Health Resources and Services Administration

85th Meeting of the Advisory Commission on Childhood Vaccines

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CASET Associates, Ltd.
Fairfax, Virginia 22030
(703) 266-8402

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

Agenda Item: Welcome and Chair Report

MR. KING: Thank you, Cathy. Welcome everybody. I know we have a few members who are on the phone, as well. I'd like us to do an introduction around the room. We will start with those on the phone first. Then, during the course of the meeting, if you are going to speak, we would ask that you identify who you are, so that those on the phone will also know who is speaking, and for those on the phone, we will know here in the meeting room who is speaking. We will start with the phone, and we will work our way around.

DR. FEEMSTER: This is Kristen Feemster, a Commission member, pediatric infectious diseases physician and health services researcher from Philadelphia.

MS. DELA ROSA: This is Luisita dela Rosa, a current member of ACCV.

MR. SHIMABUKURO: This is Tom Shimabukuro. I am with the Immunization Safety Office at CDC. I'm an ex officio member.

MR. KING: Dave King, chair of the ACCV. I am a parent of a vaccine-injured child.

MS. WILLIAMS: I am Michelle Williams. I am unaffiliated attorney and vice chair of the ACCV.

DR. DOUGLAS: Dr. Charlene Douglas, faculty member of George Mason University, representing the public.

MS. PRON: Ann Pron, pediatric nurse practitioner in healthcare ACCV member.

MR. KRAUS: Ed Kraus, ACCV member. I represent vaccine-injured individuals.

MS. MARSHALL: Valerie Marshall, Office of Vaccines, FDA.

MS. BERNSTEIN: Jessica Bernstein, NIH.

MS. REED: Jennifer Reed, National Vaccine Program Office, ex officio.

MR. SMITH: Jason Smith, I am a Commission member and in-house counsel for Pfizer, a vaccine company.

DR. VILLAREAL: Dr. Sylvia Villarreal, pediatrician, ACCV member.

MS. LEVINE: Emily Levine, I'm with the HHS Office of the General Counsel.

DR. EVANS: I'm Geoffrey Evans, Division of Vaccine-Injury Compensation, and the executive secretary to the Advisory Commission on Childhood Vaccines.

MR. KING: We have a rather robust agenda that we are going to be moving through this afternoon. Something new on the agenda, so I think I'll explain it before we begin, is we have a public comment starting the meeting and

public comment after the meeting. There is a specific purpose for the public comment before the meeting, and we would ask that no one abuse it. It is simply this, we are willing to listen to what members of the public have to say about a specific agenda item that is listed on the agenda, which has been published in the Federal Register and is on the website.

If you have a public comment that is not related to a specific agenda item, then we ask that you hold off on that specific item, until the public comment after the meeting. Having said that, I would ask that whoever speaks obviously will identify their name and who they are, and if you will identify the specific topic on the agenda that you are going to speak to. If we hear no one, then we will assume that any people who have comments will do so at the end of the meeting. We are prepared to begin that period of the meeting at this time.

Agenda Item: Public Comment on Agenda Topics

OPERATOR: All right. If you do have a comment, please press star one.

MR. KING: Cathy, I think that's enough time, wouldn't you say? Great, moving along. We have the approval of the June 2012 minutes as the order of the business. Does anyone have any comments corrections,

changes to what the specific minutes had to say, that were published in your books? Anyone on the phone? We will entertain a motion to approve the minutes.

(Whereupon, on motion duly made and seconded, the minutes of the June 2012 meeting were unanimously approved.)

Let us move on.

Dr. Geoffrey Evans, the report from the Division of Vaccine-Injury Compensation.

Agenda Item: Report from the Division of Vaccine Injury Compensation

DR. EVANS: Good afternoon. Welcome to the 85th quarterly meeting of the ACCV. I am going to give you a program update from the Office of the Division of Vaccines Compensation. In terms of the meeting highlights, otherwise, they will be following my presentation, and update from the Department of Justice from Mr. Vince Matanoski. Then, there will be reports from the various workgroups for the Commission. Three of them met this morning, and one of them, the Future Science Workgroup, has been meeting by phone, and has a draft recommendation under tab five in your meeting workbooks. Following that, there will be updates from ACCV ex officio members, from FDA, CDC, NIH and the National Vaccine Program Office.

Starting with the program data on the statistics, the numbers of claims filed, as you can see, almost all are non-autism. It remains steady, but the trend has not been going up fortunately, in terms of our ability to handle lots of claims. It has actually decreased a little bit over this past year from the previous year. With a month to go, I think we might end up with less than 382 that we received the last fiscal year. Only one autism claim, and the father was alleging autism, was filed, so again, the total was under what we had this time last year.

Under adjudications, there has been a great deal of activity under the dismissed category under the Omnibus Autism Proceeding cases. The total that I am coming up with now is somewhere in the order of 4,400 of these claims have been dismissed, and with attorney's fees and costs being worked out by the court and the various attorneys involved. Otherwise, the adjudications remain quite brisk for the non-autism cases, which you will see reflected on the next slide, on which we continue to show this breakdown of the pattern of the process. Again, the predominant way claims are compensated are through the settlement process. Then, much less frequent, through court decision and concession. The trend, although it has decreased in the past couple of years, is starting to steady out for

concessions and court decisions. I expect it will remain that way for some time to come.

The next category to go over would be the award amounts. Approximately 171 million all together, and you can see again the attorney fees and costs column has significantly increased over the past year or so. That is again because there is a lot of activity resolving the fees and costs for that group of cases. Actually, Cheryl Lee, who works in our office with Ward Sorenson, has found her workload increased 128 percent this past year. She has been very busy handling all of the attorney fees and cost things, and will continue to remain so for some time.

DR. KING: Geoff, can we just ask you a question?

DR. EVANS: The dismissed claims under the autism proceeding have to have attorney's fees and costs resolved, because as we have discussed this morning, if a claim is found to filed on good faith and reasonable basis, then reasonable attorney fees and costs are allowed. There remains, in those cases, found to be filed on that basis all these, and there are many of them. That is where all of that activity is happening.

The compensation, whether it is for petitioners or attorney fees and costs comes from the Vaccine Injury Compensation Trust Fund. That now stands at $3.4 billion.

It turns out that this particular trust fund is certainly a lot larger than what we need to operate the program obviously. The closest, in terms of outlays versus amounts of revenue, the closest we have ever come has been $120 million. In other words, it has always remained more in the black by a factor of 120 million or greater.

This year, the way I am projecting it out is I think the trust fund will have accrued $270 million, and we will spend $172 million. It is actually under the $100 million threshold for the first time in a long time. Again, it varies from year to year. Years in which there are a lot more flu vaccines sold, there is more money coming into the trust fund and so on. The highest amount of outlays was several years ago, where it was 230 million. Clearly, we are under that amount this year, so our outlays are staying fairly steady and they had actually been less than last year. The trust fund is in good shape, and will remain so for a long time to come.

Under significant activities, I attended the Advisory Committee on Immunization Practices meeting in Atlanta on June 20th and 21st. There was another significant activity that is not on that, and that is the fact that our own Annie Herzog is going to receive a special award. In addition to the fine service that she does for the

Commission, and today we had a little problem with the call-in number, and I am convinced that Annie does things like that once in a while just to show that she is not perfect. Everything she does is done so well.

Annie is going to receive from the agency the Administrator's Special Citation for Exceptional Service and Commitment to the mission of our program, The National Vaccine Injury Compensation Program, as well as the Counter Measures Injury Compensation Program. That is because Annie is one of these people that every office loves to have. When something gets dropped or there is a need for someone to fill in and help out in short-term, she is there volunteering and really helps us. She has been a help to both of our programs, in addition to runny the Commission. I just want to say congratulations.

The remaining two slides, in terms of point of contact, those wishing to contact the program should use a toll-free line, 1-800-338-2382 or visit the program website, which is www.hrsa.gov, and then forward slash, vaccine compensation, and that is spelled v-a-c-c-i-n-e c-o-m-p-e-n-s-a-t-i-o-n. If you want to offer public comment or participate in Commission meetings, write Andrea Herzog, and the address is Parklawn Building, Room 11C-26, 5600 Fishers Lane, Rockville, Maryland 20857. Annie's

direct phone line is 301-443-6634 and her email address is aherzog@hrsa.gov. With that, I will be available for any questions.

MR. KRAUS: I have a question that you may or may not be able to respond to about the impact of the recent non-renewal and resignation, I guess, of two of the eight special masters. Do you know if there has been any thought of attention paid to the impact that could have on the processing of claims?

DR. EVANS: I think Vince Matanoski, during his report, will be much better able to answer that. My sense is that I know that there were some cases that needed to be switched around and so on. I think Vince can answer that much better, so I will leave that in his steady hands. He will be up here shortly.

MR. KING: Any other questions? Geoff, thank you. Next on the agenda is Mr. Vince Matanoski. You are the acting deputy director.

Agenda Item: Report from the Department of Justice

MR. KING: Vince, before you begin, should you address Ed's question now, or do you have that in your report?

MR. MATANOSKY: I should address it. It's not in my report.

MR. KING: Why don't we address that first?

MR. MATANOSKY: First, thank you for having me here. It is always a pleasure and a privilege to speak to the Commission. I notice that Dr. Evans gets a half an hour. He only uses like five minutes. I think that is because he has been through 85 Commission meetings. He is very efficient now. The other reason is because, whenever he gets a touchy question, he just says, oh, well, somebody following me will answer that.

That is obviously a difficult question and I am not really capable of answering it. Obviously, I can't answer it for the Office of Special Masters. I do know that the Office of Special Masters is taking steps. They have contacted us, I am sure they have contacted the petitioner's counsel in affected cases, to schedule out an efficient way of handling cases that are scheduled for hearings already, to make sure that those hearings remain scheduled, and move those cases to other special masters, and get them to hearings.

I believe they are working hard to make sure the cases that have already been tried, decisions will come out in most, if not all of those cases, before special master

leaves. Again, that is their issue. Obviously, it is certainly a huge challenge for any organization, and seeing that kind of impact on your manning your personnel is significant. The court always coordinates very well with counsel, to work through these types of issues, and we try to make sure there aren't. The impact is minimized. As far as cases that were scheduled, I believe they all stay on track, the ones that were scheduled.

MR. KING: Do you know if those special masters will be replaced? Is there a process in place to do that?

MR. MATANOSKY: There is a process. I am not really familiar with the steps that they are going to be taking. I am sure that they advertise for replacements, and then there would be a selection process involved. That is the Court of Federal Claims prerogative.

MR. KING: I won't ask you this question, actually I am going to direct it to Geoff. Typically, when something like this happens, and I am sure over the course of the program, there have been times when the special masters have left, do you know, based upon your experience, how long it typically takes to replace one?

DR. EVANS: The answer is there was a significant period of time, several years as I recall, the court had special masters. Once they staffed up, around 2005, 2006,

then they began to adjudicate that, but that is claims. I don't know that there was a casual condition there that they didn't until they had more, but the additional staffing certainly forced the issues, as far as adjudicating the ones that had been put on the shelf for a while. There have been significant periods of time where there have been less than eight, but it is not common.

MR. KING: I guess the question that I had is do you know how long typically it was to replace? With your experience, is there a timeframe that typically they replace the special masters by, when they have an opening?

DR. EVANS: I don't know. I am not familiar with any specific timeframe. My vague memory is that it took a couple of years in that particular instance, and I don't know what the reasons were, why it may have taken longer that time versus what may be taken in this case, when you have two special masters who are residing, and who can very well be replaced within a much shorter period of time. That is a question that has been said that really should be directed to the court.

MR. KRAUS: Can we direct that to the court? Can we have some follow-up from the Court of Federal Claims about what the process and timeline would be?

MS. MC INTOSH: I couldn't speak to the timeline. I am not personally involved in the process. I can direct the inquiry to the Chief Special Master. I can say that the expectation is that the two special masters will be replaced.

DR. EVANS: Do you want to repeat that for the record?

MR. KING: I believe he got that. You will get back to us on that then?

MS. MC INTOSH: I will follow up with the Chief Special Master and get back to you.

MR. KING: Perfect, thank you.

MR. MATANOSKY: This is our statistics about the cases that have been filed during this reporting period. We saw 91 cases being filed. As in recent past, the majority of those cases were filed by adults. I know that question had come up in the process working group. It is still following that same pattern, where we see most of these cases being filed by adults.

