DEPARTMENT OF HEALTH AND HUMAN SERVICES

ADVISORY COMMISSION ON CHILDHOOD VACCINES (ACCV)

June 4, 2009

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Table of Contents

P R O C E E D I N G S (1:05 PM)

Agenda Item: Welcome and Chair Report, Magdalena Castro-Lewis, Chair

MS. CASTRO-LEWIS: I would like to call the meeting to order. Good afternoon. I would like to thank everybody for being here. All the commissioners that here and this is really great that we don't have anybody on the horn. But we might, Tawny. But it's great to have you here and thank you all for coming to our meeting to those in the back of the room.

Just for the benefit of people attending the meeting and some of the presenters that are new and the commissioners, I would like to just go around the table with you and introduce yourselves, all of us, so we know who's here. And what about if I start with Sherry.

MS. DREW: Hello, I'm Sherry Drew.

MR. SCONYERS: I'm Jeff Sconyers.

DR. FISHER: Meg Fisher.

MS. GALLAGHER: Charlene Gallagher.

DR. MULACH: Barbara Mulach.

DR. WEINBAUM: Cindy Weinbaum.

MS. SAINDON: Elizabeth Saindon.

MS. TEMPFER: Tammy Tempfer.

DR. HERR: Tom Herr.

MS. HOIBERG: Sarah Hoiberg.

MS. BUCK: Tawny Buck.

DR. EVANS: Geoffrey Evans.

MS. CASTRO-LEWIS: And I'm Magdalena Castro-Lewis, Chair of the ACCV. You are just in time, Dan.

DR. SALMON: Dan Salmon, NVPO.

MS. CASTRO-LEWIS: Thank you. I would like to thank Kathleen and Sarah who are part of the committee to put together the agenda for today. We have a very long agenda. In fact, the second day has been a little bit extended. So we have time for discussion. The first item on the agenda is the Chair Report. I just want to say a couple of things that have happened between the last meeting and now, some of them, just to refresh our memories.

The Outreach Committee met twice. I attended twice over the phone and in person this morning. And Sarah, who is the Chair of this Committee, will be reporting on that tomorrow and summarizing the good ideas that come out from the meeting.

Just to be sure that Jeff and Tawny and everybody is informed, the letter that the ACCV prepared with the recommendations for HHS was delivered. Jeff informed me that. It was sent on May 7th. So let's see what happened with that.

Also, a letter that was signed with the previous co-chairs and the present co-chairs of the ACCV was sent to

Dr. Evans, requesting some information on the study that is the IOM he's conducting on some of the vaccines. So tomorrow we will be also discussing, we will have Dr. Stratton from IOM coming to our meeting to talk to us about the study.

And the last two days, Dr. Evans and Rosemary, I can't say the last name, and everybody, please let me make apparent, this is if I mispronounce your name, please forgive me. I'm not good at it. We attended the NVAC Meeting. And one thing that it was clear that is also happening in our Commission is that they feel somehow the same frustration that we feel regarding the many recommendations that we sent to HHS and we don't get the results that we really would like to have. So I just wanted to share that with you. That it's not just us. All the advisory committees out there feel the same way.

The Safety Working Group, the Vaccine Safety Working Group will continue working. They're starting a Phase II. And Tawny is going to co-chair the working group. They have great results and you'll soon find out about that, too.

A great portion of the meeting was dedicated to discuss the H1N1 flu and particularly the vaccine coming out also. I just wanted to point out, you know, that there is talking about a vaccine being available during the flu

season. But, really, no more details about it. Just to keep our ears open and see what happens and how that is going to relate to our Commission.

Another interesting thing that was discussed in the meeting was the NVAC evaluation. There were a lot of very interesting points that were brought up and I think -- is that a public document that people can get -- the results of the evaluation? Do you know Dr. Evans?

DR. EVANS: Anything that was passed out during the meeting is public.

MS. CASTRO-LEWIS: So it would be interesting if any of you would like to see how they feel about it own NVAC. And, you know, perhaps in the future, we think of doing something similar for our Commission. What is our performance? What do we think? How do we feel about it? And what are the restrictions that we have about the Commission?

And Jeff, I think I'm going to put you on the spot. He attended an IOM panel in April, a presentation of the ACCV. Maybe you can tell us a couple of words about it, what came out of it.

MR. SCONYERS: This was, I think, the fifth stakeholder meeting. Was it the fourth? The fifth one is happening right now, right? So this was the fourth stakeholder meeting and it dealt with issues of vaccine

development, testing, and safety. There were four panels. The first three really were pretty scientifically-oriented and I'm not competent or prepared to comment very much on them. The final panel really dealt with the Act and the Injury Compensation Program and the relationship of the current administration of vaccine injury claims to the Act as contemplated when it was passed by Congress.

And some of the issues that came up there were the ones that we've had frequent discussions about here, such as the need for regular and periodic updates to the Table and the need to make sure that adjudication of claims are speedy.

Jeff was also there and I don't know if he wants to say more about it. This was part of a series of stakeholder meetings to gather input by the IOM and it was interesting. I didn't bring my notes with me because I thought we weren't going to do this, but it was interesting.

The final panel that was the one that I was on was very policy-oriented and included Barbara Lowe-Fisher, who, as you know, was here addressing us last November. She made basically the same points that she made with us that I think were well received.

Agenda Item: Approval of March 2009 Minutes, Magdalena Castro-Lewis, Chair

MS. CASTRO-LEWIS: Thank you, Jeff. That's it. That concludes my report. Any questions or any comments? Okay. I believe everybody received the minutes. So I would like to proceed to the approval of the minutes.

DR. FISHER: I move to approve, but I do have -- there's she's instead of he's on page 16.

MS. CASTRO-LEWIS: Okay, noted.

PARTICIPANT: Mr.'s instead of Ms.'s.

MS. BUCK: The minutes are much improved. They are really good.

MS. CASTRO-LEWIS: Yes, thank you.

MR. SCONYERS: And on day two, I am not a doctor.

MS. CASTRO-LEWIS: Thank you. Any other comments to the minutes?

PARTICIPANT: Could we get a second? Do we need a second?

MS. CASTRO-LEWIS: Yes, okay, thank you. I do have a comment. I agree with Tawny that they're much better. I read every line of it and they're very clear. I have, I believe it is page 15, where we voted on the statement that we prepared after the presentation from Dr. Salmon and we had a motion, and we approved a statement of support for the opening of and including communities in this process. And I would like to see this statement completed as we prepare it in the minutes because it says

that it was passed and it said that there was an addition to it, but we really don't have the motion. So I would like the motion to be included and be very clear what is it that we have passed. Any other comments? Okay, so all in favor to approve the minutes with the corrections and additions?

(On motion duly made and seconded, the minutes of the meeting were approved.)

MS. CASTRO-LEWIS: Thank you. So next on agenda, Dr. Evans, could you come please give us the report of the program and work us through the agenda please. Thank you.

Agenda Item: Report from the Division of Vaccine Injury Compensation, Geoffrey Evans

DR. EVANS: I'm happy to. Good morning, welcome to, actually, good afternoon. Welcome to the seventy-second quarterly meeting of the Advisory Commission on Childhood Vaccines. As usual, the meeting is assisted by Michelle Herzog in the audience, who you should be directing questions to.

And so, today and tomorrow, the agenda items are as follows. We'll have the update from the program I will provide. And then the Department of Justice from Mark Rogers. Then Chief Special Master Gary Golkiewicz will follow with an update on the Omnibus Autism Proceeding. Then a presentation on the report of the Petitioners

Satisfaction Survey, which we had presented draft copies in the past, but this is now the final report that has been delivered to HRSA. Following that there will be a presentation on the process of the Advisory Commission on Immunization Practices by Dr. Jean Smith from CDC. And then the usual updates from the Commission ex-officio members, NIH, NIAID, CDC and the National Vaccine Program Office.

And then tomorrow's agenda will have a presentation by Skip Wolfe and Kim Wung from CDC on the Vaccine Information Statements. As you know, the Commission has mandated the review of all new and changes to the Vaccine Information Statements published by CDC. Then there will be a presentation update on the Institute of Medicine Project, a committee that study vaccines and adverse events. I will lead off with some background followed by Dr. Rosemary Johanne Yang, Chief Medical Officer and Dr. Kathleen Stratton, Project Officer for the Institute of Medicine. And following that will be a report from the new chair of the newly formed Commission Outreach work that we've prepared. And also I should mention in your folders, commissioners, you have, on the right side, presentations for today and tomorrow. And there is also legislation, both of which were introduced during May, you have a copy of HR2459 introduced by Representative Dan

Burton of Indiana, which is actually a re-introduction of previous bills he's put forward which seeks amendments to the Vaccine Injury Compensation Program in various categories, many of which are similar to what was contained in the Letter of Recommendations that was sent to the Secretary. And Michelle did a very nice job of putting together a summary table with one side the bill provisions and the other side where there was contained in the letter to the Secretary affecting the Commission's recommendations. So you will see that.

And there is also another bill that was recently introduced by Representative Karen Maloney, HR2617, also a bill that was introduced previously by former representative Dave Weldon, which seeks to amend the Food, Drug, and Cosmetic Act, to reduce exposure to mercury through that. So you will find that in your folders.

So starting with the DIVP statistics of claims filed, a few trends of note; that the trends for the non-autism claims continue to increase because of new vaccines that have been filed, particularly influenza vaccines. And you can see that the trend here starts to go up with a downward trend in the number of autism claims, particularly since the beginning of the year, especially after the February 12th decision by the US Court of Federal Claims in

the three tests cases. It seems to me that those filings are decreased.

Next, in terms of adjudications, historically, as one member pointed out, the number of claims under dismissed have exceeded the numbers that are under compensable, with some minor variations in 2002, 2003, 2001, but there is a striking change of course that's noticeable in fiscal years 2008 and during this fiscal year. And the question is why? Two things that are apparent here, we've talked about this in the past to some extent, that, number one, we received 184 influenza claims during 2007 at the two-year deadline for filing retroactive influenza claims, going back eight years. Whenever new vaccines were added to the program, and influenza was added to the program in 2005, so when the July 01, 2007 deadline came up, we received, at that point, 184 claims. And it's taken several years for those claims to work through the system and be adjudicated and in doing so you can see the bump up in adjudications.

In terms of the compensable versus non-compensable, there has been a change in the program also the past couple of years in that the program has been increasingly settling cases and certainly one of the major reasons for that is the fact that in 2005, 2006, the Federal Circuit Court of Appeals issued decisions in Alfin

and Capizzano which modified or changed the interpretation of causation under the Act and the program has chosen more to litigate or to settle cases rather than choose to defend them in some instances before the court.

So those two things together, the bolus of influenza claims and the fact that the program has been choosing not to defend cases, is responsible for the dramatic change in the numbers of claims that are compensable in ’08 or ‘09. Whether that will continue, I don’t know. But that’s, at least, the influenza claims are the major reason for that.

MR. SCONYERS: Geoff, under the compensable cases, you know we’re trying to get our language straight, and I appreciate Justice trying to help us understand the difference among the different categories. But compensable, I think, includes the conceded and the settled cases. Is it possible to differentiate the compensable cases between Table and non-Table cases?

DR. EVANS: To some extent it is. But let me go to the next slide, which I think will try to graph some of this. I went ahead and did a breakdown, and this is similar to some of the data that the Department of Justice has provided the Commission in its last reports and updates. But what you’ll see here when you look at this data is that it again reflects the fact that there is an increasing

percentage of claims that are compensable, increasing numbers of claims. And you'll also see that under concessions, and a concession for the most part indicates that it's a Table condition, because as we've all become familiar with, there are few vaccine injuries which there is proven evidence of causation. So when you see a concession, that should be viewed as a Table condition. Also to point out that since there is only one injury for hepatitis B on the Vaccine Injury Table, and that's anaphylaxis, and I don't believe we have a true case of anaphylaxis that has been filed so far. So all of the hepatitis B claims are off Table and, of course, all the influenza claims are off Table. And hepatitis B and influenza represent the top three vaccines that are filed with the program.

So by inference, you can begin to put together what is likely to be Table and non-Table.

MR. SCONYERS: Very helpful. Thank you.

DR. EVANS: So this is the pattern that has been going on for the past three years and like I say, of course, the kinds of claims that have been filed. Influenza is given in much greater numbers than any other vaccine that is covered by the program. It's something on the order of 110 to 120 million doses are distributed annually. So this obviously is going to be a vaccine that will represent

either the largest or the second largest percentage of vaccines that are filed.

Continuing on, in terms of compensation, in the next slide you'll see that at the rate, we're probably going to be somewhere close to where we were in fiscal 2007, close to $99 million to $100 million dollars at the end of the fiscal year and pretty much on course. And the average, over the past seven years, has been $69 million dollars petitioners awards annually, and $5 million dollars for attorneys' fees and costs.

Everyone always wants to know about the trust fund and it turns, again, with influenza vaccine, that has significantly increased the revenues coming into the trust fund. So basically, and this is actually fairly easy to understand because you have six months of experience here from October 1 to March 31.

So that represents a total of $150 million coming in, $98 million of that revenue and $51 million interest on investments. And it was $150 million is half the fiscal year. So overall, $300 million will be coming in this year against outlays of about $100 million dollars. So the program will net $200 million dollars this fiscal year if this pattern continues.

Okay, under Significant Activities, which for all intents and purposes, was my travel plan last couple of

months. We can start with the Vaccine Safety Datalink meeting I attended in Atlanta on March 18 and 19. And then I had a particularly interesting experience when I participated as a subject expert, as they called me, in an all-day dialogue session on March 28th, at the Columbus Public Health Department. It was actually a building that was 120-130 years old and it was renovated recently by the city of Columbus. And they held one of three sessions during March and April aimed at enhancing public participation in vaccine policy deliberation, and specifically wanting to know people's values and concerns regarding immunization, and why some concerns were more important than others, and specific suggestions on the National Vaccine Plan.

And this was sponsored by the National Vaccine Program Office and I had a very interesting day as I said, listening to this and participating. They could ask me questions. Approximately 100 members of the general public came in. And I know Ray Strikus has talked about this before and we expect that the National Vaccine Plan final report will be issued, I believe in this November.

On April 1, I provided an update on the Vaccine Injury Compensation Program at the forty-third National Immunization Conference in Dallas. This was the plenary session, which is always important, when you get a lot of

people coming and the title was The Vaccine Injury Compensation Program – A Critically Important Component of the Nation's Immunization Program. And about 200 people were in the audience.

On April 14, Jeff Sconyers and I attended the IOM Committee's own review of priorities in the National Vaccine Plan. As he mentioned, there are other analysts I should mention, were Dr. Anthony Robins, former Director of the National Vaccine Program Office, and Tim Wesmoreland, who is a Professor of Law at Georgetown University and has also been working now with Henry Waxman's staff once again. He and Ruth Patts were key staffers on Congressman Waxman's subcommittee on health during the 1980's and wrote parts of the legislation that is our program.

This is someone who has an important source background and perspective on our program and I thought actually that panel, of all the panels, may be biased. But I think with Jeff's participation especially the best panel of the day.

On April 20, I attended the first meeting of the IOM Committee to review adverse effects of vaccines. Thor Somsak, the Assistant Administer of our bureau and the Health Care Systems Bureau, gave opening remarks on behalf of HRSA. And Dr. Rosemary Johann Liang, our Chief Medical Officer, provided the charge of the committee. And there

was public comment for the remainder of the hour and then the committee went into closed session.

On May 7 and 8, I attended the Annual Meeting of the Clinical Immunization Safe Assessment Project. And that was at the CISA Project, and that was in Atlanta at the CDC. And as Magda mentioned, we spent the last day or so at the National Vaccine Advisory Committee Meeting in Washington. And Magda, as liaison from our Commission, provided some comment to the Committee, at the agency update.

The listening audience, the points of contact are as follows. You can write the program, the National Vaccine Injury Compensation Program, at 5600 Fishers Lane, Parklawn Building, Room 11C-26, in Rockville, Maryland, 20857. The 800 toll free line for information is 1-800-338-2382. The url www.hrsa.gov/vaccinecompensation. And public comments or participation in committee meetings should be sent to Miss Michelle Herzog at the address I just mentioned before, Parklawn Building, Room 11C-26, 5600 Fishers Lane, Rockville, Maryland 20857. And the phone number is 301-443-0650, and the email is mherzog@hrsa.gov. And that ends my update.

MS. CASTRO-LEWIS: Thank you so much.

MR. SCONYERS: Can I ask one question? It occurs to me that there is a crash program to develop a vaccine

for the H1N1 flu. I just don't have any idea, is that going to be a Table addition? Is that going to be covered under the Act? Have you given any thought to what will happen, assuming that such a vaccine becomes available and as I assume it will be, it's going to be approved for administration to children?

DR. EVANS: So the question is, what about the H1N1 vaccine that's now being rapidly put into development? And the answer is, at the end of 2005, the Public Readiness and Emergency Preparedness Act was passed which set up what is now referred as the Preparedness Countermeasures Injury Compensation Program, and will be called a program, which will be administered by HRSA and specifically the Health Care Systems Bureau.

And it is modeled after the Smallpox Vaccine Injury Compensation Program, which is a strictly administrative program, but not, not judicial model, there are no attorneys. It was administratively carried out. And in similar legislation, similar procedures, so far, as most new programs are, it is an unfunded program. And once Congress provides appropriations for the administrative budget program, then HRSA will implement, put it into effect.

But certainly there's a lot of thinking right now about how this will go forward. And this does protect

manufacturers, industry, and people participating in the prepared countermeasures process after Secretarial declaration and the Secretary has declared recently that the anti-virals, Tamiflu and Volenza(?), as well as a future H1N1 pandemic vaccine will be covered. So those protections are now in place and the compensation program will follow. That was a very long explanation for a simple question.

MR. SCONYERS: So the H1N1 is not funded through this program?

DR. EVANS: So the answer, this will have nothing to do with -- this is an administrative program -- this will have nothing to do with the Vaccine Injury Compensation Program. This is a separate program, separate authorizations, separate authority and everything.

