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Advisory Commission on Childhood Vaccines

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P R O C E E D I N G S (8:15 a.m.)

TELECONFERENCE OPERATOR: Welcome to the 18th quarterly meeting of the Advisory Commission on Childhood Vaccines. All lines will be in a listen-only mode for today's conference. Today's call is being recorded and if you have any objections you may disconnect at this time. I would now like to turn the meeting over to the ACCV Vice Chair, Ms. Sherry Drew.

Agenda Item: Welcome and Vice Chair Report

MS. DREW: Thank you. This is Sherry Drew. I am acting as the chair of the Advisory Commission on Childhood Vaccines today and I welcome you to our 79th quarterly meeting which is taking place via telephone conference on June 9th and June 10th of 2011.

We have received a number of updates via e-mail and overnight mail, including a final agenda for this meeting. For the members of the public who have seen the draft agenda that appears on the ACCV web site I would like to mention that the only change that I can see in the update is that Vince Matanosky will be reporting for the Department of Justice instead of Mark Rogers.

As with an in person meeting, any commissioner or other person who speaks at our meeting should identify himself or herself so that the rest of us and the transcriber knows who is speaking. Speakerphones sometimes

cause feedback on the system so it would be helpful if you could pick up your handset and speak into it if you speak, but otherwise keep your speakerphone on mute.

Public comment is scheduled in our written agenda for 4:00 p.m. today and 10:45 a.m. tomorrow, Eastern time. I would like to clarify that public comment will be in fact welcome at the end of each day's session irrespective of exactly when that may be. When that time comes and you wish to speak, please speak up and identify yourself. The operator will put you on. This Commission does not answer questions at that time or at any time. It only hears comments.

Agenda Item: Approval of March 2011 Minutes

MS. DREW: That being said, I would like to turn to the first item on our agenda, which is the approval of the March 2011 minutes. Do we have any comments or corrections on the March minutes?

MS. HOIBERG: I wanted to first of all say hello to everyone. Second of all with regard to the minutes, it is not necessarily the minutes that I have a comment on, it is what happened at the meeting last time when it came to rulemaking. I did get some feedback from my constituents, that they were unhappy with the fact that we ruled against – that they feel that we ruled against sending a petition to the Secretary about adding GBS to the table. But upon

reading the Federal Register it is very clear that that is not a final decision. The only reason we said no at this time was because we were waiting on the IOM report. Just to kind of clear the air as far as my constituents go, we are not making the decision not to send GBS to the table, or asking that GBS be added to the table, we are just saying not at this time, because based on the letter that we received there was not feasible timeline, no real information that we could send to the Secretary to back up a reason to add GBS to the table. So I just wanted to make that clear,

MS. DREW: Thank you for the comment. Do we have any more comments with respect to the minutes?

MR. KING: Yes, on page 19 of the minutes for day two, at the last paragraph of the general discussion session, while I do appreciate the honor of being called Dr. King, I may not have any patients and therefore I can't be a doctor.

MS. DREW: Thank you, Mr. King. We will move to change the record to indicate that you have not yet received your doctorate.

MR. KING: Thank you. May I bring another item up? It might be more a point of order for clarification. Under the future agenda items it had that you are the chair for the next meeting and it says, at which time a new chair

and vice chair will be selected, but I don’t see that as part of the agenda. So can I assume that that is not going to happen?

MS. DREW: Geoff Evans and I discussed that we thought that it would be virtually impossible to have the usual procedure, which involves little pieces of paper passed around, at a telephone meeting. So we have put that over until the following meeting. So we will do elections, I believe, in September.

MR. KING: My question is if we approve these minutes with that in there, are we approving something that is inaccurate?

MS. DREW: No, I think that was what was discussed last time, but the fact that it didn’t happen I don’t think goes back and makes it inaccurate at the time.

MR. KING: Okay, that was it.

MS. DREW: Thanks, anything else, folks?

DR. HERR: On page 8, under Dr. Gidudu’s comments, there should be some clarification on line three where it says, with Phase I trials that enroll only a few subjects, usually between 10 and 10050. There is obviously a typo there. I am not sure which number is correct, whether it is 10 and 50 or 10 and 100, but 1005- is certainly not a few.

REPORTER: It was fifty.

DR. HERR: Okay, why don't we correct it to fifty then, please.

MS. DREW: Okay. Thank you, Tom. That was good reading. Anything else?

DR. HERR: If not then I move that we approve the minutes as corrected.

MS. HOIBERG: Second.

(Whereupon, on motion duly made and seconded, the minutes of the March 2011 ACCV meeting were unanimously approved.)

MS. DREW: Subject to the corrections that we have discussed the minutes are approved. Moving on then to Dr. Evans, he will give us a report from the DVIC.

Agenda Item: Report from the Division of Vaccine Injury Compensation, Dr. Geoffrey Evans, Director DVIC

DR. EVANS: Thank you welcome to the 19th quarterly meeting of the Advisory Commission on Childhood Vaccines. All of you should have the presentations for today and tomorrow morning in your folders. They were sent to you and I know that Annie also sent these out to the e-mail address list.

We are meeting by teleconference this time, which we have done actually in the past. We did this last July for the purposes of reviewing revisions to the Vaccine

Information Statements for the upcoming flu season. And we have done so this time for reasons, basically, there are a lot more that is going to be put together for the following meeting and we made the judgment in terms of cost and people's time, it was just more appropriate that we do it this way for this particular meeting. I should also point out that the temperature outside is now 95 degrees and going up. So that was another bit of enjoyment that we let you avoid.

Under Tab 5 in your meeting books you will note the appointment of Chief Special Master Patricia Campbell-Smith. I spoke this morning with her and she sends along her greetings and she is planning to attend the September meeting so she can have the opportunity to meet everyone.

In terms of other personnel items, we have had some ourselves since we last met. Kay Cook has moved on to the Bureau of Family Health Care in the Office of Administrative Management and we all wish her well in her new job. We have two new employees who have joined us, Commander Karen Williams, a pharmacy officer, is now part of the Medical Analysis Branch. She was formerly senior program management officer in HRSA's Office of Pharmacy Affairs. And Dr. Marcia Gomez, a medical officer, has also joined the Medical Analysis Branch. Dr., Gomez was with HRSA's Migrant Health Center Program, where she managed the

Secretary's National Advisory Council on Migrant Health. She will be taking over supervisory responsibility of the Commission, working with Annie Herzog. So you will get to meet her when you come in September. We are very pleased to have both Karen and Marcia on board.

Turning to the first topic slide, ACCV meeting highlights, after my part we will have an update from the Department of Justice with Mr. Vince Matanosky, and then following that we will have a review of vaccine information statements led by Ms. Jennifer Hamborsky from CDC, and then the agency updates from FDA, CDC, NIH and NVPO --- the National Vaccine Program Office.

The agenda is pretty fluid in terms of there is plenty of time, so we may be adjusting things here and there and may end closer to five o'clock than four o'clock, particularly with the business that we will be reviewing. Then tomorrow morning we will have the clinical updates presented by Dr. Rosemary Johann-Liang and Dr. Catherine Shaer.

Moving on to the next slide, starting with the petitions files, you can see that we remain quite busy, probably over 400 claims again this year. More details of the types of vaccines and the nature of injuries will be provided tomorrow morning when Rosemary does her clinical update. Next slide, adjudications, the non-autism activity

is about the same. I want to point out under autism dismissals, we list 104. This figure is always been different than what the Department of Justice will present in their update following mine, and that is because there is a lag time of at least 90 days between the decision, which is what Vince Matanosky will be reporting in his update, versus we wait for the final judgment. This 90-day time period has to go by before we would enter that the final judgment is entered into the data base. SO you will see a significant difference in the number of decisions, over 400 for the Department of Justice dismissals versus the 104 listed in ours which reflects the final judgment. I just wanted to point that out.

MS. HOIBERG: I am just a little confused looking at when you say non-autism omnibus proceedings – these are autism cases that just were not included in the omnibus? Is that what we are talking about right now?

DR. EVANS: No, what I meant to say is that in terms of dismissals, these are just autism dismissals and the 104 figure you see are final judgments, where the autism dismissals that Vince is going to report is going to be over 400, and these represent the decisions that are initially out.

MS. HOIBERG: All of this, these two slides, are autism and then the omnibus, right? I mean both of them

are autism and no just normal cases that are coming in? Right?

DR. EVANS: Yes.

MS. HOIBERG: Okay, thank you.

MR. KING: I have a question, Geoff, it seems there is a different measurement for the Department of Justice in terms of reporting it and for us to report it. Is there any way to get that synched so that we have similar data coming at us and don't have to do the mental deciphering?

DR. EVANS: That question has been asked at least a dozen times over the years.

MR. KING: And now it is the thirteenth.

DR. EVANS: It is such a natural one. We should have it on our list of questions that we expect to have to answer. The answer is this. We track it by fiscal year and report it that way, and that is on our web site and that has traditionally been our policy, whereas the Department of Justice approach has always been to track it from meeting to meeting. SO there is going to be that difference. I guess the advice is to keep the big picture in mind. Theirs is a closer view of the process and you just have to kind of deal with both sets of perspectives as you receive these data. Certainly that has been raised recently and we will continue to talk about it and see if

there are ways that we can do it with a little bit more symmetry.

MR. KING: Great, I appreciate that. The question is, is one view or one perspective more reflective of reality than another perspective?

DR. EVANS: I think that certainly – for example, Vince is going to report on the four hundred some odd dismissals, that is a very timely look at what is going on in that particular area, so you have the advantage of that. Whereas the year experience may not show those changes so quickly. But I don't think there is really much advantage of one over the other. I think they both have their strengths.

MR. KING: I would like to follow up on that. I don't mean to beat this horse, but at the same time I am trying to understand if there is an advantage to one over the other. Help me understand what that is.

DR. EVANS: Again, and maybe Vince, who is on the line, may want to add something. It has to do with the practices and procedures in each office and we use it ourselves just to keep the count in a bigger picture type of thing and that is for Congress or other stakeholders interested in what the program is doing. Whereas the Department of Justice, since they are on the front line and they are actually handling all these cases, it is something

more inherent to their office approach. I don't know in terms of advantage whether it may be more advantageous to have our particular data in, but I don't know that there is a downside to having them reporting it the way they are -- if I am understanding your question.

DR. HERR: Can I interrupt a second? As a possible analogy, if you assume it is sort of like the process of somebody who runs a horse riding place. One group, like the Department of Justice, ends the case or judges it when the horse comes back to the barn, and the other group is when the guy leaves the stables, the rider leaves the stables. They are both looking at the same stuff, but at different time sequence so that the numbers may be a little bit off. SO two horses may come back and one person walks out, so the numbers are different. Geoff, is that reasonable? Because it is a time sequence.

DR. EVANS: Yes, it is a time sequence.

DR. HERR: It is a stupid analogy.

MR. KING: I don't think it is a stupid analogy, Tom. I think it is a good analogy, but I would submit that there is not a little difference in the numbers, there is a rather significant difference in the numbers.

DR. EVANS: That is true. If you are talking specifically with what I have which jumped out at me when I started looking at this, that's true. But for the most

part you can make the extrapolation back and forth for the other categories and I don't think you lose much n that and you can keep track of it. But there is always going to be, in this particular area, decisions versus final judgments – there has always been this lag over the course of time. I know early on people would look at awards and adjudications and, fine, say how come these numbers don't match and these numbers don't match, and we always had to point out that these really are a reflection of this time line that occurs as claims go through the process.

MR. KING: Right, so different measurements cause the confusion is all I am submitting. Perhaps maybe we should ask the Department of Justice to change to our reporting.

DR. EVANS: We could certainly suggest that to them and I am sure right now they would have some good answers for that.

MR. KING: All I am saying is that if many people asked the same question, and the same answer is we do it differently, they do it differently and we have different snapshots in time, then I guess as long as we are all aware of that I guess it is okay. But to me it seems to confuse matters and doesn't really present the clear picture. Maybe I am alone in that thought.

DR. EVANS: As you become more familiar with the

program and its process and data, we can still revisit. But initially, yes, I understand your desire to try to make things less confusing where they can be made so.

MR. KING: Okay, I guess we should move on.

DR. EVANS: The next slide is adjudication categories. This is something we have been showing for the past year at the request of the Commission. This particularly became of interest when settlements became much more frequent in the way of conducting business in the program. You can see there is a recent trend where we are defending cases a little bit more frequently before the courts. The court decisions in this fiscal year are up from the previous fiscal year, and the concessions by our program are down, meaning that we are not conceding entitlement and in cases where we so deem appropriate we are deciding to defend them before a special master and asking for the court to decide whether there is entitlement to compensation.

Having said that you will see that settlements still remain in the seventy to eighty percent range, now seventy-five percent, so that really hasn’t changed. Just some subtle changes in the concessions and the court decisions. SO this has remained fairly steady overall.

In terms of the next slide, awards, we have awarded approximately $120 million this fiscal year, which

is on pace. The previous fiscal year as $189 million, You will note that under attorneys fees and costs that that is actually $11,697,000 at this point and that has also increased over the previous year, and that is reflective again of the autism dismissals, which are attorneys fees and costs decisions. That is not surprising.

