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Advisory Commission on Childhood Vaccines

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P R O C E E D I N G S (8:30 a.m.)

OPERATOR: Welcome to the 84th quarterly meeting of the Advisory Commission on Childhood Vaccines. Today's call is being recorded. If you have an objection, you may disconnect at this time. I will now turn the meeting over to the ACCV Chair, Mr. David King.

Agenda item: Welcome and approval of March 2011 minutes

MR. KING: Good morning and thank you. Before we get started, I think that we should do an around the room for all of the people who are at the conference table here to just quickly introduce themselves. I believe we have a member of the Commission on the phone as well. I would also, again, ask that when we speak for comment, question, or whatever, that we identify who we are before we do that.

I am David King. I am the Chair. I think that is good enough.

MS. WILLIAMS: I am Michelle Williams. I am an attorney from Alston and Bird. I am a non-affiliated lawyer on the Commission.

DR. FEEMSTER: I am Kristen Feemster. I am a pediatric and infectious diseases physician and health services researcher and Commission member.

DR. DOUGLAS: I am Dr. Charlene Douglas. I am representing the public.

MR. KRAUS: Ed Kraus. I am the vaccine injured attorney representative.

MS. MARSHALL: Good morning. I am Lieutenant Valerie Marshall from the Food and Drug Administration.

DR. MULACH: Barbara Mulach, ex officio member from the National Institutes of Health.

DR. SHIMABUKURO: Tom Shimabukuro, ex officio member from CDC.

DR. SMITH: Jason Smith, Vaccines Counsel at Pfizer.

MS. DEAL ROSA: Luisita dela Rosa, a parent.

MS. LEVINE: I am Emily Levine with HHS Office of the General Counsel.

DR. EVANS: Geoffrey Evans, Director of the Division of Vaccine Injury Compensation in HRSA and the Executive Secretary to the ACCV.

MR. KING: Ann?

MS. LINGUITI PRON: Ann Linguiti Pron, pediatric nurse practitioner and healthcare provider.

DR. VILLAREAL: Hi, Sylvia Villareal, pediatrics. Late. Sorry.

MR. KING: The meeting has just begun. Thank you very much. Before we move on to the approval of the minutes, I thought that I would give a quick report from the Chair on some items that we have discussed over the

course of the past quarter through the Agenda Committee and give some indication of a direction of some workgroups that we have set up.

One of the things that we had discussed at the end of the last meeting was items that we might want to, as a group or as subgroups, work in to explore more deeply. On the Agenda Committee, the Agenda Committee began to think about what we might be able to do. Some of the thoughts that we used to drive the process or the thinking were a couple questions.

One of the questions was what would a vaccine injury compensation program look like if it was perfect? What, if anything, is creating or causing barriers to an effective vaccine injury compensation program? Past commissions have submitted recommendations. What has been the disposition, if any, of these? Can we or should we build upon them as we move forward?

It was also suggested at the last meeting that we think in terms of grouping topics together for these meetings so that we can focus on a specific issue rather than a potential scatter shot approach. Then there was an idea that we should provide some level of information on pregnancy and vaccines.

The Agenda Committee determined that we ought to have some workgroups. We came up with what we thought were

three different workgroups that will be convening later today in separate meetings. We focused on a couple different things. One was vaccination and pregnancy, a workgroup. Kristen Feemster has agreed to chair that workgroup. We also focused on attorney's fees. Ed Kraus and Jason Smith have willingly volunteered to co-chair that workgroup. Then we have a process workgroup. Luisita dela Rosa has agreed to chair that group.

We are thinking in terms of how the attendance might be or the membership of these workgroups might be. We thought that, in some cases, it is possible that some of the doctors might be interested in the vaccination and pregnancy. At least for our purposes today, we might move in that direction. We are thinking that on the attorney's fees -- well, we already have two of the attorney's. For the process, we are thinking that we have some former chairs that are willing to be part of that workgroup as well as other members of the Commission.

What we are thinking is that while we will be meeting separately today, we are thinking that on a go forward basis, we do not want to limit people's participation in a workgroup. When we set up the conference calls that we typically have and the cadence of those meetings will need to be determined by those workgroups as to when and the frequency. What we would ask

is that we try not to schedule them all simultaneously at the same time so that Commissioners and others, who might want to be a participant on more than one workgroup, would, in fact, have that opportunity.

Of course, the overriding idea behind this is so that we would not be solely in a reactive moment of where we would sit in the commission meetings on a quarterly basis and hear reports, ask question, and, on occasion, pass a resolution, although, the last meeting was a rather busy meeting where we added a lot of recommendations.

The idea was, though, that we look and strive to find out and to see what it is that we can bring to the table to enhance the vaccine injury compensation program from a number of different perspectives. That is all I really wanted to say as it relates to that. Thank you.

Having said that, let's move onto the minutes. Does anybody have any corrections, comments, changes to the minutes? Does everybody have the minutes in front of them? If there are not comments or correction to the minutes, then I actually was going to -- so I had one question on the minutes, if I may, if no one else has. We have Dr. Evans welcomed all present and on the teleconference to the 82nd meeting of the Advisory Commission on Childhood Vaccines, but Barb, our announcer for the call, called it the 84th meeting so there is a slight discrepancy as to the

number of what it would be. Do we know which it is?

DR. EVANS: I will fix that.

MR. KING: Okay. It will be the 83rd. Great. Any other comments or recommendations?

DR. VILLAREAL: On page six, with regard to the overall process, in that paragraph, do we state when the 180 day period of public comment starts? Is it just follows from the minutes?

DR. EVANS: The 180 day period starts once the Notice of Proposed Rulemaking is published in the Federal Register. Of course, we will send you a copy when that happens.

DR. VILLAREAL: That hasn't been published yet. Thank you.

MR. KING: Any other questions or comments?

MS. PRON: Yes. Also, the paragraph right below that, I thought it was a little ambiguous -- the last sentence. It says there was general agreement among existing members to follow this approach. I don't recall which approach that was.

MR. KING: Ann, that was related to the voting on the various recommendations. We had determined that we would present information and then we would vote on that at that time after we had comments, questions, and discovery around this specific topic rather than bundle them all at

the end and vote on them individually that way.

MS. PRON: There were three options. I wasn't clear -- I know what we did, but --

MR. KING: No. It was agreed that we would follow the approach of first concurring with the recommendations and moving forward either, second, deciding against moving forward, or, third, defer recommendations. That was part of -- all three of them are part of what the Actual approach was.

MS. PRON: Okay.

MR. KING: What we are saying is that the last sentence there was general agreement to follow this approach. The approach meaning --

DR. EVANS: The three step approach?

MR. KING: The three step approach. It might be better if we put in the words three step.

MS. PRON: Okay. Thank you.

MR. KING: The three-option approach we will call it. Does that meet with approval, Ann?

MS. PRON: Yes. Thank you very much.

MR. KING: Good catch. Any other comments? I think the Chair would then entertain a motion here.

(On motion duly made and seconded, the minutes of the March 8-9 meeting were unanimously approved.)

MR. KING: The next item on the agenda is the

report from the Division of Vaccine Injury Compensation. Dr. Geoffrey Evans will provide that report.

Agenda item: Report from the Division of Vaccine Injury Compensation

DR. EVANS: Good morning. Ann, can you hear me okay?

MS. PRON: Yes, just great.

DR. EVANS: Okay. Welcome to the 84th quarterly meeting of the Advisory Commission on Childhood Vaccines. It is, indeed, a special day when you can come to this meeting in June and think that you are in California. It is so dry and cool outside. I remember a number of ACCV meetings where members would come and say, oh, I guess we are now in Washington and it is summer.

Beginning with the slide with highlights, following my presentation -- actually, Mr. Vince Matanoski from the Department of Justice will provide an update from his office. We will receive the updates from the ex officio members from the Food and Drug Administration, from CDC, from NIH, and the National Vaccine Program Office. Then we will have a review of the white paper on U.S. vaccine safety system that was approved by the National Vaccine Advisory Committee this past September. That is going to be provided by Dr. Dan Salmon.

Turning to the stats for the program as of May

24, 2012, in terms of petitions filed, we are having a busy year, again, but it looks as though we will not get anywhere close to the 448 that were filed in 2010. We are on track for about 350 claims this year. Still about half of them are flu vaccines. The majority are adult vaccines. Many of them are demyelinating conditions, as it has been before. There is a steady pace of filing of claims as I reported the past several meetings.

Turning to adjudications, you will see that there has been quite a bit of activity under the autism proceeding dismissal column. As has been discussed by Mark Rogers in the past, there is an ongoing process for those that are not going forward for further hearings for the attorney's fees and costs to be decided in many of these claims. You can see that there has been a lot of activity there. My count is that that adds up to all together about 3,500 autism claims. There are a little bit over 5,600 filed all together. Otherwise, there continues to be a brisk pace of adjudications for the non-autism side.

I know we have been looking at the adjudication categories for a while now. What has been the trend here is that, again, of compensable claims, a large percentage -- 80 percent roughly -- are through settlement for various reasons -- mitigated risk, cost of defense, settlements, and so on.

You will see that some may wonder why the concessions -- a concession, by the way, means that HHS has reviewed the medical records and the petition and has decided that, either on the basis of a table injury or by proof of causation in fact or by significant aggravation that the petitioner is entitled to compensation. In terms of concessions, it seems to be that there is a trend downward.

Frankly, in looking at this, I know that our approach isn't any different. The fact that relatively few claims are conceded is because most claims are filed alleged off-table injury. Since very few medical conditions there is actually proof of causation, therefore, you are going to find a relatively low percentage there. It will have been four case's claims conceded so far this fiscal year. You will see that there has been a great deal of settlement activity, 82 percent. The court decision making, there has been a bit of a bump up, but, again, that may be because and probably is because we are defending more claims. Again, these are very small changes overall.

In terms of the award amounts, you will see that there has been a lot of activity, again, in the attorney's fees and cost column. That reflects what is going on in the Omnibus Autism proceeding as those cases are being resolved. In terms of the amounts of the awards, again, we

are not on track to exceed what has been our highest amount, which was $234 million in outlays a few years ago. It looks like we are on pace for about $192 -- under $200 this particular year. Again, that varies from year to year.

The Vaccine Injury Compensation Trust Fund is now up to $3.4 billion dollars. You can see that this now represents a half a year's worth of activity from October 1 to March 31. You can double that and see what the amounts would be coming in for an estimate for the year. It looks at though the tax revenues will be about $240 million in a year's period. With interest, that will result in about $312. If we are going to end up spending roughly $200 million, then that would leave an excess of at least $100 million dollars. As has been true for every year since -- every year in the past, there has always been an excess balance. There has always been an excess in terms of income and revenues. The trust fund slowly keeps growing.

I also noticed that the interest percentage of income is significantly less than what it has been in the past, which reflects what has been going on with the economy these days. Usually, in the past, it has been about 33 percent or 30 percent. Now, it is 23 percent. That will change probably over time, too.

Last week, I attend the National Vaccine Advisory

Committee. Actually, this time I was asked to give a presentation and an update on the compensation program. I spent about a half hour updating them on the 24 year history of the program and the recent votes on tabled proposals and so on. There were several questions. The Committee was very appreciative to learn how the program is doing. It was a good opportunity to get us out into the public to show people that we are turning around claims on a fast basis, much more quickly than sometimes reported in the press and on the Internet and so on.

For those who wish to contact the program, the best way is to either use the toll free line, 1-800-338-2382, or even better yet, the Internet, which has a great deal of information. The Internet address is www.HRSA.gov/vaccinecompensation. Andrea Herzog is the point of contact. Her direct phone number is 301-443-6634. With that, I will answer any questions.

MR. KING: Any questions? Ed?

MR. KRAUS: Geoff, you said that you didn't think there was any significant downward trend, but there is -- it seems fairly significant to me that only three percent of the cases for 2012 have been conceded, as opposed to 14 percent in 2010. I don't know about years past. That is a pretty significant downward trend. That is my first

question. I don't know why you would characterize it as not significant.

DR. EVANS: It is significant in terms of numbers if you were to do a statistical significance test. In terms of operating on a day to day basis or what it means in terms of position of the Secretary, I view it as really not informative because we react to what is in front of us. We are not doing anything differently, in terms of concessions, that I am aware of this year versus two years ago versus five years ago.

When we began having mostly influenza claims filed with the program there were no table injuries for influenza claims. As these claims go forward for processing and review adjudication, these are going to be all off-table injuries and there are not going to be concessions unless there is an extraordinary circumstance of aggravation or whatever. This is just reflective of the kinds of claims we are reviewing. I didn't mean to suggest that it is an artifact, but I did mean to suggest that it doesn't portend anything that I can see in terms of things that we are doing differently.

MR. KRAUS: Somewhat of a related question and issue or concern -- in the 82 percent of the cases that were compensated, they were compensated via a settlement agreement?

DR. EVANS: Correct.

MR. KRAUS: In those settlement agreements, the government has language that says that there is no liability admitted. Essentially, the language is we are settling this case, but we are not admitting to any actual causal relationship between the vaccine and the alleged injury. Correct?

DR. EVANS: Correct.

