DEPARTMENT OF HEALTH AND HUMAN SERVICES

SEVENTY-THIRD MEETING OF THE

ADVISORY COMMISSION ON

CHILDHOOD VACCINES

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P R O C E E D I N G S

Conference Call Operator: Thank you for standing by and welcome to the 73rd quarterly meeting of the Advisory Commission of Childhood Vaccines. I am going to turn the meeting over to an ACCV Chair, Ms. Magdalena Castro-Lewis who will convene the meeting.

Agenda Item: Welcome and Unfinished Business from Day 1

MS. CASTRO-LEWIS: Okay, again, good morning. We have a couple of unfinished business from yesterday and I think Charlene would like to bring up an issue that she would like to discuss.

MS. GALLAGHER: This is Charlie Gallagher and I just wanted to make a clarification of some statements made by Mr. Schumacher yesterday. I recognize that he is not a scientist. He is not scientifically trained and there are some common misperceptions or misunderstandings of what the EPA reference doses are. I checked it out last night and I just wanted to provide you with the information that I was able to glean on the subject.

The EPA reference dose for methyl mercury is very much discussed and it is an exposure guideline for methyl mercury and that is the zero point one micrograms per kilogram per day standard. This reference dose means that an individual can safely consume zero point one micrograms of methyl mercury for every kilogram of body weight every day over an entire lifetime without adverse consequences. So there are three factors that I just wanted to clarify. First, it is not an instantaneous or short term exposure limit and so the way the calculation was done that was expressed yesterday is not in keeping with the way a scientist would do such a calculation. It does not have anything to do with what an individual's exposure in a single day can be and it really has to do with every day of a person's lifetime.

Then the other important thing is that methyl mercury and ethyl mercury are not the same thing and ethyl mercury is what they find in fish who have been exposed to mercury. Ethyl mercury is released upon administration of thimerosal containing vaccines and it is metabolized much more quickly and therefore is less of a concern to scientists regarding exposure. They are quite different and you can read up on it or study up on it if you wish.

I am also advised and this one I do not know for sure, but I am told that the way they did the calculation for the RFD for methyl mercury was once they reached the value they published a limit that was ten times less than the value they calculated because they wanted to be sure that they had a safety margin for anything in matters of uncertainty that scientists cannot really deal with. So I know this is not the proper forum to debate EPA reference doses. I just wanted to put clarification into the record and I did not want members of the commission to be confused by the discussion yesterday and I plan to, there is a paper I can get when I am back at my office. I will plan to send it in and we can put it into the next booklet and then everybody can read for themselves about it and what they think about it. So think you very much for giving me the time.

MS. CASTRO-LEWIS: Thank you, Charlene. I think that is an important clarification and I think it would be very good to put that paper in the next book. Being misinformed is not what we need at this point. Thank you so much.

Okay, we will review that later on just to pick up on the assignment of the working groups, but for now then let us go to the second item in the agenda.

Agenda Item: Update from the National Vaccine Program Office (NVPO)

MS. CASTRO-LEWIS: Is Dr. Salmon on the line please to give us an update from the National Vaccine Program Office.

DR. SALMON: Yes, I am on the line. Can you hear me okay?

MS. CASTRO-LEWIS: Yes.

DR. SALMON: Thank you for the opportunity to provide an update. I am sorry that I cannot be there in person. I would like to update the commission on two areas. The first is the development of the National Vaccine Plan and the second is the work of the NVAC Vaccine Safety Working Group.

In terms of the National Vaccine Plan I know that you folks have heard from Ray Strikas and had a fairly detailed description of the intention and the process for developing a National Vaccine Plan so I am going to provide a very brief update on what it is and focus a bit more on the process for moving forward. Just as a reminder, this is a strategic national vaccine plan that is updating the 1994 National Vaccine Plan and the intention of the plan is to provide a national strategic framework for vaccine activities for the next ten years.

There are five goals of the National Vaccine Plan in its current draft. Goal one is to develop new and improved vaccines. Goal two is to enhance the safety of vaccines and vaccination practices. Goal three is to support informed vaccine decision making by the public providers policy makers. Goal four is to ensure a stable supply of recommended vaccines and achieve better use of existing vaccines to prevent disease, disability and death in the United States and goal five is to increase global prevention of disease of death we face in effective vaccination.

The plan has been drafted and NVPO has contracted with the Institute of Medicine to provide some feedback in terms of priorities. We have gone through a very extensive process of public engagement including receiving nearly 500 comments on the plan. I am going to focus my comments more now on those comments and the process for considering them and how we move forward.

So the National Vaccine, we received almost 500 comments on the

draft plan. Those comments were received by advocacy groups, global health advocates, individuals including the general public and academics, industry including insurance companies and vaccine manufacturers, international comments from representatives of governments and WHO as well as healthcare professional organizations. Each of these comments were then sorted by the goal and the comments were then sent to a working group across agencies focused on each goal. That included people from CDC and NVPO, FDA, NIH, HRSA, USAID, COFDA.(?) So for example all of the comments that were focused on safety went to a working group that included the safety, most of them but not all of these groups and those were groups devised comments providing rationale for including or exclusion; made recommendations, revisions for the next draft of the plan.

Now the criteria for inclusion of comments included feasibility, non-redundancy, consistency with activities and plans relevant to the strategic plans. Each goal working group also updated considerations for priorities of each goal and reviewing the indicators that were put together for the plan, develop time lines and metrics for measurement. Each comment was disposed of or was put into one of six categories. Either the comment was accepted as suggested. It was accepted with modification. Some were not accepted. Some were determined to be considered elsewhere instead of in the implementation plan. Having done this for safety, many of the comments which were received were very, very specific often excellent comments, but where really the implementation plan focused and not sort of our larger vaccine plan. There were a lot of general comments which really did not warrant action, but were informative and then there were the more occasionally comments that were related to more than one goal.

In terms of the IOM expert committee process and timeline, the IOM has held workshops with national experts, stakeholders in medicine, public health

facts analogy and they reviewed publicly available to the publicly available National Vaccine Plan and the committee will prepare a report which includes the recommendations without prioritization in actions within the major comments of the plan.

We are expecting a final report from IOM to NVPO in November of 2009. In terms of the overall timeline, by the end of August federal agencies departments met and discussed the revised provision process which I already described to you. Between now and November 30th, Rand is holding interviews with a sample of stakeholders to provide further input. The September 15th NVAC meeting there was discussion on how that will incorporate stakeholder input on the final National Vaccine Plan. By the end of November we anticipate having the IOM report to us. By mid December, it is our intention to be able to respond to, send in a response to the IOM report and by the end of December there will be a process established to complete the National Vaccine Plan with stakeholder input using inputs from the NVAC plan to the IOM.

Let me stop there. That is all I have prepared to talk about the National Vaccine Plan, but I am happy to take any questions on that before I move on to the National Safety working groups.

OPERATOR: If anyone would like to ask a question at this time, please press star one on your touchtone phone. One moment for the first question.

MS. CASTRO-LEWIS: No, there are no questions from the party at this point, from the here from the members of the ACCV. So, any questions from any of us to them? Well, it doesn't seem like there are any questions. Thank you again, Dan.

DR. SALMON: Yes, let me just finish my report and give you a very short update on the NVAC Safety Working Group. You already received a fair

amount of detail on this before. They had completed the first charge which is a review of CDC's Immunization Safety Office research agenda and they moved into their second charge. The second charge is to look at the vaccine safety systems at a much higher level and more broadly. Specifically, the charge is to review the current federal vaccine safety system and to develop a white paper describing the infrastructure needs for a federal vaccine system fully characterized for safety profile and vaccines in a timely manner, reduce adverse events whenever possible and maintain and improve public confidence in vaccine safety.

You have already, I think several times now, the members of the working group as you moved into the second half. We added two new co-chairs to the first half who chaired entirely, I am sorry bear with me one minute. The current chairs now are Tawny Buck who I am sure you all know as she was your former co-chair at the ACCV and the co-chair, Marie McCormick is also joining Andy as they have tri-chairs. I am not sure that is the right word, but the three of them are chairing the group. We have also included the public representatives from VRBPAC, which is the key to all as well as from ACIC so we have extended the membership a bit to try to draft the second charge. We also included Bill Raub. Dr. Raub was the former Deputy Director of NIH and was most recently before retiring an advisor to the Secretary on scientific issues and often focused on vaccine safety. So we expanded the membership just a bit to try to address the second charge.

We held a kick-off meeting on July 15th and 16th. This meeting was informational gathering and included five panels. The first panel focused on policy and principle alternatives for robust vaccine safety systems. The second panel was looking at identifying innovative ways of overcoming gaps in vaccine safety science and infrastructure. The third panel was focused on the ideal safety systems vis-à-vis the public health and healthcare professionals' confidence in vaccine safety. The

next session, number four, was focused on lessons from other safety arenas and the last session was focused on enhancing the adaptation implementation of the NVAC white paper. The individual panelist members are listed on our website so I won't go through them with you name by name, but it was really a fantastic group of people. They included leaders in thought of vaccines and vaccine safety such as the American Academy of Pediatrics, academic researchers. We have heard from representatives from the National Transportation Safety Board, Chemical Safety Board, and other arenas of safety to try to see what lessons we could learn broadly from them. It included people that had historically been critical and federal vaccine safety efforts so this is really an opportunity here to a very, very broad range of people.