MS. HOIBERG: I am seeing $86 million for petitioners; awards and $7.9 million for attorneys' fees and costs. Where did you get the $11 million?

DR. EVANS: I'm at the bottom of the chart.

MS. HOIBERG: Okay, I was looking at the average – I'm sorry.

DR. EVANS: In real time this is what we are seeing now. Overall we are on pace. Fiscal year 2010 was $189 million, which is one of the largest years for outlay in many years. It looks like we are on pace for that again. Of course the program is much busier, again 400 claims a year are being filed.

MR. SMITH: What is the fiscal year? When does it start and end?

DR. EVANS: When does it start? The fiscal year]11 began October 1, 2010.

MR. SMITH: Thank you.

DR. EVANS: Turning to the next slide on the trust fund – the trust fund still remains slightly under

$3.3 billion and is growing a little bit more slowly in terms of interest because of the way the interest rates have fluctuated. But more importantly, with the increased outlays the trust fund is not netting as much money as it has in the past. So you can see over a six-month period the trust fund has only grown $44 million. SO that continues to go up and it has certainly gathered a lot more in terms of receipts once influenza vaccine was brought on board the program starting in 2005. But this is s good snapshot and tells you what the trust fund is doing.

Moving on after that. In terms of significant activities, the program was at the National Association of Pediatric Nurse Practitioners in Baltimore at the end of March. In another activity, staff attended the oral argument in Cloer v. Secretary of HHS at the U.S. Court of Appeals for the Federal Circuit that was held on May 10. Prospectively I will be attending the National Vaccine Advisory Committee meeting in Washington next week, and Charlene Douglas will be along side in her role as liaison from the ACCV to the NVAC. I will also be attending the Advisory Committee on Immunization Practices in Atlanta the week after that.

For those who wish to contact the program. Write the National Vaccine Injury Compensation Program at 5600 Fishers Lane, Parklawn Building, Room 11C-26, Rockville,

Maryland 20857. The telephone number for information is 1-800-338-2382. You can access the program's web site at www.hrsa.gov/vaccinecompensation. I will end my presentation and I am happy to answer any questions.

MS. DREW: There apparently being no questions we move on now – thank you , Geoff – to the report from Vince Matanoski, who is the Acting Deputy Director of the Torts Branch of the Department of Justice.

Agenda Item: Report from the Department of Justice, Vince Matanoski, Acting Deputy Director, Torts Branch

MR. MATANOSKI: Good afternoon everyone and thank you for having me. It is a really pleasure to appear before the Commission again. I haven't been in front of the Commission for a couple of years. Again it is even more of a pleasure to be back in the United States. I am pleased to be back here.

I am starting off with statistics, which obviously engendered some questions and I would be happy to answer questions to the extent that I can. I welcome those throughout my presentation. There was the analogy about horses. I don't think that was a stupid analogy at all. I think that was very apt analogy. I actually ride horses and any time I make it back to the stable myself –

(Laughter)

But we are apparently, HHS and DOJ, are looking at a little bit different statistics. Having been away from this for a while I had the same questions you did. I was looking at this and I thought this might be confusing. What I can say about the DOJ statistics is that we are confident I them. What we are reporting we are confident that those are accurate statistics. Now it may be different looks in time at the same slices of information. That could be confusing and I think it might be worth exploring between us and HHS in this period between now and the next meeting, whether there is a way of reporting, or at least explaining, our various looks at these slices of numbers in a way that is not at least superficially confusing. Certainly when I looked at it I had some of the same questions.

As far as our first slide there, the cases that come in, I am not going to just read the slides, I am going to try to give you some insight in trends that I see based on these numbers. As you can see, of those cases that we had come in in this period, the majority of them were adult cases. Those who have been with the program for a number of years know that that is a change in the way the program has seen cases over the years. When we first started the majority of cases were cases involving children and few

involving adults. Now it is the opposite.

I think we are going to continue to see that throughout the immediate future, the near future. It seems to me that the addition of influenza vaccine changed our demographics, if you will. They are also probably responsible for the increase in the number of cases that we have seen, so that now you press up against 400 and we probably will exceed that again this year in terms of the number of cases coming in.

If you think of the cohort that receives influenza vaccines it is a much broader cohort. It is essentially abbot 80 million I guess a year in terms of the number of doses, maybe even higher than that. Since that is going to be spread across the spectrum of ages more of those folks who are receiving this are going to be – they will have reached the age of majority, let's say, by the time they are receiving these vaccines. SO our case load, just by the sheer number of influenza vaccines that are administered, you are going to see a lot of these be adults coming in, and you are also going to see more cases.

One thing that struck me when I was thinking about that was are we going to see, since unlike childhood vaccines where you can probably figure they are administered roughly in the same numbers or the same frequency across a given year. But flu vaccine is

seasonal. We will see a lot more of that administered obviously in the fall and the winter than you'll see in spring or summer. So there we see sort of a seasonal variation in the cases coming into our program, so that they will tend to come is seasonally at the end of three years after the vaccination was administered, at the end of the statute of limitations period. So what we see is seasonal variation in the frequency of our cases coming in, the rate of our cases coming in.

I really haven't seen that so far, looking back at the cases that have come in. What seems to affect the number of cases coming in in a given week or period of time seems to be more holidays than anything else. You will see sometimes a little bit of a slowdown in the summer when people are on vacation, and over the holidays in the winter and then an increase in other times, but I haven't seen really a seasonal variation.

The other thing that I noticed recently with cases coming ins is I see far less now pressing up against the statute of limitations period. It seemed that much more of the cases are filed, not at the eleventh hour, if you will, the very end of that three-year limitations period. I really don't know why that is. Perhaps there is a more active petitioners' bar; perhaps there is just better awareness of the program. But I have seen a lot

less cases that are running close to the imitations period.

Turning to the next slide, looking at the total adjudications during this period, there are a couple of numbers that jump out at me when I look at this. One is the number of cases that have been settled by stipulation. You look at the cases not conceded by HHS – 79 – and those are a lot of cases that we are settling in that last period.

The other number that jumped out at me was of course the decisions. The total number of cases that were dismissed din this period, and the number of those that were cases out of the autism proceeding.

I wanted to speak about the stipulations or the settlements first. If you look at the end of this presentation you will see a breakdown of all the cases that were settled by stipulation, so that gives you an idea of what those kinds of cases are and how they are coming through here.

What you can take away from this is that there is a very viable and active, if you will, alternative resolution of cases that are filed under the vaccine program by these litigative risk settlements. And I know there has been some discussion of that in previous hearings, previous discussions in front of the Commission. It basically is a situation where the parties end up

agreeing that it is in their interest, each party's interest, to settle a case short of getting that ultimate decision from the special master. And there are a variety of reasons why parties decide to do that. Not all of them are linked to the strength or weakness of a case.

That is, of course, one factor, but there are a variety of factors. The other takeaway from that is a decision that is reached jointly. Each party, not one party or the other, that dictates. Each party essentially arrives at the conclusion that it is in their interest to do that. SO it is a little bit different from what you see in a decision in a case where the parties have gone in, obviously, with their positions if one party ends up happy with how it turns out but the other party ends up quite disappointed. With the settlements by stipulation the parties have decided to compromise those black and white positions and instead adopt a position where they both find something in the resolution for themselves.

Speaking a bit about the dismissed cases and this big jump that we have seem, this was predictable. I looked over Mr. Rogers discussion in front of the Commission the last time. He had mentioned how the special masters were activating the autism cases to determine what was going to happen with them in light of the decisions that have come out of the omnibus proceeding – how were they going to go

forward with their case? Did they want to present new evidence on those theories that had already been presented – the two theories, the measles theory and the mercury theory? Did they have a new theory that they wanted to go forward with. Or were they going to dismiss their cases? That process began a number of months ago and what you are starting to see now is the endpoint of that process that the court began, where the inquiries have gone out in the form of orders to the petitioners, and the answers are starting to come back.

Another part of that process that I know Mr. Rogers talked about last time, and is going in full swing now, is settlement of attorney's fees in those cases. There has been kind of a phased approach by the court where they looked at first the attorneys who had the greatest number of cases. We were trying to find efficiencies in resolving attorneys' fees since there are over 5,000 autism cases that were pending. If there was an efficiency, there were broad categories where these cases could fit in in terms of attorneys' fees and numbers could be agreed upon essentially for those categories, and it would streamline that process.

I am happy to report that in large measure that has been achieved for those cases that we have begun to look at, that the petitioner's counsel, the respondent, the

court working together have come up with some categories, some general numbers that can apply to those categories and that is greatly speeding the resolution of attorney's fees in those cases.

MS. HOIBERG: Vince, have you had cases come back that were in the omnibus that are filing under different – alleging different injuries?

MR. MATANOSKI: You know, Sarah, very good question. There are some that have identified that they intend to go forward with different theories. I haven't really seen what those theories are yet. It seems to me that they are in the phase of gathering their evidence together, but they have identified themselves as cases that intend to go forward. And even within the attorneys who have a number of cases they may be dismissing, a lot of their cases, but they also identify a few cases that intend to go forward.

As I mentioned, the court has had sort of a phased approach where they were looking first at the attorneys who had the largest number of cases filed. There again that was like five firms that had quite a few cases, were litigating a number of cases. They have also moved down several tiers of attorneys who have lesser numbers of cases, and we are working through those now as well – a laborious process but we are realizing some efficiencies in

going through it in terms of resolution of fees.

If I were to project out what you will see next time, I would guess that you are also going to see probably a similar number, if not a little higher, of dismissed cases. Then I predict you are going to start seeing that gradually go down over time. And it won't be quite as rapid a process of dismissal of these cases. You are going to start seeing the ones where the individuals desire to go forward, and you are also going to find the ones where it is hard to contact the petitioners or they are still considering, they want to spend more time considering what they are going to do.

So I think you are going to see this go up a little bit, maybe, or be about the same, and then gradually you will see it go down over time.

DR. HERR: Is it possible that some time in the future that we could sort of get little bit of a running tally of the omnibus autism cases that are still pending, that are still out, so that we get an idea of how many are still coming?

MR. MATANOSKI: I am sure we can figure out how many are still out there in each. It is a little more vague as to which ones may be going forward out of that. But we certainly can let you see – we'll be able to identify those that are pending at any given time.

DR. HERR: That would just be helpful to see where the stack-up is and how they seem to be moving through the process now that the omnibus proceedings is over.

MR. MATANOSKI: Sure. I know I can figure out how many are still pending and if there are other ways of getting information out of that data set that might look helpful to you, other kinds of information that can be gleaned from it, we will see if we can find some other information.

MS. HOIBERG: I was looking at your wonderful glossary of terms which we so appreciate. Is there any way that you could add on there the terms for the appeals, when you say affirmed and remanded? Just so we know exactly what that means. I never can remember.

MR. MATANOSKI: Sure, I don't see a problem with that and I will see about putting that in. I will try to give you – there should be a legal explanation but I am afraid it might end up being layman.

MS. HOIBERG: It could be layman. Maybe that's just, you know --

MR. MATANOSKI: I am just saying my ability to get a legal explanation may be a little compromised. I don't know if I give you, as the lawyers here would say, a Black Law Dictionary definition, but I will give you sort

of a working definition.

Affirmed essentially means that the case has been looked at on an appeal of some sort and the court on appeal agreed with the decision that it was looking at. It is saying it was a mighty fine decision. Remanded can mean – remanded essentially says that the court has a problem with the decision as it stands, and it is sending it back to whichever court issued that decision. In this instance it is the special master or the Court of Federal Claims. It is sending it back to that judicial body to look at the case again.

Usually when they remand it, it is with a specific question or issue for that judicial figure to address. Sometimes you will see a case that says the decision below is vacated, which means they have essentially done away with that decision. It no longer has any vitality or viability. Cloer, one of the appellate cases I know we discussed last time, is one where the decision by the Court of Appeals for the Federal Circuit was vacated, because the court was going to look at it en banc, in a larger group. Sp they essentially did away with the panel decision and are going forward in looking at it with their larger group of appellate judges.

We can add “affirmed” and “remanded” into that glossary of terms.

MS. HOIBERG: And “vacated” would be good, too. I am just thinking -- because we hear it all the time, and it is like, oh, okay, I remember that word. But that means this is what happened. Even for the lay person just listening in they may not know what that means.

MR. MATANOSKI: Right. We’ll get that in there. As I said, I'm good with the lay person, because that’s my understanding of it, eventually.

MS. HOIBERG: Thank you, and welcome back.

MR. MATANOSKI: Thank you.

I know that the petition processing, which is slide 7, has been discussed before. If there are any questions on that, I would be happy to -- when I look at this, I can think through this and understand the process, and this actually lays it out in a diagram. I applaud anyone who actually can think that way. But it is accurate. That’s the way that the process moves through.

If there are any questions on that, I would be happy to answer them. Otherwise, I’ll move on to give you some thoughts about what’s happening at the Federal Circuit.