MR. KRAUS: I know that court decisions from the special masters, they don't have precedential value, but this is sort of the --this raises the concern of what information is getting out there to the public to the extent if you have a court decision and in that court decision there is a finding that under the standards in the Act that it is more likely than not that the vaccine caused the injury, then that is information that gets out. How widely, we don't know, but at least the possibility of that information getting out to the public exists.

When it is a settlement, it is basically -- I don't want to use the term covered up, but it is certainly -- the only thing that people know is the government paid some money. They know the amount of the money. They know the alleged injury sometimes. They know what vaccine was at issue. Again, I am not suggesting any kind of conspiratorial motive here, but the effect of that is you

have a lot of claims that get filed and you have a lot of settlements that get issued.

Money gets paid to the individual. In that sense, the program is achieving the important goal of compensating injured individuals. It seems to me there is a bit of concern about -- I don't know if the word would be transparency, but about the ability for other people down the road, who think they might have been vaccine injured, to be able to look at court decisions and be able to point to other individuals, who have received compensation, and be able to see what sort of theories of causation were relied on, what medical experts were involved, what the experts testified to, or what they said in their report.

I am not necessarily asking a question, but I am raising a concern about a perception that there is a lot of activity that the program is involved in that is kind of below the radar, in terms of the public.

MR. KING: I think that we ought to look at that from my perspective. I know that we are not going to do that in this meeting. I think what he is saying here, Ed, is that every single individual who files for compensation -- and if not every, many of them -- literally have to pave a new road every time. Is that correct?

MR. KRAUS: To some extent.

MR. KING: So from my point of view, I wonder if that is something that one of the workgroups might want to take up, in terms of exploring because I think that the goal of the Vaccine Injury Compensation Program is partly, I would think, in terms of how do we make it better -- how do we help people receive what they might be entitled to in an easier fashion than having them have to create the wheel each time?

I don't know if that can fit into one of the workgroups that we have or if maybe a workgroup will expand its scope and possibly change its name. I am suggesting that might be something that we might want to look at in more detail. I am asking the Commission what your thoughts are on that idea.

MS. WILLIAMS: I think, Geoff, correct me if I am wrong, your point was that because more cases are now filed that are off table and that is the reason why the concession rate is different.

DR. EVANS: Correct.

MS. WILLIAMS: To your point, the question is, one, why is that? Why are we having that phenomenon? Do we know or do we not know? From a process standpoint, if that is going to be the trend of having more cases being filed that are off table, is there something that should be

done differently in the resolution of those cases that isn't being done currently?

DR. EVANS: Correct.

MS. WILLIAMS: I know the people on the phone can't see the head nods.

DR. EVANS: And, of course, that is the reason why you all spent a full day in March because we are in the process of wanting to expand the vaccine table so there will be more on table claims and so there will be more concessions. We go forward based on science and some policy considerations, but for right now, this has been the way it has been for at least the past three or four years.

Certainly, there have been a lot more settlements. It is not as transparent. I will point out that that is one of the reasons why Mr. Rogers began to, at the request of the Commission, began to include in his presentation several slides of the stipulations and the kind of vaccine allegations that were being made in these claims that were being compensated through settlement.

MS. WILLIAMS: If this is a trend that is going to continue, then the system needs to address are there ways to make the original goals of the Act be accountable for what may be a permanent trend if that is the case. We just don't know. I think Dave's suggestion about a process workgroup including this -- because what is the effect of

the majority of claims now being off table? Is there some action that should be recommended or something? I don't know the answer to that. Is that where you were going?

MR. KRAUS: I think that is an appropriate analysis. I was only -- just a brief follow up to Geoff's comment. I think that there is an implication from your comments that the only cases that are kind of right for concession are ones that are on table. I think that from a process standpoint, I don't know that the government is doing anything differently, but I think that there is an argument that there are cases that are filed where the evidence of causation is pretty strong and the government immediately will go to a litigative risk posture rather than a concession because why wouldn't they in some ways. It put them in a better position, in terms of arguing about what compensation should be.

I think that is a not insignificant issue. I am not sure the best way to address it. I think some of the reasons for it do relate to the off table nature. I think it is certainly possible for petitioners to file off table cases that are well documented in terms of causation. The possibility of a concession does not exist only for an on table injury is my bottom line point.

DR. SHIMABUKURO: Are the terms of a settlement publicly available somewhere if someone wants to read it?

Do you have to FOIA that? If somebody wanted to look at these 98 settlements and just see the terms or a summary of the terms, how would somebody go about doing that?

DR. EVANS: Could we hold that question for the next speaker?

MR. KING: Is the next speaker going to be prepared to answer that question?

DR. EVANS: Yes.

MR. KING: Tom, we want to ask that question of the next speaker. Are you okay with that, Tom?

DR. SHIMABUKURO: Yes.

MR. KING: Are there any other questions or comments? Are we suggesting -- I don't want to go to the next speaker yet. I am not prepared to do that yet. Are you saying that after the next speaker, we can then determine whether or not it would go to a workgroup? I will concede that. That makes sense. Any other questions, comments, or whatever for Geoff?

The next item on the agenda is a report from the Department of Justice. Mr. Vincent Matanoski will give the report. I don't know if you want to start with an answer to the question or if you need to provide slides first to get to that.

Agenda item: Report from the Department of Justice

MR. MATANOSKI: First, I would want to start by asking Mr. Rogers to come and speak. No, I would be happy to answer that question. I thought when I heard it that it might be best to talk about it when I start talking about settlements.

With that, I will just introduce myself. Vince Matanoski. I am sitting in for Mark Rogers, who is taking another meeting today. I am very pleased to be here to represent the Department of Justice. I think I have met some folks here before, but not everyone. I am really pleased to meet the new folks here that I haven't met before.

I am a little electronically challenged so I hope I am going to be able to work this. We also report on statistics about cases filed. We look at them from the standpoint of the last reporting period. We give them to you in about quarterly snapshots. What has happened since the last time you met? What we can see here, tracking, is we had almost 100 cases filed. They were all non-autism cases.

If you see the split here, about 70 percent -- a little more than 70 percent of the cases that are filed now are adult cases. I think this has been commented on in the past. Most of the cases that we see now or a good chunk of the cases we see are flu cases. Since flu is universally

recommended for administration, we see quite a few adults who are getting that case. Now, we have a cohort that is not just a birth cohort. It is the entire population.

In the adjudications this period, we had 731. By far and away, most of the cases that were adjudicated during that very large number were autism cases coming out of the Omnibus Autism proceeding. They were dismissal of those cases. We had 609 of those. 68 cases, if you look down at the bottom, were also -- they were non-autism and not compensated. Amongst the 54 that were compensated, five were conceded by HHS.

Now, you will see there is a little difference in the numbers report between what Dr. Evans reported and what we are reporting here. We look at cases coming through that have gone to judgment. These cases may have been filed several years ago at this point. Geoff or Dr. Evans was looking at cases that were -- he is doing it real-time what have we compensated and what have we conceded during this period.

We had five conceded by HHS. The way the damages were resolved in those cases -- four were by proffer. I looked through the minutes of past meetings and I think that has been explained what that means. If there are questions, I would be happy to entertain those. As an aside, I am happy to entertain questions at any time, no

matter what the topic is. Hopefully, it will be about vaccines, rather than some of the others. Hopefully, I will be able to speak to it.

We had one of those conceded cases that actually was -- the damages were settled. We had 49 cases that were not conceded by HHS, but, nevertheless, were compensated. By far and away, most of those were compensated by virtue of settlement between the parties. There was one that had a decision. The Special Master had awarded compensation on the case and it went to a decision actually awarding the damages. There were five where the Special Master had awarded compensation for the cases and the damages were resolved by way of proffer.

If you look at the decisions adopting settlement, then that should represent the figure of cases where there wasn't a concession. There wasn't a finding by the Special Master of compensation and yet the case was settled. They would be on the litigative risk, to use that term, type settlement.

MR. KING: Is this the time that we should talk about that question?

MR. MATANOSKI: I can talk about it now. Why don't we talk about it now? Please, repeat your questions. First, I think, I will comment on what Mr. Kraus had brought up about the nature of settlements versus

concession and does that mean that there may be cases that ought to be conceded that aren't because of the availability of settlement. Does that mean that people are inventing their case each time? That was another comment. I believe the other question was is this information available to the public so that they can see what is going on?

Dealing with the last question first, the information should be available to the public. The court issues a decision even in a case involving a settlement. The court will issue a decision adopting that settlement. The stipulation is included with that. That is filed with the case and available to the public. They will be able to see the terms of the stipulation -- the amount, what was involved in the case to the extent the stipulation portrays that or has that included in it.

What generally individuals will do -- they have an option under the Vaccine Act of trying to protect their personally identifying information. If they move to have the case -- to not have personally identifying information out there, what the court will do, generally, is they will redact, if it is a minor, the minor's initials from the decision -- redact the minor's name so that only the initials appear. The case, itself, the decision remains

out there available to the public. The information should still be out there and be able to be seen.

That is true on the other decisions as well. If there is not a stipulation, not a settlement, they are out there, available to the public. I believe the court looked at a requirement that decisions be made available electronically. I believe that applies to all courts. They publish these decisions electronically on the court's website.

The broader issue of how do settlements fit in? Are they working against some of the other goals that we might have in the program? I would say that they are useful tools. If you think about how settlements work, it has to be an agreement between the two parties involved. There isn't one party who doesn't want to enter into that agreement. It is an agreement between the parties. The petitioners, in those cases, obviously thought it was in their client's interest to enter into a settlement, however strong their case may have been.

In my own experience, if the case was very strong, but wasn't deemed compensable by HHS to the extent they thought actual causation was proven, then that will probably affect -- and the case, nevertheless, went to settlement -- that would probably affect the amount that the settlement went for. The settlement would probably be

higher, the amount that went to the petitioner that they agreed upon, because the case was strong. It may not have raised to the level that the DVIC deemed it was conceded than if they had met the standard of actual causation, but the strength of the case affects the settlement, nevertheless.

I don't think that folks are really reinventing the wheel by going through this process. The methods for filing a claim are set by the statute -- what needs to be in a petition. There are guidelines issued by the court to try to help petitioners through that process. I know the court is looking at those guidelines to update them and perhaps provide even more helpful guidance to petitioners and any practitioner in the program, frankly. I know they are looking at some process aspects of that to try to help move the process along, but also to give some general guidelines to petitioners in filing claims.

I can also speak from experience that a lot of the practitioners in the program, the ones who bring the claims, are fairly experienced. They have brought a number of claims -- there are a couple of firms that routinely bring claims. They actually have the majority of the focus of their practice if not exclusively vaccines, then a majority of the folks in the practice is on vaccine claims. They are fairly well informed about bringing claims.

They don't really need to have a lot of guidance on that. I think the guidance is out there. I don't really see people struggling as much and reinventing the wheel. I would be concerned if that were the case because that would be slowing down the process. That would be working against one of the goals, which is that this be effective and speedy.

What my concern would be more about in looking at that and thinking about the issue is would people not realize that they had claims? Would they not realize the strength of their claims if many of them were settled? Again, the settlements are posted and they are out there and available. I think that works against that as well. Looking at, in practice, what has happened, we actually have seen -- instead of claims being filed untimely, which you might think would happen if people didn't know about their -- they didn't get notice of having a claim -- they only find out about it many years later, we are actually noticing that we don't see as many claims filed untimely.

When we do see claims filed, they tend to be pretty quick after the alleged injury. We have had several, especially in the flu area, where they have been filed six months -- there is the requirement that the injury has to be in place for at least six months, but they

will filed right away, right after the six month period has been met.

I am thinking, in practice, we are not really seeing an issue with folks not being aware of the program by virtue of the way cases are processed through the program. It would be concerning if that were the case. I think there were some -- in the past, there were some outreach efforts to make sure that people were aware of the program and its remedies and what they might be able to bring.

I haven't done the -- as I mentioned when I started, I am kind of electronically challenged. I almost said I was intellectually challenged, which some might --

MR. KING: You have proven that you are not.

MR. MATANOSKI: Thank you. I suspect that if you were to go on the Internet and plug in vaccine and injury, you probably would come up with a lot of law firms, for example, that would bring your claim. You probably don't have to know a lot about it, other than a suspicion that you might have a vaccine injury and access to certain information in order to get the ball rolling on your claim.

I say that because I have seen some of these firms that are bringing claims are bringing them more nationally, rather than geographically. When the program first started -- I don't want to date myself, but I go back

a long way in the program. Generally, you saw the firms brought cases within their own geographic area. Now, we have several firms that bring cases from across the country. They might be in Florida or New Jersey and they are bringing cases from California. I take that as evidence they have a good system out there of having people find them pretty easily.

Have my comments raised other questions on score?

MR. KRAUS: A couple of things. So everyone has the correct understanding of what information is in a settlement agreement, could you go over that?

MR. MATANOSKI: I will try to do that from memory. I actually take a case every once in a while. I just settled one. We had the vaccine involved, what the alleged injury was, the date the vaccine was administered, the amount of the settlement. This was a litigative risk settlement so it had the allegation that the petitioners maintain that this injury was caused by this vaccine. The Secretary does not concede that that happened -- does not accept that is the case. Nevertheless, the parties have reached an agreement that it is in their best interest to settle the case under these terms. That is the basic information that is out there.