Some of the topics for discussion that were consistently or often discussed in these meetings and I go through this list just to give you a flavor of what was discussed. This does not reflect ACCV's or NVAC's views on the issues, but they are just a summary of the kind of issues that were discussed by these panelists. Some of the issues were things like characteristics of an ideal safety system would include things like transparency, reducing conflicts of interest, public participation, coordination effectiveness, timeliness, evidence-based decisions, focus on prevention of adverse and responsibility and respectful adhesement with all parties. Other major topics included independent safety boards, a need for more basic research, a need for more funding, new data sources including both passive and active surveillance, the potential value of genomics and the need for root perception and communication research. There was a lot of discussion about resources and the availability of resources and resources needs. This is not a preview of, necessarily where the NVAC is going with this, but rather this is what we heard from the panelists.

There has been a fair amount of discussion within Vaccine Safety Working Groups over, or since that meeting, including discussion of a possible immediate recommendation for reprogramming of funds to vaccine safety data link and to the clinical immunization safety assessment network as well as increase in the funding for vaccine safety in the President's 2011 budget. Ultimately the Safety Working Group while discussing this quite a bit decided it was premature to make a recommendation for targeted funding, but there was a fairly strong consensus that there was a need for consideration of funding issues.

In terms of moving forward to the Safety Working Group is developing a plan that outlines the process forward. There are five subgroups being developed and this was the process that was used for their task one report where they broke into subgroups based on expertise. Those five subgroups will look at structure and governance, epidemiology to detect quantifying exam and causality of vaccine adverse events, basic and laboratory science in genomics to understand the biological mechanism, risk factors for adverse event, implementation of the white paper and then stakeholder engagement.

In terms of process and product, these subgroups will do additional information gathering outlining the issues and proposed recommendations for NVAC consideration. The thinking is that there will probably be a series of reports rather than one single very thick report depending on the timing as each of these moves forward. They may not move forward at exactly the same speed. Hence the reports will likely be phased in, in the upcoming year with a goal of receiving all of charge two by September 2010.

I am going to stop there and I will be happy to answer any questions that people may have.

MR. SCONYERS: Dan, this is Jeff Sconyers. What is the timing on, I

think you said at the end, but I just didn't get it, what is the timing for the report or reports?

DR. SALMON: The hope is that this entire task will be complete by September of 2010. I think that people realize that is a fairly aggressive timeline to complete all of this work. One of the areas the Working Group is struggling is they want to be careful and thoughtful as they move forward. On the other hand, there is a certain sense of urgency that we don't want to wait five or ten years to figure out how to move forward. So they are trying to balance the timeliness issue with the ability to really have a thoughtful and complete review.

MR. SCONYERS: Thanks.

MS. TEMPFER: Again, this is Tammy Tempfer. I just have a clarification of that. Do you mean by September of 2010 we will actually see the white paper?

DR. SALMON: Yes, as I hope I clarified white papers or papers because they are moving in the direction of rather than having a single report having several papers come out and the hope is that they would all be complete by September of 2010 and for NVAC consideration at the September 2010 commission.

MS. TEMPFER: Thank you.

MS. CASTRO-LEWIS: Any other questions before we move on? Any other questions?

DR. EVANS: I have received an email suggesting people speak directly into the microphone because the listeners on the phone cannot hear.

MS. CASTRO-LEWIS: Okay. So, if there are no more questions, thank you so much, Dan, again. We are moving on to our next item in the agenda and Sarah is going to give us the report from the outreach working group.

Agenda Item: ACCV Outreach Workgroup Report

MS. HOIBERG: Good morning, every one. This is Sarah Hoiberg. We are working right now on a contract to be able to continue without outreach and we are very excited about that. Thank you very much, Geoff, for pushing that forward. So we will have more information. It is a work in progress. However, I am going to turn the floor over to Meg first who was able to get some information about the program into some very important letters. Okay?

DR. FISHER: So, my job is relatively easy. The outreach group put together really a very succinct perfect paragraph that everyone on this committee had the opportunity to review and comment on. My job was simply to get that published in different places. To date, it has been published in the section of "Pediatric Infectious Disease Newsletter" where it is on the second page. It is also going to be incorporated into the revision of the American Academy of Pediatrics' website regarding immunization so it will be right on that website which is a public website and also a website that is used pretty much by a fair number of pediatricians and other people caring for children. It is also on the New Jersey chapter of the American Academy of Pediatrics website and is being email blasted out to the pediatricians in New Jersey this week.

So that is as far as the distribution. If anybody has other suggestions of where that can go, I sort of used my contacts. Oh, the other place it is, I wrote a concise review of pediatric infectious diseases for the "Pediatric Infectious Disease Journal" and it was about novel H1N1, but at the end when I talked about the vaccines I included this paragraph as the last paragraph. I am just saying that vaccine compensation is important when we talk about any vaccines that we give. So it is also will be in that. That is distributed not only to pediatricians, but to a number of people who care for children. It is considered one of the journals that is very readable and concise reviews is in the middle of the journal. It is called the blue

pages. That will come out in the October or November issue.

MS. HOIBERG: Thank you so much, Meg. I really appreciate it.

MS. CASTRO-LEWIS: Meg, what is the readership of the magazine? Do you have any idea how many people actually receive this magazine?

DR. FISHER: Certainly in excess of 10,000. I would guess it might be a 100,000 but I honestly do not know the circulation numbers, but it is the journal of the Pediatric Infectious Disease Society and that includes all of the pediatric and infectious disease doctors which is not that many, but it is considered, most pediatricians consider themselves, or consider that they need information in infectious disease so this is one of the journals that they tend to subscribe to.

MS. CASTRO-LEWIS: I tell you for the recorder it would be a good idea to keep records of those magazines and all the issues that we have all of the magazines and the papers where we have the write-ups. You can keep it in the book.

MS. HOIBERG: Thank you. Then Dr. Tom Herr is working on a project with Geoff Evans.

DR. HERR: Hi, yes we are just working on a little bit more flushed out version of the that letter that, or that paragraphs that was prepared for the last meeting and I have been working with Geoff as far as putting in the correct acronyms and website addresses and things like that so that we should have that available for the next meeting. What we can do is have it and as soon as we get it available, circulate it so that we can then send it out. The problem is it will be going in the Academy of Pediatrics perhaps for their AAP news. It will be reviewed by them. That is a little bit more time intensive review. So it won't be able to get out as quickly. However, I think that the circulation might be a little bit larger just because it will go to all pediatricians.

DR. EVANS: I just wanted to add that in the context of the AAP news, it could very well be that an article that expanded a little further on the fact that there is now going to be the CICP and to alert pediatricians the presence of both programs and be clear on the distinctions between one and the other. I think that is something the AAP news probably would be very interested in getting out in a timely manner.

MS. HOIBERG: Thank you very much. And of course, as always, if there are any other suggestions, we are willing to hear them, but with this contract and I have not really got a chance to read it. I apologize, but we will be able to work a lot more and get a lot more of information out so thank you, Geoff.

MR. CASTRO-LEWIS: Any questions for the set up for the working group?

MS. TEMPFER: Yes, could you just clarify again what is the purpose of the contract?

MS. HOIBERG: I am actually going to hand that question over to Geoff. He can answer that better than I can.

DR. EVANS: Actually there is no contract yet. What was distributed publicly was a request for proposal for bids on a contract that will be signed hopefully within the next week or two before the end of the fiscal year, so that is what, copies of that were distributed to the work group and once the contract is signed we will be able to, to the extent that we can, furnish the information on that and of course we will have an ongoing update as the contract unfolds. The purpose overall is to help our program develop an outreach plan; a multifaceted outreach plan to the public for both the general public and parents as well as healthcare providers.

MS. TEMPFER: Can you tell me who the contract is with?

DR. EVANS: We cannot do that yet until the contract is signed so we are still in the stages of negotiation on that.

MS. GALLAGHER: Can I just ask for clarification? So the request for proposal was asking groups who are good at designing outreach plans to help you design the outreach plan. Then once it is designed then we would have to find funds for implementation?

DR. EVANS: Well correct. It is a one year contract and once it is put together the thinking would be that we would be able to within our budget which I will also say that we seem to be doing much better these days in terms of the President's budget and receiving administrative support for running the program. We are optimistic that we will be able to devote a reasonable amount of monies for the outreach kinds of projects, activities that will be part of this contract as it unfolds.

MR. CASTRO-LEWIS: Any other questions for the working group? Nope? Okay, well thank you so much today to the group and I made very specially that move forward in getting this information and putting it out there and hopefully we will continue to do, doing these kind of increasing awareness of the programs which is where we very much need.

