HEALTH RESOURCES AND SERVICES ADMINISTRATION

ADVISORY COMMISSION

ON CHILDHOOD VACCINES

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TABLE OF CONTENTS

P R O C E E D I N G S (1:00 p.m.)

Agenda Item: Welcome

MR. SCONYERS: Good afternoon, everyone. Thanks for joining us today. We have got a pretty full agenda for today and tomorrow, so we are going to just jump right in and get going.

Before we do that, I want to just make a couple of introductory comments. One, I want to thank Michelle Herzog for all her support and effort, especially the briefing book that we got that included this great CD with the orientation materials. I really appreciate, Michelle, you pulling that together.

We are going to hear from the work group recommendations tomorrow. At your places you will find a draft letter of recommendations to the Secretary of HHS. I hope that all the members will take the opportunity to read that very carefully, so that we can discuss it and act on it tomorrow.

For those of you who may not know, we have Tawny Buck on the line from Alaska. Tawny has been back and forth across the country many times in behalf of the work on the National Vaccine Plan and her role there. We will be hearing from her about some of that, but it was just too much to make one more trip. So Tawny is with us by voice, but not with us in person. She is going to drag herself out of bed at oh

dark hundred tomorrow morning when we get started at 9 a.m., which is really, really early Alaska time.

So those were the introductory comments I wanted to make.

Agenda Item: Approval of September and November 2008 Minutes

The first order of business would be approval of our September and November 2008 minutes. You will recall, we had a discussion about those minutes at our last meeting. At your places is a one page from the November minutes. There is one added sentence. The last sentence on that page was added. That was just an oversight, so that has been added in. So what I hope that we will be doing is moving to approve the minutes with this one added sentence at the end of the page. It is page number ten that should be at your places. It just adds the sentence that says, Mr. Sconyers has requested that in the future the Commission be informed of such action being table changes before final publication.

MS. TEMPFER: So moved.

MR. SCONYERS: Tammy, I'm going to take that as a motion to approve both the September and the November minutes. Is that your intention?

DR. FISHER: There are a couple of minor typos which I will give you. They are not substantive at all.

MR. SCONYERS: Okay. Do we have a second to the

motion?

DR. FISHER: Second.

MR. SCONYERS: Jeff, you wanted to say something?

DR. EVANS: I just wanted to say, regarding that one sentence, which I think is appropriate for it to be in there, this had to do with the interim final rule which became effective November 10. It removed the category of rotovirus vaccines from the Vaccine Injury Table.

Without getting into the background or much detail, the Secretary considered this a technical housekeeping matter. It didn't affect the rights of anyone. Be that as it may, we take seriously the comments and request by the Commission that they be informed in the future, and the Secretary will consult the Commission on any future changes to the table.

MR. SCONYERS: Thanks, Jeff. We have got a motion, a second. I am going to deem that the motion to approve incorporates the typographical changes that Dr. Fisher has provided to us. Is there any further discussion on the minutes? Hearing none, all those in favor of approval, say aye.

(Chorus of Ayes.)

Agenda Item: Report from the Division of Vaccine Injury Compensation

MR. SCONYERS: Any opposed? Okay, the minutes are

approved.

Our first order of business is Dr. Jeff Evans with a report from the Division of Vaccine Injury Compensation.

DR. EVANS: Good afternoon. Welcome, everyone, to the 72nd quarterly meeting of the Advisory Commission on Childhood Vaccines.

Tawny, we are starting with the first slide of the ACCV meeting highlights, which will include updates from the Department of Justice from Catharine Reeves and Lynn Ricciardella. Next there will be a report on the omnibus autism proceeding by Tom Powers, and a presentation on the Division of Vaccine Injury Compensation Outreach Plan by Kay Cook, who is the policy branch chief of the division. Then updates from our ex officio members representing the National Vaccine Program Office, NIH, FDA and CDC.

Tomorrow's agenda will feature a review of four Vaccine Information Statements led by Skip Wolfe from the CDC, then an update on the National Vaccine Plan by Ray Strikas from the National Vaccine Program Office, a report and discussion on proposed recommendations from the ACCV Recommendations Work Group that Jeff just alluded to. Then we will finally have an election of a new chair and vice chair.

Before we begin, I wanted to point out that in your blue folders you have on the right side the speaker

presentations for both days. On the left side of you folders you have a number of things, starting with articles on the omnibus decisions from the New York Times and the Washington Post, and commentaries from Autism Speaks and Talk about Curing Autism, different viewpoints about the decisions.

You will also find a White House press release dated February 20 on President Obama's selection of Dr. Mary Wakefield as HRSA's new Administrator, which we are all excited about, and there is also a summary of a Georgia Supreme Court decision this past October in a case that followed the program. The case is American Home Products Corporation versus Ferrari. Our thanks go to Emily Levine of the Office of the General Counsel for this write-up.

Starting with the VICP statistics, the trend here is one of increasing work for the program. The average over the past six years has been about 167 non-autism claims per year, and as of five months into this fiscal year we already have 104 non-autism claims. These are primarily flu claims, mostly adult claims, reflective of the fact that we did add influenza vaccine back in 2005. That is the most frequent vaccine given in this country, over 100 million doses annually, and this is not surprising that we would reflect increasing frequency of these kinds of claims.

MR. SCONYERS: What is the through date for FY '09? This is through what period?

DR. EVANS: This would be five months starting October 1.

MR. SCONYERS: So through February.

DR. EVANS: Right, those five months. Half the year has passed by, but we are looking at probably landing somewhere over 200 claims. You can see there is more work coming into our office.

In terms of autism claims, there was a trend downward up until the beginning of the hearings in 2007, and then there was increased numbers of claims, and it seems to begin to trail down again some.

In terms of awards paid, the average is $65 million for petitioners' awards for the last six, seven years. You will notice though starting in 2007 that there has been a significant increase. As we have talked before, there is an increased number of settlements. Also, the Court had staffed up to a total of eight Special Masters. One has since left the Court, but with that increased number of judicial officers, there were increased numbers of claims that were being adjudicated by the Court.

We are still with fairly frequent numbers of claims being adjudicated and paid. You will see as of this year so far that we have already awarded $60 million. I should point out that just recently, this past January, the program funded the single largest award since the inception

of the program. That was Solano. In terms of giving contracts in lump sums, that added up to a total of $13.4 million. We don't have very many of these kinds of claims, but that certainly added to the $60 million figure that you see there. So we are on track right now of ending up at the end of this year with $120 million plus in terms of outlays, or more.

Going on to the trust fund, which is everyone's favorite topic. It turns out we have nearly three billion dollars in receipts for the first three years, starting October 1, now a total of $73 million. So we are on track with bringing in somewhere on the order of $300 million. That is just a quarterly figure, $73 million times four.

Again, the increase is because of influenza vaccine being added to the program, that increased the significant numbers of vaccines that are purchased annually. Against the outlays, if we were to spend $110, $120 million, we are still netting somewhere in the order of $150, $160 million plus. So the trust fund still is growing at a significant rate.

MS. GALLAGHER: Is the trust fund invested?

DR. EVANS: I get asked that question, actually. The question is, is the trust fund invested. The trust fund is all government trust, as I understand it. It exists in the form of Treasury bills or lockboxes, it has been referred

to, so it functions to balance the deficit, or against the deficit. So it has a purpose as it is sitting there waiting to be used by the program.

Next, turning to significant activities. February was a very busy month, as both Tawny and I know. On February 2 I attended the third national stakeholder meeting of the IOM committee on the review of priorities in the National Vaccine Plan. The Institute of Medicine is holding workshops with national experts and stakeholders in medicine, public health and vaccinology to review the draft update of the '94 National Vaccine Plan, and to provide guidance to the National Vaccine Program Office.

The focus of this particular meeting is goal three, communication, which specifically supports informed vaccine decision making by the public, providers and policy makers. That took place in Washington.

Two days later, I attended the National Vaccine Advisory Committee working group on vaccine safety. That is the group that Tawny has been spending a great deal of time working with, in addition to her role on the ACCV.

They have basically been focusing on two tasks. That is, a scientific review of the draft CDC Immunization Safety Office Scientific Agenda, as well as a review of the current vaccine safety system. The February 4 morning session was open to the public, and reviewed results of the

community outreach efforts to obtain input on the ISO scientific agenda, and also a summary of written comments. They were solicited, and a Federal Register notice published in January. The afternoon session, the working group met.

On February 5 and 6, I represented HRSA as an ex officio on the National Vaccine Advisory Committee. During the agency ex officio reports, I provided an update on the program, and also introduced Magdalena Castro-Lewis, who is the ACCV liaison to the NVAC.

The second day of that meeting was devoted entirely to obtaining stakeholder input on the National Vaccine Plan. We will be hearing more about that from Dr. Ray Strikas.

On February 12, the U.S. Court of Federal Claims issued decisions in the three test cases, Cedillo, Hazelhurst and Snyder, and of course we will be hearing more about that. Finally, on February 25-26, I served as an ex officio representative of HRSA on the Advisory Committee on Immunization Practices at the meeting in Atlanta, in which I gave an update on the program.

Some of you may remember Cheryl Lee, who was a principal staff liaison to the ACCV. She has recently been promoted to a GS-13 management and program analyst, which is an extremely important part of our office. She is a compensation payments analyst, processing VSCP awards and

settlements at rates which have significantly increased over the years, and is doing a superlative job. I just wanted you to join me in congratulating Cheryl. Cheryl, please stand up.

For those of you who are listening in, the points of contact which I review each juncture I go through the program, you can write the program at the National Vaccine Injury Compensation Program, 5600 Fishers Lane, Parklawn Building, Room 11C-26, Rockville, Maryland 20857. The telephone number for the HRSA Information Center is toll free, 1-800-338-2382. The Internet address for the program, which we have a lot of pride in these days, we are trying to keep it quite current, is www.hrsa.gov/vaccinecompensation.

For those who would like to participate via public comment in Commission meetings, you need to -- first of all, every meeting is published in the Federal Register, and if you want to participate, please write Michelle Herzog care of the Parklawn Building at the address that I just gave previously, 11C-26, 5600 Fishers Lane, Rockville, Maryland 20857. Michelle's phone number is 301/443-0650, and her e-mail address is mherzog@hrsa.gov.

That ends my presentation. I am happy to answer any questions.

MR. SCONYERS: Thanks, Jeff. Are there any questions for Dr. Evans? I would like to express my thanks

to Tawny again for her participation in the vaccine safety work group, and Magdalena for her representation of the Commission at NVAC. I know that both of those things take significant amounts of time, so I am grateful to you guys for doing that.

If there aren't any questions, we are going to move on to the report from the Department of Justice. We have got Catharine Reeves and Lynn Ricciardella.

Agenda Item: Report from the Department of Justice

MS. REEVES: Good afternoon. My name is Catharine Reeves. I know you have become accustomed to seeing Vince Matanoski up here for about the last two years or more. Unfortunately for our office, he has been called to active duty for the U.S. Navy, and has been sent to the Congo. So until Mark Rogers returns from Iraq where he is serving with the U.S. Marine Corps, I will be Acting Deputy. I am going to have to fill some very big shoes, but I will do the very best that I can.

Jeff just went over some of the same steps that I am going to present to you. We have had 90 cases filed since the last ACCV meeting, 39 of which were autism cases, and 51 of which were non-autism. Thirty-nine of those cases were adult claims, and 12 of them were children. I think Jeff also mentioned that most of the claims that have been filed

recently that are non-autism are for adults, not for children.

We have had a total of 45 cases adjudicated since the last ACCV meeting. Twenty-seven of those cases were found compensable, and of those, seven were conceded by HHS, and 20 of those were not conceded by HHS, of which 18 of those were settled and two were resolved via a decision from the Office of Special Masters, and 18 of those were not compensable.

This is a glossary of terms. As I understand, we are providing this at the specific request of members of the Commission, about some of the terminology that is regularly used by us, but maybe not as plain to those who are not actively involved in litigating cases under the program.

When we say a petition has been adjudicated, that means a final judgment has been entered, and that means that the case is ready to be paid. Final judgment is when a clerk of the court issues a judgment saying what the final decision in the case is, whether it is awarding compensation or not.

If a claim is found to be compensable, a compensable claim can be achieved in several different ways. Either it is conceded outright by HHS as meeting the table requirements or meeting the standard for causation of fact, or the case is heard by the Office of Special Masters, and the Special Master issues a decision compensating the case.

We often settle cases as well.

A concession by HHS, that is something that the HHS has determined that the case has met the standards for a table case or for proving causation in fact.

A settlement is a case that is resolved. A negotiated settlement is negotiated by both parties, and there is a mutual agreement reached as to the amount of compensation that a petitioner will receive.

A decision is when a Special Master hears the evidence and makes a decision on merits of the case. A non-compensable or dismissed case is a case where the petition has been dismissed by the court.

MR. SCONYERS: Let me just pause here and say thank you very much for this glossary of terms. I think it is something that the members have been confused about, and it is very helpful to get this. So it is a good step.

If we could ask, I'm going to go out on a limb here, it would be great to include this glossary every time we get a report.

MS. REEVES: Sure, we can do that, no problem.

MR. SCONYERS: Because we will forget.

MS. REEVES: Yes, we are happy to do that.

MS. BUCK: Before you go on, can you tell me how many of the 18 non-compensables are final judgments?

MS. REEVES: That, I don't think I have the

information for. The ones that are not compensable, it depends on when they were decided, whether the time has run for the judgment to enter. When a case is found to be not compensable, both parties have 30 days from the date the decision is issued to seek a review of the decision by the Court of Federal Claims. So it is not possible for me to know how many of those judgment has issued on.

MS. BUCK: Are all of those seeking review?

MS. REEVES: I don't know.

MR. SCONYERS: You are giving total petitions adjudicated, which means final judgment.

MS. REEVES: Right. She was asking about them one to 18. You know what? You're right.

MR. SCONYERS: Tawny, I think that the 18 are all final judgments, because that is the statistic that is being reported. The first statistic is total petitions adjudicated and adjudicated means final judgment.

MS. REEVES: Chairman Sconyers is correct. I apologize. This is a flow chart that we created to explain how a petition goes through the system. I would note one thing about the flow chart. We maybe will change this before the next time we come, but if you look at conceded and not conceded, cases not conceded, then it goes to either a decision or settlement. If it is decided it is either compensated or not compensated, if it is compensated it goes

to damages. Then if it is conceded, the flow chart has it going straight to damages, but what I would like to point out is, many of those cases, in fact, I would feel safe in saying most of them, those are settled or they are resolved via a proffer on award of compensation by the respondent, to which the petitioner agrees.

MS. BUCK: Can you say that again? I'm not sure, you just lost me.

MS. REEVES: It is another term that we may have to add to the glossary as to what a proffer is. But cases that are conceded, if you look on the flow chart, it has that conceded case going straight to damages. When a case is conceded, sometimes there is a hearing before the Special Master on the level of compensation a petitioner receives. But oftentimes, in fact, more often than not, the cases are resolved via a negotiated settlement by the parties via a proffer, where respondent proffers the evidence that it feels is supportive of an award of compensation, and the petitioner agrees to that.

So my point being that oftentimes when a case is conceded, the damages are awarded through a negotiated or agreed-upon process, as opposed to having to go through the hearing process, presentation to evidence to the Special Master and having the Special Master decide it.

MS. BUCK: But what percentage of the cases do you

think go that way?

MS. REEVES: You mean conceded that end up being settled, or resolved via a proffer?

MS. BUCK: I assume it is faster.

MS. REEVES: It is faster.

MS. BUCK: Do you have any sense of what the percentage is of cases that go in that --

MS. REEVES: I would say most, but I couldn't be as precise as to give you a percentage.

MS. BUCK: I think we saw the flow chart at our last meeting too, and I pointed out at that time that also, your settled cases down there, there should be a line from settled to compensated, because I assume settled means that they are also compensated.

MS. REEVES: Yes, that is correct. The next slide is just going through, talking about the autism decisions that Jeff mentioned in his presentation. Lynn Ricciardella, who is the lead counsel on the autism cases, is going to give you a summary of those decisions when I am finished.

As you know, the decisions on the first theory of causation came out on February 12. In all three cases, compensation was denied by the Office of Special Masters. Those decisions are all available on the court's website. They are quite lengthy, but they are available to anyone who is interested in reading them.

Theory two has not been decided yet. Hearings in the three cases addressing theory two were heard in May and July of 2008. I'm not really sure when a decision will be coming out on theory two, but that is what we assume the Court is working on now.

MR. SCONYERS: For people on the line who don't have this slide, remind them what theory two is.

MS. REEVES: Theory two is that thimerosal containing vaccines alone can cause autism, whereas the first theory of causation was that MMR vaccines and thimerosal containing vaccines can combine and cause autism.

Theory three is that MMR vaccine alone can cause autism. At this time no test cases have been scheduled on theory three.