We had 502 cases adjudicated this reporting period, 72 compensated, and the majority not compensated. Again, as you can see, as the last time I reported, most of those that were not compensated were cases that came out of the OAP, the Omnibus Autism Proceeding. What I would

expect the pattern to be is you will see that number staying fairly high, but tailing off, as we go forward, because we have moved through a great number of the cases as Dr. Evans reported. As you get to the tail-end, it is the tougher cases to move through. I expect that number to stay high, but to be dropping steadily over the next few reporting periods.

The cases that were conceded by HHS, one was by settlement, three by Proffer, which we have talked about in the past what that means. If there is a question about what that means, I will be happy to answer that. The 68 cases that were compensated, but that were not conceded by HHS, the vast majority again are settled. They are resolved by settlement, they are what we call the litigative risk settlements in those instances.

There was one petition voluntarily withdrawn in this period. I believe that that was an instance, I am trying to recall now. I believe that was a case where they were no longer going to pursue their claim. They voluntarily withdrew it prior to getting a decision on the merits.

We have the glossary of terms. Let's see, we added two the last time, I think, at the request of the Commission. I think we talked about remanded and vacated.

We added those to our glossary of terms. If there any questions on these, they are not clear to anyone what we mean, I would be happy to explain those.

This is another slide that we have kept in here, because it is informative as to the processing of the claims. This shows the review process, what happens if it is conceded, not conceded, and a decision tree that comes down until you get to the final decisions, either awarding or not awarding compensation. Again, at any point, if there are any questions, please feel free to jump in.

We have added these the last time, in response to some questions by the Commission. The first slide, this is the slide that we are all on right now, gives you the tiers of review. The next slide is a little more detail, and it shows you where the case goes on appeal, that wire diagram. If there is no appeal, it goes right to judgment. If there is appeal, we go through those subsequent tiers of review.

The program is kind of unique in the sense that it has one extra tier of appellate review. Typically, in federal litigation, your trial judge, federal district court judge issues a decision, and then it goes right to the Court of Appeals from that district court judge. When you are at the Court of Appeals, in that instance, they are reviewing the trial judge decision of the trial action.

Here, the Court of Federal Claims stands in to be that first tier of appellate review. When we get to the Court of Appeals for the Federal Circuit, they are actually getting a second look at the case. You have already been through a little different role for both of these bodies. The Court of Federal Claims, they don't usually sit in as appellate court. The Court of Appeals for Federal Circuit is usually reviewing a trial decision, rather than reviewing an appellate decision. In the vaccine cases, they are actually reviewing a case that has already been through one appeal process.

Then, the final review is at the Supreme Court. We have only had a couple of cases there over the history of the program. We have only had one, Wycott, and now we have another case where there is a petition for cert pending. I will discuss that a little bit later in this presentation. Actually, I will discuss it now, my next slide, Cloer.

We have talked about Cloer a couple of times. Cloer came up here, we were talking about it because it was the statute of limitations case. It went up for en banc, very unusual for any case, certainly for our vaccine cases. We don't see very many reviewed en banc. What en banc review means, just to go over that term again, the Court of

Appeals, instead of sitting with just three judges reviewing a case on appeal, that is typically how they do it. When they do en banc review, they convene all or almost all the judges who sit on that circuit to review a case.

In the instance of the Cloer decision, what they were doing is they were reviewing a decision by the Court of Appeals, a three judge panel. They got together the rest of the court, all the rest of the judges that sit on the circuit court looked at their own decision to decide whether or not they thought it had merit. On the statute of limitations, what they did in Cloer was they decided, as a whole, to vacate the decision of the panel, allowing the case to go forward.

They said that the en banc court, that is all, I think, 13 judges sitting on the en banc court, said that the statute of limitations, three years, is from the date of the first symptom or manifestation of onset, 36 months runny from that date, and not from when the medical community necessarily would recognize it as a vaccine injury.

Subsequent to that, there were attorney's fees sought in that case. The en banc court looked at that issue, as well. Can you get attorney's fees in a time-

barred case? The precedent had been if the case is time-barred, if it wasn't brought timely, you would not get attorney's fees. By a 7-6 decision, the en banc court said no, if you have sort of a good faith basis for making your claim that it is timely, then even if was untimely, you can still get fees.

Certiorari is now being sought by the Secretary at the Supreme Court on that particular issue, with the thought being that the statute having a particular timeframe, in which you can bring a claim, the Congress couldn't have intended that if you couldn't bring the claim in the first place, then you could nevertheless get attorney's fees for bringing it. In other words, if you were barred from bringing the claim, that was a bar to coming through the door, then you couldn't come through the door and then get attorney's fees for bringing that claim.

In the case of equitable tolling, if there had been equitable tolling found, they had said, well, the case can be brought for equitable reasons, then attorney's fees could be sought in that instance, because the claim was permissible, the petition could be filed.

The Secretary filed for certiorari on August 22nd. There is a 30-day period for the petitioner, in this case the respondent, who would be the petitioner, to respond to

that and file their oppositions to certiorari or if they agree, then say we agree the certiorari should be granted. The Supreme Court doesn't have to take these cases, so you are essentially going to them and asking them to take a look at it. You are petitioning them. It is not like our other appeals, where they are as of right, the court has to take it.

The Supreme Court may or may not look at this issue. The timeline for figuring that out, as I said, it is 30 days for the next response. That would make it September 21st. I believe they can ask for an extension of time to file their response, maybe a little later. The other party involved here, the Secretary, can then ask for time, I think it is about a 10-day period, to respond to the response.

I am not certain how long it takes before the Supreme Court decides to take certiorari after that. I believe that depends on where it falls within their calendar, as to when they announce whether or not they are going to take certiorari. It is possible there is another case possibly on the horizon that the Supreme Court might weigh in on.

We had a number of appeals at the Court of Appeals for the Federal Circuit, a number that were decided

this period. Hammitt and Stone, we reported on before, those were SCN 1AK cases, Dravet's Syndrome. I know I spoke about this before, this genetic disorder is showing up with increasing frequency in our cases. I think as medical science has advanced, detection of this condition has become better. It is a genetic condition, so it is pre-existing the administration of the vaccines.

In Hammitt and Stone, the Court of Appeals for the Federal Circuit affirmed the decision, finding that there was no entitlement. The hearing en banc was sought by the petitioners in those cases, and that request was denied. As I was explaining when hearing en banc, the whole court decided that they didn't need to review those cases.

Griglock versus HHS was recently affirmed by the Court of Appeals for the Federal Circuit. That was a case where the petitioners had sought the death benefit in the case, and in addition, had made a claim for other injuries, for pain and suffering, and other expenses related to the injuries. The position of the respondent was the death claim was timely, but the claim for additional compensation, pain and suffering, and unreimbursed expenses related to an injury, would not be timely.

As we know, the statute of limitations for injuries is three years, so you have to bring it within 36 months of the first sign or symptom. Death claims must be brought within two years of the death. They have to be brought within two years of the death, and within four years of the injury. In this instance, the case was brought within two years of the death, four years of the injury, but more than three years after the first sign of the injury. The argument was, well, you can get the death benefit because you are within four years for your death claim. But because you are more than three years, you could have never brought a timely injury claim, so you can't claim the additional compensation related to the injury. The Court of Appeals affirmed that argument.

Veryzer was another SCN 1A case. This one came up in a very interesting way, however. The case went through to hearing. There was a finding of entitlement to compensation. During damages, additional record medical records, more recent medical records, the case was filed in 2005, the records up to that point had been filed. That is what the entitlement decision was based on, those records.

During the damages phase, records from later, in 2005, were produced as part of determining what the level of damages were. In those records, it was identified that

the child had this genetic problem, SCN 1A gene mutation, Dravet's Syndrome. Respondent asked that the entitlement phase of the case be reopened, so that expert testimony could be taken on whether that constituted a reason for this child's injury, other than the vaccine.

It was reopened, the special master found that, in fact, the genetic problem was the reason for the child's injury, and filed against the entitlement act when the case was reopened. That went up on appeal to the Court of Federal Claims, it was affirmed. It went up on appeal to the Federal Circuit and was just affirmed.

DR. DOUGLAS: Just for my own clarity, if the child has this genetic mutation, they should not be vaccinated, or the things that they are claiming is secondary to the genetic mutation. Is this an exacerbation thing?

MR. MATANOSKY: I don't know that anyone has looked at, from a medical standpoint, whether there should be a different recommendation for vaccination in children who have that condition.

DR. DOUGLAS: But this condition will produce the injury brought forth to the court?

MR. MATANOSKY: The condition, yes. It is called severe myoclonic epilepsy of infancy, and these conditions

are generally first seen as seizures in the child. Now, what was looked at in these cases was, was the vaccine a factor in making the condition worse, in some way altering the normal course of the condition.

The evidence that has come forward in the cases that have been decided, where there has been no entitlement, or at least the evidence that was credited by the court, was that the condition remained essentially unchanged. The vaccine did not alter the course of the child's condition. I believe there may have been some medical question about whether the condition first appeared at a different time than it would have by virtue of the vaccine. The ultimate resolution in those cases was that there was not an aggravation, the condition was not made worse.

DR. DOUGLAS: And with this condition, one will see epileptic seizures?

MR. MATANOSKY: Yes. The evidence that came forward was this will manifest itself. It was only a question of time, and what the precipitating event might, whether it might be a fever that the child has from a cold or something like that. Again, there may have been some question about whether there the vaccine may have had some precipitating impact in the case.

Ultimately, I know what the decision was. The evidence that was credited was that the condition was no different, no worse nor better, because of the vaccination. It didn't play any role in what these children were suffering.

DR. DOUGLAS: One more time, can you tell me the name again?

MR. MATANOSKY: The name of the condition is Dravet's Syndrome. It is also sometimes called severe myoclonic epilepsy of infancy, or SMEI. The gene involved is SCN 1A. It is a specific gene that is involved, that they have identified.

Viscontini was a case that was an entitlement case. There had been a finding that the petitioner was not entitled to compensation, sort of just a battle of the experts' type case. It went up to the Court of Federal Claims, affirmed by the Court of Federal Claims. There was an appeal filed at the Court of Appeal for the Federal Circuit, but it was filed a day or two late for filling the appeal, and so it was dismissed from the Court of Appeals for the Federal Circuit on that ground, that they did not seek their appeal in a timely fashion.

I am trying to remember, I believe the Locane case was a case where the individual suffered from Crohn's

disease. There was evidence that the disease actually manifested itself before the person was vaccinated. There was a finding that the vaccination did not precipitate the Crohn's disease. It actually was in place, there was some evidence that this person had been suffering before they got vaccinated.

Respondent had one appeal up at the Court of Appeals for the Federal Circuit, that was decided, the case of Heinzelman versus HHS. It was decided against the respondent at the special masters level at the Court of Federal Claims and also that was affirmed, the findings against the Secretary were affirmed at the Court of Appeals for the Federal Circuit. There was a narrow issue that was being appealed to the Federal Circuit. It was about damages. The individual involved sought compensation for lost wages, and in trying to calculate what that compensation should be, the position of the respondent was that Supplemental Security Disability Income should be offset. Whatever the award was, this individual received Supplemental Security Disability.

MR. KRAUS: Social Security Disability Insurance Benefits.

MR. MATANOSKY: Thank you. They have received these additional benefits from Social Security. The

position that the respondent took was, when you are calculating lost wages, you should take into account the fact that they are already getting this money coming in. If, say, they got $600 a month for SSDI, that is what it is called, and the calculation their lost earnings were 2000, then you should reduce that 2000 a month by 600, and give them 1400, then they would be made whole.

The special masters said no, they should get it in addition. That went up all the way up to the Court of Appeals for the Federal Circuit, and they agreed. Now, in that instance, this was not being used as an offset. They are going to be getting the amount of loss wages, plus whatever the Social Security Administration is giving them.

MR. KING: Question, so in cases, even though it was a narrow issue, that narrow issue might, in fact, appear in subsequent cases. How will the respondent handle that?

MR. MATANOSKY: It would be tough to say. You would probably look at it case by case, but I would say that, generally speaking, this has now been decided by the circuit.

MR. KING: So it is precedent setting?

