DEPARTMENT OF HEALTH AND HUMAN SERVICES

SEVENTY-FOURTH MEETING OF ADVISORY COMMISSION ON CHILDHOOD VACCINES

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Agenda Item: Welcome and Chair Report and Approval of September 2009 Minutes

OPERATOR: This is a meeting of the Advisory Commission on Childhood Vaccines. I am going to turn the meeting over to the ACCV chair, Miss Magdalena Castro-Lewis, who will convene the meeting.

MS. CASTRO-LEWIS: Why don't we start by introducing ourselves?

DR. EVANS: Geoffrey Evans. I am the Director of the Division of Vaccine Injury Compensation and the Executive Secretary of the Advisory Commission on Childhood Vaccines.

DR. SAINDON: Elizabeth Saindon with the Office of the General Counsel.

DR. HERR: I am Dr. Tom Herr. I am a pediatrician on the Commission.

DR. SULLIVAN: Dan Sullivan, National Vaccine Program Office.

MS. TEMPFER: Tammy Tempfer, pediatric nurse practitioner, Commissioner on the ACCV.

DR. SCONYERS: Jeff Sconyers. I am a member of the ACCV.

MS. DREW: Sherry Drew, ACCV Chair.

MS. CASTRO-LEWIS: Magdalena Castro-Lewis, Chair

of the ACCV. Could we go to the members of the Commission that are on the phone, please?

MS. GALLAGHER: Good morning. It's Charlene Gallagher. I am a member of the ACCV representing industry.

DR. FISHER: Meg Fisher. I am a pediatrician in New Jersey.

MS. BUCK: Tawny Buck. I am an ACCV parent representing families.

MS. HOIBERG: Sarah Hoiberg, representing families.

MS. CASTRO-LEWIS: Thank you so much. Now I would like for the people present in the room to introduce yourselves, please? No? I'm sorry.

If anybody has any comments for the minutes? I'd like to move that, anybody?

DR. HERR: I move we approve the minutes as distributed.

DR. SCONYERS: Second.

MS. CASTRO-LEWIS: All those in favor of approving the minutes as they are?

(Chorus of ayes.)

MS. CASTRO-LEWIS: Thank you. In terms of the report of the Chair, this was reported with the three working groups that we have. I am not going to comment on any of

them, just that there will be a report from each of them. Jeff and Sherry and Sarah led those committee reports, and there will be additional comments at the time.

I would like to move on to Dr. Evans' report.

Agenda Item: Report from Division of Vaccine Injury Compensation

DR. EVANS: Thank you, Magda. Good afternoon. I'm not going to tell you again that this is the quarterly meeting of the Advisory Commission on Childhood Vaccines.

In your blue folders that you have in front of you, you will see on the right side copies of this presentation and the Department of Justice's presentation and some statistics. There is a copy of H.R. 4096, which is a bill introduced this past month by Representative Tom Perriello, that has been referred to the House Energy and Commerce Committee.

You will also find a December 2009 working list of adverse events, which is an updated list, for the four additional vaccines that will undergo review by the Institute of Medicine Committee on Vaccine Adverse Events. This was just posted on the IOM website for additional comment. I am told that there is no deadline per se, but the IOM said in their list of announcements that was sent around that it would be most helpful if comments were received by January 4.

On the left side of the blue folder you will find

a copy of the proposed regulation having four vaccines in separate categories on the Table, which will be discussed tomorrow, and there is also an article on thimerosal in vaccines.

In terms of the highlights of the meeting, following my presentation and the update of the Department of Justice, there will be a work group report on causation by Jeff Sconyers. That will be followed by the Petitioners Payment Work Group report by Sherry Drew, and an update from the ex officio members of the Commission.

Tomorrow morning there will be an outreach Work Group report by Sarah Hoiberg and a report on the VICP outreach contract by the staff from Banyan Communications that I've been looking forward to. That will be followed by a discussion adding four new vaccines as separate categories in the Vaccine Injury Table, and I will be presenting that.

Moving on. We have an important announcement as far as additional staff. We have added quite a few this past year. We now have Dr. Mary Rubin, who has just joined us. Mary is local. She got her undergraduate and medical degree from the University of Maryland, and she trained at St. Christopher’s Hospital for Children in Philadelphia, which is a very highly regarded teaching facility. Since finishing her residency, she has been a hospital staff physician at Shady Grove Adventist in Rockville. Definitely in addition

to youth, she brings a fresh pediatric clinical experience and perspective to our group. We are delighted she has joined us. We are quite busy these days, as you will see.

Moving on to the monthly statistics and overall program for the past several years, this is from November 30, 2009. You all should have a copy of that in front of you, which was just provided.

Starting with claims filed, I think there are two noteworthy trends you will see now in this fiscal year and in the past fiscal year. That is that the non-autism claims have significantly increased. Just this fiscal year alone, which represents two month's worth of activity, you have 83 claims. If you project that out, that is somewhere close to 500 per year, which would be a significant increase.

Just as a quick insight into these, 41 percent of claims that were filed in fiscal year '09 that just ended were influenza vaccine. After 41 percent it dropped way down to DTAP, just under ten percent, MMR eight percent, HPV, human papillomavirus vaccine, seven percent, GD, seven percent and hepatitis B, five percent.

The other noteworthy part of this is that for the first time, adult claims were predominant in terms of the age group that filed. They were 60 percent of claims. So the program is certainly transitioning and the addition of influenza vaccine in 2005 is starting to have this effect on

the program in terms of the demographics and age groups that are applying.

The other trend of note is that the autism filings have significantly decreased. You will see that there were three this fiscal year versus 108 the previous fiscal year.

Moving on to adjudications, what we have done this time is put total adjudications on, not just the non-autism ones, because there has been activity on the autism side.

In front of you there is a handout from November 30. You will see the breakdown between autism and non-autism under dismissed claims, but overall you can see that there were 227 dismissed this past fiscal year and only a small portion of those were the non-autism. The autism claims comprised a significant percentage. That is because the Court's efforts for the past year to look at jurisdictional status and claims that are outside of the statute of limitations are being dismissed by the Court as they go along.

You have in front of you the compensable numbers, too, which are highlighted even more clearly in this slide, that shows the breakdown of compensable claims for the past three fiscal years, actually the two fiscal years and this one, but there is very little activity in this particular one. But you can see that the trend is that settlements are running 83 percent for '08 and '09 as far as the basis for

claims being compensated, whereas concessions and court decisions have decreased and continue to decrease. That is a trend that has been present now for the past three or four years. So, now litigated risk settlements are now the major order of business for the program.

In terms of the final compensation rate for fiscal year 2009, I reported it was 72 percent in September, with the fiscal year still remaining to be closed out, and overall it was 75 percent. This year of course the numbers are very small; it is over 50 percent, but it is still too early to tell how that is going to play out.

In terms of award amounts, the annual awards for petitioners have gone from $69 million to $74 million now for petitioners awards, and attorney fees have also increased slightly from $5 to $6 million as an overall average for the preceding five years. That is because of some interim fee activity, and also the significant bolus that occurred in fiscal year ‘09 with some of the interim fees for autism, the autism proceedings being paid.

You will notice also for award amounts, for fiscal year 2010 already it is $20 million, just in two months time, which if you project that out would be $120 million outlays for the entire year. So off to a very brisk start as far as that is concerned.

The next slide, which is the compensation trust

fund, a favorite subject for many, it turns out that -- again, for those that may not be familiar with the addition of influenza vaccine in 2005, we brought in a vaccine that comprises at least a third of the numbers of vaccines that are given annually. So the trust fund began to increase significantly based on the revenue that was brought in by that being added to the program. Now this past year we netted, in terms of total receipts, $334 million. If you take out the outlays and compensation altogether, that came out with a net to the trust fund of $250 million, so a quarter of a billion dollars came in this past fiscal year.

