure, pharmacists.

MS. HOIBERG: Right. It was to go to everyone. Our original goal was to literally get a list of every single provider because really, for me, I mean, you've got the Doc in the boxes, unfortunately, that's a horrible way to call them, but you know, just people that you just go through the drive through and get a shot. And so, everybody needs to be aware, I mean, emergency technicians, emergency room staff, pharmacies.

A lot of times I've gone into the pharmacy and said, you know, my daughter has this rash, could you, you know, she's taking this medicine, could it possibly be? So there are so many people that now are providing vaccines and so all vaccine providers need to be educated on the risks and benefits, and then, of course, on our Program.

But unfortunately, we are the end of the road. And so, and it's not our job to educate on vaccine adverse events. We're here because of the adverse events. So really, CDC needs to be in there, whoever, the ACIP, they're the ones that need to be informing that there are adverse events, these are what the adverse events look like. And then they too can promote the Program. So really, it's going to have to be a group effort. You know, VAERS needs

to be promoted, and then of course now then you have the VICP that you want to promote.

DR. FISHER: They may already actually be in the ACIP recommendations, but I think that's a great point. When they post new recommendations or provisional recommendations, we should make sure that there is a reference to the Vaccine Injury Program so that, and links. At this point, links will get you everywhere.

The other group I was thinking of, almost any vaccine that's given has to be given by a licensed something. So licensure bodies might be a way, you know, I have to get my medical license renewed every two years. If we could somehow link into licensing bodies so that it would go out with your license application, you know, I don't know who would pay for any of this or any of that, but I mean, I'm just thinking of ways to get it to more providers at a time when they might actually read about it.

MS. HOIBERG: Well, yes, and the idea was continued education because you have to continue, especially like nurses and all that, have to continue, you all have to, you know. Doctors have to continue to educate themselves and their requirements, and so for the Program to be mentioned in those materials, my sister-in-law is a nurse and she watches videos all the time and they always

add, you know they talk about the different programs and such, but really, she was not aware of vaccine injury or, there's so many people out there because it is so rare. A lot of pediatricians and a lot of doctors and practioners are not going to see a vaccine injury, maybe even in the course of their practice. So because it is something that is not at the forefront of our minds and not very popular, it has fallen away and it's not visible. So my goal is to make the Program visible.

PARTICIPANT: Yes, great.

DR. WEINBAUM: I'm glad that you mentioned VAERS because that was kind of absent in the stuff that you were just talking about in terms of promoting the Program. I think that promoting VAERS and the Program hand-in-hand makes a lot of sense. ISO is currently reviewing our VAERS outreach efforts and about to increase our VAERS outreach activities. And certainly in the context with that, we'll be including both electronic links and paper references to the Program.

So we might discuss kind of the avenues through which we're planning on disseminating that. And our efforts actually are more, I think I was mentioning yesterday, in areas of sub-specialties where kids end up being seen if they have adverse events after vaccination.

So we were looking at the neurologist professional organizations and other things beyond kind of primary care and pediatrics, as well as the primary care venues.

MS. HOIBERG: Thank you.

MS. CASTRO-LEWIS: So Sarah, yesterday we had the report from the survey. And I think the report points out a lot of, it gave us a lot of the key findings of the report. I think they're very useful to develop a plan, for the outreach. And I don't know, this was just suggested that at our next meeting we can go over the key findings and see how can we apply what we found in our research to the outreach so we can give it some kind of a structure to the Program. And I think your ideas are great and hopefully we can get to that point sooner than later. But then we might do, through our research findings and through an overall plan, we might be able to really get somewhere. I don't know if Geoff would like to add. I'm putting you on the spot. Does anybody have any other questions?

MS. BUCK: What does the funding picture look like for outreach?

DR. EVANS: In our operating plan we have $10,000 that has been set aside for outreach. We are hoping that that can be increased just by our trying to move monies around inside the Program. But, and we're also, with this

kind of discussion and illumination of the need can certainly help in the future in terms of getting more money. But we'll see as the fiscal year begins to wrap up, there may be even more monies that might be available, so-called end-of-year monies that we might be able to steer towards outreach.

MS. HOIBERG: Thank you.

PARTICIPANT: (Off microphone, inaudible)

DR. EVANS: That's right and I was going to answer the, you were asked a question yesterday about the plan. We recently received approval from the agency to put forward our outreach plan. We have already made plans to attend the National Association of Community Health Centers, their organization is NACHA, which, of course, is going to target the population that you've brought up, Magda and others, more the low socio-economic or minority populations that are served in these federally designated health centers.

So that's one place that we are and the other one, county and city health officials, which actually, those two are ones that we don't usually go to. So this is, in the past, it's traditionally been things such as the American Academy of Pediatrics, Pediatric Nurse Practioners, and so

on. But we're trying more and more to go to allied health and other kinds of health policy groups.

MS. BUCK: Are you giving presentations or you setting up a booth, or what is it that you do when you're at these events?

DR. EVANS: Well, it's mostly the booth. We have a fancy booth, colorful blue, and we sit and distribute and talk as much as we can to people that would come by. Wherever possible, we try to arrange some kind of a presentation. If things are going well, at the National Immunization Conference, for example, as I reported yesterday, I had a featured session. I was able to talk to more. More often, it's a workshop in which you might get thirty or forty attendees. But there's certainly value in the visibility of having a booth in there because there's a lot of traffic stopping by.

MS. CASTRO-LEWIS: Would be great at the plenary session at the National Immunization Conference, but of course, that's a long shot, I guess.

MS. HOIBERG: Geoff, do you have the materials available that you distribute? Do have those that the Commission could see?

DR. EVANS: Yes we do and we will drop them off during the break. We'll go up and get some more.

MS. CASTRO-LEWIS: We don't have a break. We can take a break, five minutes between this session and the next.

DR. EVANS: What Sarah is referring to is a project that we started in the mid '90's, with the Association of Teachers of Preventive Medicine, that was to try to develop a curriculum module to teach residents about the Vaccine Injury Compensation Program and adverse event reporting and vaccine safety requirements and so on. And unfortunately, we ran into the limitations of trying to introduce new subject matter into teaching curriculum.

So the project then became more of developing materials and we ended up with a very colorful poster that's to be distributed to provider offices, that has a series of very basic questions parents should ask about vaccines so they can facilitate conversations with their providers.

And there's also a baby booklet that we'll pass out, that we're very proud of and that the CDC has actually asked for additional copies in the past that we try to distribute at meetings. And there's also a one-page sheet of contraindications, just so people know the kinds of things that possibly can be contraindicated before vaccination.

MS. HOIBERG: Thank you.

DR. FISHER: As far as resources for this, I mean it seems like we should invest at least as much money as we spent for the survey, into doing something about one of the survey's major recommendations. So this isn't, I don't know where the funding should come from, but honestly, it would make sense to take, personally, it would make sense to take this money out of the 2.9 billion. But I don't know how you guys feel about that. I mean I think, you know, if people don't know about the Program, they can't use it.

MS. BUCK: Well maybe if there's any budget overages that are indicated from your last budget, you could maybe shift some of those funds to this as well.

DR. EVANS: That's the point, and let's be clear, and this was part of what I was going to get into in a minute. There's the administrative budgets for the three entities. That is discretionary funding that is appropriated by Congress with rules and limits. Anything other than that is the trust fund, its for compensation, and that is a total different set of rules and, of course, it cannot be used for anything but compensation. So this would be within just the administrative budget of our

Program that we could make these kinds of contributions to the effort.

MS. CASTRO-LEWIS: Do you have any kind of idea for how much money you would be able to give that you have left over somewhere please to put into the outreach?

DR. EVANS: We can't comment at the moment, but we have a former budget analyst in our office by the name of Kay Cook who makes sure that we keep the accounting straight and we will sit down over the next couple of weeks and begin to make end of the year projections.

MS. BUCK: I think I would just like to go on the records, at least for myself, I don't if I, it seems like this Commission is saying that outreach is a real priority for us. It's been indicated to us that there was a significant budget overage from your 2008 budget that was channeled to a different avenue, which was the IOM contract. And I think these are the kind of conversations that need to come before this Commission in terms of prioritizing funding if you have budget overages to make sure that some of these issues that are a priority for this Commission, at least, that was a significant overage, Meg's not talking about a lot of money in terms of the overage that you had, so that we can make sure that we're hitting multiple priorities of the Commission. Just a statement.