Okay, so the last meeting we had to, due to time, we left our presentations and the discussion on the IOM study halfway through so we are going to continue today. First we are going to have Rosemary, if she is still on the line, to do a brief on the report and then after that we will have Dr. Stratton further discussing the proposal.

Rosemary, are you there? The line operator, does Dr. Rosemary Johann-Liang is there?

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

DR. JOHANN-LIANG: Hello, can you hear me?

MS. CASTRO-LEWIS: Yes, yes we can hear you now.

DR. JOHANN-LIANG: Okay, great. I had trouble hearing you all, but I am hoping you can hear me. Okay, good morning.

PARTICIPANTS: Good morning.

DR. JOHANN-LIANG: I am just going to open this session with some brief remarks and then turn over to Kathleen Stratton to give you all an update on what is happening with the HRSA IOM study.

As we discussed during the last ACCV meeting in June, the end purpose of this IOM review is for the program to update the current table of injury which gives the presumption of causations for the petitioners. This table has not been updated since 1997 and we are long overdue. The IOM will provide us with an independent review of the current science in regards to the average event of certain vaccines that are covered by our program.

We started with four vaccines you should recall for review: influenza, hepatitis B vaccine, human papillomavirus vaccine and varicella vaccine. I am happy to report today that as was promised by our CDC colleagues at the last ACCV meeting, additional funds have been transferred to HRSA from CDC and the paperwork finalized as of this week to add the review of four more vaccines by the committee and those are meningococcal vaccine, diphtheria tetanus, Acellular pertussis and other tetanus containing vaccines, hepatitis A vaccines and the measles, mumps, rubella vaccine. This will actually give us an updated scientific review of twelve of the sixteen vaccine antigens or three-quarters of the vaccine antigens covered currently by our program.

Just as a refresher, we followed the following process to generate so this of average event for each of the vaccines to be reviewed. This is what we did for the first four vaccines. To begin, we seek data and inputs from each of the medical officers: the physicians for reviewing and the actual case materials that comes

through our program. Concurrently we search our administrative data base to get the actual data on the frequent alleged adverse events for each of the vaccines that we received. Using these data we generated initial adverse events draft list. That draft list was then circulated via the interagency vaccine group to other agencies and we received input from CDC and FDA. The modified list then was given at the charge to the IOM in April. Since then they have posted the average event list on the website to receive public comment. Public input is ongoing. They continue to receive pubic comments and IOM can add after the list based upon the public comment and also if they find that there were some adverse events that we had missed so far.

Now that we have funding in place for the next four vaccines, we will walk through the same process to generate a list for the IOM review in the coming months. I find that the next ACCV meeting and walk through the actual list with you because hopefully by then pubic comments should be open for all vaccines and average events for all of these vaccines will be under review by the IOM.

Thank you for your understanding for letting me update you by phone this morning. I am going to turn the presentation now over to Dr. Stratton and I will stay on this phone to answer your questions with her when she is done with her update presentation. Thank you.

DR. STRATTON: Thanks, Rosemary. Just so you know, everybody could hear you perfectly, so the system is working.

You have a handout that includes my slides, the adverse event list and a committee roster. You have an updated adverse event list and when we get to that I will point out the few things that were different that I had inadvertently left off.

As Rosemary mentioned, everything on the first slide, it is true that the paperwork was transmitted to us just this week for the addition of the other four vaccines, I guess technically speaking it is more than four, but for the other vaccines

to add to the list. However, the committee understood since the last ACCV that CDC was going to be helping to fund this expansion and the committee has been operating under the assumption that they would have this expansion of charge, which you will see in a minute.

Let us talk a little bit about the charge because that is what we really did not get into last time. I want to preface this by saying that this just continues the history of IOM work as congressionally mandated and the National Childhood Vaccine Injury Act, Sections 312 and 313 where Congress mandated that the IOM provide two reports: one came out in 1991 and one came out in 1994, to help the Secretary exercise his or her duties in terms of the vaccine injury table. So my understanding is that it was congressionally intended that IOM provide the scientific review and although this was not mandated, this new update is entirely in keeping with the original intent of the law.

The charge is to assess the scientific evidence and by that I mean the results of epidemiologic studies, clinical studies, and basic science research, regarding the causal association between vaccines and adverse events. As you know it is very specific vaccines and very specific adverse events. It is to specifically include an assessment of the evidence regarding biological mechanisms that might underlie these vaccine adverse events.

It has become quite clear I think to everybody that the evaluation of the biologic mechanisms in 1991 and 1994 really in fact are not deep enough or broad enough to reflect the understanding of science and physiology and vaccinology that we have today. I think it was a very appropriate treatment for 1991 and 1994, but fifteen years later, a lot more is known and a lot of that rests on the biologic mechanism. Epidemiology is a great science, but it is only type of science. There are other types of science that can be brought to bear. That is where I believe

that this committee and it is reflected in the membership which I will get to next, is actually quite different from the committees in 1991 and 1994 to reflect this emphasis on the biologic mechanisms. It also provides quite a challenge to the committee.

You have a list of the membership which shows their affiliations. What I wanted to do was explain to you their expertise so that you can see how this matches up with the challenges in front of them. The Chair is Ellen Wright Clayton. In addition to being a pediatrician, she is also a lawyer and an ethicist. She actually directs the Center for Biomedical Ethics in Society at Vanderbilt, but she is also a practicing pediatrician.

There are, as always, a number of epidemiologists and statisticians on the committee. As I said, epidemiology and statistics is one of the important tools; a major tool in assessing causality and the people who bring that expertise are listed. Many of them in fact are clinicians and still see patients on a regular basis and have clinical expertise in addition to their epidemiology expertise. In fact there are three internists; one pediatrician; an adult neurologist within that group of people who will be bringing the expertise in epidemiology and biostatistics.

We also have the other half in terms of numbers of the committee who are basic and clinical researchers. Their expertise is at the bench or in clinical research and the expertise there is both pediatric and adult rheumatology, allergy, child neurology. There are two. Dr. Bebin is an epileptologist and Dr. Patterson is an expert in metabolic disorders. We have a very basic scientist in neurodevelopment which the committee added at their own request after the first meeting. They felt they really needed a better understanding of that really basic biology and how the nervous system develops, the development of the immune system and immunitoxicology as well as adult neurology. So I think when you look at this you can see that the committee is very deep in both basic science, basic and clinical

science as well as epidemiology and at the clinical expertise and interests of the committee reflect many, in fact probably most of the kind of conditions they are in front of, in front of the committee. I think that it is an expansion of the basic scientists and the clinical scientists reflect the added emphasis in this particular contract as opposed to the ones in the early '90's to really try to understand the basic biology of adverse reactions a lot better and a lot more fully than it was possible before.

Rosemary has already started to describe to you how the specific adverse events were given to the IOM. The difference in the two tables: the one that was stapled to your packet and the update was that I had forgotten to add insulin dependent diabetes mellitus to the hepatitis B list and stuck it to the HPB list although I think we always knew about the syncope. We had that under a different kind of category which I will get to as a general category. The IOM does reserve the right to add to the list. If they either hear from people, from the public or other professions of compelling case for why an adverse event should be listed or if in the search of the literature they find evidence of their own accord that they feel should be added.

The committee has thus far retrieved 5,500 citations from the published medical literature directly bearing on these four vaccines and average outcome. Now not all of them are going to turn out to be directly relevant because it is a very broad search, but as we are working our way through these 5,500 citations, if things come up that the committee doesn't see in the list, that the committee feels are really very compelling, that would fall under this program. They will have the right and they will, and they intend to add those to the list.

DR. HERR: Thank you. This is Tom Herr. One of our speakers yesterday alluded to the idea that the VAERS Reports reduces the incidence of filing reports and letters which might be sources of your information. Would you comment

on that?

DR. STRATTON: I actually cannot comment on whether or not it is true that VAERS, I mean I don't know one way or the other whether it is true that the ability to file VAERS Reports means there are few case reports in the published literature. It is just not something I know. I know as I have been working with the committee to go through these 5,500 citations there are many case reports that are being retrieved and will be reviewed in the published literature and that many of them are current. They are not just from the old literature so whether there are fewer I don't know, but they are there and the committee is reviewing them. Okay?

DR. GIDEON: I have a question for you. I am wondering how this committee is selected and I wanted to ask whether they have a link with a sister group, the clinical organizations of test assessment? They are the ones that we at least we at CDC that I am aware of a lot of expertise with the partner Genesis and the link of vaccine adverse events and it is evaluative.