MR. SCONYERS: Jeff, can I ask you to back up one slide?

DR. EVANS: Sure, going back to the awards slide?

MR. SCONYERS: The awards slide, yes. You got an amounts listed for FY 2010. I am just trying to understand what this relates to. Are the cases compensated in FY '10 equal to the ten cases determined to be compensable in FY 2010?

DR. EVANS: Yes. There was one particular case, there was a large award.

PARTICIPANT: So the cases that were determined to be compensable in FY 09 would show up in FY '09 even if the award was made in --

DR. EVANS: No, it does take time for it to show

up. There is always a disconnect in terms of the adjudication number and the final award that is made. You cannot make that correlation.

PARTICIPANT: I understand you are saying there is one particular case, but how many cases does this compensation amount represent because it was not the ten that were determined compensable.

DR. EVANS: You raise a good question. That is something that has been asked over the years. The answer is, there is always a disconnect between the adjudications and the awards. We could certainly furnish you some information, a breakdown of which of the ones in ‘09 were actually adjudicated in ’09. I assume the ones in ’10 were adjudicated in ’10.

PARTICIPANT: I understand what you are saying, but there may be individual cases that are unusual in terms of the amount of compensation being high or low. Just looking at the trends it would be useful to see over time what the trend in compensation was on average. Maybe other members don’t think that.

MS. BUCK: I think detailed information on awards would be helpful, so I support that.

I also have a question. Can you back up on what you were saying about autism cases again? It is really hard to hear you on the phone. Did you say that you see a

decrease in the filings?

DR. EVANS: Yes, Tawny. The program has received three claims for the past two months, so during this fiscal year starting October 1 there have been three claims.

Any questions for this slide?

So in terms of significant activities, there isn't much to report from the last meeting. I traveled to Philadelphia and gave an overview on the compensation programs of graduate students in the Department of Immunology at Children's Hospital in Philadelphia. Most attendees were grad students. Also there were some vaccine company representatives, too. This particular class explores a variety of scientific and public policy issues associated with vaccines.

On October 21-22, I served as an ex officio representing the compensation program at HRSA at the Advisory Committee on Immunization Practices meeting in Atlanta. In addition to giving a brief update on the ACIP, the ACIP voted, as many of you know based on the media reports that concerned the meeting, they voted to recommend routine use of the newly licensed bivalent human papillomavirus vaccine, Cervarix, in women 9 to 26 years of age, but they stopped short of recommending routine use of quadrivalent HPV in boys. However, the committee did approve coverage in the Vaccines for Children program for boys, so those 9 to 18 can

receive the vaccine who are uninsured or on Medicaid and meet other criteria.

DR. SCONYERS: Say that again, Geoff?

DR. EVANS: Although there is not a routine use recommendation for purposes of coverage, there is going to be support for funding so that boys in that age group can receive the vaccine. It is a permissive use recommendation; those that want to receive the vaccine can receive it. Not only that, those that need economic assistance in receiving it who were qualified can also receive that benefit.

DR. SCONYERS: If it is not recommended for routine use, what will that mean in terms of the compensation under the program?

DR. EVANS: It does not mean anything at all. In fact, both vaccines, the fact that the boys do not have a routine use recommendation, does not have anything to do with their eligibility for compensation. The vaccine is covered under the program. The routine use recommendation isn't necessary for the vaccine to be covered once it is on the Vaccine Injury Table. Then any cohort receiving it, whether there is a specific recommendation for that age group or whether it is a permissive use recommendation, are still eligible for coverage.

DR. SCONYERS: The boys receiving the vaccines are eligible for coverage under the program?

DR. EVANS: Correct. The Vaccines for Children Program has nothing to do with eligibility for our program. That has also been a point of confusion in the past year.

For the telephone audience, we will read out the point of contact. Those interested in getting in contact with the program should write the National Vaccine Injury Compensation Program. The address is 5600 Fishers Lane, Parklawn Building, Room 11C-26. That is in Rockville, Maryland 20857. The telephone number is toll free 1-800-338-2382, and the Internet address is www.hrsa.gov/vaccinecompensation. Those who wish to provide public comment and participate in future meetings should write Miss Andrea Herzog, in care of the same address that I just gave.

That is the end of my presentation.

MS. CASTRO-LEWIS: Thank you, Dr. Evans. Any questions or any comments from the Commissioners?

DR. FISHER: This is Meg Fisher. If you could speak a little bit louder. It is tough on the phone. Thanks.

MS. BUCK: And additionally, can you guys identify yourselves when you speak, too, please?

MS. HOIBERG: Also, you really sped through that presentation, so it was good that I had the notes and knew what you were saying. But you went so fast that it was very

hard to follow. Maybe it is just me, but I thought it was very hard to follow what you said.

MS. CASTRO-LEWIS: Okay. Thank you both. The report from the Department of Justice, Mr. Rogers, please?

Agenda Item: Report from the Department of Justice

MR. ROGERS: Good afternoon. This is Mark Rogers. Happy to be here. I'll go through my presentation.

I guess the overview would be again the qualification that we look at the same cases that HHS looks at. The timeframe is a little different. The focus here is since the last Commission meeting. My comments are based on a litigation perspective and that end of it. So with those qualifications I'll go ahead.

On the personnel, we are still in the process of hiring two attorneys. We have continued that process. We have a great field of applicants. Hopefully by the next meeting we will have at least made our selection. They will replace one attorney who left, and we have another attorney who is on an extended detail to another branch of the Department. While they are detailed we don't pay their salary from our budget. For those of you on the budget end that are concerned about such things, we are very careful about it.

On the statistics, the total petitions filed, we

have five autism. Jeff mentioned the three; that was for the fiscal year. There are five for the period since the last Commission meeting. We are both seeing the same thing, that is, projection down towards a steady state that is very low.

With the non-autism cases, we saw the same increase. We also saw that there were a substantial number of flu cases, over 50, as I recall. They were mostly adults. In looking at them very superficially, we saw that most of them came from two law firms. Without getting into their business, sometimes law firms will bunch them and file them all at once, we suppose to realize economies of scale. As they are moving through them they will file them all at once. So we are not so sure that this can be extrapolated out through the years as a harbinger of a significant increase for the rest of the year. It remains to be seen.

We also see that we are getting more adult cases than children's cases, versus 39 for children.

On the adjudication side, the point was made here that we have adjudication and then a payout. So those numbers aren't going to necessarily correspond exactly. But we had 25 cases compensated; of those none were conceded, 20 were settled, three were by decision. The decision cases would be where we disputed whether causation had been proved, and the Special Master found that causation had indeed been shown. And two proffers. What a proffer means is that the

damages were determined by both sides agreeing that the evidence showed a particular level of compensation was appropriate. That differs from a settlement, where one side feels the evidence shows one level of compensation, the other side feels it shows another level, and the parties agree to compromise.

On the non-compensable cases, there were a significant number of autism cases. I think the point was previously made that usually those are on jurisdictional grounds or procedural grounds. A procedural ground would be the petitioner withdrawing the petition. So the statute of limitations figures prominently in cases that are involuntarily dismissed. On the non-autism side we have had eight that passed through the program without compensation.

Per your request, I have the terms defined here for you to shed light on the terms I am using. If there are any questions on those, please let me know.

MS. BUCK: Mark, this is Tawny. Before you get too far in, I would just like to clarify, on your statistics chart, is that actually showing that since the last recording period HHS conceded test cases in, so anything else that has been compensated has either gone to settlement or the other avenues, is that correct?

MR. ROGERS: That's correct.

MS. BUCK: Okay, thank you.

MR. ROGERS: Yes. And even where there is a decision, we have had the three decisions, the level of compensation, the amount of compensation would have been by settlement. I don't believe we have had a single decision by a Special Master determining the level of compensation, if you understand the distinction.

MS. BUCK: Yes, I do. Thank you. That is interesting.