Appeals. I would note that in your blue folder we have provided a summary of recent precedent setting cases in the program, again at the Commission's request. This is just a slide that shows we have two cases where the petitioners have petitioned for a writ of certiori at the Supreme Court. The Kay and Mojica cases, which both involve jurisdictional issues. Any cases that go to the Supreme Court represented by -- the government's interests are represented by the Office of the Solicitor General, not our office.

Then we have a few cases pending at the Federal Circuit. Nordwall is only pending because the petitioner

wanted to withdraw the appeal that was filed, but failed to do it properly, so it was dismissed for failure to file the principal brief. And petitioner's counsel has now asked the Court to reconsider that and allow him to voluntarily withdraw the appeal. So I don't think anything more is going to come of that particular case.

Andreu is set for oral argument before the Federal Circuit on April 1.

The next two slides are showing a number of cases, some of which have already been adjudicated, and some of which are pending before the Court of Federal Claims, which is the next level of review after the Office of Special Masters.

The Boley case was just recently affirmed on February 12. Sabella and Carrington both involve attorneys fees and cost issues.

I wanted to mention that there are five cases that are currently awaiting decisions from the Federal Claims. They all involve basically the same issue, and that is that hep-B vaccine caused autoimmune hepatitis. That is Hager, Myers, Porter, Rotoli and Torbett. They are all assigned to the same judge, and they are all represented by the same law firm.

I think that is everything that I was going to talk about, unless anyone has any questions.

DR. HERR: The adjudicated cases this past month, can you tell us, of the conceded and settled cases, what vaccines were talked about?

MS. REEVES: That I couldn't tell you off the top of my head. I don't even know if we keep stats that way. Which vaccines were involved in the cases that were adjudicated?

MR. MC INIERNY: We can get that.

MS. REEVES: Are there any other questions? Then I will turn the mike over to Lynn Ricciardella.

MS. RICCIARDELLA: Hello. My name is Lynn Ricciardella. As Catharine said, I am a trial attorney at the Department of Justice, and I work on the autism litigation. I am here to give a very brief recap of the decisions that came down from the Court on February 12 of 2009.

In those decisions, the three Special Masters adjudicated the claims on theory one. As Catharine mentioned, theory one was thimerosal containing vaccines combined with the measles-mumps-rubella vaccine, and whether or not that can cause autism spectrum disorder. The Court in each of the three test cases ruled that no, thimerosal containing vaccines combined with the MMR vaccine cannot cause autism, and did not in the individual cases that were before the Court.

If you already know some of this background information, please stop me. These were test cases for approximately 5,000 claims that are pending in the program that were put together in an omnibus autism proceeding.

There were three theories of causation that were offered by the Petitioners Steering Committee. Theory one is what I just discussed. Theory two is whether thimerosal containing vaccines alone can cause autism. That theory was tried in three separate test cases last year, two in May and one in July. The parties are still in the process of briefings. The petitioners post hearing briefing on theory two is due April 3, and the government post hearing brief for theory two is due June 2. So as Catharine did allude to, it is going to be quite some time until we get decisions on theory two.

With regard to theory one, the cases are very complex. All told they cover over 650 pages. They are very detailed, they get into a lot of medicine, but just to give you a very brief nutshell of what they held, the first component of that theory was whether thimerosal containing vaccines can disregulate an infant's immune system or cause some sort of immune dysfunction, and the Court held that no, it cannot.

The second part of that was whether or not the measles component of the MMR vaccine can cause autism as well

as gastrointestinal inflammation, and the Court held that it cannot. I am happy to answer any more questions in detail, but I thought that these decisions are very complex, so that in a nutshell are the two scientific questions that the Court had to decide.

Appeals of theory one. If the petitioners are going to be seeking review of those decisions, those appeals are due to the Court of Federal Claims on March 16.

MR. SCONYERS: When? I'm sorry.

MS. RICCIARDELLA: The 16th. If those decisions are appealed then the government brief would be due to the Court on April 15. That is just to give you a time line of where we go from here.

Then the next level of appeal from the Court of Federal Claims would be the Court of Appeals for the Fifth Circuit.

MR. SCONYERS: Is review discretionary or as of right?

MS. RICCIARDELLA: They have an appeal as of right from the Federal Circuit. If they wanted to seek review or appeal beyond the Federal Circuit, it would be to the Supreme Court, and that is discretionary.

MR. SCONYERS: Thanks.

MS. BUCK: I understand quite a bit about this process. I do understand there are almost 5,000 cases in the

omnibus proceeding. But although you have three decisions on three test cases, that doesn't eliminate -- every single case deserves attention in the Court, correct?

MS. RICCIARDELLA: Absolutely. Every case has the right to proceed individually. That is absolutely correct.

MS. BUCK: So I don't quite get that. The significance on these three, these are three people and these are three cases, but you have 5,000 more to wade through.

MS. RICCIARDELLA: That is a very valid question. We will have to wait to see what the Court decides to do. The theory behind the omnibus autism proceeding is that a body of evidence would be adduced. The Court would make findings of fact and conclusions of law, and then apply that to the other 5,000 cases. It really depends if the other 5,000 cases decide to pursue different theories of causation. It is completely their right to do so.

MS. BUCK: Isn't each case that comes before the program reviewed individually? It probably was designed not for an omnibus or a cause of action proceeding, but that individual cases be looked at on their own merits. We all understand that every single one of these vaccine injured kids is very unique and different.

MS. RICCIARDELLA: Absolutely, I couldn't agree more. Each individual case will eventually have to be looked at individually by the Court. How they decide to apply the

body of law and the factual findings that they have made concerning the science and medicine that was presented to them in these test cases - that is up to the Court.

But you are right, eventually each one of these cases is going to have to receive individual attention.

MS. BUCK: I would caution that the Court is the Court and not a lot of scientists, and it would be very troubling to think that three decisions were made that would somehow create some criteria to dismiss or not look at all of them. I think those of us that have been around for awhile know that all of these cases are really unique. So it is good to hear your reflection on that.

MS. RICCIARDELLA: The only other issue I wanted to address dealing with the OAP were interim fee petition. We have received, or actually the Court has received interim fee application in the Cedilla case and in the Hazelhurst case. Those are the test cases for theory one. We also received the application submitted by the Petitioners Steering Committee in the King case, which is one of the test cases for theory two, but that application encompasses not just what was done for the King case, but for all of the work done by the Petitioners Steering Committee since the inception of the OAP in 2002 through the hearing on theory two.

The Court has not received an application in the

Snyder case, which is the one of the test cases for theory one, nor has it received an application in the Dwyer case, which is one of the test cases for theory two.

The Hazelhurst interim fee petition has been resolved by the parties. It is awaiting a decision by the Court. The Cedillo interim fee petition, respondents filed its response to that petition in November, and it is awaiting decision by the Court. We have filed our response to the PSC interim fee application this past February, on February 6.

I don't know if anybody has any questions.

MS. TEMPFER: I am just curious. With the 5,000 cases in the omnibus hearing, how do they decide which theory they fall into? Is that dependent on like the petitioner's brief? It sounds like people were going to get assigned to a theory by the cases.

MS. RICCIARDELLA: No, the theory is actually the petitioners and their counsel. If they decide to go along with one of the theories that has been proposed by the PSC one or two theory. But that is the petitioner's decision. It is not the Court's or the respondent's.

One thing I wanted to clarify with theory three. That theory that was put forward with the MMR vaccine alone, taking away the thimerosal containing vaccines, whether MMR alone can cause autism. The PSC back in the summer informed the Court and the respondent that they would not be offering

any more evidence in that theory. That theory was subsumed in the evidence they presented in theory one. So in essence theory one and theory three have already been adjudicated by the Court, and what is remaining to be decided by the Court, at least in terms of the PSC, the causation is theory two.

MS. TEMPFER: So those cases that are still -- the thousands that are still there that there has been no decision made, they will be reviewed individually then, just through a look at what has happened with these decisions on the previous cases?

MS. RICCIARDELLA: That is correct. In trial decisions, we have had seven OAP decisions voluntarily dismissed by the petitioners. We have had a few other petitioners counsel request stays of their cases, to enable them to confer with their clients to see how to proceed from there. The pending claims in the OAP will have to consider what their next step is.

MS. TEMPFER: There is not a time line on that because all the theories haven't been heard yet? They have been heard though, right?

MS. RICCIARDELLA: They have been heard. The theory two has not been decided yet by the Court.

MS. TEMPFER: So is there a time line when these other ones will be looked at?

MS. RICCIARDELLA: We don't know. Are you

familiar with the short form autism -- I don't know how much background --

MR. SCONYERS: We have talked some about it, but I think people don't really know that.

MS. RICCIARDELLA: When the omnibus autism proceeding was put together, the Court allowed petitioners to file the short form autism petition, saying we want to be part of the autism omnibus proceeding; my child has an autism spectrum disorder. But they didn't file any records with that.

So now what the Court is doing is, every month they are activating 200 of these pending OAP claims, and telling the petitioners now is the time to start filing medical records in your cases. Then the respondent to what the court order is asked to do with all their medical records, their statement of completion by the petitioner has been filed, saying that yes, these are the totality of the medical records for my child. It is the respondent's court to make a determination as to timeliness, whether or not we think the claim was filed within the three year statute of limitations.

That is where there are all these other pending claims. It is not so much adjudication on the merits of those claims. We are just now starting to get medical records coming in. So it is going to be a very lengthy

process before these individual claims will actually go to trial.

Some petitioners are pulling out of the OAP and asking that their cases be heard separately from the OAP. If that is the case, then the Court is treating those petitions as it would any other Vaccine Act claim, telling petitioners you have a certain amount of time to get an expert report in.

Again, that is just starting to happen, so even those petitions are in the initial stage.

MR. SCONYERS: Other questions for Lynn?

MS. BUCK: Is the processing of the interim fees and payments -- I know you had a steering committee that helped work with that, so I assume that that is going fairly smoothly, and that there has not been a lot of --

MS. RICCIARDELLA: Respondent doesn't have a steering committee. You mean the petitioners?

MS. BUCK: Biff said that he was working with a group when they were hammering interim fees with payments, working with people from the PSC, that process.

MS. RICCIARDELLA: Oh, yes. We are working with them to try to see if we can work out as much as possible, that is correct.

MS. BUCK: So is there a back and forth, back and forth? Or is this an issue that is pretty much being resolved and people are getting paid, I guess is my question.

MS. RICCIARDELLA: No one has gotten paid yet. In the Hazelhurst case, we just received the application last Friday, and by Monday the issue was resolved between the parties. It was filed with the Court. So that should be paid shortly.

These petitions for application for fees and costs, as you can imagine, are extremely lengthy, so it took some time to file responses. But we are working with -- it is not just one or two attorneys.

MS. BUCK: But they are the same attorneys. A lot of these cases have been going on for a while. It is my understanding that at our last call you had already received the interim fees and payments -- I'm just a layman and I don't use legal terms, but I am just wondering how adversarial is that process going on, on something that you all agreed to do, which is to have this break point to pay attorneys fees and payments. Is it your impression that that is going pretty quickly, and everybody is pretty satisfied on the other end? Or is that a lot of back and forth, back and forth?

MS. RICCIARDELLA: It is going as quickly as humanly possible. With the PSC's fee application, it was over 7,000 pages. One firm alone had close to 30,000 line items, and respondents had 90 days to respond to that. It

was a Herculean effort to respond to that within 90 days, and I'm sure there is a lot we missed. We objected to the things that we considered to be unreasonable.

We just filed our response on February 6. We do intend to try to negotiate as much as possible with the other side. For instance, in Cedillo just yesterday, respondent would be able to negotiate with counsel on the Cedillo case for their fees and costs.

Again, these fee petitions don't just involve one or two attorneys. I think in the Cedillo case alone there were 14 or 15 attorneys. The PSC, I think there are 13 law firms, and how many attorneys per law firm. So it is a first impression file in the program. We have never had fees and costs application to this magnitude. Everything else pales in comparison to what we have received in this litigation.

MS. BUCK: I think we all are pretty clear about that. The only concern, I suppose, is that there be some piece of this process that goes fairly quickly. Clearly we all understand that this has been going on for years, that the fees and costs are massive, there are lots of attorneys, we understand all that. You have to deal with all that. But I guess there is some desire to be heard from the program or from DOJ that at least a piece of this process is moving as quickly and as smoothly as it can, and that we are all feeling for the families and for their counsel that those

areas which can be taken care of quickly, are.

So all I am asking for is some sort of comment that makes me feel better, to know that at least it is going as quickly and as smoothly as you all feel that it can.

MS. RICCIARDELLA: And I hear you. I think your comments are extremely fair. Yes, at the Department of Justice we do feel that the process is going as fairly and as quickly as is reasonably possible, yes.

MS. HOIBERG: Can I just say, it has been seven years since these attorneys have gone without pay. I wouldn't want to work for seven years without pay, and DOJ didn't work for seven years without pay. But these attorneys have worked for seven long hard years on it, and not seen a dime for it, and shelled out a whole bunch of money to pay experts and all that. So really, there should be no question as far as at least their fees. Now, if you guys want to go over hotel costs and all that, that's fine, but at least pay them for the time that they put in.

MS. RICCIARDELLA: I agree with you. But the amount of fees that they are awarded has to be reasonable, and it is up to the Court to decide what is reasonable.

Again, they put in the application, respondent has filed a response, and now -- I hate to put everything on the Court, but now it is in the Court's hands. We are willing to help the Court as much as possible. I think that we hear

from Mr. Pattas the same thing, that the parties are willing to help as much as possible.

MS. HOIBERG: Would you be more inclined to help if you went for seven years without pay? I think that to be fair, DOJ shouldn't get paid until the petitioners' attorneys get paid.

MS. RICCIARDELLA: I understand your frustration, I do. I hear what you are saying. That is just not the way the program works.

MR. SCONYERS: Are there other questions for Lynn?

DR. SALMON: I don't know if you know this, but do you have any indication of how many if any cases since these three test cases were decided have left the program and gone on to state courts?

MS. RICCIARDELLA: The question was, am I aware that since the February 12 decisions were handed down, how many have pulled out of the vaccine program and filed later in civil court. I don't know. I do know that seven so far have been voluntarily dismissed by the petitioners since the February 12 decision. Of those seven, I don't know how many are pursuing a civil claim.

DR. SALMON: Is that a preliminary requirement before you can pursue a civil claim, to be out of the program?

MS. RICCIARDELLA: Yes, you have to come through

the program. You cannot have a pending civil claim and a Vaccine Act claim at the same time.

DR. SALMON: So whether or not they are going to the civil courts, the necessary first step would be to --

MS. RICCIARDELLA: To come through the vaccine program, that is correct.

DR. SALMON: And then to exit?

MS. RICCIARDELLA: Correct. But actually you need a judgment to be able to file in civil court. With a voluntary dismissal you do not get a judgment.

DR. SALMON: Maybe I am misunderstanding this, but isn't there a time limit so they can withdraw and therefore it goes? That is not the case?

MS. RICCIARDELLA: The question was, is there a time limit that the Vaccine Act provides to allow them to withdraw, hasn't that already passed. The answer is no. There is a time limit. I think it is 420 days. The Court then will issue a 420 day order saying we have not adjudicated your claim in the 420 days, you now have to write to withdraw from the program.

They only have 30 days to do that, though. If they don't withdraw within 30 days of receiving that order, they cannot voluntarily withdraw.

DR. SALMON: So they are far beyond the time limit, but because they didn't act quickly enough that is no

longer an option?

MS. RICCIARDELLA: That is correct. It can't be a voluntary withdrawal. It can be a voluntary dismissal, but with that you do not get a judgment.

DR. SALMON: Thank you.

MR. SCONYERS: Other questions or comments?

MS. DREW: An attorney who wanted to request that, he could take his client to civil court. He can still do that. It is just a different procedure wherein you would ask for a decision, perhaps a decision on the record, and the Court would say, you have lost. Then you would reject that judgment that would come from the decision, and then you could file in civil court.

But probably there hasn't been enough time for anybody to do that with this only being less than a month old.

DR. SALMON: Thank you for that.

Agenda Item: Petitioners Steering Committee Omnibus Autism Proceedings Update

MR. SCONYERS: Anything else? Thanks very much, we appreciate it. We are going to turn now to Tom Powers, who is on the line from the Petitioners Steering Committee. Tom has been very gracious in offering his time to us on the ACCV to provide the perspective from the Petitioners Steering Committee. He is going to update us on the autism omnibus

proceeding from that point of view.

Tom, are you there?

MR. POWERS: Yes, I am. Thanks as always for the invitation to speak and provide an update. I'll keep it fairly brief so that we are not overly redundant with some of the items that Lin just spoke about.

I wanted to talk about the status of the theory one test case decision, the status of the thimerosal theory two test cases, talk briefly about the time limit of the statute of limitation issue and process. I can address maybe some of the fee questions that came up, and talk about a couple of issues that are relevant, some news from outside the program that may be relevant to the disposition of cases that are currently in the program.