DR. EVANS: Message received and we'll do what we can, whenever we can, to see that's done. This is an area, though, understand that we are under the constraints and this did not come out so much in the, came out in some portions of Kay, of Chris Sheedy's presentation yesterday to the Outreach Work Group, but we will certainly, having money is one thing, being able to put forward and get through clearance, novel kinds of approaches, some more basic than others, these are things that we will push and push hard within the agency. And I'm optimistic that we're going to be able to make some significant headway and I hope to have that kind of feedback to you in the next couple of Commissions.

DR. FISHER: As far as the American Academy of Pediatrics, I happen to be the sitting Chair of the Section of Infectious Diseases and if you have a one-pager or a two-pager or something short and sweet, or even a URL address, whatever, something that we can give out to our membership, we can send it as a blast email, no trouble. And we also have a significant number of programs at our national conference and exhibition. And we can ensure that it somehow gets included in some of those programs. But I need a, it's got to be short and I can't give out a ten-page pamphlet. It won't, it will go in the trashcan.

MS. HOIBERG: Well, I mean, and you don't need a ten-page pamphlet. All you have to do, I've said it a hundred times if I've said it once, vaccine adverse events, although rare, do occur and if they do, there is a program that can help and it's the VICP. And that's all, and then it would be a URL. But, I mean, it even seemed that things of that simple nature, the poster I wanted to create was simply the picture that's on the front of our books, with vaccine information, Vaccine Injury Compensation Program, the phone number, and the URL. But that was not possible. So at this point, I don't understand why something that simple is so complex.

DR. FISHER: Yes. Geoff, do we have anything? Do you have a one-page, would you have anything I can hand out? Or is it, does everything have to be okayed by so many levels that it's?

MS. HOIBERG: What's sad is this Program is twenty years old. There should have been information ready to go when needed and it's like, that's the part that I find, as a parent, very frustrating is that the only time that you ever even consider thinking, and I mean, my neurologist came to me, and pretty much in secret, to tell me, you know what, we couldn't find anything, so I think maybe you need to go here. So it's the dark horse. It's

the dirty little secret and it needs to come out of the closet and say, you know what, it happens, it's super rare, but there's a program to help. And there's 2.9 billion dollars sitting, doing nothing, so.

DR. EVANS: We can certainly develop something that's one or two or three pages if it's already been publicly distributed. Anything on the website, anything that we have, a brochure that's been cleared, clearly we can take parts of that and put something together. In the past, that we have worked with the Academy over the twenty years, Redbook presentations at the annual meeting, articles in Pediatrics, various workshop presentations, we've come, we went to the Academy before several times asking if something could be distributed in mailings, and that was not successful because the Academy has certain restrictions as I'm sure you well know.

But we do have a new age here and I guess yesterday kind of the light bulb went off with the web MD suggestion, I forget who made that suggestion, but I believe it was my esteemed counsel, but the point is that we now electronically can perhaps take portions that are cleared and get them on and have a new approach.

DR. FISHER: My section has a newsletter. I guarantee you, you give me something, I put it in the

newsletter. I mean it's that simple. My newsletter doesn't need clearance from anybody but me.

MS. HOIBERG: I mean and that's all I'm asking. I'm just asking that it get visibility. And that's perfect. I thank you so much.

MS. GALLAGHER: Jeff, can I just make a comment. I work with an organization where we have to implement things. And so I do have an appreciation for how complex implementation of even a simple idea might be in a large organization. If there's a possibility that there might be budget available for us at the end of the year, should we get started now to sort out exactly what we would do with it and be prepared to pull the trigger in an instant on implementing whatever it is if we have the money? Because I feel if we wait until we find whether or not we have the money, it will be too late to implement.

DR. EVANS: Nothing is simple when it comes to going forward with kinds of activities that may require a contractor and contracts and approvals and things like that. So anything that's money-dependent is likely to involve those kinds of things. As Chris Sheedy told us yesterday, anything of quality, anything that has, that's put together that's going to be effective as an instrument, needs to be developed and tested and so on. And we don't do those

kinds of things, usually contractors do those things, and contracts have to be led, and there are contract deadlines, and so on. So while I'd like to say yes, that sounds great, but I don't know that it's feasible with four months left in the fiscal year that we can do that.

MS. GALLAGHER: Are you allowed to do a request for a proposal without signing a contract or is that also forbidden, you know, reach out to somebody who might be in a position to do this and just ask them what it would cost so you would have all the information that you need to seek whatever authorizations are required?

DR. EVANS: Let's say that I will get back to you on that. We will certainly make every effort we can because if we are going to have some additional monies over the next several months, then we can possibly preemptively get started in trying to put together an RFP. That's very possible, a request for proposal. We will work that. And Kay's branch is tasked to do that. And we've already actually been talking about that even before the meeting, but there's not much I can say publicly at this point.

MS. GALLAGHER: Okay, thank you very much. I didn't know how far you could go, but however far we can go in order to prepare would be wonderful.

MS. CASTRO-LEWIS: No more comments, questions for Sarah? Okay, well, thank you Sarah. I think we didn't have a break in the agenda, but we're a little bit ahead of time, so let's take just a ten minute break. So 10:35 we will start promptly with our last section of the agenda.

(Brief recess)

MS. CASTRO-LEWIS: Okay. The last large portion of our agenda. I would like to welcome Dr. Stratton from the Institute of Medicine. She's going to discuss the IOM study that was commissioned by HRSA. Dr. Stratton, yes, give me a second to put this all in perspective, please. Thank you. Okay. She's going to talk abut the IOM study and then also in the agenda is Dr. Evans, who is going to give us background information on how this happened and Rosemary, you are also in the agenda for this. Dr. Johann Liang is also on the agenda.

But what I would like to say also is that in the context of the study, the Commissioners have some concerns. And a letter was sent by the previous leadership of the ACCV and the present leadership to all Commissioners stating the concerns. And I assume these probably are going to be brought up to date. We would have liked for these to be discussed maybe two months ago when the issues were brought up, but it didn't happen. So today is an

opportunity for everybody to get involved and resolve their concerns.

The letter has stated three main points. One was the guiding principles and how these guiding principles were taken in consideration to develop the plan and the contract with the IOM. The second issue in the letter was the use of the trust funds for the financing of the IOM study. And the third point, all the time the ACCV has consistently opposed the use of the trust funds for vaccine safety research. These were concerns.

We definitely, we need to hear about those things and I think, and then later on I would like to ask, when it's pertinent, to ask Tawny to discuss a little bit also what are those guiding principles so we have a better understanding of what are we talking about. But these are concerns, these are facts, and I think just that we need the questions. So, Geoff, you would like to go first?

Agenda Item: Institute of Medicine Project on Vaccines and Adverse Events

DR. EVANS: I'd be happy to. Thank you for setting up my presentation very well, Magda. Good morning. As you know, questions about the IOM contract did come up in April, shortly after the Institute of Medicine announced the formation of the committee and the comment period

regarding of the membership. And even though Dr. Stratton had briefed the Commission this past November on the IOM project, it was just the basics and did not really get into more of the specifics of the project, how it was being put together, what it was going to do, the process, and so on.

So once this committee was announced, it was kind of like, surprise, and some of the Commission members understandably were caught off guard and some quick e-mails ensued. And I would say, just as a quick parenthetical, that when we signed the contract in September, having gone through this before with the IOM, I knew that it was going to take many months for the committee to be formed because of the exhaustive vetting process that the IOM goes through to make sure that its committee does not have conflicts of interest.

So we had talked tentatively at that point of an April organizational meeting and that there would be plenty of time at the June meeting to go into further detail about the adverse events listed and have public comment at that time. So we already, I already knew, but it was kind of like I've got a secret, I already knew that this was going to happen, so there was no rush to begin to get into more detail. But clearly, March would have been a good time, at

the March meeting, to anticipate that there may be questions once the committee was announced.

So, with that said, I would like to take the opportunity this morning now to go into a little background, extensive background in terms of the IOM, what it's done for the Program, and what it's, and what the Commission's role has been along the way, and touch on the Guiding Principles that Tawny was just asked to talk about, but I'll see if I can help in that area, and so on.