MR. KRAUS: My follow up -- my point would be that that is information that is available that has some

use. What is not included in that is any discussion of the medical, the scientific literature, the medical expert that may have filed a report -- nothing that helps build the public knowledge about sort of the mechanistic evidence that is out there to connect a vaccine with a particular vaccine injury.

Just so we are clear, that is what I am talking about that still remains below the surface. I think you have made a good point about -- I think there has to be a distinction about awareness of the program versus awareness of sort of what the science and literature and kind of mechanistic evidence, to use the broad term, is out there. I think that is what I meant to kind of refer to as not percolating up to the surface, at least in a way that the public might be able to access it.

Having said that, I think you make a good point about the fact that the attorneys who generally handle these cases are aware from their own experience and networking with other vaccine injury attorneys -- that there is an awareness of that. I don't know that it gets beyond that kind of small community.

If I could also just respond to the issue about untimely cases being filed and the fact that you are not seeing them, I mean, that make sense, but, in my opinion, I don't think that is because there aren't a lot of untimely

cases out there. It is because there are no attorneys -- we, as practitioners, we know that if we file a claim that is untimely or arguably untimely, the likelihood -- I mean, there is no likelihood of getting attorney's fees. That could change possibly, depending on a federal circuit decision.

I think that has a lot to do with why you are not seeing untimely filed cases, whereas four or five years ago, you could make a good argument -- you could at least tell yourself, if you are filing a claim, that I am bringing this in good faith because there are all sort of factors and issues about whether it is timely. When you lose that any time you have put in as an attorney isn't compensated and also any money you have spent on experts. You don't get reimbursed and all that. I am not asking a question. I was just responding.

MR. MATANOSKI: I think, in response to that, I would say you are right. You won't see the Actual medical evidence that a petitioner may have generated in preparing their case in a stipulation. I would say what you -- if I were polling and looking through settlements and trying to prepare a case and I saw that there was a flu GBS case, let's say, and it had a really high number or another injury -- varicella vaccine and some other injury and it had a really high number and I saw an attorney's name down

there on that stipulation -- that will be on the signature page, too, their name and address --, then I would probably be giving that attorney a call and trying to find out what was that case about. This is just a practical matter of putting that information out there.

To the extent that there may be strong evidence in some cases, again, it is going to be by their very nature -- settlements are agreements between the parties. For whatever reason, each party has decided that those terms are in their interests. It might be that the speed of the resolution is better for the party involved or for the parties involved. I think factors like the strength of the case, either ratchet the number up or ratchet it down. There are a lot of factors that go into it. Again, an attorney who is representing either the Secretary or a petitioner has to look to the interest of their client and decide what is best for him or her in making a decision about whether to settle a case or not.

Are there any other questions?

DR. SHIMABUKURO: Just a comment -- I have actually read some of these decisions. There seems like there is a lot of detail in them. In a concession or in a decision, whatever documentation or paperwork is generated from that, is there a little bit more of that type of detail that Ed is talking about in those documents versus a

settlement. It seems like a settlement is more like an agreement. You agree on an amount. You might have some of the general facts in there, but that is done. In a decision, it seems like maybe there is more of this coming out.

MR. MATANOSKI: You know, Commander, actually your question brings up a good point that I neglected to think of, which is that if there is a decision in a conceded case, it generally does not go through the facts in any kind of detail or the evidence because it has been conceded. There is really not a need, as far as the Special Master or the court is concerned, to go through in lengthy detail what the evidence is in that case. There might not have been a lot of development of the evidence. There may have just been enough of that evidence to say this case should be conceded.

On the other hand, if a case is contested and it goes to entitlement and entitlement is found for the petitioner, then that kind of decision will have a lot of discussion of the medical evidence. If entitlement is found against the petitioner, then that kind of decision will have a lot of discussion of the evidence. In some ways, settlements don't have a lot of discussion of what the evidence is. The concessions won't either. It is when the cases are contested and go through the trial, whatever

the result may be, whether it is for providing compensation or not providing compensation, that you will see the more lengthy discussion of what the evidence is in a particular case.

I should also add that all of the cases are subject to a final decision by the Special Master. If the parties agree upon a settlement and the terms of the settlement, then that still has to be approved by the court. There is going to be a decision over those cases. It may not discuss what the evidence is. There is that overview of the process by the Special Master. They have to essentially agree that the settlement is all right and issue a decision adopting that before the case is resolved.

MR. KRAUS: When there is a concession the government is saying that we agree that the vaccine caused the injury. The fact that there is not a big discussion about medical evidence that is accurate, but the significance comes from the fact that the government has conceded causation. In a settlement, the government is saying we are not saying we don't agree, they are saying we disagree that the vaccine caused the injury, nevertheless, we are engaging in a settlement to resolve this case.

I do have to echo what you said as an attorney who represent clients in vaccine injury cases, the speed at which a case can be resolved through settlement is an

enormously important factor, as it should be, for clients, especially when you have serious injuries and clients who don't have access to the medical care that they need and the ongoing treatment. If there is an offer of something that is going to help them get some relief now as opposed to potentially two or three years down the road, a decision from the court, which may or may not be favorable, you can understand that that is the environment in which a lot of -- not a lot, most or all of the vaccine injury cases are being settled.

MR. MATANOSKI: Just on the concession, it would say the Secretary agreed that the vaccine caused the injury if it was an actual causation case. If it was a presumptive table case, it would say that the Secretary finds that the vaccine fits the criteria for presumptive injury and, therefore, is amenable to -- or should be compensated for that reason.

DR. DELA ROSA: When we are talking about the settlement there, are we talking about the life care plan and the money that is involved in the case? As I understand it as a parent, this process is three stages. First, the Special Master has to decide whether it is compensable or not compensable.

The second stage is how much. I don't know if this is how I understand the process. This is where we

determine the damages. The court has to decide the Actual number. The one side says that the proffer, this is what we want and does the court accept it or we meet together and this is how we are going to determine the damages and the other side says these are the kind of damages we want to be paid. Is that where the settlement comes in?

MR. MATANOSKI: It is all of the above. If you look at the slide up there, maybe I can use that to help make a couple of points on that. If you had a case, let's say it was conceded by HHS so we know it is going to damages at that point, there might be life care planners used in that instance to determine how much or what the kind of damages are, what the kind of services are that are needed, and how much they cost.

There may not be. It may be fairly straightforward. The petitioner may believe that they know roughly what they are going to require. There may or may not be life care planners involved. The more complex the injuries, the more likely life care planners would be involved in those incidences. Now, how that gets awarded could be a decision by the Special Master. That will usually happen if the parties can't agree upon what the damages are.

If the parties can agree upon what the damages are, then it will either be a proffer where the parties go

to the Special Master and say these are the damages, we have had our folks look at it, let's say a life care planner has looked at it, and these are the damages and we agree upon those or it might be a settlement where the parties say we have looked at the damages and we agree that this is the amount of damages in the case. There could be three different ways that the damages are awarded in that instance.

You could be looking at -- if you have a settlement, you could also be using life care planners. Each side may be engaging life care planners, particularly if it is a complex injury, even if it is in a litigative risk posture. That is the court isn't going to decide entitlement on this. The parties have said hold off on deciding entitlement because we want to talk settlement. You still might be involved in a somewhat complicated process to determine what the damages are in a particular case.

Again, a lot of that is driven by the complexity of the injury involved in the case -- how much is necessary to do to determine the appropriate level of damages. Now, in the litigative risk context, that might be done because the parties want to gauge what their exposure is -- how much money is at stake in a case. You are going through, you are saying, okay, the damages in this case may come up

to a million dollars. Now, I may take a little less than that because I am getting this certainty that I will get an award of damages through this process rather than the uncertainty of going forward where I might not get any award because my case hasn't been deemed yet entitled to compensation.

There are a lot of factors that go into that that attorneys have to think about. As Mr. Kraus was saying, one of them might be the speed at which the damages are resolved in a particular case. Does that help?

DR. DELA ROSA: So the settlement, at least that you are talking, whether Special Master decides what it is prior to deciding whether it is supposed to be compensated or not compensated?

MR. MATANOSKI: If we are looking at it from a standpoint using the term -- I was using the term litigative risk. If they are looking at it in a litigative risk standpoint, that is the parties are gauging should I settle this case before the Special Master decides entitlement in the case. Those are decisions that are made or settlements that are reached before the Special Master has decided whether or not an individual is entitled to compensation. They tend to be decided earlier because of that -- because they haven't gone through that process.

DR. DELA ROSA: I see the difference now. Thank you.

MR. MATANOSKI: If they go through the process of having the entitlement decision, then there could still be a settlement. The settlement would be about the damages. Sometimes the parties reach a litigative risk settlement after there has been a trial on the merit, but before a decision is reached because they then might assess their risk differently of an adverse or a favorable decision and are able to come to settlement terms at that point. Generally, after a decision is reached, you aren't going to see a litigative risk settlement. You are probably going to see a settlement about the damages, themselves, if there is going to be a settlement. Or you will see one of those other manners -- a decision by the Special Master awarding damages or a proffer awarding damages.

DR. DELA ROSA: Thank you.

MR. MATANOSKI: You are welcome.

MR. KING: A question I have. On the cases conceded, they can be broken down by presumptive versus causal. Do we have that breakdown?

MR. MATANOSKI: I don't know what that breakdown would be. I can think of a couple of cases that were actual causation. I think most were presumptive injuries

when there have been concessions. I don't really have a breakdown. That is just a sense that I have.

MR. KING: Would it be helpful for us to know that?

DR. EVANS: I will tell you 90 percent plus are going to be presumptive. It is the exception if there is causation in fact.

MR. KING: By presumptive, what we are saying is that because it is on the table. If it is on the table, we automatically presume that that is the reason for the injury and, therefore, it gets conceded. If it is not on the table and most of these cases, I believe, are not on the table now -- is that correct? That seems to be how we have trended. That is why we are seeing more settlements as opposed to concessions because they are not on the table and we do not concede or say that these are causal.

We basically fight that -- I think that is the way to describe it -- we fight that to say that is not what caused this. In the ongoing exchange back and forth, we then say, well, the juice isn't worth the squeeze for us to continue to fight this so what we will do is we will settle and make everything go away and we will move on. Is that the general idea of what is happening here?

MR. MATANOSKI: I think that is right. I think so.

DR. FEEMSTER: It is not a requirement that the injury is on the table to be conceded, right? It is not about a fight, per se. You are weighing the available evidence to decide whether or not there is causation. Even if it is not on the table, if in the weighing of evidence, it is determined that there is a causal relationship, it would still be conceded. Really, it is all about -- well, fundamentally, it is all about the evidence. It is either settled because you have evidence for or against, but it is not enough to meet the bar of causation and then that is settled. It is conceded if there is causation or it is on the table.

MR. MATANOSKI: That is correct. Conceptually, I would think you would want to see -- this is just conceptually, not speaking to whether this is actually working this way -- but conceptually, you would want to see that most of the injuries that are conceded should be conceded because they are presumptive. If there is good scientific evidence that the vaccine is causing that, you want to see that move onto the table as a presumptive injury. Yet, you have the safety net of allowing folks to prove actual causation and get their case conceded if they have enough evidence to do that.

MR. KING: But I would think that the table is a lagging indicator of injuries because of the fact that it

takes a while for the science to be found and to be determined and then there is a process to get it on the table so that the injuries may, in fact, be occurring, but that before they get to the table, it is going to take some time. It is usually not a four month process. It usually takes several years, I would think. It is a lagging indicator of what the injuries really are.

MR. MATANOSKI: That is right. What you might see if there was good science is the cases brought -- conceded as actual causation for a period of time and then it move onto the table. You would have the ability or the safety net that there is still a way of getting -- that the agency looking at it, in this case DVIC has a mechanism for conceding cases where the evidence is strong enough to say, yes, there was actual causation here while there is that lag period to get it onto -- or to catch, maybe, those that are so unusual and fact-specific that you aren't going to see necessarily enough evidence develop from a scientific standpoint to move it onto the table, but in the particular case, there was enough to say that it was causal in that case.

MR. KING: I do not know if this can be resolved here, but it may be something that a workgroup may want to look at. It would seem, though, that when we have a presumptive versus causation versus settlement that what we

have is a disagreement over what the facts mean, in terms of their interpretation. Some will say this clearly shows causal. Others will say I am not convinced at all that is it and there are other factors that caused it. The science is the science of what it is. It is just that it is interpreted differently by the different parties.

MR. MATANOSKI: That would be a fair assessment. I feel like I have been way out of my lane in some of my commenting, but being engaged in this conversation -- it was such an interesting discussion.

MR. KING: So I think what we are trying to do is do what is best for the way the Vaccine Injury Compensation Program works. I guess the question becomes is that the best way for this to be moving forward and being conducted, even though it has been that way? To me, I think this is something that a workgroup might want to explore as opposed to us at this meeting. It might be a process type of thing that we might end up having to take a look at.

I would like to add one more to it. I think the issue came up a good 12-15 minutes ago related to the timely component, in terms of whether or not they are being filed in a timely manner or it appears that they are. There are not too many that are untimely. I think the idea is, as Ed brought to light, was that attorneys, if they can't win, there is no reason to be the martyr for the

cause here. We are not going to go down and lose all of our money.