First off, with the MMR, again not to be redundant of Lin's presentation, but yes, the three test case decisions have come down. I would agree with respondent's characterization of the findings, except that the decisions did not find that thimerosal cannot suppress the immune system or that the MMR cannot trigger autistic regression. What those decisions found is, the evidence presented was not sufficient for the petitioners to meet their burden of proof.

So I am not trying to quibble, I'm just trying to be clear about what the decisions were. The petitioners as you all know have the burden of proving the elements of their

case by a preponderance of the evidence. The Masters did not rule that it would be impossible for these theories to be proven, but that the theories were not proven, the cases were not proven, by the evidence presented in these three test cases.

I mention that because there will be individual petitioners and their attorneys who will be reading those decisions, reviewing those opinions, and making an assessment as to whether they think that they have a case that might be able to proceed under that theory with different evidence. Since these are evidence based hearings, I have no idea if anybody is planning to move forward with a shorthand calling a theory one individual claim and seeking to have that adjudicated on the merits. But a door certainly would be open to that, particularly if they thought they had different and frankly better evidence to support their claim for compensation.

The petitioners right now in all three of those cases are contemplating motions for review. Any motions for review do need to be filed by the 15th. The petitioners are also considering potential motions for consideration in one or more of those cases, based on the new evidence and new peer reviewed published scientific literature that has come out relevant to the theories in those cases, since the close of the briefing. So all of that is moving forward. On March

16 the Court and the parties will have a clear record as to what we would be looking to do post decision, post opinion, and ultimately following appeals and judgment.

On the theory two cases, the thimerosol test cases, as we reported, we are currently on a briefing schedule and working on all three of the test case briefs for the round two test cases. Those will be briefed during the course of the summer, and we will be on a time line then with the Special Masters once the briefing is closed to get decisions in those cases.

There was a question that I was able to hear asking about how the theory one test cases and decisions in those, and ultimately decisions coming down in the theory two test cases might serve to resolve additional claims in the program. It is absolutely true that every single petitioner during the pendency of the omnibus proceeding has maintained the right to have his or her case heard individually. The vast majority of claimants in the omnibus proceeding have elected to keep their cases stayed and to keep them in the omnibus and not withdraw them from the omnibus and seek individual adjudication. But I would anticipate that the petitioners working with their attorneys and medical and scientific experts might review any of these decisions, and even in the theory two cases before the decisions come down, might review the record in those cases, and look at the

evidence that came in, and make decisions about whether they might want to pursue additional claims for compensation, or quite frankly might want to seek the dismissal or withdrawal of their claims from the OAP and from the program altogether.

So that is a process that will take place over a very long period of time, but I think as Lin said it is fair to say that we are seeing some activity on that front, with cases being withdrawn from the OAP and moving ahead in the program, as well as cases being withdrawn from the program altogether.

The backdrop to all of this on the statute of limitation issue is that activation orders are continuing to issue from the Court, going out to waves of petitioners on a monthly basis. A series of orders goes out every month. Petitioners and their counsels receive these orders, pull their medical records, organize the medical records.

They send them in, and DOJ conducts a review, and based on the DOJ's review, there typically would be one of three things that a petitioner would hear back. The first is simply a statement from respondent that based on a review of the available medical record, it appears that the claim on its face is timely and seems to satisfy the jurisdictional requirements of filing under Section 16 of the statute.

That communication typically reserves DOJ's right, based on any additional information or additional records, to

challenge the time limits, but Lin, if you are listening, I use this in a very non-legalistic sense. It is a concession that at least as a threshold issue that case isn't being contested on the time limits.

The second thing a petitioner might hear back is a communication from the respondent saying that based on the available medical record, there is not enough information available to respondent to make a determination at that threshold level of whether the case appears to have been filed on time. It will essentially be a request to file additional medical records, and the ball is then in the petitioner's court to produce those records. If the records are not produced, typically the Special Master will get involved and issue an order to show cause why the record shouldn't be produced, or ask if the record is being produced why the case might face dismissal.

Then the third category is, if DOJ determines in their judgment that there is an issue of timeliness, that the claim to them look as if it was filed later than allowed by statute, there might be a motion to dismiss that claim.

That process is going on at this point probably with all 180 attorneys with claims in the program. Virtually everybody, even those with a small number of cases, has been in a position to start responding to these orders. Working with the Court, particularly with the Chief Special Master

and with DOJ, the PSC folks at our end have been doing the best that we can to collaboratively make this process work logistically. So there is formal cooperative agreements about how to make this process work smoothly and not burn the resources of the parties or the Court to get these records in, reviewed, and decisions made about timeliness.

Then there was the discussion a little while ago about the pending interim fee petitions. My firm in particular has been very involved in the larger PSC interim fee petition that was filed in the King matter. There were about 13 law firms involved in that petition. Our firm took responsibility for organizing the submissions of those lawyers so it wouldn't be 13 ad hoc, scattered over time and scattered in format, submissions.

We had agreed with respondent and again with the Special Masters to consolidate all of those into one pleading, into one petition, and submit that. It is expensive. DOJ's opposition is also expensive. I think there will be some areas that we can agree on. There will be areas that we may need to pursue in an adversarial way, not necessarily to the point of litigation, but I think we are all looking at the option again of not burning the Court's resources. The Special Masters ought to be deciding claims for compensation first and foremost, and not have to spend time resolving fights among the lawyers about expenses, costs

and fees. So we are looking at the opportunity to get an outside the program mediator involved if need be to help resolve issues that we cannot settle and negotiate informally. Then if there are any issues remaining after mediation, those likely would have to be litigated. But that is an ongoing process, and it is a heavy load to carry, but I think everybody has been taking it seriously, and we have been making some progress, just given the bulk of the submissions on both sides.

The last thing to talk about was in the news yesterday. It is outside the program, but at least for some folks might have an impact on cases that are currently in the program. That was the U.S. Supreme Court's decision in the Levine versus Wyeth Pharmaceutical case yesterday.

It was a six to three decision of the U.S. Supreme Court affirming the Vermont Supreme Court's affirmation and a Vermont trial court's verdict against Wyeth Pharmaceuticals for injuries suffered by a woman who lost her arm because of the inadequate warnings on one of Wyeth's drugs.

Wyeth had argued that the failure to warn claim was preempted by virtue of the product's approval by the FDA and by the company's compliance with the FDA's warnings label and licensing requirements. That federal preemption issue is important in these cases, because in at least one vaccine compensation case that opted out of the program, and

attempted to pursue the federal remedy in federal court. This is the Sykes case that a couple of years ago was filed in the Eastern District of Pennsylvania. Having gone through the program and complied with the NVICP prerequisites, filed a civil case in federal court, and the vaccine manufacturers challenged that lawsuit on a number of grounds.

One of the claims in the Sykes lawsuit was a failure to warn claim related to the thimerosal content of the vaccines from two or three different manufacturers. The district court judge in that case found that those failures to warn claims were preempted and therefore barred and dismissed because the vaccine products did comply with the labeling.

The rationale for that decision is something that is essentially reversed in the Supreme Court's decision yesterday. That will not have any effect on the Sykes case itself for any petitioner in the program who is contemplating seeking a civil remedy. It certainly removes at least one of the perceived legal obstacles to pursuing that claim in the civil system.

I don't know, and I have no idea at this point, if anybody is planning to do that. But I mention it because it is a very significant development in the law. It is certainly a huge development in the world of pharmaceutical litigation, and it may have an impact on some of these claims

currently in the program.

That is pretty much all that I had on updates. I'd be happy to take any questions.

MR. SCONYERS: As always, Tom, we appreciate you making your time available to speak to us. Are there questions for Tom?

MS. BUCK: I know that the decisions on the first three test cases came out quite a bit later than we originally expected. I know you don't have a crystal ball, but are you expecting that the time line is going to be that way on the pending decisions as well?

MR. POWERS: I honestly don't know. It is hard to say. My gut instinct, and this is just me, it is not based on anything, just my read of it, in a sense these cases, the theory itself is somewhat less complex. You don't have this combined exposure. So I think that to some degree, the scientific and the medical issues are a bit more straightforward. It is somewhat easier to focus on some key pieces of evidence, some key issues of scientific and medical debate, key pieces of evidence.

So to the extent that that is all true, it might speak to a shorter time line. But there is no doubt about it, even with a little bit more streamlined description of causation in these cases compared to the first cases, the Masters are going to have an awful lot to work through to

reach their decisions.

MR. SCONYERS: The Levine case is a drug case. Wasn't there a device from the Supreme Court last year that went the other way of failure to warn and the FDA approval process?

MR. POWERS: That was the Riegel case. That involved the Medtronic implants. Those are class three medical devices, and class three medical devices under the MDMA, the Medical Device Modernization Act, there is an express preemption provision that relates to civil lawsuits involving certain class three medical devices.

The Riegel decision, that is an apple compared to the Levine oranges, where conflicts implied preemption. There is no express preemption language in the FDMA, the Food and Drug Modernization Act, and the various amendments to it since 1962. The lack of express preemption language in the pharmaceutical context by the same Congress that considered and adopted express preemption language in companion legislation related to devices, regulated by the same agency, was very compelling to the Supreme Court, and led them to conclude that Congress did not intend to preempt theory one claims with all the pharmaceutical products.

MR. SCONYERS: Thanks. I have the feeling we are hitting an advocacy nerve for you.

MR. POWERS: Oh, no. I am just reporting what the

Supreme Court said. It was a great decision yesterday.

MR. SCONYERS: Any questions or comments for Tom? Hearing none, thank you very much for taking the time again.

MR. POWERS: Thanks, you guys, as always. I don't mess up the line if I just hang up at this point?

MR. SCONYERS: I don't think you will. Michelle says that will be okay, and Michelle knows everything, so that will work.

MR. POWERS: Thanks again. I will sign off.

MR. SCONYERS: Thank you, Tom.

MS. BUCK: Thanks, Tom.

Agenda Item: Discussion of Decisions in the Omnibus Autism Proceeding

MR. SCONYERS: We have some time on our agenda to discuss the autism decisions that have come out. We specifically put this on the agenda at the request of the agenda committee. This is time for the members to have whatever they have to say about it.

I would ask you, if you do have comments or questions or observations to offer, there are two microphones. Those are the only two microphones that actually allow Tawny to hear us. So when you speak into these silver microphones, what you are doing is putting it up into the air up here. When you speak into the two little microphones here, you are putting it over the telephone line

so that Tawny can hear us. So either project real big or come up to where you can speak close to those.

MS. BUCK: Thanks, Jeff. I would also like to mention that I am not the only one. We do have members of the public that are listening to this proceeding on the phone lines. So it is really important that they hear Commissioner comments. I can't hear Sherry and I can't hear Sarah, and there are a few Commissioners that I know have spoken that I can't hear. I'm sure that has got to be frustrating for people in the public who are trying to stay on top of what we are doing and using the phone lines to do it.

So I know it is a pain, but I would really appreciate it if you guys could do that.

MR. SCONYERS: So I will just open it up. Comments, questions, observations?

MS. BUCK: My only real comment about what has gone on so far is, I don't know, this is just me personally, but it just feels to me like a little bit of the spirit of the program has been lost in this omnibus proceeding. I am disappointed for the families. I am disappointed that the reporting has been that these issues have been resolved and that the courts have spoken and the science has been proven.

For me, I think this comes down to absolutely every single family that has a child that they believe has been injured, and that they deserve thorough review of what

happened. Each case is very unique about that. The program wasn't designed to prove the science. We know that by the statute and how it was written and the spirit in which the program has been designed.

So I am really hoping that despite these three first rulings, which I don't think were much of a surprise, but still a disappointment, that these families will still get -- every one of these 5,000 families will still get their opportunity to have their case looked at individually and assessed, based on the spirit of the program and not the politics of the day.

So that is just my little commentary. Thanks.

MS. HOIBERG: I would like to second Tawny's words. I feel that in a way, these omnibus cases are going to hurt families and not help them. I think now that any family coming in stating that their child is autistic because of thimerosal, they are autistic because of the MMR, the Special Master is just going to immediately go, we already proved that, and sorry, you are done, dismissed.

I really think that it is going to hurt families and not help them at all. I think in the end this was almost a means to an end. I think that it is horrible. I think that it is going to hurt, it is not going to help.

DR. FISHER: I can't not give the other side of it, which is the scientific evidence is pretty clear, and I

think the Special Masters were clear that the cases that were presented for these three people were not convincing.

So I think if the case is not convincing and the person is going to use the same case, it is not going to be any more convincing. I'm not saying they shouldn't be heard, but I think that at some point we have to say that we have listened to the theories enough, we have looked at the science enough, and it is settled.

MS. BUCK: I'm not disagreeing with you in that these three families have gotten their time. They got their attention, they got the ruling, they got all of that.

What I worry about is that this program was never run this way before. It wasn't designed to do an omnibus proceeding. That is not its purpose. It is not a proving ground for the science. Even the way decisions are made is not supposed to be that way. It is more likely if you can't find anything else. You know all that stuff.

I'm not arguing with you about that. What I am saying is, I am really worried that the rest of the families that are concerned about their children will somehow not get that kind of attention and that kind of time, because we have done this test case thing.

When my petition was brought forward, I didn't have to pick some theory. I had a sick kid. This is what happened. We worked through it and tried to determine what

happened. I didn't have to pick some line and check some box and say, yes, this is my theory.

So that troubles me about the whole process, not about the three rulings, but what that may lead to in terms of the overall process. It is troubling to me that it has gone down this path, and I am really hopeful that it doesn't end up eliminating people from the opportunity to get that much time and attention on theirs as well.

So maybe I didn't state it clearly the first time, but that is more of what I am talking about.

DR. FISHER: I absolutely hear what you are saying. I guess I am also concerned for all the non-autism cases that need to be heard. I think if the autism case is not something that is significantly different, to spend the same amount of time and effort on those 5,500 cases is not going to allow the other cases to be adjudicated, and for people who also think they have very legitimate claims and injuries, for them to be heard and for them to also get their day in court.

So of course I would like this all to just go away. That is not going to happen, but I would like us to be able to get past this to the other cases. I am concerned that this is going to drag on forever, and not do justice to all the other people that want to be heard as well.

MS. CASTRO LEWIS: This is a question maybe for

the lawyers or anybody who will attempt to respond to this. What is the difference between saying the science was very clear, and then in Tom's presentation he says, the evidence was not sufficient to prove the case.

So how do you compare those two? Is the science providing that or not? I am really confused on that.

MR. SCONYERS: I don't really want to hazard much of a guess. I think you heard from two people who have positions on the issue. Tom's point being that petitioners have to carry the burden of demonstrating that the injury is due to a vaccine administration. His point is that in these three cases, they did not carry that burden.

I think there is an opposing viewpoint that says the reason that those petitioners didn't carry that burden is because the scientific evidence doesn't exist to support that case. I think that is what you heard from the other side. So I think both of the things that you heard are true, but they are seen through the lens of a particular point of view.

Tom, I think you had a comment.

DR. HERR: I'll try to make myself heard as well to everyone. I think we need to remember that children are injured here. They may be injured by vaccines, they may not be injured by vaccines. The investigation under the omnibus program seems incredibly extensive, very thorough, much more thorough because of the extra discovery that is being allowed

in this situation than in the routine proceedings.

I think that because of that investigation and because of the summary, we have to try to decide were the vaccines at fault or were they not. We would all like to see these children taken care of. Our Commission is to take care of children who are injured by vaccines. We feel very badly about the fact that they may not have been and they still need care. But our responsibility here is to take care of the kids who were injured by vaccines.

What we would like to see, perhaps by the result of some of the discussion in this proceeding, we may find some other reason why these kids have been injured or gotten sick, and then point science or medicine in that direction to help these children recover and to treat them and to prevent them in that way. But it is unrelated to the vaccine.

I think we have to keep to our idea that we are here to talk about vaccine, and make sure that that is our responsibility, covering the children who have been injured by them.

MS. HOIBERG: I just felt that Meg's comment pretty much was like, we are wasting these autism cases are a waste of time. It is making these children in these 5,000 some-odd families with children who are horribly injured, it seems like they don't count, that they don't get a fair chance. It is not wasting our time.

I think you are going to find as each one of these cases comes through that there is going to be evidence. Just like in the Hannah Poling case. The vaccine triggered a pre-existing condition.

I'm not here to say that vaccines are horrible and they shouldn't be given. I'm just saying that these vaccines could have triggered an unknown -- in her case it was an unknown mitochondrial disease. Unfortunately this generation is so sickly and so weak, that we are not able to still use the same medicinal practices of 50 years ago. We are a different generation. It is like we need to upgrade our medicine, upgrade our way of thinking. We are so stuck in the past, because it worked in the past. Well, we don't live there anymore. We are here in 2009, and we need to start thinking that way. We need to start thinking, some of these children may have low birth weight, some of these kids may have autoimmune disorders. Some of these children may have others, or they could have been sick at the time of administrative.

So each child needs to be looked at individually, and they should each be given an equal chance. They should not be discriminated against because what comes through is a possible autism.