DR. STRATTON: Yes, it is a great question and I probably should have addressed the committee membership. The way that the committees are put together was very similar to the way all IOM committees are put together which is that we think about what the expertise is. Some of them we need a neurologist and we need an epidemiologist and we need an rheumatologist just because we know the general types of you know the adverse events that you all, you know that the program faces. We solicited suggestions very broad and wide from other experts in the field. I do not remember how many names were ultimately considered, but it was a whole lot more than the eighteen who are on the list. There were many, many. We have very strict rules about conflict of interest and so no one on the committee has current financial relationships with any of the companies who make vaccines even if that relationship is on the drug side of things. The company is the company

so they can't have stock in the company. They can't have active contracts with the companies. We did not consider it appropriate to have one on the committee who had served on any of the major federal vaccine advisory committees. That is not a financial conflict of interest but it certainly would be a perception that the people would be biased. There is a thought that people who were involved in the approval of a vaccine would not be able to honestly evaluate. Whether we believe that or not is not important. What is important is that there are people who believe that it would put a damper on the credibility of the committee, so none of these persons served on Burback or ACIP for example. There are other, you know, things that we consider so they are not vaccine researchers. None of them are vaccine researchers. None of them and that give great pause to vaccine manufacturers and other vaccine researchers, but the committees have done it before and they will do it again. They learn the field. The work very, very hard and I would like to say for those of you who have not heard me say this before, that these people are not paid for their time. They are volunteering their time. They will work hundreds and hundreds and hundreds and hundreds of hours for free on this project and it is a lot of work. I already told you there is 5,500 citations and a great many of them are going to have to be read and studied in depth and that is only just beginning so you just need to know that these are people who come at this fresh. Who come at this willing to spend all of this time because I think that the program is important and they think it is important to understand the science.

So now with regard to your question about the CCAS, as you can see, the CCA investigators would not meet our conflict of interest criteria for this particular committee because they are paid by CDC to do research and CCA. This is by no means a statement about their scientific qualifications. There are, I know several of them. I have read reports from them. I presumed they are some of the best

scientists interstate and vaccine adverse events in the country, but it just would not fit the way we operate to have them on the committee. The committee will read the CCA publications if they have questions about what the CCA investigators might be finding. They can invite them to an open meeting and they can present their information, but they are not a member of the committee not are the VSD investigators or researchers who have done the clinical trials you know for the vaccine manufacturers for licensure.

MS. HOIBERG: My question is, this is Sarah Hoiberg, if the committee members are working for free, what is the millions of dollars going for? Who does that money just to you know buy papers or

DR. STRATTON: It goes to the IOM and it pays for staff. It pays for travel. It pays for the public meetings. It pays for, we are buying up the papers. It pays for printing the final book: a lot of things. It is just important for you to know that these people do not make a penny off of doing it.

MS. HOIBERG: Thank you.

MR. SCONYERS: Just had a follow-up question to Dr. Herr's question. Is VAERS data a data source?

DR. STRATTON: Yes, the VAERS data has been a source in the past. Was VAERS around in '91? Yes, it was. Anyway, the passive surveillance system reports are a source. Exactly how the committee is going to handle them for this committee has not been determined, but it is actively being discussed. I am sure that they will be reviewed in some fashion.

MS. CASTRO-LEWIS: I have another question and I am not sure the terminology that goes here but are the petitioners cases that is it compensated or not and are they, any of this information would play into the difference.

DR. STRATTON: We are exploring looking at the cases to see the

arguments about mechanisms that have been put forth by the petitioners' attorneys and literature that was cited for some of them to make sure that we have combed all of the literature; that it was identified and then the committee will independently evaluate those data. That is not something that the '91 and '94 committees did. I don't even think the cases were easily available. The fact that they are not available online, so they would be used as a source of published literature that the committee might not have identified.

MS. HOIBERG: I was going to say, this is Sarah again, if you were to go through and read a case and say it was decided in, you know against the petitioner, and everyone felt that the decision should have been for the petitioner; that it really was a vaccine injury, is that something that you could I mean will it ever be able to be disputed or is it just a closed case and you go well that is just a fact that it should have really been a. Do you understand what I am saying? Like it is a decision, say you read a case and the case was you know the special master decided that it was not caused by, the injury was not cause. What if in going through your doctors and everything decides that well you know it actually could have actually been caused by the vaccine. What is going to happen with that? Is it just going to be a?

DR. STRATTON: Oh, that is not a question for me actually. I think that is a question for Emily or for Jim.

MS. LEVINE: Hi, I am Emily Levine. I am with the office of general counsel. I am filling in while Elizabeth is out this morning. Basically once there is a judgment in the program, it is final judgment so whether folks think it was wrongly defended either way, it is a final judgment.

DR. STRATTON: And I should say that in the committee's preliminary decision to look through these cases for evidence, your scientific papers and theories

about mechanisms, it is not there, they will not spend the time nor is it their job to make any independent decision whether that individual case was causal or not. Again, we are looking at it as a source, as rich source of potential literature that perhaps escaped their initial scan.

MS. HOIBERG: Okay, thank you.

DR. STRATTON: These are great questions. There are some general considerations that have been put for the IOM to consider in addition to this specific adverse events and they are listed here. There could be some other ones that will pop up as the committee does its review or as the program thinks about the next four vaccines. One thing in particular that Dr. Johann-Liang had asked the committee to think about was the time interval for anaphylaxis. The committee will make comments about interval from vaccination to adverse event where the literature allows that to happen and I think it was a specific interest in the anaphylaxis time window, but for all AEs the committee will be thinking about that and say what they feel the literature supports or not.

There was an interesting administrative reactions that Dr. Johann-Liang had given; direct versus and I think indirect. That is what a syncope sort of came in which is why I have it on the list. Direct I think might be say so right here on the right is for example there could be a direct cause, distances I understand it so if there is a physician here who knows I am saying this wrong, please correct me. There could either be an administration reaction from the needle or there can be an immune reaction from the vaccination so, some of these I think it was of interest whether or not the committee felt they were direct or indirect on reactions.

The live versus the inactivated vaccines, I think this, as I understand the intent when Dr. Johann-Liang presented it to us, is there general thinking mechanistically about the risks of a live vaccine versus an inactivated vaccine or the

different types of vaccines. In fact we had an entire discussion at the last meeting, last workshop about that and I will get to that in a minute. Obviously everyone is very, very concerned about whether or not you can identify vulnerable or genetically susceptible populations and if there is anything that the committee can do to help arrest that it is clearly one reason why the committee added Dr. Patterson to the committee. It is what he works on and thinks about day in and day out. We had talks about that at the last meeting. Immune dysfunction, I have in quotes only because I think that is not exactly a medical diagnosis, but the question is can vaccine adversely in generally affect the immune system. The committee will do their best to think about that. We have some excellent immunologists on this committee. I mean very, very high level basic in clinical science immunologists to thinking about this. Then there was a question about repeat vaccinations meaning the sequential injections of the same antigens. So is the fifth time you get the influence of vaccine riskier for you if it is riskier than the first time, or even the series or the booster so I think there is a lot of questions there about the repeat administration, sequential injections of the same antigens. So these are some of the general considerations that the committee will think about. They have started looking at some of the literature on this and have had some talks exactly how they work that into the final review of course I don't know. They have really just begun and there could be other general considerations that you may all have that you can bring to our attention or to double conflict themselves.

MS. HOIBERG: This is Sarah, again. When you talked about sequential, you are going to be looking at the sequential injections, would someone be able to study to see if after like say maybe two vaccinations that a child is protected enough? Do you understand what I am saying?

DR. STRATTON: Again, I think that is not a question for me actually

or this committee because this is really not about, it is not studying the efficacy of the vaccine. It is very specific to the rest. I presume that is a studyable question but it is not for this committee.

Okay, so the committee process, the original committee membership was announced in April. At the first meeting the committee requested an additional person be added and that was Dr. Martha Constantine-Paton who is a very basic neuro-developmental biologist. She was added and then in June, because we had just heard that CDC had intended to forward the money to complete the full funding in anticipation of that we just knew that was coming. We added five additional committee members; four who were at the August meeting due to this anticipated increased responsibility. It really, a little bit about expertise, but more just about people to do the work. It is just a phenomenal amount of literature to be reviewed.

The committee will meet a total of eight or nine times over a two and one-half year period. Last time I would have said a year and a half to two years, but with the expansion of work comes extra people and extra time.

Public input is welcome throughout the process. I will show you some of the way that that can be done and what has been done so far. We still have a long way to go. The report is not due out for two more years.

The first meeting was April. There was a very brief open session when Dr. Johann-Liang came and presented the charge and answered some questions along the lines of some of what we have been discussing today. The committee met in June of 2009 and had an all day public workshop where they discussed causal inference from an epidemiologists' perspective and two epidemiologists' perspective including a good strong take on how do you involve biologic mechanisms and just thinking about causal inference and how do evaluate those data. Then there were also talks on the basic mechanisms involved in multiple

sclerosis which was chosen as prototypic central demyelinating disease which plays so prominently in the program. So as one example of what is the basic science known and how might vaccines affect multiple sclerosis.

There were two talks on models and molecular mimicry which is one of the mechanisms that might explain, that has been hypothesized for how vaccines might cause many of these adverse effects, but that is a link with the multiple sclerosis and then there was a talk from a computational geneticist who actually spent part of the group that has identified some genes that might be related to why some people react systemically to the smallpox vaccinations as opposed to the locally. So it is a good example of how this kind of data might be available in the future. Smallpox is not the subject of this committee, but those techniques and that idea that you might be able to identify people. It is very interesting work.