We are going to only fight those battles that we have a semblance of getting a return on our investment, meaning that we are going to get paid. I think there is an attorney's fees component on it. I am wondering if the iceberg that we are looking at of timely -- if there is a whole bunch below it that is based upon a whole bunch of different factors that things are not being filed in a timely manner and they are not being filed at all because if it isn't done timely, then you are not going to get any concession or settlement. It is just not going to happen.

Is it something that we should be looking into that maybe the span of time that we allow might not be appropriate? I don't know that we have explored what is underneath that iceberg.

MR. KRAUS: I think what you are talking about is expanding the statute of limitations from the three years. I believe that is a proposal that the ACCV has recommended in the past to the Secretary. I know there have been legislative efforts to expand the statute of limitations beyond the 36 months from the onset of injury. I, for one, as petitioners' representative or attorneys who represent vaccine injured people, it is, of course, very much in the

interest of those people to expand the statute of limitations for precisely that reason.

I can only speak from my personal experience. I get calls from people who have potential vaccine injury claims that can't get filed because the injury manifested four, five, six, seven, eight years ago.

MR. KING: That might be something for a workgroup.

DR. DELA ROSA: From what I understood, if you had the vaccine this year and three years later some injury showed up or at least the first symptom that has really showed up and you can relate it to the vaccine, I think the time starts from that, not the date of the vaccine, but the time the first symptom showed up. If it is even 10 years down the line, that is when the count starts, not the time of getting the vaccine. That is how I understood it. Is that correct?

MR. MATANOSKI: That is correct.

DR. DELA ROSA: Even if it showed up 10 years later, if there is a way of showing clearly that it is vaccine related, then that should be issued within the statute of limitations.

MR. KRAUS: Just so we are all clear that is never in reality -- theoretically, that isn't possible. You are never going to be able to prove causation in a case

where the first symptom is four years after the vaccination. You have a temporal gap that you are not going to be able to overcome. We don't have science -- I shouldn't say never, but it would be incredibly difficult to prove causation if you had a vaccine in 2008 and your first symptom is in 2012.

Is it theoretically possible? Yes. What usually happens if you are arguing in 2012 you realize you have a condition and if you are trying to relate it back to the vaccination, just as a practical matter in proving causation, you are almost certainly going to have to go back and look at what was happening in that gap.

If you identify, for example, the fact that there was a -- if it is a kid and it is a developmental issue, if you identify that the child had a speech delay a year after the vaccination, the government would likely argue that is the beginning of the statute of limitations and that was 39 months ago. That is the position the government took in the autism cases, which had, obviously, all sort of other issues.

Within the autism cases, that is where it became crystal clear that you can be somebody who doesn't realize that you have been injured by a vaccine because your doctors never told you about it and because you never put one and one or two and two together and you can then decide

-- become aware of the fact that maybe the vaccine is what caused your child's injury, file your claim, and it will be untimely. That is just -- the court has interpreted that as basically that is how Congress wrote the statute, 36 months from the date of the first manifestation of the first symptom of the injury. It is a whole other discussion.

MR. MATANOSKI: I noticed that I am already beyond my time. I will move through this quickly. If you need to cut me off, please do. You have seen the glossary of terms. Unless there are questions about that, I won't go through that. You have also seen the petition processing.

Now, this next slide is the slide I am going to focus on. The levels of appeal in Vaccine Act cases. This is new to the presentation. It was prompted by questions received last time about what happens on appeal. This slide gives you the hierarchy, the appellate hierarchy. A decision by the Office of Special Masters will be reviewed by the U.S. Court of Federal Claims. That will be the first tier of appellate review.

A decision by the Court of Federal Claims may, itself, be appealed. That will move up to the next tier of appellate review. That is the U.S. Court of Appeals for the Federal Circuit. A decision by the Court of Appeals

for the Federal Circuit -- the next appellate level would be the Supreme Court. Now, there also can be what is called en banc review. That is each decision that -- the normal process at the federal circuit is a panel of three judges will hear the appeal and issue a decision. The federal circuit is composed of more than just three judges. It is 11 or 14 judges. I forget the Actual number at this point. It fluctuates a little bit.

If you seek en banc review, the court, as a whole, all of the judges sit if they grant it and hear your case. Now, appeal to the Court of Federal Claims is appeal as of right. You get to do that. It is your right to appeal to the Court of Federal Claims. Appeal from the Court of Federal Claims to the Federal Circuit is appeal as of right. You get to do that automatically if you choose to do that. En banc review by the Federal Circuit is if they -- that is the Federal Circuit -- decides to grant it.

Supreme Court review is also discretionary with the Supreme Court. It is not as of right. You may ask them to review your case, but it depends on whether or not -- they have to grant what is called a certiorari petition in order for you to be heard by the Supreme Court.

We took a stab at giving a wire diagram of how this works and what could happen on appeals. A decision by the Office of Special Masters, as I mentioned, you might

not appeal it. If you don't appeal it, if you look at that chart, then it is going to go to judgment, whether you are awarded compensation or not awarded compensation. That decision not being appealed goes to judgment. If you appeal it, then it is heard by the Court of Federal Claims.

The Court of Federal Claims, if you get a decision from them -- you will get a decision from them. They can do one of two things basically. They can affirm the decision below, saying we agree with whatever the Special Master said or they can reverse it, saying we don't agree -- or I don't agree because it is a judge sitting alone. I don't agree with the decision by the Special Master. They can just straight out reverse it saying I don't agree.

They may enter their own findings, their own holding in the case. They may say I see a problem with it and I don't agree so I am reversing it, but I am sending it back to the Special Master for more action -- probably guidance. This is the problem I saw with how you decided the case. I want you to go back and do it again or do this part of your decision again. That is called a remand. If you see on the wire chart there, it shows that it is a reversal and they have remanded the case back to the Special Master for more action.

After the decision from the Special Master at that point, there may be an appeal from that decision after remand and we start the process back over again, back to the Court of Federal Claims. The Court of Federal Claims issues a decision and let's say you are not happy with that. Well, you can appeal it as of right as I mentioned, to the Federal Circuit. * It goes up to the Federal Circuit. The Federal Circuit can do the same thing that the Court of Federal Claims did. They can either affirm it; they can reverse it. Same sort of process involved, if they reverse it, they may have an outright reversal entering their own decision. They may remand it. They may remand it back to the Court of Federal Claims saying we disagree with your decision.

It may end up being really just a shot to remand it all the way back to the Special Masters because let's say the Special Masters did something that was affirmed by the Court of Federal Claims. If it's up to the Federal Circuit, and the Federal Circuit says no, we think it was wrong, they may be issuing instructions that will eventually mean the case goes back to the special master for more action. Final tier, it goes up to the Supreme Court. As I mentioned, that's not as of right. The Supreme Court has to accept the appeal in that instance.

Turning to appeals, we had several that were decided in this last period, Hammitt and Stone have been discussed here before. They were Dravet's Syndrome, or SCN1A cases, each of them. They were considered together by the Federal Circuit. The Special Masters and the Court of Federal Claims had-- the Special Masters had found that the SCN1A was a genetic mutation that was responsible for the condition that was alleged to be caused by the vaccine and therefore did not award compensation, because it was the genetic condition that was actually responsible for the injury. Eventually the Court of Federal Claims agreed with that, and then the case was appealed by the petitioner up to the Federal Circuit. The Federal Circuit just affirmed the decisions of the Special Master and Court of Federal Claims in those instances.

Simanski is a case that-- I guess one interesting thing that you should look at in the Hammitt and Stone instance is one of the issues involved is the genetic mutation. The appearance of it can be triggered by things like fever, and fever can be associated with vaccines. It may first appear after a vaccine because the fever that was associated with the vaccine may make the condition itself become manifest, the underlying condition. There was some discussion about that in those decisions.

Simanski turns on kind of a legal issue. The case was dismissed by the Special Master had issued what's called an Order to Show Cause saying that the petitioner had not at that point established what was necessary to prove their case and that their case would be dismissed if they did not take any further action. They needed to bolster their expert report in order to prevail. The petitioner did not, so the case was dismissed under this order to show cause. That was affirmed by the Court of Federal Claims.

At the Federal Circuit it was reversed, because the Federal Circuit said, technically what you were doing there was issuing a summary judgment on the case. In the instance of a summary judgment, you have to look at the evidence of the party that you're about to issue the judgment against in the light most favorable to that party. You had not given that benefit to that party when you took the summary judgment action. We're sending it back to you, Special Master. You can either look at it using that standard and determine whether or not the case should be dismissed, or you can go forward and take more evidence in the case and have it proceed farther. It's back at the Special Master level at this point.

There were two appeals by respondent that have come up. Hager was a companion case to Rotoli and Porter

that had previously been reported on. Those cases were appealed by respondent because the Special Master had found that based on an assessment of credibility and the evidence in front of him, the credibility of the experts, that the petitioners were not entitled to compensation. They hadn't proven the vaccine had caused the injury. On appeal to the Court of Federal Claims, that finding had been reversed. The judge at the Court of Federal Claims said, no, I don't agree with those credibility findings and re-weighed the evidence.

We appealed that, the Department, and HHS appealed that because we believed that the operating standard is that there's deference to be paid to the fact-finder on those kinds of factual determinations and credibility determinations, whether they're in our favor or not in our favor, but there should be deference accordingly. When Porter-Rotoli went up, the Federal Circuit agreed that there should be deference, that the Federal Circuit judge should not have inserted their own views on the strength of the evidence or the credibility of the experts in that instance. Hager was a companion case. After Porter was decided, Hager went the same way. It was reversed, the Court of Federal Claims finding. The finding of the Special Master was reinstated.

Cloer has been reported on here in the past, I believe. It is a statute of limitations case. Some of the discussion, I withheld to comments when the discussion was going on about statute of limitations knowing that I'd speak on Cloer. As one of the commission members mentioned, statute of limitations runs from the first symptom. Cloer reaffirms that. It's running from the first symptom of the injury. It is not when you discover you have a vaccine claim. If you didn't realize that that symptom was related to the vaccine, the fact that you knew there was a symptom is going to start the running of that clock, that 36 month clock. Cloer says that's absolute. It's a bright line. At 36 months from the date of that symptom, if the case has not been brought, it is untimely.

Some of the questions or comments about attorneys not getting fees may not bring a time-barred case, if they get fees and bring a time-barred case, it still will not-- the petitioner will not be benefited from that. The attorney may get paid for bringing that if they can get the attorneys' fees, but the bedrock finding in Cloer on the statute of limitations is going to be that that case is untimely.

Now, it did, as I believe has been mentioned here, reinstate at the Rotoli, which had not been available previously in light of an earlier decision by the Federal

Circuit. If you can show that the reason for your appearance in court late, for filing your claim late, is that one of these extraordinary circumstance involved in equitable tolling applies to your case, then you may still be able to bring the case. It is exceedingly hard and extremely rare to find those cases. That really, I think, was one of the reasons why Porter-Rotoli in one of the earlier decisions by the Federal Circuit, they said Porter-Rotoli is not available because it really was not being--they were not finding cases where it would actually apply to a great extent.

It is available again, in light of the Cloer en banc decision. During this period, and additional aspect to Cloer was explored and decided. That had to do with attorneys' fees. The attorneys for Dr. Cloer asked for fees in front of the Federal Circuit, and said we'd like to get our fees for bringing this case. The case was determined to be time-barred. The position of the Secretary was that if a case is time-barred and it couldn't have been filed because it was time-barred, then attorneys' fees are not available in that case.

In a 7-6 en banc decision, the majority of the Federal Circuit said, if the claim was filed, it was not frivolous when you filed it. There was a reasonable basis to bring this, what was a time-barred claim. It was brought

in good faith, then you still might get attorneys' fees. At the end of the day, Dr. Cloer--her petition isn't heard because it's untimely, but her attorneys get paid for bringing the case in court. That's where Cloer stands right now. The dissent disagreed. They looked at the text of the statute and said-- the statute essentially says, may not be filed. A petition that's untimely may not be filed, so Congress couldn't have intended that a case that they said shouldn't be here in the first instance should nevertheless get attorneys' fees from it. That was the dissent.

Where this leaves us now is-- we'll have to see how this develops. The dissent warned about this. There may be a lot of transactional costs involved if untimely cases are brought, found to be untimely. That's always been the-- if they're not timely then the petition ends, but then we have a lot of litigation involved about whether the case, the attorneys' fees should be paid or not. They were concerned about the transactional costs there. We'll have to see where that develops as this goes forward.

In particular, this may become important with the autism cases that are being resolved now. The attorneys' fees are being resolved in the autism cases. A number of those were untimely when filed, and deemed to the untimely. The attorneys may nevertheless now be seeking to try to show that they had a good faith basis to bring the untimely

claim it gets under an equitable tolling standard, and try to get their attorneys' fees for bringing that untimely claim. It could be an area where we see a lot of litigation involved, I would expect, in court. It may drag down quite a bit of the litigation resources, divert them to litigation about attorneys' fees and cases that have been deemed untimely.

We had two new appeals at the Federal Circuit. Viscontini--

MR. KING: One question, let's go back. The issue might be that we might have litigation resources dealing with the attorneys fees rather than in other areas and it being a zero-sum game. Is there any way to add resources to address that problem as opposed to take those resources away from areas that we should be focused on?