So all the ACCV members during the orientation, I'm sure you remember most of these details, were briefed on Institute of Medicine studies and the Act and Section 312 and 313. But bear with me, I know you probably remember most of this, but I'll go over it again just so we're all clear.

The Act that passed in 1986 had two sections, 312 which called for the Institute of Medicine, which is a chartered institution by Congress to perform scientific evaluations so to help policymakers in areas of science and policy. And it was asked by the IOM to perform two studies, one under Section 312 for Pertussis and Rubella vaccines and one under Section 313 for the remaining vaccines under the program.

And also the same language called for the Secretary to make, to propose modifications to the Table based on the results of the IOM study. So this was put into place by Congress in 1986.

The first report on Pertussis and Rubella vaccines was published in ’91. This was a several year project, had a lot of publicity, a lot of notice because it pertained to Pertussis vaccine, which was the leading vaccine, of course, that lead to the creation of the Program, the DTP vaccine. And once the IOM published its results, the Department went through an extensive review process, starting with an internal task force.

Then there was a Notice of Proposed Rule-Making that was published. And even prior to the Notice of Proposed Rule-Making, the public, excuse me, the Department, our Program, went to a sub-committee of the National Vaccine Advisory Committee and went over proposed changes. And those proposed changes were then presented to the Commission. The Commission voted its recommendations and then it was put in the form of proposed rule-making and a rule. There was six months of pubic comment, during which time there was a public hearing. Many, many comments were received and it was, it was, the final rule was published in 1995.

I should just also add that because of particular, a particular issue that arose with DTP vaccine and chronic nervous system dysfunction, the IOM then went back and actually issued a second small follow-up report that was published in 1994. The Department decided to allow additional public comment for two months and the Commission was once again briefed on and allowed to comment on this follow-up to what was known as the British National Childhood Encephalopathy Study.

And so the Commission actually had two opportunities to provide public comment, to provide comment to the Secretary on the proposed rule. And the rule was finally published in March, ’95. So two-year effort, two-three effort by the Commission. Two to three, three to four year effort by the Department to get this thing finally published as a final rule. Extensive process.

Fortunately, the second effort, the second report, which was published by the IOM in 1994 involving the remaining vaccines in the Program, in addition to Hepatitis B and Haemophilus vaccine. That was published in ’94 and again, the same review process. Ad hoc sub-committee of the NVAC first looked at it, but then took that to the Commission. The Commission gave us its viewpoints on votes and then that was published as a final rule in l997. And

the l997 final rule is the last time that the Department has made changes to the Vaccine Injury Table based on IOM input. There have been no studies published since then.

So, and just a couple points about the IOM. In this very extensive process, the government really had no control over it. As is true now, with the project you're going to hear about, the government came up with a list of adverse events for the IOM to study, but the IOM made the final decision on what was going to be studied. And in one instance, even added a condition. The only thing that the government was able was to dictate or sponsor is which vaccines that the IOM would study.

So each IOM committee required, each IOM committee held several public workshops, invited speakers. The public had many opportunities to provide input along the way. The IOM's methodology and approach to deciding causation, that is, starting from a neutral position, and letting the literature decide if the conclusions would shift it in favor for or against causation that was a time-tested successful approach to helping the Program modify the Table to bring it in line with science. And each time the IOM came back to the Commission and briefed it on its findings whenever the report was released.

Now since the last set of IOM-based changes, the Program added five new vaccines by 2004. And it was in 2004 that, realizing that there were no further IOM studies, no additional conditions were being added to the Table, that the Program decided it would try to maybe move the process forward by coming to the Commission and briefing you on some possible changes to the Vaccine Injury Table.

We couldn't say that they were proposed changes because we didn't think that they would necessarily be able to receive Department approval. But we tried to at least to, try to jettison the process forward and see if we could get something done in that regard. And the Commission looked at the proposed changes, over the possible changes, and voted nearly unanimously or unanimously for all of them.

So that we thought that was a very successful effort. But not surprisingly, because there were no independent studies of these vaccines and adverse events, nothing happened within the Department following that.

So in going through these possible changes, the ACCV recognized, in its wisdom, that some guidelines would be helpful and decided to form a task force, excuse me, a work group, and that work group met for the next year and came up with two products, a Resolution and a set of Guiding Principles.

And the set of Guiding Principles, which basically contained a whole different, various ideas about how policy should be applied to science and Table changes, the kinds of evidence that the Commission could either evaluate through looking at studies that were published or looking at evaluations of studies, and so on. This was mainly, in the absence of an IOM report, but could also be used with an IOM report, but it was basically their ability to try to achieve some consistency in the future.

There was also a recommendation to the Secretary, recognizing that there were no IOM studies on the horizon, and that recommendation was to appoint a standing scientific panel of recognized experts to review the Table and to recommend changes. The IOM was not mentioned in this. Some members felt the IOM should not be specifically mentioned because there were some criticism of the IOM at that point, in 2004, over its report on vaccines and autism. So some of the members felt that they wanted to be neutral about the recommendations to the Secretary.

I want to be clear, though, that this recommendation calls, called for an independent panel to be appointed by the Secretary, which is difficult to do because obviously the Secretary has a vested interest in the Program and its policy. And some could look at that

and say, well how can the Secretary be independent. So I voiced at the time that I didn't know that this was going to be feasible, but clearly the Commission wanted to go forward and have something, have more injuries added to the Table.

So they recommended that, and also there would be no conflict of interest, that the scientific panel have certain disciplines represented and that the charter would require ACCV consultation on which adverse events to study and sources of data to be used. These are things that the IOM, of course, as an independent body, would not be doing with the Commission. And the IOM, to be clear, has never studied vaccines, has never made recommendations on changes to the Vaccine Injury Table. And that was a key difference in the ACCV recommendation versus the independent activity that the IOM had done twice for the Department.

So this is the back drop to what happened and so let me put up a slide, and this is just a very, this is so you don't have to look at me the whole time. So in April, after the committee was announced, there were a series of questions and concerns that were raised. And I wanted to lump these in various categories so you could see, and this is how it broke down.

So basically the guiding principles, and this was in the letter that was sent to me in April, and the guiding principles, the point was made that these principles should form the basis of the contract. If not, the project is useless. And clearly, the guiding principles really have very little to do with the IOM contract because the IOM, in its methodology, made very clear that it's approach, and it's been the same approach in terms of the kinds of weights of evidence it gives to various kinds of scientific evidence, and so on. So these principles, these specific kinds of things that were mentioned in these guiding principles were already part of the IOM methodology to begin with.

And there was also a request to see the IOM contract to verify that these principles were put into the contract. And understandably, there have been many requests for that. And I wanted Elizabeth to just mention what is the status of being able to furnish the contract at this point.

MS. SAINDON: We hope to have, we hoped to have that available for you today, but unfortunately, it needs to be released through our FOIA office, our FOIA officer. And it has, the redaction process and the final release by

the FOIA officer was not able to be done today. But we will get that to you as soon as we possibly can.

DR. EVANS: I should mention that the Management Plan was sent by the IOM in April, which had a lot of the details of how, the approach that was being requested. Again, we had very little say in putting together this contract, how the IOM was going to conduct the study. Just the numbers of vaccines, pretty much. And, of course, the big question, how much money? And, so that's the second set of questions.

And so where did the funding come from? I can tell you that the IOM contract was funded 100 percent with HHS monies. And of the $1.698,000 of the contract, all but $100,000 of that came from HRSA, using the funds for the necessary administrative expenses of the Compensation Program.

Clearly, this activity falls within the mission of the Program. Some questioned that. All you have to do is look at the fact that Congress mandated these studies to be done so the Program could begin to function. And the ACCV, at various times, called for the IOM to perform these studies. Although a little more recently, it was more of have an independent panel do it. So it was kind of a doggone if you do, doggone you don't. We're criticized for

not having IOM studies, then began to be criticized for having IOM studies. So that was a unique experience to go through.

So this funding basically included a variety of activities, salaries for Program staff, expert witnesses' fees, and so on. The remaining 100 thousand dollars came from the National Vaccine Program Office. And that was using its discretionary funds, which are available for the support of vaccine activities, including vaccine safety. No Department of Justice funds were used to support the IOM contract. And some funds were transferred from the Department of Justice to HRSA and they were used to support the Expert Witness Program.