The verbatim transcript and most of the slides are available on the project website, which I will show you again. I want to explain why I say most slides. Sometimes people come to meetings and they present on a slide something which they do not own copyright or hold the copyright for and we cannot put copyrighted material on the website if there hasn't been permission. So that is the reason for most is that we had to blank those out.

The third meeting was in August, but they are discussed in the verbatim transcript. You just can't actually see the copy written material if they did not have permission. Their own work, which is copy written we can show. August 2009, there was another committee meeting and there was a half day workshop. There was a fascinating talk on the blood brain barrier and the development of the blood brain barrier prenatally and post-natally and then through adulthood, so very important question about what role that plays in immune reaction, what possible role it played in immune reaction: very, very interesting. There was a good talk by Dr.

Neal Halsey, who is one of the CCA investigators, on what is known about differences in immune response between vaccines versus natural infections, between the different types of vaccines and through time as well as in special populations. It was very, very rich talk that really got the committee moving forward in trying to think about specific populations. Then a talk about Dr. Bruce Cohen on mitochondrial disorders, very interesting. Again, the verbatim transcript and most of those slides are available on the website for anyone who wishes to look at them.

The committee is going to meet again in January. At this point they want a closed session for January so they can really deliberate on the many, many scientific studies they have been reading from August until January. They likely will meet again April, July and September of 2010 whether any or all of those will be open for workshops or some sort of is at their discretion and we certainly have not made that decision yet.

Additional meetings can be scheduled as necessary. They also have teleconferences on a very regular basis, so that is how we sort of got through this. The report is due in the Spring or Summer of 2011. It is a little bit far to know precisely when, but that is what we have anticipated in the contract.

There is an email address and there is a list serve which is not very active. We don't send out information about vaccine safety generally. We send out announcements about this project specifically. So for example when there was going to be a public meeting; when the new list of adverse events comes to the IOM maybe we want to let people know that it is on the website if they want to make comment. An email will go out about that. This not something you will be getting daily. Email is about, but if you do want to be kept up to date on the public activities of the committee, then you can do that. That is the, you can see the website in front of you and again, presentations there is not a lot up there, but you can find the

presentations and the two verbatim transcripts.

I think that ends my presentation. I am happy to keep taking questions although you might have expended all of your questions.

MS. CASTRO-LEWIS: Thank you so much. I actually have a follow-up question to the question that I did before.

DR. STRATTON: Oh, sure.

MS. CASTRO-LEWIS: A lot of cases are being settled and so how, and my understanding is that information is not available to the public. Is it in anyway available to the scientific community for this kind of studies so you can use that information?

DR. STRATTON: There is nothing that is available to the committee that is not available to the public. We don't and if something is made available to us, it must be made available to the public. We have public access rules. I know nothing about what happens with settled cases and I just want to make the point that these in and of themselves the cases are not, whether they are settled or how they are decided is not scientific information. We are reviewing the documents in case there is scientific information being argued you know during the course of this. There is a lot of really good experts who are brought in and so the committee would like to avail themselves with their thinking and their literature, but I know nothing about what happens in settled cases. Maybe Emily or Geoff?

DR. EVANS: I was going to say if Rosemary would let me make my comment because you asked the programs which of course apprise you of the kinds of cases and the kinds of validations that were being made and the conditions that we were seeing and that information was given to you and comprised a lot of the settlement.

DR. STRATTON: Actually I, thank you, I need to add that to the slide

set. The committee did ask Dr. Johann-Liang. They wanted to be sure that the adverse events in front of them represent the adverse events the program is dealing with so were there any, I forget how it was worded. They wanted to make sure that the program was not hiding claims of adverse events from the committee and in fact we were looking at the serious ones. I forget the exact numbers and we could certainly come back to you with that, but Rosemary did go back and look at the number of cases and the adverse events that put forward and that would have included the federal case in her analysis and it was an extremely high proportion of the case that were claimed for these four vaccines and presumably the same analysis will be done for the other four so at least the adverse events that are being, the conditions that are being fettled would be reflected.

DR. JOHANN-LIANG: Hello. Can you guys hear me? This is Rose. I just wanted to make sure they understand that when we were like when I talked about the very beginning about the positive of generating we have received, it was important that it not after, it wasn't just as a data on after the review of the petitions by the physician and the program and the types of diagnosis and type of adverse events that was post review. It was important for us to actually look at the data where the alleged adverse event came in so it is just really raw administered data of what the folks were saying. My vaccine, you know how the vaccine and this is the injury that or rightly so. We looked at that data as well to and put those together to generate that initial adverse event so there was really nothing that the committee has gotten that admit. Now obviously here is an alleged injury and there in one case or a couple of cases that really has no theme or consistency of cause. There are too many for the committee to look at, but anything that came in based upon the frequency and you know that caused yourself injury such as the demyelinating conditions and all the different permutations there are, those were all included. As I

said in the beginning, I think it would be a good idea for all of these eight vaccine adverse events this having given the IOM then it is now open for the public to make comment to the IOM in case they want to add anything. So even if with the CDC we can actually go over some of the program data and how the risk was generated you know for the sake of just open transparency so that everybody will be clear. Hello, did I say?

MS. CASTRO-LEWIS: Yes, no, we appreciate. Any other questions?

MR. SCONYERS: Thank you very much. This is a great presentation. I am very impressed by the work that you are undertaking; the scope of it, the depth that you are going into it. I appreciate it a great deal.

I am aware that there is a tremendous amount of research being done in immunology, auto immune processes right now that we are only beginning to get a really decent understanding of the human immune system and disorders of the immune system. So my comment is really directed to Dr. Evans more than you which is that this would be a great study to capture the day and I hope that it will be possible to continue to perform this kind of a literature review and study as we learn more about immune processes so that the table can continue to be updated for new discoveries about the relationship. I mentioned in June genetically susceptible populations. I think we are only just at the very dawn of understanding what factors may cause someone to be genetically susceptible to an immune disorder and as our understanding grows, it will be important to maintain the scientific integrity of the table as that moves forward.

DR. EVANS: Thank you, Jeff, for your comment. Of course the program absolutely agrees with that and of course in Dan's report on the National Vaccine Program, Dan Salmon's report this morning, you couldn't begin the details but I will tell you that one of the action, that is probably not the correct way of

characterizing, one of the measuring criteria for the future implementation plan would be that the program, I believe the wording is, is to update the table at least every five to seven years. So that kind of thinking is part of the National Vaccine Plan as it goes forward.

MR. SCONYERS: If I could make just one other comment and this is more administrative. I see Dr. Stratton's slides include an email link and a web link and that is wonderful. We have them in paper. It would be great if we could get them in their native format, that is electronically so that instead of having to enter the information I could just click on it to access this.

DR. STRATTON: Do I need to actually read these aloud so that for those listening and for the transcripts? Sorry about that. The email address for the IOM committee is vaccinesafety, all one word, vaccinesafety@nas as in National Academy of Sciences, dot edu. (vaccinesafety@nas.edu) The website is http://www.iom.edu forward slash Vaccine Adverse Effects, all one word, VaccineAdverseEffects (http://www.iom.edu/VacineAdverseEffects) and the phone number is 202-334-2077 and I would be happy to send the ACCV members these electronically so you can just click it.

MR. SCONYERS: That would be great.

DR. HERR: One more follow-up on what Jeff and Geoff were saying, will it be part of the IOM's report that of a recommendation of future follow-up studies?

DR. STRATTON: Meaning specific studies as in research agenda?

DR. HERR: We have done this now and this is what we see and because of the advances in the fields, we think that this should be re-evaluated in x number of years.

DR. STRATTON: Probably not that. I think what the answer - the yes

that Geoff was starting to nod about is that it actually specifically is not in the committee's charge to make recommendations for important research that needs to be done to help resolve some of the questions that they see. But, I will tell you that no committee of eighteen scientists could help themselves from making research recommendations. So that is different. That is about specific issues and how they might be resolved one way or the other. The general question about issue being reviewed over and over again it really kind of would be like our recommending giving ourselves work, which we are not allowed to do.

DR. HERR: I guess my concern is it really, at what point does it become productive to look at the data again and looking at the research. That is something that this Commission cannot answer and politics is a little bit different, but the science community can look at what progress is being made, what studies are being done and saying this is a reasonable thing to look at in x number of years.

DR. STRATTON: I am going to have to think about that. I don't know what to say.

DR. EVANS: Nor do I really know what to say in terms of your specific question, but in any one of the '91 and '94 reports in total identified insufficient evidence in two-thirds of the conditioned study so I guess one bit of advice would be that to the degree that the committee can shed light on the kinds of research that should be going forward to try to make it so that fewer insufficient evidence adverse events would be very helpful. The reason that we in the National Vaccine Plan feel that five to seven years is viable is because it takes several years for example for the IOM to do this kind of a very ambitious research effort. To try to go through all of the literature and of course it takes seven years for the department proposed changes to the table. So that is the best we think we could do, but it is certainly something that we would like to see on an ongoing basis and hopefully the administrative support to

do that will be ongoing after this effort.