MR. MATANOSKI: I would think that's a budget issue. We have a staff that's right now at the Department of Justice fully engaged in working cases. We've been pleased that actually the processing times over the years have come down. That's due to hard work and use of working the court and use of other tools and petitioners willingness and cooperation in the use of other tools such as settlements to move cases along. It's things like hiring freezes. There are budgets that are probably not subject to--

MR. KING: I think that we don't necessarily have an issue, but what you're doing is giving us a potential that something might occur. We have to be cognizant that that might happen.

MR. MATANOSKI: If I were to look into a crystal ball, I would say we are going to be talking about this in the future if this stays as it is. To offer comments, I don't know how many cases out there might be deemed eligible for equitable tolling. If the past is prologue, probably not many. The cases that were deemed eligible for equitable tolling, they will be then timely so their attorneys will be eligible for compensation regardless of this holding with Cloer. What we may see is a lot of litigation that really doesn't net--all the litigation off attorneys' fees doesn't really matter to a lot of the cases coming in that are found eligible for equitable tolling.

In Viscontini, that was a case involving Hep B vaccine and Crohn's disease, the Special Master found that the petitioner was not entitled to compensation. The Court of Federal Claims agreed. They had some concerns about--they might have found a little differently on one issue or another according to the judge at the Court of Federal Claims, but overall she was satisfied that the position was proper under the legal standard. That's been appealed. That

one is pretty fact specific, so we won't see much out of that other than the facts of that case, I believe.

DOE 21 is a case that the Special Masters who have been involved, and there have been a number as it's passed through several hands, ultimately found that the respondents, or the Secretary's experts were more credible on the scientific issues involved. Upon review, the Court of Federal Claims judge disagreed with those credibility determinations in that finding. This case has been appealed by the Secretary because we believe it involves issues similar to those that we saw in Porter and Rotoli about deference to the Special Master or to the fact finder in making those types of factual determinations. That's now pending at the Federal Circuit.

We had several appeals at the Court of Federal Claims decided in this period. Paluck was a decision involving a mitochondrial case where there had been a finding by the Special Master that a petitioner had not shown actual causation in that instance. It was reviewed and scrutinized on the facts by Court of Federal Claims judge and then reversed and remanded to the Special Master. There weren't suggested findings-- the Court of Federal Claims judge did not enter his own findings on it, but he had problems with how the case was decided, and the

findings that are below and so sent the case back to the Special Master.

Phillips-DeLoatch was an unusual case for us. We don't usually see writ cases. Writs go back to common law. A writ of mandamus was sought by the petitioners to force the Special Master to order Merck, I believe it was, a drug company, to produce certain information about-- Merck was not a party of, it's the Secretary-- the petitioners had sought the Special Master to issue a subpoena to Merck to get certain information about the Gardasil vaccine, I believe.

The Special Master found that they had not made the showing for this extraordinary discovery that they were seeking, the petitioners went to use the writ authority at the Court of Federal Claims to try to get to the Court of Federal Claims to issue a writ ordering the Special Master to do that. The case has not been decided. The merits of the case have not been decided. This is a preliminary matter, so it went up on that. The Court of Federal Claims denied the writ. It's back at the Special Master and proceeding along.

Deribeaux was another SCN1A or Dravet's case that went up, similar issues to what you saw in Stone and Hammitt. It was recently affirmed by the Court of Federal Claims. I'm going to move along very quickly now. McKellar

and Woods were interim fees cases appealed by the respondent who had concerns about interim fees being awarded. We thought that there had not been a reasonable basis established at that point in the case for the cases being brought in each instance. We also had concerns about whether or not the Avera case that allowed interim fees would have contemplated interim fees being awarded in these instances. In each instance those cases were reversed, the findings awarding interim fees and sent back to the Special Master.

We've had a couple of new cases filed at the Court of Federal Claims, the ones in yellow. Graves was a death case where the Special Master awarded $60,000 in pain and suffering in addition to the $250,000 death benefit based on a case called Zatuchni by the Federal Circuit. It was appealed by the petitioner to the Court of Federal Claims because the petitioner contended they deserved more than the $60,000 in pain and suffering and the $250,000 in death benefits. That's pending now at the Court of Federal Claims.

Castaldi is a case where it was appealed-- it's a case that potentially got a statute of limitations problem. There was a finding of fact, but not a final decision in the case by the Special Master. The fact finding by the Special Master, or the order announcing that, was appealed

to the Court of Federal Claims even though there had not been a final decision in the case. It presents a kind of interesting, what we call, interlocutory appeal in a case, whether or not that's appropriate to be taking a case up before there's been a final decision.

Contreras is a-- I think that's a factual determination that's being appealed there. Davis is an attorneys' fees case. The Special Master had not awarded any attorneys' fees for the appeal to the Federal Circuit. It allowed some to the Court of Federal Claims, but none of the fees that were sought for the appeal to the Federal Circuit because the Special Master believed that there wasn't a reasonable basis to bring that appeal in light of existing case law, and case law that had not been examined or cited in the argument that the petitioner had made. That case is now pending appeal seeking the rest of those fees.

Going through the settlements, you have this. I won't go through them in any kind of detail. I'll give you the broad-- I want to first talk about the three oldest cases there. There are two that are 12 years old. They were both Hep B cases. We look at these cases when they've been around for awhile to see what the circumstances are in those cases. They were Hep B cases that went into the Hep B Omnibus, which may have been mentioned here. They were sitting without any action for a period of time while this

Omnibus proceeding was going on. They only recently became active. A good chunk of those 12 years was while they were sitting idle, awaiting something to happen, the outcome of the Hep B Omnibus.

There was also a six year case out there that we took a look at. That case went from 2005, I believe, until about 2010 awaiting an expert report from the petitioner. In 2010, that expert report came in, and then the case started moving forward fairly quickly, and then I believe there was a trial held, but before a decision was reached a settlement was entered in the case.

We also looked at the three shortest cases, to see what-- if there's anything to be gleaned from those. All three of them either were filed with all the records on the filing, or the records were completed within one month of filing. I think the shortest of the three was filed with records and an extra report by the petitioner. I think that was resolved within five months. They move through pretty quickly in those instances.

I also wanted to get a sense of how fast overall are cases moving through if they go through the settlement process. There are 44 cases listed here. 29 of them, or roughly two-thirds were resolved within two years. If you go out to three years, you capture over 80 percent of the cases that went by settlement. The settlement process seems

to move the cases very quickly through. We're still seeing that. I think that might have been recorded in the past, but I take a look each time we generate this chart.

This last slide should say "questions". If there are any questions based on what I've said, I'd be happy to entertain them now.

MS. WILLIAMS: I have a question. Thank you for doing all of that. It was a very good presentation, and thanks for looking at the cases and how long they've taken. This is a question that may need to be answered at the next meeting, but I'll put it out there. Recognizing that we appear to have a trend that's not going away of more cases being filed that are off-table, I think that's-- everybody's talked about that. It may not be going away. Those cases from a practical standpoint take longer?

MR. MATANOSKI: Not necessarily. They may take longer because they may not have a very good basis at all, and that may mean that they're resolved fairly quickly. They may have a good basis, or an arguable basis, and they may move into a settlement process and resolve fairly quickly that way. They may not rise to the level-- they may not have evidence that they meet a presumption or rise to the level that DVIC believes had actual causation can be proven, but they may be strong enough nevertheless to move through either entitlement by the Special Master or through

settlement in a fairly quick process. I would say that conceptually presumptive cases would move faster--

MS. WILLIAMS: It is sort of intuitive that those cases would move a little faster, and would it be useful to give us some statistics about the different time rates for table cases versus off-table, and how long they're taking? If they do seem to be taking longer, that's intuitive--

MR. MATANOSKI: Intuitively, you would think that because you've already short-circuited the entitlement process. You're beyond that. You're now right into damages.

MS. WILLIAMS: Right, exactly, so maybe that would be useful for us to look at, and if there's something that would-- if we had that information with your procedures, I would think that if you're going through the shift from table to off-table, how you're handling cases is going to change. Again, intuitive, it may not be the case.

MR. MATANOSKI: We could look at what we could find in terms of we could mine the data that we have and see when we look at these snapshots, we can see the cases that have come out in that period, how long they've taken. Let's see what the numbers show.

MS. WILLIAMS: Because it was just said that the program is not doing anything differently, so the question then arises: should it? I don't know that there is an answer. It's just a question.

MR. MATANOSKI: Just thinking a little bit forward not knowing what the evidence may show, what the numbers may show, one caution I would have about drawing any kind of conclusions from whatever they show is that you might see the conceded cases, for example, take longer than cases that were not conceded. That might be because they've gone into damages, there were complex damages. We'd have a fairly small sample size of cases, and that number could be very high, whereas a sample of cases that were not conceded are going to include a lot of cases that went by litigative risk. They didn't go to entitlement either.

They kind of are quicker through the process because they didn't have to have a hearing necessarily. The damages might not have been as complex for the individual who brought the claim and agreed upon the settlement may have had an overall number in mind that they met during that settlement that was acceptable to them, so they didn't go through the more lengthy damages. With that caution, but to the extent that we can look at this data that we have and see if there's something that we can give you, for whatever purposes that it might help you, we'll do that.

MR. KING: Any other comments?

DR. VILLARREAL: On page two, the Rotavirus, is that the original Rotavirus that came to market or is it--

MR. MATAONSKI: I think that might be-- oh, is it on one of the settlements?

DR. VILLARREAL: Adjudicated settlement, it was nine months.

MR. MATONOSKI: That would be a newer one.

DR. VILLARREAL: One of the newer ones? Thank you.

MR. KING: Any other questions? I want to thank you very much.

MR. MATANOSKI: Thank you, and thank you for the indulgence.

MR. KING: While it is not on the agenda, we need to take a break. Let's do a 15 minute break.

(Brief recess)

MR. KING: We are going to restart the meeting after the break. The next person on the agenda is Dr. Barbara Mulach with an update on the National Institute of Allergy and Infectious Diseases. Are you doing it from there?

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

DR. MULACH: Good morning everyone, this is Barbara Mulach. I just wanted to provide an update on a few things that are going on at NIH. I think Jessica Bernstein, my colleague, mentioned a few things to you and also talked

broadly about the fact that a lot of what we do is basic and early stage research, but we do have a few things that I think you'll be interested in. Certainly, if there are other topics that are of interest to you guys, we're happy to bring those topics to you, so just let us know.

We had a discussion at the National Vaccine Advisory Committee about pertussis and some of the concerns about some of the outbreaks and the waning immunity. In light of that, in the discussions of this workgroup on pregnancy, I want to let you guys know that we are doing a study in pregnant women of the pertussis Tdap vaccine looking at safety and immune response, and looking at the immune response in the babies. We know there's a recommendation to give the vaccine to pregnant women. We're looking to better define the immune response and what we know about the vaccine and how it works with pregnant women.

We're also getting ready to start a study of Tdap in postpartum women to look at protection of the baby in that way. We're also looking at the extent of the immune response in those women, so should they be having multiple pregnancies? Would that protect beyond the first child being born and understanding what we can about protecting those newborn infants? I believe Jessica also mentioned that we were getting ready to start a Hepatitis C vaccine

study. That study started in March of this year. We're currently recruiting. It's a Phase, Phase II study, so we're very excited and hope that we'll be able to report those results to you in the coming meetings.

I also wanted to remind you, Jessica mentioned that the Jordan Report was available online. For those of you who aren't familiar with it, it's a book that NIAID puts out about every five years, and it talks about the status of vaccine research and development in many different areas. It also has expert articles, and I just wanted to let you know one is on immunization in pregnancy, so some of you might be interested in that. I did bring a few hard copies, but also, I'm willing to send them directly to your place of business or your home if you'd rather not carry them. Please let me know if you're interested in a copy.

Finally, I just wanted to let you know that one of the institutes at NIH, the National Institute of Mental Health, the director, Dr. Insel, has started a series of blogs on topics related to his institute. In April he had several very interesting articles talking about some of the new numbers that they're looking at in terms of the number of autism cases in the United States and globally, and sort of a perspective on where the research fits in and what we know and what we don't know and what the research is

evolving and in terms of treatments as well. I'm happy to share that link with you if you guys are interested. Again, it talks about the genetics versus environmental factors and how they contribute to what we know about the disease and what they're doing to try to better understand it, treat it and prevent it. I'm happy to answer any questions.

MS. WILLIAMS: For the public, can you give the blog?

DR. MULACH: The blog is on the www.nimh.nih.gov website, and I can send you the more direct link.

MR. KING: Any other questions, thoughts, comments? That's it. Thank you so very much. Next on the agenda is Lieutenant Valerie Marshall with the update on the Center for Biologics, Evaluation, and Research

Update on the Center for Biologics, Evaluation and Research, LT Valerie Marshall, CBER, FDA

LT. MARSHALL: Good morning, I have a very brief update this morning. Dr. Marion Gruber has been appointed as the permanent director of the Office of Vaccines Research and Review at the Center for Biologics, Evaluation, and Research at the Food and Drug Administration. Since our last meeting, OVRR, which is the Office of Vaccines Research and Review, we have not approved any new vaccines since our last ACCV meeting, however there are a number of vaccines under review for

licensing, traditional age groups, or indications. That concludes my update.

MR. KING: Any questions?