At the Federal Circuit we saw four cases essentially decided since last time the Commission met. Two of those involved fees. They actually involved similar issues. They were both brought by attorneys in Wyoming.

They both were involving attorney hourly rates. Since Avera(?), there was a decision that essentially came out and said that hourly rates generally are going to be those reflecting the forum in which the case was tried. They were looking at Washington, D.C., because the Court of Federal Claims and the Office of Special Masters are here in Washington, D.C., and that would be the forum, so the rates of Washington, D.C., would apply. Now, they had an exception. Those rates wouldn't apply when most of the work was done outside of Washington, D.C., and there was a significant difference between the local rate where the work was done and the rate in Washington, D.C. Hall and Masias both involved that issue, whether it was proper to use the local rate versus the forum rate, because there was a significant difference in the hourly rate that would be applied.

They also had a collateral issue, which was, what is the proper rate to look at in Washington, D.C.? Is it sort of a general rate for attorneys doing similar work in Washington, D.C. or is it what's known as the Laffey, which is used in some cases -- complex litigation involving the federal government.

In both instances the court found that the local rate should apply and that Laffey rates were inappropriate. Again, it really wouldn't matter once the local rate was

applying anyway. In both instances the Federal Circuit agreed that that was appropriate. I guess, factually, in both those cases there really wasn't anything done in Washington. I think there were no hearings in Washington. Any of the work that was done was done over the phone. There really wasn't any travel to Washington or anything significant that was done in Washington, D.C.

The other cases that were decided -- Davis was a case where it was originally alleged as transverse myelitis. When the respondent filed an expert report saying that, in fact, it didn't look like a transverse myelitis case but rather a condition called neuromyelitis optica, the petitioner's expert changed their opinion and said they agreed it was neuromyelitis optica, but then they alleged that that condition was caused by the vaccine. In this case it was an influenza vaccine. The theory that they had -- the special master found that the theory lacked reliability. He didn't find the evidence supporting the theory. The theory was that there was first one reaction to the endothelium in the individual and that led to a second reaction, which was to the myelin sheath and led to a demyelination. The special master didn't accept that.

That case went up, as you can see, to the Federal Circuit. They fairly quickly resolved it. Within days after the argument, they did what's called a per curiam

decision. That is one where they really essentially don't write -- they essentially just say, "We affirm the decision below. They didn't really find enough in there to be worthy of writing a decision to be published on or extensively discussed.

The other case, McCollum, was a little different. It was a case that was resolved in damages many, many years ago. There was a reversionary trust in that instance that was used. Those who have been on the Commission for a while probably have heard of reversionary trusts. They are vehicles for resolving damages. It allows you to essentially to put a little bit more money into a case than, necessarily, the parties would agree that damages support. That's for some future contingencies. If those contingencies don't ultimately arise, then there is a reversion of any extra money that was put into the case when the person dies, when the injured individual dies. The extra money then reverts back to the trust fund, essentially.

In this instance, there had been a reversionary trust. It called for paying for damages -- the expectation was that the child would go into residential care, but it also provided money for taking care of the child at home if the decision was that the child should stay at home. So there were two different paths that the injured child could

take in the future that were covered by the reversionary trust.

The litigation seemed to involve, actually, something different. One of the parents wanted to essentially be paid as the caregiver, keep the child at home and be paid as the caregiver. Ultimately, the courts below found that that couldn't be addressed at this point; in fact, that wouldn't be permitted under the vaccine program, to pay the parent for being the caregiver, although the vaccine program could pay a professional to come in and be the caregiver. The Federal Circuit affirmed that decision.

Cloer was briefly touched on. I think we're all anxious to see what the Circuit is going to say. I know Mr. Rogers explained last time that this is very unusual, for the Circuit to take a case en banc, where they essentially have all the appellate judges at the Circuit looking at an issue. It allows for them to go back and overturn earlier Federal Circuit decisions and write new law. Normally one panel -- that is, the three judges that sit at the Federal Circuit to hear a case -- can't do anything to disturb an earlier decision by a three-judge panel of the Federal Circuit. They may disagree with an earlier decision, but they can't overturn it. When they sit en banc, they can do that. They can write new law,

entirely new law.

In this instance, they vacated the panel decision in Cloer. They met early in May to hear the oral arguments. The case has been fully briefed.

I attended the oral arguments. The questions came from across the panel. I think every single member of the panel had questions for the counsel that appeared before it. It would be idle to speculate from the questions that I heard where they are going to go with it. It really ran the gamut. I didn't see any kind of tree that you could glean from that as to which way they might be leaning. We are all anxious to see what they are going to say on statute of limitations, and perhaps on equitable tolling.

The only other appellate cases that I was going to touch on were two that came out of the Court of Federal Claims. I commend all those cases to you, if you are interested in reading the decisions that are on the Court of Federal Claims website, but two that I draw your attention are Caves and Jane Doe 93. The reason I call your attention to those are, they are similar cases in terms of the injuries that were alleged, the vaccines involved, the issues that were involved in the case, and there are exact opposite conclusions by the judges that heard the case.

In both instances, in front of the special master, the special master found that transverse myelitis was not caused by flu vaccine. In both instances the special master found that the theory that the petitioner's expert had relied on was not reliable. In Jane Doe 93, the judge at the Court of Federal Claims said that the special master had used too high a standard in judging the reliability of that theory and reversed the decision and remanded it back to the special master, with instructions to rehear the matter and redecide it.

In Caves, the other case that involved this issue, the same issue, different result. The Court of Federal Claims judge there said that the special master was appropriate in rejecting the expert's theory, used appropriate standards to measure the reliability of the petitioner's expert's theory.

I suspect that Caves will be appealed by the petitioner, so it will go to the Court of Appeals for the Federal Circuit. Jane Doe 93, since it's back in front of the special master, won't be on that same track. It won't be ripe for appeal to the Federal Circuit until sometime in the future. So Caves is likely to go there first.

I did want to mention, on the slides that give you the stipulations that were filed, it also gives you the time it took from the case first being filed to the

stipulation being filed in the case. There is a wide range in terms of the number of months that it has taken to get these cases done, but they trend towards one end of that spectrum. There are a couple of outlier cases. They both involve hepatitis B vaccine. They were both stayed for a number of years during the hepatitis B omnibus proceeding that the court had convened. Those look to be kind of outlier cases. There was one that was nine years and eight months and one that was 11 years and some months.

What I thought was interesting -- and I wanted to see what it looked like -- was, if you added up all that time, if you reduced it to months -- say, nine years and eight months equal however many months -- and you added all those up for all the cases that were settled during this period, and then you divided it by the number of cases, which was 74, what would be the average time it took from data filing to the time the stipulation was filed? Not being good at math, I got somebody else to do that. What we came up with was, if you looked at all these cases, 22 months from filing to the stipulation was the average time. If you took those two outliers -- I do consider them outliers, the nine-year and the 11-year case -- out, then it was 19 months.

We obviously would like to see that lower if we could, but that’s not bad, really. We’re getting to where

we are moving the case along in a pretty efficient manner, at least as far as those that go through settlement.

I imagine this has been touched on before. A lot of factors go into how long it takes to get a case from time of filing to resolution. One of the big factors is just how complete it is when it actually gets filed. Obviously, the more complete it is when it's filed, the faster it is to resolution.

But I think that timeframe of getting these resolved -- again, we would like to push that even lower, but if we're down to about a year and a half, I don't think the cases that actually go through hearings and go all the through to a decision will rival that in terms of speed at which it's resolved. I think that is one of the factors that goes into parties' decision-making process when they decide whether or not to settle a case before the special master actually goes through the process of having a trial on the matter. The speed at which it's resolved is an attraction for parties.

So those are just some insights. I may be giving myself too much credit to say they are insights. They are just some thoughts, based on what I have seen in the statistics and overall what I have seen in what's going on with the program.

I'm happy to be speaking in front of the

Commission. It's a real pleasure to be back in front of you all. I really admire the work you do. I would be happy to take any questions that you have.

MS. HOIBERG: We are still awake. Thank you very much.

MR. KING: I thought this was very helpful and explained very well. Thank you for that.

When you started, you talked about the remarks related to some of the questions that I had of Geoff earlier on the disparity of the data. Literally, it's because of a different snapshot in time. You have given thought to the idea that maybe there is something that could be done between now and the next meeting. I don't whether that's your responsibility, our responsibility, whose responsibility. But if there is a way to do something like that, I know, from my perspective, I would certainly appreciate it. I really don't know whose domain that falls in.

MR. MATANOSKI: What I would suggest is that we here at DOJ would get together with HHS and see if there's a way that can -- since we are looking at different snapshots, there may be value in seeing both of those -- if we can look at a way that makes it clearer what it is you are looking at, so there is less confusion. I hear you. I had the same thoughts. Maybe it's just because I came back

to this after being away for a while. But I could see where there would be questions and would like to do a better job of being able to make sure you don't have questions. Even if we are giving you the same information, if we are going to continue to give you that information, we would like to have it presented in a way that's not confusing. When you look at it, at first blush, it is confusing. At least it confuses me. And maybe I'm not a good guide because I'm not all that smart.

MR. KING: Together, we are the same.

MR. MATANOSKI: Maybe if both work on it together, maybe we'll come up with answers. Separately, I'm with you. I'm having trouble.

MS. DREW: Vince, thank you very much for a really informative report. I guess we are putting you in charge of expanding the glossary a little bit to include the terms that Sarah mentioned in all upcoming statistical reports. Since we have kind of a constant turnover of commissioners, as they come on, I'm sure that they appreciate going over things that people who have been on longer understand.

So thank you again. I guess we'll move on now to Dan Salmon.

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

DR. SALMON: Thanks. I have a fairly brief update. It's really about the Vaccine Safety Working Group and the NVAC.

The Vaccine Safety Working Group -- I have provided you folks an update on their work before. They are developing a white paper on how enhancements can be made to our safety system. There is a draft of that white paper that went out about a month ago. There is a stakeholder meeting on Monday. That stakeholder meeting is an opportunity for the working group and the NVAC to hear from a broad range of stakeholders what they think of the draft white paper. It's set up as a series of panels -- medical associations, public health associations, consumer groups, and then kind of an "other" group that is fairly broad. Each of the panelists will provide the working group and NVAC members that are in attendance their impressions of the draft report and suggestions for how to make it stronger or to revise it accordingly. This is a full-day meeting.

On Tuesday and Wednesday is the actual full NVAC meeting, and on Tuesday in the late morning there will be discussion and deliberation of that report. It's anticipated that a vote on the report will be at the

September NVAC meeting.

So that's really all that I have. If anyone is interested in looking at the draft report, it is available online, on our website. Let me just end there. I'm happy to take any questions.

MS. DREW: It doesn't seem like there are any questions. Thank you very much, Dr. Salmon. We'll see you next time.

DR. SALMON: Thank you.

MS. DREW: We are just about half an hour ahead of ourselves here on the schedule. I have a feeling that the vaccine information statement portion of our meeting is going to be longer than the 15 minutes that we have scheduled for that, so unless anybody really wants to take a break now, I believe that Ms. Hamborsky is available.

MS. HAMBORSKY: Yes, I'm here, and so is Skip.

MS. DREW: Would it be all right with everybody if we go ahead with the information statement review?

("Yeses")

MS. DREW: I will put you in charge, Ms. Hamborsky. Let us know what you want us to do and what to do first.

Agenda Item: Review of Vaccine Information Statements, Ms. Jennifer Hamborsky

MS. HAMBORSKY: Okay. The first statement that

you would have received would have been the HPV statements. There were only minor, minor changes to those since the last time the committee members reviewed them. Basically, all that was changed was that we incorporated the indication for the prevention of anal cancer into Gardasil. Any comments other than that addition are probably ones -- I'm not sure if you guys have a lot of comments, but that's the only new information on HPV.

MS. DREW: Does anybody have any comments on the HPV business?

MS. HOIBERG: My only question was on the first one that we did, which, I guess, is for the -- which is the first one? Is this the Gardasil? It talks about HPV vaccines in section 4, the second paragraph: "HPV vaccine is not recommended for pregnant women. However, receiving HPV when pregnant is not a reason to consider terminating the pregnancy."

Isn't that kind of harsh? Maybe you could say it may not pose a threat to the fetus or something of that nature. I don't know. To me, it was kind of shocking to see that.

MR. WOLFE: I think that is the language ACIP uses. I agree. It is different from saying that there's no -- saying that there is not a reason to terminate the pregnancy and saying that there is on risk are really two

different things. We would have to clear that wording with the epidemiologists here before making the change.

MS. HOIBERG: That just shocked me. I stopped and had to read it three or four times, going, okay, well, pregnant women shouldn't get it, but don't consider terminating your pregnancy if you find out your pregnant after the fact. Have they done tests?

MR. WOLFE: Probably not. You mean to see if women were actually considering terminating the pregnancy?

MS. HOIBERG: No, no, no. Have they don't tests to see if there was harm done to the babies, like mental retardation or deformities or anything of that nature that was caused by the vaccine?