MR. SAINDON: A simpler explanation is that the tax on the type is only on trivalent influenza vaccines. And this would be a monovalent vaccine. It would not be covered.

MR. SCONYERS: Right, unless it were added.

MS. SAINDON: Right. And it would need to added intact.

PARTICIPANT: But there’s a separate

DR. EVANS: That was near the end. I thought you were asking something else.

DR. HERR: Question. Does the Act only cover the trivalent because the last presentation meeting, we talked about adding a second B strain to the current vaccine for this coming fall, this coming year. So if now it becomes a quadrivalent influenza vaccine, does something new have to be done to have that covered?

DR. EVANS: The answer is if FDA were to license a quadrivalent vaccine, whether it's part of an H1N1, or actually there was a discussion about a quadrivalent even before the swine flu virus became evident, if that were to happen, then Congress would need to pass legislation to make quadrivalent influenza vaccine covered. The specific tax code language says trivalent.

MS. HOIBERG: So what happens to people if they have it?

DR. EVANS: Well, if it's the new vaccine, it's a trivalent, it's already covered. If it's a monovalent, then it would be covered under this new program that I talked about. If it's a quadrivalent, then yes, legislation would have to be enacted.

MS. BUCK: Can I ask some questions before you go on. Back to your slide that I think you put together in response to Jeff's questions about compensable, adjudication. It would still, I would find it very helpful, and I don't know if it's possible to, in that column

compensable, where you've got -- I understand the concessions because those are table and they don't get very many of them, settlements, for me, it would be really helpful to know what vaccines causes what injuries in that, and also to understand what criterion is being used to evaluate litigative risks with these vaccines. I don't know if that information is available or how you go about getting it. But I would find that very helpful. Is it possible to get that, or do I just have to dig through the records?

PARTICIPANT: We can access that.

DR. EVANS: In some respects, it's a moving target in terms of the vaccine because sometimes the vaccines that are alleged are not the vaccines that have been compensated or settled for.

DR. HERR: Which speaks to another page, you've got another page that was just sent out and both of us talked about how many cases have been very, very light instances against various vaccines since the inception. Well, that's nice. But what about now? I mean, were all of these twenty years ago, or how many years happening now?

MS. BUCK: You know, the ACCV is gone to be, I assume, consulted with on the IOM contract in terms of giving feedback on what adverse events have we looked at. At least, that's my understanding of the process. And this

would be helpful information for us to have, to know what injuries are being caused by what vaccines.

DR. EVANS: I do understand. We will certainly take that under advisement. We've talked before about the fact that the myelinating conditions are clearly the predominant category of vaccine and that would be for both influenza as well as to a certain extent tetanus and hepatitis B, but influenza first.

PARTICIPANT: But is that a litigative risk? Is that a question for DOJ?

DR. EVANS: That's something that Mark Rogers can certainly address during his presentation.

MS. CASTRO-LEWIS: Jeff, could you please just speak up a little bit. People are having a hard time hearing and that's for everybody, please just speak on the microphone.

MS. GALLAGHER: Can we just clarify that. If it is really a litigated risk, maybe you should talk about what injuries are allowed.

MS. BUCK: I don't actually want to know under litigated risk. I want to know what criteria they're applying to determine whether they're going to do a litigative risk settlement. I want to know what they're looking at these cases and why they're deciding to do that. I understand what you're saying because I know that that

doesn’t necessarily mean that vaccine caused the injuries that are being alleged.

But I think it would be interesting for us to understand what that process is and what criteria they’re using to make those determinations.

MS. GALLAGHER: I do not think, I was just discussing the language and instead of saying 1, 2, 3, 4, 5.

MS. BUCK: Right. Under the, but it would still be helpful I think for this Commission, as we’re trying to give advice on what adverse events to study to the IOM to at least know what vaccines or what injuries?

DR. EVANS: Well, we have certainly given the IOM its working list of adverse events, the wealth of information and experience we’ve had in the categories of vaccine adverse events and they are utilizing that. I just want to be clear. Are you asking, say, if this particular case was six weeks with this vaccine and this injury, or are you just wanting something broader?

MS. BUCK: Well, how about the information that you provided to the IOM? Is that information that we can look at?

DR. EVANS: The information to the IOM was simply what you see, 96-98 percent of it is the list that you see there. We just said these are the kinds of vaccines and adverse events allegations that we’re seeing in our program

and no more explanation is needed. I mean, if you look at the first two IOM reports, a lot of these conditions were part of the studies they did back in 1990.

MS. BUCK: That conversation continues. I don't want to get into it. I know we're doing that tomorrow. I just want to make sure that -

DR. EVANS: You're just so anxious, interested.

MS. BUCK: No, I'm not. Part of it does tie into your presentation and part of it does tomorrow. But I want to make sure that I'm clarifying it right.

DR. EVANS: Absolutely. As I will sheepishly tell you tomorrow, we had long planned that the June ACCV meeting would be everything would come together and we'd talk about the adverse events, but you know, that's tomorrow.

MS. CASTRO-LEWIS: Any other questions for Dr. Evans or Tawny's comment?

DR. FISHER: Just one. Let me just follow one more time. If we look at 4.2, that has 2,349 compensated cases. So, Tawny, in the binder. So what we really want, or what would be of interest, knowing what those were, what those injuries were.

DR. EVANS: In real time?

MS. BUCK: Yes.

DR. FISHER: So that's really what we want?

MS. BUCK: Yes.

DR. EVANS: We'll see what we can do..

MS. CASTRO-LEWIS: Okay. Thank you so much Dr. Evans. The next item in our agenda is a report from the Department of Justice. Mark Rogers.

Agenda Item: Report from the Department of Justice, Mark Rogers

MR. ROGERS: Good afternoon. Glad to be here. Glad to see some new faces and I don't want to say old ones, but ones I know. On personnel, since the last meeting, I guess Vince Matanoski had left before your last meeting. He was mobilized by the Navy. We have one attorney inbound, who's a replacement for one who left. So we have a zero sum gain on our attorneys. The same complement.

On the statistics, we were talking to HHS yesterday, and let us know if this is helpful or not, we take a different snapshot of the statistics. Our time reference is since your last meeting, and it's more of a litigation focus. And I think though that the statistics, although using a different time frame, are fairly consistent, looking at HHS. We had 99 filed since the last meeting, of which 24 were autism cases, leaving 75 non-autism. The age of the injured party was about split evenly between those less than and more than 18 years old.

We had 61 adjudications. Twenty-eight were compensable. Not compensable were 33, and that sounds like an even split, but we're including autism cases in that number, so if you take those out, it's about the ratio reflected in HHS's numbers for the fiscal year. The autism cases that are coming out of the program tend to be voluntary dismissals. There's been an uptake in those since the decisions came out on theory one, and I understand that over the past couple of weeks we've had a strong uptake, so we expect next meeting statistics to reflect at least 140 more. There have been 140 over the past couple of weeks. And that very well could continue.

You have in your materials a page of statistics that digs into this a little bit in greater detail. It gives you the breakdown on compensable cases that were conceded. In the past several months or since the last meeting, there haven't been any concessions. Of those not conceded by HHS, the path to compensability, if you will, included a settlement in all of them.

Now, I warn on that statistic, that that includes two types of cases. If HHS does not concede the case, the petitioner can get to compensation through what we call a litigated risk settlement. That is where the petitioner and DOJ attorney, usually supervised or encouraged by the Special Master, agree on a comprehensive settlement that

includes damages. We'll get to the next slide, or next several slides later, a wire diagram that we hope is helpful on explaining how we get there.

But the other category is where HHS doesn't concede and the Special Master formally determines that causation has been shown. In that case, in the past three months, they have always been resolved this way, there has been a settlement on damages. So if you understand, there are two kinds of settlement. One encompasses the whole case, including causation and damages. The other, the Special Master decides and makes an award, a decision on causation for the petitioner, and then we settle the damages portion of the case, with both resulting in a judgment awarding compensation.

Decision Awarding Compensation, that zero is for decisions that determine the level of damages in a litigative context. That hasn't happened. So I think that's a good number. What it means is that all the parties concerned shook hands and agreed on what the award should be. We already talked about the non-compensable cases. They were mostly autism cases and they were voluntary dismissals.

Let me define some of our terms. I understand that you asked for that so that you understand the language

that we're using and please ask me any questions if you have them.

DR. FISHER: So the 28 that were settled, by our definition of settled, don't involve the Special Master. I thought you said that the two ways it can be settled is by the Special Master or the litigated risk. I lost that.

MR. ROGERS: It does encompass two categories. One is for the Special Master to determine causation has been shown, over against the HHS's not conceding the case. Understand, the Special Master made a decision that there is evidence of vaccine causation and then what was settled was damages.

DR. FISHER: That sounds like a decision though.

MR. ROGERS: Well, it's a settlement on damages, a decision on causation.

PARTICIPANT: Even the glossary of terms doesn't make it easy.

MR. ROGERS: Well, okay. Let's work on that. Okay, I see what you're saying. Our definition is the petition is resolved via a negotiated settlement that encompasses -- the resolution is the final judgment awarding a certain award. Now there may have been a contested causation case, part of that. But the last act in the case was a settlement on the level of damages. Does that help?

PARTICIPANT: Okay, pardon me for being very simple, but is it an issue of the injury itself? Is it a decision to settle a case and to award damages and then is there a decision to award damages due case that was most likely caused by the vaccine?

MR. ROGERS: Why don't, if you could hold the question, and we flip to the next slide, maybe this helps. I hope it does. Our wire diagram. And maybe the best way to explain this is to work our way through it with a couple of scenarios.

All right. Petition's filed, common to all cases. HHS review, common to all cases. Then the road, the path diverges. If HHS concedes the case, we go down the right side of this chart to damages. On the issue of damages, we either, the left block is the hearing by the Special Master. Traditionally, there's always been a hearing. He has the authority not to conduct a hearing, but in a contested case, the Special Master always does. And there's a decision. That's the Special Master deciding the case. Didn't happen this reporting period.

The middle route is a settlement on damages, where the parties agree to file a stipulation. Then judgment is entered on the level of damages.

That is a proffer. That didn't happen over the last three months, but that's an alternative way of

resolving damages that's good. What it basically encompasses is when both sides, the most typical case would be one with, where the parties have agreed to a single life care. And the life care planner renders an opinion that both sides aren't going to litigate obviously, but it's not a formal settlement that has to go through the process of approval through DOJ. It's submitted to the Special Master. Both sides say it looks good to us and the Special Master approves it. So that's the conceded. Any questions on the conceded case?

MS. CASTRO-LEWIS: So what is the difference between the proffered and the settlement for damages, because you can't -- on the surface they are the same.

MR. ROGERS: It's very similar in that there is hand-shaking and heads nodding up and down, and everybody is happy with the way it is, there's no disagreement. It's one of formal processing. With the settlement, there's a disagreement over what the level of damages should be.

MS. BUCK: So like three levels of happiness.

MR. ROGERS: Petitioners think it ought to be a little higher, quite frankly. And the respondent, DOJ, HHS, think that's a little too high, but let's split the difference. And there's an agreement to do that, with compromise. It has the virtue of an agreement in the end,

that both sides were drawn to it. And on the DOJ side, we have to get approval for that.

On the left side, the parties just couldn't agree, the hearing. The parties couldn't agree. The Special Master had to decide the case. The good news is, for those cases coming down this track, we're agreeing. So that's the conceded side. We'll get back to this side, a little complicated, but as I said over the last three months, there were no conceded cases.

The left side is where the action is, if you will. They're not conceded cases. Two things can happen with a not-conceded case. The parties can comprehensively settle their differences. That's the left side, where they say, hey, HHS says we don't think you've proven causation. However, we will settle this case for X amount, parties negotiate and come up with an amount. And that is submitted to the Special Master and the Special Master almost always approves it. So that's your left, far left side. That's a litigated risk settlement.

DR. HERR: Quote, unquote, damages are less than if it was conceded? Payments would be less than if conceded and there's no assumption of causation?

MR. ROGERS: That's fair to say. That's where the whole case is encompassed by a settlement agreement,

damages and the issue of causation. HHS is not agreeing on causation, but they are settling the case.

MS. BUCK: And that's the column that I have a lot of questions about. What is the criteria for? What are those cases? What are the injuries that have been alleged, even though the settlement doesn't mean that the injury caused, what are the vaccines involved there, there's a lot of questions about why, what goes on there, how the decisions are made, what vaccines are falling into that category, what injuries are in there. I don't know how much you can offer on that, but that's where a lot of questions come up.

MR. ROGERS: I appreciate the interest in it, particularly given that this is one of the most common routes to compensation. A lot has gone into bringing us to where we are today. I think you can go back to the original intent of Congress, it was for a very expeditious program, the Special Master decision at the end of it, within 120 days in that timeframe, and all of that.

With the Special Master's decision, you would have the kind of transparency that you're seeking. We know exactly what cases are being compensated. And a Special Master's decision is designed by rule to be very exhaustive in how it explains, how it arrived at that decision.

The settlement is a far different vehicle for resolving a case. By it's nature, it's not transparent. It is let's get just the people in the room that have an interest here and let's try to resolve this expeditiously. Traditionally, settlement agreements have had confidentiality clauses to try and speed the way to an agreement so that both parties aren't looking over their shoulders at the public implications of what they might do. This is where we gravitated because it's fast.

I think if you start it, to the extent you try to open the door on that, you would jeopardize the goose that's laying the golden egg, if you will. I think parties would start posturing. There would be a tendency for parties to start posturing for their constituency. And there would be a reluctance to settle the case by either side, under certain circumstances, because of the precedent, if you knew it was going to be public.

So there's a tension here on your need for information to act in that public policy capacity and that vehicle for resolving a case quickly.

MS. BUCK: That's understandable. However, you know, if most of your cases are going through this process. Then the lack of transparency on what's happening here is fueling a lot of the distrust in terms of public perception on what happens in the program. And I can appreciate

exactly what you're saying, and yet, you can probably appreciate what I'm saying, too. And I don't exactly know where to go with that, but because you're taking this route, which is quick and trying to meet the purpose of the program, but in a way that's not transparent, is problematic.

MS. GALLAGHER: Yes, I was going to suggest something that might bridge some of Tawny's concerns and give her some information and yet not jeopardize the settlement process, which I think is a very good route to bringing compensation to families. I wondered if the pleadings themselves are public documents, and if we could merely have a list of what was alleged in the pleading of the case, would that in any way compromise the settlement? I'm not asking for the details of how you arrived at your decision, but simply, I think it would say what vaccine, and I think it would say what injuries were alleged, if that document is allowed to be made public?

MR. ROGERS: It's an interesting thought. I think that the data would elude you because it is not uncommon for the initial claim to list many vaccines and many injuries. And as the case developed, we would focus down. The other problem is that the settlement process is so free-wheeling, if you will. The factors that go into a settlement decision, I think, would just deprive trying to

glean public -- I would be very reluctant to make public policy decisions based on a settlement, just based on what vaccines have been alleged and what injuries alleged to.

For instance, and I'm pulling these out of the air, but we could have an issue on either side where your expert has gotten sick. And your expert can't continue in the case. That becomes a factor in settlement, where you develop the case with a particular expert and here on the cusp of trial, that expert has a problem and can't testify, and you have to start over again. From HHS's standpoint, it becomes a significant factor, understanding that we need to resolve these cases expeditiously. It has nothing to do with causation. In a close case, that can close it.

Other factors are, you have a particular Special Master who has a particular view of a particular petitioner's expert. We, on HHS's side, would say, you know, that kind of tilts it toward settlement. And then in the end, we have a ratio, a litigated risk ratio, let's say, chances of losing here are about 20 percent. We think we have a very good case, but we could settle this at 10 or 15 percent because of the cost of litigation. That's the kind of evaluation.

Now, if you were to take the fact that we could settle such a case, and draw any sort of public policy conclusion that hah, with this vaccine and that injury,

there's something to it. It may be 10 percent to it. It may be even less than that. See, these are real factors that have played in the settlement decision.

MS. BUCK: No, the thing for me, Mark, is that what you're doing in that process is exactly what you should be doing. This is a program that's based both policy and science, and you are weighing those two as you go through that process. But it's happening in a way that wasn't, you know, you said it use to go through the decision process with a Special Master's. It used to be a public record. But it's going through this way now that's not transparent.

So it's a rub for me because what you're doing, what you're weighing, and how you're doing it in that, is the design of the program, I believe, because you're weighing both factors there. But the lack of transparency, the concern to keep it in a private and closed proceeding so that there's not some sort of a public perception that A caused B is a real conflict within the program itself.

MR. ROGERS: I think it is a very fair point in the context of a public compensation program, that the settlement process is shielded from scrutiny. And I can say, as you might expect, internally within DOJ and HHS, there is a common sense desire to be consistent from one case to the next. But then, our experience is that as you

move through individual cases, the number of variables at play is mind-boggling.

So I think that, to the extent, there is a desire that the program become more transparent. I hate to say this, a few Special Masters just walked in, it would be along the lines of a decisional process because decisional processes is, by it's nature, explanatory. The Special Masters are obliged to explain in great detail how they got to the bottom line.

Whereas the settlement process is, by it's nature, non-explanatory. But I want to concede to the fair point that it's frustrating to have all the cases resolved that way and have it be shielded from view, if you will. Although I would say that your key issue is the case that's not conceded. Let me back up and say it a different way. Your key point is the causation decision, not the amount of damages. I assume that's not a focus of concern. It's what vaccine caused what injury.

You do still have, even though we have the 28 settlements, not all of those are, shields the Special Master's decision on causation. And I would submit that you do have a fairly good, we call it stare decisis, that's a body of decision, published decisions by the Special Masters and the Court of Federal Claims and the Federal Circuit, that give you a pretty good idea of what kinds of

cases are being compensated and that body of law, published law, drives our settlement process. It's one of the key factors driving that settlement process.

MS. CASTRO-LEWIS: So is there a tendency on some of the specific vaccines that are more settled than others under these processes that you are talking about? Maybe I didn't make my question clear. Is there one vaccine in particular that has more cases settled than all?