MS. HOIBERG: Geoff, I'm sorry, but wasn't really the total amount of the $1.7 million, or $1.69, wasn't the majority of that monies left over from the omnibus cases that were not tried, that was going to be used for expert witnesses, as you were saying. That's where that money came from. That wasn't money that you had deemed that you were going to use for this Program. It was money that you had left over, that, you know, I mean, unfortunately, could have gone to supporting the Program and as far as Outreach and other means.

DR. EVANS: I can say that a significant portion of the money came from the fact that the omnibus autism hearing reduced the number of theories that were adjudicated that year. Yes, that is correct.

MS. HOIBERG: Thank you.

DR. EVANS: Another question was, was this put in the 2008-2009 HRSA budget request? The answer to that is no. Just so you all know, it takes two to three years for budge requests to become approved and final. So right now we are putting in request for fiscal year 2011, so the planning is usually way ahead of time. So this was something that really became viable as the year went on and we realized that we would have some additional money available for a contract.

MS. BUCK: Can you explain that process though? It's my understanding that you provide a budget to Congress, with approval for your particular line item. So then, if you have an overage that you're going to change your use for, so for all intents and purposes you had an overage in your expert witness amount and you've shifted it to fund this contract, you must have some communication with Congress for approval to use your money that way? And I think we've asked for this before, but, can you provide us with that? I mean, how does that process work and where is

the communication back to Congress that your original intent for the funds have been changed?

DR. EVANS: So what Tawny is asking is bullet number three on this and that is was Congress made aware of what we're doing. And for the most part, the scenario that you raised does not happen. But in this particular time, it turns out that, because of the unique circumstances, HRSA budget officials cleared the use of these administrative funds with the appropriate Congressional Appropriations Committee staff in both the House and the Senate and with both majority and minority members.

MS. BUCK: So can you provide us with that just so that the Commission has more than just your word? I'm sorry, but, you know, we are, we have asked for that before, more than just your assurance that that's done. But some, you know, we're being asked for that from the sectors that we represent, some proof.

DR. EVANS: I really don't think that there is proof that I can give you other than the fact that I have now said on record what we did. And if that's not the case, I assume that, why we'll hear back.

MS. HOIBERG: When were you planning on involving the ACCV? And why didn't you come to us and tell us that you were going to do this?

DR. EVANS: Well, I had a kind of a, I can answer that. When we were planning, the basic answer is June, in terms of talking about the process, the adverse events and providing input on that. I did not really appreciate that source of funding, nor the fact the vaccine research issue that was raised, because of course we did not view this as vaccine research. The IOM, when it conducts this, these evaluations, does not do any original research. So tying together the Commission's view of not using trust fund for vaccine research never entered my mind that was an issue. So if that's the basis of your question, in terms of consultation

MS. HOIBERG: No, my question is, my comment is, that, you know, you entered into a contract without telling someone, I'm not saying that you had to ask for our permission that you entered into this, and we were completely blindsided by it. You talked about it, but you didn't really say how it was going to be done and what it really involved and really our name is kind of stamped on it. I guess, you know, I mean, and like Tawny was saying, our sectors are going, what are you doing? And plus, you're sitting on $1.7 million to pay people to read old research? It doesn't make any sense, Geoff, I mean, really. What are you trying, are you going to add injuries to the

Table or are you going to take injuries off, or what is your purpose, what is the purpose?

DR. EVANS: You may have to remind me one of the questions you asked. First of all, let's be clear. The Advisory Commission on Childhood Vaccines advises the Secretary on policy. Okay. It does, you know, it is not, as one commenter said, HRSA can enter into contracts without the knowledge and consent of the ACCV. The ACCV's advice is important. You play a critical role. You will play an increasing role if reforms to the Vaccine Injury Compensation Program are actually, seriously reviewed and put into place in the next couple of years by Congress, and so on.

But we function in our Program under the auspices of the Secretary, and your advice is considered. Sometimes it's taken, sometimes it's not. And some of you are frustrated over the many years that you've gotten letters back saying thank you very much for your opinions and we'll take them under consideration. And that's all that's happened. And I understand that that's frustrating.

But that is no different than what Magda referred to yesterday in a work group meeting, at the NVAC meeting two days ago, where NVAC was also expressing frustration at its recommendations not being followed and its advice not

being listened to and a GSA Advisory Committee Engagement Survey found that there's widespread frustration among advisory committee members on this very fact. So you're no different.

But your role is to simply advise the Secretary. And we don't need to, in order to go forward with the contract, to get your permission or to provide specific details beyond the fact that the activity is going on. And I think there's been some confusion on this point.

MS. BUCK: Just a comment to that. And I'm very clear on our role. And so some of the frustration, and I appreciate what you're doing today, and even some of the things, like freeing up the contract, because, you know, for me it was, very clearly understanding that we do advise the Secretary. And it's hard to fulfill that responsibility when you're not sure exactly everything that you need to know. So I appreciate that you guys have been able to free up that contract for us to look at and get a better idea of what the scope of charge of this project is and the purpose and all that, so that we can do our jobs.

DR. EVANS: Okay. Thank you and I do want to also get to another of Sarah's points. It's an important one. And I wish that this was going to happen sooner, but actually, Cindy, yesterday at the end of the day, dropped a

small little important piece of information that people actually didn't hear very well.

We now have the additional funding for the IOM contract and it was part of the stimulus money. So it means that we're going to be able to double the number of vaccines that are studied and it will be another new set of adverse events that will be coming for consideration in the next couple of months.

But the point being that this project, which is a very important one, one we have been waiting for a long time to have, for it to be underway, is probably not going to come up with a final set of conclusions until mid to late 2011. And then if you talk about a three year process plus for rule-making with public comment, because that's by statute, it has to be six months and there has to be a public hearing too, then we're talking about, you know, you can do the math. Hence, that means 2014 before these things ever get put into place.

It's important that the Table reflect current science. It's important that we have as many injuries as possible on the Table because it provides an important legal presumption of causation. I think what, the final point being, that once the IOM renders its findings, there

will be a very public process. You will be centrally involved in that process.

I would expect that there will be conditions that will be added to the Table as a result. And whether there is anything taken off or not, I don't know. But I think the key thing will be that we'll be able to provide some very updated scientific information in order to make informed choices and apply policy as a result. And the ACCV will be there to do that. Okay? All right, now.

I'll try to not take too much longer. I keep losing the slide here. Okay, so I think that, and I think that I've answered the last bullet, why it wasn't discussed at the November meeting. Just didn't anticipate it. In terms of the remaining things that were asked in the e-mails, I think that the process is, the purpose of the contract is to study vaccines and adverse events, and to both publish conclusions on biological mechanisms as well as to provide some category of the strains of causation, either for or against, for these various adverse events.

As Rosemary Johann-Liang, I'm blank on your last name, yes, Johanne Liang, because Magda started it as Rosemary. As Rosemary talked about at the April 20 organizational meeting on the vaccines that were decided by the Program were based on the priorities for the Program.

Influenza vaccine is, we have many, many cases on the influenza vaccine. Same for Hepatitis B vaccine. Varicella vaccine was added in l997. There's adverse events that potentially could be added that was, that's one of the key reasons why we would like this.

But at the same time, the human papillomavirus was chosen because of the recent publicity over questions of adverse events. And we thought, even though there's not going to be a great deal of post marketing experience, that it would be important to include this, too. So there are various reasons that brought us to choosing these four vaccines.

The additional four vaccines, which I can now say will be studied, are going to be Hepatitis A vaccine, meningococcal vaccine, the MMR vaccine, and DTAP and Tetanus and Diphtheria Tetanus in combination. This will be an update to the MMR. This will be an update to the MMR that was last studied in the 1994 IOM report. So it's been that long.

So I will leave, and I think in terms of the fourth bill, that I think you have now a very rich revisit to the process that's involved once the IOM report is published. And so it's something we can look forward to in

the future. That's it for me. I'm happy to answer any questions.

MS. GALLAGHER: Charlene Gallagher here. I just want to go on record as saying that a group of commissioners worked on this letter and these issues on a rather urgent basis, at a time that I was not available and didn't have an opportunity to comment. I only received this letter after it was sent and I want to make it clear that I would not have written it this way. And so I just wanted you to know that Geoff.