MR. WOLFE: There is probably not enough data. Presumably, there are either none or very few instances of pregnant women getting the vaccine, so there is probably not enough data to make any definitive statement.

MS. HAMBORSKY: And there is an HPV pregnancy registry. They are trying to capture that information. The next bullet does say that if you are inadvertently vaccinated, to contact the registry.

MR. WOLFE: You're right, though. I was kind of shocked by that statement, too.

Dr. FEEMSTER: Maybe it would be helpful to suggest something like, "Data thus far hasn't shown any

adverse events related to immunization while pregnant."

MR. WOLFE: We can certainly run that by people.

DR. GRUBER: Two comments regarding that. I think we are still very much in the data-gathering and finding mode in terms of looking at pregnancy outcome in women that may have received Gardasil vaccine, or the HPV vaccine. So if you say "data have not shown," it implies that there are really data. I would really caution against such a statement.

The other point, just for everybody to know, is that in terms of the FDA labeling, this product would be based on animal studies conducted, and there was no negative finding. Then it states to give the vaccine if clearly needed.

It's okay, from my point of view, to say it's not recommended for pregnant women. However, this language about considering terminating the pregnancy is, in my opinion, very, very harsh, considering the pregnancy category that it has and the fact that there is a pregnancy registry for this vaccine.

Thank you.

MR. WOLFE: And B is fairly unusual among vaccines, too. Most of them are category C.

MS. HAMBORSKY: I think the reason why, probably, this language appears in the ACIP statement is that when it

boils down to it, that's the question women have. If I am inadvertently vaccinated, what do I need to do? I think that's the reason why it's written that way.

MS. HOIBERG: Is there a way to say -- if you know you are pregnant, then you are not going to get the shot, but if you didn't know -- the way it says, "However, receiving HPV vaccine when pregnant" -- how about, if you receive the vaccine and you didn't know you were pregnant, then you can contact this HPV pregnancy registry. That whole thing about -- if I was -- as a mom of two, just seeing that, I was, like, oh, my gosh. Not very many people read this. But that does kind of put a huge scare into a pregnant woman -- "oh, my gosh, what have I done?" It may lead to people going, "Well, maybe I should just terminate just because" -- I don't know -- "maybe my baby is going to come out with two heads or something."

MR. WOLFE: That might be a good compromise, to say, if you are inadvertently vaccinated when you are pregnant, ask your doctor about contacting the registry.

DR. GRUBER: I'm sorry, but you know what? Pregnant women and their health-care providers are encouraged to contact a pregnancy registry in any case, upon inadvertent exposure to the vaccine during pregnancy, if they don't know it or even if they know it. So I would not really make that distinction.

MR. KING: In the paragraph that you are talking about, the immediate paragraph following does talk about what happens if you learn that a woman gets pregnant after.

MR. WOLFE: We already mention that, right. I was thinking of another vaccine where we were just discussing it a couple of minutes ago. Yes, it is.

MS. HOIBERG: I just don't like the whole thing about terminating the pregnancy. That's very harsh.

MS. WILLIAMS: Following on these two paragraphs, I wonder if we could consider -- you start talking about pregnant women or not pregnant and then you talk about breastfeeding and then we talk about pregnancy again. That line about "women who are breastfeeding may get the vaccine" sort of gets lost in that. To me, if you are breastfeeding, you are probably not pregnant. It's possible. Probably there are some. But it just seems to me that that sentence should have its own bullet, unless you want to talk about women who are breastfeeding and who are pregnant.

MR. WOLFE: No, let's not break it down that far.

MS. PRON: I have an issue, since we are on that paragraph, with the first bullet. It says, "Tell your doctor if the person getting vaccinated," et cetera. It's in that line and it's in every line, if you have a reaction, and how you can learn more. I would petition

them to include health-care provider instead of doctor, because many women use midwives, they may see nurse practitioners, et cetera. Children -- later on when we discuss all the other ones -- many of them see nurse practitioners.

MR. WOLFE: Interestingly, we just had that tested in some focus groups, and we went the other way, because, overwhelmingly, parents, even if they know it's a nurse or a midwife or somebody else, prefer the term "doctor."

MS. HAMBORSKY: Right. We actually had some pretty extensive focus groups in five cities. I attended several of them. Overwhelmingly, they said just "doctor." "Provider," interestingly enough -- there was a lot of confusion with the term "health-care provider." They interpreted it as being their insurance carrier. A lot of people, when asked, "What's your health-care provider?" said Blue Cross/Blue Shield, United, Aetna.

MS. PRON: The other issue is -- for other vaccines, not necessarily for HPV -- well, actually some for HPV as well -- they may be getting their vaccines from a nurse.

MR. WOLFE: Right. But no matter who they get it from, they prefer the term "doctor."

MS. PRON: They didn't like "nurse"?

MR. WOLFE: Right. We have changed this many times over the years. We started out by saying “doctor,” then “doctor and nurse.” Then we started getting messages from nurse practitioners saying, why don’t you say nurse practitioners, too? Then pharmacists. That’s when we started using the term “provider.”

MS. HAMBORSKY: Now we’re back to “doctor.”

MS. HOIBERG: I know we are kind of jumping around, but with this particular vaccine, a lot of the people getting it are older females. Maybe they are coming in by themselves. They are 18 or older. Is there any way -- where it says, “Tell your doctor if the patient feels dizzy or lightheaded or has vision changes or ringing in the ears,” could it be to inform them if you yourself or the -- it might be me going in and getting the shot.

MR. WOLFE: The patient would encompass both of those. I hate to add words if we don’t have to. That’s the only objection I have to that.

MS. HOIBERG: Right. That was my only other thing. Other than that, it looks good to me.

MS. PRON: Going to item 6, which is, what if there are severe reactions -- and I know that this is my first time to be reviewing VIS statements, but I’m just wondering, if you are talking about a severe reaction, including breathing difficulties, why they came up with

“call doctor or get the person to a doctor right away.” You shouldn’t really waste time calling; you should be going to an ER, most likely, if you have problems breathing, not even a doctor’s office. They don’t want you in a doctor’s office if you can’t breathe.

DR. HERR: I agree. I was going to comment on the meningococcal vaccine. You talk about difficulty breathing, et cetera. I would say, call an ambulance. Don’t call the doctor.

MS. HOIBERG: Yes, call 911. If you have a severe reaction --

DR. HERR: If you can’t breathe, call 911.

MR. WOLFE: Several years ago, we actually discussed that in an ACCV meeting, and at that time the Commission said, “No. Forget 911. Say to call a doctor.” I can’t remember why.

MS. HAMBORSKY: I think the rationale was that -- as I remember, they said that if your child is not breathing, you’re going to call 911 anyway. You are probably not going to get your VIS out to call your doctor. There was some concern that people would be calling 911 or going to an emergency department for other reactions.

MR. KING: Probably an over-reaction on some people’s --

MS. HAMBORSKY: Right. That’s what the concern

was. So that's why we said, call the doctor or get the person to a doctor right away. Pretty much everybody agreed that if your kid is not breathing, you are going to call 911.

MR. WOLFE: What if we suggested just taking out the "call a doctor" part and just say, "Get the person to a doctor right away"?

MS. PRON: I would feel better about that.

MR. WOLFE: If people are going to call, they are going to call.

MS. WILLIAMS: One, I don't know -- someone on the call may know -- 911 may not be nationwide. It certainly is extensive, but I would have to check to know if 911 was used absolutely everywhere.

The other thing is, I'm not so sure that "get somebody to a doctor" is as good as calling 911. Then you get these people putting somebody not breathing in a car when they should be calling an ambulance.

MS. HOIBERG: I totally agree. When it happened with my daughter, I was on the phone with 911. I didn't even bother calling her pediatrician. Forget that. She was dying in my arms. I had to call 911. For the most part, I think people are going to, but sometimes you have to hold their hands.

DR. HERR: I agree. I think the other thing we

want to push is that we hope that people are going to read these information sheets before there is a problem and before anything happens, rather than waiting until something happens and then saying, “Oh, where’s that piece of paper they gave me.”

MS. PRON: I guess I just worry about having them reflect inaccurate information. That “call a doctor or get them to a doctor right away” is really less accurate than the reality of the situation.

MS. HOIBERG: I mean, like, honestly, would you take -- you know, I wasn’t going to take Kaitlin to her pediatrician. I would have taken her to a hospital. If a person is having a severe reaction, they need the hospital, not --

MS. PRON: Absolutely. I agree with you. But the VIS statement isn’t reflecting reality there.

MS. HOIBERG: Right. Why don’t we say, “Get the person to a hospital” --

MR. WOLFE: How about if we say a hospital closer than 200 miles away? If they get in their car and start driving 200 miles to the nearest hospital -- we don’t want to say that either.

MS. HOIBERG: What if we say to get them to a hospital or emergency center --

MR. WOLFE: If we say to get them to a doctor, I

think people are going to interpret that as a hospital, if there is a hospital very close.

PARTICIPANT: Why don't you say, "Get emergency assistance"?

MS. PRON: I would agree with that.

MR. WOLFE: Because they might call the fire department. I don't know.

PARTICIPANT: That's okay.

MS. HOIBERG: That's okay. At least our EMTs have oxygen. Our fire trucks --

DR. GIDUDU: Here I think the worries are not -- the longer you delay in administering the drug, the worse for the patient. So I think getting to the doctor is the right thing to do.

MS. HOIBERG: We want to get them to the doctor, Dr. Gidudu, but we can't -- I guess we're just trying to -- you are not going to bring the kid back to the pediatrician. My pediatrician couldn't have done anything for her. They don't have oxygen and stuff. I don't believe they do. They need to get to an emergency help station, something that can help --

MR. WOLFE: Supposedly doctors' offices should be prepared to deal with anaphylaxis, but I guess that doesn't mean that all of them can.

MS. PRON: But it also doesn't mean they can help

with breathing necessarily. Then they are going to have to call 911. It's delay.

MS. HOIBERG: I don't know -- Dr. Tom, do you carry like an intubation kit in your --

DR. HERR: We have things available, where if something happens in the office, we can take care of it while somebody comes to help. But if somebody is not breathing, I'm not going to call them to my office. It's less qualified and less enabled to help someone who is having a lot of problems.

MS. HOIBERG: All our doctors' offices, when you call, the very first thing it says is, "If this is a life-threatening emergency, please hang up and dial 911."

DR. HERR: I think some of our things on these discussions -- if it's a minor or moderate question of an allergic reaction, you can call the doctor. If we are talking about this under the serious part, then I think the fact that it's serious -- I think it's reasonable to go that way. I think there is certainly some concern of overburdening the system with somebody who really isn't all that sick, but on the other hand, it happens all the time. It happens all the time when somebody says, "I'm having trouble breathing," and you end up going to the emergency room, and you are not having trouble breathing at all. But I think on this kind of stuff, under the serious reaction

part, it’s reasonable to say emergency care, whether it’s through ambulance, whether it’s through emergency room, whether it’s through a hospital. I think “emergency services” is a very reasonable thing to say, because it is thought to be serious.

MR. WOLFE: We can look at this and try to come up with some kind of wording that encompasses all of this as efficiently as we can.

MS. HAMBORSKY: I remember there was some discussion that we have to tease out -- you definitely wouldn’t want someone calling 911 for a rash and you wouldn’t want them calling it for swelling, but you would want it for swelling of the mouth and lips or if they weren’t breathing. There was a huge, long discussion about teasing out by symptom.

DR. GIDUDU: The problem there is that anaphylaxis -- all these symptoms will be unfolding together.

MS. HAMBORSKY: But specifically rash was what people had concern about. They didn’t want someone calling 911 for a rash.

MS. HOIBERG: You can get a life-threatening rash. A rash could be the beginnings of -- I mean, I know with some of the medications, you can get a life-threatening rash. That’s one of the things I had to look

for. I don't know if -- if you are having an allergic reaction and your whole, entire body breaks out in life-threatening hives, that's a rash. I don't think there needs to be a fear of overburdening the system. I think you need to be more fearful of getting these people -- giving them correct information. I would rather have them call 911 for a rash and it end up being nothing than for them not to call or just try to call their doctor -- "oh, it's busy. I guess I'll call later."

MR. KING: I think your point is well-taken.

PARTICIPANT: One comment I would like to make, not about this specific one, but about all of them in general -- if our problem here is anaphylaxis, shouldn't all of the VISs be consistent? Just looking at the influenza vaccines, they have sort of different wording for what to do if you have a severe allergic reaction, and then they describe the reaction differently. It seems to me that they should all be the same.

MR. WOLFE: They mostly are. I think somebody might have suggested slightly different wording on the flu ones. I can't remember offhand how it differs. But generally they are consistent.

MS. PRON: Actually, the meningococcal vaccine lists severe and moderate together, which sort of muddies the waters.

MR. WOLFE: We may have let that slip in there by mistake. Generally, I think we are getting rid of the term “moderate” and just saying “severe.”

MS. PRON: This is bullet 6, when we get to that one, meningitis.