DR. EVANS: Yes, I want to be clear about something. There has been talk about a quadrivalent influenza vaccine. There's one licensed quadrivalent influenza vaccine so far. This would be for seasonal use, and this was a vaccine that would not be covered, right now, under our program because it's a four-antigen, four-virus vaccine. Is there talk about this quadrivalent being used for the next flu season, do you know? Or is it going to be after that?

LT. MARSHALL: Typically we don't state when those vaccines are made available. We do refer the public to the manufacturer to find out that information, just because we're a regulatory agency. We have to be careful about when we state when vaccines are released. I'm not even sure when that-- I can check back with the agency and see if I can find out that--

DR. EVANS: That would be of interest, and there would be questions of, if they were to go forward without the excise tax in place, for example, it can always be added, and then you have eight years of retroactive coverage through new vaccines. Would this be considered a new vaccine? There's some legal permutations here. I know

when I saw that it had been licensed that those thoughts began to come to me. It's something that the commission would be interested in as this plays out.

LT. MARSHALL: I can certainly provide you with information as it is made available to me. That vaccine was licensed in February.

MR. KING: I have one, Geoff, if this vaccine moves forward, it would not be covered under the Vaccine Injury Compensation Program, is that correct?

DR. EVANS: In the immediate sense, it wouldn't be, but there have been times in the past where there have been routine use of vaccines that had yet to be added to the program where we all knew that they would be because they were routinely used. For example, in the mid-90s we knew the Hepatitis B vaccine was going to eventually be covered by the program, but people that were getting that vaccine in 1995, they were getting it without any-- the program was not covering it. We knew that soon because of legislation it would qualify, and it would be added. When it was finally added in 1997, it was eight years retroactive coverage. You could reasonably say to people in 1995, yes, there's every reason to believe that you could be-- that's what we're saying, if this issue were to come up.

MR. KING: So, on our vaccine information statements, would we have that for this vaccine?

DR. EVANS: For the vaccine information statements, that would just be presumptive. I presume, as they've done in the past, that they would have some information about this, but it would not have the requisite-- it would not conform to what's required under the Act because it's not a VICP covered vaccine yet. It would certainly list the benefits and risks with it as the other vaccines do. Eventually, it would be revised once it's covered by the program.

MR. KING: Would it list on that information statement that it is not initially part of the vaccine, in other words, don't call here?

DR. EVANS: It wouldn't be on the list for that potentially. I don't know how they would do it for that particular vaccine, but it would not have the information about the Vaccine Injury Compensation Program because it's not covered by the program.

MR. KING: It would be omitted?

DR. EVANS: There's would be on there because that still applies, but it would not have the availability of the VCIP on there. My sense is that this is not going to be an issue, that by the time that this gets into mass distribution in the next couple of years that there will

probably be a tax in place, and it will be covered, but these are just the questions that sometimes come up.

MR. KING: My only concern is that sometimes we like to anticipate the ball. If it isn't-- suppose things don't go the way they have in the past. It's possible that things will be different. In other words, it doesn't mean that it's going to be covered then. Is it covered through legislation?

DR. EVANS: Yes. What happens is usually the legislation is industry seeks coverage by talking to the tax committees in both houses. It's not something that the Secretary or HHS does proactively. It's something that industry has done historically. The arguments are persuasive. We have a vaccine that's going to be routinely recommended by CDC and it's going to be distributed to tens of millions of individuals, and there's no reason why it shouldn't be covered by the program.

Because of the specific language in the tax code that came with the 2005 addition of influenza vaccine that said trivalent vaccines-- that there would have to be a legislative amendment that would make it so that the quadrivalent vaccine-- and this legislative change, the legislative amendment, might in the end be as simple as saying something like "all seasonal flu vaccines". There's a bivalent that's a seasonal or there's a trivalent that's

a seasonal or there's a quadrivalent that's a seasonal, versus a monovalent that's for a pandemic or bioterrorism related thing, that's a different use that would not be something that would be covered by the program. This is probably TMI--

MR. KING: What you are saying is this is probably going to go forward, so the pharmaceuticals in general and people can correct me if I'm wrong here, would be petitioning say this needs to be covered because it's recommended, and then people would then-- so the only danger is that legislation is politics.

DR. EVANS: It is something that has never happened.

MR. KING: We would argue that people wouldn't, but politics are politics. Who knows in today's climate how long or what would happen to it?

DR. EVANS: Even if there was a delay, because what you need is the proper legislative vehicles they talk about in Washington parlance. You need a tax bill that's going to go through. Even if there is a delay, what I'm saying is that because of the eight years of retroactive coverage, that easily makes up for any shortage under the label.

MR. KING: Unless, of course, you happen to be the individual who might be injured by the vaccine and

waiting for others to catch up, because you can't do anything, you're in a paralyzed state of any litigation or appeal specifically under this program because you'd be tied up, if it wasn't legislated, you wouldn't be able to do anything.

DR. EVANS: But based on what we have gone through in the past, these are issues that at the time, I remember the American Academy of Pediatrics in their AAP newsletter when these vaccines are going to soon be added to the program, you have every reason to believe that you will have coverage and protections and so on. Those kinds of statements were made at the time, and who knows if they might have to be made again in this sense? These were short-term problems that were quickly resolved.

MR. KING: When are we going to start delivering this vaccine?

LT. MARSHALL: That information hasn't yet been made available.

DR. EVANS: Certainly within the next couple of flu seasons. You'll have two As and two Bs, viruses, rather than two As and one B. They're adding a second B virus.

MR. KING: If people knew that it wasn't covered initially when they were receiving it, would it prevent them, and would they say, I don't want that one?

DR. DOUGLAS: I'm not sure people who go to get flu vaccines even know about coverage or tables or this program or anything. It's a flu vaccine. They don't want to go to a hospital. I'm not sure how many adults are even seriously cognizant of this, or what's in the vaccine each year.

MS. LEVINE: Prior to the vaccines being covered, the liability protections of the vaccine aren't in play and the availability for compensation as yet don't apply, so one who was potentially injured, to the extent that it's not covered in the future will be able to sue the manufacturer and then wait for those protections to come about.

MR. KING: They'd have some recourse of action. Okay, thank you, any other questions, comments? The next on the agenda is Dr. Tom Shimabukuro, update on the Immunization Safety Office.

Update on the Immunization Safety Office
Dr. Tom Shimabukuro

DR. SHIMABUKURO: I have a pretty brief update for this meeting, just three topics and I'll move right into them. I just want to make you aware that in the first National Immunization Conference online was held in late March. The National Immunization Conference happens every year, it's just this was the first year they had it online.

This is going to be rotating every other year in-person, online, at least in the near future.

At the Vaccine Safety Session, there were three presentations. The second presentation is the presentation you've heard from Dr. Johann-Liang probably a couple of times, and the HPV vaccine safety review. There was really nothing new in there. That was a recap of the ACIP presentation from the previous ACIP meeting. The first presentation on immunization errors, it's a pretty interesting presentation. If you have time, you might want to click on the website. You get the slides and you get the audio, either together or separately, but you can basically view the session just like you were attending the conference back in March.

This covers immunization errors or medical errors, errors during administration which are kind of unique. You can have a medical error or administration error that doesn't result in an adverse health event, or you could have one that potentially does. For example, a pregnant women who didn't know she was pregnant or shouldn't have received a live vaccine may receive a live vaccine and there is no adverse health event as a result of that. However, that is an error in administration of a vaccine. Maybe in an improperly administered vaccine too high on the shoulder resulting in SIRVA, and you've heard

presentations on that. That's also a medical error that actually results in an adverse event. We covered these in this presentation. It's a pretty interesting presentation.

There will be an ACIP meeting next week. The agenda is available online. There will be an influenza vaccine safety update on our routine monitoring. There's also going to be an update in that presentation on GBS and H1N1 vaccine. There will be an update on GRADE, which is the process that ACIP-- it is the evidence-based process ACIP is moving towards to make vaccine recommendations. Updates from the IOM committee on identifying and prioritizing new vaccines for development, not a vaccine safety issue, but an interesting report.

There will be two scheduled votes. One is on recommendations for the 13-valent pneumococcal conjugate vaccine among immunocompromised adults. The last ACIP, the pneumococcal group went through the evidence for that and this is-- they're probably going to recap what happened the previous meeting and the vote on that. Also, recommendation for influenza vaccine use for 2012-2013, that's the routine vote that happens every season for seasonal influenza vaccines.

I just want to cover some recent publications. These two publications address GBS following monovalent H1N1 vaccine. The Greene paper is a VSD paper. Tokars'

paper is using the emerging infections program database, and the Wise paper also used the emerging infections database. These three papers at least, the bottom line is that in these surveillance systems they detected a small increased risk for GBS following monovalent H1N1 vaccine.

It was in the range of increased risk that we observed in some previous seasons with some previous seasonal influenza vaccines, but much less than the risk observed during 1976 with the swine influenza vaccine. I will say that at ACIP, we're going to show a summary table addressing these studies and also other studies as well. There are some variability in the results. Some showed a small increased risk, some there was not a statistically significant increased risk. We'll recap that, and those slides will be posted on the CDC website, usually fairly quickly after the ACIP meeting.

The next slide, the Klein paper is a VSD paper. I think the significant take-home message for this is we know that there's an increase risk of febrile seizures following MMR and MMRV in young children at the age when they receive their first MMR or MMRV, that's 12 to 15 months. They looked at the second dose of MMR or MMRV, which occurs around four to six years, and their conclusion was that there was not an increased risk of febrile seizures following MMR and MMRV in four to six year olds.

The second paper here used the VAERS database, and that was looking at the first year of use for high-dose TIV, which was this past season. The results there were reassuring. There were no new serious safety concerns identified. That's all I have, and I'm happy to answer any questions.

MR. KRAUS: At the last meeting you reported on the IOM committee that was assessing the feasibility of the study of vaccinated versus unvaccinated children. Do you have any update on that committee's activities?

DR. SHIMABUKURO: I'm actually going to defer to Dan on that, the National Vaccine Program Office, Dan Salmon. It will be covered in the later presentation.

DR. VILLARREAL: With the Klein article, do they exclude kids who did have seizures at age one, which is a normal time for the MMR or were they in the same pool?

DR. SHIMABUKURO: I'm not sure about that, but I believe having a previous febrile seizure is a risk factor for having a subsequent febrile seizures, but as you know, by that age, kids have moved out of that time-interval for risk.

MR. KING: Any other questions, comments? That's it, thank you. On the agenda, we have Dr. Dan Salmon and the National Vaccine Advisory Committee White Paper on the Vaccine Safety System.

Update from the National Vaccine Program Office
Report on NVAC Committee White Paper
Dr. Dan Salmon, NVPO

DR. SALMON: Thank you, so this is Dan Salmon from the National Vaccine Program Office. I was asked to give an update on the Vaccine Safety White Paper. Before I do so, I can respond to your question about the IOM committee. I think you folks have heard before that we charged the IOM with conducting analysis of the feasibility of studying various health outcomes associated with children that were fully vaccinated, partially vaccinated and unvaccinated. This was co-funded by CDC and NVPO. I think Tom or I either could have given this update, but essentially what the IOM has been asked to do is to look at how feasible it would be to do studies that compared children that are vaccinated by different schedules in looking at different safety outcomes.

Just to be very clear, this is not a study of unvaccinated children. It's an assessment of the feasibility. It's looking at things like, what would the utility of doing such a study be? What might be gained from it? How hard would it be? What are issues of confounding bias and study design? How costly would it be? What are the ethical implications? In other words, what could be done, and how useful would it be, and what would the barriers be? They've held three meetings, which I think is all they have

scheduled at this point. They've been open to the public. Two were in DC; one was in Seattle, Washington.

They've also commissioned a paper written by Martin Kulldorff from Harvard. Martin looks at many of these issues. This paper is for the consideration of the committee. This is not in lieu of or a part of their report, but rather is useful for them in considering their issues. My understanding is there's going to be a second version of that paper that will be out shortly. That paper is available on the IOM website. They are still soliciting public comments on the IOM website, and they recently brought in an international perspective as well.

The thinking is that in different developed countries you have, different immunization schedules that are being used. Although often they're quite similar, there are differences. Many of these countries also have large databases, and those large databases help outcome databases like in this country, the Vaccine Safety Datalink, can be used for these sorts of studies. After the last meeting in DC, they had someone from Canada speak. They had Liz Miller from the UK speak, and potentially they're going to bring in other experts from other European countries they can add to the deliberations of the committee. That's my update on the IOM Committee. Let me stop there, and just see if there's any other questions?

One other thing I'll mention building on what Tom discussed on the GBS post-H1N1, we are in the process of finalizing a meta-analysis. For H1N1, we had six different systems that looked at GBS. Tom mentioned several of these that CDC ran. There was the Vaccine Safety Data Link. There was the Emerging Infections Program. There was PRISM. The VA and the DOD also had surveillance systems looking at GBS. Those results, many of which have been published, some showed a small increased risk that was statistically significant, and some didn't have a statistically significant finding.

What we've done is we've taken these six different databases, these six different studies, and we've combined the data. Those captured more than 20 million vaccinated persons. By combining them, we take advantage of the diversity of populations that were covered because several of these, like EIP and VSD and PRISM, are the general populations. CMS is primarily the elderly. The VA is a population with a lot of co-morbidity. DOD is an unusually healthy population, perhaps under a lot of duress, but very healthy. By combining them, we can really see the full diversity of populations and also gain statistical power from having such a large population.