DR. HERR: One other little comment. I guess as a general pediatrician, I have to say I think our kids are

healthier than they have been in the past.

MS. BUCK: I think my only point for the Commission, and you guys won't have to listen to me much longer, is that I think it places too much importance on these three rulings. That is my focus, is on these three decisions, and we say it has all been solved. I think that is just not right. I think it is too quick a jump. It is too soon to say they have been solved. Had the ruling gone the other way, I'm pretty sure we would be having the opposite conversation right now, saying that the Court isn't qualified to show the science because that is not what they do.

I know enough to know that there is still a lot of science and studies that need to be done. I know enough to know that there are a lot of things still being looked at. I just worry like Tom so much about kids and vaccine injured kids, and not wanting them to get lost.

Yet I would have to disagree, that dismissing these 5,000 cases or hoping that we move them out of the way, it is not going to solve a whole bunch of problems about being safe, with the public's concern about vaccines. I just think that to say that everything has been fixed will take away the opportunity to look at these other families and try to look at them and see what is happening, and make sure we are not missing a true vaccine injury.

So what it is worth, and it will be my final comment on this, because I know that this could go on, and I know Jeff Sconyers does not want that. I will be done now, but that was the last thing I wanted to say.

MR. SCONYERS: The one final thing I want to say is that you have a range of views expressed in the articles that are in your blue folders from mostly the popular media. I think it is important for us to listen to and respect the views of people that are being expressed around the table here, with which we don't necessarily agree.

I want to just acknowledge that everybody who is involved here is sincerely interested in these individuals who are experiencing autism or experiencing other conditions. Whatever the limitations of the program and the compensation available under it, no one disputes that these families and these individuals are facing a very, very difficult situation. So I want us all to listen respectfully and carefully to each other and keep that in mind.

So with that little sermonette -- oh, Charlene has a comment.

MS. GALLAGHER: I think I would like to reiterate that the real tragedy for these families is having children who have disabilities or any kind of afflictions that require medical attention, and necessarily change the whole family situation. It is the same disorder that children who have

vaccine injuries have all the time, but I think there is a similar set of circumstances for the family.

I think that set of circumstances is true in families who have children with disabilities that are unrelated to vaccine. I think we all understand that it is very, very important to address these issues for the children and address these issues for the family.

We have been asked to serve on a Commission that makes recommendations to the Secretary of Health and Human Services about a program that has as its basis vaccine injuries. So while in my heart of hearts I think I would like to reach out to all children, I have been directed during the period that I am serving on this Commission to focus my attention on children who have been injured by vaccines, and I am trying my best to do that, no matter what my personal views might be.

I think what I have taken from what has happened very recently is, without taking a personal view one way or the other, that there was a long -- which I didn't attend and didn't listen to, where many experts gave testimony on causation issues related to autism and autism spectrum disorders.

For those three cases, in any event, the burden of proof wasn't met. The way the law works is, the person bringing the action or the claim needs to prove what it is

they are claiming. I don't know if there are any other experts out there that the group of plaintiffs' attorneys who are working on these cases are aware of. I think that remains to be seen.

It would appear that perhaps the way that it was presented in these cases was not sufficient to prove injuries in these children. I think the rest of the petitioners' attorneys and families have to assess that individually in their cases. I thought that the reason for doing it in this omnibus way is, it was felt that it might be economic, and that if a group of experts were able to prove a general causation issue, then each individual case wouldn't have to do that.

It hasn't turned out that way. I know many people are very disappointed, but I still really believe in the law and the process, and I am hoping that we all go forward with respect for one another and be understanding what it means and what it doesn't mean. I don't think the cases are thrown out as of today, but I do think that people have to contemplate long and hard whether they can bring in new evidence, whether there is new evidence out there.

It might be one of those cruelties of fate that these are not understood until 50 years from now. I am certain I won't be around then. It will be a shame for everybody who suffers from autism to not have answers for

that long.

In my own family I am struggling with also with a disease that they don't have answers for, so I know how frustrating that is and how much I wish that science could give the answers right now. So I guess all that being said, unfortunately the law still asks the petitioners to prove causation. I think that is where we are left. Thank you for letting me speak.

MR. SCONYERS: Thanks, Charlene.

MS. BUCK: The last thing I want to say, since I am an outgoing Commissioner here shortly, for those of you who are staying on, to please watch and protect the process. I don't want to argue about points of view on the science, but this program was designed in a certain spirit. It was designed in a certain process. I'm not sure at all that an omnibus proceeding is something that should have ever occurred or is the correct process for trying to get to the bottom of concerns for families.

I think you guys who will be continuing on need to think about how this is played out, whether or not it is the appropriate way to handle things, whether or not we are doing what the spirit of this program was designed to do, or if this program is being used in a way that is benefitting others perhaps and not the families.

So at some point it will be very important for you

all to look at the process, particularly in this case, with these omnibus proceedings with autism, and make some recommendations about whether or not you think it fits in with the original intent of this program that it was designed to do for families who believe they have children injured by vaccines, and whether or not it is in the best interests of people that we are here to serve and what our charge is.

So I appreciate Charlene's comments about what our role is and what we are asked to be doing. I would suggest that you try to step away from the back and forth argument on the science and the passionate feelings about autism and focus on the process within this program and whether what is occurring here is appropriate and really meeting the needs that was intended by this program.

MR. SCONYERS: Sherry, do you have a comment?

MS. DREW: Yes. Tawny, this is Sherry. I just wanted to comment with respect to individual attention on the 5,000 cases. What is going to happen, I suspect, because this is what has happened with other omnibus proceedings, is, once the decision comes down, the attorneys review each of the cases and compare it to that decision. They are really the only ones who give personal attention to the clients, unless they think they have a case that they can go forward with.

I know through the years, there have been autism

cases or children who had an autistic outcome, or PBB outcome, that have cases that have been compensated. My firm had two. I know all of the other firms that do a lot of this work have had others, but those were almost always the outcomes after either a table injury or other known injury of the vaccine. In other words, the child would have encephalopathy, and when the child began to function again he functioned at a much lower level. Autism is such a broad definition that if he had behaviors that were consistent with autism, he would be said to be autistic.

So there have been autism cases that, I think if any attorney saw a case like that, they are going to take it out of, or probably already have taken it out of the omnibus proceeding. But I think that is the only individual attention that the cases are going to get. I don't know who an attorney could get to testify in favor of his client if his client was similar to the test cases.

MR. SCONYERS: Seeing no further hands in the air at this point, we are going to take a short break. We are going to take a 15-minute break and commence promptly at ten until three with the remainder of our agenda for the afternoon. Thank you all for your consideration.

(Brief recess.)

Agenda Item: DVIC Outreach Plan

MR. SCONYERS: The next item that we have on is

the outreach plan from the Division of Vaccine Injury Compensation. Kay Cook, who is the Chief of the Policy Analysis Branch, is going to walk us through what the current outreach plan is.

This is preliminary to a conversation we are going to have in June when we expect to have the results of the petitioner satisfaction survey available. So I am going to let Kay take this away.

MS. COOK: Good afternoon. This is the long-awaited presentation on the National Vaccine Compensation Program outreach effort.

The program has two overall goals on outreach. The program intends to increase awareness of the availability and to increase the overall knowledge of the program to our stakeholders. The program's outreach strategies include written materials such as brochures, the DVIC website, the Vaccine Information Statements which are mandated by CDC, and presentations and attendance at legal and professional meetings.

The program's 2008 communications efforts consisted of a Vaccine Information Statement. The program itself has a call center which receives a large amount of phone calls in which 523 were sent to the program for a more detailed response, which is about a ten percent increase over 2007.

We also sent out roughly about 1,267 booklets in Spanish or English. Brochures, we sent out a little over 1300, English or Spanish.

The program also received about 174 e-mail inquiries in 2008, which was a 65 percent increase over 2007. We also maintained the DVIC website.

The program is in the process of obtaining approval to exhibit at medical conferences. This is something that we were unable to do for 2008. Among that, this is a listing of potential targets that the program has come up with that we will try to exhibit at.

The program's future outreach strategies include, the program staff is currently working with HRSA's Office of Communications to explore target areas. The program is exploring the option of working with an outside media consultant, and the program will continue to seek speaking engagements.

That being said, the program welcomes suggestions on methods of reaching out to the general public, attorneys, health care providers and the committee.

MS. HOIBERG: I would say, like the public service announcements. Is that what you mean when you say an outside media consultant?

MS. COOK: Absolutely, that can be something.

MS. HOIBERG: Then also, not only just the

brochures, but posters in doctors' offices as well as billboards.

MS. CASTRO LEWIS: What has been the distribution means of the brochures and the materials that you have available in the program?

MR. SCONYERS: I don't think --

MS. HOIBERG: She asked where are the brochures and how are they being distributed.

MS. COOK: Basically that would be from a request from an individual calling in and asking for the information.

MS. CASTRO LEWIS: What?

MS. COOK: An individual calling in and asking for the information, or if they would write to us, that would be something that we would send out to them.

MS. CASTRO LEWIS: The question is, what kind of information that people call in and are requesting the materials, or if there is a plan to do anything in communities where information can be given, where people can go and have a conversation.

MS. COOK: What type of community outreach other than going to conferences would you suggest?

MS. CASTRO LEWIS: The conferences are mostly for professional people. There are many community events and there are community-based organizations that include communications in the community there, in communities where

there is language needs, they know the language. There are churches, there are health fairs hosted by communities. There are many events that can be utilized to provide information about the program.

MS. COOK: Do you happen to have some type of list of potential community-based organizations that we could contact?

MS. CASTRO LEWIS: I think there is a list of Spanish speaking community-based organizations. They have all types of things that we could provide information.

MS. BUCK: Can I suggest partnerships too with state immunization officers? I think that is definitely something. Also, there is ASTHO, which would probably be a group that you could work through, and also along the lines of what Magda was saying, NGOs that represent children's health. I think there are some that are pretty prevalent. I don't think they are that hard to find. You could be developing strong partnerships that are discussing the program and talking about it in ways beyond just handing them brochures.

I have been hearing quite a lot of public feedback that people don't know about this program. Not knowing about this program affects their ability to file claims within a very short period of time on the statute of limitations. I think you could be really proactive in using some of these

state and nonprofit organizations that are working with children's health to educate them about the program in the process and the short window of time that they have to file claims.

MR. SCONYERS: Tawny, I want to go back. We had a fire engine go by just as you were making some of your comments. Your first suggestion was state immunization officers, is that right?

MS. BUCK: Yes, and then Association of State and Tribal Health Organizations. I think they are probably aware of the program, but they may be helpful in handling your information beyond handing out brochures, to answering the phone and maybe going to a few conferences, which I think is probably not hitting your target audience quite well enough.

MR. SCONYERS: Okay, I just wanted to make sure that your comments weren't lost in the ambient noise of the fire engine going by.

MS. HOIBERG: As far as I'm concerned as a committee member, I would be more than happy -- Jacksonville has tons of health fairs. We have even our little community fair that we have every year, this huge agricultural fair. You can get a booth there for next to nothing, to have an information booth there.

We do a citywide baby shower, where they have tons of pediatricians and all sorts of medical services. I would

be more than happy, armed with information, to go and be able to hand out information about it.

MS. CASTRO LEWIS: What did you learn from the survey? What are people learning about the program?

MR. SCONYERS: The question was, what did we learn from the survey, how are people learning about the program.

MS. COOK: The content of the survey, I really don't think we got what we thought we were going to get. So, nothing.

MR. SCONYERS: I will just remind you, we are going to have a presentation and the analysis of it in June. I did view this agenda topic as an update. I think we will have -- well, what I think is not important, because I am not going to be the chair, but I think we will have an opportunity for a more extensive discussion of outreach activities in that June meeting in the context of looking at survey results. I think it is important to have that in mind.

DR. HERR: We have people in place all over. We have county health departments. Why can't we fund or in some way provide money to the county health departments to provide some of this, find some way to do something. But if we are looking at ways to get out there, we have the public health nurses in every county, and these people do go to health fairs, these people do go to schools, these people do go to

other community groups. What we need to do is -- and they also provide immunizations. Why can't we empower them to go out and provide the information that we would like to have them provide on your behalf?

MS. CASTRO LEWIS: I would love to see the brochures. Do you have them? Did you bring any?

MS. COOK: I will bring them down.

MS. GALLAGHER: I happen to be aware because of the work that I do that there are a number of states that have programs that they call every child by two, or different state programs that encourage immunization of children. If you reach out to them, they already send out materials. It seems to me that would be an easy avenue to have materials that are directly related to their mission included as well. That would get straight to the parents and the guardians of the children who are getting immunized.

I think another area that you might want to consider is mayors' offices. Lots of them have outreach people who might be able to put you -- sort of like a networking exercise, put you in touch with the person who would be most appropriate to distribute them at their local health fairs or their sponsored event.

So it may not be you and your budget having to do it other than to provide the brochures and provide contact means. Maybe we could get local pediatricians or local

nurses who are interested enough to volunteer some time. I think in these hard times, people are starting to think about volunteering a lot more than perhaps they did before the budget deficit got so expanded.

So those are just some ideas for opportunities that should be explored.

MS. CASTRO LEWIS: The CDC has as grantees national organizations that receive funding from the CDC to provide education in the community. Part of the program is to provide comprehensive information about immunization, which would include everything that is available. So that information should be part of the course for all of the immunization information that these programs are providing.

I think that we need to go to the community. There are many, many levels of the community for public and private health. Some of them have volunteers, but I think having this available, you can probably do a lot.

MS. COOK: Right, absolutely.

MS. BUCK: I'm not getting a sense of a real organized -- what I am seeing is what you did in 2008. You answered about one and a half phone calls a day, and had half an e-mail inquiry a day on average, which I assume to those you sent maybe a brochure or sent to the website.

I think what is missing here is, what is your plan? What kind of active plan have you got in place for

doing outreach besides having us brainstorm things for you to do?

MS. COOK: Other than doing what we have been doing, trying to add the exhibit booths back again and possibly contacting a media consultant, we need help. We don't know where else to go. I think that is what I pretty much asked for.

MS. BUCK: I have been saying for the past three meetings that I have been here, public service announcements, public service announcements, posters on the wall of the doctors' offices. It is falling on deaf ears. All you need is a couple of public service announcements and billboards on the side of the road, and people will go, oh, there is a plan for that. Advertise like the lawyers do.

MS. COOK: We have heard that, and we truly understand it. We are hoping with this new Administration that we are able to go back and do our outreach stuff. We were not allowed to do some things in the past.

MS. BUCK: Is that what we are doing now, is trying to brainstorm? Because there is no budget for you here, so it is hard for us. We can brainstorm all day about what you can do, but if we don't know what your budget is, it just seems like a funny process. We are not experts on outreach. We are just a group of people that can give you some suggestions. But it seems like there ought to be places

for you to go that can help you with this and work within your budget and that kind of stuff.

MS. GALLAGHER: I have a suggestion. I think that most of the committee feels that this is an important issue. Maybe we could organize a subcommittee to dig in deeper and to perhaps come up with some recommendations. Some would have budget implications, some would not. I am thinking maybe Sarah or --

MS. COOK: That would be great.

MS. GALLAGHER: I don't know if we would want to create a subcommittee at this meeting or the next meeting, but to me that seems like a sensible way to dig in and understand this issue and come up with good recommendations.

MS. CASTRO LEWIS: I was going to say something similar. I think we need to look into the objectives and see what is it that we want to accomplish. It is not just throwing brochures into the community, but we need a plan and something that we can measure. It has to be something to really reach out to the community. So a plan that could be worked out with the committee or whatever way we decide that.

MS. HOIBERG: I am volunteering my time. I'm not saying that we need to hire people. I have media experience, I have public speaking experience. I don't have a problem going armed with information about the program to specific mothers' groups. If I have to go to the media I will go to

the media, but this is something that is desperately needed to get out there.

I can't tell you how many people don't even know what a vaccine injury is, first of all. Then when you tell them about, like in my case, my child, they are like, oh my God, I know three or four people that that has happened to. None of them have been compensated because they didn't know about the program.

So the reason that the program got such horrible reviews is because it is in really bad shape.

DR. EVANS: There has been a lot that has been thrown out that I would like to respond to.

First of all, believe me, I'm not just giving lip service. I think publicizing the program is very important. We have struggled with this over the years, as you know. I feel your frustration. I have been frustrated, too.

In the past there have been budget issues. In the past, also there was HRSA policy in terms of centralizing all of the outreach activities. We were told frankly, no, you are not going to be doing this anymore, we are going to be doing it, this is part of HRSA. That was previous leadership, and now the leadership has changed over the past couple of years. Now we have the opportunity to do more outreach.

How do we effectively do outreach? I have sat in

booths for days on end at the American Academy of Pediatrics and other professional meetings. That is thousands of dollars. I shake hands, I hand out materials. That has a certain effectiveness, but it is limited. We need help in how to be more effective at doing it.