MR. ROGERS: You know, I actually haven't done that count. But I guess my point was that you do have a considerable body of cases that do exams, examines specific vaccines and specific injuries, you know, like the recent public cases of autism decision, that examine the available evidence of causation and make a finding. I would even caution on the public policy standpoint that I would be cautious about using decisions that are made in the legal forum to drive public policy. And that's the other point I wanted to make, that things happen in the legal forum. I just don't know that a Special Master's decisions, with all due respect to Special Master's decisions on an issue like that, should drive the medical side of the public policy equation. I just urge caution.

DR. HERR: I'm here again to continue this discussion of compensated cases or whatever. It calls into question, in some ways, the implications you arise from

this table, the steps provided us as far as injury compensation program, listing down to the various vaccines, that how many were compensated, how many were missed. The fact they were compensated can, doesn't necessarily make it clear as to what the causation was or whether that was accepted or not accepted or what, just that they were compensated.

MR. ROGERS: Yes. And there's so much on the settlement side that goes into that equation. I guess I'm agreeing with you in repeating it.

DR. HERR: It gives us a gray idea but recognizing it gray.

MR. ROGERS: Yes. On the disclosure part of it, Special Masters are not loathe to explain to petitioners at that Rule 4 conference what their chances are based on their accumulated experience. So, I don't think petitioners are left in the dark. They've got a Special Master there that's laying it out for them.

MS. BUCK: But really, you're not settling cases that you don't, I mean, certainly you're not settling cases that you don't think that there's some factor in the causing of the injury?

MR. ROGERS: We are settling cases that we don't think causation has been proved. But we believe there is a litigative risk that there may be a finding of causation,

nevertheless. A lot drives a settlement policy. There are very few cases that we would not even discuss. There's another, shed more light on it.

MS. BUCK: So I guess that's where I always go. What is that criteria? Are you looking at, you know, that's what I always get back to.

MR. ROGERS: I would say the short answer is we look very carefully at the litigative risk. And if it's very small, we're very disinclined to settle. But it's almost never completely out of the question.

MS. BUCK: Can I ask one more question, then I promise I'll be done? Is the Department of Justice contributing in any way to the funding of the IOM contract, the HRSA IOM contract?

MR. ROGERS: My answer to that would be no, that we traditionally, we have always, almost always, had additional funds, or excess funds, that we've been able to transfer to HHS. To my knowledge, it has never gone to them with a string attached other than to administer the program.

MS. BUCK: So this current contract at the IOM, HRSA's contract with the IOM to study these adverse events, to your knowledge the Department of Justice is not contributing?

MR. ROGERS: My answer to that would be no. What HHS, how it uses those funds, we don't direct that in any way shape or form.

DR. FISHER: Can I go back to this diagram? Where does the Special Master actually enter?

MR. ROGERS: The Special Master gets the petition the same time we do. It is filed, the Special Master hangs back, under the rules, until we've had a chance to review it and file a Rule 4 report, which is our review of the case. And in that Rule 4 report the Special Master would be looking for whether it's a conceded or non-conceded case. The Special Master is there and aware of it, but not active.

DR. FISHER: I guess my question is if it goes all the way down the line, the settlement line, is it not possible to never involve the Special Master?

MR. ROGERS: No, it's not. And the reason is that they are obliged to run that Rule 4 conference to find out what's going on. And so they superintend over the process. How active they are depends upon how amicably the parties are working towards a resolution. The Special Master is very interested in having the case resolved. If the Special Master is satisfied that it's moving very quickly between the parties, there will be hands off. So, to answer your question, they're involved with it start to finish.

MR. SCONYERS: Do you have more to get to Mark, because I have something?

MR. ROGERS: Actually, not too much.

MR. SCONYERS: I'd like to comment on something that you said, which is the disclosure risks around settled cases and the possibility of proffering. I think we've had this conversation at various times since I've been here. There is a real problem, I think, in the lack of commonality in the definitions of what causation means within the health provider world and what you look at as you're looking at settling the cases.

I know what the standard of proof is for cases. It's much less than the scientific standard of proof. And then when you get to the point of looking at settlement, of course, you would have to take into account the risk that that lower standard of proof will be met through any number of circumstances -- the evidence is on how a particular witness plays on a particular date, whether the expert is available or not available, all of those things that go into the mix of actually dealing with litigation is what I do, too.

And so I think one of the basic problems this program has right now in the public perception is the inability to make a meaningful distinction between scientific proof about the causation or the lack of

causation of a particular injury by a particular vaccine, and the logical, reasonable, and appropriate response of the two departments, of Justice and the HHS, to settle cases, when on the whole, they are cases that ought to be settled.

I just would encourage you guys to find a way to talk about those two things at the same time because you're not talking about either of them right now. And as a result, I think, people have a trust level that's lower than it could be. And both the vaccine system, the basic safety of vaccines, and the existence of the program to compensate people who do have an injury that might be related to vaccines, not necessarily is related to vaccines, but that might be related. Because I think the standard you're applying is a lot less than has been proven to be related to vaccines, at least as far as science. That's not how either Justice or HHS talks about.

So people don't know that the program actually is trying to take care of people who might be able to demonstrate a connection between it.

MR. ROGERS: All right. Any other questions or would you like me to comment on that. I take that is an admonition.

MR. SCONYERS: If you feel like it.

MR. ROGERS: It's a point well taken. It's along the same lines as Ms. Buck's comments that, you know, it's a fair point that the settlement process that has overtaken this process, not completely, is shielded from public view. So there is a mystery, and where there's mystery in a public program, suspicion can follow closely. The point's well taken.

I think, though, we do, we do very carefully look at these cases through a legal prism. It's not necessarily a scientific one. HHS leans toward the scientific prism, and we lean towards the legal one. And we kind of work together and we come up with a settlement policy.

It maybe something, though, for the Commission to look at as well, on a way to resolve this that tilts it back towards the a public decisional framework that would be more transparent. So we are where we are today and the point is well taken.

Okay, on autism, as you know, we had the trials last year and the decisions have issued and they're on appeal at the Court of Federal Claims. Argument has been scheduled in Hazelhurst for June 11th, Cedillo for July 7th, and Snyder for July 29th. So we're getting close to having those cases finally submitted for a decision before the Court of Federal Claims.

On theory two we just filed our post hearing brief in Mead, King and Dwyer. So those are now submitted to the Special Master.

On appeals, there have been two significant decisions and those have been the Supreme Court's decision to deny certiorari in Mojica and Kay. Both of those were jurisdictional questions. It is becoming very, very settled law in the program that a late filed claim, there is no jurisdiction. Mojica follows the Brice cases which found the same. And in Kay, that was a decision on attorneys' fees, that attorneys' fees are not appropriate in a time-barred case, a case for which there is no jurisdiction in the program. That could be considered settled law.

On the Court of Appeals for the Federal Circuit, the only significant update is that the Nordwall case was withdrawn by petitioner. The Nordwall case. That was a standard appeal of the Special Master's position on causation. It was brought by the petitioner and they did not prevail at the Court of Federal Claims. That wasn't a jurisdiction, it was rather causation.

Turning the page, we have a number of cases before the Court of Federal Claims. What I would point out here is that there all filed by petitioners. That is

consistent with our practice and institutional reluctance to appeal. The bulk of these are on the issue of causation.

And that concludes my presentation, subject to your questions.

MS. CASTRO-LEWIS: Okay, thank you so much. Does anybody have any follow-up questions?

MS. BUCK: I have one more. Glad you said that. I have one more. Is it possible to find out, in the budget, how much is being spent on just the autism cases?

MR. ROGERS: The short answer is no. You know, I can give you some guidance that we have three or four attorneys, kind of do the math, but no, we don't track it. It's about a third of our office effort, that's kind of a very global, my perspective judgment. But, no, we don't track it.

MS. GALLAGHER: First of all, I'd like to say I was so pleased to see you back. And I'm so happy you're back safely. And second of all, I want to say that I think it's laudable that the Department of Justice does settle so many cases because I think pushing all cases to a hearing would slow down the process and would actually not be good for claimants. So notwithstanding the public perception issues and all the other issues that have been discussed by everybody who made really good points, I do think it's really a good thing that your Department has been doing by

reaching settlements in these cases and I just want say that publicly.

MR. ROGERS: I appreciate that.

DR. FISHER: The last 1, 2, 3, 4, 5, the last five appeals apparently are done. So I'm assuming affirmed means the appeal didn't make it? And what is remanded mean?

MR. ROGERS: Remanded, if I can give you, with the Doe 11, yes, affirmed, when the appellant was petitioner, they were appealing and it's affirmed, that's bad news for the petitioner. That means the Special Master's decision is approved, if you will.

Remanded means, in Graves, it was, for instance, for further fact-finding. That means that the court has concerns it wants the Special Master to address. Loving, the same thing. That was, in that case it was the Court of Federal Claims wanted the Special Master to consider a significant aggravation analysis. Again, it's the Court of Federal Claims thinking the Special Master should have done something more and remanding it to him or her to do that and then issue another decision on remand, from which other parties could again move to review.

MS. CASTRO-LEWIS: Thank you so much. I actually learned a lot more today than in previous sessions from the Department of Justice. Thank you.

Now we have the honor to have Special Master Gary Golkiewicz, and forgive me if I mispronounced your name. But I'm going to let Sherry introduce him a little bit more formally and tell us why we have the honor of his presence here.

MS. DREW: The Chief Special Master has been asked to give us and the public an update on what's happening to the thousands of autism cases. We understand that some of them have been dismissed, but most of them are still pending, pending the appeals. And we wanted to know how long those were going to take and what people with cases can expect to see in the future. And I've also asked him to address a couple of recent Special Master decisions that have some significance to petitioners and their attorneys.

Agenda Item: Omnibus Autism Proceeding Update, Gary Golkiewicz

MR. GOLKIEWICZ: Thank you Sherry. First of all, I would like to offer my public welcome back to Mr. Rogers. Second of all, I apologize for getting in here late for his remarks and the discussion on settlement. I would much rather talk about settlement, more interesting than topics I was given, but I was tied up with the security. I couldn't get through, no matter what I told them.

The three topics that I was given though, one is the decision in Masias, which was the interim attorney's fees case, dealing with irreducible minimum. The second is a ruling in I think it's Miyake, the pronunciation, regarding various issues involving annuity experts and brokers. The third was, as Sherry mentioned, the omnibus autism proceedings. Now these three topics, I mean, we could talk about these for an entire day. So I have thirty minutes, so obviously I'm going to gloss over a lot of this and just hit the highlights.

But first let me talk a little bit about -- you'll notice Mr. Rogers was having a difficult time catching up with HHS technology. You see my legal pad. Masias and the irreducible minimum, this decision represents a practical resolution of the disputed interim attorneys' fees, pursuant to the Federal Circuit's decision in Rivera. That is, the irreducible minimum is that amount that no reasonable litigant would deny was owed to the moving party.

Now, take it back just a step. In Rivera, you might recall, that the Circuit said that the Special Masters could award the interim fees. And they didn't tell us much as to when, how, and so forth. They left the details out. But in essence, it's about one line, to prevent undue financial hardship; I added the word

financial, hardship from protracted proceedings and costly experts, to ensure that petitioners have a stable of qualified counsel.

Interim fees, in effect, has added another stage of litigation in the program, in addition to entitlement, damages and final fees and cost, we now have the issue of interim fees. And I must say, we're still feeling our way through this issue, when the interim fees are appropriate, and should they be awarded just once or on multiple occasions. As I said, the Circuit didn't tell us much.

Thankfully, so far, as with final fees and costs, the vast majority of these cases have been resolved informally by the parties. An example to date, I've issued, I believe, two opinions on interim fees and all the remainder of them have been resolved informally.

However, we get some cases that are presenting as they do in final fees and costs. They present a legitimate issue on hourly rates, numbers of hours, and so forth. And that's where Masias comes in. It's sort of, it's recognizing the limits of resources and so it therefore awards what is not in dispute, irreducible minimum, which we believe meets the Avara(?) objective of getting money to counsel quickly, while tying up the resources of the Court, the Department of Justice and the petitioner.

And then the disputed issues are, in essence, deferred to either a later date that the Special Master has time to get to them or all the way to the final award of fees and costs. So, in essence, that's what it is. It simply is taking the dollar figure that everyone can agree to. I recently had one and the Department agreed that they wouldn't object to X amount of money and we would defer the rest. So the entire thirty pages, or whatever it is, is reduced to the minimum of the irreducible minimum.

The second topic of Miyake, the annuity expert, unfortunately I have to give you a few minutes of background on this and have to take you all the way back to 1988. The original Act provided the payment of awards in a lump sum. Petitioners came in and they suggested that they should receive, write into the litigation, the suggestion that awards should be given out in an annuity. However, the Special Master's interpreted the Act at that time, did not believe they had the authority to pay to the insurance company money to provide an annuity because of the statutory language.

That changed in 1989. Congress gave the authority to the Special Masters to pay the awards in either a lump sum or in an annuity. The annuity offered two obvious advantages. One, the insurance company bore the risk of the life expectancy. With a cash award, the

Special Master would have to make a determination as to what the life expectancy of the injured in calculating the amount to be paid out.

Two is that it eliminated the petitioner's burden to invest the cash and to get a rate of return that was sufficient to maintain the stream of income. That is if we use a two percent discount rate based on the premise that you're going to invest and get seven percent for your money over a span of years, you in fact have to get that seven percent or you're going to run out of money prior to the projected life expectancy. Again, the insurance company bears that risk.

Another benefit that became known very quickly was that if the government bought and owned the annuity, there would be generous tax advantages to the petitioner. Thus, the Special Masters determined in a couple of early decisions that it was advantageous to the petitioner to order the government to purchase and own the annuity on the petitioner's behalf. A note in the decision makes clear that there's nothing in the statute that says that the government is to be the exclusive purchaser of the annuity. But every time the issue is brought up before us, the tax issue made it perfectly clear that it was in the petitioner's advantage that the government be ordered to purchase and own the annuity.

The petitioner in Miyake challenged that process, saying it was unfair to the petitioner. The issue as I see it, and boiled down to that decision, is one of transparency. Is the broker, the annuity broker, merely cranking numbers, that is, taking the negotiated items of compensation, or determined items of compensation, and shopping those numbers with the insurance companies to get the best cost for the fund from a company that meets certain standards of safety and provides the stream of income determined that the petitioner is entitled to.

If yes that the broker is merely cranking numbers, all aspects of the annuity purchased should be open and available to the responding petitioner and the court. Or, is the broker involved with assisting the respondent and formulating the settlement offer? Stated another way, are they operating as respondent's experts? The latter is alleged in Miyake by the petitioner and the Special Master agreed, finding that petitioners are entitled to get their own financial experts at their interest.

Now, a rough analogy of this is to a real estate agent, who owes the fiduciary duty to a seller who pays the agent, and some high ethical standard, which I never was able to understand what that is, to the buyer. You can't serve two bosses. I was never happy with the seller real estate broker representing me nor are many others, since we

now have buyers' agents. The petitioners are understandably concerned with respondents annuity brokers representing their interests.

I'm not sure how big of an issue Miyake represents and what impact it's going to have, if any at all. In the past, petitioners have retained financial experts to review awards. They were paid without objection by the respondent. But I must say that, given this particular petitioner's counsel, former Department of Justice attorney in the program for many years and also very active in the claimants bar, this decision could have legs and set some trend. It's too early to tell. But the one thing to understand is that if in fact it becomes common practice for the petitioner to get a financial representative, there's going to be a cost to the program because they're going to get compensated.

Lastly, the omnibus proceeding. I've listened to several of the past meetings, including the last one, and I read the transcript of the last one pertaining to the discussion. I believe Ms. Ricciardella and Mr. Powers have done a very nice job of representing to the Commission what has transpired in the omnibus proceedings to date. And we certainly are not going to go over any of that.

What I would like to say, in just reading through the lines of the transcript, that what everyone wants to

know is what no one can answer. And that is what the impact of the first decisions, and what the impact of the next round of decisions will be on the remaining 5,000 cases. No one knows because the only binding decisions will be issued by the Federal Circuit or the Supreme Court, if they go that far.

Therefore, we won't know anything until the appellate process is completed. And that is going to take some time, especially with such an important group of cases. To give you some idea of how slowly litigation can grind, and I don't want to scare anyone, but this is reality. This happened over the weekend. There was a piece in the Washington Post business section about a Federal Circuit affirmance of a contract case. It involved the A12 fighter plane. That's the extent of my knowledge of notes. Mr. Rogers here mentioned that. I hope it's the fighter plane. But I know it was A12 contract anyway. The litigation has been going on for 17 years. It's been remanded back to the Court of Federal Claims judge, at least on three occasions that I can recall and back to the Federal Circuit and fighting against the contractor and with promises of further appeals.

That's an unusual case by all means, but to give you a better sense of, in the vaccine program, I pulled out and took a look at a vaccine lawyer's particular case of

note, the only case that has ever gone to the Supreme Court, and heard by the Supreme Court in the program is Whitecotton. And I just tagged a little bit of the litigation to give you a flavor of what can happen, case in point happened here, what can happen with a case.

The petition was filed in July of 1990. This operated under the old system. The Special Masters issued a report. The Special Masters issued a report to the judge did then confirm the Special Masters finding against the petitioner in August of ’91. It had to move pretty quickly. That decision of the judge and Special Master was subsequently reversed by the Federal Circuit in a decision in February of ’94. I never noticed why three years ago it went back in for a Federal Claims decision, Federal Circuit’s decision ’94.

So the Federal Circuit reversed in the petitioner’s favor. The government ruled for a re-hearing. That was denied. The government ruled for an en banc decision by the full court. That was denied. The government then sought a cert before the Supreme Court. The Supreme Court took the case, and the Supreme Court reversed in the government’s favor in October of ’94. I’ve got a February date in ’94. So that then led to a remand to the Federal Circuit.

The Federal Circuit re-heard the case and they reversed and remanded the case. They reversed in the Department, in the government's favor where they remanded to the Special Master. That happened in '96. There was a request for a re-hearing by the petitioner. That was denied. And a request by petitioner for a hearing en banc, that was denied. So it was then sent down to the Court of Federal Claims, to the Special Master. By then the original Special Master had left and therefore it was dropped into my lap. And so I had this case of six years and about seven or eight decisions into it.