DR. HERR: Geoff, I just want to say that, overall, I think the important thing here is to try to get information on vaccines and the adverse effects. And the idea of starting this kind of a project, however it came about, is exactly what we want. We want to get more information so that decisions that we make and recommendations that we look at, as far as the Vaccine Table, are based as much as possible on science and the best science available. And that's what I think this project brings forth. So thank you on that.

MS. BUCK: Are we in a comment section, or what, can I ask questions, or what are we doing?

MS. CASTRO-LEWIS: We have time to do some questions before the presentation from Dr. Stratton.

MS. BUCK: The Program was not set up to be a science-based, but it was set up to be a combination of science and policy. The initial concerns from the basis of the letter are that a lot of the development of this project went around the ACCV. It looks like we're getting a lot of the information that we have requested now, although there's been frustration in that process. We were told we could not have the IOM contract, but now we can.

The lack of transparency in a process like this creates a lot of distrust. And I believe most of the frustration has come from that. Additionally, this Commission has come out very strongly in stating that trust fund monies should not be used for vaccine safety research and I understand that we will probably have to agree to disagree on that topic in terms of the purpose of this project.

This is the first time this type of a project has been funded in this way. The previous two IOM studies were not funded this way and this is new. This is a new approach to funding a project of this manner and that has certainly created some concern about the intent of it, the nature of it, the duration of it, the potential for this to occur again.

The ACCV prior to us went on record with their guiding principles and if you go through meeting transcripts and minutes, they were very clear on why they established the guiding principles, the type of scientific experts they wanted to be included in this process in when it even came to doing review of literature and existing science, to give them the information that they were seeking to propose changes to additions to the Table.

The guiding principles were to be intended to be forwarded to the Secretary. I don't believe that ever happened. The intent, I think, was to lay a foundation for, I know the intent was to lay a foundation for commissions, as we continue to roll through, to understand what the people before us had intended for this process to look like. And we will all not be here when this process continues, probably.

So to have a rich discussion about the purpose, to have as much information as possible about this process, about your intent, about why it is so uniquely different than how it's been done historically before, is not necessarily an attack. It is laying the foundation for those who are going to proceed us, who are going to have to pick up these pieces and look at the work that was done and figure out how they want to use it to kind of meet with the

goals that have been established from commissions before them.

So the effort to be more transparent is very appreciated. And I think that as long as we can continue to stay in that process, perhaps it won't feel quite so much so adversarial in trying to get information from each other as we go through this.

MS. CASTRO-LEWIS: Any other comments, questions?

DR. FISHER: I think I will go record as saying I agree that an IOM report is not vaccine research at all. It's an evaluation. And that I, I think it does make sense and it is the right way if we're going to make Table changes to have an independent body. It's kind of to me, it's a proven body. I, you know, I don't always like what comes out of it, but, I mean, I think it is a very well-vetted group that does all of the things that we really do have in the guiding principles.

MS. BUCK: Well, if you look at the composition of the group, it has, it's still called the provisional committee. It is made up of quite a few pediatricians and epidemiologists and yet, one of the reasons that some of these vaccines were picked is because they're being used in the adult population.

So, you know, some of that thought was gone into by the prior commissions when they said these are the types of people we want to do the review. You know, I mean, pediatricians and epidemiologists aren't even considered expert witnesses in the vaccine court because they rarely see adverse events and they don't often, they're not experts on them.

So, you know, even when you get into the nitpicking on the make-up of the committee, and I agree with you about the overall concept, but it's those pieces that trouble me because I think that prior commissions were really clear about, okay, if we're going to do this, let's have a really rich group of people doing these kinds of reviews and really qualified people who really know what they're looking for. And I think there can be some criticism on the make-up, the balance of the make-up of the committee. So for me, I think it's more the detail than the purpose.

MS. CASTRO-LEWIS: Okay. If there are no comments, please, Dr. Stratton.

DR. LIANG: You know, I'm also hearing from all of you that you really want some information. And I want to try to provide you with at least the medical aspect of the rationale as to how we're approaching the charge to the

committee. Again, at the end of the day, it is the independent committee that's going to finalize what they're going to be reviewing.

But we from the Program, our primary goal is really the Vaccine Injury Compensation Table needs to be updated. It's been long overdue and really we think that we need to add injuries to the Table because the process of compensation, it really is streamlined when you're doing a Table case. You can actually just say this was the vaccine, this was the injury, and you know, and we look through the records to make sure that medically that makes sense.

And this is the interval of, the time interval that's specified, and therefore we give presumption of causation. It gets right to compensation. And for right now, as you discussed yesterday, most of the cases that we are compensating is off-Table, in a settlement way, and we would like for it to be more transparent and more based upon the latest science.

So it is really been a tremendous effort to try to push this along, to, but what I want to just go over with you, and it's going to take a little bit of time, and you guys can let me know if you want me to summarize it more, or you want me to

But I'm going to actually through with the Commission the charge that was given to the IOM on April 20th because it was, I think many of you were sort of on the phone and it may have been that some of the message that were being charged to the committee may not have actually carried through. So just feel free to let me know if we're taking too much time. You can just tell me to wrap it up, et cetera.

But I'm going to actually, so what went through with the committee, the IOM committee, the Provisional committee, remember that's not finalized either. This is really the beginning steps of trying to get this moved along. I went over with them a little bit of background of Vaccine Injury Table as it currently stands and where we are with that. And then we went through, what our objective is really is to get an independent scientific review.

Again, it's not novel studies that IOM does. They take the body of the literature that's available and really try to categorize or to organize it and try to make sense out of it at the clinical level, epidemiological level, but also at the biological mechanism level because, as you pointed out, some of these injuries are a very rare event and we may not be able to get an epidemiologic

evidence to really come to terms with what actually happened.

So because of the, actually funding issues, we really had to think about what are the first four vaccines that we wanted IOM to think about. And we were hoping that we can actually increase that to eight vaccines, which covers most of the petitions that come in. I'll show you some of the data. So there was an actual, a very rationale, sort of a scientific rationale, that went into why those vaccines.

The scope of work is what adverse events that we would like for the IOM committee to consider. But as we looked at the specific adverse events, it was very clear to us that there are, you know, within the vaccine there are injuries that may relate to each other and across the vaccines there are general themes that keep occurring.

So it was also important not just to look at vaccine injury in the interval, but to also to consider general mechanisms that may be at play or general injuries that may be at play. So that was sort of the overview to them.

And even Geoff went through, Dr. Evans went through this already that the last time the IOM-based Table changes occurred was l997. There were only seven vaccines

covered then. We are now at sixteen vaccines. And there's also a changing landscape of the Program itself, which you'll see on some of the tables, I mean the figures that are coming up.

So you're very familiar with this Table, but this was for the purpose of the IOM committee. We just kind of wanted to go over how this is laid out. And this is sort of a second part. This Table is followed by the qualifications and aids to the interpretation. So, encephalopathy, what exactly do we mean when encephalopathy, et cetera, it's spelled out in the, as you're very aware. But I just wanted to point out those four red sort of items, the vaccines that I put there, this was to show you that in this second page, you see that the vaccines are listed but no conditions are specified at all.

So even if the vaccines are covered, we don't have any way of giving compensation by presumption of causation. And especially those four, they're new vaccines that have been added to cover, but we don't really have adverse events associated with them on the Table.

So this is now going into some of the rationale about the changing landscape. And as, I think maybe it was Tawny pointed out, yes, we are definitely moving, if you look at this, this figure, it shows you in 1998, these are

claims by age bands, we just broke it up, this is what I thought made rationale sense is to how you break up the age bands, and you can see just as the Congress first intended when this Program came into being, that this was really a pediatric-based program.

Ten years later, this is how the landscape has changed. We are reviewing many more adult claims. There's all sorts of different types of neurologic conditions, and if you think about a child with a certain condition but then an adult with all the underlying illnesses, and on top of that, a claiming of injury to a flu vaccine that they get every year, it's a very different type of medical situation that we deal with day in and day out.

So this is the, one of the reasons why we really do need to look at the overall science again, to review it. I know that it's not new studies and certainly, in so many areas of vaccine safety, we need to do new studies. But the breadth and the amount of information that's out there, it's really important.

Sometimes, you can take the same information and depending on how you look at it, you may come up with different interpretations. And that's why it's really important to have an independent body take a look at what's available and organize it and sort of come to, show us the

rationale behind what we think the information is saying. That's why it really is important to do this independent review at this time.