MS. CASTRO-LEWIS: No more questions for Dr. Stratton or Rosemary? Wow. Okay, well I just want to thank you both for the presentation. I think it helped us tremendously to understand what this study is all about and to mitigate some of the doubts that we had about it so this is wonderful.

I just have one quick question. Will this kind of a study allow for you to give us some kind of interim report as to where is it going or do we have to wait the two years all this period of time to get the final results?

DR. STRATTON: One of the very frustrating parts for the public and stakeholders of the IOM process is that we really don't give interim reports other than processing interim reports; you know sort of where we are. It is just not what we do. So, sorry. The website is not going to help you. It is just now what we do.

MS. CASTRO-LEWIS: Okay, well thank you so much. Okay, so this gives us a little bit of time to take a break. Let's take fifteen minutes. We could reconvene at 10:35. Thank you.

(Break)

Agenda Item: Report on the Countermeasures Injury Compensation Program (CICP)

MS. CASTRO-LEWIS: Get back to your seats and so we can continue the meeting. Our next guest speaker is Dr. Caserta from HRSA and he is going to give us a report on the Countermeasures Injury Compensation Program.

DR. CASERTA: Good morning.

PARTICIPANTS: Good morning.

DR. CASERTA: Good morning, everyone. What I am going to try and do this morning is to give folks an overview of the new Countermeasures Injury Compensation Program so that they can understand it is a different program from

VICP and I will compare and contrast at the end of the presentation. So I am going to give an overview. I am going to tell you what is covered currently with the CICP. I am going to try to explain why things are covered and what is needed for compensation for someone to apply to the program. Then I am going to focus on influenza because the program covers more than just influenza, but we will focus on that. Then I am going to compare and contrast with the program you guys love dearly, which is the VICP. So why don't we go ahead and get started.

Why don't we go to the first slide. The covered diseases within the program are influenza and it is very important to note that it is just the pandemic influenza: not the seasonal influenza. Seasonal influenza of course you guys know is covered by the VICP, but the monovalent vaccine and drugs used for the pandemic influenza would be covered under the CICP. Other diseases that are also covered are anthrax, botulism, smallpox and radiation poisoning.

The purpose of the program is to provide a liability protection and a compensation scheme for bioterrorism and for pandemic issues so that the Secretary can make the environment better for manufacturers and others to bring these necessary products should we have a bioterrorist attack or a pandemic to have them at the marketplace so that they would be ready for such an emergency.

With the program, what one would get if one were found eligible would be unreimbursed medical expenses, lost wages and a death benefit if the person dies from the direct effect of the countermeasure. So the Secretary adds new diseases and countermeasures through PREP Act Declarations so the program is constantly in flux with new countermeasures and diseases in the pipeline depending on what the current threat is.

DR. FISHER: Meg Fisher, can you clarify what is the PREP Act?

DR. CASERTA: The PREP Act is an act of Congress that was passed

in I think 2005, is that right Emily? Yes, that lays out the liability protections for the most part for manufacturers and administrators and distributors and public health officials who may be involved in getting these countermeasures to the public and also the compensation for the program. If you want specific information about the PREP Act, my last slide will have out website and that can link you to the PREP Act. There are also links where there are Q's and A's about the PREP Act so there is plenty of information on the web if you want more detail.

DR. FISHER: Thanks.

MS. HOIBERG: I was just looking and I do see a clarification. This is Sarah. I just need a clarification that when you call it unreimbursed medical expenses, is that like a life care plan where they go through the same process and get a life care plan and be taken care of?

DR. CASERTA: That could be, yes. So in other words, we are the payer of last resort. If any insurance or disability coverage or whatever pays for it or is obligated to pay for it, we would not. It would be up to those insurances and other entities to pay and then once they a have paid then we make things whole by paying what is out of pocket for the person so that they have no out-of-pocket expense. And just to make clear, too, the vaccine that is covered by the program, by our program is the monovalent influenza vaccine whereas with the VICP of course for the seasonal disease is the trivalent vaccine. So that is where the distinction is and what is covered with regard to vaccines. We cover the monovalent one, the pandemic vaccine; you guys cover the trivalent, the seasonal vaccine.

So what does one need to become eligible for the compensation program that I am describing; this new program? Well, you need to meet the programmatic conditions just as like with VICP, if you file after three years you are out of luck. With our program, the filing deadline is one year. The countermeasure

needs to be covered in a Declaration by the Secretary and it needs to cause a serious adverse event. It cannot just be something that is non-serious.

A serious adverse event is defined as something that is life threatening or that results or can result, in a permanent injury. The countermeasure needs to be used or there needs to be a good faith belief that the countermeasure was used within the construct of the Declaration for that countermeasure. Usually the Declarations speak to the coverage dates, the disease or health threat that the countermeasure is used against. What I mean by that is for example, we cover Tamiflu which is one of the antivirals for influenza. So if the Tamiflu is given with the intention of preventing or treating the pandemic influenza, we would cover it. But if it is used to treat or prevent the seasonal influenza, we wouldn't and the benefit of the doubt will go to the person who is requesting benefits. So if it is unclear, we will just assume that it is for the monovalent or the pandemic disease. Also, population and geographic area is usually specified within these Declarations or is specified and the Declaration sometimes speak to specific situations. So if you meet all of those things, then the program may be able to assist you.

Now I am going to go ahead and focus on flu and get away from anthrax and radiation and all of the other things that the program covers. The program covers all of the monovalent influenza vaccines that have been put into the pipeline in case any one of these would become a pandemic. So we cover H1N1, which is the one that is in the news now. H5N1, which was the old bird flu, know back a few years ago and it is still happening, but we don't hear much about it where there those few cases in Asia and they were quite lethal and we were worried that the virus would mutate and become more transmissible. It hasn't done that yet, but it is one of the covered vaccines so that it is in the pipeline. Manufacturers have made it. It has been tested. It is ready in case we need to use it. Also, H2, H6, H7 and

H9; those are just other serum types that are covered and again we do not cover the seasonal vaccine or the trivalent vaccine.

With flu, we also cover Tamiflu and Relenza which are two antiviral drugs and we cover diagnostics, you know tests used to test for the flu. I cannot imagine how there would be any liability and compensation for that issue so we don't expect to see much from that, but we also cover personal respiratory protection so things like N95 masks and there may be injuries related to that if someone is claustrophobic or mental health issues related to that, so we may see some things, and respiratory support devices. In other words, mechanical ventilators are also covered to treat people who are sick with pandemic flu. So someone who becomes very ill with pandemic flu needs a respirator, is put on the ventilator, a mechanical ventilator and has an adverse event from the ventilator, we would cover it. So this is quite different from VICP. Yes?

DR. HERR: So you don't cover the mask or the ventilators, you just cover if it doesn't work.

DR. CASERTA: We cover adverse events; not if it doesn't work. We cover adverse events from the mask or the ventilators. So if the ventilator causes barrel trauma and you get adult respiratory distress syndrome because you were put on the ventilator, we would cover that. If you get fit tested for an N95 mask and you develop a terrible latex allergy and your skin becomes inflamed and you become very ill from that, we would cover it.

DR. HERR: But the effectiveness of the mask would not be covered.

DR. CASERTA: The effectiveness of the mask would not be covered. It is adverse events from the use of the mask: not the effectiveness.

MR. SCONYERS: Isn't that an adverse event?

DR. CASERTA: No.

MR. SCONYERS: Well, it seems pretty adverse to the user.

DR. CASERTA: With any modality, there is a certain percentage that is not going to work. It is true with Tamiflu. It is true with aspirin. It is true with whatever drug or vaccine or anything that you are given so it is understood that it is not going to work for everybody, but you are given it with the understanding that most people are helped by this and you probably will be helped. But, if it does not work for you and say for example you have an N95 mask and it leaks and there are anthrax spores and you get sick, we would not cover that. Just like with the VICP, if someone gets a measles vaccine and it does not take, there is five percent of people who get measles vaccine and it does not take and you get measles and very sick from measles, we would not cover that either. So it is the same sort of thought pattern.

MR. SCONYERS: I don't want to belabor, but it just makes no sense. If we are deploying healthcare workers in reliance on PPE, they are in good faith providing care to the people who are sick. They are relying on their PPE to prevent them from getting sick. They get sick as a result of the PPE's failure, so do they need to sue the manufacturer for the failure of that PPE on a liability basis?

MS. LEVINE: I don't want to get into all of the liability protections of the PREP Act because they are pretty complicated, but the liability protections that exist under the PREP Act are not identical to the same class of people who gets compensation under the program. In other words, the statute differs and the liability protections of the PREP Act are remarkably robust. They are much stronger and more comprehensive than those in the Vaccine Act that apply with VICP petitioners. So the circumstances in which the liability protections might apply are broader than the compensation under the compensation provision. That is the way the statute was written.