Thankfully, both sides were worn out by the litigation. But, in actuality, the government, as Mr. Rogers indicated, they don't appeal much. They appeal legal issues. They won what they believed the legal issue was involved in Whitecotton, so they, at that point and time, they sat down and they settled the case with the petitioner. Now, if they had not settled it, there would have been another evidentiary hearing by the Special Master, which could have given rise and surely would have in this particular case the way it was going to another round of appeals.

So, it finally resolved somewhere in '96, about six years after it was filed. And I had counted up, there wre at least ten decisions that were issued. So, again,

I'm not saying it's going to happen here, but in something so important, it would not be unexpected that you might see partial affirmances, remands, and further appeals. It's going to take some time before these cases, the final appellate rulings are issued and we can move on to the remaining 5,000.

Second point I'd like to make is that this idea of the omnibus proceeding, it's not new to the program. Omnibus simply describes classed, similar things. Here, we're talking cases and issues. We frequently hear common cases without calling them omnibus. We just do it by nature.

But I went back, and I was thinking back to the first years of this program. It actually, in the first couple of years of the program, we grouped over 200 IPV cases that were alleging the reduction standards for the IPV vaccine allowed for some residual live virus to remain in the vaccine and thus caused polio. Ironically, the government's counsel, lead counsel at that time was Vincent Matanoski, who was also taking the lead in the autism cases and also presented the first large discovery effort conducted in the program.

These polio cases, it made no sense to try 200 cases. The individual petitioners could not get experts for their 200 cases, and the same expert was not going to

testify 200 times. The respondent had the same challenge. One expert I remember was Dr. Wayne Muir, was not going to testify 200 times. The Special Master, me, was not going to try all 200 cases. Thus, you try one case, decide it, and then challenge the losing party to distinguish their case.

As it happened, the petitioners' expert declined to testify on the eve of the trial. Petitioners were then asked to put on their own cases. But since they relied on the same expert, they couldn't, and they dismissed. As I recall, not one IPV case ever went to trial.

What makes the autism cases so different are the numbers and the public awareness. That is obviously with the Internet. We had no Internet back in the early '90s and the public awareness was less. But the essence of it is the same. Petitioners put on their best case. Respondent puts on their best defense. And Special Masters decide. Ultimately, the Federal Circuit will resolve it. Hopefully in doing so, will give us the framework for resolving the remaining cases.

And that is the key, is that hopefully the Federal Circuit, when they resolve these cases, makes it perfectly clear what parts of the Special Masters decisions were correct, that if there's parts that were wrong, what

parts were wrong, what standards should be applied in resolving the remaining cases.

If that's done, then we'll move forward quickly and hopefully efficiently. If that's not done, then we'll have some problems. That's basically the three issues and hopefully I've touched on all three sufficiently, but obviously I would be happy to answer any questions.

MS. HOIBERG: I had a question about the interim fees, and I was just wondering if the Department of Justice has offered to discuss the irreducible minimum fees with any of the petitioner's lawyers?

MR. GOLKIEWICZ: You'll have to ask the Department of Justice on that particular question. I will tell you that I mediated the Delo interim fees and my experience has been with lawyers on both sides, a very good experience, and we've resolved most of that. I'm in the midst now of setting up meetings for the fees as well. That will be an issue.

MS. CASTRO-LEWIS: Anybody have any more questions?

MR. GOLKIEWICZ: You had as much interest in the topics as I had.

MS. BUCK: Litigated risk settlements. Want to talk about that?

MR. GOLKIEWICZ: Love settlement. Be happy to take questions.

MS. BUCK: Do you want tell me what criteria you think is being used to determine litigated risk settlement?

MR. GOLKIEWICZ: I thought Mr. Rogers answered that question very well. I've spoken on that issue before the Commission and I will say on the issue of public awareness, we're in tune to that and what we do, we post on our website the decision, even on the settlement, and we put catch words up there. So if you look at our website, you'll see a settlement, you'll see the vaccine and you'll see the injury.

So at least, from an awareness standpoint, it doesn't have the criteria and what went on at some point, but one will be able to at least see that, and you can tell it's a settlement just by the boilerplate decision, a paragraph and so forth that's in there. You'll see hepatitis B and whatever, whatever it is. So if you have a similar case, you can at least bring up with your attorney, hey, why aren't you talking settlement here. There's at least some awareness.

I would echo what Mr. Rogers said is that what goes into litigation sometimes is not pretty. Whether that's right for this type of a program or not, that actually was an issue that right from the very beginning of

the program -- I saw David Banore in the audience awhile back -- right from the beginning of the program, the government took the position they would not settle cases. It's a compensation program, and you either qualify or you don't. There was no settlement at all. And so every case was decided.

Now obviously that has changed tremendously and being from the judiciary, I'm a big proponent of settlement. I think it's a good way to resolve cases. But sometimes it's not pretty because you have, in addition to the medical factors and the risk factors that the Department has to gauge as the petitioners have to gauge as well, you have the Special Master factor, the decision-making factor.

I trained in mediation with magistrates from around the country and we had a law professor that was instructing us, thirty to forty magistrates from around the country. And the law professor, he got up with a textbook, teaching us mediation, and remembered to think we were magistrates, you have to be kidding. My judge golf's every Wednesday. If I don't settle those cases on Wednesday, he comes back Thursday morning and he's got these cases -- that is not good. So that was a factor in settlement. Now the bar knows that and so forth, you know, that that particular judge, that magistrate, you have them on Wednesday, you know you've got to settle or you've got a

problem on Thursday. I'm not suggesting that goes on here by any means, but what you do have is the Special Master that, right or wrong, forms a view of a particular case. And he sits down with counsel, either as Mr. Rogers mentioned, but it's the Special Master giving their views at that conference call or after trial.

Look, I listen to these experts, you know, and these experts are not moving me at all. So I think what you need to do is resolve this case. And both counsel look at him and well no, we have a great case to cover. Well you had better because one of you is going to lose and I don't have a clue as to what's going on here. You don't want me to decide.

MS. BUCK: I actually think, you know, what you say makes sense. It does. But I think that my concern is that this is different. This is a program that people maybe hear about, maybe they don't. They've got a very short statute of limitations. They may not have counsel. It's difficult to find counsel now that wants to take cases. They may not have experienced counsel. They may have difficulty obtaining expert witnesses, particularly if trying to get people to be expert witness and they can't, you know, there's a long time before they pay them. I mean that, I believe, doesn't level the playing field in terms of coming to the table in a settlement because it's not

quite that fair. You know, I mean, there's actually people being told yes you should get an attorney, you don't have to fill out a few forms. I mean the program isn't presented that way and so because of that, I think, although we're asking for cases to go through quickly and I understand that settlement maybe does that and that I like the idea that settlement is balanced on policy and science and I understand what you're saying and I actually agree, except that I think that probably the playing field isn't quite level when it comes to petitioners coming to the table thinking that this is a program that they have to go through a litigated risk type settlement to get what they want.

MR. GOLKIEWICZ: Well, those are policy issues that can be debated. And you're right, I mean, I personally side with information. I think everyone should have the same information. There was a meeting, it might have been a subcommittee meeting held downtown at a hotel and I spoke there, and I suggested at that time, and I would suggest it again, the one thing that people can do is to chart out and see what kinds of cases are being settled. And if you get some similarity in those cases, then, you know, maybe the Commission should look at that.

I would always encourage the Department to try to be consistent, and anybody who listens to me on the phone,

I mean, they might put me on mute, but we certainly, and we talk about it in the office, look, I just had this type of case, this injury, and someone will go around the office saying I just had a settlement in this particular case and I'm sitting there with the same vaccine and injury, and I'm going, whoa, wait a second, conference call, why did you settle this case when you're not settling mine? Now we use the information internally.

MS. BUCK: See, that's cool.

MR. GOLKIEWICZ: Well, and I assume there's good reasons why my case didn't settle and the other one did. It could be some of those factors that are there when you're dealing with human beings. They've got a Special Master that's gone flat out on ruling against you, so you either settle this thing or not, and cash it in for risk factors and do it. Is that right or wrong? Litigation is the right thing to do. And this type of a program is right? I don't know.

We are on a leveling playing field. These interim fees have helped a lot. The other thing is that we have a new Chief Judge in court. Let me tell you, he's all for moving cases. He's all over my back right now. That's where I was before I came up here, you know, is explaining cases and why they're so old, and so forth. And we are doing our best to get to the old, move them. There is

going to be a brown bag lunch of bar associations in August. I've already talked to, August 21, I've already talked to the attorney that's involved about some of the issues and possibly the topic is going to be, what I focused on was what can we do to at least get cases positioned more quickly to move through. In some of those issues, the biggest problem is getting records completed so we can get moving. But what can we do to move that process quicker?

The other issue I wanted to talk about was the early use of a facilitator in trying to determine, you know, we're settling a boatload of cases, more than ever in the history of this program. And that's a good thing in my book. They move quickly. But I think we're doing it too late. What we would like to do ideally is to capture those cases earlier and try to get them resolved earlier before we devote a lot of resources, in both time, money resources, experts, and more.

That's where the time really goes by and people get really frustrated with the program and the parents understand this all. I mean, lawyers are having a great time and that's normal process, 60 days plus, that's nothing. And that's what the Chief Judge made perfectly clear to me as I explained, well, there's a 60 day extension. Yes, but you had five of them, you know. But those topics are legitimate topics to discuss.

I think the key is to move, well there's a couple of keys. One is to zero in on getting the cases ready for resolution more quickly. Two is more and earlier use of ADR or some sort of facilitation. And three is, to the extent possible, to make sure that petitioners are being treated the same, to the extent possible, so much grey in there, I don't know. That's for others. I can handle the process part and I can guarantee that I will be doing that. I've been told I will.

MS. HOIBERG: (Inaudible question)

MR. GOLKIEWICZ: It's difficult for people to understand it, when you sit in this seat, that what you did yesterday you wipe aside and start over again. I can tell you from experience in mediating cases, in the past I mediated a number of my cases and people would say, well, wait a second, how can you participate in this informal conversation and then go and decide the case if it doesn't settle? I'd said before, I had no problem at all. What I did today is gone. You have evidence and you weigh it.

I don't think that's a problem at all, but I would tell you, as Tom Powers mentioned in the last meeting in response to questions and concerns about individual petitioners, and I looked back at General Order Number One actually had it in there in terms of the process.

It's always been understood that these decisions will, again through the Circuit, give some framework. It's also always been understood that you then, petitioner, government, or whomever it is, you will go back to, and say now look, this is what the Circuit has said in terms of what the Special Master found, correctly or incorrectly, what standards, you know, whatever the stakes were. How is your case similar, different, or whatever?

In essence, if it matches up exactly the same, say the Circuit reverses and finds for the petitioner and says this, you will go the government and say, look, he will ask the petitioner, is your case the same as what the Circuit found? They'll come in and say yes, a, b, c, d, here it is. Go to the government and say it matches and win.

That's what lawyers do well. They look at information and match it to a standard. Where we get into battlegrounds is between standards. I personally don't see that, I don't see that as a problem. I see the problem being that there's going to be a lot of room for interpretation when it eventually comes out.

But even there, again, an efficient moving party will go to the petitioner and say, you know, looking at this decision, what's good for you, what's bad for you. If it's bad, what are you going to do different?

See, if the petitioner comes in, and let's take the example of a losing case. Say the initial pre-decisions go up, they're affirmed completely as they stand. Lawyers are going to look at that, and some have already looked at it, and say I have nothing else to offer. When you think of it, you know, unless their case is different, it probably won't. We put all this time and effort into putting your best case forward. And it's somewhat naïve to think that, unless another study comes out they're not going to then muster a different set, they're not going to muster a different set of experts.

MS. HOIBERG: Autism has very many different levels. Lots of children with autism have horrible issues that could have been caused by it.

MR. GOLKIEWICZ: I understand. Again, going back to General Order Number One, if you hadn't read it in a long time I could get you a nice copy of it, is we told petitioners back then, if you have something different that what the omnibus was presenting, get your case out of here. It's in there, that directive, and I believe George Hastings would have put it in his orders that followed it. I was, you know, if you have a different case, you don't belong here. Get it out. So if you have, if you're alleging encephalopathy or seizure disorder or something,

don’t come in here, because you’re going to get tied up on something that doesn’t pertain to your case.

Now what we have had is the reverse. And I think this is logical, in fact I just not too long ago had one. The petitioner alleged a table encephalopathy. And we went through, the petitioner’s counsel actually went through and talked to the experts and came back in and said I can’t prove it and asked that it go in the OAP. We denied the table encephalopathy, put him into the OAP. But clearly, and we’ve had cases that pull out, not too many for some reason, for underlying injury reasons.

DR. HERR: I appreciate what you do and I understand that it’s difficult. And certainly the idea of settlement is appropriate. The problem is, as it was pointed out earlier, is that there’s also public misconception when there is compensation settlement. Then that’s an implication of association of guilt. And one of the purposes of the Act was to increase and maintain the public confidence, and we have to recognize that one of the process undermines one of those purposes.

MR. GOLKIEWICZ: Yes, I think that’s a problem when you get involved with court and litigation. I remember almost twenty-five years of court, and even before that I was an agent of the court, and my first boss told me, just remember what you’re here for. What’s that? Resolve

cases. I don't care how you do it, just get them out of here. Court resolves cases. Policy issues, that's left to other people. I understand where you're coming from, and that's why we have this debate.

MS. CASTRO-LEWIS: Thank you so much. I think we are really interested in seeing coming through the last few points that you made about the process, because there is a concern in this committee to better serve the community and the people.

So again, thank you so much. And let's take about ten minute break only, because we are already behind the schedule. So, we'll convene at 3:10.

(Brief recess)

MS. CASTRO-LEWIS: Is everybody here? Yes, okay, Commissioners, okay, thank you. Did you receive, have the opportunity to look at the report from -- the microphones are working better now -- to look at the report for the feasibility evaluation of the National Vaccine Injury Compensation Program? We have Dr. Swamy, is going to present on the results of this survey, the Petitioners Survey that has been, for awhile we have been waiting for this report. It's a very good report with a lot of good and bad news. So, if you could please walk us through the report.

Agenda Item: Petitioners Satisfaction Survey, Namratha Swamy

DR. SWAMY: Sure. Thank you for welcoming me here today and allowing us to update you on the final results of the survey study. We have presentation slides to make it a little bit easier to walk through the report. So a little bit about the background of the project.

The Altarum Institute was contracted to do an evaluation and feasibility study in September of 2005 to determine whether certain components necessary to conduct an evaluation actually existed, such as whether there was sufficient data available, were there program measures in place, and common program goals, et cetera.

And so what we were, what we determined in that feasibility study, what we were assessing, was that were there a commonly recognized set of VICP goals, processes and outcomes, the successes and challenges experienced by VICP, the data available as I said, and possible evaluation projects that we could conduct.

The Evaluation Feasibility Study Report was submitted to DVIC in March, 2007, and in June, 2007, there was a decision made to move forward with one of the ideas that we presented about an evaluation project, which was the Petitioners Satisfaction Survey.

The purpose of the evaluation was to determine the extent to which petitioners who have completed the claims process are satisfied with the process and their outcomes. And with this information, we were hoping to make recommendations for improving the processes of the program. And some of the key questions that we were interested in learning about was do petitioners feel capable of navigating the legal process, do petitioners feel that the decision on their claim was reached in a timely manner, and do petitioners who receive awards believe that the award was adequate. Those were some of our key questions.

As far as our methodology goes, our study population included petitioners whose claims were resolved within the last five years, meaning they were either compensated or their case was dismissed and closed, and who were also represented by an attorney. And the sample does not include those petitioners who voluntarily dropped out of the process. And to determine our population location, for example, we used the DVIC database to determine who should be included. We looked up the claim resolution date, the decision status, in addition to the attorney's contact information.

We developed the survey in collaboration with DVIC and ACCV. We were interested in learning about

certain topics, such as how did they, how did petitioners first learn about the program, how satisfied were they with the filing of the claim and the hearing process itself, the satisfaction with the process and the adequacy of award amount, and also, the satisfaction with the length of time to complete the full process. And also, we wanted to learn about demographics of survey respondents in terms of age and race, ethnicity, et cetera.

The surveys were sent to petitioners through their attorneys to ensure confidentiality. Each petitioner received a cover letter with survey instructions, an informed consent statement, the survey itself in hardcopy, and a return envelope. We also distributed thank you and reminder letters through the attorneys. And English and Spanish versions were available.

The evaluation questions that we'll cover today are how did the petitioners learn about the VICP, to what extent are petitioners satisfied with the information they received from VICP on filing a claim, to what extent are petitioners satisfied with the clarity, ease, and navigability of the process, with the length of the process, and with the decision regarding receipt of compensation and adequacy of compensation. And finally, with the VICP's negotiation with Medicaid to reduce and/or eliminate the lien when applicable.

The data collection process was challenging. Our data collection period was June, 2008 to December, 2008, so a six-month period. And we have a schematic here just to show you, to give you an idea, of exactly how, what was involved in our survey response and to speak to why we have a very low response rate.

We started off with 716 petitioners in our universe that actually met our inclusion criteria that I had mentioned a couple of slides ago and that was equivalent to 265 attorneys. And then what we, as we contacted those attorneys, we found that 142 attorneys did not participate due to their non-response or refusal. So that equated to 232 petitioners that were not included in our study. That left us with 484 petitioners, meaning 123 attorneys that received our initial mailings. Thirty-six petitioners have confirmed undeliverable addresses. And so that left us with 448 petitioners that were possible survey respondents. Of those, 107 petitioners ended up responding. So that leaves us with a response rate of 23.88 percent.

MR. SCONYERS: So you seem to think that's a low response rate. What were you expecting?

DR. SWAMY: Well, ideally, what we would like is about at least 35 percent response rate. And we'll talk about this a little bit more, well, we'll talk about it now actually about, just in terms of our generalizability of

the results. We want to caution you, these are 107 petitioners. And so we really have to be cautious about how we interpret these findings, how generalizable these findings are. It is 107 of a possible, in our case, we had 448 petitioners that are, really were our universe. But there were 716 petitioners that potentially could have participated. But because of attorney intermediary refusals, that dropped us down significantly by 200 petitioners that were immediately excluded from that process.