I should also mention, I have said this before, and some of you are probably tired of hearing it, there is a natural barrier to our talking about our program. You don't have to look any further than when there is an immunization month, and look at all the materials that come our during national immunization month, and see if you can spot anything about the compensation program. That is because it is difficult, whether it is a national effort or a county effort or a library or a state level, people talking about the importance of immunizations and saying at the same time, oh, by the way, there are adverse events. Oh, by the way, you can be injured, but you will get paid for it. It is a difficult message to put across effectively, and people in the front lines communicating don't exactly seek us out.

MS. HOIBERG: And Jeff, like I told you before, after every single commercial for a pharmaceutical product, there is a laundry list that they legally have to say of all the adverse reactions to the particular medication that they are advertising.

So yes, we know that if you take whatever nasal

spray it is going to clear up your congestion, but you could get coma, you could get cancer. People are going to -- if they need it, they are going to take it. For as many years as I can remember, it is always that the benefits outweigh the risks of the vaccine.

So people know that there is adverse reactions. There are adverse reactions for taking Tylenol in some cases. So I feel that with you guys not advertising it, it is hiding the fact that you can get hurt from these vaccines. They can hurt, they can kill. But we will take care of you.

DR. EVANS: I just want to finish my thought though, if I could. I will just tell you from a big-perspective viewpoint, other than being on the ABC Nightly News and announcing deadlines in '92 and the publicity around Hannah Poling, which was mainly cable, some mainstream, I think the program has never seen the amount of publicity, and the availability of the program has never been as in front of the American public as it was February 12 and February 13. Every single nightly news show had the program. Cable stations around the clock had it. So America learned about the compensation program.

DR. HERR: On the idea of publicity, maybe we can get Congress to do something that they do all the time, which is the unfunded mandates. Right now, the government provides a lot of vaccines to the states, through the Vaccines for

Children program. Why can't we require the state do this job for us? Is that in their vaccine distribution, the Vaccines for Children stuff, in their information that needs to be done, in their process, trying to immunize the children in their state, that they will provide this information to their state representatives.

MS. HOIBERG: Right, it is on there now in a very big way.

DR. HERR: I understand. But we are talking about another effort, increased effort by the states that is tied to the Vaccines for Children program.

MR. SCONYERS: I'm going to call a timeout here. I think none of us knew that what we were going to have here today was a request for suggestions. I don't know that we are necessarily prepared to give our best thinking about suggestions to the program today.

I kind of liked Charlene's suggestion that we identify a couple of people who are interested in this topic to work with Kay and Jeff between now and our June meeting to develop some more comprehensive and systematic approaches to the issue of outreach. I think what the program is probably hearing from most of us here is that defining outreach in terms of administrators of vaccines is not necessarily what many of the people around the table think outreach ought to consist of. I think we are aware of the

difficulty of communicating a message of, you should get vaccinated but there are risks associated with it, but I think most of what I am hearing is, you need to find a way to overcome that complexity rather than shrink from it.

So that was my editorial comment. What I mostly want to do is see if there is interest in two or three people to form a small work group to between now and the June meeting draw up some recommendations and a more robust discussion to bring back, in the context also of the survey results. I see Sarah's hand in the air, and I believe that she would like to do that. Do I see any other hands in the air? Sherry would like to do that.

MS. HOIBERG: Tom, and Magdalena.

MR. SCONYERS: That is four. That is more than I wanted, but more power to you. I am going to saddle one of you with being chair, but I'm not going to say who it is yet. I have to think about that. Do I have a volunteer? Sarah, would you like to do this? Thank you.

So we will appoint a small work group of Sarah, Tom, Magdalena and Sherry to work with staff and to bring back a discussion to us in June.

MS. GALLAGHER: Can I just suggest that you may be delineated by suggestions that need funding, suggestions that don't necessarily need funding. That would be a useful separation, in my mind.

MR. SCONYERS: Very good idea. Any other comments on this topic?

MS. CASTRO LEWIS: I'm just saying we state our objectives and have some kind of evaluation plan.

MR. SCONYERS: Develop objectives and an evaluation plan. I think that is very important. Thank you very much.

Next item on our agenda is the report from the Advisory Committee on Immunization Practices on the MMRV vaccine. This is Dr. Karen Broder and her colleagues from the CDC. Dr. Broder is with the Immunization Safety Office at CDC. Dr. Broder, I'm not sure who you have on with you in this presentation. You have slides in your folders. So take it away.

(Remarks off the record.)

Agenda Item: Update from the National Vaccine Program Office

MR. SCONYERS: We are going to probably move for a little bit back to exactly the time that she expects us to be on. We are going to take a presentation out of order and welcome Dr. Dan Salmon to give us an update from the National Vaccine Program Office.

DR. SALMON: You are going to hear tomorrow from Ray Strikas from our office, who is going to give you an update on the National Vaccine Plan. I am going to talk a

little bit about some public engagement we have been doing. NVPO has had a pretty busy couple of months, so I guess you are getting a lot from us this time.

Let me just say that much of the presentation that I am giving you today is part of or adapted from a presentation that Keystone gave to our Safety Working Group last month, and of course done with their permission.

I think I have shared this with you before. NVAC Safety Working Group had two charges, to look at CDC's Immunization Safety Office research agenda, and provide feedback on the content and the prioritization of the research that CDC does. The second charge is to look at the vaccine safety system more broadly. The charge is up here and it is in your handouts. The work I am going to present to you today is focused on their first charge.

This is a working group that includes members of the NVAC as well as people that have been added to the working group. This slide and the next slide goes through who those people are, what their disciplines are, and the group that they represent.

The Chair of the Safety Working Group is Andy Pavia, who is a peds I.D. We also have a broad range of expertise, ranging from neurology, genomics, immunology, epidemiology, pharmaco epidemiology, toxicology, ethics, law and biostatistics. Tawny Buck from the ACCV is a member of

that Safety Working Group. We also have another consumer rep who is Trish Parnell, a consumer rep for NVAC. She is the parent of a child with an infectious disease and the founder of PKIDS, Parents of Kids with Infectious Diseases.

This work on the ISO research agenda stems from a report from the Institute of Medicine in 2005. That report called for CDC to develop a research agenda in this case about their Vaccine Safety Data Link, which is one of the tools. It makes sense that the IOM limited their recommendation to the VSD because is what they were asked about. But ISO and CDC expanded it to be a research agenda for the office more broadly.

You will notice that in this recommendation from the IOM, they asked that the group meet publicly and allow interested persons to observe the process, and importantly to provide input through established mechanisms. What I am going to talk about is those established mechanisms.

The first meeting of the NVAC Safety Working Group was April 11 of last year. By FACA requirements, working groups don't have to be open to the public and they don't have to be announced in the Federal Register, but we tried to embark upon an open and transparent process, so they were both open to the public and announced.

In the fall of 2000 we brought in Keystone, which is a group that has expertise in facilitating these sorts of

public engagements. A steering committee was set up. This included representatives from the NVAC Safety Working Group, HHS, CDC, ASTHO and NACCHO.

The goal of this steering committee was to help us plan these community and stakeholder engagement activities. So this rather complex figure tries to depict as simply as possible what this process looks like. What we see on the left-hand side are the three blue circles which are community meetings that we held in Birmingham, Ashland and Indianapolis. I will talk more about those. In addition, written comments were received, that is the first green circle, and these were all presented to the NVAC Safety Working Group at the February 4 meeting.

We are now in the process of planning a stakeholder meeting which will be March 16. In preparation for that meeting we had a writing group that met a couple of weeks ago. That writing group develops materials that the larger stakeholder meeting can respond to.

With this public input and stakeholder input, the Safety Working Group will develop draft recommendations that will go to the NVAC and ultimately to CDC. That draft will be made publicly available and will be another opportunity for written comments.

I am going to talk a little bit about what these public meetings were set up to be. There were three

meetings, Indianapolis, Birmingham and Ashland, Oregon. Indianapolis and Birmingham were chosen because they were cities that had active state and local health departments, as did Ashland. Indianapolis and Birmingham had somewhere around average rates of vaccination, and they were from different parts of the country. Ashland, Oregon was chosen because about a quarter of the parents refused some vaccines for their children. So this is a community with a high rate of vaccine hesitancy.

A little bit about what the day looked like. There was first an overview from Keystone that described what the purpose of the day was. There was some background information, first an overview of vaccine safety. That presentation explained what we know the benefits of vaccines are, what we know the risks of vaccines are, and then what we don't know about vaccine risks. Next there was a brief presentation about the scientific agenda developed by CDC.

The group then broke into small group discussions that were facilitated by those listed on this slide. Those small groups tried to do a couple of things. They tried to identify general concerns. This was done partially through the use of scenarios, which I will describe in greater detail. Then there was also an attempt to allocate research funds to studies. This was done at the second two meetings.

After the small group discussion they went back to

the plenary where there was broader discussion. There was polling which I will describe more in detail in a few minutes, and then some summary, next steps and a wrap-up.

So it is important up front to say what these meetings were and what these meetings were not. They were not a statistically verifiable random sample of views in the United States; they weren't. There was no effort for them to be so. If you want to know what proportion of people in America hold a certain view, then you do a survey. You make sure you sample properly and you get a high response rate and you can make generalizations.

That is not what this was. It was a sampling of three communities in different parts of the United States about what they think about vaccines and vaccine safety. There was a very rich discussion, but they were not intended to be something you can generalize to the U.S. They were not designed with the intention to persuade communities to a particular viewpoint.

We went here to listen. Often I got lots of questions from people, especially in the small groups. My response, and the way other moderators handled this for the most part was, we are here to listen. Your questions are important and over lunch or after the meeting I am happy to answer your questions, but our goal here is to hear what you think. So they were intended to encourage dialogue and to

increase understanding about what people were concerned about, and specifically to get at values that could help determine what priorities should be done for vaccine safety research.

So this is a little bit of information about who came to the meeting. There were 45 to 70 people at each meeting, the majority of whom had children. You can see lots of information here, and you have this in your handout. I would just point out that in Ashland, about half of the people had attended or completed graduate school.

We did do a pre-meeting survey where we asked questions about things like how much confidence you have in vaccines and vaccine safety research, and here is the breakdown of those responses by site. You can see again that Ashland was very different in their attitudes about vaccines compared to the other two sites.

In terms of small group discussions, this is a fairly brief summary, but some of the issues that came up repeatedly were autism, autoimmune disease, diabetes, arthritis and asthma. Specific vaccines that were raised were MMR, Gardasil and flu. There was a lot of discussion about vaccine ingredients. Here is some of the language that came from the participants. So this is their language, this isn't our language. The issue of mandatory vaccination came up frequently.

Some of the concerns about vaccines as currently listed were given here, issues like the ingredients, the schedule, the combination, interactions with other meds. For the most part, these were themes that came up repeatedly at the meetings, with the one exception of manufacturing security, which was really just an interest of one person in Indianapolis. But for the most part, what you are seeing here were recurrent themes that we heard often.

There were also a fair amount of questions and concerns about the data of studies and the vaccination system more broadly. One of the issues that came up repeatedly was why hasn't there been a study of vaccinated versus unvaccinated populations.

Here are some other issues which we heard throughout these meetings. Questions were raised about the effectiveness of vaccines, long term, short term effectiveness; is there enough to provide protection, and issues of vaccine supply.

There was a lot of questions about special populations, what about the individuals that were genetically predisposed, differences in race or gender, premature babies, pregnant women, elderly, immunocompromised individuals. Again, these were recurring themes.

Issues of trust, what was the decision making process, the studies, the reporting. People wanted to know

who was the NVAC. People wanted to know who was in charge. There were questions about conflicts of interest, and a lot of discussion particularly in Ashland about the independence of scientists.

Other issues that came up, while not a focus, were those of access, the cost of vaccination, the issues of insurance coverage and access to health care. There was also quite a bit of discussion on education, and do the doctors know what the risks and the benefits are, how can people and parents learn more, and where can one go for complete and accurate information.

So to provide some background on the scenarios, there were five stories that provided people with tradeoffs. These were based on real vaccines and real adverse events. We didn't give the names of specific vaccines. We really struggled with this, but we didn't want to give the actual names for a lot of reasons. One is, you can't help but thinking about the diseases that in fact the vaccines were meant to prevent, and also it adds a lot more complexity. So they were intended to elucidate values.

As you went through the five stories, increasingly the questions and the scenarios become more complex. This is an example of how it started, the first scenario. There is a vaccine given to all infants, and it causes fever in one of 20 children and causes brain swelling in two out of every

million children. Which of these side effects concerns you more? In blue you see concern about severity, in red ones that were more frequent, and in yellow or tan, there were people that were undecided.

So what we saw from this was, there was clearly more concern about the severe side effect, one that causes brain swelling but only very rarely, compared to the more frequent one, although there were still a fair number of people that were concerned about the frequency of fever.

In terms of polling, this was done to quantitatively measure values, to allow others to see the results in real time, and to validate what we heard in small groups. Every person was given a little clicker and was asked to respond to questions, and as people did you can see the results on the screen.

Pulling together what we heard in the scenarios and the polling, people were more concerned about rare serious adverse events than more common mild adverse events. There was a real interest in children, more so than adults. People thought that both public and scientific concerns were important and should be a factor in deciding what studies to do. There was tremendous interest in vulnerable populations as well as susceptible populations, and especially for the issue of autism.

MR. SCONYERS: Dan, I'm sorry, what is the

difference between a vulnerable population and a susceptible population?

DR. SALMON: We talked about vulnerable populations. I'm sorry. I have gone through this pretty quickly. Vulnerable populations were referred to as groups like premature babies or pregnant women, whereas susceptible populations would be -- an example was given with autism, where there may be people that are genetically at risk for a certain adverse event. I'm sorry that wasn't entirely clear.

We asked people to spread out their dots. Everyone got three dots. They could vote for one of the following categories of research. They could put three dots on one question or two dots on one question and one on another or three dots on three questions. This was done in Ashland and Indianapolis. These data summarize what people felt were the most important scientific studies to be given the highest priority. I will allow you to read those for yourself; they are in your handouts.

Clearly the top three in these two places were new vaccines for infants and children required for daycare and school, with scientific concern about severe injury. The next were vaccines for infants and children, also required for daycare and school with severe but uncommon injury. The last were vaccines for infants and children, scientists find no link with autism, but the public and some scientists are

concerned about a risk of autism in some children. I think the way it was worded was, a subpopulation of one in 4,000, which would result in about 1,000 children per year. That is a birth cohort of four million.

DR. FISHER: And you have just the three dots.

DR. SALMON: You've got three dots. So if you wanted to, you could put your three dots on the top one, you could put one dot one place. We did this out of the experience in Birmingham.

The reason we did this was, people had a really hard time choosing. They thought everything was important. We said, we have to prioritize because there are limited resources. So if you have to prioritize, what would you do first. What we got in Birmingham was, you should do it all. If you don't have enough money, get more money. If Congress isn't giving you enough money, tell me the name of my Congressman and I will write him or her.

So we got, everything is important. That is fair, I think that is an important message, but we were trying to elucidate how do you make tough choices. Even if CDC had twice the budget, they would still have to make choices.

Any other questions before I move on? I know that I have covered a lot very quickly.

MS. BERNSTEIN: I have one question, Dan. Can you talk a little bit about how you recruited participants?

DR. SALMON: It was Keystone that did this. First they reached out to the local and state health departments through ASTHO and NACCHO, and they tried to get a sense of the community organizations. They then went directly to the community organizations. These varied by community.

So for example, in Birmingham there was an organization of churches that had a group that focused on public health. They were tremendously helpful. They went to PTAs, they went to minority organizations, they went to medical and alternative medical practices. They also ran ads in newspapers. They ran radio spots. So they had a very broad recruitment effort that was tailored to the community they were working on.

So in Birmingham, going through this network of churches that had an interest in public health was tremendously helpful. In other communities they went through different venues. When people signed up, one restriction they placed was that you had to live within, I think it was 100 miles, maybe it was 50 miles, of the location. The idea was to get local participants, not to have an organization fly all its members in to a particular meeting, but to try to sample from that community.

MS. BERNSTEIN: Thank you.

DR. SALMON: Sure. Any other questions before I move on? Other issues that people wrote in. There were

people that said, I don't like any of your choices, and I want to put my three dots for a study of vaccinated versus unvaccinated population, or some of the other issues that were raised. There was also a lot of interest in improving reporting of adverse events. I'm sorry for my acronyms here; AE throughout is adverse events.

Some limitations of the meeting. There was a wide recruitment effort. If you look at the prescreening questions, I think they were fairly representative of the communities, but they were not perfectly representative, and they weren't planned to be so. I think there could have been a fuller list of what we don't know about vaccine safety; at least some people thought there could have been. The facilitated reporting on the small group discussion was not as consistent as we would have liked. I think in hindsight we could have made improvements to the scenarios and the polling questions. We wish we would have learned earlier and asked the allocation questions, the dots issue, in Birmingham as well.