And basically, the objectives are laid out here. We would like for folks to provide us with a framework of categorizing the evidence of causality. We want to know that the strength of evidence that's underlies the biologic mechanisms that may be playing on those theories and because we want to go beyond just theories when we are trying to discuss some injury relationships.

And then to develop a report which would be public that everybody can use. And IOM is not the one that's going to actually change the Table. We would take their review and from then on there will be much work, as Dr. Evans pointed out, to actually get that into rule-making and into change the Table of Injury. Okay.

So, and Geoff touched on this a little bit too, why these four vaccines to start. Now I think we're actually going to have to add the next four. But when we, we started with basically what are the claims that are coming into the Program, all the adverse events, and started with that. And if we add these four vaccines, it's about 50 percent of the current claims filed. And then if

we add the next four vaccines, that will be 92 percent of all vaccine injuries claims filed to the VICP.

So that really is the first rationale. What are the adverse events and which vaccines are being alleged with those adverse events. Okay? So, and these are some of the other rationales as to why these four vaccines were chosen as the first ones to go to be reviewed. And now we're going to be thankfully adding the other very needed vaccines for review. And that's spelled out here.

I'm just going to go a little bit faster here. So we are now at bullet number three, right? We've looked at all the claims that came in and then we went on and asked different sister agencies within DHHS. So certain adverse events, and I can actually show you specific examples if you like. But you have different adverse events that came into our Program but then, especially for vaccines like HPV, there may be claims that are going to be coming down the line that we haven't seen yet. There is a delay in time before a vaccine gets licensed, goes out to the public and then claims of injury happens a couple of years later.

So we also wanted to make sure that people who monitor VAERS, people who monitor VSD and other aspects of the government, also had input into the adverse event list.

An example would be HPV where we have not seen injury claims coming in for hyper-coagulable states yet. But that was something the CDC relief felt should be part of the list. So we are now at bullet number three and the bullet number four, the public comments that can be either channeled through the HRSA channels or directly through IOM, is ongoing so that ultimately, IOM could, they may choose to add to the list were it really finalized depending on what public comments are coming in.

So it is as a, hopefully, a pretty transparent process that we're trying to do here to make sure that we are, at the end, coming up with a product that would be really helpful to the families and to the children, and adults now, many adults. Okay.

And so these are some of the specifics of the charge that was given to the IOM committee and I start off with a general considerations one. This is really looking at injuries that cross many vaccines, such as anaphylaxis. We've found that when we're looking at the actual cases that are coming in, that although right now if you look at the current Table, it specifies zero to four hours, and if you meet that, you get presumption of causation, you go to compensation.

But we've actually gotten cases that are outside of that time interval. What do we do with that? We have to, in that case, actually write a report that says this is causation in-fac, and not as a presumption of causation. It would make things much easier if we can actually have the group look at this independently and say no, let's try to extend this time interval to, you know, zero to twelve hours, or whatnot. Okay? So that's one example.

Let me, some of the other cases that we've seen a lot is actually, we're having older folks who are getting influenza vaccines right into the shoulder. And we're beginning to see that sometimes it seems that maybe it's the way the shot is given. And perhaps there is actual injection into the bursa, which is the capsule around the shoulder, and there is a bursitis, and then they get this complaint of frozen shoulder. Is this something that is really happening?

So these are syncope in adolescence. We see this typically with HPV. But it could happen with other vaccines as well. So these are chronic vision of pain syndrome, something I don't think the IOM ever thought about before. This is another, you know, adverse event that keeps coming up and we would really like for them to take a look. Okay.

Then going through specific vaccine adverse events. Would you guys like to, it's all in your slides. So this is the list for varicella. This is the list for influenza. Just to point out there is the live attenuative vaccine and the inactivative vaccine. And you know, depending on whether something is live, that's attenuated, that's injected, or inactivative, there may be different adverse events profiles. So that's important to know.

I just wanted to point out for influenza, that demylenating neurological conditions is a huge issue. This is something we see over and over again. Someone wanted to know what are the adverse events you are seeing? This is what we're seeing. And this is something that we really would like the committee to consider.

MS. BUCK: Can I, this list that you're going through. This has been produced from cases that you're seeing or settling or what? I mean, I don't really need the list. I want to know where this information is coming from. Everything I've read on three different handouts here that you're consulting with the ACCV on the AE's that are going to be studied. So I need to know where this is coming from.

DR. LIANG: Okay. As I started off in the beginning, the adverse event list that was first put

together for each of the vaccines is exactly from what we are receiving as petitions. Okay? So I can give you, for example, for influenza, demylenating diseases make up 60 almost 70 percent of the adverse events coming in. GBS is the major factor. So that's how we start. It's very concrete. There's no, nobody's pulling anything off the air.

But, as I mentioned before, for some of these vaccines, the injury compensation data that we have may not encompass what may be coming in in the future, especially. So we want to make sure that we ask people who monitor post marketing adverse events, such as the VAERS group and CDC, to see if there's something that we should be adding to the list. So that was the second step that was done. And that's kind of where we are. This is a working list.

Now it's being shown to you guys after we've given the charge to the IOM. And the public or the advisory group comments to the list really is something that IOM will review and they will finalize the list. So it's really not up to us to actually finalize the list. I really think that our charge was to come up with a list that best pulls together our charge, which is to look at the adverse events that are coming in and how we can, in the end, modify and add to the Vaccine Injury Compensation

Table, to give the best presumption of causation to expedite the process of Vaccine Injury Compensation Program.

MS. BUCK: It just, it seems to me like, you know, the program, as it was originally designed, being a both of policy and a science marriage of the two, and you've got this list of adverse events that you see and that you're looking at. I'm not sure why it's your charge to do the scientific certainty piece. I mean, and I know that people disagree with me on that, and I think that answering the questions of scientific certainty on some of this stuff is very important. But I'm not quite sure in a program that's based on both science and policy in determining compensation for a vaccine injury that I get it, really.

DR. LANG: It's not up to us. I think the reason, the list is, as I said, specifically concrete numbers of the petitions coming in. We're not making up the conditions. It's what it is. And actually, the folks who really want an independent body to take that and update us the science on. We're not updating the science on it. We are, you know, doing

MS. BUCK: Are you like looking for affirmation that you're compensating for are indeed correct?

DR. LIANG: It's not looking for affirmation. We want to make sure that when the Table of Injury is updated,

that it is based upon the current science. We want to try to update that Table. That's the primary goal of this exercise.

MS. BUCK: I think having an updated Table is a good idea. But the Program itself is about both science and policy. Your decisions are being made with the two, as far as I have been told. And then in the discussions that we found out about yesterday, where you have litigated risk settlements and things, again, you're talking about both. So, you know, I guess I'm trying to understand that.

DR. LIANG: Right. But the first, the policy piece will come in once a scientific review is done, right? So the IOM is not going to be weighing on policy. They're going to be reviewing what is the current clinical, epidemiological, biological mechanisms evidence underlying some of these adverse events. We're at the very beginning.

MS. BUCK: And I understand that. My statement on the record is that I don't think it's appropriate.

MS. CASTRO-LEWIS: Yes. We have another question from Jeff then we need to move on.

MR. SCONYERS: Can you just tell me what the question is that the IOM study is going to answer? Is it, I don't understand the precise question. Is it whether there is any support in the scientific literature for an

association between the condition and the vaccine? Is it whether there is convincing scientific evidence? I just don't understand the precise question that's being asked and therefore being answered.

DR. EVANS: This is Geoff Evans. Maybe this will help. In '91 and, the '91 and '94 reports, as they were utilized by the Secretary, the approach was as follows. If there was, based on the causal categories, there were two causal categories and one category against causation, the other two were either insufficient evidence or no evidence. So of the two causal categories, causative categories, if the condition was on the Table, it remained on the Table.

If a condition was not on the Table and there was evidence of continued affects, then the Secretary proposed adding it to the Table, almost without exception. So that's the way, and the reverse is true. If there was evidence against a causal relationship and it was on the Table, then the Secretary, in most instances, proposed removal of that condition, encephalopathy being the opposite, the exception.

MR. SCONYERS: You're answering the table question. I'm asking the IOM question. I don't understand what question the IOM is answering.

DR. EVANS: The, I'll let Rosemary go over this again.