And so as you funnel down, you realize, well 107 petitioners of a possible 716, that would have been great to have received their response on. That actually is not as high as we would have liked. So all that says is that we just have to be cautious about generalizing these results.

DR. HERR: I'm sorry, I wasn't able to get this before this meeting, but did you analyze the people who did respond versus the people who didn't respond, the types of petitioners, their awards, the non-responders?

DR. SWAMY: We actually didn't have that information about the petitioners.

DR. HERR: Okay.

DR. SWAMY: That's an ideal - it's a great question because in a survey, that's usually what we would

do. But in this particular case, we had an attorney intermediary, we wouldn't be able to do that.

DR. HERR: I'm sorry, I didn't think about that, confidentiality.

DR. SWAMY: That's a great question. Now we can jump into results and findings. We'll talk a little bit about the demographics and who our respondents were. The majority of the respondents were the parent or guardian of the injured party, followed by the injured party themselves, and then the partner or spouse at 1.87 percent.

The next slide, we are, here the information presented is the most respondents were 36 to 49 years of age. The next slide is age of injury. Here is a distribution of respondents reported age at the time of injury. We have another graphic that we haven't included here, but about 25 percent of the reported injuries occurred in children six months of age or younger.

PARTICIPANT: What was it, what was that, 25 percent?

DR. SWAMY: Twenty-five percent, and that's in the report. That graphic is in the report. The next slide speaks to race. Most respondents were self-identified non-Hispanic white, and 7 percent were Hispanic. The majority of the respondents were non-Hispanic at 93 percent. Most respondents were college graduates or held a graduate

degree at 56.19 percent. So, a very educated population. And also, with a fairly high income. The distribution of income is reflected here with the greatest percentage earning 80 percent or more. I'm sorry, $80,000 dollars or more.

This was a slide that we just wanted to include to give you a sense if you were interested in how, what our distribution, geographically, of our, the survey respondents were. The black dots is a little bit hard to tell, I realize that, in the graphic it's a little bit more clear, in the report it's a little bit more clear, but black dots show where one petitioner respondent was located. The blue dots show two petitioners, and the green dots show three petitioners.

And so we overlaid that against the population density, just to give you a flavor of the representation and if it brought any ideas to your mind that, you know, again about generalizability and the need for further studies in the future. But just to give you a sense, this actually, the respondents overlaid with population density actually tracks well with population density.

We'll now get into the survey findings, specifically. The information source is about the National Vaccine Injury Compensation Program. I have to say though, we did realize that we made an error in the slide while we

were presenting it. This is actually the majority of the respondents did indicate that the Internet, a non-VICP website, was the most used information source. But the second most popular information source was the VICP website, at 17 percent. So we'll make that correction. And then the rest of the information follows, that other health care providers, attorneys, et cetera, and so the rest of the distribution is

The next slide, we asked the question about how easy was it to get information about the program. And there were different opinions on this question. Thirty-five percent has a very easy or somewhat easy, and 37 percent said very difficult or somewhat difficult.

The next question, how helpful was information provided when filing a claim with the program. Again, there were different opinions. Thirty-five percent said very helpful or somewhat helpful. About 30, 31 percent said very unhelpful or somewhat unhelpful.

And we asked about suggestions for improvement. Respondents provided us some information here. One suggestion was that health care providers should be made more aware of the DVIC Program and be responsible for providing that information about the program to the participants, I'm sorry, to patients, and 17 people actually suggested that.

Also, 9 people suggested that patients, or parents, guardians should receive this information at the time of vaccination and then also that the program should be more widely advertised. Outreach materials should be developed, et cetera. And so 14 people actually spoke to that.

We asked about the life care planner arrangements as well. Thirty-three respondents had life care planners and among those respondents, the most common arrangement that they had were, was to have two life care planners, a petitioner and one from the government. In terms of the satisfaction of the life care planner, 35 percent were very satisfied or somewhat satisfied. And about 43 percent were very dissatisfied or somewhat dissatisfied with their life care planner.

And we asked about the reasons for satisfaction or dissatisfaction. Satisfaction was, the reason for that was that the life care planner was focused on their needs of the patients, they were responsive, paid personal attention to the claim. Reasons for dissatisfaction, that they weren't very realistic when accounting for current or future needs of the patients. So just not as much attention to the matter at hand.

The ease of finding an attorney. Thirty-seven percent said that it was very easy or somewhat easy to find

an attorney. Forty-two percent, however, said it was very difficult or somewhat difficult. And again, we asked respondents for suggestions for improvement on how to help the situation. And 23 respondents actually said that they would like to see an up-to-date list of attorneys who handle vaccine injury complaint claims be published and actually be made accessible. Health care providers also could provide attorney contact information to patients at the time of vaccination.

Satisfaction with the claim filing process. About 34 percent were very satisfied or somewhat satisfied with the claim filing process. Forty-six percent were very dissatisfied or somewhat dissatisfied.

The ease of obtaining additional information after filing a claim. Twenty-one percent said very easy or it was somewhat easy to obtain this additional information. However, 51 percent said it was very difficult or somewhat difficult.

DR. HERR: What's additional information?

DR. SWAMY: Any follow-up information that was required as part of the final, of the claim process. We didn't specify exactly what that was and the respondent didn't provide that information. But any follow-up information that's necessary from the health care provider, for example, or any other additional details.

And we asked about suggestions on how to improve the claims process. The respondents had said it should be shortened, it should be streamlined. Also that if there could be more information provided about the program, that would be helpful. And outreach to health care providers. So the health care provider issue comes up time and time again.

Satisfaction with the hearing process. Thirty percent had said very satisfied or somewhat satisfied with the hearing process. And also 37 percent said they were very dissatisfied or somewhat dissatisfied, so there is differing opinions about the hearing process itself.

As far as receipt of a financial award among our respondents, 59 percent had not received an award. Forty-one percent had. Among those that did not receive an award, we asked about what steps did they take after not receiving the award. The options were appeal the decision. Nineteen percent appealed the decision. Another 15 percent withdrew after 240 days. Five percent withdrew after 420 days, and 2 percent pursued civil action. And a somewhat substantial percentage, which was about 28 percent, did not, reportedly did not remember exactly what they did after they did not receive award.

Satisfaction with the award process. Thirty-two percent were very satisfied or somewhat satisfied with the

award process. However, 42 percent were very dissatisfied or somewhat dissatisfied.

Helpfulness of the VICP with the Medicaid lien. Most respondents did not have a Medicaid lien, but among the 9 respondents who did, 33 percent said it was very helpful. Eleven percent said very unhelpful, and 11 percent said somewhat unhelpful. So again, the span is 9 here. And 44 percent didn't have a strong opinion either way regarding the helpfulness of the Medicaid lien.

We asked about the adequacy of the award to cover future and past medical expenses. And 29 percent said either very adequate or somewhat adequate. However, 51 percent said very inadequate or somewhat inadequate. And we asked about what suggestions they would make for improvement. And 14 people, 14 respondents had said hat they would have liked to see more timely and flexible payment mechanisms.

There were certain family structures, for example, that should be taken into account in determining who receives payments, allowing the payment to be disbursed as a yearly lump sum, for example, just to have that flexibility in how the payment structure is implemented. And also 6 responded that the award amount should be more comprehensive in accounting for vaccine injury costs and including future disability and pain and suffering.

Satisfaction with the length of claims process. We asked how satisfied are you with the amount of time it took to complete the entire claims process. Eighteen percent said very satisfied or somewhat satisfied with the length of claims process. However, 64 percent were very dissatisfied or somewhat dissatisfied.

We asked how satisfied are you with the way you currently receive award payments? And here you see 37 percent, 38 percent said very satisfied, 18 percent said somewhat satisfied, and about 17 percent in total said very dissatisfied or somewhat dissatisfied.

We also wanted to assess the association, if there was an association, between satisfaction and the receipt of award. And what we realized was is that there actually is an association. So those who did receive a financial award, I know, that seems pretty obvious, but we also wanted to send DNA analysis just to confirm it, that there is. So the receipt of financial award is associated with increased satisfaction on the claims filing process and the hearing process and the length of process.

So all of this information, we gathered it, we assessed it. And what we concluded was that there are certain recommendations that we would like to make based on our study findings. And one is that to continue to elicit petitioner feedback on the claims process in order to

inform the program's performance and implementation. Also, to conduct future evaluations that elicit a diversity of perspectives and perhaps that would include a range of stakeholders, such as petitioner attorneys, or DOJ staff, DVIC staff of course, and other court staff, just to obtain a comprehensive review of the program implementation. There are a number of interfaces there that you may want to consider.

Also, to continue outreach efforts to build awareness of the program and to consider options to streamline the VICP claims process. And again, just recognizing that there are many factors that need to be taken into account, such as the attorney-petitioner interface, but also the attorney-VICP interface. So all of those things impact the implementation of the program and satisfaction of the petitioners as well.

Are there any questions?

DR. FISHER: In the very beginning, did you ask the lawyers who refused, why?

DR. SWAMY: It was, most of the time it was just non-response on their part. They were just, we can assume that they are very busy on their part and they just were not being responsive to our multiple attempts to seek them out. I believe, in turning to my colleague here, Kara Rudolph, did we have any reasons for refusal to participate?

MS. RUDOLPH: (Inaudible)

PARTICIPANT: Can't hear you.

DR. SWAMY: There were only a few that we were able actually to get on the phone. And those that did, they really didn't provide a real response. It was just that they didn't have time, or then they would say they would, but then they never followed through.

DR. FISHER: So it really wasn't refusal. It was really inability to access them or to get them to respond.

DR. SWAMY: Well, there's non-response but there's also non-access. So we actually had some attorneys that just didn't want to participate.

PARTICIPANT: Which you have that as only two.

DR. SWAMY: Right.

MR. SCONYERS: You did chi-square analysis on receipt of an award. Did you look for another? Did you analyze whether there are other correlations with satisfaction factors?

DR. SWAMY: We actually thought that was the most important to assess. Are there other ideas that you would like to put forward?

MR. SCONYERS: That's the one that you tested?

DR. SWAMY: Right. That's the one we tested. If there's any additional hypotheses that you would like us to

actually test out, we're happy to do that. But that just actually made, I just, we had hypothesis

MR. SCONYERS: To me, as I read through this, there was, for all but a few questions, a very bimodal distribution. It was essentially impossible to discriminate between the happy and the unhappy people. They were fairly evenly matched. Is that true? With a few notable exceptions, like how long it takes to resolve a claim, the attitude towards it, things like that.

I have one question about one of your recommendations. And I'm going to try not to make this sound harsh, your recommendation to conduct future evaluations to elicit the diversity of perspectives. I read the report to try and figure out where that came from. I don't see anything in the report that suggests that. And I'm wondering why you think that would be important to ask the people who function within the system rather than the people it's designed to survey?

DR. SWAMY: Well, this study was seeking the feedback from petitioners themselves. However, the petitioners, I think what we're saying basically is that there, we're recognizing the fact the program itself, there's so many players. There's the DA's, DOG's, staff, core staff, it's not just DVIC and the petitioners. There are the attorneys also involved. And so, given our

experience in interfacing with the attorneys themselves, we realized that the attorney intermediary has an impact on the petitioners' satisfaction with the larger process. There's many perspectives, I think, that we might want to take into account. And so this recommendation actually comes from our experience in interacting with the attorney.

But, also from our conversations with the DVIC staff also about how does this program actually, how is it actually implemented? And because there are multiple stakeholders involved, from our point of view, it would behoove the program to understand how those interfaces actually interact and what, and how that might contribute to petitioners' satisfaction level.

MR. SCONYERS: I guess I'm questioning the characterization of those groups you're identifying as stakeholders. Some are just participants in the process. Stakeholders are the people who are intended to be benefited by this program. And I think it is right to focus on the people who file petitions. And of course it's right that the people who work with that set of people have a bearing on how the process works. But their satisfaction with the process doesn't seem to me to be very important as compared with the satisfaction of the people the program's intended to benefit.

DR. SWAMY: Oh, I agree with you. I, really, it's about, the participants in the process, if we understand what their perspectives are, perhaps that will actually inform the level of dissatisfaction or satisfaction of the petitioners. That's, to me, that's why I really wrote that question, that's what, it's not about their satisfaction, it's not about the participants' satisfaction. It's about petitioners. I'm better understanding the petitioners' satisfaction.

DR. EVANS: I have one question about the slide that was the ease of obtaining additional information about how we classify a claim. And the observation is yes, we should provide more assistance to petitioners than, we are not in the position to, once the claim is filed and it's going through the litigative process, of course, we're no longer involved, and of course, DOJ is not going to be giving any information, too. So that is just a clarification. I don't know which part of DS&P(?) they were referring to, but that really is specifically petitioner-dependent.

MR. SCONYERS: I'm not sure I understand what you're saying Jeff.

DR. EVANS: Well, it says that we ask the Commission to provide more assistance to petitioners in obtaining information after filing a claim. We are

prohibited from having any contact with petitioners, as is DOJ. They have representatives. Petitioners have representatives. We have nothing to do with their obtaining information as they go forward in the litigative process.

MS. HOIBERG: It's their personal attorney that should be giving them any information if they have that information at all. So that should have been, the question probably should have just been stricken from the survey because it doesn't, it's not, I guess it's not a question, it's a suggestion. But is it a suggestion?

DR. HERR: No, it's the respondents, it's the people. It's not, it's what the people themselves said. And it's because they have a misconception of what the program is.

MS. HOIBERG: A misconception of what the program is then.

MS. DREW: Excuse me, we have in our packets some correspondence involving a Sandy Bigelow, who was not part of this survey, but who was a petitioner. And one of the things he suggested was that either the court or the VICP should either provide something of an ombudsman or even some written guidelines to petitioners' attorneys who are going through the process with their clients for the very first time and don't really know how long to expect various

stages to last. And I could see where the VICP could encourage something like that to be done, just to sort of assist petitioners' attorneys and their clients in the understanding of the process. And I know there is stuff available on the website, but this gentleman thought that would be of some benefit, would have been to some benefit to him as he went through the program.

MS. TEMPFER: Is it common in surveys to, for the respondents to kind of pick and choose what they answer, because it seems like on some of the questions, you had really a low response rate, like the life care planners and

DR. SWAMY: If it applied to them, then they responded.

MS. TEMPFER: You mean like the level, it is common, they just don't answer all the questions, which probably really skews your results again.

DR. SWAMY: Right. Exactly. Exactly.

PARTICIPANT: You don't have a life care planner in every case, so that's why it wouldn't apply.

PARTICIPANT: On the demographics did they answer race or income?

DR. SWAMY: It's a paper-based survey, so we weren't administering it. It's a self-administered survey, so they can skip how they, on the back end, we look at the data and if there's any inconsistencies, we try to correct

as much as we can, even dropping questions or dropping, eliminating a survey respondent altogether if they haven't responded to the majority of the questions, for example. But we really actually don't have control over which questions they answer, not in a paper-based survey.

DR. FISHER: Dr. Swamy, even if you read the letter, the introductory letter to them, from this, it, we value your privacy and ask that you only provide us as much information as you feel comfortable sharing. So, I mean, I think the whole process left the door open for people to, and I think that's a good thing, because somebody might look at this and say, if I have to give my income, I'm not filling out the rest of it, or if I have to, you know, if you care about my race, then erase me, I'm not going to fill out the rest. So I think it was, I think that was a good idea, but it does, and I did take home those surveys and fill out some, not all.

MS. CASTRO-LEWIS: Yes. I actually have so many questions about this report and you counted out also as the door to many possibilities for the outreach things that we can, the outreach program, the outreach committee, but, I mean, there's so many. I'm going to start with one. The respondents, for the most part, were highly educated people. But then, at the same time, they were kind of, almost evenly divided about the difficulty about the process.

Anything that you can tell us as why that or is it just statistic with no explanation or you didn't get any light somewhere that as why that, because what made it for one group of people, easier for another group of people, if there's an indicator?

DR. SWAMY: It's a great question and I think in order to obtain that information, I think we would have to have a follow-on study. I will not be able, this study will not be able to inform that question that you have. It was a very simple survey, intended to be so. To get the actual reasons for their dissatisfaction or the reasons for their satisfaction, we asked the question if they, you know, if they would like to elaborate, it's up to the respondent to actually complete the response, provide us that response. And so I, we, the survey, didn't have those results to provide.

MS. CASTRO-LEWIS: Thank you.

MS. GALLAGHER: Can I just make a comment to Dr. Evans that I was actually surprised at how much satisfaction was expressed in this survey and I think that's a tribute to him and his staff that so many people actually think their compensation was sufficient. The system is working. I recognize there are many areas that we can address to improve things, but can I at least see the silver lining in the cloud and say congratulations for

all the things that you did well and now let's roll up our sleeves and try to work on some of the other things.

DR. EVANS: I would also include the Department of Justice in that.

MS. GALLAGHER: Absolutely, I agree.

MS. CASTRO-LEWIS: Does anybody have any other questions?

MS. HOIBERG: No, I just think that I'll be using this in our presentation tomorrow because it just really, if anything, backs me up on what I want to do. So, shows me that I'm going in the right direction, which excites me, so.

MS. CASTRO-LEWIS: Yes, one of the results, if I remembered, was the education of those, to let others know about the program. I think this question is mostly for Dr. Evans because he said that many of the participants in the survey find out about the program in magazines, in radio, and newspaper, so what exactly has the program been done in this area, because I don't remember seeing that, but maybe in the past, and I don't know.

DR. EVANS: Can we defer that question for tomorrow when we discuss the outreach work? Because I think in that context it would probably be a more timely discussion. We have talked before in the past about

efforts and what we've done in the past, but let's see if we can hold that off until tomorrow.

MS. CASTRO-LEWIS: Sure. Yes. I think that most of the questions that I have are in regards to the outreach and, you know, how can we use this report to really move forward and have the basis for whatever we decide to do.