MR. ROGERS: This chart, what we are seeing is what we saw the last time, what we have been seeing for quite awhile. The cases generally run down the left side of this chart -- petition, HHS review, not conceded, and settled. So that is where the bulk of these cases now are getting to the finish line.

In autism cases, on theory one, the update is that two of the cases were appealed, Cedillo and Hazlehurst, and Snyder was not. So in Snyder, the case is over.

MS. HOIBERG: Was their reasoning to why they didn't appeal, or they just chose not to?

MR. ROGERS: We don't know what that reasoning is. All we see is the deadline passes for appeal without an appeal, which requires that the case go to judgment.

MS. HOIBERG: Is this the second appeal for Hazlehurst?

MR. ROGERS: This is their appeal to the Federal

Circuit, yes.

MS. HOIBERG: Okay, thank you.

MR. ROGERS: You're welcome. On theory two, the status is the same as it was at our last meeting. That is, the trial is completed, the briefing is completed, and they are awaiting decision by the Special Master.

MS. HOIBERG: Do we have any idea where the Special Masters stand on that? Because they have had it for quite awhile now.

MR. ROGERS: I heard an estimate that we should we seeing them in the first part of the year. That was awhile ago. The better answer is, I don't know.

On appeals, we have had three new appeals. We have broken them down by fees and cost, just to give you an idea of the level of litigation that we have in that area. We have also broken them down by who filed the appeal. As has been the experience of the program for some time now, virtually all appeals are filed by petitioners.

This is the second page, Court of Federal Claims. You will see on this page, about half to more than half were fees and costs decisions that are being appealed.

This will correspond -- you will see in the statistics that Jeff gave that there has been a significant increase in the payments of attorneys fees and costs. In this program the way to get to those payments is through that

same process. It is a litigated process. It is either settled or decided by the Special Master, and it is subject to appeal. So the increase in the amount of attorneys' fees that is being paid has had a corresponding increase in the amount of litigation and appeals.

We have also had the Federal Circuit decision of Avera. Avera determined that an award of interim fees and costs is available under the Act. That has created a new area of litigation, that being when those fees are appropriate and in what amounts. So that has accounted for some of the increase in litigation in that area.

We had some decisions by the Court of Federal Claims. You can see the breakdown of what happened to those decisions on appeal. Affirmed means the appellate court agreed with the Special Master. Remanded means that the Court of Federal Claims determined that additional work was required by the Special Master. I see a reverse, in part.

That concludes my comments, excepting any of your questions.

MS. BUCK: Mark, this is Tawny. I have a question on your statistic page again. Do you have any idea at all of the eight not compensated non-autism cases, what happened to them? Have they gone into civil court?

MR. ROGERS: After they leave the program, we don't follow them. We really don't have a good source of

information on that. I would have to say I don't know.

MR. SCONYERS: I am looking at your statistics and then Dr. Evans. Jeff, you had indicated two concessions in FY ‘10, but Mark’s stats were no concessions. Help us square that up.

DR. EVANS: I assume that that occurred in ‘09.

MR. ROGERS: I see what he is asking. This is since the last meeting. We have to look at what your concessions are, and we will reconcile that.

MS. CASTRO-LEWIS: Thank you. Any other questions or comments?

DR. SCONYERS: I would just like to say thank you for the summary of cases and for the statistical presentation. You have been very responsive to all our requests.

MR. ROGERS: You are very welcome.

MS. CASTRO-LEWIS: Thank you so much. We want to take advantage of Meg being on the phone, and we are a little bit ahead of schedule. I would like to move to the next item on the agenda, which is the ACCV Causation Work Group report. I am going to let Jeff lead the discussion.

Agenda Item: ACCV Causation Work Group Discussion

DR. SCONYERS: Sure. Thank you, Magda. If you will recall, and as our minutes reflect, at our last meeting I suggested that we consider making a formal recommendation

to the Secretary regarding the administration of the program with reference to the Althen and Capizzano decisions. So we constituted a work group. That work group was Tom Herr and Tammy Tempfer and me.

We took some time getting that work group scheduled. When we did get it scheduled, we had the three of us participating along with Dr. Evans and Elizabeth and Kay and Annie on the phone, Magda as well, because she is a glutton for punishment.

You all have received a memo that my legal intern prepared summarizing the decision on causation standards under Althen and Capizzano along with those two Federal Circuit decisions. We spent a long time in conversation talking about what if anything this work group wanted to recommend to the Commission in terms of advising the Secretary on the administration of the program.

The short answer to that question is we do not have a recommendation to bring forward at this time after giving a full discussion to the various considerations. Let me briefly summarize, and then I am going to ask Tom and Tammy to comment, and anyone else who wants to comment.

The argument in favor of making a recommendation, and this is really my argument, is that Althen, Capizzano and the other decisions of the Federal Circuit are in fact the law that govern the determination of petitions under the

program. It is the basis upon which the Special Masters, the Court of Federal Claims and the Federal Circuit will make their decisions.

Since that is the case, then my suggestion was that we administer the program consistent with them. Specifically on the issue of discussion versus settlement, the program concede cases that would meet the Althen and Capizzano standards.

I think the other side of the coin, if I can put it that way, is that when we look at the statistics for the program, as we just did, it is clear that a great many cases are in fact being settled. When you look at the statistics over time you can see the percentage of cases being settled is going up, the percentage of cases compensated is going up. So it is not clear that there is a need for any change to the way the program is administered for cause.

In fact, I think people who participated in the program would say those cases that would be entitled to compensation under the Althen and Capizzano standards are in fact being compensated on the basis of settlement decisions, if not on the basis of concession. So there are a few concessions and a lot of settlements, but those add up to the cases being resolved in the petitioner’s favor that would be entitled to be resolved in the petitioner’s favor under those cases.

There is a range of opinion, I know, on this Commission about how advisable the standards enunciated in Althen and Capizzano are. Some people believe that those cases go too far away from requiring the strict scientific standard of proof for entitlement compensation. Some people think they don't go far enough. They are the law. I kind of walk down the middle. That has been my point. They are the law. I believe that the program, while it is the law, it needs to be administered consistent with them. My observation simply is, that is happening. So I feel a little bit fumble-mouthed in trying to put this forward, but that is where we wound up. We are not prepared to make a recommendation one way or the other in terms of advising the Secretary.

So let me pause there and give Tom and Tammy a chance to make their comments. Then we will have whatever discussion seems appropriate.

MS. TEMPFER: As part of Jeff's second conclusion, after reading the cases and in full discussion about medical evidence it really seems pretty clear to me that the program is looking at all of those things. They are carefully reviewing medical records, but they were also looking at the letter of the law. They are trying to look at causation and temporal association. They were using those ideas when they were determining cases. I was impressed with the percentage

he has, about 84 percent, I believe.

So I think those things are definitely being looked at. At this point I don't think a letter is really necessary. I see the program and the courts working very well together.

MS. BUCK: It sounds to me, Tammy, that you had access to close to 90 percent of all the cases that are going to litigated settlement. You were making the comment that it looks like they are using all of this well and carefully. Did you guys have access to the information on all these cases that have been settled?

MS. TEMPFER: Which cases?

MS. BUCK: Ninety percent of the cases going through the program are now going to litigated settlement. So I don't understand what you are talking about when you say that.

MS. TEMPFER: Just looking at how statistically it has increased the number of cases going to settlement, is what I meant.

MS. BUCK: My comment here is that this program when it was designed was not supposed to be a secret handshake program. It was intended to be very clear at how it was being administered, how decisions were being made. What we have moved into is a program that it is deciding everything on a litigated risk basis, which is confidential

and closed. We have no idea what adverse events are being settled, what vaccines, or anything else.

So I am looking at this issue maybe differently than you guys are, but my problem is this trend we have gone to, this program is a big old secret where there is no way to know who is being compensated, what adverse events get compensated, what vaccines or anything else. So I am certainly not prepared to go on record and say they are doing a really good job in applying Althen and Capizzaon to the cases they are settling. We don't even know what process they are going through.