We've conducted this meta-analysis. We're putting the final touches on it, and we anticipate that it will be

submitted for publication shortly. I'll just mention that. This has been a very comprehensive safety monitoring program, one that's been coordinated by the Assistant Secretary for Health. This ties into the Vaccine Safety Working Group report that I'll discuss, and the Assistant Secretary for Health has a Federal Immunization Safety Task Force. This is a task force that includes high level and technical experts from the various agencies within HHS that work in vaccine safety, FDA, NIH, CDC, HRSA, CMS, AHRQ, IHS, there's probably some more alphabet soup that I'm missing, as well as other federal departments that work in vaccine safety, in particularly the Department of Defense and Veteran Affairs.

These are the different parts of the federal government that work in vaccine safety, and this task force is an opportunity under the direction of the Assistant Secretary for Health to bring it all together and make sure that the resources of the federal government in vaccine safety are well-coordinated, and we leverage the expertise across the Department and across the government. This task force has looked several times at vaccine safety, H1N1-GBS. This is a very comprehensive effort. It's a very well-coordinated effort, and I think we'll see the results of the GBS meta-analysis published within a reasonable short

time. Let me stop there for a minute, if anyone has any questions on that?

MR. KRAUS: Is all the focus on adults in the GBS meta-analysis?

DR. SALMON: No, it's not just adults. It includes kids as well. It's trying to find by three age groups, under 18, 18-64, and 65 and older. Seeing no other questions, I'll move onto what I was asked to talk about, which is the vaccine safety white paper. This was provided to you in your notebook. I also passed around this red book, which is the National Vaccine Plan.

I've given this to the commission before, and I brought a copy today because I really want to highlight-- and one of the take-home messages I'm going to make-- is the overlap between the recommendations that are in this NVAC report and what we, the government, plan on doing in vaccine safety. If you look at the National Vaccine Plan, the expected goal relates to the Vaccine Safety Systems. That starts on page 22. I'll get back to this in more detail. I know that our time is limited.

There is an awful lot in this NVAC report, and an awful lot in the National Vaccine Plan. I'm going to try to highlight some of the major components of both. I'm going to give a rather brief overview of the NVAC white paper. As I do that, I'm going to highlight areas that are in the

National Vaccine Plan to show that overlap and to really emphasize that and also talk about some of the ongoing and new activities that we're doing that are consistent with both the National Vaccine Plan and the NVAC safety white paper. Then I'll be happy to answer any questions that you might have.

DR. LINGUITI PRON: Excuse me for a minute, I'm just wondering if you were talking about different parts of the paper if you could reference it by page, it would make it a lot easier for me because it's not there physically.

DR. SALMON: This is the final report. It was approved by the NVAC in September of 2011. Moving on by page numbers, there's a brief background, but I would first point to page 4, where on the mid-right is in a box the charge to the NVAC in this regard. The charge was to review the current federal vaccine safety system and develop a white paper describing the infrastructure needs for a federal vaccine safety system to fully characterize the safety profile of vaccines in a timely manner, to reduce adverse events whenever possible, and to maintain and approve public confidence in vaccines.

The charge of the NVAC in this regard, broadly speaking, is to look at the system, and to figure out what can be done to improve the system to meet these goals. I would point out that-- the NVAC formed a working group to

do this. That working group had already been around to do a review of CDC's immunization safety office research agenda. That review came out a couple of years earlier, and you folks had been briefed on both that ISO research agenda as well as the NVAC report. The group, when they hit this charge, was already up and running and functioning fairly well.

If I could take a minute and talk about the membership of that group, and that's on page five. It included 18 members, nine of whom were current or former NVAC members. They're listed in appendix three, and this is on the top of page five. They had a broad range of expertise from pediatric and adult infectious disease, genomics, immunology, epidemiology, public health, maternal and child health, pharmaco-epidemiology and biostatistics. This is really the breadth and depth of expertise one would need to look at vaccine safety. It also included the public members from the four federal advisory committees or recent public members, including Tawny Buck, who was a former chair of the ACCV.

The group was co-chaired by Tawny, by Marie McCormick, who's a professor of maternal and child health at Harvard. She also chaired the IOM committees on vaccine safety, and Andy Pavia who's a peds-ID doc at University of Utah. It was a very diverse group with a tremendous amount

of expertise. They spent a lot of effort trying to hear from the public. They had worked with the Keystone Center, and did a lot of public engagement activities where efforts were made to solicit ideas, views, thoughts from interest groups, from advocacy groups, from partners in immunization and public health as well as the general public.

I want to next draw your attention to the figure on top of page nine, which was their description of the vaccine safety activities and primary purposes by group in lead roles. What I really want to do is just show you how complex the system really is. I think you'll find this, beyond making your eyes a bit blurry, to really emphasize that the vaccine safety system is a very, very complex system and it utilizes the expertise and the resources across the federal government, as well as non-federal partners ranging from industry and academia and professional organizations and advocacy organizations. This complexity is really a part of the challenge that the NVAC had to address when looking at the safety system.

In these pages preceding and immediately following this figure, there's a brief description of what the safety system looks like. We posted a report on our website, which is still there, a few years ago, which is a comprehensive review of the Federal Vaccine Safety System. If you're looking for more depth and detail than is in this

report, it's there. The point I want to make is it's a very complex system. It's a system which to understand and to think about improvements, one really needs to think about the complexities of what is done by whom, and how much is done.

Moving through to page 25 is that description of the safety system. I'm not going to go through that now. I think many of you are familiar with what we do in vaccine safety. You've heard reports from various components of the program. I've provided an overview to the commission before. I'm just going to move beyond that. That was really a review of what's going on. Starting on page 25 is the findings and recommendations. I really want to draw your attention to the second paragraph of page 25.

I want to read to you the beginning of that paragraph. It says, "as reflected in this review of the current system, the NVAC finds that the United States Vaccine Safety System is a fundamentally sound system for monitoring vaccine safety that has functioned well since the enactment of the National Childhood Vaccine Act of 1986, and believes the current system components should be maintained even in times of federal funding and uncertainty." In their review of the safety system, their conclusion, their primary conclusion is the system works

well and it's functioned well. It's a well-functioning system.

With this said, their charge was to say how to optimize the system. Taking an approach of continuous quality improvement, they do make recommendations. I'll very briefly go through those. I think the take-home message from this report is the system works well, and the system has served the nation well. As in any system, as there's new technology and new information in different areas of science, there's opportunity to make something that works well better. That's what this report focuses on. That's in fact what the National Vaccine planning goal two focuses on as well.

The recommendations are really in several categories. I'll start on page 28 where there's recommendations for leadership. Recommendation 1.1 is to reaffirm the system structure. 1.2 is organizational changes in the national vaccine program. 1.3 is the national vaccine advisory committee charter. I'm not going to go through each of these because of brevity and time restraints. To give you some examples of what is being done in this regard, for example, in recommendation 1.2, it recommends that IHS and AHRQ participate in the National Vaccine Program, and in fact, this is happening. IHS is a part of the Federal Immunization Safety Task force. They're

in Ex Officio at NVAC meetings. AHRQ is working with us as we're conducting a comprehensive literature review to support a federal vaccine safety research agenda, which I'll talk with you more about as well.

There's also discussion of the federal immunization safety task force or similar body, and as I mentioned, this has been a group which is under the direction of the Assistant Secretary for Health. It's been very active. It meets every two months by phone, sometimes in person. Some of the topics which the immunization safety task force has addressed as been H1N1 safety issues, GBS in particular, review of the Institute of Medicine on causality assessment, and consideration of changes in the table. This is an area this Commission is very familiar with, this estimate of vaccine safety during pregnancy and specific programs like the Vance Program that looks at safety during pregnancy. In fact, this is something which is a very important priority to the Department as reflected in the immunization safety task force.

Recommendation 2-- I'm sorry, this is where the task force should be mentioned. 2.1, expand the role and composition of the task force, and recommendation 3 is in terms of assurance and accountability. I'm sorry I'm now on page 34. 3.1, enhance the role of NVAC, 3.2, enhance the role of the relationship between the task force and other

coordinating bodies, 3.3 is an external assessment of adverse-event causality, and 3.4 is to monitor progress in enhancing the safety system.

I should say more broadly, this report is still being reviewed by the Department. It's fairly new, and many of the recommendations are still in consideration. I'm going to highlight some of the things that are being done, but I'm not going to try to tell you point for point on each one, because it's really not possible to do so in the time that's permitted. On page 39 we get into recommendations on research. 4.1 is development of a vaccine safety research agenda. This is a major priority for the Department. It's also one of the goals, or one of the Activities of goal two in the National Vaccine Plan. It was recommended by the Institute of Medicine as well.

We're in the process of developing that research agenda. We have worked with AHRQ to fund a very comprehensive review of vaccine safety science. In many ways, it's similar to what the IOM did, but it's a little bit different, and let me explain how. The IOM was asked, was this adverse event caused by this vaccine? They would ask the IOM about very specific relationships, these vaccine and these adverse events. When looking at that relationship, they looked at all the science. It was

limited to the relationship specified in the contract or added by the IOM.

Potentially, there's a science in vaccine safety that isn't related to the relationships that they look at. That's why we're doing a comprehensive literature review. There's been a contract issued by AHRQ to do that. Once that is complete, then we'll look at all the science in vaccine safety and develop a research agenda. As you're familiar with the Immunization Safety Office Research Agenda, it really builds on that effort.

ISO recently went through the exercise of developing a research agenda for CDC, however, potentially there's work that can be done in vaccine safety beyond CDC. The ISO research agenda was a CDC research agenda, and this is the creation of a research agenda for the entire federal government, in fact, for the whole US.

Recommendation 4.2 is building a vaccine safety research community. 4.3 is research funding and investigator training. 4.4 is ascertainment of public concerns and perceptions. 4.5 is research directed at clinical practice. 4.6 is data access. 4.7 is biological specimens. I'll just comment a little bit about this last one, 4.7.

The NVPO about a year and a half ago put together a meeting on development of a vaccine safety bio-bank. This

is a very complex issue, but also a very important one. If you think about studying serious adverse events to vaccines, fortunately, they're very rare. We don't see common adverse events. Because they're very rare, they're very hard to study, and they're particularly hard to study prospectively if you think about the funding cycle of five years, for example, which is a typical funding cycle of an NIH grant or a CDC grant for that matter.

Let's say you wanted to look at something, let's take GBS as an example, and let's say hypothetically that GBS is caused by a vaccine one in 1,000,000 times. If you tried to study this prospectively, it would be really hard, because it might take you five years just to collect enough cases to do such a study. That would still be very difficult. Fortunately, there aren't that many cases. If you want to understand the biological mechanisms by which a vaccine might cause a very rare adverse event, or if you want to understand the individual level risk factors, maybe there's something about the person. Maybe it's genetic. Maybe it's concurrent or previous illness. If you want to understand that, you need to study these rare cases.

By developing a bio-bank where you can accumulate them prospectively, and once you have a sufficient number of cases to do such studies would be an important enhancement. It's something that's mentioned in the NVAC

report. It's mentioned in the National Vaccine Plan, conceptually. It's something that NVPO has been working with the agencies to try to figure out how to do. With this great potential is that it's extremely difficult to do and extremely expensive to do. We're starting to think about how one might do that optimally.

Moving onto recommendation five, recommendation 5.1 relates to post-licensure surveillance, 5.2, data considerations, and 5.3 implementation of programs. I'll speak broadly about this. FDA was charged to put 100,000,000 people under active surveillance. To do this, they put together the mini-sentinel program. That's about one third of the US population. It's not a magic number, but it's the number that Congress used, and it's an enormous number of people. I think that H1N and vaccine safety really helped us with this, because as I mentioned, we put together a whole bunch of systems, many of which were already in use or being developed. For example, the Vaccine Safety Datalink, which is really the backbone of the vaccine safety system, and probably more than a decade ahead of drug safety, has been around for a couple of decades.

There were other systems that had been in the process of being developed, like the Department of Defense and CNS and Indian Health Services and VA where they have

these large databases that they were starting to do work on. There was recognition before H1N1 that there was the potential to use these databases for safety monitoring, and they were beginning to do that. Then there were new systems developed. For example, PRISM, which I think we've talked about before, the post-licensure rapid immunization monitoring system, took large health plans and linked them to state immunization registries. This built upon earlier work that had been done, but never a system put together like this linking the registries for safety monitoring. If you put these systems together, it's a very large number of people in active surveillance.

For H1N1, the programs that were being developed were rapidly deployed, and PRISM was put together. Since then PRISM has been picked up by FDA as a part of Mini-Sentinel, and it's now a part of their ongoing infrastructure. This has been-- I think H1N1 helped us realize the potential of large linked databases in the US and push our ability for active surveillance further to include more people in more diverse populations and to make sure that effort was well-coordinated.

Moving onto recommendations in six, we have 6.1 which is clinical practice improvements, utilizing improvements and barcode labeling. Then recommendation 7.1 is communications. 8.1 on page 51 is stakeholder and public

engagement. Lastly, on page 53 and moving on, cost evaluation, 9.1. There's a very comprehensive compilation of recommendations ranging from how the system works conceptually, operationally, coordination, oversight, the different components looking at surveillance, looking at clinical practice and biological mechanisms, at the health of the research community, specifics like communication and public engagement, and then broader issues of funding.