Do you have any other questions, Jeff, no? Okay, well. With that, thank you so much, Dr. Swamy.

DR. SWAMY: Thank you, thank you very much.

MS. CASTRO-LEWIS: I think our next presenter, Dr. Smith, from the CDC -- is Dr. Smith on the phone?

DR. SMITH: I'm on the line.

MS. CASTRO-LEWIS: Okay, so Dr. Smith is going to talk about the ACIP, on how their recommendations regarding immunizations are made. This was highly suggested at the sub-committee for the agenda and the need to understand how decisions are made at this level. So, Dr. Smith?

Agenda Item: ACIP Presentation on Process for Recommending Vaccine Use, Jean Smith

DR. SMITH: I'm on the line. Can you hear me? Okay. There's a little bit of an echo, but I'll do my best. Okay, ready to start? Is the slide presentation up? Okay, hello everyone. This is Dr. Jean Smith, calling in from CDC in Atlanta. Today, I'm going to talk about the role

and function of the Advisory Committee on Immunization Practices. You can move to slide two.

I'll review the process of immunization policy development in the United States and I will discuss the responsibility, structure, and function of the ACIP and I will also review a little bit the interaction of ACIP with other organizations and societies in the public and private sectors. Next slide please.

The ACIP goes back to the date of establishment in 1964 by the Surgeon General of the US Public Health Service. The history of this is a little bit interesting in that it came on the heels of the Vaccine Assistance Act, which was passed by President John F. Kennedy in 1962, granting the sum of several million dollars for purchase of vaccines by the US government.

In those days, there were only five vaccines that were recommended for routine childhood use. And with the increasing use of vaccines, there was recognition of a need for an expert advisory group to develop recommendations for the use of these vaccines in the pediatric population.

So the ACIP was established with the role of providing advice and guidance to what is now called the Office of the Secretary, Department of Health and Human Services, it had a different name back in those days, and

the Director of CDC, on the most effective ways to prevent vaccine preventable diseases in the civilian population.

So those include recommendations regarding vaccines and related agents, for example, anti-sera immunoglobulin, and anti-viral agents. The charter of the ACIP states that ACIP can make recommendations for vaccines that have been licensed in the United States by the FDA and on occasion, unlicensed vaccines if warranted. In truth, to date, the ACIP hasn't actually made any recommendations for unlicensed vaccines. But that wording is included in the charter for special situations. Next slide.

The next key date in the history of ACIP came in 1972 when the Federal Advisory Committee Act, or FACA, was enacted. This was passed as a mechanism providing for the ability to seek advice and recommendations from US citizens in the federal government decision-making processes. FACA committees are designed to provide relevant, objective advice from members of the population external to government.

In the FACA language, it states that meetings of the Federal Advisory Committee should be open to the public and that all Committee documents are available for public inspection. So although ACIP had been in existence since 1964, up until this time, meetings were closed. And then as of 1972, with the passing of FACA, at that time, ACIP

became one of several FACA committees. Today there are probably around a thousand of which only some are health-related, and others relate to other fields. Next slide.

The next key date for ACIP came during the Clinton administration in 1993, when the Vaccines for Children Program was established. And this program has been operational since October, 1994. This program operates under unique statutory authority that was established by the Omnibus Budget Reconciliation Act. And this act gives ACIP the authority to determine vaccines that will be provided for under the VFC Program.

That means that these vaccines are actually purchased and paid for by the US government. Eligible children for this program are children through the age of eighteen years, who are Medicaid eligible, uninsured, American Indian or Alaska Native, and underinsured. At the present time, roughly 43 percent of purchased vaccines are covered under this program for the US pediatric population.

The VFC is a federal entitlement program with a current cost that is estimated to be around three billion dollars, annually. And at the bottom of this top slide are two web links that will take you to a website that will give you more information, if you’re interested. Next slide.

The next slide is a diagram that shows you that the steps going from the time of vaccine development and testing on down to when vaccines have uptake in the public sector and private sector, and the stepwise process to get from vaccine development and testing to where the vaccines are actually coming into use in the population. And what I've done here is to circle the box that shows you ACIP, to show you the point at which ACIP has a role.

So, if we can follow from the top with vaccine development and testing, this is at the level of vaccine manufacturers, to when the manufacturer has taken the vaccine through all the necessary steps, submits a biologic license application to the FDA, which then considers the application and decides when it's time to license the vaccine.

On the left side you can see a box demonstrating another FACA committee, Vaccines and Related Biological Products Advisory Committee, or VRBPAC, which advises the, which is an expert, external committee that advises FDA on licensure decisions. Now once FDA grants the license, it is at that point that ACIP can become active in terms of taking active votes and making recommendations. So the left side of this flow chart shows the CDC, which is the public sector side, and then the right side shows the American Academy of Pediatrics, in a parallel process, with

their advisory panel, which is called the Committee on Infectious Diseases.

So ACIP advises. CDC takes ACIP guidance into account and then ultimately issues the final recommendation. Recommendations, once they have been accepted and cleared through necessary channels, are then published in the MMWR, in the public side, that's the Morbidity and Mortality Weekly Report, which is CDC's publication. And then on the right side, simultaneously, published in Pediatrics. And it's really at this point that we can consider that an ACIP recommendation becomes official policy. And then after that, to the implementation step, uptake of financing, with some input from state laws, and then uptake of financing in the public sector and the private sector. Next slide.

This slide just shows you an example of what the DLA approval looks like when it comes from FDA. Once FDA has granted the license, then a letter is sent to the vaccine manufacturer and it is at this point that then ACIP can actively begin to take votes and make recommendations on that particular vaccine.

On the next slide, I've here shown you the composition of the ACIP, which is laid out in ACIP's charter, which is renewed every two years. There are fifteen voting members, including the Chair. As I said before, these are people who are external to government.

They are nominated to serve four-year terms, overlapping, so that in any one year, maybe about a third of the ACIP review is rotating off and then replaced by new, incoming ACIP members.

Candidates are nominated by the ACIP's Steering Committee, which I'll talk about in a few minutes. And then suggested candidates', or nominees' names are forwarded to the Office of the Secretary of DHHS and it's the Secretary of DHHS who makes these final selections. And then the Chair of the ACIP is selected from among current members from, the Chair is selected from those who have served at least two years so far as an ACIP member.

In addition to the fifteen voting members are eight ex-officio members. These represent other US government agencies and bodies, such as DMS, Department of Defense, Veterans Affairs, FDA, PRSA, Indian Health Service, and so on. These eight ex-officio members are non-voting except in a situation where there may not be a quorum of voting ACIP members, in which case, the Executive Secretary of ACIP can appoint one of the ex-officio members to vote.

And in addition to these people, we have representatives of twenty-six liaison organizations. These are representatives of professional societies and organizations who are responsible for vaccine development and immunization programs. These liaison representatives

are non-voting. I will say that in my three plus years since I took my position, I've been very impressed at the interplay among and between these three groups that comprise the ACIP.

Some of these liaison representatives in particular are key and very much valued because they bring a side of, more from, I would say, the implementation side, from the actual clinicians out in the community who will be administering vaccines, that brings an excellent balance to what is brought by the fifteen voting members and the eight ex-officio members. Next slide.

The fifteen voting members are selected very carefully on the basis of their expertise. And we attempt to have a good balance of different areas of expertise and perspectives on the ACIP at any one time. So examples of areas of expertise I've provided here, for example, infectious diseases, immunology, pediatrics, internal medicine, family medicine, public health and preventive medicine, vaccine research and policy, economics and cost effectiveness. And it's also written into the ACIP charter that one of the fifteen voting members should also be someone who represents consumer concerns. Next slide.

This slide, I don't expect you to read all the details, but this presentation is available to you and also, all of this is available on the ACIP's website. At the

moment, we have twenty-six ACIP liaison organizations, for example, the American Academy of Family Physicians, the American Academy of Pediatrics, and so on. We also have representatives from the counterpart of ACIP in Canada, the Canadian National Advisory Committee on Immunization and a similar body in Mexico. These representatives are, must, any interested organization applies to be included as a liaison, with justification of having some kind of broad interest in immunization. The application is reviewed by the ACIP's Steering Committee and then forwarded to the Director of CDC and onward to the Secretary of DHHS, with final selection made by the Department of Health and Human Services.

Next slide shows you the process of ACIP. The ACIP meets three times every year, always in February, June, and October. And the meeting dates, for those who are interested, are posted on the ACIP website and are available through the year 2012. The meeting agenda is developed based on topics that are solicited from ACIP members, liaison representatives, CDC staff, and others, using a standardized format. And the meeting agenda is finalized at least six weeks in advance at the meeting by the ACIP's Steering Committee.

ACIP meetings follow from the rules and procedures of the Federal Advisory Committee Act. The key

highlights of which state that meetings must be open to the public. There should be time for public comment and that meeting minutes should be published and available within ninety days of every meeting. And, in fact, meeting minutes are available to the public for any meeting, dating back into the past as well, and can be obtained from our website. The recommendations that are voted upon by ACIP are published in the MMWR, following approval by the CDC Director and the Secretary of Department of Health and Human Services. Next slide.

Although the ACIP only meets three times per year, an enormous amount of work is done throughout the year in the background. ACIP work groups is where the background data collection, review of studies, and development of policy options has been done. So the work groups are responsible for developing draft policies and options that are then reviewed and voted upon by the full ACIP in the public meeting. Work groups typically work by teleconference throughout the year and sometimes also get Atlanta to ring ACIP meetings during lunch breaks and evenings, and so on.

By ACIP policies and procedures, work groups must be chaired by an ACIP member and must include at least one other ACIP member. Other members of work groups include a lead CDC staff member, who usually is a subject matter

expert in the topic at hand as well as other concerns, CDC staff, ex-officio members, lead liaison representative, members of the Association of Immunization Managers, which represents state immunization managers, state level immunization managers, and then key consultants as requested. For example, a member of an academic faculty, who happens to have an expertise in that particular question. Work groups may be disbanded when the work is complete and new work groups are formed as required. Next slide.

At the moment, ACIP has fifteen active work groups, of which four are permanent, for obvious reasons. None of these topics goes away, adult immunization schedule, general immunization recommendations relating to things such as immunization techniques, storage and handling of vaccines, and so on. There's the childhood-adolescent immunization schedule, which is called Harmonized, which I've shown in quotes here, which reflects the fact that this childhood and adolescent immunization schedule is harmonized between the ACIP's processes and by the American Academy of Pediatrics. And then finally, the influenza vaccine work group.

Next slide shows you the lineup of the task-oriented work groups as of this month, which are currently eleven in number. And, as you can see, out of all these

evidence-based recommendations, hepatitis, human papillomavirus, and so forth, one of the existing work groups is the MMRV vaccine safety work group, which I believe Karen Broder is going to be giving you an update during the next session. And so as I mentioned earlier, these work groups, task-oriented work groups, are established and then disbanded according to the needs of the day. And when the work is completed, then that particular work group will be disbanded.

The next slide shows you the work of one of the four permanent work groups. One of the four permanent work groups works on the childhood and, actually this used to be called childhood and adolescent immunization schedule. Now they are referred to according to their age distribution, zero through six years, seven through eighteen years, and then a catch up immunization schedule. These schedules are put together by a work group that takes the various existing vaccination recommendations for each vaccine and then assembles them into an overall schedule that can be used by providers, by pediatricians and clinicians, and nurses and others who administer the childhood vaccine.

Next slide shows you the analogous schedule for adults, which is assembled every year, reviewed and revised, as are the pediatric schedule. Both of these are revised, reviewed and revised on an annual basis. And this is done

by the adult immunization work group, which is also one of the four ACIP permanent work groups.

The next slide shows you some of the factors that are considered in development of recommendations by the ACIP. First and foremost, of course, are the license indications and schedule for a particular vaccine, as established by FDA licensure.

In addition to that, each work group looks at disease burden overall, and diseases, certain high risk groups for the particular disease in question, data on safety and efficacy in general and in specific groups, the feasibility of implementing that the use of the vaccine in the context of existing recommendation, the access to vaccine and good use of public funds, and in particular, this refers to cost effectiveness consideration, and then also recommendations of other groups, such as the American Academy of Pediatrics, American Academy of Family Physicians, and American College of Physicians.

The next slide shows you the two broad groups of types of ACIP recommendations. One might be for universal use of a vaccine. This usually is an age-based recommendation. And for clinicians and providers of vaccines, this type is the least confusing and the easiest to implement. And for those types of vaccines, must

benefit all in the population under, the target population that's being specified.

And then in contrast to that, we have risk-based vaccination recommendations where a vaccine is recommended for a certain risk group. For example, use of anthrax vaccine in laboratory workers who happen to be working with anthrax. So here you might have medical, or occupational, or behavioral risk. These types typically are more difficult for providers to implement because it may be more difficult to identify people who should be vaccinated. And so often the risk-based recommendations may be less well implemented than the universal.

The next slide shows you the changes that have occurred in the past couple of decades. Back in 1985, when there were seven antigens in the routine childhood schedule, up to the current time in 2009, where there are sixteen vaccines that are recommended in the pediatric age group.

I won't spend much time on this. This slide just tells you about management of ACIP. At the level of CDC, the Executive Secretary is Dr. Larry Pickering. He has responsibility for ensuring that meetings follow guidelines and in particular adhere to the FACA rule. And most importantly, Dr. Pickering provides briefings to the CDC Director on pending decisions that are coming up to ACIP and also the results of ACIP recommendations. And then

there's myself, the Assistant to the Director for Immunization Policy. I'm responsible more for the day-to-day work of ACIP and coordination of work groups and also linkages among and between the liaison organizations as well as international counterparts and then an ACIP committee management specialist. So really, those three people comprise the management of ACIP on the ground. Next slide.

Learn a little more about the CDC management. We have a Steering Committee, which I'll talk about in a second. And then there is at CDC, there's a Federal Advisory Committee Management, and this is a group that's responsible for ensuring that ACIP adheres to the rules of the Federal Advisory Committee Act and assists as liaisons for the Department of Health and Human Services. And then the Office of General Counsel advises on legal questions, including potential conflicts of interest on the part of ACIP members, but also on the Vaccines for Children Program, and then spending.

The next slide shows the membership of the Steering Committee, which has fourteen members, several acronyms on the left, most of which represent the various centers at CDC which have responsibility for vaccine for immunization. And in addition, ISO is the Immunization

Safety Office. FDA has representation. The current ACIP Chair, and then ACIP Executive Secretary and myself.

The Steering Committee has three main responsibilities. To prepare the meeting agenda three times per year, based on the input that comes from the work groups and other people who have topics to suggest. Secondly, to recommend to the Secretary, nominees for ACIP membership once a year when certain members' terms will be coming to an end. And then finally, to review and make recommendation for certain ACIP processes, such as consideration of economic analyses, evidence-based recommendations, consideration of immunization safety, and so on.

Next slide is list of key documents related to ACIP, the charter, the policies and procedures, the guidelines for work groups. We don't have these posted on the ACIP website, but if anyone is interested in any of this, I'm happy to make any of these documents available to you by email after this meeting.

The next slide is kind of a graphic that I like that was actually created by a Japanese student who was here studying for his masters in public health at Emery for two years, who ended up working with us because this became the topic of his thesis at Emery. And he has actually gone back to Japan now and is in the process with Japan's

Ministry of working to set up an ACIP-like body in Japan because to date, they don't have anything like that. So development of recommendations for their country has been done more on an ad hoc basis. And he created this slide because when he first started working with ACIP, he had the impression that the ACIP was the three meetings per year, each of which is two days in Atlanta. And as he worked, he became aware over time that there's a lot under the surface, under the tip of the iceberg, that's ongoing throughout the year to develop these recommendations, particularly the work groups. But then all these other people as well, researchers, the private sector, vaccine manufacturers, and so on.

The next slide gives you the URL to the ACIP website, which you're welcome to visit at anytime and we work hard to keep it up to date and to add new items of interest as they come up. And the next slide is just a screen shot that shows you what the ACIP, the main web page looks like.

This next slide shows you something that was instituted a couple of years ago. And I actually think that Karen Broder had something to do with this suggestion. Many times the ACIP will take a vote at a meeting on use of a certain vaccine. For example, ACIP might make a recommendation about use of HPV vaccine. But then it takes

time to get the recommendation through the clearance and have editing done, and so on and so forth. So that there may be lag anywhere from three months up to as much as a year until the final MMWR comes out.

So the suggestion was made to post provisional recommendations on the ACIP website, ideally within two weeks of a vote being taken. These are brief, one to two page bulletin, that's sort of the meat of each ACIP recommendation. So this is an example to show you the herpes zoster vaccine provisional recommendation when it was posted and then use of T-Dap? among pregnant women. These have both been replaced by the final recommendation, which takes me to the next slide.

So that I you go to, on the ACIP website, if you want to see the recommendation, you can go to the list of final CDC recommendations and then click and bring up the full recommendation document.

The next slide gives you a little bit of information about the upcoming ACIP meeting, which is starting just three weeks from yesterday, here in Atlanta, at the Global Communications Center at CDC, June 24th through 26th. The topics, the key topics are listed there. As you can see, at the URL, if anyone is interested in attending, you can register and obtain the complete agenda. And one thing I'll mention about this particular meeting

that's different is that because of what's been going on recently with novel influenza A, H1N1, we have decided to add an extra, essentially an extra day to the meeting, which will be devoted to presentations only on novel influenza A. That will begin Thursday afternoon and run until 1:00 on Friday, the 26th.

And my next slide is my closing slide, which shows a shot at the children being vaccinated in the US in 1965 and then a similar shot in India in 2008, with some polio national immunization days for polio eradication being conducted in India.

And that is my presentation, and I would be happy to take any questions.

MS. CASTRO-LEWIS: Thank you Dr. Smith. Any questions?

DR. FISHER: Actually I have a comment more than a question. This is Meg Fisher. I just wanted to make it clear that work groups are working on the recommendations well before licensure of the vaccine. So the goal is that as soon as the vaccine is licensed, or as soon as possible after a vaccine is licensed, there's some recommendations for how it would be used. So when you look at that first graphic, it seems like nothing starts until after licensure and nothing could be further from the truth. The work groups are working on it well in advance and we're getting

and thinking about how they're going to use the vaccine. So there's no rush, you know, it's not like the vaccine's licensed today and suddenly within a week you have to figure out what you want to do with it. They've been thinking about it for months, years.