MR. KING: I have a question. This may be throwing a monkey wrench into things. Along the severe reaction -- and we may be ahead of ourselves, because I know that tomorrow we talk about the chronic regional pain syndrome and how that may be an antecedent, possibly, to the vaccine administration itself. I guess what I’m saying is, what should I look for? Except for the intranasal for the live flu vaccine, should we have something in there that relates to that as well, in terms of what I should look for?

MS. HOIBERG: Are we still on the HPV?

MR. KING: We’re on all of them now -- well, we’re on all of them except the live intranasal, any injection.

MS. HAMBORSKY: You are saying that there is new safety data that is being presented later?

MR. KING: I’m saying that tomorrow, in the “In Summary” component of the chronic regional pain syndrome, it says, “The vaccine administration itself or the local injection reaction may serve as the antecedent injury that

leads to chronic regional pain syndrome."

Additionally, it says that they are three times more frequently diagnosed in women and that the number of cases among adolescents and young adults is increasing. That's under the "Susceptibility" component.

DR. GRUBER: That data is coming -- what's the data source for that piece?

MR. KING: It's a slide presentation that we were given that is going to be covered on day two in the agenda. But my concern is that it may have an impact for information that we are relating right now as we talk about this.

GRUBER: That's true, but I'm still unclear as to the data source.

DR. EVANS: This is a case series from our claim that is going to be presented by one of the medical officers tomorrow.

MS. HAMBORSKY: It sounds more like that would be in the contraindications of future vaccination, not in what to look for as an adverse reaction after vaccination, if I'm understanding it correctly. I'm not familiar with this regional pain syndrome data. But it's saying that if someone gets this regional pain, you wouldn't do another injection in the same site? We have not seen that, so we're not sure. But that would be something that ACIP

would have to address for us to make major changes.

DR. HERR: I am not sure whether we are really trying to make these vaccine information sheets sort of a dictionary of all the potential problems that could happen down the road with a particular vaccine. I think the idea on this part is looking for immediate serious, life-threatening events that the patient and the family should be aware of, not necessarily something that may happen a week from now, three months from now, six months from now, depending upon the situation.

So I think we are looking at two different things. It's not to say that one symptom or syndrome may be ultimately caused by the vaccine in certain individuals, but what we are now looking for is, what is an immediate response that we have to be extremely concerned about, and what do we recommend people to do about it?

MR. WOLFE: Yes, because the former case is something that may be an adverse event, and that would go under section 5, what the risks are, not under "what do I do if there's an anaphylactic reaction or a severe reaction now?"

MR. KING: It does say that early signs indicative of this can begin minutes to months after the injury, most often within hours or a few days.

MR. WOLFE: Is that a life-threatening condition?

What exactly are the --

MR. KING: It says, extreme sensitivity to stimuli, local swelling, a change in skin temperature and/or color -- that sounds like a rash, potentially -- joint tenderness and stiffness, abnormally increased sweating. I don't know. If I'm suddenly going to start sweating and I haven't exerted a lot, I might think I have something, like a fever or something along those lines.

MR. WOLFE: As Jennifer said, I think we need to wait for ACIP to weigh in on that before we can make any changes, because that's where we get our --

MR. KING: Are they even aware of it to weigh in on it?

MR. WOLFE: I don't know.

MS. HAMBORSKY: Is that what used to be called RSD, or reflex sympathetic dystrophy?

MR. KING: I believe that that is correct.

MS. HAMBORSKY: We have never had RSD -- ACIP has never addressed RSD as a contraindication to vaccination. There may be new data coming out, but none of the ACIP statements list RSD as a contraindication for vacation.

DR. EVANS: This has to be taken in context. It's a case series that the staff has put together that will be explained tomorrow, and maybe some of these questions will make more sense then. But as is being said,

we can certainly raise these questions as a potential signal, as other passive surveillance systems can do also. It's up to ACIP to consider these when they are talking about their usage recommendations. So this is a first step in that process.

MS. PRON: I just wanted to clarify also that -- I know that we are interested in giving folks information about a severe reaction, but the majority of folks will have a mild reaction. For my patients at least, it's helpful for them to see in print what I have just reviewed with them and tell them what they should do about it if they have side effects, not a severe reaction. It's just a clarification.

MS. HAMBORSKY: Were there any other comments on HPV?

MS. HOIBERG: No. That was all I had.

MS. HAMBORSKY: Let's move on to influenza. Basically, the changes in both inactivated and live influenza from last year -- the main changes were that we removed references to the pandemic H1N1. That's not really relevant anymore. There used to be wording in there related to whether people had received monovalent H1N1. But since this season the H1N1 was in the trivalent vaccine, that language was removed.

We also changed some language about egg

allergies. The subject-matter experts have indicated that that is no longer just an unequivocal contraindication.

We dropped the wording about TIV being injected into a muscle because of the new intradermal-indication TIV. Also we have retained the precaution for Afluria. That may change after the ACIP meetings a week and a half from now, but for now it's still on the VIS.

MS. HOIBERG: I was looking at this, because one of them said about if you had received a vaccine within the past four weeks, you should possibly wait.

PARTICIPANT: That's probably for the live attenuated.

MR. WOLFE: That may have been under the LAIV. That actually came from --

PARTICIPANT: We did that.

MS. HOIBERG: Right, we did that. But then it says on here, down a line, that it can be given with other vaccines.

MR. WOLFE: It can be.

MS. HOIBERG: What's the point? I don't understand why -- explain, please. What's the difference?

MR. WOLFE: Two live vaccines can be given simultaneously, but if they are not given simultaneously, they have to be separated by four weeks.

DR. HERR: On the LAIV sheet, I think the

statement about whether somebody has asthma or not is still a little stronger than it has been in the past.

MR. WOLFE: What number is that?

DR. HERR: It is on the second page of the LAIV sheet, number 4, second bullet: Children younger than 5 years of age with asthma or one or more episodes of wheezing within the past year. I have sat in conferences with pediatric allergists, and, golly, some of these kids -- one wheezing episode a year is really little, and they may be fairly healthy. In the past some of the discussion has been on children with serious asthma -- please discuss this with your doctor or provider, however you want to call those, and leave it up to that person to decide how sick that person is. If they are coming in frequently with asthma, of course you don't want to give them a shot. But if they had one episode of wheezing, for a day or so, in January and they are coming in in September for their flu vaccine, it's probably not relevant.

MS. HAMBORSKY: Unfortunately, this is the exact wording from the statement. You're right. Just on a personal note, I have a child who has had wheezing, but her pediatrician gave her LAIV. I was, like, "Wait. That's a contraindication."

DR. HERR: Go for it. I'm with that person.

MS. HAMBORSKY: That's what I'm saying. My

daughter's pediatrician is, like, "Oh, she doesn't have asthma. It's a better vaccine. She has only been wheezing a couple of times. Give her the LAIV."

But, unfortunately, because that's what it says in the statement, that's what we have to have on the VIS. It is a clinical judgment.

DR. HERR: And it's really only the kids under the age of 2 who had any problems during the studies with LAV.

MS. HAMBORSKY: We can ask the subject-matter experts if there is going to be any -- we don't have a final ACIP statement yet. I don't know if it will be addressed, if the wording will be any different in the upcoming statement. But this is what is currently published.

MR. WOLFE: We can't contradict that. And as far as I know, the people who are working on the ACIP statement -- I don't think that's going to change. But we'll see.

DR. GRUBER: In terms of the prescribing information, the labeling for FluMist, under the warnings and precautions section, it states that FluMist should not be administered to small children less than 5 years of age with recurrent wheezing because of the potential for increased risk of wheezing post-vaccination.

DR. HERR: That says recurrent. That's more than one.

DR. GRUBER: I just wanted to make that comment. Thank you.

DR. HERR: Marion, I'm sorry. I'm just kind of teasing, but it is true.

DR. GRUBER: We'll talk more in a little while.

MS. HAMBORSKY: That's what it comes down to. We need a definition of recurrent. But for the VIS, we can't change that.

DR. HERR: Okay.

MS. HOIBERG: When it talks about what the risks are of LAIV and then they talk about the mild problems, I think this is where people run into believing that they have gotten the flu from the flu shot. A lot of the side effects are flu-like symptoms. It seems to be more so with, of course, the live attenuated than the inactivated.

MR. WOLFE: Sarah, are you suggesting making a change?

MS. HOIBERG: I just don't understand. I remember going over the influenza ones a couple of -- what was it, last year that we went over the --

MR. WOLFE: Probably every year.

MS. HOIBERG: And I think I always make the same thing. Why am I going to get it then, if my kid is still

going to get a runny nose and possible vomiting and fever and wheezing and headache and diarrhea and all that kind of stuff. I mean, that's just not pleasant.

MR. WOLFE: Under number 6, the second paragraph, where it say it does not cause influenza, but can cause mild symptoms, and then it describes the symptoms, do you think we should say more than that?

MS. HOIBERG: Well, I mean, I guess it's just like -- I guess you can't reassure them that they don't get the flu, because they are going to possibly get the flu that they are not being vaccinated against. I don't know. I'm glad that we have all the side effects here, and this is possibly what's going to happen.

DR. HERR: The truth is that they do get infected. That's the whole idea.

MS. HOIBERG: That's the idea. You are not getting the full-blown flu, but you are getting the flu. It's going to be there for one to two days. You are getting the flu. It's not the big mama flu, but it's still the flu, because you are giving them live virus.

MR. WOLFE: I wish we could use that wording -- "not the big mama."

MS. FEEMSTER: I think it is important to note that it says that children and adolescents of 2 to 17 years of age have reported these symptoms, and that it's not

definitively a causative statement, that they got the vaccine and the vaccine caused these symptoms.

MR. WOLFE: Right. No, we can't say that.

MS. FEEMSTER: When we have addressed this issue with staff, because we have a mandatory flu vaccine program, one response that we have tried to say is that a lot of people have reported these symptoms after vaccination, but there are many other respiratory viruses that are in circulation at the same time. It's important to distinguish between saying it's definitely the vaccine that is doing this and it's because these symptoms are happening and people can get vaccinated at the same time that they may develop another virus.

I think it's important to have the statement that this is the weakened virus. It does not cause influenza. The vaccine is supposed to induce an immune response. There have been reports of these symptoms, but -- I can see that it can be difficult to interpret, but it is "have reported" and not "the vaccine causes these symptoms."

MS. HAMBORSKY: Right.

MS. HOIBERG: It's fine. If you read over them, the third or fourth time you see every -- like, I didn't see that "LAV may" -- you know, that the vaccine can cause mild symptoms.

MR. WOLFE: Unfortunately, when parents read them

in the doctor's office, they are going to skim over them, too. But there's not much we can do about that.

Incidentally, FDA has given us a few comments on these. Those comments aren't reflected in the ones that you got because we just got them back a couple of days ago. One of the comments that they made -- where we say protection lasts about a year, they suggested, instead of saying "about a year," saying "lasts through the influenza season," just so it won't make people think they don't have to get the vaccine the following year.

MS. HOIBERG: The other thing I wanted to ask about was, where we talk about GBS -- I have been on the Commission now for three years, I guess. We did have the whole thing with the signals going up -- weak, but they were still signals for GBS. I can't remember if that was -- and, Dr. Gidudu, maybe you can clarify -- was that just with H1N1? Were we just talking about H1N1 or were we talking about the actual seasonal influenza?

DR. GIDUDU: I think it was the H1N1.

MS. HOIBERG: But now the H1N1 -- is this live attenuated -- does this one include the H1N1?

MR. WOLFE: Yes.

MS. HOIBERG: So I guess, with -- we have had quite a few cases. And, yes, millions of vaccines are given out every year, and we get a couple hundred reports.

But in order for it to have caused a signal, it had -- the numbers were really, really, really high, if I remember, and then for it to cause a signal, that would be like -- and I guess I was -- it was explained to me that -- say they said, okay, we're expecting to see 50,000 cases or 80,000 cases of GBS. That's going to be acceptable. Then anything above that would cause a signal. There were signals in like three out of the five reporting systems, if I'm remembering my numbers correctly. But there were quite a few signals. Weak as they were, they were still signals for GBS.

So I just feel like it's kind of not given its weight here.

MS. HAMBORSKY: They may be going to present additional information at the ACIP meeting next week about that. But as of right now, we don't have anything that we could say any additional information. Plus, if those were the signals that were from single-antigen H1N1, I don't know if the data -- Dr. Gidudu might know better at this point -- would be coming in from the most recent season with the H1N1 in the trivalent vaccine. Maybe that's what they are going to present at ACIP next week. But until it's presented and the data is published, we can't really change anything in the VIS, because it has to come from the ACIP statement.

MS. HOIBERG: Because we all know that GBS is caused -- you can get GBS from the flu itself. It's not a far cry that if you are prone to it -- I think that it's good that you have it in there that if you have ever had GBS, you need to inform your doctor and that you should maybe not get the shot if you have had it.

MR. WOLFE: That is part of the ACIP recommendation.

MS. HOIBERG: Right, and I think that's good. I'm glad that that is in there and I commend them for that. I feel like that's a step toward the more transparent -- being more transparent as far as possible reactions.