DR. LIANG: The IOM is charged, and I think that these are the objectives. We are not giving them, does this adverse event

MS. CASTRO-LEWIS: Can I interrupt you? Is that a good question that probably the recipient of the contract to do this research can answer? What question does she have? What to resolve for the, I mean, she, IOM, what is the scientific question we're having had?

DR. LIANG: Well I don't know. Did you want, this is the scope of the work. What would you like to be clarified? They're going to be looking at the frameworks

MS. BUCK: You're giving them adverse events and then asking them to find out within scientific certainty whether or not they actually have it. Is that what's happening here and why are we paying for that? I don't get it.

MR. SCONYERS: My question is I don't know what frameworks for categorizing the evidence of causality means. I don't know how that to get a report that answers a question. I don't what that question is.

DR. LIANG: Jim, do you want to answer or do you want me to? The body of the literature is vast. I mean, we would like to know when an adverse event is alleged in a patient based upon the review of the current literature,

how do we think through the logic of whether there is an association or not. Okay? So.

MR. SCONYERS: That's a methodological question. So are you asking the IOM to give you a methodology ?

DR. LIANG: They're going to be - maybe you can talk about the workshop that's coming up in June.

DR. STRATTON: Rosemary, do you have the exact paragraph of that statement? I thought Rosemary was going to have it in her slide, so I don't actually in my slides have that three sentence statement of task.

DR. LIANG: Well this is just a short version of what's listed in the Statement of Work, right?

DR. STRATTON: Right. But what, I'm paraphrasing slightly because I fell asleep and didn't reproduce it on this because I thought Rosemary had it. We didn't coordinate beforehand. The committee is asked to look at the epidemiologic, clinical, and biologic literature bearing on,

PARTICIPANT: Is this a specific study, causality?

DR. LIANG: Okay, so this may be a little bit of a tweaked wording too, but what I have is please develop a framework. So it is a framework for assessing the evidence regarding biological mechanisms supporting or refuting theories regarding adverse events associated with vaccines.

That's one objective. Next, conduct literature review on the relevant epidemiological and clinical literature bearing on the causal relation between each specific vaccine and specific adverse health events.

Thirdly, please hold a workshop to review select theories regarding vaccine to adverse event relations where the strength of evidence regarding biological mechanisms underlying theories are described. Finally, develop a report which brings together the epidemiological, clinical, and biological literature on the current evidence regarding adverse events associated with vaccines.

So it is, it's a framework to think about how to think about causality. I mean, that's needed to actually provide a rationale as to why we think a certain adverse event may be causal from a certain vaccine.

DR. STRATTON: If I may, the, some of what is in that Statement of Task are the steps to the ultimate product, okay, which is, are, you know, a report that summarizes the strength of the evidence about vaccines and adverse events, whether it's epidemiologic literature, whether it's clinical literature, whether it's biologic literature. Animal studies, in vitro studies, other sorts of non-epidemiologic or clinical trial kind of studies.

In order to do that, the committee has to decide what, they haven't yet because they've only met once, which I'll get to in a second, what kind of categories, what kind of criteria, what kind of language are they going to use? There's a history in the '91 and '94 reports of the five categories and the wording, which actually changed from '91 to '94.

This committee can choose to keep that same set of wording or they can change it if they don't feel that that's the best way to describe it. They will define, as best they can, as clearly as they can, what does it mean to be in category four versus category five? What kind of evidence do you need to say it establishes causality or it favors acceptance of causality if we use, I'm not answering your question.

MR. SCONYERS: Well, I think you are and what it sounds like is the first task is to define what causation means and then to answer the question whether causation exists. So this, I'm sorry, it seems fairly epistemological to me. As we've had multiple conversations at this Commission, there are lots of different meanings to the word cause. And it's sort of interesting that you're going to define what cause means, but I guess I would have hoped that the Program knows what cause means in the

context of the Act and was asking you to answer the question as to the meaning that's being applied, since this study presumably is going to be used to administer the Act.

DR. LIANG: That's, okay, so I don't know if we're trying to ask IOM to define what cause is. It's in relationship to the evidence, the amount of evidence that underlies the association or the causal relationship that it's going to ultimately say in the report with these facts and these adverse events because that's really important because in medicine, you have different levels of evidence. Your clinical trial data, where you're doing a perspective with a randomized cohort, randomized subjects with control, the evidence that you get, that's where you can ultimately say there was really a causal relationship between this and the outcome.

After that, you know, the epidemiologic evidence, the biological evidence, observational studies, cohort studies, we really need to know when an IOM does a literature review because you're going to have all these types of studies on hand. They really need to define for us, they are making this type of statement after a review of everything based upon what levels of evidence.

That's the framework that we're looking for. And the language, we don't want to tell them this is a language

we want you to use either. We would like for them to independently come up with how they're going to have a framework of assessing the evidence that's in the literature. This is not trying to wordsmith or anything. This is a very, I think, scientifically speaking, I think we think in this way, what is the level of evidence that belies this sort of, you know. So that's really what we're asking. Does that make more sense? We're not trying to come up with a causal

MR. SCONYERS: I'm always alarmed by scientists and physicians who think that words only mean one thing. That's what I hear going on here. But I think I understand what you're saying.

DR. SALMON: If I could just ask a question for clarity. My understanding is, and perhaps you can confirm this, is that when the IOM is looking at causality assessment, you're looking at the scientific standards for causality assessment. You're not considering the types of causality assessment that may be done, for example, by the Injury Compensation Program. So you raised I think, earlier yesterday, an interesting point, that there's a lot of confusion because there's various definitions of causality. But my understanding is, and please correct me if I'm wrong, that what the IOM is doing is scientific

causality assessment. It's not considering the application to a compensation program. It's not considering the policy issues. It's strictly scientific standards. Is that correct?

DR. LIANG: Well that's exactly, so that's why it's the very beginnings of what's to come. We really want to first start with what's grounded in science because that's, in the end, ultimately fair to everyone. But obviously, that first step is going to be used in the end to administer the Program. But there are many steps in between with, you know, with policy coming in and, sure, wrap it up.

MS. CASTRO-LEWIS: I'm going to have to hurry it up a little bit. Charlene you can ask a question and then we're going to have to

MS. GALLAGHER: Okay. I started out as a scientist and then in a detour I went to law school. So I understand that there are legal definitions of words and there are scientific definitions of words and then there are also ordinary human discourse. And they can all use the same word and mean something different. I guess what I'm gleaning from this discussion, and you can correct me if I am wrong, is it reminds me of when you're doing a clinical study and you're monitoring what's happening and

you see some adverse event. And you have to, as an investigator, come to some conclusion with very, very limited information.

And so you say either possibly related to whatever substance is being studied, probably related, or definitely related, or not related. And you come to these conclusions based on whatever is available to you at the time. Now there's a lot of information that goes behind you coming to these determinations.

And what I think the Institute of Medicine is trying to do is take all the information that is out there in the public arena and trying to categorize things sort of in that way. The policy then comes in when you decide whether or not possibly related, probably related, and definitely related all get compensated. Or do you just go with two of those categories.

And so I think that it is really a useful exercise and that you need some scientific basis in order to make the policy decisions. And so it may be the policy will be if somebody thinks it's possibly related, that would be enough to trigger compensation in the minds of people who are making that determination, although science couldn't say for sure. And so that's just my summary of what I think I heard here.

DR. LIANG: Just to add that though, even within those broad categories of possibly, whatever, it would be important to have the science and the evidence for each of those categories and what the level of evidence that was so that we can use that to really be consistent and fair as, so that really is important. That's what we're asking IOM to do, is really the first steps of the science that's currently available because it's been a long time.

MS. CASTRO-LEWIS: Okay, I love the discussion and I bet everybody also liked it. But we've run out of time, unfortunately. I would like to suggest that, I apologize with Dr. Stratton that after all we didn't get to do her presentation. Several people need to take, you know, leave at noon to leave the city. So what did you think? I'm just going to ask you, would you like to put our next minutes as what we have in the agenda items for the next meeting? Would you like to continue to meet and dedicate more time for it and is that something we would like to do?

MS. HOIBERG: This could take like an all day meeting to absolutely go through everything that needs to be gone through and questions that need to be answered. And I don't think it should be rushed. So yes, I think that it should definitely be on the agenda for next time.

MS. CASTRO-LEWIS: Anybody has another? Anybody agrees?