MS. TEMPFER: I asked that question about the individual cases. What I understood was that actually a decision is published on each case.

MS. BUCK: I clarified that with DOJ in the past, and have been told just the opposite. So somebody needs to be very clear about that, but at this point I don't think that is true. A decision maybe, or some piece of it, or maybe something is published saying that this case or these people but the specifics are not available like they would be if these cases were conceded. In the last reporting period I have just been told that Justice conceded, and that is where the information lies. And we bat around updating the table, we have IOM looking at adverse events that should be added or shouldn't be added. There is no information available for

the public to know what you are paying, what you are compensating, what adverse events, what vaccines, what amounts or anything. It is all just very craftily composed to a very secret and non-transparent program. And this is part of the problem. HHS has now conceded nothing in the last quarter, according to DOJ, according to Jeff, too. I don't even know who is correct there, either.

So for me, the problem comes down to an accountability, a transparency of this program in terms of what you are compensated for and how it is being done. I absolutely disagree with somebody telling us that that information is out there, because it is not.

DR. EVANS: This is Jeff. I've got a couple of responses, Tawny. This is something that Mark discussed at length, I believe, at the previous Commission meeting.

First of all, you're right, the decisions on settlements do not have any significant information in terms of medical issues or contributions. They are fairly brief final decisions in a particular case. So that is true.

In terms of the kinds of cases that we have, we have talked about for example influenza vaccine and the predominant category claims that we have, the kinds of cases -- transverse myelitis, Guillain-Barre syndrome, even multiple sclerosis, central nervous system diseases, ADEM -- these are things that have been compensated by the courts,

these are cases that have gone through. Also there have been decisions on hepatitis B vaccine and some of the other vaccines that are a significant percentage of the claims compensated. So many of the more prominent categories of illnesses that are a part of the program have been discussed publicly and they are there.

In terms of litigated risk settlements, as Mark Rogers very well articulated, it is a different process than going through a concession. It is a process of negotiation. It does not lend itself to visibility to a lot of light in terms of the dynamics of what goes on with decision making, because it is a process that involves negotiation and there is uncertainty and many factors involved.

That said, as was pointed out this morning, petitioners bar, practitioners who practice in front of our program have a very good idea of the kinds of cases that are litigated or settled. There should be nothing to prevent them from sharing that information among themselves and providing it to any potential claimants that seek their assistance.

MS. BUCK: Yes, but to me that is just not good enough. This has been the problem, and it continues to be a problem in the vaccination program and the federal government. That is a lack of transparency and push off on saying the information is out there and you can get it if you

want it.

I think that leads to information being distorted, information being put out there second hand or on the Internet or all these avenues that you all generally get pretty uptight about when people go to find information.

I think this program was designed for you guys to be very transparent, about types of cases that you are settling, the types of injuries you are seeing and the amount of compensation that you are providing, to build a real trust in the public to say, look, we understand that although rare, when adverse events do happen we indeed step up and take care of people. I believe you lose your basis for saying that by driving your cases through litigative risk settlement.

I understand the upside to that is that perhaps it is more streamlined and quicker. And of course the petitioners bar is going to like that because they get paid faster. But the reality is, it does not solve the problem that you have and that will continue to go on when you keep these cases closed away from the public and you use secondary sources to try to get the information out there.

So for me, this whole conversation is based on causation in fact comes to this one point. I'm just never going to go down being comfortable with the system running the way it is, because I think you are just burying way too much information and creating a lot of mistrust.

MS. HOIBERG: I agree with everything that Tawny is saying. As members of the general public, when you talk about our children in particular being vaccine injured, again it comes to the visibility of the program. It is not visible. No one knows about it. So the only time anybody is going to know anything about it is if they have the time or go on the Internet or even think about looking up vaccine injury. It is not visible.

So all of this ties into the whole outreach situation. But this program is such a secret, I feel like it is the government's dirty little secret that they don't want anybody to know about. Regardless of Banyan and all that you are doing with that, it is still going to stay the government's dirty little secret.

I don't understand the fear that you guys have about advertising the program and letting it get out there. Pharma does it all the time with their drugs. Their commercials are downright scary. So why can't you say it is rare but it happens. These are cases that have happened. But like Tawny said, your government is here to take care of you, and this is how well we have compensated people. Petitioners sign a note of privacy, you can be Jane Doe or John Doe or whatever, but you guys need to be out there going, you know what, you are going to get the flu vaccine, but look at how high the numbers have gone since you guys

have added it to the Table. It is ridiculous. Yes, it causes injuries, but we are here for you and we want you to be healthy and we want you to be safe, but if something happens and you are one of those one in a million, you are going to get compensated, you are going to get paid. But you can't say that because you drag them through the wringer to get there, even if they make it through.

MS. CASTRO-LEWIS: Thank you, Sarah. I think we have a response to the initial comments made by Jeff.

MS. GALLAGHER: May I make a few comments, please?

MS. CASTRO-LEWIS: Okay, then Tom is waiting to comment on Jeff's initial report.

MS. GALLAGHER: First of all, I want to thank the subcommittee for all their hard work on this very difficult issue. I respect the conclusion that they came to, given that I think that it is good for all the various members of the Commission to come to consensus on it, to make a recommendation to the Secretary.

I have to say that first, I think that encouraging settlements for vaccine injured children or adults is a really good thing. I applaud the program for doing that. I also recognize that some others on the committee wish that the process weren't as complicated as it is, but it is set by statute, and to a certain extent nothing can be changed in some of the technical areas, as was pointed out, without a

change of the statute.

But I wanted to say that I personally couldn't have come up with a recommendation that I would have made to the Secretary. So I respect the subcommittee that said, we thought about it very hard and long, and we can't come to a consensus on what to say. I just wanted to thank you for your efforts.

DR. HERR: This is Tom Herr. I have two comments. One of the first ones is on the idea of the causation work group. Jeff did put a lot of work into this, and I really appreciate his efforts and his leadership in that, and his understanding.

As far as the direction of the letter, I follow some of the concerns of trying to cut to the quick and say this is the way things are going, why do we waste a lot of time? I think the difficulty I have from my position on increasing and more automatic concession is the implications to the public of true causation.

What I consider true causation is scientific causation, in the sense that this vaccine caused that injury in the same manner that this virus caused that illness. In legal terms, it is not the same, but the public don't understand that. If we have more policy of concession, it gives the wrong impression. It actually deflates the public confidence in vaccines because they are being proven and

being shown to be accepted by the government and cause significant injury and often injury.

So I think that we need to continue the program as we are doing. We do need to continue through the courts, we do need to have them act as the law at this time states, and what they should follow. Now we don't know whether the law will change, whether the interpretations that come down may sometime be overturned. That is up to the future to decide. But I think we have to take as much importance as we can in scientific knowledge on the basis of some of these and many of these decisions. The Act is riddled with the term scientific causation and scientific reasoning. It wasn't put there to be ignored.

On the question of the settlements and whether there be a conspiracy to hide things, my question is, in all cases, whether it be with vaccine litigation or any kind of litigation, are settlements always public knowledge? Is it something that there are rights of privacy that we, as a part of the government, cannot put out just because we might like to, but the other parties may not be interested in having that released.

So maybe the idea of the transparency of the program – and right now I kind of hate that term -- is that while it may be an intent, there may be a lot more barriers than a contrived conspiracy.

MS. BUCK: Obviously I feel very strongly about this. I don't think this has anything to do with outreach. I absolutely agree that we need to follow the law. I think that the law is quite clear when it developed this program on how it should run. It talked about a very good mesh of science and policy. I think we should all be reminded that our job here is not to promote uptake rates of vaccine, our job here is to compensate those unfortunate people that were injured.