MS. CASTRO-LEWIS: Does it include all the period for the development and the testing and the trials and all that which is there also, before it comes to the ACIP?

DR. SMITH: Yes, that's a very good point. I couldn't hear the name of the speaker just now, but usually when I have more time to present this, I really emphasize that work groups typically are set up. It's well-known in advance that a vaccine may be licensed. It's not known exactly when it will be licensed, but there's some kind of time line. So for example, in the case of HPV vaccine, human papillomavirus, that was well-known at least two years in advance and so a work group could be set up as much as two or three years before anticipated licensure to allow plenty of time to assemble all the information and come up with draft recommendations.

MS. CASTRO-LEWIS: Thank you so much. Dr. Evans.

DR. EVANS: I have the pleasure of attending ACIP three times a year. It is my favorite meeting, outside of Rockville, it's my favorite meeting. And it, there's a great deal of work that's done. I think this meeting

that’s coming up, there’s going to be eight votes scheduled on recommendations, which is a tremendous amount of work. This is even before the third day. The third day, I don’t think there’s any votes that are taking place. And work groups do, as you said, an incredible amount of work ahead of time, also ignoring the hours of the day. So if anyone ever has the opportunity to attend, I would certainly encourage it. As the HRSA representative or ex-officio, I have on occasion voted. It’s rare, but whenever people are conflicted and they don’t have a quorum, then the ex-officios are called on to vote. And we also on the second day, all the ex-officios provide updates on their programs in the five minutes you’re given. And that’s the time I voice what’s been going on with the programs and the committee. And that room usually has 200 plus people in the audience. It’s a very, very big and well attended meeting.

MS. CASTRO-LEWIS: Okay, thank you so much. I don’t think there are any more questions here, but I’d like to thank you again, Dr. Smith. This was very useful.

DR. SMITH: You’re welcome and I will just say that Jeff Evans has my contact information and I’m more than welcome if anybody in the future has questions or wants any documents, just feel free to contact me.

MS. CASTRO-LEWIS: Thank you so much. Do you want to say something?

DR. EVANS: I just want to thank Dr. Smith for a very informative presentation.

MS. CASTRO-LEWIS: Thank you again. Next on our agenda we have the update on the Immunization Safety Office. Dr. Broder please, from the Centers for Disease Control, I'm sorry.

Agenda Item: Update on the Immunization Safety Office (ISO), Centers for Disease Control and Prevention (CDC) Vaccine Activities, Karen Broder

DR. BRODER: Hello. I'm Karen Broder and I'm going to be providing the update on the MMRV vaccine safety working group. I fully agree with Jean Smith's assessment that the working groups really do a lot of work and we really believe in what we do. So I'd like to thank the ACCV for inviting the MMRV working group to provide this update and acknowledge some colleagues who are on the phone bridge. We have, I hope, Dr. Tempte, who is an ACIP member and who is the lead of this working group.

DR. TEMPTE: I'm here if you can hear me.

DR. BRODER: Thank you.

DR. TEMPTE: Very good.

DR. BRODER: And we have Dr. Mona Maren, who is my CDC co-lead in this working group. We're actually very

lucky because we have two of us and I hope Mona is on the line.

DR. MAREN: Yes, I am Karen.

DR. BRODER: Thank you. And then we have Alan Janssen, who is the CDC Principal Investigator for a study that you'll hear about in a few minutes on Perceptions of MMRV and Febrile Seizures Among Mothers. And Alan, are you on the line?

DR. JANSSEN: I'm on the line Karen.

DR. BRODER: Wonderful. So as a reminder, the working group presented a detailed update in March, a few months ago, to the ACCV. And I looked through the briefing materials you had and there is minutes summarizing this meeting on page eleven, which I think are a nice summary.

At that time, we informed the ACCV that two post licensure studies suggested that children age 12-23 months, who were receiving the first dose of MMRV vaccine, had increased risks for febrile seizures in the first to second week after vaccination, compared with children of the same age who received separate injections of MMR and varicella vaccine, and at the same dose.

And at that time, we talked about some of the policy options under development. The MMRV working group will be, one of the votes, will be presenting our final interpretation of the risk data and policy options for vote

on MMRV use at the June meeting and we're currently scheduled for the second day, which is June 25th, in the morning.

The working group is considering many factors in it's deliberation around MMRV policy, which you heard outlined by Jean Smith. And one of the factors that we are considering is information we received from a study of mothers' perceptions about MMRV and febrile seizure use conducted during the month of May, largely by Alan Janssen and his team. And we are very happy because Alan Janssen is on the phone today to provide some preliminary information from the study to the ACCV.

We would look forward to any of your comments on this information because Alan is also planning to not only, well we use this as a working group to help inform our deliberations, but he'll be presenting it to the ACIP. And so with that, I'd like to go ahead and turn it over to Alan unless there are any questions. And we'll hear his talk titled, with a typo in it, How are Mothers' Perceptions of MMRV Vaccine Preliminary Results.

DR. JANSSEN: Thank you very much Dr. Broder. It's a pleasure to be here today and make the presentation. If I could, being in Atlanta, I'd like to make sure that the title slide is up now. It is? Okay. If we could,

let’s move on to the background slide and we’ll go ahead and get started.

What I’d like to do is kind of basically quickly summarize again what Dr. Broder mentioned is that, you know, as we look at this towards the issues involved for this study and they are measles, mumps, rubella, and varicella. There are two options that exist. One is a combined vaccine called the MMRV and then also the other option is two separate injections of the MMR vaccine and a separate varicella vaccine.

Now two post licensure studies suggest that the risk for febrile seizures is increased during the 5-12 days after the first dose of the MMRV in children in age 12-23 months. Now this is compared to separate injections of the MMR and varicella vaccine at the same dose. This is approximately the two-fold increase in risk.

Now CDC studied the perceptions of mothers regarding the risks and benefits of MMRV, who have been informed on policy development and all the suggested communication materials to communicate this. Can I move on to the first methodologies slide please.

The data was collected for this study by means of a mini-focus groups. Now these are, we recruited up to six participants per group. We assembled a commercial market

research facility in both New York City and Brooklyn in Washington. Brooklyn is a suburb of Seattle.

Our sessions lasted about an hour. We used a professional moderator with 24 years of experience to guide the group in the discussion. Along with that, members of the group, the participants, were also provided a background and draft communications material about MMRV and febrile seizures. We have assessed reviews about the combination vaccine in general, dose one of MMRV for children age 12-15 months, and also communication materials. The second methodologies slide, please.

The participants were mothers of children age seven months to three years of age. They reported that their child had neither experienced seizures nor had a condition that would compromise the child's immune system and therefore, their ability to receive vaccines. And the mothers also reported during the screening process for this group that they expected children to receive all or most of the childhood vaccinations that are recommended. Could we move on to respond to characteristics? Next slide please.

We conducted sixteen of the mini-focus groups, with eighty-two participants there. Among the respondents, the mean age was thirty-one, with a range of twenty to forty-six years. Sixty-three of the respondents reported to having at least one college degree. Respondents were

white, African-American, Hispanic, Asian, and mixed race. Moving to the next slide on the results.

When asked about the combination vaccines in general, the mothers produced a modest list of advantages, a longer list of disadvantages, and an even longer list of questions. Some of the advantages were cited across all the grids were that the combination vaccine, the MMRV, meant that a child would have fewer shots, perhaps less pain and trauma, protection against several diseases at one time, fewer doctors trips, and lower cost.

Some of the disadvantages cited by the mothers were an inability to pinpoint the source of allergic reaction if one occurred, an increase in side affects, and that the combination of all the vaccines might be too great a challenge for the child's immune system and also less parental choice.

Questions included, from the parents, included in terms about the side affects and also is this combination vaccine as effective as separate vaccines? And what does this mean in terms of a schedule, including what does it mean in terms of maybe a catch up schedule? Next slide please.

The degree of acceptance to the MMRV vaccine varied substantially among the participants. After reviewing the materials on the MMRV vaccine, mothers were

asked if their physician recommended that dose one MMRV be given to their child, age 12-15 months, and then to rank their acceptance of that recommendation on a scale of one, which is no way or no how, to seven, which is accept without reservation.

Interestingly, 18 participants said that they would not accept the vaccine, which is the one ranking. Eighteen participants also said that they would accept the vaccine. Then in between we had roughly seven participants lean towards not accepting the vaccine. Twenty-three participants were in the middle. Fifteen were favorable to the vaccine. Moving to the next preliminary results slide please.

Just a comment about their choice in terms of the one to seven scale, one again being no way, now how would they take the vaccine to seven, they would accept without reservations. You can see that a lot of these selections seem to be somewhat risk-based in terms of what the parents were doing. They also commented in terms of the risk of seizures were there. And then a couple, one of them would like to talk a little bit more about what the risks were to learn a little bit more. So these were, kind of those comments.

Moving on the next slide, we see more positive kinds of comments that were made. Again, seven is accept

without hesitation. You can see that there's a great deal of trust put into physicians in terms of making the recommendation for the vaccine and making the selection for them. Again, the principal thing we heard over and over again was I trust my pediatrician to help me make this decision.

Moving on to the next preliminary results slide. For some, the MMR vaccine was seen as combining two vaccines that were each unappealing in their own way. We were a little surprised in that a number of folks that were out there refer to the MMR vaccine as the autism vaccine. And a few responded associated with the preservative thimerosal, despite the fact that, you know, the MMR vaccine didn't contain thimerosal.

Several responded to expressed reservations about the MMR vaccine. When asked about, they also said that they knew that there really was no scientific basis for the concern, but they really weren't too sure and they were really questioning whether they wanted to take the risk. Very few of the participants, although we did hear it, expressed severity with measles, mumps and rubella vaccine.

The varicella vaccine was perceived to be somewhat of a less than necessary vaccine. The respondents reported that chicken pox was not a life threatening disease, rather it was seen by many of them, as kind of a

rite of passage. Below this you'll see a series of quotes that are from the parents in terms of this. These are direct verbatim from the respondents. Moving on to the next slide.

The mothers were generally less concerned about the fever than the seizures, although some respondents expressed a substantial anxiety about the occurrence of fevers. And their assessment of the importance of the difference between the separate and the combination vaccine varied, as you saw in kind of their response to would they take the vaccine or not. Moving on the next slide.

Their perception of the post vaccination fever in general appeared to be somewhat affected by their own experience. Most of the parents, several of them I would say, really didn't know what a febrile seizure was. And so as we went through this and explained it to them, they became somewhat concerned. A number of them had mentioned that they had friends or relatives that had experienced that and had some experience for having a febrile seizure. Moving on to the next slide.

There was general agreement among the participants that seeing a child having a febrile seizure would be an extremely harrowing experience for most of them. And for some, the information on the rate of the febrile seizure was of significant concern and for others it was

not. Let me give you one of the quotes, here's what they, "have never heard of a febrile seizure before," and on the other hand we have quotes in similar to them, that numbers were not alarming to them, a particular person. Let's move on the final preliminary results slide.

There was a universal preference, as we tested some of the health communications materials, we looked at, you know, what was the best way in terms of presenting the material, and if you would go ahead and advance a little bit to the next slide and I'll talk a little bit about the draft communication table. There was a universal preference for the table format of presenting the comparison of the combination and separate vaccine, compared to what was a narrative form that we put together.

Respondents, almost universally, said they were more clear, was more straight to the point, rating the numbers was better. They had something to actually judge their decision on and the results worked very well for them. And you could see the draft communication table used in the focus groups. We talked about the number of shots that were needed or were required, what you could expect in terms of fever with the MMRV or the MMR and varicella vaccine separately, and the possibility of a febrile seizure within 5-12 days after vaccination for the MMR and varicella and also for the MMRV. Okay, if I could move on

to the preliminary results or preliminary summary slide one please.

The study was conducted with a small sample of mothers who reported that they intended to have their child vaccinated. They generally expressed a very high degree of trust in their pediatrician. The mothers, it was interesting though, they, even though this was a very positive group, they differed in their conclusions regarding the data about the MMRV vaccine and the rates of fever and febrile seizures and their acceptance of the MMR vaccine. Preliminary summary number two please.

Then after reviewing and discussing the two versions of information, the MMR vaccine, almost a third of them declared themselves to be highly resistant to having their child get the MMRV vaccine. And roughly about a quarter of them were neutral to the decision.

And then finally, in terms of our health communication material, the study suggests that the framing of the MMRV risk information really impacts the risk perception and that the parents preferred again to have the table with the information presented to them so they could be involved in making their decision.

And then in coming to a conclusion, I would like to acknowledge our MMRV perception study team, the vaccine basic working group, and those who participated in the

study. Also Dr. Tempte who joins us, and also Elizabeth Andrews, who provided some advice and consultation in the preliminary study design. And with that, I'll turn it back to Dr. Broder.

DR. BRODER: Thank you very much and I know that we really appreciate everybody who worked on this. I know, in particular, Alan Janssen worked on this also while he was working on the influenza response. So this was done for the purpose of trying to make the best decisions for MMRV.

And I want to ask first, before we get to questions, Dr. Tempte and I attended at least one day each of the focus groups. Dr. Tempte, would you like to make any remarks?

DR. TEMPTE: Sure, very briefly, but it was, at least for me, just very wonderful to step out of my usual role and be behind the smoky glass windows, watching real people talk about their real feelings and responses to safety issues as they perceive the vaccines. To some extent, I have to admit, it changed some of my impressions, especially the two things that I really took home is just the wide range of perception of safety that what was very acceptable to some people was not acceptable at all. And the other thing that came through very clearly was that relationship between parents and their physician when it

comes to immunization and their, of their children. That was such a very poignant piece of information that seemed to be a common theme across several focus groups.

DR. BRODER: Thanks. So we had a really great discussion last time in March and, in fact, I think some of you even brought out some of these issues about thinking about parental opinions. So we would be very interested, and not only in seeing if there are any questions for Alan, but any suggestions or feedback you have just before we make our final decisions.

MS. HOIBERG: My question is what has been decided about the MMRV? Is it still going to be recommended? Is it still available? Is it something that's going to be pushed? I mean, what's

DR. BRODER: Well, as we presented previously, there are four options being considered, which will be proposed for the ACIP in June and they will decide. And we're going to propose, under Dr. Maren's leadership, separate votes for the dose one and dose two. And at this point, all four options are still being discussed.

So the four options that we talked about last time were having a preference for the MMRV vaccine compared to the individual; having choice, either you do MMRV or MMR, varicella vaccines, it doesn't matter; having a preference for the component vaccines, MMR plus varicella vaccine over

the MMRV; or recommending removal of the recommendation and just recommending MMR and varicella vaccine. Those are the options being discussed. We do expect that there is an anticipation there will be a vote on those in June.

The current standard of care, which was published in the MMWR in March of 2008, is a choice, either or. However, MMRV is not available on the US market, for reasons unrelated to safety or effectiveness.

MS. HOIBERG: Okay, because my question with these is the possible reason for the increase in febrile seizures. Could it not be the fact that the varicella portion of the vaccine is seven times stronger than the normal, than, you know, than the plain varicella.

DR. BRODER: Sure. So one of the things we're doing, and again we'll be presenting this portion of the update at the ACIP, is we're reviewing the risk data. Not only from the epidemiologic data but also what you have discussed, some of the biological plausibility data. And we do think that the, there is biological plausibility behind seeing an increased risk for febrile seizures because you see higher fever rates after the MMRV compared to the separate vaccines. And there is some question about whether the different properties of the vaccines might be accounting for that increase in fever rate. And we'll be going into some more details on this. There is also a

slide presentation posted on the ACIP website from October that has some more scientific details if you're interested.

DR. FISHER: Was there any thought to asking the mothers about the second dose, because interestingly, when you use the combination for the second dose, there does not appear to be any increase in fever or seizures.

DR. BRODER: I'll take a stab and then turn it over to Alan. We actually had a limited amount of time and really needed to maximize the time with the mothers. So the focus of the focus groups was for the mothers was around the first dose. I will say there is another component to the study that we will be preparing for the ACIP, which was the discussion with physicians. And that included opinions about both doses. Alan, I turn it to you to ask whether in the context of the discussions, some of the second dose issues just came up and whether you had any comments about that?

DR. JANSSEN: I believe the second dose issue was more common among the physician respondents than it was the parents. I'm trying to think back and right now, it may have come up one or two times, but it didn't seem to be something that was repeated among a number of participants.

MS. CASTRO-LEWIS: I do have a question. I am Magdalena Castro-Lewis. In terms of their knowledge of the focus group participants, I just want to clarify this.

Were the mothers provided with some information about vaccine adverse reaction before the focus groups or you went into the sessions with the knowledge that they had at the time regarding the vaccines?

DR. JANSSEN: We have a sheet that basically describes the different types of vaccines, the single dose vaccines and the combination dose vaccines. Also I believe discussed live and attenuated vaccination in more simplistic terms than that. And then also talked about sometimes there were side affects.

DR. BRODER: Alan, that was presented to them in the context of the meeting. There was no material about it before they showed up?

DR. JANSSEN: No, no. As a matter of fact, we generally make sure that when we recruit people, they do not know exactly what they're coming in for. So they are not allowed to study up for it and learn more about the particular subject area. We did however, upon their arrivals, have them complete a full informed consent sheet and they were aware of who we were and we also identified ourselves at the beginning of the session.

MS. CASTRO-LEWIS: Thank you so much. Does anybody have any other questions? No. Okay. Well, thank you so much Dr. Broder and Dr. Janssen for this presentation.

DR. JANSSEN: Thank you, thanks for having us.

DR. BRODER: Thank you.

MS. CASTRO-LEWIS: Dr. Salmon.

PARTICIPANT: We wanted to also give you a general update on the Immunization Safety Office of the CDC.

MS. CASTRO-LEWIS: Okay, so you want to do it. Okay, I'm sorry. I thought our time was going

DR. WEINBAUM: So let me just give you a very brief update.