MR. MATANOSKY: Right, and we have not gone up to the Supreme Court on the issue. I would imagine that you

are going to see this pretty much taking care of now in cases. If I were to guess, you are not going to see much argument now. You are going to see that actually awarded. If someone is getting SSDI, it is not coming out as an offset.

I think I may have confused Deribeaux with one of the ones I was talking about. Deribeaux might have been the one where SCN 1A came up during the trial of the damages of the case. In which case, I fully briefed you on Deribeaux. Deribeaux is the one where it came up during the damages, I apologize. You now know the story of Deribeaux, and that has been appealed by the petitioner to the Court of Appeals for the Federal Circuit.

Now, I will brief you on Veryzer. I apologize, Veryzer was pretty much a case where there were some experts that were brought by the petitioners, but they were found to be not reliable. Their evidence was not going to be credited by the special master, it wasn't allowed in. The petitioner did not get another expert to provide other information, other than the ones that they have had. The case was dismissed for those reasons, they didn't prevail. It was pretty much a battle of evidence, and they didn't have enough evidence in prevail on that.

The other cases that have been appealed by petitioners, actually, the only new one is Deribeaux. The others have been addressed already, they are still just pending a decision by the Court of Appeals for the Federal Circuit. I am not sure there is anything that I could mention on these that we haven't covered already.

We have got three new cases at the Court of Federal Claims. We have Castaldi, in which the Motion for Review was denied in this case. They filed it. It says Statute of Limitations. There is a Statute of Limitations issue involved with the case.

The appeal to the Court of Appeals for the Federal Circuit was taken prematurely. There was a decision by the special master, making certain fact findings in the case, but not deciding entitlement in the case. The petitioner went up and sought review of the interim decision, if you will, on these facts. The Court of Federal Claims dismissed the appeal.

Davis was an attorney's fees and costs case. Davis has already been up to the Circuit. In that instance, when they were arguing the entitlement, the petitioners had not talked about a specific Federal Circuit case that was bearing on the issue that they were raising. That was mentioned in the special master's decision, this

particular Federal Circuit case. It was briefed and argued by the respondent at the Court of Federal Claims. It was briefed and argued by the respondent at the Federal Circuit, and it never was mentioned by the petitioners.

The Federal Circuit decided the case, largely based on its previous decision in that prior press in that particular case that had not been mentioned by the petitioners. They had commented on the fact that the petitioner had not discussed this case that was, in their view, dispositive of the issue. The special master then looked at attorney's fees for the appeal, and denied all attorney's fees on that appeal, saying that there was not a reasonable basis for the appeal, because they had not taken into account this prior precedent.

The special master alternatively found, if you appeal me now on this decision, and find that there are some fees that are appropriate, despite my ruling, then this is the amount of fees that I think are appropriate. If you think there should be some, it should be this amount. That went up to the Court of Appeals for the Federal Circuit. The judge there said, actually, I think there should be some fees awarded for that appeal, remanding it back to the special master, I think, to issue

a decision awarding the fees. It is back in front of the special master on that particular issue.

UNIDENTIFIED SPEAKER: Could they get into an argument on the fees, though?

MR. MATANOSKY: They could.

UNIDENTIFIED SPEAKER: So it could continue on?

MR. MATANOSKY: It could. I would have to look at exactly what the scope of the remand is. If the remand were such that it said this goes back to special master, just to enter a decision saying this. You have already said what the amount is, now enter a decision on that, so a judgment can enter and they get paid. Then, there wouldn't be anything more about that.

Except, presumably, that decision from the special master would then be appealed by petitioners, back up to the judge. You can imagine what the judge, if they had already issued an order saying, this is what I decide, they are going to pretty quickly dispose of that. That would be the necessary step to get to the Court of Appeals for the Federal Circuit, to have the issue reviewed by the Court of Appeals for the Federal Circuit. It is kind of a torturous process to get there, but it is not necessarily done yet.

Shapiro is a Hepatitis B case. This was a battle where the experts made the case, as well. The special master found the respondent's experts and the respondent's evidence to be more persuasive and dismissed the case. That was affirmed on appeal.

We have two new cases this reporting period at the Court of Federal Claims. The Vaughan case has been filed. This is again just another dispute about the strength of the evidence. The court credited the respondent's evidence over the petitioner's in that case. It has now been appealed to the Court of Federal Claims.

Silva is an attorney's fees and costs case. I know we have been talking about those issues, and whether or not I care to take up any more of our time. This is just another instance where there has been an attorney's fee decision issued, a dispute about that, and now it is on appeal.

There was another attorney's fees that doesn't appear here, but another late-breaking case, if you will. I don't think it is appearing here, but Macias(?) is another attorney's fees case, where there has been an appeal to the Court of Federal Claims. We have got two pending now on attorney's fees.

Hiland, I believe we have talked about this, but there may have been a development since the last time I briefed you. Hiland was a case that the respondent took up interim fees and costs. The court required the petitioner to file an expert report. At that point, counsel said that they were not going to go forward with the case anymore, and withdrew from the case and sought interim fees and costs.

We appealed the decision awarding interim fees and costs because we thought the case had no reasonable basis. We thought also that this was not the appropriate circumstances for an award of interim fees and costs. The hardship that had been discussed by the attorney in seeking the fees and costs were attorney hardship, rather than petitioner hardship, in seeking the fees and costs. In fact, in withdrawing from the case at that point, one might say that there was more of a hardship to the petitioner from the withdrawal of the attorney, than if the attorney had stayed in the case and continued on.

The case is still pending at the Court of Federal Claims. While it has been pending, the case was dismissed by the special master, because they found there was insufficient evidence to find in favor of the petitioner.

The appeal remains pending because we have appealed on no reasonable basis for attorney's fees ground.

The kind of interesting thing that you can see that plays out in this, the appeal goes up to the Court of Federal Claims. The petitioner, pro se now, doesn't have counsel, doesn't respond because they don't really have an interest in that appeal.

It is only about their attorney, so the attorney, who has now withdrawn from the case, seeks to come into litigate the appeal of the case, even though they are no longer representing the petitioner. That created a new wrinkle to this, that we hadn't seen before. It still remains pending right now because, even though the underlying claim has now gone away, the issue about reasonable basis is still there.

We have one argument scheduled for the Federal Circuit upcoming, and that is September 14th. That is in Connor, one of the cases we briefed previously. If you are around in the area, those arguments are open to the public, so you can come in and see those arguments, if you ever have an interest in seeing it.

Settlements, we had 65 settlements this period. Sixty-four were litigative risks, one was out of a conceded case. I broke down, and you will have all of these cases

here and you can get a sense of what these cases are about. Again, as the last time I spoke to you, Guillain-Barre predominates. If you want to look at one particular injury, it is Guillain-Barre, after influenza vaccine. Otherwise, I am not seeing really a pattern of another kind of claim that is coming up, associated with a particular vaccine.

MR. KING: When we talk about the influenza, are we talking primarily adults now?

MR. MATANOSKY: Yes, that is primarily adults. Now, it could be that we would see an infant, but yes, it is usually the adults that we are seeing on those cases. I am looking through, and I don't think there is anything I saw in here about the injuries. Again, I keep an eye on and I see all the cases coming through. I have the lucky task of deciding who in our office gets to handle them, so I assign them. I see them all coming through the door, and I read the cases to see what is being alleged.

This is getting away from our settlements and more to what is coming in. I am not seeing any patterns developing, other than again, GBS and flu being the predominance of that injury with that particular vaccine. I did break out, and I was trying to get a sense of how fast are these stipulations moving through, these cases not

stipulations. How fast are these cases getting to resolution, if they are going by litigative risk or if they are going by settlement.

Breaking that down, 19 of these 65 cases were resolved in a year or less. An additional 25 were resolved in two years or less, that brings us to 44 of the cases of the 65 were resolved in two years or less. If you move it out to three years, you pick up another 17. At that point, you have got 61 of the cases of the 65 have been resolved in three years or less. I did some percentages, 29 percent of those cases that went to settlement were resolved in a year or less. By the time you get out to two years, you have 67, or two-thirds of the cases are being resolved in two years or less. There were four cases that were greater than three years, and that comes out to 6 percent of the cases that went to settlement.

I will give you a brief rundown. We try to take a look at the three longest, and I will actually give you all four of those cases that took more than three years, to give you a sense. Again, we want to look again and see if there are sticking points, things that we could work on, to do it a little better. One of the cases that took a while, that was filed in 2005, the expert report by the petitioners was not filed, so March 2010. About five years

went by before the expert report was filed. It moved fairly quickly, after that had been filed, through the settlement process to litigate a person's settlement.

Another case that took over six years to resolve, it looks like it is being worked fairly diligently throughout the amount of damages involved in the case, even though it went to settlement, was over a million and half dollars. It was a fairly involved case from the standpoint of damages, so my sense is that the negotiations during the settlement, figuring out what those damages were, figure out what your exposure is in the case, were fairly involved.

Another case filed in 2008, and went to settlement eventually this year, it got to an entitlement hearing in 2010, so there was actually a hearing in the case before there was a settlement. It seemed to me that that one moved along fairly rapidly, considering the amount of processing that was involved in the case. It had actually gone to a hearing, for example, two years after getting filed.

Finally, there was a case, and it was actually the longest one that was out there, the 10 years and two months. That case was a migratory arthritis and ataxia case, that is how it was filed in 2002. It was

subsequently amended to add autism as one of the allegations, and it went into the OAP, and sat there in the OAP while the OAP proceeded.

After the end of the OAP, it moved out of it, cited it no longer wanted to be a part of the Omnibus Autism Proceeding. The petition was amended again, this time to go back to its original claim of only migratory arthritis and ataxia, and then relatively quickly after that, it was settled.

Our three shortest cases, I was hoping to see a pattern in that amongst either the injury or the vaccine. Two were a flu vaccine, one was the flu GBS vaccine that was resolved in six months, another was flu and encephalomyeloneuropathy, that was resolved in seven months. The final one was a tetanus-diphtheria-acellular pertussis, and that involved skin conditions, and that was resolved in six months.

I can't even say I see necessarily two of those settlements were relatively modest amounts of money, but one wasn't. I wouldn't even say that there was a pattern developing with those. What I have noticed in the past is the cases that have come filed, complete with all of the materials that the statute requires, move through more rapidly, as would be expected.

There was a question that was posed, and I forget which Commission member posed this last time, about our conceded cases, do they go faster than non-conceded cases. Do settlements go faster, and actually, I think the question was do conceded cases go faster than non-conceded cases. Now, I have to search for my note on this, because we actually took a look at that, to see.

We are struggling with how do you go about this, because there aren't that many conceded cases. How do you draw a sample that is going to be representative, so that you can get a good comparison. I know that I caveated this, and there are a lot of caveats that had to go behind this because there could be a conceded case that has very involved damages. It may take a long time for the damages phase, even though the entitlement phase goes very rapidly.

There could be a non-conceded case that goes pretty rapidly because the damages aren't involved, the entitlement is fairly simple and straightforward. What we decided to do, to take a look at that question, was we looked at the cases that went to compensation this period, to determine. There were four that were conceded that went to compensation, and there were 64 that were not conceded, that went to compensation.

Most of those that went to compensation that were not conceded, went by litigative risk settlement. We went to compare those and see what happened, what kind of numbers do we get up for average processing times. The four conceded cases took an average of 20.6 months to process, from the filing of the petition to judgment. The 64 non-conceded cases that were resolved by stipulation took an average of 23.2 months from petition filing to filing a stipulation.

Now, there were four non-conceded cases that were resolved and compensation was awarded, because again, we want to try to compare apples to apples to some extent. If you are just comparing non-conceded cases, where there is no compensation, then it is not really a good comparison with the conceded cases, because they are all going to go to compensation.

There are four non-conceded cases that went to compensation during this period, and they didn't get settled. There wasn't a stipulation settlement. They took an average of 60.7 months to resolve. It was obviously significantly more. Again, the sample size is not great, because you only have four conceded cases, only four non-conceded cases. The majority fall in the stipulation.

If we can spare the time and resources, we are going to keep trying to track this, to see what might develop over time, and give you a better sense, because you will have a bigger sample if you continue to add information to this, and see what comes out of that. I think that is it for what I had.

MR. KRAUS: Do you know what the average time from the settlement being filed to the petitioner actually receiving compensation is?