We did do a post meeting survey. Here are the results broken down by site. What Keystone liked to see the most was, the vast majority of participants indicated that the discussion was fair to all, and that the process was effective in identifying values.

We didn't drill into what important points were

left out of the discussion, and I wish we had. Our sense and Keystone's sense was, a lot of people had questions about vaccines, and we didn't spend time answering a lot of their questions. The purpose here was for us to listen and not for us to provide information. Our sense is that may be what people felt we left out. But we didn't ask that question, so I can't really say for sure.

In terms of discussion and implications for the agenda and our second task, there was a lot of interest in reporting, in increasing dialogue and transparency, questions about credible science and who was credible and to whom. There was interest in education and communication, access, and then the overall approach to vaccine safety, does the system really work, does it track the right information, does it have the right approach to safety.

There was clearly values and interest in children as special, precious, vulnerable populations, the future. There was interest in the issue of choice, informed consent and social responsibility. Transparency was really something we heard continuously from participants, the importance of independence and trusted science, the value of parental instincts, the knowledge of parents, and that all lives are important and deserving of care and attention.

I went fairly quickly. I am happy to answer more questions. I just want to go back to one slide. What we see

here are these three meetings. We also had public input. Now we are getting ready for the stakeholder meeting on March 16.

A couple of weeks ago in Salt Lake City we had a writing group meeting. This was a group of about 20 persons that had an interest in these topics. It included medical and public health, it included advocates in issues of autism and mercury. Tawny was at that meeting. I probably should have stopped sooner and given Tawny a chance to share her views on this, I am very interested in them.

The group met for two days. They drafted materials for the larger writing group to respond to. My feeling was it was a very good meeting. We had people with very divergent views, who have a lot of time and passion in this issue and came together to focus on the importance of doing good science in vaccine safety.

You can see the work products from that meeting on our website, as well as a consensus statement where people all spoke to the value of the meeting.

Maybe I can just stop there. But maybe first ask Tawny if she has anything she wants to add to this, because she has been very involved in the process.

MS. BUCK: Thanks, Dan. That was a very good presentation. I know there is a lot of information there that is hard to go through quickly.

I think the things that are important to let you all know is that the design and the development of the community meetings with Keystone, which has done a really good job with listening to everybody's concerns on all sides, and trying to design community meetings that would provide relevant feedback from all different points of view.

I was very impressed with the meetings. At the last work group meeting that we had in early February, we had observers from those meetings come and report back to the Safety Working Group and share with us their impressions of how the meetings went.

Overall, the communities were really pleased that they had the opportunity to be heard. They felt like they were heard more than they were talked to, which is really important. If you are going to ask people to give their input, then you need to be willing to sit there and listen. I believe that was the type of environment that was created at these meetings. So it was interesting to look at the feedback. It is interesting to hear not in terms of just the content, but also in the way the meetings were done and the types of participants that were there.

I would also like to mention that the NVPO was at these meetings. These meetings happened -- I think one happened the week before Christmas, but since then all this work has happened since the start of the year. So there has

been a ton of work, lots of meetings, an immense amount of travel. The people who need to hear the message have been going to these meetings, they have been there. I was very impressed by that, the effort they are making to show they want to hear this.

The Salt Lake writing group, which happened about a week and a half ago, was really interesting, because that meeting was designed to bring in different points of view all over this issue, even from people who don't spend a lot of time thinking about vaccines, but more thinking about children's health.

We pretty much locked in for two days. We worked through every meal, we had working dinners. We really had our nose to the grindstone for two strong solid days. You have to go to the website and look at the work that came out of that. The work is interesting, but what is more interesting is the environment that we were able to create of respect and mutual listening. We had points of view that went everywhere across the board, but we came together as a group and did some really good work.

Personally, I think it is a great model of public engagement. NVPO and CDC had people at these meetings who were active participants. It was a really interesting process to be a part of. I was just like all the other people very comfortable with putting our names on a joint

statement, saying that this was a process that was worthwhile, and everybody felt that they had the opportunity to be listened to, to be heard and to be respected.

A little side note on that, a commentary on what has happened. We have a stakeholder meeting coming up next week, which is important to the process. One of the things that I want to ask this Commission to consider is, I think NVPO has been almost ahead of history in terms of the way they have done public engagement and transparency in this process. President Obama has come out and made it very clear that this is the kind of a model that he would like to see. But we started developing this even before him.

I think because of that, and because of a lot of the issues that we are dealing with affect the people that are listening in, and are concerned about the ACCV, and even some of the groups that we represent as Commissioners, we might consider drafting a statement of support not of the work, because the work isn't done. At this point the work is just there, it is groundwork and guiding papers for the NVAC to look at. More a statement of the process, and acknowledging that the NVPO has really done a good job of transparency and public engagement.

I think part of the reason that this would be an important thing to do is, there is a need from the public to have this ongoing, to not just have this be a one-time deal,

but to have these kinds of meetings and these kinds of conversations within their community continue. I think having the importance of this work being acknowledged by an outside Commission like ours that has some input would be helpful in adding some weight to that statement, saying this is an interesting process, this is the kind of transparency that is needed to understand how policy is being set in terms of vaccine safety, vaccine concern issues, public trust issues and so forth. We have gotten feedback from the public saying we are very comfortable with where this is at.

I hope that my input here has been helpful. I hope that the Commission would consider providing some sort of a statement of support for the process, and where we are at so far.

MR. SCONYERS: Thanks, Tawny. Other questions or comments?

MS. CASTRO LEWIS: I just wanted to comment that this is a great model in terms of the process and the public engagement and the transparency. The results that you guys got from the focus groups, if you want to call them focus groups, I think is all great. I have listened to this a couple of times, and I was thinking more about it.

I also like the fact that when you wanted to find out the values and what people think, rather than having some -- it is kind of new. We normally try to find what do you

think, not necessarily values.

So are there any plans to reach to the community? This is a very specific community, so are there any other plans to find out about values in the communities and minorities, et cetera?

DR. SALMON: I think that is a great question. We are struggling with that now. Jeff also suggested that I provide some context.

There was an effort nearly a decade ago or about a decade ago to do public and stakeholder engagement around vaccines. I think that it was -- some people thought it was very valuable, and other people didn't. I have to say that what we have done with this is fairly controversial. We have gotten a lot of pushback. There were several groups that cancelled a few days before the meeting and decided not to come, and there are those that don't think that anybody but scientists should provide input on what science has done by a federal agency.

So this has been a challenging process. It has taken a lot of time and resources. Maybe this is part of what Tawny meant when she said that we may be a little bit ahead of the curve here. I don't think this is something which everybody has embraced.

I appreciate Tawny's support for this. I think that if this Commission thinks that this sort of process is

important, that would be a useful statement. It relates to your question, which is what is planned in the future. These are our three communities. Even the stakeholders were a limited group of stakeholders, so we can't possibly say this represents a larger United States; it doesn't.

The answer to your question is, I don't know. I don't know if this is going to be considered a high enough priority or worthwhile endeavor to continue as an ongoing activity. My own feeling was that we learned a lot and that it was really helpful. As was mentioned, I think this is where this Administration is going. We started this activity almost a year ago, so we didn't do this in response to this new Administration, but it is very consistent with it.

So the answer to your question is, I don't know. I think that if you all think this is a waste of our time and efforts, then weigh in and tell us so. If you think this is valuable, I am interested in your thoughts on that.

MR. SCONYERS: I'm not seeing any clear evidence that this is a waste of anybody's time.

MS. HOIBERG: No. I'm sitting here looking at this going - this is a really great outlet. Could a representative of ACCV have been there and talk about the program?

DR. SALMON: Tawny was very involved in this as the ACCV rep.

MS. HOIBERG: Did she talk about the program?

DR. SALMON: The goal of this was not to educate people.

MS. HOIBERG: So just to listen.

DR. SALMON: Yes. There was this vaccine safety 101 talk, which was like a 15-minute talk that said, this is what we know about and this is what we don't know about. But there was a real decided effort not to make this an educational activity. It was really to listen. So the answer to your question is, no, there really wasn't that.

MS. HOIBERG: It is often that you actually had people in the public express their fears. I think people have lots of fears and lots of questions.

MS. CASTRO LEWIS: I think we need to continue sharing about it. If you need some leaders to support this in an effort to extend the community, I think it will be very valuable.

MR. SCONYERS: I have a suggestion to make as a process point. That is, I am sensing around the table that we all are very impressed actually by the work that has been done and the effort to solicit input and take the temperature of these communities. I don't get any sense that there is anything but support for that.

May I suggest that we ask a couple of people to draft a statement of support for this public engagement

process from the ACCV to Dan's office to express our support? I would like to suggest that we task Tawny and Magda with that.

DR. SALMON: Magda doesn't want to do it.

DR. SCONYERS: Tawny will draft it, and Magda will review it.

MS. CASTRO LEWIS: Oh, thank you.

MR. SCONYERS: Tawny, I just volunteered you for that. Is that okay for you? It is not going to be a tome.

DR. FISHER: I would say, I think it should come from all of us. Tawny is perfect, except she was part of the process, so I don't want it to seem as though it is self serving in any way. So I would love for her to write it, but I think all of our names should be on it, because we are really talking about the entire Commission, unless anyone feels differently here.

MR. SCONYERS: Thank you, that is exactly my intention here, is to express the view of the Commission. I just don't want to engage in a group drafting process here.

MS. BUCK: I'll put something out tonight and we can look at it tomorrow. I'm just going to do a couple of sentences. I don't think we need more than that, right?

MR. SCONYERS: Yes.

DR. HERR: My only next question is, we had these meetings to try to get opinions and get ideas, and not

necessarily get a consensus or a reasonable or representative sample. Isn't the next step, if we are going to take some of these ideas and perhaps take action on them, to try to get a representative sample?

DR. SALMON: That is a great question. We had a similar discussion in the NVAC meeting. This is being done on behalf of the NVAC, that has been charged to respond to CDC's research agenda. They had a meeting the afternoon of the 4th, and I can tell you, and Tawny as a member can comment on this as well, people really listened to what the community had to say. That doesn't mean everything that everybody said I'm sure will not be in the report, but they listened to it.

My feeling, having done a lot of survey research, is that surveys are really good to measure some things, and they are not good at measuring others. I think getting at values and having these scenarios is really hard to do in a survey. So I think they serve a different purpose.

I think this provides a richer discussion, where you can get at more depth, but you give up the nationally representative. I think a survey can get -- if you want to measure the proportion of people that believe X, do a survey.

What I did see though was a lot of consistency about values in these different communities. That made me feel like maybe we were getting at something which is fairly

common across populations. But it is still three communities. The Hispanic population was not well represented. Maybe Hispanics have different values than African Americans.

DR. HERR: But if you are going to use this information to try to think about a policy, wouldn't you want to make sure that you were making policy in the right direction? Not particularly because of the views that were taken, but just because it potentially was a skewed population. You may be taking your policies in the wrong direction.

DR. SALMON: I think this was one data point. Maybe you would be interested in hearing from Phil Smith and the attitudinal module of the National Immunization Survey, where they are asking survey questions to a good random sample of people. They try to get at some of these general issues. I think this is one data point, and I think there are other data points.

DR. HERR: It may be exactly where we want to go. I think before you invest a lot into it, you probably ought to make sure that this is the direction to go.

MS. BUCK: Can I clarify also a little bit? At this point, the input that is being given is on the ISO, your scientific agenda, is already a document that is in place. That was something that was put together in a different

process. There is information on how that was done. The NVAC is being charged with giving some feedback on that. But that is already there. It is not like the input that is being given on the process is just an open conversation. It is being requested on a very specific set of information that is basically a policy that is already in place in some way.

MS. GALLAGHER: I am slightly confused, forgive me for not following it. I have been listening. First we said we were going to draft a supportive statement. I'm not even sure what we are going to support, so I thought I would wait until I saw what -- and then I heard that this is just one data point. When Dr. Salmon said they were all very consistent, Ashland seemed more consistent to me, and I don't think Ashland is very typical of the United States in general. They certainly are outliers. I think it is really important to know about outliers.

DR. SALMON: We don't really know if they are outliers or not. We can't draw a time line yet.

MS. GALLAGHER: All I am saying is, there is perception and misperception. I think that it is really important to know what they are in general out there.

MR. SCONYERS: Here is what I think we are doing, and here is how I would like to put a bow on this, if we can, for our agenda purposes. I think we are at a high level expressing support for a continuing process of engaging the

public in its various guises input into the development of this plan.

MS. BUCK: I'm not suggesting that we have anything to do with the content of the work at this point. If you want to give your feedback on the content of this work, then you can get your public comments, you can come to a stakeholder meeting. There are a lot of opportunities for that to happen.

But for me, this is a very unique process of asking people outside of Beltway their input on this scientific agenda and other issues regarding vaccine safety. For me I think it would be a statement that could be made that this process of transparency and the dialogues with the communities is something that we support, not the work itself. There are other avenues for you to comment on the work itself.

MR. SCONYERS: Not any particular point of view, but just the process we support.

MS. GALLAGHER: Can I make one further comment?

MR. SCONYERS: Yes.

MS. GALLAGHER: Is there any way that we can take this experience and translate it or use it somehow in our committee?

MR. SCONYERS: I'm sure we will have it figured out by next time. I am going to amend my earlier delegation

to a work group of two, and designate Tawny a work group of one for purposes of coming up with a statement that we will take a look at. We will have something for the Commission to look at tomorrow as a general expression of support for this process of public engagement.

Anything else, Dan? Thank you, Dan. Do we have Dr. Broder on the phone?

DR. BRODER: Yes, I am here now. Can you hear me?

MR. SCONYERS: Yes, we can. We are going to get your report from the ACIP Work Group on the MMRV Vaccine. We have your slides.

Agenda Item: Report from the ACIP Work Group on MMRV Vaccine

DR. BRODER: Wonderful. I would like to start by thanking Jeff and Rosemary if she is there for inviting us. I also would like to acknowledge at CDC Mona Marin and our chair of this working group from the ACIP, Dr. Jonathan Tempte. They should both be on the speaking line, so I just wanted to confirm that you two are both on the speaking line?

DR. TEMPTE: I'm here, Karen.

DR. MARIN: Me, too.

DR. BRODER: This is a very large collaborative effort, and we are very happy and excited to be here by phone with you today to share some of our work with you. I will just go slide by slide.

If you take a look at slide two, this is an outline of what we will cover. We will briefly review some background on our working group, describe a little bit of information on febrile seizures, discuss our evidence framework for risk assessment, provide some of our interim synthesis data for dose one MMRV, and I will tell you more about MMRV in a moment, the vaccine safety activities underway, considerations for policy, and some very interesting results from our preliminary survey of physicians, and we are going to do this in a very short time period of about 15 minutes. Please let me know if I need to slow down. I tend to talk fast.

On slide number three, this is to give you a little bit of background about the MMRV vaccine. For those of you who don't know, this is a combination vaccine to protect against four diseases, measles, mumps, rubella and varicella or chicken pox. It is a live vaccine. It was licensed in 2005 by the Food and Drug Administration for use in children 12 months to 12 years. Shortly after in 2006, the Advisory Committee on Immunization Practices or ACIP recommended use of MMRV vaccine.

What is interesting, for those of you who don't know, since the '90s the ACIP has had a general recommendation, a process statement for use of combination vaccines. So when this vaccine became licensed and

recommended, it rolled into the general preference. So MMRV was preferred over separate administration of the component vaccines, which are MMR, which is the measles-mumps-rubella, or varicella vaccines. You see the vial. It looks like most vaccines. It is an injection.

When you look at slide four, this is a little bit more detailed background. In the prelicensure studies, MMRV was said to be safe and as effective or immunogenic as the component vaccines, MMR and varicella vaccines. They work about equally in terms of disease prevention. But it was noted that within six weeks after vaccination, the children who received MMRV first dose had a higher fever rate from those that received separate injections of the MMR and varicella vaccines. You see the fever rate in the MMRV group was 22 percent, compared to 15 percent in the MMR+V group.

This fever was usually seen in the five to 12 days after vaccination. We will come back to this a little later when we talk about biological plausibility.

As a result, when this vaccine was licensed and recommended, the post-licensure studies considered this observation of increased fever. And because it is known that febrile seizures are something that can happen with childhood fever, that was a specified study objective.

The Vaccine Safety Data Link, which is a collaboration between CDC and eight managed care

organizations, conducted a study looking at risk for seizures after MRV, and separately Merck, the manufacturer, sponsored a study with the express objective to look for febrile seizures. I'll tell you a bit more about those studies in a moment.

At the ACIP meeting last year in 2008, February, preliminary information from both of these post-licensure studies suggested an increased risk for febrile seizures during the first or second week after the first dose of MMRV vaccine, compared with separate injections of MMR+V, in children aged 12 to 23 months.