My problem always lies in these litigated risk settlements that have become the trend in the last few years. The program has been around for a very long time. This is new. It has not followed the heart of the statute that created the program. I think that some of the points that Tom made have some validity; I could disagree with some of the other ones.

I'm not sure I would want to come out to support any recommendations that didn't support the law. But I am seeing a trend that is very -- that is causing a lot of heartburn in the public about the secrecy with which settlements are made.

DR. EVANS: I appreciate your comments, Tawny. A couple of thoughts. In terms of something to look at, the updated list for example that the Institute of Medicine has posted as well as the previous one that Dr. Johann Liang

talked about at the previous ACCV meeting, that list represents the claims experience of the program that was put together by the medical staff. In the kinds of conditions they review and see frequently in the program, there is no quantification in terms among the various conditions that are listed there. But that is a very accurate snapshot of the kinds of injuries and conditions that are routinely filed with the program for each of the vaccines that are studies and that represents and that represents about 85 percent of the vaccine filings workload that currently exists in the program.

So that is one bit of transparency that uniquely exists because of this project and will continue to, but your comments have importance, and we will certainly think about ways that we might be able to provide some additional information on the settlements and we will discuss that with our colleagues at the Department of Justice.

MS. BUCK: That was great, Geoff, thank you.

DR. FISHER: Just to weigh in, I certainly agree with the general consensus that there is probably not a statement or a letter that we should be writing to the Commission at this point. Obviously I share lots of Tom's sentiments.

MS. CASTRO-LEWIS: Are there any other comments? Jeff do you think the group would like to continue discussing

this? Is this sufficient?

DR. SCONYERS: I don't think there is a purpose in continuing this work group on this project. Two-thirds of its members will no longer be members of the Commission by the time of the next Commission meeting in any event.

So I think we dealt with the task that we were assigned. We didn't come back with a recommendation, but it wasn't for want of trying. So I think our work is done. Whether there is an additional item for another work group to look at, I think that is something we will assess at the end of this meeting probably to see what the ongoing work is for next time.

MS. CASTRO-LEWIS: Thank you so much for this work group. It was difficult to get it done because of the scheduling but the job Jeff did in putting together all of the information that we needed for the discussion was and incredible amount of work that facilitated our understanding of these very complex issues.

So with that, thank you again to the work group. I think we are going to go to a 15-minute break. At 2:25 we will reconvene.

(Brief recess.)

Agenda Item: ACCV Petitioners Payment Work Group Report

MS. CASTRO-LEWIS: We are going to hear from

Sherry and the working group that is the ACCV Petitioners Payments. Sherry is going to report her work with Sarah and Dr. Fisher who just left the line, but Sherry is going to start with the report. Thank you so much for leading that discussion.

MS. DREW: Unlike the last work group, I think my work group started out in agreement to begin with that it would be helpful --

DR. HERR: Easy topic.

MS. DREW: That's right, it was an easy topic. It was an easy topic to agree that it would be good to have interim or prepayments made to petitioners who have financial difficulties and who could use some assistance during what can be a long process towards resolving their cases.

But after giving it a great deal of thought and reviewing the Vaccine Act, and from my own knowledge as a petitioner’s attorney, we were also in agreement that there are legal and practical hurdles to having interim payments to petitioners.

First of all, the Vaccine Act specifically says that you can't make a payment to a petitioner until the petitioner has made a timely election to accept a judgment. Obviously any prepayment would be pre-judgment. So you are starting out with the fact that you first need a change to the Act itself.

The second hurdle that I could foresee in any case involving children or incompetence would be that their funds belong to their state, not to their caretakers or their parents. You can't just take the child's pain and suffering money or future lost wages and give it to mom and dad and say, here, you can use this for the time being to pay your day-to-day living expenses and expenses of the child, because that money, once it leaves our Federal Court of Claims here, goes into the child's local county court and is under the jurisdiction of the judge there, who has the child's best interests at heart, but the child's best interests are not necessarily those of his parents.

So the judge might not let the parents take that money or touch it in any way, leaving them in the same position except that they have expended money to set up an estate before they have money that they can spend.

The only money that we could foresee not being subject to probate courts or surrogate courts would be the parents' past unreimbursed expenses. In the case of an adult, and we have just seen that many of these cases involve adults, it would be the past unreimbursed expenses of the person, the adult, and that person's past lost wages. That is something that children don't encounter. They don't lose wages because they have sustained a vaccine injury. Their parents may, but usually somebody can keep working to have

income.

So it was our suggestion that there be an amendment recommended to the Secretary, an amendment to the Act that might have to go through Congress, that in any conceded case where entitlement is conceded, and in any other case if the Secretary is feeling that it is appropriate, in those cases with the consent of the respondent, a petitioner could be permitted but not required to request an interim payment from the court. We further suggested that the interim payment would be only those amounts that the Department of Justice does not contest.

In other words, if it is clear that this person was earning $100,000 a year and has lost a year of work because of a conceded injury, that person should be able to get that money while the rest of his case is resolved. If the parents have spent X amount of money on therapy for the child and the government doesn't contest that as being a vaccine related amount, we believe that that money could be awarded as an interim payment.

The downside to petitioners is, if they are going to get this money, then they would have to make an election or opt into the program. Once they took money, they could never choose to opt out and go file a civil suit because once they have got money they have accepted money.

Tom?

DR. HERR: It has already been conceded.

MS. DREW: Even though the case is conceded --

DR. HERR: They just haven't accepted it yet, so it is not final.

MS. DREW: Theoretically such a person would have a conceded case and get money back that person thought was insufficient and still elect not to take the money.

DR. HERR: So they could get to the end and say, I don't think this is enough --

MS. DREW: I am going to file a civil case.

DR. HERR: -- forget it, let's go on.

MS. DREW: Right, that is theoretically possible. I don't know that it has ever happened, but it is theoretically possible.

So that would be the downside to the petitioner. I have typed up my suggestions and they are in your blue books. I think at this point what my committee wanted to do was bring this to you folks, let you think about it. If you have any suggestions you should make them to Megan and Sherry to discuss it at great length and maybe bring it up next time, if this is something we might want to recommend.

MS. CASTRO-LEWIS: Thank you, Sherry.

DR. HERR: Somebody said tell me a good reason why we shouldn’t do this.

MS. HOIBERG: This was kind of my baby that I came

up with with Meg and Sherry. We were so excited about it, because we thought, hey, it is a slam dunk. It could be an amount of money that no one would contest, a set amount.

As I was riding to the airport, I realized, because Sherry and I discussed this at length, that because it is in the hands of the judge once money is handed to the parents, it really doesn't work. But the reason that somebody would not do this, Tom, is because of what Sherry said. They give you the money, and then you are in. You can't get out. We feel as petitioners that we possible could, excuse the term, but low ball then after, because they have given us money, we already have it, and we can't go anywhere else. So we see it as almost a Catch-22, in that yes, the money would be great for us to be able to use to pay my child's expenses or pay off our debt, but it is not going to possibly help in the end; it could actually hinder.

DR. SCONYERS: I just have a question, Sherry. In your one page summary here, you have a couple of bullets or numbered paragraphs. Then there is a paragraph that starts, petitioner would retain the right to revisit.

I just don't understand what that says. Petitioner by accepting the uncontested amounts would be precluded from electing to reject the ultimate final judgment. I just don’t get it.

MS. DREW: That is what I just told Tom. That is

what Tom and I were just talking about. If the petitioner takes money, I see no way that that doesn't mean that he has opted into the program. Petitioners can at the end of the case elect to accept or reject a judgment whether it is for or against him. If he has already accepted money, I think he would have to be required to accept the final judgment, whatever it might be, which is a downside to a petitioner doing this, which is why we are making it optional.