MR. MATANOSKY: I don't. I don't know what that timing is. I think there was, at one point, because there were a lot of attorney's fees coming out of the OAP, I think there was a drain or there was a huge demand, a huge signal for administrative work to get those claims processed for payment. I am not certain what the timeframe is for that. I believe that big workload that was for taking care of all of these additional cases that were coming in for payment, for attorney's fees, I think that has been worked down now. We still are seeing there are a lot of cases being processed for attorney's fees out of the OAP, so I know there is still a bit of work.

MR. KRAUS: Is there somebody else who might be able to answer that, only because I think people should understand that, from your perspective at DOJ, you are

saying we have done everything we can do. Two years, two months, the settlement is filed. There is a period, and I don't want to overstate it or understate it, but at least several months before the petitioner typically gets a check. It is my understanding, in the cases that I have worked on, and from what other petitioners' counsel have said.

I know it is everyone's goal for that time period to be as little as possible, but I just wondered what we are looking at, on average.

MS. MC INTOSH: In terms of when the settlement is reached, it has to go to judgment. Then, they have an opportunity to elect to accept or not to accept the judgment. Once all of those steps happen, then it is only then that the program authorized to make the payment. My experience has been it has been very rapid generally. I don't know what the statistics are, I am sure they could get them for you in another meeting.

MR. KRAUS: I ask because I know that there are petitioners' attorneys who have reported that at times, in some cases, it has been not a really short period of time. It has been several months. I understand that after the settlement is filed, there are still some additional filings. Really, maybe the question is, once all the

lawyering is done on the case, how long does it take for the office to cut the checks.

MS. MC INTOSH: There is one delay that I am aware of, which is if the settlement for the decision requires that a guardianship or a conservatorship be filed. Sometimes they say, no payment shall be made of X or Y type, until a guardianship or conservatorship document is filed. My experience has been, in the ones where there is a few-month delay, is because we are awaiting that documentation. We advise the payment cannot be made until we receive this. Once it is received, it is generally issued.

MR. SORENSON: There are many variables, as Emily mentioned. In the early years of the program, it was about three and a half years from a filing to a payment, because settlements are speeding up the process, awards filed in 2008 1.7 years. Four days to request once we get the judgment.

MR. KING: But there is a process that it has to go through, before it gets over to you. How long is that particular process on average, do we know?

MR. SORENSON: It varies. That 90-day window is.

MR. MATANOSKY: I practiced in the program as a trial attorney for a long time, before I got to a role

where I didn't have to do any work. The 90-day period, it was kind of a pitfall for petitioners, counselors who were not very familiar with the program. I took to, in my own practice, making sure and sending out a letter, with an election to accept judgment, that they could use. The case is done, it is now on autopilot. Then, it is off your desk and you are just thinking things are going to proceed, but that election has to be made.

First, there is an appeal window of 30 days. If you don't do anything, nothing is going to happen by the court, no judgment is going to issue until that 30 days has passed. Now, if you are doing a stipulation, and everybody is happy with the case, or you are both equally dissatisfied, but willing to live with it, you can waive that 30-day period and get to judgment faster. Even after that judgment enters, there is a 90-day period to elect to accept or reject that judgment. The petitioner has to do that. It can sometimes be forgotten, and that can move back the time, the difference.

Attorneys who are familiar with the practice, do the practice a lot, I am sure they have checklists. They move through that, so it really hasn't been a problem for them. Somebody who is new to them, my practice has always been, if it was somebody that had not been doing it and

working with the program before, just remind them of that, just so it didn't slip off the radar. Sometimes, it does anyway, and sometimes the clerk's office may take longer on issuing a judgment for whatever reason.

I would encourage the petitioner's counsel, if there is an undue delay to contact the DOJ attorney who is involved in the case to let them know. I know that that does happen because if it has slipped through the cracks for some reason, if there was something that has been forgotten, then that can be addressed.

But steeped in the democratic traditions, as we have been over the years, if it is already in line for payment, you don't really think that someone should skip ahead of somebody else who has been waiting for payment.

MR. KING: No cutting in line?

MR. MATANOSKY: No cutting in line, exactly. That is kind of the equities that you would say. If there is a certain amount of time that it takes, if there isn't an equitable reason to move ahead of somebody else who has been waiting, then you ought to let the process move its way through. Now, if something has fallen through the cracks, if the 90-days was missed, somebody forgot to elect the judgment, if we, at DOJ, forgot to inform HHS that the

case was ready for payment, then those things can be addressed and contact can help with that.

As I said, when a whole bunch of those OAP cases were coming out for attorney's fees, they kind of overloaded the system. There isn't a flexibility, you can't have all this staff standby to do that. I know that they were working really hard to try to keep that process moving through. Actually, petitioner's counsel were very understanding of that. The calls that I got said, I understand, I just wanted to make sure people were aware of it.

That was just a trying time, but I think we have moved through the bulk of those cases now. I wouldn't expect that to be giving pressure on getting the cases to payment, but it is a really good point. I mean, just getting a case to judgment, there is still more to be done before the money gets to the petitioner. You always want to be looking at that, making sure it is working in the most efficient way it can. We are working on the end to get it to there, but there is more that has to be done before it actually gets a check issued.

MR. KING: In summary, when we look at these reports and we see how long it was to settlement, we should not confuse that that is actually payout, and that there is

a process then from settlement to payout, and that process starts with a 30-day window of accept or reject. Then, there is a 90-day window that could be utilized, as well. We are looking at, at a minimum, if things go on the norm process, or in a worst case scenario, without anything slipping through the cracks, that you are going to be in a four-month period. Then, I am sure it takes time to cut the checks and do things like that, which I believe is a four-day process.

MR. SORENSON: It is an average of four days.

MR. KING: We will call it a week and just round it, so we are now at four months and a week. Assuming that things go in perfect scenario, and there are no holidays in between or anything like that, everybody has got to wait a minimum of four months. I guess the question that we would be curious to get the answer to, is what percent is falling through in the perfect process, which gets you in a little over four months, and how much extends beyond that.

If we are doing 85, 90 percent of these that are really moving along pretty quickly, it seems like a problem that is not too difficult. It may be other things where it is really falling through the cracks, and it could be the petitioner's fault, it could be somewhere else. It is not necessarily your fault because it could be the petitioner's

attorney who didn't do something. I guess I would be curious to know that, before we made any value judgments of any sort. Is that information available to us, do we think we could get it?

MR. SORENSON: Yes.

MR. KING: Since the bulk of the cases seem to be moving more toward the influenza and adult, there seems to be a trend line moving in that direction. The awards, actually based upon Geoff, they are not completely identical, so I don't know if I can draw a direct correlation between these two, but I am beginning to think, is the payout for the influenza typically on average less than what it had been in the past for others, or is that something that we don't really know?

MR. MATANOSKY: I can just give you a sense of what I have seen, and it is all over the place on GBS. Guillain-Barre Syndrome. It is rare that I think you would go up to the highest end award, but there are certainly some adults who have very involved cases.

That is why I was hoping that maybe I could see something in our shorter cases, to see, oh, they are all under $50,000 or something like that, but it isn't. I have seen in the GBS cases, the damages may not be that extensive. Then, in others, the damages may be pretty

extensive. It would be hard to generalize from what I have seen so far. Actually, we are getting a pretty good understanding, because we have had so many come through. With the numbers that we are seeing, I think we can say we know that we can't say that there is one particular pattern of injury or one particular case presentation. It would be great if there was, because we could probably look towards this is the amount to be awarded in these types of cases.

MR. KING: Thank you.

Agenda Item: Report from the Future Science Workgroup

MS. WILLIAMS: Under tab five, you have a recommendation that we would like to discuss and present, and make today to the Secretary. I am not going to go through this, line by line, but this comes about as a result of discussions with the parents on the Commission. Sarah Hoiberg is a former Commission member, and some other parents, who felt that now that there were a substantial number of cases that had gone through the system, that there would be benefit if some of the medical information that was in the case files, or that had been developed through the process, was able to be used by researchers in the field of vaccine safety.

The charter contains a provision that we should make recommendations to the Secretary about the field of vaccine safety. In line with that, we had several discussions about what medical information was in there, recognized that there are a lot of constraints on that information, and that there are lots of barriers to potentially using that information.

We do know, however, that even just within the fund operations, we have seen a small amount of scientific study that has been done, and attached to the resolution, attachment A, is a Division of Vaccine Injury Compensation Bibliography. In other words, these are studies that have utilized medical information in the vaccine injury files, all in accordance with law. The fund, and Geoff may be able to speak to this better, physicians and people that are the medical officers, this is extra work for them in a sense. I am not sure that we can expect that they could keep up with maybe the amount of scientific knowledge that might be able to be gleaned from these records.

Our recommendation is that use of this information be reviewed, and any barriers to using the information be addressed, so that any information that is in these files be potentially made available for scientific

research to enhance the safety of vaccines for future vaccine recipients.

MR. SMITH: The barriers that are referred to in the recommendation that you drafted from the workgroup, does it identify what some of those barriers would be?

MS. WILLIAMS: We did identify some of them. We decided that that was probably not our charge to go and figure out how to resolve those barriers. The statute itself has restrictions on how information can be used, so there are those restrictions. Then, there is information in the court files, there is information in the Department of Justice files, there is information in HHS files. Each of those agencies has their own regulations about protection of information.

Rather than try to catalog them, we felt that would be something that was an operational issue, that should be looked at and addressed. It could be something as simple as asking participants in the claims process in the beginning if they could be contacted after the process, to determine if they wanted to say contribute their medical records to a database.

The biggest barrier, I think, is that the information is all probably paper information. As some of the researchers on the subcommittee have indicated, it is

also self-directed information. It is not information that is collected to a protocol, to an existing scientific protocol.

All of that said, there wasn't anyone, even the researchers, who indicated that they didn't think that there was valuable information in there, if there was a way it could be utilized. Although some people have a less optimistic view that it would be able to be utilized.

MR. KING: We think the sun is shining and rising.

MS. PRON: I want to comment. I wanted to commend Michelle because this occurred over a long period of time, so lots and lots of discussion to put together in a comprehensive document.

MR. KING: What we are looking at, would this be what we would be sending? This would be the actual resolution, okay.

DR. DOUGLAS: Dr. Evans, as you are formulating your comment, you are not going to say anything. It is like you are thinking, and I want you to get it out, but I can say something while you are still thinking. There is, within most IRBs, most research protocol, the provision that data be reported and handled in aggregate form. It is a bunch of data that is somewhere.

It is in a central somewhere, but it is data there. As long as we keep it in aggregate form, it can be put into, I mean, it is done all the time. Secondary data analysis, it is called cleaning the data, and we can do that. In research protocol language, it is done all the time and there is a reason it can't be done here.

MS. WILLIAMS: One of the things we would want, or would expect, that the Secretary would make sure is that no one would think that their claim would be compromised in any way, which is why we have called this closed claims vaccine research. In other words, if research were able to occur, it would only be after the adjudication of a claim, and it would have no bearing on the claim, totally separate process. This is the time where you discuss the resolution.

MR. KING: Technically, we should put a motion on the table to do it, and then we have our conversations around it, if we were to follow strict rules.

DR. DOUGLAS: Pursuant to a charge that I have heard often, and I know to be incorrect, that there is just not the research done. It is just not being done, that this is another significant piece in that journey. Given that I move that we accept the recommendation of the Future

Science Workgroup, that this recommendation be forwarded to the secretary for the ACCV.

MR. KING: We look for a second of that.

MS. PRON: I will second that.

MR. KING: Now, that it is truly on the table, does anyone have any comments, thoughts, criticisms, concerns with this?

Since no one seems to have any comments, concerns or whatever, I think we should call the matter to a vote. We call it to a vote.

(Whereupon, on motion duly made and seconded, the resolution was unanimously approved.)

MS. WILLIAMS: This is definitely a team effort. I commend the Future Science Workgroup. For the record, it is Sarah Hoiberg, Sherry Drew, Ann Pron, David King, Kristen Feemster, Charlene Douglas and Daniel Salmon. We also had input from special master. We appreciate everybody's input.

MR. KING: Does that mean that the Future Science Workgroup -

MS. WILLIAMS: We are disbanded.

MR. KING: Are you, or are there issues we could throw in front of you? That being said, we actually have time for the next item on the agenda, which is the report

from the Maternal Immunization Workgroup. Kristen, that would be you, Dr. Kristen Feemster.