Anyway, that's all I have.

MS. HAMBORSKY: Was there anything else on the LAIV?

MR. WOLFE: Or the TIV, as long as we are looking at both of them?

MS. DREW: No, I think that was it.

MR. KING: I have a question. On the inactivated -- the shot that is given -- where you say some inactivated vaccine contains the preservative thimerosal, is it that people would know that they -- do people have a negative reaction to thimerosal?

MS. HOIBERG: Yes, that is the mercury.

MR. KING: That's the mercury, okay.

MR. WOLFE: People are afraid of it, at least, so we need to tell them that it's there in some of the vaccines.

MR. KING: Will they understand that that's mercury?

MR. WOLFE: Maybe not. It's interesting that you bring that up. Another one of the suggestions that FDA made was that we make that explicit.

DR. GRUBER: Yes, that's true, Skip. We thought that needs to be made explicit, and we have suggested some wording.

MS. HOIBERG: Dr. Marion Gruber, is there a reason why thimerosal is -- and in such a large amount -- in the flu vaccine?

DR. GRUBER: Why are you saying in such a large amount? The point is that our law requires the presence of a preservative in multi-dose vials of vaccine, and influenza vaccines are made in vials that are either multi-dose vials or single-dose vials or prefilled syringes. If it's a single-dose vial or a prefilled syringe, there is no requirement for a preservative. These influenza vaccines do not contain preservatives -- in this case, thimerosal. Multi-dose vials, however, will contain thimerosal.

MS. HOIBERG: But we were also told that it did have more thimerosal than the other vaccines out there that

are now considered to be --

GRUBER: The doses are 25 micrograms mercury per .5 milliliter dose. That is really driven by a test that the manufacturer has to conduct to show that the preservative is effective in terms of inhibiting growth of contaminating germs.

MR. WOLFE: In the other childhood vaccines that contain thimerosal, it's not there as a preservative; it's there as a remnant of the manufacturing process.

DR. GRUBER: And I really wouldn't refer to the other childhood vaccines. There are, I think, two or three which contain a trace amount of thimerosal, but not, as you stated, as a preservative. That was just during the manufacturing process. There are some trace amounts left. But there is a big difference here, yes.

MR. WOLFE: I think only TD and other vaccines that are not for infants are the only other ones that actually contain thimerosal as a preservative. I think TD might be the only one.

DR. GRUBER: There is one, TD. But that is a vaccine that is not even usually recommended. It's actually tetanus toxoid vaccine. That's for those people who can't, for some reason, not take the diphtheria toxoid-containing vaccine. That's right.

MS. HAMBORSKY: Any other comments?

We are going to go on now to meningococcal. There were two major changes with meningococcal. The main one had to do with the change in the licensing. Also, as we mentioned earlier, FDA was reviewing this concurrently, and FDA had a lot of changes and suggestions that were not incorporated into the version that you would have received. Skip is going to go through and add some additional information that you guys don't have yet.

Let's first talk about what changes you did have.

MR. WOLFE: And there are not that many, actually, from FDA either. They are specifically in a couple of places. We will get into those in a few minutes.

MS. HOIBERG: What is the real difference between the MCV4 and the MPSV4? Is it stronger one that you would be giving to older people?

MR. WOLFE: The MPSV4 is a pure polysaccharide vaccine. The MCF4 is what they call a conjugated vaccine, where there is a protein carrier attached to the polysaccharide that makes it more efficient. Usually the polysaccharide vaccines don't work very well in children, and they are not very good for boosters. The conjugated vaccine, in a nutshell, is better for kids and it's better for boosting than the polysaccharide. And the polysaccharide -- no, I'm sorry, I was thinking of pneumococcal. They do have the same number of components.

MR. SMITH: I have a question on section 4. It's the last bullet. It's right above section 5. It makes reference to MCV4 and MPSV4 and administration to pregnant women. The last line reads, "It should be used only if clearly needed." I think the "it" refers to MCV4, which is the recommendation in the package insert. I guess my question is, MPSV4 has the same recommendation in the package insert, but yet it's not referenced in that last section. Is that done on purpose?

MR. WOLFE: We should be saying "they?"

MR. SMITH: "They," correct.

MR. WOLFE: The wording is not exactly the same. "Have not documented adverse effects."

Actually, the ACIP for the polysaccharide vaccine says pregnancy should not preclude vaccination with MPSV4 if indicated. So the wording is slightly different in the ACIP statements.

MR. SMITH: I guess I was looking at -- I'm pretty sure it's a polysaccharide -- MedImmune and at least the recommendation in the FDA-approved package insert. It has something along those lines, but the last line in that section of the PI does say it should be given if clearly needed.

MR. WOLFE: If we have to change it somehow, we do need to make sure that statement encompasses both

vaccines.

DR. GRUBER: I am sorry that I have to chime in here again. Just for clarification, yes, the prescribing information for MPSV4 has a category C, and so has MCV4. That “should be given if clearly needed” is directly from our Code of Federal Regulations. It’s prescribed language that we have to use.

But the point to be made is that both vaccines can be given if clearly needed, and they are not contraindicated for use in pregnancy.

Reading this bullet makes me think of yet something else. If you say MCV4 is a fairly new vaccine and has not been studied in pregnant women as much as MPSV4 has, that sort of implies that there are actually studies in pregnant women with the polysaccharide vaccine, and I am not aware of any of those.

MR. WOLFE: Oh, okay. That’s interesting.

MS. DREW: I have three comments on this.

First of all, you need the language statement up at the beginning of the VIS, the one that says this is translated into a bunch of different languages.

MR. WOLFE: That just didn’t show up in the Word document.

MS. DREW: Okay, that’s fine.

In number 2, the first full paragraph after the

bullets, it ends with “but they do protect many people who might become sick if they didn’t get the vaccine.” That seems to be saying they protect the people that they protect. It doesn’t make language sense to me. I’m not really sure what you are saying there.

MR. WOLFE: Maybe it is not worded well, but I guess the point is that there are a number of serotypes that the vaccine does not protect against. But it does protect against some of them.

MS. DREW: Maybe we should try to think of some better wording for that. I know you are trying to say something, but it just isn’t clear.

I think maybe along the same lines, the last sentence in 5 says, “MCV4 should be better at preventing the disease from spreading from person to person.” That’s a really bad sentence. It should be better than it is? It should be better than the other vaccine? What is it that we are saying?

MR. WOLFE: Where is this?

MS. DREW: In number 2, the last full sentence.

MR. WOLFE: It should be the better of the two vaccines.

MS. DREW: That’s kind of what I thought, but it implies something else.

Okay, that’s all I have.

MS. PRON: I just want to bring up number 6, where it does say, what if there is a moderate or severe reaction, and what should I do? You were thinking that you were going to take that word “moderate” out.

MR. WOLFE: Probably. How does the Commission feel about that.

MS. PRON: There’s no definition. It just says mild problems and severe problems.

MR. WOLFE: That was a holdover. We used to say moderate or severe for all of them, and then at one point we thought, well, we don’t really define moderate; why don’t we just say severe. If somebody has a problem, they are going to think it’s severe anyway.

MS. PRON: Severe allergic reaction, serious allergic reaction. The rest of the paragraph is all the same.

I think you should just take out “moderate.” That’s my opinion.

MR. WOLFE: Okay, I’m happy to go along with that.

MS. HOIBERG: This whole thing -- what should I do? Call a doctor or get the person to a doctor right away. Tell your doctor what happened, the date and time it happened, and when the vaccination was given. This is kind of like after the thought, after you have gotten yourself

taken care of. If you have just had the shot, if this has happened -- this happens within hours, maybe a day later -- I don't know.

MR. WOLFE: I don't think we are implying that if you call the doctor, you need to tell him all that stuff right then, but at some time you should.

This language has been part of the VISs for --

MS. HOIBERG: Oh, I know it has. We have played with it probably every time. We always find something else to pick up.

MR. WOLFE: Certainly we are willing to change if we can make it better.

MS. HOIBERG: I think it looks okay to me, aside from that.

MR. WOLFE: Let me bring up -- this is under number 2 -- FDA suggests mentioning that there are two different vaccines. We have Menveo and we have Menactra for the MCV4. It also suggests mentioning the difference in the age approvals for those, which are different.

What do you think about that? My opinion is that from the parents' point of view, that doesn't matter, because the recommendations are the same for both vaccines.

DR. GRUBER: I think I need to clarify. Perhaps our comment was misunderstood. I don't think it is really needed here to spell out the number of vaccines available.

We were just concerned that the bullet, “Meningococcal conjugate vaccine is the preferred vaccine for people younger than 55 years of age,” is a little bit misleading. If you want to be precise and really look at the data that are generated, one of the vaccines is approved for 2 years and up and the other one carries an indication of 9 months and up. There is no such thing right now, no product license for kids or for individuals less than 9 months of age. We were saying, if you say people younger than 55 years of age, technically that includes newborns, and we don’t really have any data.

That’s where we wanted to go. I think it’s a little bit of a sweeping statement to say it’s the preferred vaccine for people younger than 55 years of age, without basically making some description about the age cutoff. I think that was our point.

MR. WOLFE: We usually don’t mention the minimum age for a vaccine unless it’s relevant to the ages when it’s recommended. Meningococcal vaccine is not recommended for kids that young anyway. That’s why we don’t mention it, because if you follow the recommendations, you are not going to be giving it to kids younger than 11 anyhow.

DR. GRUBER: Again, this is a suggestion that we had, to add some more precision to the VIS. I guess that’s our point.

MR. WOLFE: Okay.

MS. DREW: Did you say that you were going to use the brand name in this?

MR. WOLFE: No. Generally we don't if we don't have to. For example, we have the two VISs for HPV because the recommendations are different. But where the recommendations are the same, we don't want to confuse people by using brand names.

MS. HAMBORSKY: Have we gotten everybody's comments?

MS. DREW: I believe so.

MS. HAMBORSKY: Thank you so much, everyone, for your time and your comments. We don't anticipate there being any major changes to any of these, but there may be some minor changes that come out of the ACIP meeting next week. Other than that, thank you so much for your time.

MS. DREW: Thank you.

It is a little bit after 3:00, and this is probably a good time to take a break. Does anyone feel the need to take longer than a 15-minute break? Does anybody need to accomplish anything, other than the usual?

Why don't we take a 15- or 20-minute break and come back at 3:30 Eastern time?

(Brief recess)

MS. DREW: Dr. Gidudu, from the Immunization

Safety Office, is here to give her report. I think we'll go directly to her.

Agenda Item: Update on Immunization Safety Office, Dr. Jane Gidudu, ISO

DR. GIDUDU: Good afternoon, everybody, and thanks again for having me.

In March, I provided an overview of the key projects within our office. For today, I will be talking about the scientific agenda of our office and our office's contribution to the H1N1 safety monitoring, for the new people. I'll give a brief update on febrile seizures in young children following concomitant use of the 2010-2011 current trivalent inactivated vaccine and the 13-valent pneumococcal vaccine that will be presented in the ACIP later this month. I will give a brief communication update and publications.

Within our office, our office has four main surveillance projects that conduct vaccine safety scientific activities:

· The Vaccine Adverse Event Reporting System, or VAERS.

· The Vaccine Safety Datalink, or VSD.

· The Clinical Immunization Safety Assessment, or CISA.

· The Vaccine Analytic Unit.

Moving on to the next slide, I'm going to be talking a bit about ISO scientific agenda.

Some background on the scientific agenda: The process of developing this scientific agenda took a while. In 2006, CDC initiated development of the scientific agenda, which was mainly developed on the recommendation of the Institute of Medicine. This was addressed by ISO as an opportunity to enhance excellence and transparency in vaccine safety science and patient safety initiatives. The agenda gives our scientific activities, projects, and studies for the next several years.

The first draft was completed in 2008. This initial draft was then presented to the National Vaccine Advisory Committee, NVAC, its vaccine safety subgroup, in a public meeting in 2008. At the request of the CDC, the Vaccine Safety Working Group conducted a review of the draft, a process that included both public and stakeholder engagement. It was a very elaborate piece.

In June 2009, CDC received NVAC's recommendations to the draft agenda. Each NVAC recommendation was reviewed and considered by CDC before finalizing the scientific agenda.

By November of last year, CDC responded point by point to NVAC's recommendations and incorporated the changes. In February of this year, the Assistant Secretary

of Health, HHS, reviewed and approved the ISO scientific agenda. It has been available online since March 17.

The actual implementation of the agenda depends on resources, feasibility, advances in science, change in circumstances, or events on the ground, and the agenda has to be aligned with both CDC and ISO missions. As the Department of HHS and CDC's priorities evolve over time and our scientific knowledge of vaccine safety continues to improve, activities may be added, discontinued, modified, or reprioritized. ISO must also be prepared to reprioritize activities in response to unexpected events -- for example, during the national response to the last H1N1 influenza pandemic.

On the next slide, which is slide 7, ISO's activities prior to the development of the scientific agenda had addressed some of the recommendations. ISO had begun implementing activities to address the majority of the 17 general and capacity-building recommendations that are in this report. ISO has begun or implemented some of the 15 specific recommendations, including metabolic or mitochondrial studies and some of the research questions prioritized by NVAC. I will later mention some of the examples in the studies that may be done.