At that time, the ACIP took two steps. The first step, they voted to remove the preference of MMRV over separate administration of MMR and varicella vaccine. The exact wording is in the backup slide. This basically allowed for providers and parents to theoretically choose between using MMR+V or use the combination vaccine. I say theoretically, because at the time this recommendation was made, there was very little supply. There have been supply issues with MMRV for reasons completely unrelated to the safety issue. However, there were still some clinics and practices that had this available, and this was an option for them to use either choice.

At that time, the ACIP also recommended forming our working group as a specific vaccine safety working group

to look at the MMRV issue. The recommendations of the working group were published in the MMWR last March.

Recognizing that our working group had to consider risk, and also had to consider risk management or recommendation development activities together, and recognizing the importance of doing deliberative processes, we formed a working group which included two co-leads from CDC, ourselves representing the vaccine safety side and Dr. Marin representing the recommendations side. So we had two specific terms of reference. The first term of reference as you see on slide six is risk assessment. That is to evaluate post-licensure safety data on risk of febrile seizures after MMRV vaccines, to identify data gaps and propose additional analyses or studies for consideration. In addition, there were two encephalitis cases that were detected in the VSD study, and our work group took the charge on to have those reviewed.

A very important objective of our working group is to communicate the vaccine safety findings related to MMRV with the ACIP and the public in a very clear and transparent manner. We completed an interim synthesis of the evidence for febrile seizure risk after MMRV vaccine, and we presented that in the October 2008 meeting. I will show you some of the findings from that presentation.

The next term of reference being led by the

colleagues in the immunization programmatic side of the work is a risk management activity. This is to formulate policy options for use of the MMRV vaccine for the ACIP to consider for a vote, considering benefit of vaccination and risks for vaccine adverse events, and then to identify and reconcile potential inconsistencies in the ACIP statements related to febrile seizure prevention.

There were still some recommendations for using Tylenol, and we wanted to make sure that we harmonized goals with professional societies and made sure there was one consistent statement. That work is underway. In fact, this whole process really just started last fall.

As a reminder, one of the reasons we had a bit of luxury of time is that MMRV is not being distributed in the U.S. The manufacturer has said that although they are committed to bringing the product back, there is not an expectation of this product being on the market this calendar year.

DR. HERR: Is it still in production?

DR. BRODER: I believe at this time MMRV is not currently -- from what we heard, not currently under production.

MS. HOIBERG: But you did say that it is on some doctors' shelf still, is that correct?

DR. BRODER: As a few months ago. I don't know

about today. We know for example from the Vaccine Safety Data Link, they have been using it since the recommendation last February. I suspect, this is a guess, but as more time elapses, there is less available on the shelf.

DR. MARIN: Merck wasn't taking orders for MMRV starting in June 2007. So if there is anything, it is someone that has stored MMRV for more than a year. That is most likely.

DR. BRODER: Slide eight shows the representatives on our working group. I will just preface this by saying we have very diverse representation. We intentionally tried to seek representatives from different parts of the government and from different fields. You see that we have Rosemary representing HRSA and Dan representing NVPO, and we really appreciate the work of our FDA colleagues as well.

If you look at slide nine, that shows our list of members who are outside the federal government. I want to make a point that we are the first work group to have an epidemiologist on the group, and we have a wide range of people with different areas of expertise.

Turning now to slide ten, and please feel free to stop me if you have questions, otherwise we will take them at the end. This is just a reminder about febrile seizure. This group I imagine has discussed it before, but as a reminder, febrile seizures are seizures that occur in

children who have a fever, but they don't have it as occurring in intracranial infections such as meningitis or a metabolic disturbance, or they don't occur in kids who already have a history of febrile seizures.

They usually occur between six months and 60 months. The peak age of interest is between 14 and 18 months, which overlaps with the age of MMRV or MMR+V recommendations. They are relatively common, depending on your definition of common, in that they affect about two to five percent of young children in the United States. Although they can be very frightening to parents, they tend to have an excellent prognosis, and children who have several febrile seizures are not at greater risk for epilepsy than the general population.

I would like to thank Dr. Brown, who is a neurologist in our working group, who contributed this part of the discussion.

Mechanisms leading to febrile seizures. There is thought to be an age related increased susceptibility to seizures; they are just like fever. Newer literature suggests that peak temperature is a major determining factor. There are certain infections that are known to be associated more with febrile seizures. One of them is roseola.

From the perspective of vaccination, DTP vaccines and MMR vaccines are known to be associated with increased

risk of febrile seizures, although febrile seizures can occur in any setting with fever, which could be seen in a setting with fever after another vaccination.

Turning now to slide 12, I won't review this in detail, but early on we realized that with our risk assessment charge we needed to develop an evidence framework to help make sense of the data coming from different avenues. We developed a three line evidence assessment, borrowing from the Institute of Medicine assessment as well as World Health Organization criteria.

The first is something we are still working on and we haven't presented yet, the ACIP, which is clinical importance of the event. I would be very interested in getting some discussion around this if we have time after the talk. That would consider not only the medical issues such as potential consequences of the event medically, but also social impact.

We have gotten a lot of comment on population-based risk, which is assessing the epidemiologic evidence regarding the possible causal relationship between the MMRV vaccine and the adverse event, which is febrile seizures in this case. That is largely through a review of the two studies, which are published studies. One is coming from a government sponsored study and the other is coming from an industry sponsored study.

I want to make the point, there has been outstanding collaboration, and people have been very forthcoming with the data from both study teams, and we think that has contributed greatly to this activity.

Then we spent a bit of time trying to consider biological plausibility of potential increased risk of febrile seizures.

For those of you who would like more details on this, there is a more detailed slide show of the ACIP presentation in October that goes into some more technical details.

Briefly I will just tell you, on slide 13, this just shows our methods. Our methods involve closely reviewing the unpublished data, looking through the literature and talking with experts. Then we did try to conduct a mini-survey of working group members to try to rate the quality of the evidence for our assessment that we presented in October.

Slide 14 is the scientific slide, but we thought it would be easier to show it to everybody this way. If you look at slide 14, I'll take a moment to walk through it because it is a little bit complicated, you will see the post vaccination interval. The VSD study has as the principal investigator Dr. Klein, and the Merck sponsored study has the principal investigator Dr. Jacobsen.

Both of these studies in general looked at a group that had MMRV vaccine and compared it with a largely historical group who received the MMR+V vaccines at a different point in time earlier. They assessed for risk of febrile seizures. They had some differences and some similarities.

In brief, the VSD study was in children at ages 12 to 23 months who had received the first dose. They only reviewed charts that confirmed the diagnosis of febrile seizures in seven to ten days after vaccination. So we don't have chart review data at this point in time on other intervals. In the seven to ten days after vaccination, they showed that there was about a twofold increased risk of febrile seizures in the MMRV group compared to children who received the MMR and varicella vaccine separately.

Another way of looking at it is that there were about five additional febrile seizures per 10,000 kids that got the MMRV compared to what would have happened if the kids had gotten MMR+V.

If you look at the Merck data, the sponsor data, you will see what our epidemiologist described as remarkable consistency in the early window. They looked at a full 30-day window and did a chart review, and also did an adjudication process and used the Brighton case definition.

In the five to 12 days they also found a twofold

increased risk. They also found a similar number of excess febrile seizures of about four per 10,000. What the Merck data showed that was a little bit beyond the VSD data, they showed some experience of a later interval.

I'll just jump down into the one to four week interval. They did show in their data that they didn't identify an increased risk overall of febrile seizures. If you look at that middle column, you will note the .6 relative risk for the three to four weeks. That was a non-statistically significant finding, but what that suggested was that there might be a trend for a slight reversal of the risk pattern in three to four weeks after vaccination, whereby the kids that have the MMR+V might be the ones that have a little bit higher risk for febrile seizures.

There was one school of thought put forward that maybe there wasn't an increased risk in the month after vaccination, but rather a shifting of risk. Then there is another school of thought which is that there is a really a real strong risk in the early window.

So there are a couple of things going on to try to assess that. One major thing going on is that the Vaccine Safety Data Link is now conducting a chart review in the later windows, so we are waiting to make our final assessment until we get that back.

Another thing that we tried to consider was

biological plausibility. We looked at biological plausibility for a variety of things, but to focus on the main one here, we thought long and hard about the biological plausibility of an increased risk in the early window. We think that the argument shows a strong biological plausibility for increased risk for febrile seizures after MMRV versus MMR+V during the five to 12 days after vaccination.

This is our logic. First, during the eight to 14 days after vaccination with MMR, we already know from the previous study that there is an increased risk of febrile seizures, and you get about one extra febrile seizure per 3,000 to 4,000 kids with MMR compared with children who weren't recently vaccinated.

We also know that the vaccines have different properties. The MMRV has about seven times more varicella component than the varicella vaccine or Varivax, although it does have the same amount of measles component.

Of interest, the immune responses with MMRV suggest that measles virus replication might be higher if it is a weakened form of measles virus after the vaccine. But are they higher after MMRV compared with MMR+V? We know from the earlier slide that there were higher rates of fever with the MMRV versus the MMR+V, and that febrile seizures occur in fever. Simply put, we have this window of fever that makes

sense biologically, and it makes sense that we might see increased risk for these febrile seizures in an early time period.

MR. SCONYERS: Dr. Broder, I just want to interrupt. We have got about ten minutes left, and you are about halfway through your slides.

DR. BRODER: Okay, so I'll speed up. Slide 16 shows you the picture of the medically attended fevers. You will see that the blue bar is MMRV and you will see the peak is occurring in that MMRV group at about five to 12 days. You do see a peak in that window for a change which are measles containing MMR and varicella, so this is basically supportive of the biological plausibility.

In the interest of time, I am going to have you all read through the evidence statement, that basically just describes what I just said, that we are seeing an increased risk in the early window, but on the overall assessment of what is going on in the month after vaccination, it is not clear to us, and we have insufficient data to make a conclusion about that.

If you look at slide 19, it basically just describes some of the activities underway, to complete our evidence assessment and our febrile seizure clinical importance review. That is underway and will be presented in June to the ACIP.

Turning very briefly to policy, slide 20 lists the elements of the policy side that Dr. Marin put together for the working group. You will note that we are going to be considering a range of issues in our policy considerations, including vaccine safety as well as social expectations, which is somewhat relevant to the earlier discussion we had. Then of course, burden of disease, immunogenicity and effectiveness, program implementation, equity and access and recommendations of other groups, particularly American Academy of Pediatrics.

Slide 21 lists in our current thinking the main policy options on the table. This is under deliberation in the working group. The one that is currently in place is no preference for MMR versus separate injections of MMR and varicella vaccine. But there are three other ways that you could imagine voting. One would be a preference for the combination vaccine which was originally in place. The other would be a preference for separate injections over the combination vaccine, and then a potential option could be not to recommend MMRV.

Turning now to the update, the survey data will be very interesting to this group, and I will end with this. Dr. Tempte and colleagues from the University of Colorado conducted a survey to try to assess physicians' perspectives about this issue. What they found in their survey of family

docs and pediatricians is that the majority of physicians felt that febrile seizures were a mild to serious adverse event, but the majority of the physician felt that belief of the parents, the physicians' belief that parent attitudes, felt that febrile seizures were very serious.

If you look at the e next slide, when we asked about intended practice after we gave them some of the risk information from the last ACIP meeting in February 2008, most of the physicians said their intended practice for use of MMRV in the 12 to 15 month group was to probably or definitely recommend the individual vaccines compared with the MMRV.

Then if you look at factors that were associated with recommending the individual vaccines, you will see that one of the strongest factors was physician concern for febrile seizures. That was probably associated with recommending individual vaccines. Another factor that was associated with this decision was the importance of the professional recommendation.

The next slide looks at factors that were associated with use of combination vaccine. The factors were potential to improve varicella up to date rates, parent preference for fewer injections and physician specialty, pediatricians versus family physician.

Slide 27 tells you our plans in June are to

complete our evidence assessment, looking at findings from the VSD final study, the final study results from the expanded chart review data on the later windows after MMRV. Then we will be expecting to propose policy options for a proposed vote for the ACIP to vote on these other vaccines.

Thank you. I appreciate your time. We are happy to take questions. Also, given your consideration of vaccine safety, I would be interested if there is opportunity to hear any of your immediate views.

Thank you.

MR. SCONYERS: Thank you, Dr. Broder. I know we sped you through that. There is a lot of data in these slides. Do we have comments, questions?

MS. HOIBERG: My question would be with the fact that they are known to cause febrile seizures, which regardless of how mild people think febrile seizures are, there is always that risk of brain damage when it comes to seizures.

I would be very, very interested to see in the cases that have come through, the ones that are sitting right now in our program, which ones got the MMRV vaccine, and if they did, fast track those puppies into compensation, no questions asked.

Seriously, if you guys know that it causes that, then there should be no questions asked. I am glad to see

that they took it off the market right now. I think that is very smart, but it brings up my concern and concretes it in the combination vaccines. We are adding now five in one, four in one. It is too much. The fact that it is one less injection, still that is just one shot that they are getting among possibly two or three other injections.

DR. EVANS: There are a couple of misconceptions.

DR. HERR: The kids with seizures that I see, I see far more children who have seizures with fever have it with illness than I see with children who have vaccines.

The other thing is the whole definition of seizures with fever as opposed to children who have seizure disorders with fever and also have fever. Children with classic febrile seizures are children who are previously neurologically normal, and they have a short seizure during this period, and there is no risk of brain damage with these kids.

The thing is, there is a small percentage, one to three percent, that later on will develop a seizure disorder, but for other reasons, presumed other reasons. But the idea and the presumption that a simple febrile seizure is going to cause brain damage is a misconception.

Children who have seizure disorders will have increased seizure frequency when they have fevers. That can be a problem because of their underlying seizure disorder,

but not simple seizure with fever, which is what we are talking about here, as I understand.

DR. TEMPTE: One of the questions in this working group that we have, and I will just put this out there, and if you are able to provide any feedback it would very gracious. But in the realm of, for physicians and other medical people, we look at febrile seizures as being fairly benign events. But stripping away that professional knowledge and putting on the eyes of the general public, what is the perception of policy that may or may not favor -- or at which level of risk is it a losing proposition?

I think we are very acutely aware of our constituencies out there, the public, and the safety aspects. But the question is, what is a rational or reasonable policy out there?

MS. BUCK: I think that is a fair question. I think that we have heard from some of the work that we have done in the Vaccine Safety Working Group from the public that public concerns about something is just as valid as scientific concerns. I think you have these great examples going on in the last two comments.

I think it is very wise for you to ask that question and to consider that. It doesn't really matter to a lot of people whether or not your doctor or pediatrician can explain away a febrile seizure. I believe it is very

important to listen to parents, and if they don't want their kid to go through one, it doesn't matter whether or not there is some scientific basis to explain why it happened, or that it can't hurt your child or any of those other things. Parents don't want it to happen, period.

Your question is really valid, and I'm glad you asked it and I'm glad you are thinking about that. Karen, you brought those two up for those reasons, and I think it is really important to think about that. At some point in this process with vaccines and vaccine safety, you have to be willing to say to parents, this is above your threshold of willingness. If you don't want this to happen with your child, we need to listen to that. We need to find another way to keep your kid safe from these diseases without it being a potential for febrile seizures.

DR. BRODER: Tawny, can I make a clarification? I really appreciate that. I forgot to clarify an important point. In any recommendation from the working group, it would go without saying that the risk and benefit information, the best we had, would be communicated.

One of the questions that comes up is, if the working group was to communicate as clearly as possible what we know and what we don't know about the risk of febrile seizure, as I said, we are reviewing the clinical importance from both the medical perspective, but also, one of our

colleagues did a very big review of the literature looking at parental perception, and we will be presenting some of that in June.

What is really interesting is, there are two things that could happen along the lines of what you are saying, Tawny. One would be that doctors and parents will have the choice of deciding what is best for them, and know the risks and benefits, and have a choice.

Another would be that there would be a specific preference that would be in place for one way or another. Then doctors and patients would still have a choice, but they would have a preference in place.

It has been unclear, I have not been able to get a sense from the public perception on that issue.

MS. BUCK: I think providing options is always the best way to go. But I think ultimately your public is going to say to you, can you find a way to protect our kids from these diseases without incurring the febrile seizure. If you have a way to do that as a parent -- because I don't want it to happen, I don't honestly believe that it doesn't do damage one way or the other, so if there is an option, if there is an alternative way to do this, and I am willing to go with four pokes instead of one, I really like that, Karen. I like that you are thinking that way, because ultimately I think it comes down to that, providing optional plans for parents and

their pediatricians to work through together to weigh what you are saying, which is the risks and benefits.

DR. BRODER: For clarification, the extra seizure that one would get from MMRV could be prevented, but it is known that the MMR vaccine is associated with some risk of febrile seizure, and that is in the Vaccine Information Statement.

DR. FISHER: I sit on both the Committee on Infectious Diseases and the Section on Infectious Disease for the American Academy of Pediatrics. It has been very interesting, listening to the different viewpoints of pediatricians. We also have a representative family practitioner.