Agenda Item: Report from the Maternal Immunization Workgroup

DR. FEEMSTER: Hello, this is Dr. Feemster here. I am happy to provide a summary of our working group activities, since we met for the first time on June 14th. We have had three meetings, two in person, the one today, one on June 14th and also a phone conference call. It made some progress.

Just to provide some context, the reason for the Maternal Immunization Working Group is really to consider the recommendations for immunizing women during pregnancy really expanded. The recommendations to immunize women against influenza, pertussis and tetanus during pregnancy, and there are also some vaccines in the pipeline that would be recommended just for administration to women, to protect their infants against RSV, as an example.

This is certainly important to protect women, who may be at increased risk of some outcomes from infection from influenza, for example, during pregnancy, but also to protect their young infant before they may have an opportunity to be fully immunized against things like influenza and pertussis. RSV is another good example where

young infants are at particular risk for severe illness, and before they would have opportunities to either be vaccinated or develop immunity.

It certainly is important to make sure that current safety assessment and monitoring processes can really identify and respond to safety issues. There are plenty of elements of the vaccine safety infrastructure that have maternal immunization workgroups in place. This also does include ensuring that the Vaccine Injury Compensation Program is able to offer appropriate support to mothers and their infants, when vaccines are administered during pregnancy. We have really spent the bulk of our time really developing a charge that is most appropriate to address some of the issues that are associated with maternal immunizations. We have also begun doing some kind of background information gathering.

I think some of the biggest issues that we have been talking about is, one, what is covered. Certainly, the immunization program now, or the Vaccine Injury Compensation Program now, covers vaccines that are routinely recommended for children. This includes influenza and pertussis. If a vaccine targeting RSV were to be recommended just for administration to pregnant

women, how would we address coverage by the Vaccine Injury Compensation Program for such a vaccine.

The second question is who is covered. A mother is a recipient of a vaccine could file a petition for herself, but how do we consider a petition for a mother and her child. Also, how do we consider the definition of recipients, when we are considering in utero exposure. These are some of the issues that we have begun to discuss.

Thus far, I think we do have a charge and it has undergone multiple revisions. I can tell you what we talked about today, regarding our charge. We really have three main areas that we would like to cover.

The first is to look at compensability of injuries from vaccines that are not currently covered by the Injury Compensation Program. We would provide information to the ACCV regarding eligibility for compensation by the program for injuries, with respect to vaccines recommended for, and sometimes given to, pregnant women. These vaccines are not recommended for routine administration to children, so they would not be currently covered under VICP.

We will explore both the pros and cons of covering such vaccines, and then develop a draft ACCV recommendation. Then, we would do a similar set of

activities related to compensability of injuries from covered vaccines.

Then, as a kind of a third item, we would really like to kind of provide information regarding a current safety monitoring infrastructure of vaccines administered to pregnant women. That is our kind of revised charge that we did approve today as a group. Thus far, we have begun to collect information or evidence. We have done literature reviews regarding vaccine safety in pregnant women, especially related to influenza vaccines. We also had a presentation today from NOVA Vacs(?). This is a group that is developing an RSV vaccine, which if approved would be recommended for pregnant women.

We have had a lot of good discussion, and we look forward to continuing our work. Our goal is to have a set of draft recommendations to you by March. Any questions?

MS. PRON: I just wanted to ask, the vaccine that is under development for RSV in pregnant women is not going to be a live vaccine? It is going to be a different formulation?

DR. FEEMSTER: No, it would not be a live vaccine. It is a recombinant vaccine. I should say that the goal is essentially passive immunization, so the

development of antibodies that a mother would develop. It would be essentially passive immunization to an infant.

MS. PRON: It is different than anything that is on the table now.

DR. FEEMSTER: That is correct. It is true that this is not a vaccine that is approved or currently recommended, but in preparation for the recommendation we thought it was important to really talk about these issues, because there is also a vaccine for Group B Strep that is under development.

I think it does also offer an opportunity to think about some of these issues, such as who can file a petition and how we define recipient. I should say that when we are talking about compensability of injuries, that we are looking at live-born infants, regarding vaccines that would have been received by the mother while the infant was in utero.

MR. KRAUS: I have a question, is the working group already proposing there should be a recommendation to the Secretary, that the program would cover live-born infants?

DR. FEEMSTER: No, we haven't drafted any recommendations for the Secretary at this point. In terms of guiding our own discussion and our work, that is our

charge is to consider injuries sustained by a live-born infant from covered vaccines, received by the mother while the infant was in utero. Does that answer your question?

MR. KRAUS: I am just trying to figure out, I understand that the working group is looking at the scenario of children who are born, who potentially might have received the vaccine injury in utero. Are you trying to decide what recommendations, if any, to make to the Secretary about whether the program should or should not cover?

DR. FEEMSTER: Our goal is to look at what the program would currently cover, and then determine whether or not we would recommend any changes, either administrative changes or recommend even any legislative changes to the current program, based upon some of the issues that I just reviewed regarding maternal immunization. We will present exactly, this is the language, and this is what it does and does not cover. Do we need to make any changes to ensure that our injury compensation program is really addressing and providing appropriate support to mothers and infants who would have been exposed to a vaccine in utero.

MR. KRAUS: Okay, thank you.

DR. FEEMSTER: Anyone else from the group can certainly jump in, if I have missed any important points.

MR. KING: Okay, Kristen, I think that is terrific, thank you very much. Good luck. We are at the stage where we are scheduled to have a break.

(Brief recess)

MR. KING: We will resume. The break is done. The next item on the agenda is the report from the Process Workgroup. Luisita dela Rosa, you are scheduled to give that report. Are you able to from where you are, or do you need some assistance from the home front here?

MS. DELA ROSA: Dave, could you make the presentation?

Agenda Item: Report from the Process Workgroup,

MR. KING: I would be happy to. I am not going to read everything, but I will give a summary of what has occurred with the Process Workgroup, since we have begun to meet in the month of June. I will give that report in lieu of Luisita. Luisita, if I miss something that you deem of tremendous report, do stop me or add it when I am done. How is that?

MS. DELA ROSA: Okay.

MR. KING: There have been three meetings, two of them in person, one not. At the meetings, at the Process

Workgroup, a couple of things that have been determined and that we have been doing as we did it was to take a look at or begin to discuss what it is that the Advisory Commission on Childhood Vaccines has done in the past as it relates to process. We needed to then go back and look at both legislative proposals and those ideas that have germinated, but not necessarily get put forward in a legislative proposal to make recommendations to the Secretary for changes and additions related around the process.

For the record, I will very quickly summarize what some of those are, so that everybody has them. It was increased benefit caps for death, and pain and suffering, clarify that a petitioner that establishes a vaccine-related injury and death is entitled to both death and injury benefits, compensation for family counseling, guardianship, conservatories of trust and expenses related to that.

Interim fees and costs, petitioner's attorneys, modified procedure for paid fees and costs solely to petitioner's attorney. Extend the Statute of Limitations for injury and death claims, allow para-physicians for compensation, appointment of adult with vaccine-related injury to the advisory Commission, change the quarterly

meeting requirement, so that it is not required to be four times a year, but at the call of the chair.

Clarify the definition of the manufacturer, clarify definition of vaccine-related injury, and add definition of vaccines, those three are really related to the thimerosol issue, and things that had come up related to that. Then, finally, in the (?) to pursue, design defect claims against vaccine companies, post the Vaccine Injury Compensation Program adjudications.

None of these things are necessarily cast in stone. The Process Workgroup is looking at each of these. What we did in today's meeting was we had a rather lengthy conversation around some of these, and also in terms of how to break forward and move forward. Some of that was determined that what we would do is that we might segment these by ones that are regulatory versus legislative, and determine what those are. Actually, the workgroup did do that today.

Then, in addition, it had options of should we begin to think about making changes, or should we let the judicial process, where some of these are under adjudication today, the idea being that if we let the courts resolve the issues, it is in the courts, it may in fact be what we wanted anyway, so it might not make a lot

of sense for us to rehash and refight something that might get resolved according to what we want. If it doesn't, we could still make an additional recommendation. It is one avenue that we have thought that we might go down.

An additional avenue was to prioritize and begin to look at which of these are most important, in terms of the program and the success of it, and is it more important for us to be focused on the petitioners, the actually individuals who are injured, as opposed to necessarily just focusing on the attorney's fees, and trying to solve all the problems of the world in one fell swoop. But rather, pick and choose specific battles that are most important for us to focus on.

In a nutshell, that is the general direction, and where we resolve the meeting is that we are going to the Process Workgroup meeting is to create that stack, prioritization among the workgroup members, and then, from there, begin to determine which ones they want to really specifically focus on.

Another avenue of discussion that came out of it, and in fact, could have a resolution either today, or subsequently at our next meeting, had to do with the issue of an adult member being appointed as one of the general public, a person, an adult member meaning someone who has

been injured by a vaccine as an adult, since they seem to represent greater than 50 percent of our cases now, that it would probably be a good idea to have some level of input from those individuals.

It was determined that that did not require legislation, and was just a function of asking the Secretary to, in the process of recruiting Commissioners, to do that. I don't believe, based on that, the next letter doesn't go out for several months. We actually would have time at our next meeting to pass a resolution to do that, should we so desire, or we could do that now, if we want. It could be one or the other.

Luisita, is that in effect a summary of what we have done over the past several meetings?

MS. DELA ROSA: Yes, it is, except a little bit more active way of showing it presenting it in our report. Congratulations, that was a better way of.

MR. KING: Thank you. It is only because I am so nervous, they are all staring at me. Does anyone have any questions? A number of folks in this room were at the Process Workgroup's meeting today, but does anyone have any questions as it relates to anything that we just talked about on the Process Workgroup?

MS. PRON: I wondered if we could get any discussion by other members of the Commission that were not at the Process meeting, as to whether they would have a problem with recommending to the Secretary that an adult or a representative of an adult that had been injured from a vaccine be one of the Commissioners recommended the next time.

DR. VILLARREAL: We had asked with the Maternal Immunization, also, and Ann would look at it on the charter. If you look at section one, nine members of the charter, that is three health professionals really looking at an adult doc representative, family medicine, whatever, and then an adult member of the general public would be advisable. They are going to look at the charter, to find out how we can change it.

MR. KING: In the Process Workgroup, we had that conversation and we were advised by the representative, Emily specifically, that it was okay for us to be able to do that without changing anything in the charter, because the room for that individual is, in fact, there under the general public. You could just appoint an adult there, because it only requires at least two of them be either parents or guardians of a child injured by the vaccine.

Therefore, the third individual could be an adult person who was injured by the vaccine, it could just be done.

DR. DOUGLAS: Would there be someone who simply represents the general public? That person doesn't represent the general public. My concern is part of our charter is also offering insurance to the general public that vaccines are largely safe and good things to have done.

I represent the general public, doesn't want unvaccinated kids breathing on their kids, and would like to see vaccinated kids in public schools. There is that voice, that voice exists in this country. That is the general voice, that is the overwhelming general voice. A parent or two parents?

MR. KING: By the charter, the requirement is that there be two parents and/or guardians. They don't necessarily have to be the parents, they could be guardians, of the injured child. It is not required that it be a parent, although, I think traditionally it has turned out to be that way. A guardian acts as the role of the parent for a child.

The third one really can be anyone. It could be a third parent, it could be, as you I think justifiably bring forward, a person of the general public, or it could

fulfill, based upon the Commission's past requests, that there be an adult who has been injured by a vaccine be added to it.

What the Process Workgroup determined was that that did not require a statuary change, and it did not need to be done through legislation. It could just be done, because it could fit within the charter. The question on the table, and it's not really on the table, it's just some point of information because no one has made a resolution or anything.

I think what Ann said is what are people's opinions of that and feelings of it, because not everybody is going to be able to attend the workgroup meetings. I think this is valuable input actually, on what you are saying. Does anyone else have any other input, or thoughts regarding that?

MS. WILLIAMS: Is there a timing issue because the invitations can go out in January, is that how you do it?

MR. KING: From our understanding, letters go out roughly in the January timeframe, to solicit input from the various parties, for who might make a good Commission.

MS. HERZOG: It is actually a Federal Register notice, just like the meetings are published. There is a

notice published in the Federal Register, asking for nominations for the advisory, based on the criteria that is listed in the charter.