MR. SCONYERS: That is not what I am asking. I am asking about what Dr. Caserta is saying is a non-covered event under the act which is the failure of the PPE that is part of the covered countermeasures, but the failure of the PPE results in harm to the user of the PPE but that harm to the user is not covered, it sounds like. So what is that person's remedy?

MS. LEVINE: Well, what I am saying is the liability protections might apply in those circumstances even if the compensation program is not available. I think it is a pretty complicated, sophisticated analysis both in terms of whether the compensation would apply in a liability protections would apply, but just because the compensation does not apply does not necessarily mean the liability protections would not exist for that healthcare worker who is administering it.

MR. SCONYERS: So as the administrator at a hospital who is responsible for our emergency preparedness activity, I will tell you this is a difficult explanation to offer to our workers that we were deploying to the front line of a potentially deadly disease.

DR. CASERTA: We will certainly take that back to the Secretary and ask her, the folks who write these Declarations because you make a good point, I think. The way it is currently written, that is not covered and we have to go with what is written and what the Secretary puts out.

MR. SCONYERS: And that is as a result of the Declaration?

DR. CASERTA: Yes, it is the Declaration that controls this. What the Declarations say, and the Declarations can be amended and changed so what the Declarations say is what we work under. Currently, although you make a good point, it is not covered.

MS. LEVINE: I guess just to look on that, I think Dr. Caserta is concluding it is not covered by the compensation program but in fact the healthcare

provider may be protected under the liability protections and there is a whole bunch of Q's and A's on the department's website about the liability protection.

MR. SCONYERS: I am sorry, the notion that my organization is somehow protected is the last thing that is on our minds. We are concerned about our employees who are going to potentially catch a deadly disease and die as a result of the failure of PPE. This is not about liability protection for us. This is about protection for the workers that we are trying to have take care of these patients.

DR. HERR: And the manufacturer is protected for the failure of the mask by this Act.

DR. CASERTA: Again, you are getting into the liability protection portion which is not the compensation, the countermeasure injury compensation program. We sort of focus on the compensation side of it. So there are two sides. There is the liability protection and the compensation side and as Emily mentioned, they are not equivalent. So I really cannot speak to the liability piece because it is immensely complicated in trying to understand the Act and I don't know, really can you add anymore?

DR. HERR: I think as Jeff Sconyers put to it. It is important for all of us, and everyone involved in the care of these sick people whether they be children or adults, that things, you know where the protection lies. The purpose of the Act was to protect the manufacturers so they would go ahead and do these things and make these things available and if we are going to be covering any adverse effects of the countermeasures, then we need to look at the failure of the devices if they are properly used as opposed to just gee I am sorry.

DR. CASERTA: Right, right and sometimes drawing that line could be difficult. I mean if you are put on a mechanical ventilator and the ventilator malfunctions, would the compensation program cover that or not. That would be a

difficult analysis. My preliminary thoughts on that would be that we probably would, but if an N95 mask fails, that is very different and the way it is currently written, I don't think we could. Even if we wanted to, I don't think we could.

MR. SCONYERS: Just one further question about ventilators, I assume that it is not just any ventilator. I assume it is FDA approved ventilators?

DR. CASERTA: Yes, I mean you couldn't use one unless it is either FDA approved or under an emergency use authorization if it is not licensed. So it would have to be a device that has gone through the FDA process or under an EUA, emergency use authorization.

DR. FISHER: Meg Fisher, I am sorry. I guess I am getting confused in this. So you are really talking about the respiratory support device that are part of the national stockpile that would be released if there is that kind of an emergency. So we are not talking about a healthcare worker or a person who gets H1N1 and ends up in a ventilator in a PICU. You are not covering them?

DR. CASERTA: Yes, I am.

DR. FISHER: You are covering anybody, anyone in this country who happens to get pandemic influenza?

DR. CASERTA: No, what we are covering is adverse events from the mechanical ventilator.

DR. FISHER: Every mechanical ventilator?

DR. CASERTA: Every mechanical ventilator because it is being used, if it is being used to treat someone with pandemic swine flu, then the way the Declaration is currently written, we cover them.

MS. HOIBERG: If they received the vaccine?

DR. CASERTA: No.

MS. HOIBERG: No?

DR. CASERTA: No, not necessarily. Not necessarily, because the countermeasure of the ventilator is a separate countermeasure from the vaccine. So we cover the vaccine. We cover the antivirals Tamiflu and Relenza, and we cover the devices, the N95 masks and the ventilator. So it is quite different from VICP in that regard.

MR. SCONYERS: We are currently treating empirically once we tie to flu-A. Kids may wind up on vents; vents may fail, we need to then do the serum typing to determine whether it is H1N1 and therefore covered under this?

DR. CASERTA: It would be helpful, but it is not necessary. We frequently even with VICP work with incomplete records and incomplete information and we will make our best determination based on each individual case scenario.

MR. SCONYERS: I guess I am going more to the intent of the act which I think clinicians are treating flu-A empirically.

DR. CASERTA: Right and as I said, the benefit of the doubt will go to the fact that it is and that is the way it is written.

So at the bottom of this slide are the links for the Declarations that deal with influenza so if anyone is interested. Also, all of the links are available on our website for all of the Declarations.

If someone receives the monovalent influenza vaccine, what would make them be covered? They would need to receive the H1N1 between the 15th of June, 2009 and the end of March, 2013. That is the period of time for the monovalent H1N1. The other vaccines have a different period of time and their coverage ends the 28th of February of next year. The intent of covering the other ones, for the most part right now, would have been for their testing and clinical trials and that sort of thing because these things have not been deployed or there is no plan to deploy them at this point.

MS. HOIBERG: I have a question, this is Sarah again. I am looking here and it says federally purchased vaccines. Now they were giving out H1N1 flu vaccines, or maybe it was just for the other flu vaccines, at the airports. That is just regular? Okay.

DR. CASERTA: All of the H1N1 monovalent is all federally purchased so that is why the bottom of the slide says broad coverage because essentially anyone who gets the vaccine is covered by definition because we are giving it because we are in a pandemic and it is federally purchased.

So persons who are covered would be someone who is in part of a clinical trial to study the vaccine and if they have an adverse event or an activity conducted through a grant or cooperative agreement with the federal government.

The next two slides speak to Tamiflu, Relenza and the N95 mask and mechanical ventilators. I am just going to skip over those because it really is outside the vaccine world, but I gave you the slides so that you have the information. If you have any questions, you can please feel free to contact me or you can ask now too, if you would like.

Now I would like to go ahead and compare and contrast the CICP with the VICP. You guys know the VICP very well and that could be a good basis for understanding the CICP. The CICP is administrative. It is not judicial, so there is no court process with the CICP. So someone would file a claim and we would administratively review it and come to a conclusion. There are no courts involved. Whereas the VICP as you know what happens, the claim comes to us in the department. We give a medical position for the Secretary. That position is provided to the court together with petitioner's position and then the court decides. So it is a different sort of way of doing this. We do not pay legal fees whereas the VICP does.

Our decisions are based on statutory language, are based on valid,

reliable, compelling scientific evidence and the decisions are made by a physician in house whereas the VICP, the decisions are based on the court's interpretation of what more likely than not standard; what that standard is and it is made by a special master or a judge.

We do not pay pain and suffering whereas the VICP does. There is a one-step administrative appeal with the CICP, so if we come to a decision and the amount of payment we would provide is something that the requester feels should be more, he can appeal that or he can appeal our decision that he is not eligible to another administrative level. It is always administrative.

We cover vaccines, drugs, biologics, devices, or anything that the PREP Act and PREP Act Declaration might cover whereas the VICP just covers vaccines that are recommended for routine use in children.

On the next slide, with the VICP someone can only sue the manufacturer for willful misconduct which is a difficult standard to prevail under. Not only, it is actually two steps. There has to be willful misconduct on the part of the either manufacturer or provider or distributor and that willful misconduct must lead to the injury so you have to prove both of those things in order to prevail under willful misconduct. The willful misconduct is the only complaint that you can take to court and the court has jurisdiction to hear that. Everything else, the courts would not have jurisdiction for a CICP coverage countermeasure. Whereas with the VICP, a person can exit the system after they have been in a prescribed amount of time and then sue the manufacturer so there is more freedom within the VICP to sue the manufacturer as compared to the CICP.

As I said, we have a one year filing deadline whereas VICP has a three year filing deadline. We do not have the sequela clause in our language where we would require a sequela lasting six months or surgical intervention like the VICP

does. Our language says the injury must be serious whereas with VICP it does not necessarily have to be serious as long as it meets the six months. So with VICP, someone could have a mild case of thrombocytopenia after measles vaccine. It is not really serious, but if the doctors continue to monitor and the child needs to get intervention because of it over more than six months, the VICP generally covers that whereas we may not cover that under the CICP because it is not serious. Again, we cover the monovalent pandemic vaccine, but not the trivalent seasonal vaccine. VICP is the opposite. You cover the seasonal trivalent and not the monovalent and we both use tables and actual causation as our way of getting to whether or not it should be compensated.