So that's about the scientific agenda, unless somebody has any questions.

(No response)

This is a kind of living -- some of the sections need updating. It's already a little bit outdated. But it will be changing.

Next I'm going to be giving you some highlights from what ISO did in the pandemic, for especially the new people. This was one of the largest vaccination programs in the history of the nation. There were various vaccine safety concerns that were mentioned previously, given the history of GBS following the swine influenza in 1976. A lot of focus was also on pregnant women, who were designated as an early target group -- a lot of studies and focus on reviewing reports and ensuring safety.

One concern -- was to provide vaccine to -- vaccinated as rapidly as possible. As you may remember, this was quite --

Monitoring systems that were used were enhanced rapidly. We enhanced -- in VAERS. We received over 10,000 reports following the vaccinations. These were really, really -- as I mentioned, the special focus on pregnant outcomes -- we looked at GBS. We looked at anaphylaxis -- as well as some other unusual cases that came up, to verify or dispute what they were.

The rapid cycle analysis in the Vaccine Safety Datalink was also in-house to provide more timely data.

Other systems, like the Clinical Immunization Safety Assessment Network, reviewed more reports. We had additional enhancements on systems that were also -- that evaluated GBS. We had new systems introduced, like a real-time immunization monitoring system, that -- so there was a lot of effort ongoing during H1N1.

The impact of this effort -- rapid monitoring efforts provided early evidence that the H1N1 influenza vaccine had a similar safety profile to seasonal influenza vaccine. Comprehensive monitoring was a key component of maintaining confidence in the vaccination program and of informing policymakers and the general public on the safety of 2009 H1N1 vaccine. Relatively strong vaccine uptake continued further into the influenza season than was typically observed.

The last bullet is what we are really very happy with. It strengthened and enhanced collaboration efforts with FDA and other federal agencies.

Our surveillance system VAERS provided the first national data during the H1N1 response. Within the first two months, the data was published -- the data was published three months after the start of the program, which was very, very terrific. The safety profile of H1N1 vaccine in VAERS was consistent with that observed for seasonal influenza, as I have mentioned. These two

publications cite that. I left it in there for reference, for those who are interested in reading what we did in VAERS.

The next slide is showing some selected publications. I won't go into the details. These are publications by Lee and others. The first one is a computer simulation that really basically supported adherence to ACIP policy following prioritization recommendations for the H1N1 influenza vaccine when vaccine is in limited supply.

The second study, by Lee again, is one which evaluated economics of employer-sponsored workplace vaccination to prevent pandemic or seasonal influenza. The main message was that additional waves of an epidemic can be mitigated by vaccination even when an epidemic appears to be waning.

The next slide is what I presented previously to the Commission. It was preliminary results from the EIP that was monitoring GBS patients hospitalization. It showed an estimated age-adjusted ratio of GBS incidence of 1.92 per 100,000 person-years among vaccination persons and 1.2 per 100,000 person-years among unvaccinated persons. I already discussed this, but we have a lot of ongoing studies that are being wrapped it, and these will be published when they are ready. I will not be presenting

any of the unpublished studies.

I will move on to the febrile seizures.

On slide 14, I'll give you some background on fever and febrile seizures. The fever following vaccination in young children is a common event. Fever following vaccination can potentially increase the risk for febrile seizures in children. Febrile seizures in general and following vaccination have a good prognosis for outcome, but definitely they are still frightening to caregivers, especially parents. It's very frightening -- ISO and CDC monitoring for febrile seizures in the current season -- consideration.

Last year in the Southern Hemisphere, TIV manufactured by CSL Biotherapies was associated with a transient increased risk for febrile seizures in young children in Australia. As a result of that, the U.S. CSL TIV was not recommended for children aged 9 years and younger. Fluzone is the only recommended TIV product for children 6 months to 23 months. FDA and CDC implemented enhanced monitoring for seizures after these vaccines in VAERS and VSD based on the Southern Hemisphere experience.

VAERS data mining detected an increased proportion of reports of febrile seizures following Fluzone TIV compared with other inactivated vaccines. Reports were primarily in children of 2 years of age.

At about the same time, in December last year, VSC rapid cycle analysis detected a signal for seizures following TIV in children 6 months to 59 months. Further evaluation of the VSD RCA signal focused on the role of concomitant TIV and PCV13 pneumococcal vaccine vaccination. The preliminary findings of the febrile seizure investigation were presented at the ACIP in February of this year. I gave you an update during the March meeting.

Preliminary findings of the febrile seizure investigation indicate an increased risk for febrile seizures identified following concomitant TIV and PCV13. There was a significant excess risk for febrile seizures on zero to one day following vaccination noted for TIV and PCV13 vaccinees among 12- to 23-month-old children. However, we cannot rule out contributions by other concomitant vaccines, especially DTaP.

There was an attributable risk of 61 per 100,000 doses in 12- to 23-month-old age group. This is comparable to the excess risk of febrile seizures, 43 per 100,000 doses, for MMRV and rubella and varicella vaccines given separately. You are aware of this -- already gave an update on that previously.

The next steps are to continue with the VSD -- the chart review of seizures cases to confirm the febrile seizure diagnosis, update relative risk and attributable

risk estimates based on the chart review data. There will be further analyses planned to evaluate the role of other concomitant vaccines and VSD.

The ACIP General Recommendations Working Group is the sub-working group on febrile seizures that is reviewing information on febrile seizures following vaccination with these two vaccines. They will be providing an update on these results during the next ACIP, and those who are coming to the ACIP will see that. They can give links to their presentations after they have been presented. They are usually available and public.

I will then go on to a brief communications update.

This slide is just to show you these flu blogs. Somebody is doing that. We have additional resources, like the CDC expert commentary on Medscape for providers and CME on influenza safety. That's also Medscape. These are just to show you what was done and what has been improved on within our communications group.

The next slides are basically giving you selected publications that I want to share with you. We definitely published more than these, but I'll just highlight a few.

The Sharon Greene paper was in -- it's a near-real-time surveillance for selected adverse events following pandemic influenza vaccine. It basically shows

that it is possible to do -- in VSD, when data are updated at least weekly. And I have -- the next paper is from our -- colleagues. It basically looked at children who had a history of asthma and the genomics of wheezing after influenza vaccination. A family history of asthma appears to be a risk factor for wheezing after influenza vaccination. Given the limitations of the sample, this pilot demonstrates the feasibility of performing a genome-wide association study, or a GWA study. This was a pilot to then do more studies. It demonstrated that it can be done.

This slide shows additional studies -- the Yen study on detection fecal shedding of rotavirus vaccine in infants following their first dose of pentavalent vaccine. These findings will help better define the potential for horizontal transmission of vaccine virus among immunocompromised household contacts of vaccinated infants for future studies.

The next study is one about metabolic errors. Klein and others looked at immunization rates among children with inborn errors of metabolism. The conclusion is that children with inborn errors of metabolism received vaccines on the same immunization schedule as healthy infants. Immunization was not associated with increased risk for serious adverse events, providing overall

assurance to this vulnerable group.

The next study also looked at kids with metabolic disorders -- again, it also supports the safety profile, that this vulnerable group can also receive vaccines.

The next paper is on pregnant women following TIV. It reviewed a lot of data and reports in VAERS, by Moro and others, within our VAERS project. There were no unusual patterns of pregnancy complications or fetal outcome that were observed in VAERS after administration of TIV and LAIV. There are, relatively, not very many reports, as you may have expected.

Lastly, we had a special supplement in *Pediatrics* that was focused on vaccine safety. It includes a series of vaccine safety articles, with several ISO projects or authored within ISO. This was coordinated by Dan Salmon. I want to say thank you to Dan for coordinating this effort.

So that's it.

MS. DREW: Thank you, Dr. Gidudu.

Does anyone have any questions?

MS. PRON: I have a question on slide 18. I realize that this is early in the investigation. You said there is an attributable risk of 61 per 100,000 doses of febrile seizures for those children getting TIV and a pneumococcal vaccine at the same time, and that this

compares to the excess risk of febrile seizures for the MMRV versus the MMR plus the varicella separately. Are you thinking that this risk is going to be meaningful, this excess risk for those with the TIV and pneumococcal?

DR. GIDUDU: I think I will wait until the data is in, given the public forum at the ACIP. Definitely they are going to give an updated number, at least a strengthening of what they had -- the data that they are going to be providing in a week and a half -- so I would guess that they are going to be providing updated --

MS. PRON: So this is just the beginning of considering a special advisory, I guess.

DR. GIDUDU: Could you say that again?

MS. PRON: This is just the early stages of how you would follow an investigation towards making a recommendation in the future.

DR. GIDUDU: That's correct. When they verify the -- and they are more confident with the data -- that's what is going to be presented at ACIP -- then the ACIP will decide whether to provide a recommendation.

MS. HOIBERG: I have a question about the febrile seizures. I know that a lot of doctors -- I know that you said that it's scary to the caregivers and whatnot of the child when it happens. But can't it train the brain to seize? Can't a febrile seizure -- can't that just kind of

give it a pathway to continue to seize? Can't it lead to seizure disorder?

DR. GIDUDU: Typically, overall, seizures are common. These are the numbers that have been relatively -- I wouldn't call it totally benign, but the sequela after a febrile seizure is usually that the person gets back to normal function. You can't rule out that a small proportion may continue to get seizures later, but attributing that to a vaccine is -- but overall most of them get better.

MS. HOIBERG: But have you followed these children? Has it been a study in which you have followed these children that have gotten -- who have presented with a febrile seizure directly related to the vaccine, and then have you followed them to find out if they have continued to have febrile seizures after that and maybe, possibly lapsed into epilepsy?

DR. GIDUDU: There are a couple of studies in febrile seizures. Those that are monitored -- only those that are serious get additional follow-up. So those that don't make it to the "serious" category we definitely don't follow. Those that are followed up are serious. More data to follow over time. They are being followed.

MR. KING: The number of doses in the 12- to 23-month-old children -- the attributable risk is 61 per

100,000 doses. How many actual doses are given in that age group?

DR. GIDUDU: I do have that information. I can send it to you. At the time of this presentation, PCV13 had been around since February, so the doses we were looking at were -- last year. For the entire year -- those numbers. This vaccine was recommended in February of last year, and the uptake kept on improving. It was in March that it picked up. So the doses -- I don't have the numbers with me, but I definitely can give those to you.

MR. KING: Do you have a ballpark number? Is it a million? Is it 2 million? Is it 100,000 only?

MS. HOIBERG: Because that would be important to see. If you had 50,000 kids that reacted with febrile seizures and only 100,000 were given, that's pretty bad.

(No response)

DR. EVANS: Dr. Gidudu, you can probably get back to us with those answers, I'm sure.

These data have been presented, and additional data from the Vaccine Safety Datalink are going to be discussed at the meeting at the ACIP. There is a workgroup that has been looking at these with the idea that there may be some change in the recommendation, just like there was some change in language in the recommendation when MMRV versus MMR and V separately came up a year or so ago.

So this is being looked at actively. We'll see what comes out of this next meeting.

MS. HOIBERG: Thank you, Geoff.

MR. KING: But we don't actually know the number, though, now of the number of doses.

DR. EVANS: Well, we know it's distributed. That's what Jane can get hold of.

MR. KING: Right. We're back to that age-old question.

MS. HOIBERG: But you can have, like, a million distributed and only 500,000 given. So that's not --

DR. EVANS: There is usually a better correlation than that. Usually a significant number of what's distributed -- there is uptake. But that's something that they can clarify for us.

MR. KING: Will you send that information out after it is received?

DR. EVANS: Sure.

MS. DREW: Have we lost Dr. Gidudu? Is she still here?

(No response)

MS. DREW: I don't think so.

MS. HOIBERG: You scared her away, Dave.

DR. EVANS: We'll be sure to follow up with her.

MS. DREW: That being the case, I guess we can

see if we can get Dr. Barbara Mulach to hang up on us as well.

Agenda Item: Update on National Institute of Allergies and Infectious Diseases, Dr. Barbara Mulach NIAID

DR. MULACH: I'll try not to hang up.

I just have ea couple of things I wanted to highlight for you today.

The first is something that was announced in late April of 2011, which is a *Journal of Pediatrics* article that talks about a questionnaire that has been developed for children at their 1-year checkup to try to identify early on those children that might have autism or autism spectrum disorders. This study was led by Dr. Karen Pierce of the University of California at San Diego and her colleagues. Basically, the idea is just to try to get a read as soon as possible about whether or not there is a child that you need to be following up or if there might need to be some additional behavioral or other interventions that you can do to try to build up their abilities early on.

They worked with 137 pediatricians in San Diego County. They screened children with a short, 24-question survey, asking about a child's use of eye gaze, sounds, words, gestures, objects, and other forms of age-

appropriate communication. They screened nearly 10,500 children.