MR. KING: Even though, Charlene, in your case, you understand that if we continue with the parents or guardians, it is your position and your term doesn't expire until, I believe, December of 2014.

DR. DOUGLAS: It is not about me, it really isn't about me. It is about keeping a voice for the public's health on this Commission, a general voice for the public's health.

DR. EVANS: You are not a member of the general public. I know that you have a driver's license, I know that you have to pass through the regular security we do. You are a kind of a little bit of a different stakeholder. You have a nursing background and you come through things a little differently.

If you talk about a member of the general public, non-parent general public, that is a different animal. I just wanted to bring that up, because I think as was pointed out before, we have had people usually allied with public health in that third-parent position.

MR. KING: The reason I bring it up is because even though for the position that you hold, so the vacancy

won't occur until 2014. Except, we believe that it might be, because it takes years from when you first start recognizing as possibly being - speaking from personal experience, we spoke for years before I became a Commissioner.

DR. EVANS: We are hopefully in a different paradigm now.

MR. KING: We don't know, so we think that it wouldn't hurt to have that information out earlier. It would make sense to have it.

DR. EVANS: Who is '13, who was in the graduating class of '13? Just three of you on the graduating class of '13, and it is going to be at the end of the year, so you will have almost three years total, right? It really will be three years for you all.

MR. KING: It was '11, it was March of 2011.

DR. EVANS: '13 is going to be barely two years that you are on.

MS. HERZOG: I will check when I get back.

DR. EVANS: Why don't we do this? Why don't we go back and just check, because I know we have the unusual situation of six of you all coming on at the same time, and then three followed. Let's get our numbers straight, and this is something we can always work out.

MR. KING: I agree. We have time, because nothing is going to go under the Federal Register until the new year, 2012, so we have time to sort this issue out for the subsequent meeting. We need to put this on the agenda for the next meeting. It is an automatic agenda item.

Any other questions, issues, comments as it relates to the Process Workgroup? Okay, the Process Workgroup has dutifully given its report. Thank you, Luisita. We will now move on to the next item on the agenda, which is the report from the Attorney's Fees Workgroup. We have co-chairs, Mr. Ed Kraus and Mr. Jason Smith, esquires. Which of you gentlemen is going to give the report?

Agenda Item: Report from the Attorney's Fees Workgroup

MR. KRAUS: I am going to give the report, and Jason will chime in. The Attorney's Fees Workgroup members include Jason Smith and myself, along with Emily Levine is meeting with us, as is Jocelyn Macintosh from the Office of Special Masters, and Julia McInerny as sort of a liaison from the Department of Justice. The reason we formed an Attorney's Fees Workgroup was to figure out if there were some specific recommendations that we could make, that would make the program more effective for vaccine-injured

individuals, that relate to the issue of attorney's fees. We sort of framed our approach to identifying a couple of different competing, not necessarily competing, but issues in sort of figuring out what might fall under those, not necessarily issues, but questions.

The first question was, and is, does the program provide competitive fees to attract and retain highly competent counsel, to help ensure a just and speedy outcome for petitioners. We know that that is sort of, from a program level, the most important issue in question, is are there things about payment of attorney's fees that are interfering with vaccine-injured petitioners getting payment.

Then, at the same time, we wanted to consider whether or not the government's legal resources are being disproportionately dedicated to litigating attorney's fees issues. We recognize and acknowledge that under the statute, there has to be some amount of litigation over the issue of attorney's fees, hourly rates, how you determine what is a reasonable hourly rate, whether or not attorney fees can be awarded in certain circumstances. For example, if it is a claim that is not timely, as Vince was referencing earlier, can a court nevertheless award attorney fees?

There are some issues that need to be litigated, that relate to attorney fees. The question is, are there other issues that maybe don't need to be litigated, or at least for which litigation could be avoided if there were certain recommendations or changes made to the program. That is kind of what we have been moving forward and starting to consider.

We had a meeting, I guess, in July perhaps, by phone, and then we met today and it felt like a very productive meeting. Vince Matanoski was present, along with Julia McInerny, and they were very helpful in answering questions that the workgroup had about DOJ's sort of position on certain issues relating to attorney fees, and also giving us some sense of how litigating on issues of attorney's fees affects the general kind of work of the office.

We, at this point, are going to meet again in probably October, I think is what we were thinking. We are continuing to gather information along those lines. We have asked Jocelyn if she could help us get some information about whether there are petitioners who would like to be represented, who are not able to find attorneys. That is obviously a big concern, and the Office of Special

Masters is in a position to probably provide us some good solid information on that issue.

I have put it out to the petitioners' bar that we are, as the ACCV, addressing these issues. I can't say that I have gotten a lot of feedback yet, but there is likely to be a meeting of the Vaccine Petitioner's Bar in November at the time of the Court of Federal Claims Bar Conference, which this will be on the agenda. I will be able to at least provide some additional feedback from other petitioners' counsel about what attorney's fees issues they believe might be important for the ACCV to consider. Anything to add, Jason?

MR. SMITH: No. Very good summary, I thank you. I think the one other thing is that there is a lot of overlap on some of the issues we are looking at. I think it was a very good discussion we had with the different stakeholders today.

This may creep into other areas, whether it be looking at the revolution of interim attorney's fees and how that issue is progressing through the courts, and that will probably be the subject of a future workgroup meeting, to at least examine that issue. We are working very closely with the Process Group, because there is some overlap there. These are not siloed-type issues or

meetings. I think there is a fair amount of collaboration across those groups, and that is, I think, helpful. That is it.

MR. KING: When you coordinate your next meeting, you will coordinate through Annie, so that if we want to have a dial-in number or something like that, that will work, right?

MR. KRAUS: Yes.

DR. VILLARREAL: Are there courses that lawyers take for specifically on this topic, so if parents ask me for advice, who to send folks to? Just like we have subspecialists in pediatrics, we have legal expertise that are sort of premature toenail specialists.

MR. SMITH: I'll answer the simple one. Ed can speak more specifically with his experience. It was funny, I was just talking to Jocelyn during the break, and the one nice thing on the website, with respect to the program in the Office of Special Master, there is a fairly comprehensive list of attorneys, of law firms, who do this work on a very regular basis.

So more of the subspecialist type of category, and these are very experienced firms in this regard. There is a resource readily available for parents, for

caregivers, to get that information, or conversely, for adults who may be looking for a resource.

MS. WILLIAMS: It would seem to me that it would be hard for parents to wind up on the Office of Special Master website.

MR. SMITH: I think what Sylvia was asking was, where could I refer a parent who is asking me about the program.

MS. WILLIAMS: They are on the Court web site, right? That would be a hard place for parents to end up.

DR. VILLARREAL: I assume you are saying we should have it on our website.

MR. KING: Or a link to the Court's website. I think that is a good idea, actually.

MS. PRON: Is it possible that one of you could send us a link in our email, to exactly where the pages are?

DR. EVANS: There is a link from our website to the court website that furnishes that information.

MR. KING: The information that we are specifically furnishing is where a parent could find legal advice. It is a list of attorneys that specializes in this particular area.

DR. EVANS: We have always been very careful, because we don't want to be recommending. It then becomes a de facto recommendation from us. This way, if we are linking to the court, that way it doesn't seem as though we are doing it.

MS. WILLIAMS: I understand that and I think that is fine, but my question is, just as a practical matter, how easy is it? Maybe Sylvia, you could do a little field work and see how easy it would be to do it.

DR. VILLARREAL: I will give it to one of my parents to do. I will say, you go find it for me and they will.

MS. WILLIAMS: See how long it takes for them to find it.

MR. KING: Isn't there a way to put the link specifically to the list of the court site, that lists what the attorneys is, with some level of disclaimer on our site that it is not a recommendation, but rather a resource that the courts have listed, and that is not a recommendation?

DR. EVANS: I think something could possibly be worked out.

MS. WILLIAMS: Emily can tell us next time.

DR. DOUGLAS: Emily can wordsmith that so that nobody ends up in jail.

MR. KING: So we'll follow up on that. Any other questions for the Attorney's Fees Workgroup? None being offered, we thank you guys for your report. We will move on to the next report on the agenda, which is from Tom Shimabukuro, and it is the update on the Immunization Safety Office. Dr. Tom?

Agenda Item: Update on the Immunization Safety Office Vaccine Activities

DR. SHIMABUKURO: This is Tom Shimabukuro from the Immunization Safety Office at CDC. Today, I am going to give an update on planned influenza vaccine safety monitoring activities for the 2012-2013 influenza season. The vaccination season is actually started. There is vaccine out there and it is being administered. I am going to give an update on some key topics from the June 2012 ACIP meeting, and then go over some selected recent publications.

Planned influenza vaccine monitoring for 2012-2013, we will conduct a VAERS routine surveillance, like we do each season. This consists of automated data analysis to identify potential signals. At CDC, we use statistical methods, primarily a proportional ratio to identify statistical signals which may indicate potential safety signals.

We will also look at reporting trends over 10 years for all reports, and for serious adverse events, deaths and GBS. We do this every flu season. FDA will be performing data mining.

There are a few areas for enhanced VAERS surveillance, specifically Fluzone Intradermal, which is in its second season of use. I will just say that when new vaccines are introduced, we also have a period where we conduct enhanced surveillance of VAERS. This is really reviewing reports that come in for these specific products. In the case of the anaphylaxis with egg allergy, looking for individuals with specific conditions that we want to track.

For Fluzone Intradermal, in the second season of use, and Fluzone High-Dose is in its third season of use, those are both inactivated vaccines. Anaphylaxis with egg allergy, this season, 2012-2013, is the second season following the change in TIV recommendations for egg allergic patients. I will have a slide specifically describing what we saw last season for that, coming up.

In VSD, we will be conducting active surveillance for selected conditions, including seizures and GBS following trivalent and activated vaccine, the live attenuated influenza vaccine, using automated data. In

VSD, if we do see signals, we go in and we do an assessment, using more traditional epidemiologic methods, which could include a chart review, if we need to.

Moving onto slide four, these are some June 2012 ACIP meeting highlights. This is really a review. This slide has a review of the past flu season safety monitoring. We continue to observe disproportionate reporting for febrile seizures in young children following Fluzone in VAERS data mining for 2011-2012, the previous season, as was first seen in 2010-2011, two seasons ago. This is not unexpected, given that there was not a formulation change for the 2011-2012 season. Also, considering the possibility of stimulated reporting when that safety issue became known to the public.

The elevated relative risk observed for seizures following TIV in children, age 6 to 23 months in VSD surveillance -- we continued to have an elevated relative risk observed for seizures, following TIV in children 6 to 23 months in VSD surveillance of automated data this past season. The magnitude of this risk was consistent with the risk we observed in 2010-2011. That was the season we detected and assessed the signal. There was no increased risk in children 24 to 59 months old.

There was no disproportionate reporting for GBS following TIV or LAIV in VAERS data mining for 2011-2012, and that was the case for 2010-2011. There was no elevated risk for GBS following TIV or LAIV in VSD surveillance of automated data for 2011-2012. That was also the case for 2010-2011.

MR. KING: Tom, a couple of questions are coming through.

MR. KRAUS: Tom, I had a question about what was the timeframe you were looking at, in considering seizures following the TIV for the kids, 6 to 23 months?

DR. SHIMABUKURO: In VAERS, there really isn't a timeframe. VAERS reports, they just look at an exposure with a vaccine, and an actual reported event. In VSD, the risk window that we are looking at is zero to one day, so that is the day of vaccine to the day after vaccine. The comparison window, I believe, is 14 to 20 days, it is around two weeks out.

The reason that we use the zero to one day risk interval is because that was the risk interval where we were seeing the increased risk in the Australian vaccine, back in 2010-2011. When we did some adjustments in our surveillance for 2010-2011, based on the Australian

experience, it was clear that the children were experiencing the seizures in the zero to one day interval.

It is actually good to choose that more defined interval, because if you extend that interval out, you can actually wash out some of the effect, if that makes sense. If you use a longer interval, you can actually wash it out.

MR. KING: Any other questions?

MS. BERNSTEIN: I am curious about if you have information on what percent Fluzone was used, in terms of immunizations that were given? How much Fluzone was used versus other vaccines?