MS. HOIBERG: That is why we are bringing it to you guys, so that we can have more mind melding and thinking about a better idea, or if we can add on to it. In the end we are here to help the petitioner and get them compensated for their injury or the injury to their child. So we want to make this as painless as possible, but because the program takes so long in many cases you may have had a case that was conceded, but you sit there and you can fight for years on damages. So that is why we were trying to figure out if we could give them something to start out with.

It sounds so good and then it is like, wait a minute, no. We were given the option to receive the past medical expenses to be reimbursed for the money that we had paid out, and we were advised against that. So I think that it is an option, depending on your attorney who you have.

Like I said, it sounded really good at the beginning, but then on the ride home I was like, no way, it

is not going to work. So I don't know.

MS. BUCK: I think my biggest concern would be that families that are dealing with sick injured kids are going to be -- this is going to be some sort of a desire to be able to get the funding and some money, and it is going to be very difficult to make an objective decision about that and how it can play out for you in terms of a final decision on your settlement.

MS. HOIBERG: Exactly.

MS. BUCK: So I'm not very comfortable with this idea. For me, I think I would still try to tackle the issues of -- I hate to be a broken record, but if there was more clarification as to what is being compensated, what injuries and all of this stuff, perhaps you could expedite the entire process without having to put something in here for the family. It is all about getting the process quicker.

MS. HOIBERG: Exactly. But Tawny and I have talked about this, and I don't know if you have thought about it, but if there was a way to say DTAP injury with side effects, like in your daughter's case, X amount would be the jumping off point. In Kate’s case the jumping off point would be here, and then if you had an adult then the jumping off case would be here.

But there is no minimum and there is no maximum. So I think there needs to at least be a minimum requirement

for the life expectancy of a child with a brain injury, what is their care going to entail? Honestly, I think that somebody could take from all of the cases that have been and look at all the settlements and come to a happy medium. Does that even make any sense?

MS. BUCK: I don't know if you are asking me directly. The piece makes me very uncomfortable, about trying to -- I know the intent is good here, but I think trying to lock people in – I just think these cases are far to individual and complex. For me it gets more down to expediting the process, getting families in and out quicker. I think that the DOJ has done that with interim payments of attorneys fee, I think I think has been helpful.

I totally get it. Families need to get in and out of the program as quickly as possible. They don't need to have something halfway through that may or may fit their bottom line at the end.

MS. HOIBERG: Right, and that is why we have in a way X'd it. But Sherry has put together a quite an interesting document, in that it gives the option of payment or not.

But I totally agree with you, that there will be some people that are not going to see the end. They are just going to see it as like waving the banana in front of the monkey or whatever. It is kind of like an incentive, and

they are not going to see the final picture.

But I absolutely agree with you, Tawny. That is why we have been hesitant with this, and that is why we have opened it to the floor, to get more information from everybody.

DR. HERR: I think from the discussion and from the beginning and your explanations, this is an effort which -- we thank you for your interest and your activity, but I think it is something we should reject.

MS. DREW: I don't really have an opinion. I think it would be nice. I think that people who have attorneys would probably reject these offers. But I also have cases that I know you occasionally have to delay for years because the child is too young to do a life care plan when you don't know what the child's injuries are going to be.

In some cases, I could see where it would be a benefit, but I don't know if it is a big enough one to go through the effort of trying to pursue a change in the Act.

MS. CASTRO-LEWIS: The only way to do this would be through Congress?

MS. DREW: I think so.

MS. HOIBERG: Let's just go back to then improving the program and getting it to move faster. I know that that all depends on petitioners' attorneys and how fast they get

DOJ the information and how fast DOJ can then process it. But if we could make this a more expedited process, this would not even be an issue.

Again, it goes back to why this program was created. It was supposed to be a fast and generous, less adversarial way to do things, and it is none of those things. So let's go back to the basics and fix what is broken. Thank you.

MS. CASTRO-LEWIS: Thank you. So I think this is going to be work group number two, with a similar results from the group number one, that we don't have really anything solid yet. I will ask you the same question that I asked David. Do you think, is it worth it to follow up a little further with this and explore other idea? Or this is the end of that?

MS. DREW: I don't really think so. I think that the interested representatives here think that it is not workable.

MS. CASTRO-LEWIS: Okay. Well, thank you, Sherry, for the work that you did on the work group. If there are no other questions or comments regarding Sherry's presentation or discussions, then we are going to move to the update from the National Vaccine Program Office, Dr. Salmon.

Agenda Item: Update from the National Vaccine Program Office

DR. SALMON: Thank you. There are a few activities I want to update the Commission on, two of which are related to our NVAC and an additional brief update on the National Vaccine Plan that I know you have heard before.

Let me start with the NVAC Safety Working Group. This is the working group that has been around for a couple of years now. The Commission's Tawny Buck is the co-chair of the working group. They had two tasks. The first was to review CDC's Immunization Safety Office research agenda. They issued a report on that about six months ago.

The second task which they are now working on quite actively is to review the vaccine safety system more broadly, and to write a white paper on what the optimal safety system would look like in order to prevent adverse events, to characterize them in a timely manner when they do exist and maintain and improve public confidence in vaccines.

The group has been working on this since early summer. In June they held a two-day meeting where they heard from a broad range of experts and stakeholders on these topics. They have divided it into five subgroups. Three of these subgroups are content-based and two are process-based; I want to go through them briefly.

The first subgroup is focused on structure and governance. The second is focused on epidemiological methods in surveillance, and the third content focused subgroup is on

biological mechanisms of adverse events. There has been some thinking and discussion about whether these would result in separate reports or one complete report. I think it is still up for discussion. The feeling is that it depends on the timing. It would be great to package this all together, but certain portions are ready sooner, and that is great.

There are two additional subgroups that are process-focused. One is on stakeholder engagement. As we use the Keystone Center in our first task, the Keystone Center is then engaged on this one, and is considering different approaches to involving a broad range of stakeholders in the work of the working group.

In particular it seems like structure and governance is really the area where we have sensed the most interest by stakeholders. So there is being a lot of consideration to how a broad range of stakeholders could be engaged and contribute to these deliberations on the optimal structure and governance for vaccine safety.

The last group, which again is process focused, is on implementation. The thinking here is that at the end of the day, while the charge is to write a white paper, the NVAC is really interested in the results of these efforts being more than just a stack of white papers, but actually having change and improvements to our safety system. So by considering issues of implementation early on, that may and

hopefully will enhance the likelihood that the final product of the working group will be something that affects policy in a positive way.

So that is where they are right now. The hope is that within the next year, I think September 2010 is the target date they are shooting for for these activities to be completed.

Would you like me to stop there and take any questions or move on to the rest of my update?

MS. CASTRO-LEWIS: I think you can continue and then at the end we can take questions.

DR. SALMON: Okay. The NVAC has formed a second working group focused on vaccine safety. It is an H1N1 vaccine safety risk assessment working group.

This group is charged with looking at all of the H1N1 vaccine safety data as it accumulates over time, and providing reports to the Department on what the safety profile of the vaccine is. That is what it is. What it is not doing is, it is not looking at disease epidemiology or vaccine benefits. It is not making recommendations for vaccine usage. It is looking entirely at the safety profile of the vaccine.

The working group consists of members from the five federal FACA committees that have vaccine activities in this regard, VRBPAC, ACIP, NVAC, the NVSB and the Department

of Defense's Defense Health Board, as well as several other members added for expertise that were either former Vaccine Advisory Committee members or prior IOM members, just to round off the expertise.

They had an in-person meeting. They are meeting every two weeks by phone. Then once a month the NVAC is meeting to discuss and deliberate upon those reports. December 16 is the next NVAC meeting.

What they are basically doing is providing rapid ongoing advice to us on what the safety of the vaccine looks like. This stems from an earlier NVAC recommendation.

The last area I mention to you is the National Vaccine Plan. I know Dr. Strakis from our office has given you updates on this plan more than once. We are anticipating an IOM report to be probably available in the very near future. The request to the IOM in this regard was to look at the first draft of the report that was publicly available and provide feedback to the Department on priority items. So we anticipate that that report is going to be coming out very shortly.