It's just very interesting how they are able to start identifying earlier and earlier potential ways where they could try to help these children and identify them earlier. They are in the process of trying to improve their questionnaire even more so that they can eliminate any false positives.

I can send you guys the article if you are interested in more information on that.

I also want to make sure that you are aware that, in addition to the few things that we talk about at our meetings, NIH has a lot of information that's available and stories, with people explaining some of the research that we do. There is a section of our website called "NIH Research Matters," where they talk about a lot of the things that are going on. We have podcasts and radio stories. If you are interested, I would also be glad to send you guys the link to that, where you can search for the topics that are of most interest to you. I think you can also sign up to have tweets or other updates as you are interested.

In particular, NIAID has recently put together some information on the Web that is just a really nice snapshot of how NIAID research has been conducted over the

years, in partnership with academia, industry, and nonprofits and other government agencies, to translate scientific findings into practical medical applications.

So it's sort of a historical overview of some of the things that we have been involved in over the years. It's just a nice snapshot, if you ever have a few minutes. It's very short snippets. It highlights our advances, particularly in development of vaccines -- for example, for hepatitis A, conjugate technologies for pneumococcal and Hib vaccines, improved pertussis vaccine, and even development of some rotavirus vaccine.

In addition to that, it talks about risk factors for asthma, development of food allergy guidelines, advances in HIV research and treatment, and diagnostics for diseases like malaria and tuberculosis.

I will be glad to follow up with some links for you, to kind of give you just places where you can go look for information if you have any questions or you just want to know what's going on and what we are supporting at NIH.

MS. DREW: Thank you. I think we would all appreciate it if you would supply that to Geoff Evans, and he can see that it's forwarded on to the rest of us.

DR. MULACH: Will do.

MS. DREW: Thank you very much, Doctor.

Just to get back to Dr. Gidudu, I believe that we

were finished, unless you have anything else you need to say.

DR. GIDUDU: No. Thank you.

MS. DREW: Thank you very much for your contribution, both of you.

Now we move on to Dr. Marion Gruber -- oh, I'm sorry, does anyone have any questions for Dr. Mulach?

(No response)

All right, on to Dr. Gruber.

Agenda Item: Update on the Center for Biologics, Evaluation and Research, Dr. Marion Gruber, CBER, FDA

DR. GRUBER: Hello. I actually have a brief update only today, therefore would like to take the opportunity to actually make a statement after this update.

As we discussed this afternoon when we looked at the vaccine information sheets, we have two vaccines licensed to prevent meningococcal disease caused by certain serogroups of that bacterium. ACW and Y are the serogroups. We recently, on April 22, have approved one of these meningococcal vaccines -- namely, Menactra -- that is manufactured by Sanofi Pasteur to include safety and effectiveness data to support use in children 9 to 23 months of age, to prevent invasive meningococcal disease caused by these serogroups in children. Again, there is only one vaccine licensed for the age group 9 to 23 months

of age now, with that recent approval.

In addition to these types of meningococcal bacteria, serogroups ACW and Y, there are other groups that cause meningococcal disease, and these are the group B bacteria. They cause a significant amount of endemic and epidemic meningococcal disease around the world. They are responsible for about a third of invasive meningococcal disease overall and about half of the disease in kids less than 1 year of age.

The disease caused by group B meningococcal bacteria is rather severe. It's just that the annual incidence rate in the United States is low, with 1.79 per 100,000 infants, less than 12 months of age. That makes it very challenging to do efficacy or effectiveness trials to demonstrate that the vaccines that are developed against these bacteria to protect -- in other words, a clinical trial conducted with these vaccine candidates would take several hundred thousand, even over 1 million participants. That is just not feasible for a vaccine manufacturer to undertake.

Since there is great interest on the side of vaccine manufacturers -- not only the vaccine manufacturers, but public health -- to really have vaccines against meningococcal B bacteria, we convened an advisory committee meeting in April and we discussed paths forward

to license these vaccine candidates for the prevention of invasive meningococcal type B disease. As I mentioned, it is not possible to do these clinical endpoint efficacy studies, so we were thinking, together with the experts, of other ways by which effectiveness of these vaccine candidates can be demonstrated. One of the cases made was to look at the immune response that is induced by these vaccines, because there is evidence from past epidemics and other vaccine candidates against meningococcal B that are developed that the immunogenicity of certain antibody type would predict protection.

So that was actually the subject of discussion at this advisory committee meeting. Several vaccine manufacturers continue now to develop these vaccine candidates against group B meningococcal disease. I thought that was a very interesting discussion that we had there. It's going to be a very important vaccine. This is, of course, to be continued when these products are close to licensure.

So that is really regarding updates. We haven't had major approval actions, apart from the one that I mentioned, since I gave my last update.

Coming, then, to the second part of my hour of glory here, I would like to take the opportunity to clarify some inaccuracies and perhaps misconceptions that were

embedded in the statement made by Mr. Wolfe of the CDC during the ACCV meeting of September 17, when the committee discussed the vaccine information sheet statements for rotavirus vaccines.

Unfortunately, I was not present during these discussions because I had some other competing priorities. But I attended in the afternoon to provide the ACCV with an overview of rotavirus vaccine postmarketing studies and regulatory action that FDA had actually taken to update the labeling of the rotavirus vaccines.

But going back to the discussions of the vaccine information statements, Mr. Wolfe stated the following, and I would like to quote from the transcripts that were published on October 28. I should state and stress that we have had quite some internal discussions at the FDA in regard to the statement made, and I was encouraged to clarify this here at this ACCV meeting.

Mr. Wolfe stated at that time, when rotavirus labeling and vaccine information statements were discussed, “One thing that may be worthwhile ignoring is that the FDA -- the product labels are kind of like throwing in the kitchen sink. In some ways, frankly, they are less reliable documents than ACIP documents, and if there is ever basically an assertion of some association with something, it gets thrown into the labeling. And the ACIP

makes more of an effort to try to find out, is this accurate? Is this actually happening with a particular vaccine? So the recommendations that come out of the ACIP are, to use your term, “refined,” and so we would argue that they are actually more accurate, typically, than the labels.” End of quote.

What we would really like to clarify here in front of the Commission is that the agency, the FDA, has provisions, laws and regulations, by which we must comply with binding regulations regarding information that is included in product labeling. In other words, the law states that the labeling must contain a summary of the essential scientific information needed for the safe and effective use of the drug. The labeling must be informative and accurate, and neither promotional in tone nor false or misleading in any particular. The labeling must be updated when new information becomes available that causes the labeling to become inaccurate, false, or misleading.

Furthermore, the regulations state that no implied claims or suggestions of drug use may be made if there is inadequate evidence of safety or a lack of substantial evidence of effectiveness.

Therefore, the FDA would like to stress that the information that we include in product labeling is driven

by data that are derived from studies by the vaccine manufacturer. In other words, before we approve a biologic license application for a vaccine, we undertake a detailed review of the proposed labeling and we allow only information for which there is a scientific basis to be included in the FDA-approved labeling. I have presented to you in the past the Federal Food, Drug, and Cosmetic Act and stated that the Public Health Service Act really gives us authority to license vaccine products. We make approval decisions based on a comprehensive scientific evaluation of the product's risks and benefits under the conditions of use prescribed, recommended, or suggested in product labeling.

So the labeling for the product really reflects our thorough review of the pertinent scientific evidence and communicates to the health-care practitioner the agency's formal conclusions regarding the conditions under which the product can be used safely and effectively.

Thank you very much. That concludes my update.

MS. DREW: Thank you, Dr. Gruber.

Does anyone have any questions for Dr. Gruber?

(No response)

There being none, thank you very much for your informative presentation.

We are now to the public comment portion of our

meeting, but I thought before we did that, I would just ask if any of the commissioners have anything that they need to address or that should be covered tomorrow?

MR. KING: I know that originally scheduled for tomorrow was going to be the Future Sciences Group meeting, but I think that's not happening now. I just want to make sure that we are all -- Michelle, maybe you know the answer to this better than I.

MS. WILLIAMS: It is going go ahead.

MR. KING: We are having the meeting?

MS. WILLIAMS: Yes.

MS. HOIBEG: Is there any way that we could do it tonight, like now, since we are done at 4:00? Is there any way? I mean, since we are all here --

DR. EVANS: Roe (phonetic) is not available right now, and she is a key component to this.

MR. KING: So we are doing it at 11:00 tomorrow. Is that correct -- or roughly thereabouts?

MS. WILLIAMS: Yes, that's correct.

MR. KING: Okay, great.

MS. WILLIAMS: And I'm sorry for the confusion.

MS. PRON: I guess one question I would have is, seeing that some people have some time constraints, if the meeting is scheduled from 9:00 until 10:45, can it be started beforehand?

MS. WILLIAMS: I don't think so. We have published in the *Federal Register* and we are kind of bound by what we have already published, as far as the ACCV meeting.

DR. EVANS: If you are saying can the ACCV meeting adjourn earlier than 11:00, my understanding is that it can.

MS. WILLIAMS: Yes, it can. It can't start earlier.

MS. DREW: Do we have the operator here?

OPERATOR: Yes. Would you like to take public comments?

MS. DREW: Yes, we would.

Agenda Item: Public Comment

OPERATOR: To make a comment, please press *1. To withdraw your comment, please press *2. Once again, if you would like to make a comment, please press *1.

One moment while we wait for our first comment.

(Pause)

OPERATOR: Our first comment comes from Jim Moody.

MR. MOODY: Thank you. Thank you, Sherry and members of the committee.

My comment today is on behalf of the National Autism Association, where I'm a director. Thank you for

the opportunity to make comments.

First, I want to call the Commission's attention to a just-published study by the Elizabeth Birt Center for Autism Law and Advocacy. It's titled "Unanswered Questions from the Vaccine Injury Compensation Program: A Review of Compensation Cases of Brain Injury." Through a two-year or so investigation process, the team from EBCALA was able to locate and describe 83 cases from the program in which the government has compensated individuals for hundreds of millions of dollars for decisions and concessions involving at some point a diagnosis of autism or autism-like features.

These cases make the government's claim in various forms that there is no evidence that vaccines cause autism, at best, misleading. Since all of these cases come from an evidence-based compensation program, they obviously provide powerful evidence, perhaps even better than epidemiology studies, that vaccines do, in fact, cause autism. A footnote in the end of the statistics table that emerged after the Poling concession that HHS has never conceded in case that autism was caused by vaccines is also, at best, somewhat misleading. HRSA's explanation for the apparent inconsistency is that we have compensated cases in which children exhibited an encephalopathy or general brain disease. Encephalopathy may be accompanied

by medical progression of an array of symptoms, including autistic behavior, autism, or seizures.

With all due respect, this is very confusing to the public and does need to be clarified in part so that people who do have potential cases can file them in the program. Perhaps a bad metaphor, but the continued general denials are like saying gunshots don't kill people; they die of lead poisoning.

I would urge ACCV to work for a much clearer statement of the connection between vaccines and autism.

My second point is, we have had a lot of calls recently and at conferences about the future of the OAP cases, especially from several hundred people who are appearing in that proceeding at this point pro se, meaning without a lawyer. The concern is basically that there is an extraordinary pressure coming from the Justice Department and in some cases the special masters to either dismiss the cases or to present new evidence on existing theory or a new theory of causation. A desire to simply make these cases disappear cannot substitute for the sound science necessary to resolve cases on the merit -- i.e., to be able to reach an informed decision on whether the particular child's autism was caused or exacerbated in any way by a vaccine.

Considerable science has been published since the

test cases, most especially focusing on mercury toxicity and on a connection between mitochondrial dysfunction and autism. Most importantly, the greater recognition now by NVAC and by CDC that the lack of baseline data on unvaccinated children as an important gap in the science -- I understand that CDC's ISO is working on preparing a feasibility review to do a study on unvaccinated children.

Now that the Supreme Court has decided the Bruesewitz case, design defect claims cannot be filed in civil court after exiting from the program, which is, I think, kind of contrary to the congressionally stated purpose of Congress, which is to provide that remedy as a safety net. Once the OAP cases are dismissed from the program, these children may never have an opportunity to receive compensation for what may turn out to be vaccine injuries. This takes away a safety net absolutely essential to maintain public confidence in the universal program of vaccination and fuels efforts for reform or just abolishing the program altogether.

What these children need right now is ACCV's help to ask the Secretary, as the client agency in the program, to declare a moratorium on dismissing further OAP cases until the matter of a scientific stay can be addressed at a full ACCV meeting. Nothing can be gained from dismissing cases from the OAP at this point. Leaving them on hold at

no cost to the government or petitioners will at least provide the opportunity for those cases worthy of compensation to receive that, based on the developing science.

Thank you very much.

MS. DREW: Thank you, Mr. Moody.

Any more public comments?

OPERATOR: We have no further comments at this time.

MS. DREW: That being the case, we will end the meeting for today. It’s not really an adjournment. We will do that tomorrow. We’ll finish for the day. Our meeting will begin again tomorrow at 9:00 AM Eastern time. I will talk to you people then. Good evening.

(Whereupon, the meeting was adjourned, to reconvene at 9:00 AM, the following day.)