DR. SHIMABUKURO: We don't have coverage data. Well, actually, we may have coverage data in VSD, I am not sure. Fluzone is overwhelmingly used in the United States. It is actually the only licensed vaccine for children 6 to 23 months in the United States. If you are looking at that age interval of 6 months to 59 months, sort of at the right end of that, you may get some other products. When we are looking at the 6 to 23 months old, it's Fluzone, because that is the only licensed vaccine.

MR. KING: Any other questions?

DR. SHIMABUKURO: This is a table, which actually, this table is available online and on the ACIP website. It is the exact table that is posted online right

now. At ACIP, I gave a summary of the GBS results for H1N1 vaccine. You have seen versions of this table, because I have presented this at previous meetings. This is the most updated information we had, at least as of June.

It shows on the left-hand side the vaccine safety system. We have EIP, VSD, PRISM, the CMS data, the DoD's data and the VA data. The next column is the study design. The third column over is the relative risk or the odds ratio. Then, the last column is the risk difference or attributable risk, and probably that is the one to focus on.

The significant risk, relative risk and attributable risk are in that reddish or rust color. The non-significant risks are in the blue, where they are available. I think the take-home from this message is that, during the pandemic, in some of our systems, in some study designs, we detected a statistically significant increased risk for GBS, following H1N1 vaccine, in the risk window, which was 0 to 42 days.

Overall, this risk was around one to two additional cases per million doses, which is similar to the risk we have observed in some previous influenza seasons, with seasonal influenza vaccine. It was much lower than the risk observed after the 1976 swine influenza vaccine.

I should stop here, if people have some questions on this table.

DR. VILLARREAL: CMS is the VFC data, is that correct?

DR. SHIMABUKURO: CMS is the Center for Medicare and Medicaid Services. It is quite tilted towards the elderly. It is mostly Medicare data. This is not really new information, although it might be slightly updated from some of the information you have seen on previous tables.

As far as allergy and anaphylaxis, following TIV, the vaccine recommendations for egg allergic patients were updated for the 2011-2012 season. Those recommendations are available online. Sort of in a nutshell, for patients who experience symptoms like hives, only after eating eggs, the recommendation was to provide vaccine for those patients and observe them.

For patients who had a history of a severe allergic reaction, an anaphylactic reaction after eating eggs, the recommendation was to refer those individuals to an allergy specialist, who has expertise in treating those type of reactions, before getting vaccinated. However, it is no longer a contraindication to give those individuals vaccine. It was really a provider decision.

After this recommendation, we had conducted monitoring in VAERS, the season following the recommendation. The end result was there was no increased reports of allergy or anaphylactic reactions in VAERS from 2010-2011 to 2011-2012, from the seasons before the change in recommendation to the season after, which is reassuring.

We understand that sometimes the uptake of these recommendations, it takes a little while, so there is lag. In the season after these recommendations were liberalized, for lack of a better word, we did not see an increase in reports of allergy or anaphylactic reactions in VAERS. For high-dose and intradermal, there were no new safety concerns identified.

There was one vote, that was a recommendation for a 13-valent pneumococcal conjugate vaccine, or PCV13 use, among immunocompromised adults. Probably most of you know, PCV13 is routinely given in children and some other individuals. ACIP voted and passed to recommend PCV13 for adults with immunocompromising conditions and functional or anatomic asplenia, CSF leaks or cochlear implants, so other conditions which might put them at risk. Some of the details are in these two bullets below, but I am not going to walk through those. Those get to the specifics of how this recommendation would be implemented.

DR. VILLARREAL: Tom, go back to that slide. One of the things for VFC, the 13 is for kids up to 48 months. Are you saying for adults, 18 and older, or kids, 5 and older, do P13 if they are immunocompromised?

DR. SHIMABUKURO: This is for adults. This recommendation is for adults, so individuals 19 years and older. I am not sure what the recommendations are for children, but this was specifically for adults with immunocompromising conditions.

DR. VILLARREAL: What I am asking is, there is no ability to get 13 for anybody over the age of 19 years, we are using VFC funds.

DR. SHIMABUKURO: I believe the VFC cutoff is 18 years. Yes, these individuals would not be covered by VFC.

MS. PRON: Is it not true that many times insurance plans do cover the ACIP recommended vaccines?

DR. VILLARREAL: Most of our kids don't have insurance. Okay, thank you.

DR. SHIMABUKURO: I am just going to go over several selected publications. A paper recently came out in the American Journal of Epidemiology, and this was looking at the association between immunization and Bell's palsy in children. They looked at two vaccines, trivalent and activated influenza vaccine, and hepatitis B vaccine,

and also combined other vaccines to get a larger pool. They came to a conclusion there was no association between immunization and Bell's palsy in children.

We had another Bell's palsy paper come out, and this was using VAERS data, and focused on H1N1 vaccine. This was a review of VAERS reports. The authors reviewed 65 cases of Bell's palsy reports that came into VAERS. There was no pattern in the demographic and clinical characteristics to suggest an increased risk of Bell's palsy after 2009 H1N1 vaccination.

There was a higher reporting rate of Bell's palsy to VAERS on receipt of H1N1 vaccine, compared to seasonal vaccine. We believe this is probably due to stimulated reporting. There is a stimulated reporting for a lot of conditions during 2009. When they reviewed these reports on an individual basis, they didn't see any concerning patterns.

Moving onto the next slide, the top paper here, on adverse event reports, after tetanus toxoid, reduced diphtheria toxoid and acellular pertussis vaccine in pregnant women. This looked at VAERS reports during the time that Tdap was not routinely recommended in pregnancy. These would have been vaccines which were either administered off label or given to a pregnant woman by

accident, and then were reported to VAERS. The authors do not identify any concerning patterns of maternal, infant or fetal outcomes.

In fact, the most common report was no adverse event. This was a VAERS report, just acknowledging that there was an error made in administering this vaccine. The next most common report was spontaneous abortion. This was well below the background rates.

The final paper was a paper by one of our VSD investigators. This looked at biologically plausible and evidence-based intervals in immunization safety research. They focused on risk intervals for febrile seizures and for ADEM, which is acute disseminated encephalomyelitis. What they did was they looked at the literature and they made a determination on what is a biologically plausible risk window for a febrile seizure and ADEM. Their determination was a biologically plausible risk window for febrile seizure was 0 to 48 hours, which coincides pretty well with the 0 to 1 day interval that we use to monitor febrile seizures.

Then, they actually broke the ADEM risk intervals up into a short interval, which was 5 to 28 days, and a longer period, which is 2 to 42 days. This is just really

to inform vaccine safety research about what are appropriate risk intervals to use. That is all I have.

MR. KING: Questions?

MR. KRAUS: I was wondering if you could report on the joint committee that is looking into the feasibility of a vaccinated versus unvaccinated population study?

DR. SHIMABUKURO: I don't have any information on the status of that.

DR. READ: I can comment on that later in a minute.

DR. VILLARREAL: Tom, do we have data on Flumist and the intranasal, and any adverse effects?

DR. SHIMABUKURO: I think the question was do you have any data on adverse events following Flumist. For common and known adverse events like runny nose and sore throat, I mean, those things, yes, we know about that. We expect that, we see that.

One of the issues for LAIV is it is not used that much, although it is being used more. Rare outcomes are hard to study. For the outcomes that we do study, like seizures and GBS, we haven't seen any safety signals for those type of outcomes in our VSD surveillance. The data, so far, for LAIV has been reassuring.

DR. VILLARREAL: We are pushing it for kids 2 and over. It is just a lot easier to mass immunize or mass spray. One thing that we have seen is some noise about is potentially egg allergy, where they will just blow up their face. You will get periorbital edema and nasal edema. I was just wondering if you had that in the literature at all.

DR. SHIMABUKURO: I am not aware of that in the literature. I mean, the things for LAIV that I am aware of are fever, runny nose, sore throat, asthma exacerbation, in children younger than 2. That is why it is actually not licensed in that age group.

I am not aware of an increase, or I am not aware of any disproportionate reporting in VAERS for allergic reactions. That isn't something actually that we monitor for in VSD, but I will certainly mention that to our VAERS folks, and maybe I can see if we can pull up some reports. This would be a hypersensitivity reaction to LAIV. Is this immediate or is this delayed, do you know?

DR. VILLARREAL: It is fairly immediate. It is usually within 15 to 30 minutes. They will start first with like a severe rhinitis and wanting to take their nose off of their face. Then, you will start seeing some

erythema, and then periorbital edema, lymphedema, facial edema.

DR. SHIMABUKURO: Do you treat it with like Benadryl or something?

DR. VILLARREAL: With magic Benadryl, yes.

DR. SHIMABUKURO: And these resolve and they are fine?

DR. VILLARREAL: Usually, they resolve pretty quickly. Also, they stop scratching because they just sedated them with Benadryl. There have been a couple of cases where they gave them epi.

DR. SHIMABUKURO: I can certainly look into that and see if there are some reports in VAERS. There is not any data mining. They look at the whole. Although it would be hard to tease that out, because there is only one intranasal vaccine that I know of. Anyways, I can look into that for you.

MR. KING: Any other questions? Tom, thank you very much.

DR. SHIMABUKURO: My pleasure.

DR. KING: Next on the agenda is Dr. Barbara Mulach, the update on the National Institute of Allergy and Infectious Diseases.

Agenda Item: Update on the National Institute of Allergy and Infectious Diseases (NIAID) Vaccine Activities

MS. BERNSTEIN: I am standing in for Barbara, Jessica Bernstein. I know Barbara and I have both reported on the NIH Vaccine Safety Program announcement in the past at ACCV. NIH just made four awards under this program announcement, so I wanted to mention those. One is, I think, might be of particular interest to the Commission. It is called Genome-Wide Association Study of Febrile Seizures Following Measles, Mumps and Rubella Vaccine.

I put on the handout the grant number actually for each of these. If you want to look in a NIH report to find out more specific information, you can. Basically, this is exploring whether there are genetic polymorphisms that are associated with an increased risk of febrile seizures following MMR. They will be comparing genetic data from children who have had these seizures following vaccination, who have had seizures not associated with vaccination, and then who have not had seizures. This is taking place in Denmark.

Two more studies under this PA have to do with developing malaria vaccine immunization strategies. I didn't put the details of those on the handouts, but you can look those up if you are interested. There is also

vaccination strategies to overcome immune deficiencies in neonates. This is basically looking at the possibility of adjuvants that might make vaccines safer for neonates. That is very basic research, that is an animal study.

I also wanted to mention a recent publication about the HPV vaccine. In that publication, which was supported by NIH work, it showed that there is actually herd immunity induced by HPV vaccine, which is kind of interesting because you usually think of herd immunity more as pertaining to things like influenza. In this case, it is a similar effect, where basically there is less of the virus circulating. It offers protection to those who are not immunized, as well as to those who are immunized. It came out in Pediatrics in July of 2012. The citation is on the handout, too.

DR. DOUGLAS: Is the level of immunity still around 80 percent?

MS. BERNSTEIN: I don't know, but I have a copy of the article, if you want to have that. I brought a couple of copies of the article, so I don't know. It may be in here. Just two more things I wanted to mention, one is we have a new section of our website that we are calling the WOW files.

http://niaid.nih.gov/about/organization/dmid/success/130/2/

e249.full.html That is sort of the nickname, but it is basically sharing scientific success stories.

What we are trying to do is put forward stories that explain how basic research eventually leads to products that are used in clinical practice, products and techniques. Because there is such a long time lag between basic research and when something goes to market, a lot of times, the effect of basic research or the role of basic research is lost. We have got about probably 10 stories posted right now, and about 50 more in the queue to be further developed.

It is kind of to educate the general public about the role of basic research and how it impacts what you get in your doctor's office. Then, also to track the fingerprints of basic research.

The last thing I wanted to mention is the NIIAID Showcase, which also talks about some accomplishments that have been supported by basic research and have gone through the product development process, and now are in clinical practice. Those two websites are both on the handout.

DR. KING: Any questions, comments? Jessica, thank you. Next on the agenda, Lieutenant Valerie Marshall, update on the Center for Biologics, Evaluation and Research.

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

LT. MARSHALL: Good afternoon. I will give a brief FDA update. On August 13th, the US Food and Drug Administration approved the 2012-2013 influenza vaccine formulation for all six manufacturers licensed to produce and distribute the vaccines in the United States, and that is for the influenza vaccine.