MS. CASTRO-LEWIS: Sorry to interrupt you. Could you please introduce yourself?

DR. WEINBAUM: Sure. I'm Cindy Weinbaum and I'm the Acting Director of the Immunization Safety Office of the CDC. Since this is my first ACCV meeting, thanks for inviting me. So just kind of a brief update of what's going on in the Immunization Safety Office at CDC.

In the last months, there have been a couple of published studies coming out of the Immunization Safety Office related to the safety of T-Dap vaccine and neurological outcomes, which was a negative study.

There was a study looking at the experience of seasonal flu vaccine in kids ages two months to two years, which also didn't find any specific adverse outcomes for those age groups. And then there was a review of experience with Gullain Barré and it's relationship with

vaccines. Just kind of a review paper which I think will be very useful as we go forward and look at the possible H1N1 vaccines that are going to be developed.

Of course, the Immunization Safety Office has been gearing up for the possible introduction of a vaccine against the novel flu strain. Our plans for monitoring that have lots of pieces to them. We have to be able to do some active surveillance with HMO's that are in the vaccine safety data link. We expect to do some enhanced passive voluntary reporting. There's, in terms of increase in our outreach both to vaccine recipients and to providers, as well as to specialists who might be the ones who will be seeing an adverse outcome. So in terms of really trying to enhance our passive reporting.

We are in the process of recruiting a new permanent Director and are hopeful that the candidate that's currently under consideration will be on board before the end of the summer. ISO has had a series of reorganizational challenges within CDC as it's moved from one part of CDC to another. And having a permanent Director, I think, will really make things like our consistent presence at ACCV much more feasible. As well as you probably know that CDC is getting it's new Director on Monday. So we're looking forward to the arrival of Dr. Freidan.

We continue, of course, to monitor new and niche vaccines including doing regular monitoring of HPV vaccine and a couple of conjugate vaccines in an ongoing way.

And then finally, in response to an Institute of Medicine recommendation in 2005, we, the Immunization Safety Office at CDC developed a draft five-year agenda, which just completed review by NVAC, that I'm going to let Dr. Salmon talk about. CDC is also going to be contributing to the current IOM review of vaccine safety through funds provided by the stimulus package, the ARRA, and so we're looking forward to that happening as well.

DR. FISHER: Can I ask you for just clarification. The very first study you mentioned, T-DAP and neurologic, and you said it was a negative study. I'm presuming that means it showed there were no signals or no evidence that there was a cause. Negative studies, you know, are good, but.

DR. WEINBAUM: That' correct. That's right. There is no evidence of any causality. Oh, sorry, yes.

DR. EVANS: Cindy, could we have those sites or copies of papers or something so we can provide that.

DR. WEINBAUM: Yes, absolutely. I'll send those to you.

MS. CASTRO-LEWIS: Jeff, did you have a question?

DR. EVANS: I had the same question Meg had.

MS. CASTRO-LEWIS: Okay. Does anybody have any more questions. No? Okay. Thank you so much, Cindy, that will be easier for me. Now I think we have a little typo here. Dr. Salmon, please, the update from the NVPO.

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

DR. SALMON: I think that some of what we've been doing has already been discussed and I'll just talk for a few minutes about the safety working group. So that the first task of the working group you've all heard about before and Dr. Weinbaum just mentioned, but it was based on an IOM recommendation for CDC's Immunization Safety Office to develop a research agenda, and then for the NVAC to review that agenda and provide comments on content and prioritization. You've heard about this before.

The report was voted on and unanimously passed earlier this week. So that should be posted on our website. So this was a fairly robust process that I think we've all heard a lot about, so I'm not going to spend much time on, but just so you know where it goes from here. The NVAC makes recommendations to the Assistant Secretary for Health. So that report will go to the Assistant Secretary for Health, who presumably will then communicate the findings to the Centers for Disease Control. So the working group

has completed their efforts on that task and Tawny Buck was very helpful and participated actively in that process.

They're now getting ready to move on to their second task, which is to look at the safety system more broadly. So the charge is to develop a white paper to describe what the optimal safety system would look like, to define the safety profiles of vaccines in a timely manner, to prevent adverse events whenever possible, and to improve and maintain public confidence in vaccines.

So, what should the safety system look like? It may need some small changes in the membership of the working group to address this because as the task changes, the expertise will need to move a little bit as well. So they have gone to a tri-chair, I don't know if that's the proper, triad, it's more than a co-chair because it includes three people, the joint chairmanship. So Tawney has joined as a co-chair, as Marie McCormick. Marie is a Professor in Maternal and Child Health at Harvard. And they will be helping Andy in serving as chair positions.

They've also added three people, are in the process of adding three people to their membership. Currently, we have public representatives from two of the four Federal Advisory Committee, Tawny from the ACCV and Trish Parnell who is a public rep to the NVAC. We've now, are adding two public representatives from the other two

advisory committees, Robert Beck, who is the ACIP Consumer Rep and then Vickie DeBolt, who is the VRBPAC Advisory Committee Public Representative. And the effort here was not to get the new rep, but to get the person that's really worked with the advisory committee the longest. So, for example, I think Tawny has probably, I don't know the details, but you're probably pretty close to the edge of your time here.

Robert Beck, I think, is also towards the end of his tenure with the ACIP. But the thinking is to have somebody who really spent a significant amount time with that group so they understand how it works. And then lastly, Bill Robb was added to the working group. Dr. Robb was the Deputy Director of the IDH? for quite some time.

And then he was most recently the Senior Scientific Advisor to the Secretary of HHS, which was Secretary Lovett, and he was very interested and involved in vaccine safety activities before he retired when the new administration took over. So we think he is, that NIH has a very important role, and having this experience with both would benefit the working group.

So they're in the process of reconstituting that. They're having a kick-off meeting July 15th and 16th in Washington, DC, and this is really a informational gathering meeting. The intent is to have a series of

panels where a really broad and diverse range of people will come in and share their thoughts on a variety of areas.

There are five panels that have been put together. The first panel is Principles and Policy Alternatives for a Robust Vaccine Safety System and will be responding to questions like what are the basic principles that should guide the safety system, what aspects of the current system are important for or insufficient to meet these principles, how can the system be coordinated, how can stakeholders come together to improve the system. And the way this is going to work is the panelists will each respond to these questions for about ten minutes and then there will be an hour discussion with all the panelists and the working group.

The next panel is focused really on some more hard-core scientific issues by identifying innovative ways to overcome the gaps in the vaccine safety science infrastructure. The third panel is the ideal system to aid the needs of the public, public health, and health care professionals for confidence in vaccine safety.

The next panel was lessons learned from other safety arenas. So the idea is to bring in people that have worked in other areas of safety, not vaccine safety, but areas like drug safety, transportation safety, chemical safety, and you know, what have they learned in their

safety systems that may be applicable to vaccine safety. So it's a real effort to think outside the box. And this is, the focus of this meeting is to try to get some new ideas and some new thinking.

And the last panel is on enhancing the adoption and implementation of the white paper. So the intent here is to start thinking early on about how can the process of developing this result in it being implemented because clearly the NVAC is not interested in simply writing a paper that sits on somebody's shelves. But they very much want to see that their efforts result in some actual change and improvement to the system. So by thinking early on about how such a process can enhance the likelihood of the end result being an improvement to programs and not just a government document.

I haven't gone through the list of participants. It's a fantastic group of people ranging from the President of the American Academy of Pediatrics to outstanding academic investigators, on to advocates from a variety of groups and organizations. I think this will be a very interesting meeting. And I'll stop there and I'm happy to answer any questions that you might have.

MS. CASTRO-LEWIS: Thank you so much for that. Okay. Is that it? Are the panels, the panel discussions

open to the public in the way that maybe some of the CDC members, if they would like to attend, please, so it open?

DR. SALMON: Yes. So this is an issue which the working group has really struggled with because they've made a tremendous effort from their beginning to really be open and transparent and to really involve as many people in groups as possible. Just about all of their meetings have found that when open to the public that they've been well casted and often there's been coverage by media.

In this case, there's a real effort to get people to think outside the box and take some risks. And the concern was that if there's a movie camera in the back of the room, people are less likely to take risks in what they say. And you know one way was expressed is if you have an idea which you're not even sure it's a good idea, but it's worth throwing out there for discussion, we want you to feel comfortable enough to throw it out there. And the concern was by having it open to the public, and highly publicized it may inhibit that sort of candid discussion, so the decision that was made that anybody who's on a panel can stay for the entire meeting. But it would be limited to panel members. Keep in mind that panel members include a very diverse range of people. So probably most advocates or groups will have somebody in the room that they feel represents their views.

So it's a struggle. And the answer to your question is no, it's not open to the public, and that's why it's not. But there will be a very broad range of people involved. And I would just also point out this is the beginning of the process. And it's the beginning of informational gathering, so there's no question that there will be future meetings, that they will be open to the public, and we're consulting with Keystone to try to think through a longer term strategy for how to involve the public as well as stakeholders.

MS. CASTRO-LEWIS: Thank you very much. Any other questions?

MR. SCONYERS: Your task one report you think is going to be out soon? I'd just love to get notification when it's up on the site.

DR. SALMON: Yes. You know, it was sent this afternoon from our office to our web guide. And I haven't yet seen an email, although my blackberry has buzzed a couple of times since I started my report, but it's just a matter of it being uploaded. So I suspect that it will be there by tomorrow.

MS. CASTRO-LEWIS: Probably, you think that Michelle will send it today?

DR. SALMON: Sure, I'll send it to Michelle and have her send it down.

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

DR. SALMON: Thank you.

MS. CASTRO-LEWIS: Dr. Mulach.

Agenda Item: Update on the National Institute of Allergy and Infectious Diseases (NIAID), National Institutes of Health (NIH) Vaccine Activities, Barbara Mulach

DR. MULACH: Thank you very much. I was actually hoping that FDA would be giving a presentation this afternoon too because one of the things I wanted to talk about briefly was just some of the efforts that NIH is working on for the 2009 H1N1 vaccines. So, you know, a lot of times I've come here and talked to you guys about H5N1 and other potentially pandemic strains and how we were really doing a lot of research to try to understand what these new strains might be like in terms of developing a vaccine, what kind of doses might be necessary.

And while it's not H5, we've learned a lot from those studies and I think we're taking a lot of that knowledge into the proactive efforts that are ongoing now. So FDA, CDC, and HHS's BARDA office are all working at, working with manufacturers to see what's going to be coming down the pike in terms of potential vaccines for the H1N1.

And in terms of NIH's role, we have vaccine and treatment evaluation units that are primed and ready to do

clinical studies. What we're waiting to find out is what the manufacturers are going to be doing in terms of their core studies. And then we'll be working with FDA and others to identify other studies that need to be conducted that the manufacturers either don't have the capacity or aren't focusing on because they're doing the main studies.

So we'll be looking at special populations, possibly pregnant women, children of different ages, people with specific conditions that aren't considered a healthy adult population, to try to round out. If we do need to use the vaccine, what can we learn in those populations and to understand as much as we can about the vaccine before we go trying to use it on a large scale effort, should we need to do that at some point.

We're also looking at dosage as did with the H5N1 and others. Do you need more of the vaccine? Do you need multiple doses? What is the timing between doses? A lot of discussion around dose sparing and trying to use adjuvants. Those decisions have not been made, but we're looking at all the strategies. And you know, it may not be as simple, everyone gets the same amount of vaccine, the same amount of adjuvant, or not adjuvant. It may be that we look at different alternatives for different populations.

So we're really going to have to look at how to protect as many people, but also, you know, very important

to understand as much as possible about these vaccines so that we can provide it in the safest and most efficient manner. So we'll be doing that.

And a lot of what we'll be doing too is looking at the best data that we can get to inform policy decisions. So depending on what the lay of the land is in terms of how severe the infections are and how we might implement, what information do we need to do that. So again, do we need to use one manufacturer's vaccine with another manufacturer's adjuvant? Do we need to be looking at specific vaccines and specific populations? Thimerosal, no thimerosal, those kinds of things.

So, I'll be happy to answer any questions. But again, understanding it's a changing environment and you'll be hearing updates, I'm sure, and we'll be glad to keep you guys informed. And, thanks.

DR. FISHER: When US declared the public health emergency and that released the stocks of Oseltamivir and also allowed us to use it in off-label use for the younger children, does the same type of thing, or will the same type of thing, apply to the vaccine? And I guess the reason, or is that a separate group that takes care of that? It's not an emergency.

DR. MULACH: Right, so I think that's probably a better question for FDA, although again, can we really

answer it? I think a lot of good questions will circle around whether or not we're using adjuvant. Because one of the things they're talking about right now, if we're not using adjuvant, they may be able to consider it similar to a seasonal strain. But if they're using adjuvant, then that's a whole separate issue and that brings up the potential to have to use an emergency use authorization. So it really changes the lay of the land.

So again, it's sort of a stay tuned, we're going to be, again, gathering as much information as we can over the summer, knowing as much as we can about the individual vaccines and individual adjuvants and the use of them. So that, again, depending on how we would have to implement, and CDC is very involved in the implementation phase, and how can we do that, again, in the safest manner.

MS. HOIBERG: Are adjuvants the things that are, the different ingredients? Is that what adjuvants are? .

DR. MULACH: So an adjuvant is basically something that's not necessarily specific to the influenza virus, but that it kind of helps the immune system mount a response. So it kind of gives a little push.

MS. HOIBERG: So a little like formaldehyde, and all that kind of stuff, right?

DR. MULACH: Right.

DR. FISHER: It's a detoxifying agent, it's different. It's not meant to be there to augment your response.

MS. HOIBERG: Okay.

DR. MULACH: So, the other thing I just wanted to say briefly, I think my colleague Jessica Bernstein talked at the last meeting about the National Children's Study, and I just wanted to let you guys know that in April, five additional sites were starting to recruit pregnant and soon to be pregnant participants, so they really are gearing up.

For those who don't remember, the National Children's Study is meant to be sort of a way of looking at children over the course of about a twenty-one year time frame, and they're looking at trying to recruit, over the course of multiple years, 100,000 children. They're looking at both rural and urban populations and just a lot of different environments. And the idea is to really see what we can learn about different children as they're growing and being exposed to different things and what it is that we can do to look for trends and try to identify, you know, what might help to identify what people might be exposed to and what might cause them to disease or health.

MS. HOIBERG: Are you going to separate them and have a group that is not vaccinated and others that are?

DR. MULACH: These are actually people that we're watching. We're not proactively telling them to vaccinate or not vaccinate. But we are gathering information about vaccination. So in as much as they're altogether in the end going to be 105 study locations, so there will definitely be, you know, the range of what you have in the general population, people who are and aren't vaccinated.

And again, we'll be getting, we'll be gathering some basic information about vaccinations and actually there's an inter-agency work group kind of talking about how the information on vaccinations is going to be gathered.

MS. CASTRO-LEWIS: Any other questions or comments? No? Thank you so much Dr. Mulach. And I think this concludes the part of presentations and discussion. Does anybody have? One second. Any other comment or anything to add to today before we go into the public comment? No? Okay.

Agenda Item: Public Comment

MS. CASTRO-LEWIS: Yes, please, we are ready for public comment. Did you have any?

OPERATOR: If there are any questions on the phone, please press Star 1 at this time. One moment for any questions, please.

(Pause)

At this time, there are no questions.

MS. CASTRO-LEWIS: Thank you so much. Any comments from the floor? Anybody? No? Just a moment please. Where's the microphone?

MR. MOODY: Yes, thank you, Jim Moody from Safe Minds. I would like to highlight one of the recommendations that came out with a unanimous approval of the Vaccine Safety Working Group Report two days ago by the National Vaccine Advisory Committee. And that was the recommendation for a feasibility study on the vaccination, first time vaccination, of children study. And there's some talk about alternative vaccination schedules.

The reason that is so important, and that reflects upon this committee, is because it is impossible to tell the extent of chronic adverse events, from vaccination, without making a comparison of chronic health status of unvaccinated versus vaccinated children. And I had actually thought this was something done back in the '60's, when the vaccine schedule was first initiated.

But to my surprise, looking at literature a couple of years ago, that was a gap and now that gap has been officially recognized and identified as a research need. And it's important this get done with all deliberate speed rather than sort of kicking a can down the road because, as this mothers' survey was talked about earlier, indicates we're sort of at a tipping point because of the

asymmetry of risk perception, as the serious infectious diseases disappear, parents should be even more and more worried about the chronic adverse effects following vaccination.

And there's even the addition of a two times increase in febrile seizures that created really a big reaction in the "hell no" category. And as the vaccines got a little more complicated and we saw of the 36 vaccines and 60 adjuvants on the schedule, more and more parents, as Dr. Salmon's article recognized in the New England Journal about a month ago, are going to be opting out of the vaccine program.

So it's very, very important to get that good solid baseline data on the health status of unvaccinated children so that either the parents' concerns can be allayed, or if there are a difference in product adverse reactions, necessary steps can be made to change the vaccine from the schedule or identify specific children so the public's confidence in the vaccine program can be maintained in the highest state as possible.

Dr. Alexander, head of NICHD, said at the December meeting of the IAC, Autism Advisory Committee, could be as many as 5-10,000 unvaccinated children in the National Children's Study. That will provide, hopefully, sufficient statistical power to get a good baseline data

going forward. Those results won't be available for years. So while that's a very useful study, and should be incorporated in an ongoing basis as the schedule changes, the importance of getting good baseline data pursuant to the recently approved recommendation, should be done with all deliberate speed to keep public confidence as high as it can be. Thank you.

MS. CASTRO-LEWIS: Thank you so much for your comments. Anybody? Okay. I think we had a really good, really good presentations today that will be very helpful for our discussion tomorrow. We'll be starting with a report and also Jeff's, Dr. Evans' report. I think tomorrow we're going to have probably a busy morning. I'd like, really, don't have anything else today. Just that everybody have a good evening, and do I hear a motion to adjourn the meeting?

DR. FISHER: Move.

MS. HOIBERG: Second.

MS. CASTRO-LEWIS: Second? So, meeting adjourned.

(Whereupon the meeting adjourned at 5:15 PM)