DR. HERR: Yes. If we're going to be asked to decide to put things on the Table or what goes on the Table or doesn't, or I'll say not decide but make suggestions or recommendations, then I think that we need to really be comfortable with the methodology of how it's going to be decided so that when we do get that recommendation, we have some, we can make some sense of it, feel comfortable with how it was arrived.

MS. CASTRO-LEWIS: Yes, and then understand how we're going to use it.

MS. HOIBERG: Exactly and the IOM will have more information, yes, by September. You'll have more information or have done more.

DR. STRATTON: But by September, I'm not going to be able to tell you a whole lot more than I could tell you now, but I'm willing to come back when you have more time. We will probably, because I understand we're getting more adverse - more vaccines, we'll probably have more adverse events and more committee members, so that, you know, they will have had a workshop. I can sort of tell you about that and I can think about the questions that were raised here today. Although, I think I knew them before and see

if I can answer them a little more specifically in terms of where the committee's thinking in going, we don't share that. But I would certainly welcome for as long as you want.

MS. HOIBERG: What I would like to comment on and, I mean, maybe it's just me as a simple mom, but I want to know that you're looking at newer vaccines. What type of information are you going to be able to get or obtain from something that there really isn't any research out there? So there needs to be research done in order for you to make an educated decision.

So I feel that that, in a way, is wasted time on your part because you're just going to be reading things that have already been published that there not considering the paralysis and all of that, that information. There's not enough information on those vaccines in order to create a Table

DR. LIANG: What we can do for the next commission meeting is, now that we're going to be expanding the four vaccines to the eight vaccines, we'll be working on gathering data to see what are the injuries that have been coming in for the other four vaccines. So by that time, hopefully, we will have that initial list for that and then you guys can, you know, we can talk about what we

have thus far and go on from there so that you'll be coming a little bit earlier than the first four vaccines. That would be

MS. CASTRO-LEWIS: Okay, two more questions then we need to wrap it up.

DR. FISHER: When you were talking about the different types of adverse events, one of the things you said was if a vaccine is administered improperly. So I just wanted to clarify how that would fit. For instance, if somebody gave a vaccine intravenously, which is not the way it's supposed to be given, or they actually gave it into a joint, I mean that to me seems a different, a different way to go than adverse events following appropriate immunization. So I don't, would this program compensate people for inappropriate administration or does that go down some separate pathway?

DR. LIANG: That's a big issue, a big topic. It's different, it's, but to answer your question. We are compensating but there are, we need to really have a legal discussion about that, case by case.

MR. SCONYERS: The question I want to ask and if we're going to have this again, I'd be interested to hear how you're taking into account individual genotypes. So what I understand is that in at least one case that's been

compensated under the Program, an existing mitochondrial disorder led to compensation. Obviously, if the evidence is that in the bulk of the population a condition isn't caused by vaccines but there are individual genotypic differences that lead to those, I just, don't know whether there's literature on that, but I'm very interested because that seems to be where some of the science is heading. So I'd be interested to hear how you're going to

MS. CASTRO-LEWIS: Okay, Dr. Evans thank you so much for your effort in response to all the questions of the Commission and Dr. Liang, thank you so much. Dr. Stratton, we look forward to seeing you again in our next meeting. We're going to move quickly to the public comment. Operator, is there somebody that would like to do a comment?

Agenda Item: Public Comment

OPERATOR: Thank you. If you would like to ask a question or have a comment, please press star one on your touchtone phone. Again, star one on your touchtone phone.

MS. CASTRO-LEWIS: Is there nobody, apparently?

OPERATOR: I'm showing no members from the audience in queue ma'am.

MS. CASTRO-LEWIS: Okay, thank you so much. Anybody from, present here, would like to, that has

questions or comments, please? Yes, you come please to this one.

MS. DEBOLT: Hi, my name is Vickie Debolt and I'm here representing the National Vaccine Information Center. I have a just a general methodologic question. When I was looking through the list of adverse events, potentially related to specific vaccines, how are you going to deal with the issue that more often than not vaccines are administered in combination. So how do you attribute, you know, an event to which could actually be the result of some type of a synergistic effect because it's not just Hepatitis B vaccine or HPV that's given, it's HPV Plus, Meningococcal Plus.

DR. STRATTON: Vickie, your point, of course, is a good one and I don't have the answer to that because that's a committee decision. They've only met once. They're only beginning. We have a two year process ahead of us. They're aware of that problem, will they know that and that will come out in the studies. I don't know how they're going to tease that apart, but it's a very, very good point and it's a problem.

MS. DEBOLT: Okay.

MS. CASTRO-LEWIS: Thank you. Mr. Moody, you have also a comment, a question?

MR. MOODY: Thank you. Thank you for the opportunity to make a comment. Oh sorry, Jim Moody from Safe Mines. First thing is that in terms of the very good discussion that was going on about the charge to the IOM committee, I think it, you have to come back to the purpose of the program, which was to protect, both the efficacy of the vaccine program and to ensure the moral responsibility to people who are injured in this war against infectious disease by resolving doubt in favor of people seeking compensation. Meaning by doubt, I mean scientific doubt.

And so the standard, the evidentiary standard of the IOM committee should use is the standard designed by Congress and the standard suggested by the courts most recently in Althem and Compazono, which is biological plausibility.

And if I understand the charge to the committee, it's going to be looking for evidence of biological mechanism, which is a much, much higher scientific standard than is required under the Program, which is a more lenient, relaxed standard of biologic plausibility. So unless the IOM panel is tasked with looking at the standards set by Congress, at best it will be just a waste of money because someone won't be able to inform this committee and the Secretary as to how to redesign the Table.

The Table is the heart of the Program. As the Table has been gutted in the ‘90’s, we seen more and more injuries being handled as off-Table cases and that won’t help the people in the agency do their compensation mechanism if more and more of these cases go to court.

The second thing I’d like to point out is that the IOM committee needs to look at autism or at least the biological injury that manifests as a behavioral diagnosis of autism. More seriously, the courts have been compensating autism cases under the Program since l991. Sir Michael Rudder in a paper in l994, an English gentleman, identified autism as a vaccine injury, well before Dr. Wakefield ever got around to the topic.

Most recently, the courts compensated the Banks’ case, which was adem(?) leading to autism. The Poling case is, of course, very famous. The committee in, this committee, needs to take seriously what factors separate vaccine caused autism from other possible causes of autism. Address that because there’s still 5,000 cases pending in vaccine court.

The public confidence is sort of at a tipping point now. There’s a Zogby International Poll that showed it was 55 percent of the public thinks that either vaccines cause autism or aren’t sure. And ACCV is challenged to get

out in front of this wave of public confidence concern before it erupts in a mass vaccine revolt. Thanks very much.

MS. CASTRO-LEWIS: Thank you so much. Okay. Anybody else? Any other comments? Future agenda items. Couple of our Commissioners left but for who is still, we can discuss that. I think the first item will be to bring back the panel that we had for the discussion that, on the IOM study. Any new items that you would like to include in the next agenda? No? Okay.

MR. SCONYERS: What's the outcome on outreach? Is there further work that's going to be done on that?

MS. CASTRO-LEWIS: Yes, we'll continue working. We will have an update on that. Yes, the agenda committee, I just ask Tom Powers if he will be in the agenda committee and I have to vote with Sarah. But because she left, I couldn't do that. But Geoff, what is the rule for the, regarding Jeff, Tawny, and Tammy? I don't want this to be their last meeting without recognizing. I believe there's nobody else, so please let us know what's --

DR. EVANS: We have not received any word yet on the status of the nomination package that has gone up. As you know, Secretary Sibelius was confirmed, I believe in March, so everything that is, flows as a result of a new

Secretary and all the administrative kinds of things gets slowed down a little bit, but we will keep inquiring. In the meantime, I would hope that you could make reservations, Jeff, Tammy and Tawny, to join us in September until further notice.

PARTICIPANT: Yes, thank you.

MS. CASTRO-LEWIS: That is what we want to hear. Okay. If there is no any other questions or comments or

PARTICIPANT: I move we adjourn.

MS. CASTRO-LEWIS: And second?

PARTICIPANT: I second.

MS. CASTRO-LEWIS: All in favor? Okay. So meeting adjourned. Thank you, Geoff.

(Whereupon, the meeting adjourned at 12:00 Noon)