On June 14th, 2012, FDA approved Menhibrix, which is a combination vaccine for infants and children, ages 6 weeks through 18 months, for prevention of invasive disease caused by Neisseria meningitidis, serogroups C and Y, and Haemophilus influnzae type B. A meningococcal disease and Haemophilus disease can be life-threatening. These bacteria can affect the bloodstream, causing sepsis, and the lining that surrounds the brain and spinal cord, causing meningitis.

In young children, Neisseria meningitidis and Haemophilius influenzae type B are important causes of bacterial meningitis. The Menhibrix vaccine is given as a four-dose vaccine at 2, 4, 6 and 12 through 15 months of age. The first dose may be given as early as 6 weeks of age.

On June 19th and 20th, NIH and OVRR met for a meeting to discuss development of a universal influenza vaccine. A universal influenza vaccine would provide protection against all A strains, including pandemic vaccines. This vaccine would not need to be renewed annually.

The Food and Drug Administration Safety and Innovation Act was signed into law on July 9th, 2012. It gave FDA renewed authority to collect user fees from industry, to fund reviews of innovative drugs, medical devices, generic drugs and biosimiliar products. This September, the Vaccines and Related Biological Products Committee will meet in an open session to discuss consideration of the appropriateness of cell lines derived from human tumors for vaccine manufacturer. This meeting will be webcast free of charge. That concludes my update.

MR. KRAUS: What kind of vaccine is the Menhibrix?

LT. MARSHALL: It is a combination vaccine. It is for prevention of Neisseria meningitidis, serogroups C and Y, and Haemophilius influenzae type B. It is going to help protect against bacterial meningitis.

DR. VILLARREAL: It is not meningococcal, it is Neisseria?

LT. MARSHALL: Yes, it is Neisseria meningitidis.

DR. VILLARREAL: It is for which group?

MR. KRAUS: Break it down here, for the non-medical people. Currently, it is not recommended for infants to get the -

LT. MARSHALL: It was just approved in June. The four-dose series starts at 2, 4, 6 through 12 months of age. The first does is at 2 months.

DR. VILLARREAL: This is for at-risk, like if they are in areas that they have it? I am thinking you said meningococcal with Haemophilus influenzae B. Haiti, Dominican Republic, so it is for that at-risk group that folks are going to be in areas that are endemic to have mening at a young age?

DR. EVANS: This is probably going to come with a permissive use recommendation, to be determined by ACIP. It doesn't have a use recommendation yet. The ACIP has been talking about this for some time. There are several candidate vaccines that are under development. This is the first one that is out, that is correct.

The question is, everything in vaccine recommendations has to do with the benefit cost ratio, risk benefit, risk cost ratio and all that. It turns out that when 10 years, 15 years ago, when these companies began to

do research on these vaccines, there was so much higher incidence of meningococcal disease in the 1 to 2-year age range. We have implemented an immunization program for adolescents and young adults, and even to the lower age groups, and the profile of meningococcal disease now in very young children has changed.

There have been discussions in a workgroup with ACIP the past couple of years, over the very issue of well, okay, is there now a strong argument made for routine administration to children in the 1 to 2-year age range, given the fact that you can't get protective levels early in the first half of the first year of life, when they would be at risk.

Secondly, that the disease levels themselves had dropped dramatically in that age range. Third, the serotype (?) that they are exposed against isn't in the vaccine. One of them, B, the B is not even in that particular kind of vaccine. Fourth, you have the increased immunity of individuals around them, that have a protective effect.

The thinking is more and more that the ACIP may very well agree to permissive use recommendation, meaning that those who would like to have their children immunized can certainly ask their practitioners to do so,

understanding also at the same time, that it will be covered under DFC. There is a good chance it will not be covered by insurance companies and third-party payers.

This has been a conundrum that has been floating around in the workgroup for some time. It was expected that this particular vaccine was going to be licensed as early as February. That didn't happen. Now, it is a little bit later in the year. It remains to be seen how this is going to play out.

The vaccine is covered under our program, regardless of the fact, if that is one of your questions. It is covered, because right now, you have HPV. For women, it is recommended for use, in males, it is permissive. Once the vaccine is taxed, it is a covered vaccine, regardless of the individual use parameter while it is being done.

MS. BERNSTEIN: Will that meng vaccine for kids substitute for the adolescent vaccine?

DR. EVANS: It remains to be seen. They are not taking that one on, yet.

DR. READ: When will this be addressed by ACIP next one, in October?

DR. EVANS: Next, yes, they are going to discuss it.

MR. KING: Any other questions, comments, thoughts? Thank you very much, let's move on.

Agenda Item: Update from the National Vaccine Program Office

DR. READ: This is Jennifer Read from NVPO. I just have a couple of updates.

MR. KING: Before you being, Jennifer, there was a question that was on the table earlier that you were going to address, if I am not mistaken.

DR. READ: Yes, I will go ahead and cover that first. As you know, there is an IOM committee that was tasked with doing an assessment about the feasibility of studying health outcomes in children who were vaccinated according to the CDC recommended schedule, versus those who were not. They were either unvaccinated children or children vaccinated with an alternative schedule.

We just met with the IOM staff last week, and they are estimating they will have their final report ready late fall. We don't have an exact date yet, but I would say between end of October to mid-December is the goal. If something is delayed, they will probably delay it until after January 1 to release it. They estimate it will be late fall they will be done.

As you know, they have had a series of public meetings, and then they have had some closed meetings, so this is the outcome. The NVAC meeting is coming up next week, and topics for discussion on the agenda now include implementation of the National Vaccine Plan, Healthy People 2020 immunization goals, there is an update on national pertussis cases. As you know, there have been outbreaks in several places.

Immunizations and health information technology, and then updates from various NVAC working groups. The ones who will be reporting are maternal immunization, immunization infrastructure and global immunization. Then, there will be a session dealing with vaccine hesitancy.

Many of you were at a workshop that we organized last fall that was called Progress in Overcoming Barriers to Influenza Immunization of Pregnant Women. I am pleased to announce that the supplement is now physically present. It has just been published and it is in the American Journal of OBGYN, September 2012. This has almost 100 pages dealing with various aspects related to immunizing pregnant women against influenza. That is it.

MR. KING: That was quick. Any questions?

DR. READ: Several people here participated in the meeting and Anna has a very nice article that is based

on her talk at the meeting that deals with legal liability issues, related to immunizing pregnant women.

DR. EVANS: Is that copyright available?

DR. READ: I can send you the table of contents, but I can't transmit this to anybody. I can get you the citations and you can access the articles.

LT. MARSHALL: It was also published with Marion Gruber.

DR. READ: That is right, and Valerie did a very nice article about regulatory issues with Marion Gruber.

DR. EVANS: Okay, well, then, there will be two articles.

DR. VILLARREAL: When NVAC meets, they are doing EMRs with immunization. Is it scheduling, is it registries, do you know?

DR. READ: I didn't write down the details, there are two or three talks in that area. I didn't write down the names of each of the talks.

DR. VILLARREAL: A major issue with pediatrics and anybody else is that, with meaningful use, we are trying to meet the criteria of giving everybody their immunizations before age 2. If we have alternative schedules, we will never meet that requirement. Again, it becomes difficult to do any tracking which immunization

that child got, other than what we have with EMRs. I was just interested if people sort of look at how much is cumbersome for us to document, as far as under 2, immunizations, when people are on alternative schedules.

MS. PRON: Do you know if there is going to be discussion about National Immunization Registries?

DR. READ: I didn't bring the agenda with me. I just was trying to summarize some of the areas of discussion. Again, there will be two or three talks, and you can access this. There is a 1-800 number to listen to the meeting. Even if you can't physically come to the meeting, you can hear all of the talks during it.

MR. KING: Okay, any other questions? Jennifer, thank you.

DR. READ: I am going to pass this around. I just need to get it back.

MR. KING: The next item on the agenda, and we are a little bit ahead of schedule for this, is the public comment section. Cathy, I guess you need to give instructions on if anybody wishes to make a public comment.

Agenda Item: Public Comment

MR. KING: First off, is there anyone in this room that would like to make a public comment first? No, and then we will move on the phone.

OPERATOR: All right. If you would like to make a comment, please press the star 1. We have one coming up, one moment. Theresa?

MS. THERESA WRANGHAM: Can everybody hear me okay? This is Theresa Wrangham. I am the executive director for the National Vaccine Information Center. I want to thank the committee today for the opportunity to give public comment.

I would like to thank all of the workgroups for their efforts today. I only have a few short comments. I had an outreach suggestion. There was discussion about how the public is able to access information with regard to attorneys who are versed in vaccine injury claims. NVIC keeps that information on the our website. However, we do receive quite a number of inquiries about this.

I am wondering if, outside of links on agency websites, if there should be some sort of effort to work with organizations such as NBIC or other similar stakeholder organizations to get that awareness out there, around the VICP itself, and how to find an attorney, if you should feel that you need to file a claim. Just a suggestion.

Also, I was hoping that perhaps in the interest of transparency, if the Department of Justice could

additionally break down the report that is furnished online. They furnish a report that delineates the total award amount per vaccine. I think it would be nice for the public to know what types of injuries, for example, if influenza awards are being made for GBS or transverse myelitis, if those breakdowns couldn't be available, of course taking out any sort of identifying information that is not something that should be available to the public.

Those sorts of breakdowns are of value. I think they are also of value in terms of message clues(?) similar to what the Future Science Workgroup was speaking to today. That was all of the comments I had today. Thank you so much.

MR. KING: Thank you for your comments. We appreciate it. Any other comments?

OPERATOR: There are no other comments at this time.

Agenda Item: New Business and Future Agenda Items

MR. KING: Does anybody have any new business or new items to bring before the Commission? Well, then, may I? Michelle has left me something, and she is out of the room at the moment, so I will just proceed. I was going to

read a resolution that we were going to place, and we can discuss and/or vote on. I will read that resolution.

In recognition of Dr. Evans' years of public service, and his leadership of the ACCV, the ACCV would like to make a few comments for the record. Dr. Geoffrey Evans was born in Washington, D.C. and did his undergraduate studies at the University of Richmond. Following graduation, he attended George Washington University in the District of Columbia, earning his medical degree in 1978.

Dr. Evans was in private practice for general pediatrics for several years during the mid '80s in Lake Tahoe, California, occasionally providing medical services to the children of the performers appearing at the local casinos. He also served as a physician at Kaiser Permanente in Fairfax, Virginia, before joining the Vaccine Injury Compensation Program, as a contractor, in 1990.

While a federal physician, Dr. Evans has served as a chief medical officer, medical director, and for the past several years, as the director of HRSA's Division of Vaccine Injury Compensation. Dr. Evans has devoted his public service years to HRSA's Division of Vaccine Injury Compensation and to leading the ACCV as its executive secretary. Dr. Evans has been with the Vaccine Injury

Compensation Program since its inception, and has been a stalwart steward of this critical public trust.

The ACCV recognizes Dr. Evans' dedication to the Vaccine Injury Compensation Program operations, and specifically recognizes his dedication to children, one of our most cherished and vulnerable populations. Over the course of 85 meetings, the ACCV has had the benefit of his vast institutional knowledge and diplomatic demeanor.

Dr. Evans has handled his responsibilities with great professionalism, dedication, integrity and compassion. He is the epitome of the selfless public servant. Accordingly, the ACCV resolves to commend and thank Dr. Evans for his 22 years of selfless work, and his many enormous contributions to the development of the program and the science of vaccine safety. We thank you and appreciate you.

(Applause)

For those who didn't know, Dr. Geoffrey Evans is resigning or retiring. We have a resolution on the table. We would like to see it seconded, and we would like to vote on it, because we want it in the public record.

DR. VILLARREAL: Second.

DR. KING: All in favor. Any opposed? Any abstentions? The resounding "ayes" have it, well done, thank you, all right.

(Applause)

That being said, if there is no further business to come before, I will take a motion to adjourn.

Agenda Item: Adjournment

DR. KING: I will take a motion to adjourn now.

COMMISSION MEMBER: I move.

DR. KING: Second to that motion?

COMMISSION MEMBER: I second.

DR. KING: Second, done, all in favor, aye, we are out of here, bingo, well done.

(Whereupon, at 4:36 p.m., the meeting was adjourned.)