This is a midpoint of the development of the plan. There is still going to be further iterations and additional engagement of stakeholders and the public before any sort of plan will be finalized.

So that is it for my update. I'm happy to answer

any questions you all have.

MS. CASTRO-LEWIS: Thank you. Does anybody have any questions? Does anybody on the phone have any questions or comments for Dr. Salmon?

MS. HOIBERG: No. Thank you very much, Dr. Salmon.

MS. TEMPFER: I just have a question about the H1N1 safety surveys.

DR. SALMON: What they are doing is, they are reviewing all the data. So their job is to look at the safety data as it accumulates.

Before H1N1 we had a fairly complex vaccine safety system, and for H1N1 there have been lots of tweaks and enhancements, and some systems that are entirely new, typically for H1N1. They are run by DoD, by VA, and then different agencies within HHS, primarily FDA and CDC, but CMS has a data set, the Indian Health Service has a data set. So each of these acronyms represent groups that work very hard to provide safety data. Each of them will bring these data to the NVAC group.

So the NVAC vaccine safety risk assessment working group isn't going to be doing the analysis themselves. That is an impossible task for an advisory group to do. It is up to the agencies or the departments that run the programs to bring those data to the working group for their review.

So at this point they have reviewed some VAERS data, which is most of what we have. Then we have a bunch of active surveillance systems that are just starting to get enough people vaccinated to have data to look at, and they are starting to look at those data.

I should have mentioned, there is a report that we posted a few weeks ago on flu.gov. That describes the H1N1 vaccine safety monitoring system. I mentioned a bunch of groups that have programs and activities for monitoring the safety of these vaccines. That document describes fairly comprehensively what these programs look like.

DR. HERR: Not necessarily in your group, but do you know when is the decision made on next year's seasonal flu vaccine? When is that being made?

DR. SALMON: Is Marion on the line? Maybe she is not. It is typically in February, at the February meeting.

DR. EVANS: What has commonly happened is that VRBPAC has met in either January or February where they have considered worldwide data and have made recommendations in terms of which viruses should be in the vaccine. That is what has happened commonly in the past. There are delays here and there, but that is generally the time frame.

DR. HERR: The thought is it sure sounds like they were going to include this in next year’s seasonal vaccine. So part of your surveillance is going to also blend into next

year as well, because it is going to be in that group.

DR. EVANS: One of the challenges potentially in that sort of surveillance is to distinguish between seasonal flu versus H1N1 vaccination. That is somewhat less of an issue than it might have been, because the vaccine availability was not at the same time.

The overlap provides the opportunity for someone to receive both vaccines in a very short amount of time, which provides some challenges for safety monitoring as potentially for compensation, because one needs to figure out which vaccine is the suspect and culprit.

MS. CASTRO-LEWIS: Have there been any reports specifically for H1N1?

DR. EVANS: The first source of data we have is VAERS, the Vaccine Adverse Event Reporting System. It is a passive reporting system. So this is useful for detecting signals. Pretty much anybody can make a report of anything to VAERS, and there is no requirement that it be documented, how it is diagnosed or what the criteria are for diagnoses. And of course we have received as many VAERS reports for H1N1 as we have for seasonal flu. The patterns for H1N1 look very similar to what they would look like for seasonal flu. These data are available online to anyone. They are updated weekly on CDC's website, as well as some interpretation of the data.

I just emphasize that interpretation part, because

it can be very difficult to interpret VAERS data. It is intended to receive everything, and as a result, everything possible. It is very hard to know what in fact is caused by the vaccine versus what is just a background rate of disease.

MS. CASTRO-LEWIS: Thank you so much. Any further questions, comments? Thank you so much for the report. I think Dr. Gidudu is on the phone, so we will move to the update of the Immunization Safety Office from the Centers for Disease Control.

OPERATOR: I do not see the participant on the line right now, ma'am.

MS. CASTRO-LEWIS: Would you please let us know when she is on the line?

OPERATOR: Certainly.

MS. CASTRO-LEWIS: Meanwhile, we are going to move on to the next item on the agenda, because we are a little early, so that is why she is not available yet.

Dr. Mulach, would you please give us the report that you have?

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

DR. MULACH: Sure. This probably would make a little bit more sense after the CDC presentation, but it is fine. We can connect with CDC afterwards.

Just to let you guys know that we are continuing our studies of the H1N1 vaccine in different populations. This probably made more sense in September when we were very early on in the vaccination process, but the idea was early on to help inform our public health decision making about how much of the vaccine we would need, what kind of immunogenicity you would get from it, and what the safety profile was in the initial participants. So we were doing some of the trials and the vaccine manufacturers were doing some of the trials. Many of our trials have completed the vaccination component and now we are in the safety follow-up.

We do still have several trials still ongoing. We are looking at several special populations, including HIV positive population, pregnant women, asthmatics. So a lot of that information that we are following will help to inform us about what dosing is the best and what the safety profile is for those vaccines in those populations.

We do have a safety monitoring committee that meets and that oversees all the trials, and that monitors any adverse events that we see, and looks at the data and makes a recommendation if everything is okay on the trials.

Again, as you will hear from CDC, we have a lot more experience in giving the vaccine out to the general public now as well, and a lot of that is being captured through VAERS and other adverse event reporting mechanisms.

I think this has been a really good experience for us, to help us to understand better how developing a new vaccine would work in the population. One of the other questions we were answering was whether you can get the seasonal flu vaccine and the H1N1 vaccine at the same time, if there would be interference or any additional adverse events. So far what we are seeing is that you can receive the vaccine at the same time. It doesn't appear to cause problems in terms of immunogenicity or safety. But again that is early data; we are expecting more data on that to come in about the next three to four weeks.

A lot of our information is posted on our website and details of clinical trials are on clinicaltrials.gov. So if anyone is interested in knowing more about the individual studies, I would be happy to send you guys information about where to receive that information. Then our bulletin is about the data as it becomes available.

MS. HOIBERG: My question is regarding the flu vaccine. I find it alarming, but maybe for the amount of flu vaccines that are given, maybe the numbers aren't that alarming. But there seem to be an awful lot of injuries being reported here just in the beginning of the fiscal year. Many of them are to adults.

Are there any precautions that maybe adults could take when thinking about receiving the flu vaccines? Maybe

it is not a good idea to get both of them at the same time. Maybe those are the injuries that are coming in.

DR. MULACH: I'm not aware of any specific issues with the simultaneous administration. Again, that is why we are conducting the study, but so far we haven't seen any real signals that would indicate that receiving the seasonal and the H1N1 at the same time would be a problem.

I think as with any person in the public, a lot of people have various health conditions, and it is very important to stay connected with your doctor and make sure you are well when you are taking the vaccine and follow the CDC guidance.

MS. HOIBERG: Unfortunately the flu vaccine is being given out in Walgreen's, so there is no medical history taken or anything. It is just, here you go, here is your shot, good for you. It is being given out in airports. That concerns me. I feel like this is fast immunization with no follow-up.

But also, my concern is that there was information coming out saying that H1N1 cancels out the seasonal flu or vice versa. Have you guys looked into that as well?

DR. MULACH: One of our studies is looking at that. If you get either the seasonal flu vaccine first and then the H1N1 vaccine, or if you get them on the same day, is that going to cause any kind of problem, special problems.

So far the indication is that there are no differences in receiving the vaccines --

DR. HERR: Excuse me, which kind of vaccine? Are you talking FluMist?

DR. MULACH: We are talking inactivated vaccine. We have not been doing the studies with the live attenuated vaccines.

MS. HOIBERG: Is there a reason why you wouldn't be doing it with both? Don't you think it would be safe to do with both?

DR. MULACH: To be quite honest, when we were developing these studies, we were doing a series of trials to try to get some basic information about what we could be getting. We couldn't possibly do every iteration. It had to do with vaccine availability and our trial sites. It wasn't meant to be all inclusive of all different iterations.