MS. HOIBERG: How is this program funded?

DR. CASERTA: Direct appropriations from Congress so again there is no trust to fund, funded by a tax like the VICP. So when we need money, we are going to need to go to Congress and ask them for it. Currently we have about 14 million dollars in the Treasury to pay claims and that is where we are. We have two million dollars for administrative costs.

MS. DREW: Do you have a given amount as a death benefit?

DR. CASERTA: Yes, it is based on a statute that compensates law enforcement and police and currently it is around 300,000. It changes every year and I don't know what the exact figure is. Emily, do you remember? It is about 300,000.

The last slide is our contact information. We have an email address and a phone number. If anyone has questions, they can contact us through that and we have the website where there is information about the program and links to Declarations and PREP Act and all of that.

MS. CASTRO-LEWIS: Could you please read the phone number and

the website for those on the phone.

DR. CASERTA: Sure. The phone number is 1-888-askhrsa, so it is 1-888-275-4772 and the email address is CICP ask HRSA dot gov. That is CICP@hrsa.gov. And the web address is www dot HRSA dot gov forward slash countermeasures, with an s, so countermeasures comp, c-o-m-p (http://www.hrsa.gov/countermeasurescomp) and that should get you there.

In addition, I have a bit of fantastic news for the program. This week I learned that because I have been praying for help because I have been the only person working on this for at least a month, they sent Tamara Overby down to, on a detail, to help me for a hopefully long period of time and I just wanted to introduce her. You guys probably all know her because at one time she worked with VICP and she was in charge of the commission and I am so, so happy to have her come down and stand up. Say hello to everyone. I am so happy that she is back.

Any other questions? Well, thank you.

MS. CASTRO-LEWIS: I actually want to summarize something. Let us see if I understood the whole thing. So this program for the H1N1 prevention through the vaccine general reactions and also the treatment all the flu remedies and masks have that the authority prevention and treatment which supports under these, to put it in my own terms.

DR. CASERTA: Yes, so it covers both prevention and treatment at least for the, and each Declaration is different, but for the influenza it covers both prevention and treatment so if Tamiflu is used to prevent or if it used to treat, it would cover both.

MS. CASTRO-LEWIS: Thank you so much. You got more to questions that you have got to be vaccinated. That is sort of true. I bet you did not expect that, but okay. Thank you so much.

Okay, we are going to have a little bit of update of time on our agenda. That is good for the travelers. I would like to go to the public comment and then we will do our future agenda and other items that we have pending.

Agenda Item: Public comment

MS. CASTRO-LEWIS: Operator, are there any comments from people on the phone?

OPERATOR: If you would like to ask a question or make a comment, please press star one on your phone. One moment for the first question. The first question is coming from Jim Moody. Your line is open.

MR. MOODY: Thank you and thank you again, madam chairman for the opportunity to make a comment. This relates to the IOM study. The people with injuries is the heart of the program and what makes it work and work well or fail and must reflect upon the nation standards determined by Congress and most recently affirmed by the Circuit in Althen, Capizanno and Pafford according to that recent briefing yesterday and most recently affirmed in Andreu. The problem with the task as it was seemed to be described lastly at this meeting is that it is designed to incorporate the more narrow standard set forth and rejected in Stevens requiring basically medical literature, scientific proof, epidemiology yet the standards identified by Congress and affirmed by the courts is not proof of biologic mechanism, but preponderance of the evidence of biologic plausibility. I think that the IOM task should, if it would be useful, to reform and revise the table it should reflect the causation standard not as appropriate in the outside tour world, but as appropriate in this particular program as set forth by Congress by being generous and easier than the actually tort standard. Otherwise it will be a report that everyone will spend a lot of money on but an extraordinary amount of work on and be perhaps useful for a review article in a scientific leadership, but it won't be useful to inform the program to

make it work better. The more pages that are off table, the public will tend to lose confidence if the program works for them and there will be way more cases that will eventually find their way into the civil tort system thereby undermining the other feature of the program, which is to protect the manufacturers form unnecessary liability for unavoidable injuries. So I think that the task needs to be redesigned and re-specified to be consistent with the standard of causation actually used in the program.

The other important thing is that I just cannot even begin to understand how we can get an appreciation for adverse events following vaccine without good baseline data on the public unvaccinated children. IOM actually called for this data in 1994 report, most recently NVAC at its June 3rd meeting noted this as a scientific outcome in its recommendation number seven on the CDC's safety agenda. The problem is that NIH, at least at the moment, is censoring this kind of work, on financially put that $16 million out of the office and research plan last December. Hopefully we can get that; put it in. It would be very helpful if IOM and ACCV would strongly reaffirm and endorse the need for getting baseline data on unvaccinated children to visit with the mandate for safer childhood vaccines infectious 27 of your statute so that we can at least sort of see what the starting point is before we can start counting up the adverse events understanding what the plausibility of the mechanism issues. Okay? Thank you very much.

MS. CASTRO-LEWIS: Thank you, Mr. Moody for the record, would you please state your affiliation?

MR. MOODY: Yes, it is Jim Moody. It is M-o-o-d-y and my organization is Safe Lives.

MS. CASTRO-LEWIS: Thank you. Any other comments from the line, the telephone line?

OPERATOR: We have no further questions at this time?

MS. CASTRO-LEWIS: Comments? Thank you so much. Anybody from in the room have any comments? It looks like we have no comments at this time.

Agenda Item: Future agenda items.

MS. CASTRO-LEWIS: Okay, so let us talk about the future agenda items. Let me start by summarizing the two work groups that we have.

The number one is the one Sarah, Sherry, Meg and Charlene will have to be in this group and the issue will be a recommendation to advise the Secretary to allow for more than one payment to the petitioners for pain and suffering and medical costs. So that is the issue that we are going to discuss in this working group.

The work group number two which Geoff is going to lead and is going to be working with Tom and Tammy. The issue is the recommendation to advise the Secretary to adopt an approach to resolution and concession of off table cases that is fully consistent with Andreu and Capizanno and that results caused courts regarding causation in favor of injured plaintiffs.

So these are the two working groups.

MR. SCONYERS: It is actually primarily Althen and Andreu a little bit, but Althen primarily.

MS. CASTRO-LEWIS: Okay. So let us make that note. Okay, so I would like to open for any other future item agendas. Anybody has anything in mind that we should. Meg?

DR. FISHER: I actually have a question about the vaccine information, the VIS forms. Will there be one for the novel H1N1? If so, normally we get to look at those before they go out. I think time wise that is probably not going to

happen, but if we can that would be nice.

DR. CASERTA: To answer your question, yes. There will be a VIS specifically for the pandemic monovalent vaccine. There is no obligation, legal obligation to have a VIS because that vaccine is not covered under the Childhood Vaccine Act, but CDC recognizes the value of the VIS and we have pushed to have our particular language in there so it will be there. I think just about in final form, if not already in final. So it will not be coming to this committee because it is not under the act for this committee.

DR. FISHER: Okay then I guess what I would just encourage you to do is make sure that the CI, whatever the write-in.

DR. CASERTA: CICP?

DR. FISHER: Yes, information is on that sheet.

DR. CASERTA: Yes, it is.

DR. FISHER: Okay, thanks.

DR. CASERTA: Thank you.

MS. HOIBERG: I just wanted to get it on the record that I am still requesting the presence of Secretary of Health and Human Services at our next meeting, at least by phone.

MS. CASTRO-LEWIS: Thank you, Sarah. Any other requests for agenda items or anything? Oh, well. So you are going to leave it all to the agenda work group which this time Tom to serve last time so this will give you second chance and then I would like to ask for a volunteer to work on this working sites. Everybody now has an assignment. You know I don't want anybody put it on, but if I have another volunteer. If there is no volunteer then I will assign. It is as simple as that.

MS. HOIBERG: I will be on the agenda committee. I was on it last

time, I know but I missed last time so I can.

MS. CASTRO-LEWIS: Okay, thank you, Sarah. You are going to be in three committees, you realize that.

MS. HOIBERG: I know, I know.

MS. CASTRO-LEWIS: Okay.

MS. HOIOBERG: I wanted to see my mom, you know.

MS. CASTRO-LEWIS: Yes, but you are a busy mom. Okay, Thomas and Sarah. Thank you so much. Well, we are really ahead of schedule so if anybody has any other comments, questions or anything, we have a little bit of time. If not,

MR. SCONYERS: Move we adjourn.

MS. CASTRO-LEWIS: Anybody second?

MS. HOIBERG: Second

MS. CASTRO-LEWIS: Okay, all in favor?

PARTICIPANTS: Aye.

MS. CASTRO-LEWIS: Okay, so the meeting is adjourned.

(Whereupon, the meeting adjourned at 11:15 a.m.)