I think that while we feel that febrile seizures are not a risk and not the problem, I think the vast majority of people felt that there is no parent and in fact, no pediatrician, that likes to watch a seizure, and that it would be an extraordinary hard sell to knowingly use a vaccine that causes more seizures.

So I think that was the major sentiment.

I think you have to go back though for a second and say, why do we combine vaccines and why did we combine this vaccine. This is a situation where the public has changed faster than the industry. So the whole reason to make the combination vaccines was because the big complaint

was, we don't want to have all these sticks.

In fact, in Canada children could not be immunized if they were going to do multiple sticks. The families were not accepting of that. They wanted it all combined into one so that there was only one shot.

So I think that at a time when that was the public perception and the public request, we have now come to a time where some of the public still wants that, but a new vocal group -- and we don't know how large the group -- is now much more concerned about the combination vaccine.

So it is kind of an ironic thing that we find ourselves in this position.

MS. BUCK: The public probably didn't know you were going to add quite as many vaccines when you combined them. I argued that. The public didn't want as many pokes, but this is a vaccine that has been added.

DR. FISHER: But again, Tawny, it depends on the public that you are talking to.

MS. BUCK: You come across as pretty much saying, there is a vocal, crazy group out there that --

DR. FISHER: No, no.

MS. BUCK: The public asked for this. That is the perception of your comments and quite frankly, I have been on the line like you for a long time now, and I am telling you what you need to listen to. It is not a crazy small faction

of people from Ashland that are saying this. It is good that policy makers and people are starting to take notice of these concerns.

DR. FISHER: I don't think they are crazy. I think they are vocal. I don't know how big they are. That is what I was trying to say. I don't think I have ever characterized them as crazy, and I hope that I haven't given that impression.

But anyway, I think that is where we find ourselves. I think it will be, as far as for the work group asking our input, I think it would be difficult to go back to a preference for this particular combination. So that is the feeling that I have gotten from most of the pediatric infectious disease people to whom I have spoken.

MS. HOIBERG: Why would that be hard to decide? You have two vaccines, you have the MMRV and then you have the MMR+V, where you choose to separate the varicella from the MMR and not get it at exactly the same time. It is not hard.

I am the parent of a child who is vaccine injured, and I didn't want them to have all of these pokes at one time. But you have these parents way back then that didn't realize the risk of lumping all of the vaccines into one and giving that child, yes, only one poke, but receiving four to five vaccines at one time.

MR. SCONYERS: We have got Charlene who has a comment, and I know Sherry does.

MS. HOIBERG: I have one more thing to say. I want to thank Dr. Broder for coming forward and being honest about the risks of this vaccine. Thank you, Dr. Broder.

MS. GALLAGHER: I just wanted to weigh in on the discussion and say that I think we have heard a lot of views. I think it is a difficult choice by any measure. But I also hope that what doesn't get lost in this discussion is the risk of febrile seizures from the underlying illnesses.

Now, when I was growing up, this was a time when you didn't have vaccines for any of this stuff, so I got every one of those illnesses. Luckily I didn't have any bad to follow. But two years ago, three years ago, my son slept over at a friend's house and the next day the friend's sister went into the hospital because of measles and a very high fever. I will tell you that it was like holding my breath for a couple of days, worrying because my son had slept in her bed because it was two boys and they kicked her into the single bed so the boys could sleep together.

There is a real person who I know who lives two blocks away who had a child who was having a terrible time because of the underlying disease. So while there may be room for choice between vaccines with different risks, I think that we should still remember the public health issues

and trying to protect the children from these diseases that cause very real concerns.

MS. BUCK: There is nobody out there who believes in what you say more than those of us raising medically fragile children. So believe me when I say, we are saying to the people who are making these vaccines, figure out a way to make them because our kids are going to die now if they get these diseases, because they are already medically fragile, but don't do it in a way that causes any other adverse events.

So you are right, nobody wants that, either. This community is not saying go back and take MMRV because of this. We are saying, find a way to do it that doesn't cause febrile seizures and all this other stuff.

MS. DREW: One last thing. I believe that our kids are getting an extra needle stick because we took OPV off the market and substituted IPV. So now they are getting sticks for polio, and I don't hear anyone complaining, because they would prefer that to a very small number of paralytic polio cases that happen.

Although I know simple febrile seizures presumably don't have any long term consequence, I have seen cases in my practice where the child had a febrile seizure after vaccination that turned into status epilepticus and went on to be a really nasty condition.

So I don't think we can just say it is just a simple febrile seizure. I would certainly trade off an extra needle stick to prevent a chance in a thousand of getting a febrile seizure in my child. It is too scary. Let them get stuck.

MR. SCONYERS: We clearly have a range of opinions.

DR. EVANS: I just wanted to thank Dr. Broder and Dr. Tempte and Dr. Marin. I have been on ACIP now for about ten years; I have never seen a work group put together as quickly and for a strictly safety issue like this and have expertise and the diligence in following through on the issues, and having the survey of practitioners all in a very short period of time. I think it is an extraordinary bit of information put together, and I am very pleased that you brought that to our Commission, because this is one of the few times a single vaccine issue like this has been brought.

So thank you, and a very impressive job.

MR. SCONYERS: My closing comment here is going to be that there was a lot of material on the slides that we didn't necessarily have a chance to think about very carefully. I would encourage whoever is going to be on the agenda committee for our June meeting to consider whether there is a reason to continue this discussion in June, because clearly there are a number of concerns being

expressed around the table that are very valid and appropriate for this Commission and for this program to be taken into account.

Dr. Broder, we really need to move on.

DR. BRODER: Yes, I know. I will take a minute to make this comment. I just want to say that I think it is important. I second what you just said; let's continue the discussion in June, and also be mindful that we are still doing analysis, and I don't think that anybody should jump to conclusions prior to having all the data in house and a complete analysis being done.

Agenda Item: Update on the National Institute of Allergies and Infectious Diseases Vaccine Activities

MR. SCONYERS: We are going to move on to hear from Dr. Jennifer Bernstein from the National Institute of Allergies and Infectious Diseases at the NIH on vaccine activities.

MS. BERNSTEIN: I just have a very brief update, so I'll help you make up some time here. I am filling in for Dr. Barbara Mulach today. Dr. Mulach is on jury duty, so she couldn't be here.

I just wanted to mention that the federal strategic plan on autism research was released today. The Interagency Autism Coordinating Committee released this plan, which will advise federal agencies and Congress on needs and

opportunities for research investigating autism.

I want to give you the website for that, to access the plan. Www.iacc.hhs.gov.

I mentioned in the past our vaccine safety program announcement. I think when I reported here in the fall, I mentioned that CDC and NIH had released a program announcement for research on vaccine safety. We have applications coming in for that. They are under review now. That is really all I can say about that at this point, but they are in study sections.

Also, the National Children's Study sponsored by NIH, by the National Institute on Child Health and Human Development recently starting recruiting participants. They are recruiting right now in two locations, Queens, New York and a rural county in North Carolina called Duplin County. In April five more centers will begin recruiting, and ultimately this study will have about 40 centers recruiting from more than 100 locations.

This is a very large study that is going to recruit more than 100,000 children, and follow them from birth through age 21. The work is going to focus on a variety of topics, including how genes and environment interact to influence children's health.
Right now they are looking into disorders of birth and infancy such as the health consequences of preterm birth, but

as you can imagine from the depth of the study, there will be many topics covered.

That is all I have from NIH.

MR. SCONYERS: Any questions?

MS. HOIBERG: The autism research, what does that actually entail?

MS. BERNSTEIN: The site I gave you is the strategic plan for autism research. But you can get to the Interagency Autism Coordinating Committee from the address I gave you.

DR. HERR: On those kids that you follow, are you going to follow them if they are not immunized? Or are all these kids going to be immunized?

MS. BERNSTEIN: Well, out of 100,000 kids, I'm guessing some won't be. I don't know for sure.

DR. HERR: It is an opportunity to get some sample, maybe not how big a sample, but you might get some sort of a sample that some people are looking at. Whether that means anything I don't know, but if you decide to keep people that only are immunized and follow them for 21 years, you are only going to get one particular group.

MS. BERNSTEIN: I don't know the specific criteria of who they are recruiting. As I mentioned, recruitment has just begun. But there will be more information, and we can certainly keep the Commission updated.

DR. SALMON: Actually, the Vaccine Safety Working Group has been looking at this quite a bit. Whether or not people are vaccinated has nothing to do with whether they are in or out of the study. They are not going to be thrown out because they are not vaccinated. About 28 percent of the population of young children get no vaccines, so we are probably looking at about 800 kids that get no vaccines. However, the manner in which the immunization history for these kids is being measured is suboptimal, because it is not the provider reported immunization histories, it is parental reporting with a shot card, which is not terribly accurate.

So I know that our Advisory Committee, NVAC, is writing a letter requesting that consideration be given to measuring immunization histories from provider records.

I think the answer to your question is, it could be helpful if we get good immunization histories, and it certainly will include some kids that are not vaccinated.

MR. SCONYERS: If it is possible to include a comparison of vaccinated versus unvaccinated kids, that would be a good thing.

DR. FISHER: This is the same study that has been talked about for about the last five years, --

MS. BERNSTEIN: I think so.

DR. FISHER: -- but the funding had died and gone away, and now it is back. So it is actually going to happen.

MS. BERNSTEIN: It is happening.

DR. FISHER: There has been a lot of thought put into this.

MS. BERNSTEIN: Yes, it has been in the works for awhile.

MR. SCONYERS: Anything else for Dr. Bernstein? Thank you very much. Dr. Gruber.

I should introduce you, I'm sorry. We all know who you are. Dr. Gruber is here from the Center for Biologics Evaluation and Research at the FDA on their vaccine activities.

Agenda Item: Update on the Center for Biologics Evaluation and Research Vaccine Activities

DR. GRUBER: Thank you very much. This is going to be a brief update. Since I reported to you in November of 2008, there have been no new vaccine approvals.

We are still working on review and license applications for a number of vaccines, including a human papillomavirus vaccine, a Japanese encephalitis vaccine, an adenovirus vaccine for a limited population, another thimerosal-free influenza vaccine and a meningococcal vaccine. We are expecting a number of additional new vaccines to hit the doorstep in spring, so I think maybe my next update will be a little bit longer in terms of what is new, in terms of vaccines being in clinical development or

approaching licensure.

I would like to say a couple of words regarding our latest Vaccines and Related Blood Products Advisory Committee or VRBPAC that took place February 18 and 19. The committee discussed three topics. The first one was the influenza vaccine seasonal strain selection, or what is the influenza vaccine for the upcoming flu season, the 2009-10 season, going to be composed of.

There was discussion whether it would have merit to perhaps add an additional influenza strain, a second B strain, in currently licensed vaccines. Then we had an interesting, very complex discussion on the issue of our pediatric clinical studies that would evaluate the safety and immunogenicity of pandemic influenza candidates in the absence of a pandemic.

The first point. The committee decided as the WHO had decided in February of 2009 that the seasonal influenza vaccine that is going to be made for the 2009-10 season is again a trivalent vaccine. Usually there are three different strains, two A strains and one B strain. The two A strains will remain the same compared to the last season, but there will be a switch in the B strain. Who is interested, I can give that information.

When we talk about the B strain and other switches being made, that has triggered quite a number of discussions

that started in 2007, whether it would be a good idea to add a second B strain in the currently available seasonal influenza vaccine, or have trivalent vaccines and in addition make quadrivalent vaccines available.

The reason for that is, there are two circulating lineages of influenza B strains circulating around. People are trying to match the vaccine strains to what is believed to be in the environment. That is not always successful. If you have a mismatch, then you are unprotected against the B strain that is out there.

So discussions, since there are two A strains in the vaccines, centered around the idea of why not adding two B strains to the vaccine. So the FDA gave a presentation and the CDC presented some data in a model that predicted the impact on public health if a second B strain would be added to trivalent inactivated influenza vaccines.

That model did predict that there would be a modest but a positive impact on public health, and that an additional 300 or so influenza related deaths could be prevented, and there would also be fewer hospitalizations if a second B strain would be added.

VRBPAC was not asked to formally vote on the issue of whether to add a second B strain, and thus is making quadrivalent flu vaccines available. But in the discussions they heavily leaned towards the idea of adding a second B

strain would have merit. The manufacturers who were at that meeting discussed that because of increasing manufacturing capacities over the last couple of years, it would be a possibility to make trivalent as well as quadrivalent vaccines available. The FDA will need to map now the regulatory path in terms of what preclinical and clinical data would be needed to support the safety and the efficacy of a quadrivalent vaccine.

Last but not least, this is a future outlook. It is not going to be happening in the upcoming season. If a quadrivalent vaccine is going to be introduced, then probably at the earliest the 2010 and 2011 season.

The last discussion point is quite complex and interesting. That was the issue of doing clinical studies in pediatric populations with pandemic influenza vaccine candidates. Why is that such a complex issue? There are several candidate pandemic influenza vaccines that are actively pursued, and they are in clinical studies. The issue has thus arisen if there is also a need to study these vaccines in pediatric populations. These issues and considerations are actually very complex.

One argument is that pandemic preparedness is necessary and one would have to do studies in pediatric populations to get good data on the doses and schedules that would be recommended to immunize pediatric populations in the

event of a pandemic outbreak. But on the other side, we have regulations, so-called Subpart D regulations, that govern clinical studies in children in order to minimize risk. Why this is important is that since there is no pandemic influenza circulating right now, what is the risk versus the benefits to the pediatric population in terms of studying these kids.

So there was quite extensive discussion. We had a pediatric ethicist from the FDA discussing these issues. Various companies provided an overview of their clinical development programs of pandemic influenza vaccine candidates. They also had started already a couple of studies in pediatric populations, mainly in countries outside the United States.

Again, we did not ask for a formal vote by the committee, but I think it is fair to say that the overwhelming majority of committee members felt that pediatric trials with pandemic influenza vaccine candidates should be conducted, because there is a real risk of another pandemic, and the question is not if, but when it would hit, and we would need to be adequately prepared.

That of course charges the FDA again with outlining a regulatory path and finding the preclinical and clinical safety and immunogenicity data that are necessary to support licensure of these vaccines in pediatric populations.

That is complicated by the fact -- and here I will get to my last point that I want to report, that many of these influenza vaccines, especially with pandemic influenza vaccine candidates, are formulated with what we call adjuvants. Adjuvants are components that can increase the immune response to the vaccine antigen components.

The only licensed vaccine adjuvant in the United States is an aluminum compound. There is a number of adjuvants in clinical development. Some of them are already licensed in Europe. None of those have been licensed in the United States, but they are in clinical trials.

There are some safety concerns with these adjuvants. In addition to increasing the immune response to the vaccine antigen, they have some immune modulatory activities by themselves. So clinical studies with these vaccine adjuvant combinations are going to be very, very challenging in terms of how do we evaluate the safety? What safety database is necessary?

In order to make some progress in this area, we had a workshop in December of 2008. We invited a lot of people, industry representatives, government regulators and scientists from around the world, toxicologists, clinical trial experts, to say what do we know about these adjuvants, what do we know of their safety profiles preclinically and clinically as far as studies have been conducted in Europe,

because some are licensed over there; what is the scientific knowledge base, where are the safety data gaps, how can we formulate a research agenda to close these gaps in order to improve safety and efficacy assessments of adjuvant vaccines for treatment or prevention of disease.

That concludes my remarks and it is five o'clock.

MR. SCONYERS: You are so punctual. Thank you so much. Are there questions or comments for Dr. Gruber? Tawny expresses her appreciation for your report, as always.

MS. BUCK: Yes, thank you. I'm still here.

Agenda Item: Public Comment

MR. SCONYERS: Operator, we are at the public comment portion of our agenda. So if you could check to see if there are people online who would like to make any comments, we will stand by for that.

OPERATOR: Thank you, sir. If you would like to ask a question, please press star, then one on your Touchtone telephone. To withdraw your question, you may press star two.

At this time, sir, I have no questions for you.

MR. SCONYERS: Thank you very much. Do we have any comments from anybody here? Seeing none, anything further from the members? If not, we will convene at nine in the morning.

We have had a full agenda today as you well know,

and we will have a full agenda tomorrow. So I really encourage you to be on time. We have a number of Vaccine Information Statements that we need to get through. I know already from sidebar conversations that there are some significant comments on those. We will have an update and discussion from Dr. Ray Strikas about the National Vaccine Plan.

I really encourage you to read the proposed recommendation letter that has come out of the work group very carefully, because I want to have our discussion tomorrow and either move forward on that or not, but I want you all to have an opportunity to have your say about that before we take action. So please review that carefully. It should be at your place. If you have got any questions about anything that is in it, you can talk to any of the work group members, and certainly feel free to talk to me about it.

Anything further for today? Then we will reconvene at nine in the morning.

(Whereupon, the meeting was recessed at 5:05 p.m., to reconvene Friday, March 6, 2009 at 9:00 a.m.)