Again, if you look at goal two, and I really want to bring this to your attention, because it's the National Vaccine Plan, which highlights where we, the federal government, think the National Vaccine Program needs to go. This is the Red Book I passed around, and I'm looking on page 22, which is enhancing the vaccine safety system. I just want to go through these very, very quickly because I know time is short, but I think you'll see a lot overlap with what we've just talked about on the NVAC report. 2.1, we need to make sure the system is robust, that it focuses on high priority areas.

2.1.1 specifically mentions the research agenda. 2.1.2 is having a good workforce. 2.1.3 is laboratory capacity. Again, 2.1.1 and 2.1.2 completely overlap with the NVAC report and highlight what our priorities are. Objective two is to make improvements in the manufacturing process and regulatory approach. 2.3 is common detection

and verification in safety systems. 2.4 is the evaluation of those signals. That's really a compilation of passive surveillance, of looking at concerns among the public and providers and then active surveillance like the systems I've been talking about.

2.5 is causality assessment. 2.6 is understanding why people have adverse events and among whom, and again this relates to the biological mechanisms and potentially a bio-bank. 2.7 is the clinical practice, again, discussed in the NVAC report, and 2.8 is enhancing collaboration in the vaccine safety systems, which we correspond with the first recommendation of the NVAC. I've covered a lot of material there. I think much of this you've heard before. Some of this is new. I'd be happy to stop there and answer any questions you might have.

DR. DOUGLAS: I'll just make a statement that the white paper captures beautifully my personal experience of being liaison with the NVAC. It's such a large role. The wealth of expertise is almost astounding, of people who are working every day in vaccine safety. The rigor with which they approach this is also incredibly impressive. Our work on compensation is just a very small slice of what's going on, but to those listening and for the committee to know that it's a huge machine of just exquisitely prepared

researchers who are doing this work every day, so the vaccines are not being given in a vacuum.

MR. KING: Anybody else?

MS. WILLIAMS: Is there anything that you have discussed that the ACCV will be involved in?

DR. SALMON: That's a great question. I think one of the working groups this afternoon will address that. At our last NVAC meeting, we established a maternal immunization working group, and this is an important area for a bunch of reasons. There could be vaccines that could be developed specifically for pregnant women. There could be vaccines that are used for pregnant women that are also used for other populations. There's a potential benefit to the newborn child, as we've recently seen data with influence vaccine where if you vaccinate mom, there's likely protection to baby.

There's also the importance of protecting the mother, in the case of pertussis where mom may be a source of transmission to the child. There's potential benefit both to mother and child, but also a need to do very comprehensive safety monitoring both for the health of the mother and the health of the child, which can be quite challenging to do. NVAC has formed a working group to look at this. I understand that the ACCV is as well. I think this working group is meeting this afternoon. I'll join

that meeting. This maybe an opportunity for NVAC and ACCV to find some synergy.

I should also mention that this is the last meeting with the Commission. I'll be leaving federal service at the end of July. The new NVPO representative will be Jennifer Reed. One of the areas that Jennifer has focused on is maternal immunization. In fact, she with CDC, and other colleagues, posted a meeting about six months ago focusing on maternal immunization. As you move forward with this working group, you'll have her as a resource to help focus on this issue.

MS. WILLIAMS: Thank you for your service.

DR. LINGUITI PRON: Thank you Dan. I wanted to comment as well that this is a very comprehensive document, and a little bit hard to digest in its expansiveness. I'm thinking that it would provide also some answers to future science workers who had concerns all along about how things go forward. Thank you very much for your work.

DR. VILLARREAL: Dan, on page 42 with the post-licensure, one of the things for private physicians and clinics and universities is really this meaningful use. Is there going to be a move for us to use EMRs, the AAR Act getting computers into the system so there will be ways of generating some of this adverse effect-- say we have a web portal and the families need to report that something has

happened with the shot, immunization. Is there a way that we're looking at that for meaningful use, collecting data?

DR. SALMON: That is a great question. We had a call a few weeks ago with OMC, which is the group at HHS that looks at these issues. There are efforts to make sure that the meaningful use data, and more broadly, electronic health records and vaccine safety surveillance and reporting are really linked together. Those communications are now happening internally. I think there's a broad recognition that the two need to work well together. That's what's happening. I don't have a specific-- I think your question is broadly, is there a relationship, is there coordination and working together? I think the answer is yes.

DR. VILLARREAL: When you look at meaningful use and if you look at the peds population, we have really small parameters and cores to measure us. If we could open that up and be more robust as far as, yes, the children got these immunizations but also were there any sentinel events or even minor events, fever, achiness, anything that parents can talk about, I think that that would help families collaborate a little bit more with immunizations, if they had the ability to get online quickly. Again, we get points for having a web portal, but it's fairly stupid if we don't use it.

DR. SALMON: I think that's a great point, there's also an effort at Harvard Pilgrim where they tried to make electronic reporting to theirs more effective and efficient, and Tom may be able to discuss that in greater detail. I think that was ISO funded, but the idea is it's actually what you're saying, which is to make it easy for the clinician to make various reports. Tom, do you want to add-- are you familiar with this project?

DR. SHIMABUKURO: We actually briefed OMC a couple of weeks ago as well on meaningful use. We're currently engaged with Harvard in a project that looks at algorithms and computer technology to actually prompt a clinician to consider whether they want to submit an adverse event. It uses computer algorithms to look at an actual vaccination and then using ICD-9 codes that occur within specific risk windows. If any of those in the program flag or pop-up, then the provider can receive a prompt should they-- asking whether-- basically saying, this exposure occurred, this outcome happened, would you consider moving forward?

Then it's got features to assist them in completing the report, like RO population of certain fields to facilitate that whole thing. Not only does that increase awareness, for certain fields it probably increases accuracy and also ease of actually submitting a report. It

can also-- the way that they're building the software now, they're trying to build it so it's universal, so it can be used with multiple EHR systems not just a specific organization's.

They're going to have a feature where you can do a secure upload to VAERS as well. This is, I want to say, this is in the R&D pilot stage right now, but we're certainly looking to take full advantage of modern technology.

DR. VILLARREAL: It gets to Ed Kraus' point as far as the lawyers need the data, the doctors need the data. The major problem is right now it's so mushy because your second issue is the barcoding. That becomes very critical for us. If that vaccine barcode is not punched in correctly by someone, then you've got wrong data right away. You cannot say if there's a safety issue. You don't even know what you gave, what vaccine.

The barcoding is really imperative, and also the data collection. If you can simplify it on the clinician level, anybody administering doses and letting the families also know, if you have any adverse effect of immunization, this is the fast way of going in there and telling us besides giving us a call. I think that if we can have some of those linkages, especially now with the meaningful use

and the ARRA ability for physicians to get computer use data quickly to organizations.

DR. SALMON: I agree and I think this conversation really exemplifies the tone, tenor, and purpose of the report. The system works well; the system does lots of things. However, there's new technology. What you're talking about wasn't possible five or ten years ago. What would be possible in the near future may not be possible today. I think as an approach to continuous quality improvement, one always wants to look at new technology and be at least with the curve if not a little bit ahead of it to make sure that technology is used. Some of it may be barcoding, and EHR, but it's also these large databases, which until recently, there were very few that were available, but now there's a lot more. I think the way that you're thinking about this and framing this and talking about it is exactly what we need to do to make sure the system works as well as it possibly can.

MR. KING: Any other questions or comments?

DR. SHIMABUKURO: I started working in the immunization program at CDC and I think that's when I first met Dan, and started working with Dan and have continued to work with him as I went into the Immunization Safety Office. Before you go, I just want to thank you for all

your work in vaccine safety and your leadership at NVPO, and good luck at Hopkins.

(Applause)

DR. SALMON: Thank you.

MR. KING: The next item on the agenda is for any public comment, if anyone has any specific public comment either here in the room or on the phone.

Agenda Item: Public Comment

OPERATOR: Thank you, we'll take public comment. Please submit your request for public comment on the phone by pressing "star, one". You may withdraw your request by pressing "star, two". We do have one request for comment coming from Theresa Wrangham. Your line is now open.

MS. WRANGHAM: Thank you, can everyone hear me okay? Good morning, I'm Theresa Wrangham. I'm the executive director for the National Vaccine Information Center. I thank you today for the opportunity to offer public comment. For over 30 years, NVIC has been the oldest and largest parent-led charitable non-profit organization representing public vaccine safety concerns and informing about protections in the public health system. As an independent clearinghouse for information on the status of vaccines, NVIC does not advocate for or against the use vaccines. We support the availability of all preventative

healthcare options including vaccines and the right of consumers to make educated voluntary healthcare choices.

During last week's meeting at the National Vaccine Advisory Committee, there was a great deal of discussion on strategies to increase the uptake of vaccines in pregnant women and the question of whether or not unborn children would be covered by the Vaccine Injury Compensation Program for vaccine injuries sustained prior to birth. Dr. Evans responded that pregnant women would be covered for injuries they sustained, but there had been no injury claims to date filed with regard to vaccine injuries sustained in utero and that we take a congressional action to extend injury compensation to unborn children harmed by vaccines.

We would ask this committee to task its new working group to investigate this and respond to that question and consider recommending compensations be extended to unborn children harmed by vaccines received by pregnant mothers. We would again thank this commission for its thoughtful process in extending the vaccine injury table in light of the recent findings at the Institute of Medicine in this regard. However, as the Commission is aware, the IOM report was unable to make causal determination for 85 percent of the adverse events under the IOM's review due to the lack of quality science.

The IOM's acknowledgement of this lack of science underscores the urgent need for ongoing independent vaccine safety research. We would again request that this Commission make recommendations to close these acknowledged research gaps, as is their purview under the legal mandate for safer childhood vaccines. This research is not only urgently needed, but it would also have the beneficial effect of decreasing the number of cases dismissed or treated as litigative risk. It would make the claims process less adversarial and more expeditious.

The ACCV discussed the recommendation at its last meeting, but the discussion seemed to become sidetracked on how research would be funded. We would assert that there is no requirement for the ACCV recommendations to identify funding in order to fulfill the charge for ongoing documentation research. There was a suggestion during the last meeting of the ACCV that the vaccine injury trust fund could be used for funding research. We would remind the Commission that those funds were intended to compensate those injured by vaccines.

Given the ongoing expansion of the vaccine schedule, fast-tracking a vaccine for licensure and the acknowledged vaccine safety gap, these funds must continue to serve the injured and must also be acknowledge that there's an equal likelihood that the vaccine injury table

will also expand as is most recently demonstrated by IOM findings. We would ask that any recommendations for ongoing research made by the Commission also seek to protect the original intent of the injury compensation fund.

In closing, we would ask that presentations made to the Commission be made available to the public prior to the meeting, and/or be a webinar to enable members of the public attending via teleconference to be able to follow the presentations during the meeting. Thank you again for allowing me to speak today.

DR. EVANS: I just want to make a clarification on the comments about what I said at NVAC last week. I believe what I pointed out was that the program has received about a handful of claims in the 24-year history of the program. None of them have been compensated, and none had gone actually-- maybe one had gone to the merits, actually, of the science. It was the preliminary-- the issue at hand was whether the program covered, was able to adjudicate the claim based on the language in the Act, which says that it's the vaccine recipient that is covered by the program.

Since the mother is the one that's receiving the injection and not the baby inside, the fetus, that was the sticking point. There were mixed decision on that at the Special Master level, and also one case went up on appeal.

There's not ever been a case that's gone through and found to be meritorious both in terms of the law and so on. It's never reached the circuit where there would be a decision that has precedential value to it. Right now, it is still uncertain to the extent to which an allegation of harm to the fetus can be covered by the vaccine that was administered to a mother during pregnancy. I should also point out the vaccination and pregnancy workgroup will hear more about this from Anna Jacobs during the session this afternoon.

MR. KING: Any comments, questions? Any additional comments?

OPERATOR: We show no further comments on the phone.

MR. KING: I have a question as it related to the public comment, which is the availability of the presentations and slides. Is there availability prior?

MS. HERZOG: Yes, they are posted on the web site, on the ACCV website.

MR. KING: The presentations that are given during the meeting are posted on the website for the ACCV so that one could follow along. That's a good point.

DR. EVANS: That is a good point, and HRSA's intention, especially in light of the remodeling efforts that are ongoing and the reduction of conference rooms,

HRSA's clear intention is to start coming up with teleconferencing and webinars and those kinds of technologies in the future. There's been lots of questions back and forth in terms of numbers and how often people are meeting and so on. That's actively being pursued. I don't see it for us at least in the next meeting or two, but it's something I would predict a year or so from now could very well be the way that we would be meeting at times. I know that's not going to make the chair happy in terms of the touchy-feely aspect that might be missing, but in terms of the budget aspects of running the program, the agency sometimes is looking more at ways to save money.

MR. KING: Understood, so the chair will make a comment on touchy-feely. Let us not forget that it is human beings that interact with each other, and it is not the technology. It is important that we remain and maintain the humanity component to get things done in terms of relationships and how we work. Without there being any additional comments, I will seek motion to adjourn.

(On motion duly made and seconded, the Commission unanimously approved adjournment)

(Whereupon, at 11:55 a.m., the meeting was adjourned.)