But you raise a good point. I think it is important when you are getting any vaccine that you read carefully what the recommendations are for that vaccine. The live attenuated vaccine, of course you would want to follow any recommendations with that in particular.

MS. HOIBERG: Could I make a suggestion, that the live one be tested? I am quite disconcerted. That makes me doubt the vaccine even more, if you guys don't test each type. I'm not saying go through and test every single vial,

but you need to at least test each product that is going out there, each brand. I don't like to hear that at all, that the FDA or the CDC approves things that aren't completely tested then.

DR. MULACH: To clarify, it is not that each vaccine is not being tested. It is that combinations of different vaccines aren't all tested. So every single one of the H1N1 vaccines that is out in the public had to go through the FDA process and provide data before those vaccines could be licensed.

So it would be much better if someone from the FDA could comment on that. Maybe when Marion comes, we could bring that back to her.

I appreciate your comment. For our particular studies I don't have any information on the live attenuated vaccine.

DR. SCONYERS: This is an unusual situation where we are administering two flu vaccines essentially simultaneously. So it is great that you are doing the studies to try to see whether there is interference, because there is a lot of speculation about it.

DR. HERR: We do three flu vaccines every year.

DR. SCONYERS: No, we do one trivalent vaccine. What we are doing that is different this year is that we are administering two different vaccines. I think it is

appropriate to try to understand whether there is any interaction between them.

MS. HOIBERG: That is why I am saying, maybe you could test the live one as well, because that also is being given in conjunction with the -- do you understand what I am saying? I honestly think that -- yes, that is great that they tested the one, but they didn't test the others, so they have no data. So what if that one is interacting or is making the other one not any good?

DR. MULACH: I understand your point. Maybe MedImmune has done some of those studies. I'm not aware of them. But I will see if I can find out if there have been additional studies with the live attenuated, and I'll share any information I find with the committee.

MS. HOIBERG: Thank you very much.

DR. SCONYERS: I know that the recommendation by the administration of the live attenuated are to separate those doses in times so that they won't interfere with each other, on the theory that it has been pretty well demonstrated that they would if administered simultaneously.

DR. SALMON: Let’s hold on for a second. I think there is a really important point that needs to be here, which is that H1N1 vaccine is a strain change and every year it is a strain change, so these are vaccines that are made the same way by the same companies, using the same process

and the same ingredients that every year flu vaccine is made. So it is not a quote new vaccine, it is not a novel vaccine.

It is a very important point, because the clinical trials that Barbara is describing -- and Barbara, feel free to jump in here at any point -- are not trials that are required for licensure, because this is a strain change, it is not a new vaccine.

So it is wonderful that these trials are being done, and certainly there are other trials that one might consider to be valuable. I just think it is important for everyone to realize when you are talking about this, it is not a new vaccine. It is a different strain. It is a strain change. That is the way the FDA has considered it.

MS. BUCK: Certainly I have heard that many times, and I appreciate the comment. I think the concern obviously comes from the number of doses, particularly in children, that are required for this year, with an active virus already circulating, and looking at that in terms of adding that to their regular vaccine schedule.

I think that is obviously where a lot of the concern and a lot of the questions lie. Looking at the NIH clinical trials and certainly appreciating the work that they are doing to look at this, there is still a lot of subpopulations that aren't being looked at. I hope that as trials go along, we will see a little bit more information.

I have mentioned this in NVAC meetings before, I certainly think that there is a need to do a clinical trial on neurodevelopmental people, especially children who have neurodevelopmental delays and injury. They seem to be the most susceptible to complications with H1N1, and knowing and understanding how they react to the vaccine is something that I really wish would be looked at.

So just my comments on this issue.

DR. SALMON: Thank you for your comments. My point wasn't to suggest that we wouldn't benefit from more study and more science, particularly in subpopulations. I just wanted to clarify the use of the word new vaccines being used.

MS. BUCK: And I appreciate that. I just think it is important to make that distinction.

MS. CASTRO-LEWIS: Are the clinical trials for H1N1 already concluded, and are the results available to the public? Where can we get more information about the different populations, pregnant women and children.

DR. MULACH: Whenever NIH conducts a clinical trial, we put information about what is entailed in that trial in clinicaltrials.gov. So that is a really good place if you want a description of what the trial is, whether or not the trial is recruiting or closed for recruitment. There is a nice summary. For each trial we have a summary document

with clinicaltrials.gov and on the NIAID website, and I would be glad to share those links with you.

Many of our trials, the trials in healthy adults, healthy elderly, healthy children, those trials, they have all gotten their vaccine and now we do at least a six-month safety follow-up, as we do with many of our clinical trials.

So while the trial is not completely over and tied in a bow and wrapped up, we have preliminary data that we have on our website in the form of press releases and bulletins. I can send you some of those links, as much as you are interested in. There are a lot of pages a lot of Q&A documents.

MS. CASTRO-LEWIS: A little summary?

DR. MULACH: I can get you a little summary, too, yes.

MS. CASTRO-LEWIS: That would be good. Thank you so much, Dr. Mulach. Any other questions or comments for her?

DR. HERR: One of the points that I was thinking about as Tawny was talking. I think the thing we need to be concerned with, the neurologically handicapped children and other subpopulations with the H1N1, there clear data that shows they have more trouble with the disease. I'm not sure there is any data that shows they have trouble with vaccine.

MS. HOIBERG: You are injecting the live virus, so

why wouldn't they have a problem? The whole thing with the pertussis antigen in the vaccines is that they were finding in studies that a lot of children that would have contracted the pertussis disease and whatnot would have died from the actual pertussis, and that is why they reacted so strongly to the pertussis antigens.

DR. HERR: There are all sorts of better scientists than me that could explain that to you.

MS. BUCK: My point, Tom, was that I think we need to do some trial studies to make sure that the vaccine is indeed safe for these kids. As far as I understand, those trials haven't been done, and there is no plan to do them. So maybe I'm like you, I am just not willing to take that leap until I see some data there that says that if they are susceptible to the illness itself or to the virus itself, we need to make sure that there isn't something in this vaccine that could cause a problem.

DR. HERR: My point is that there is clear data that disease is a lot more serious to these kids than the vaccine.

MS. BUCK: I disagree, and I haven't seen that data, so I'm not going to go there with you. I know that there is data that shows that the virus itself is harming the kids, but show me the trial data and the test data that shows -- that has been done on the subpopulation of those children

that shows that there is not a problem there. I haven't seen that on the vaccines.

MS. HOIBERG: And believe me, Tawny and I both through our conversations, you better believe that we would do anything in our power to protect our babies, especially Caitlin and Quentin, from getting that terrible virus, if we knew for a fact that if we gave it to them that they would not suffer even greater loss than they already have.

So as far as being coined as anti-vaccine, I wish I could give my daughters the flu vaccine, because I really don't want them to get it. But I can't after what has happened. It is gun-shy, it is like being gun shy.

DR. EVANS: The only thing I want to add is that unfortunately we don't have Meg Fisher on the line right now. Meg, being a member of the Red Book Committee in the Academy of Pediatrics, is very well versed on the H1N1 and influenza vaccine and the benefits and safety profiles of what is being done in the various age groups. So perhaps we might be able to benefit from some of her knowledge tomorrow morning when she rejoins the call, if she is able to.

This is one of the reasons why we try to have someone on the Commission at any particular time who can answer these kinds of issues when they come up. I know they are concerning to us. Unfortunately Meg was just not able to be on the phone call past a certain time this afternoon.

MS. CASTRO-LEWIS: So we will make a point tomorrow morning to get back to this issue. I don't know if you mentioned it or not, but have there been trials for these populations that Tawny and Sarah are talking about, special children, with the regular seasonal flu vaccine?

DR. MULACH: Not that I am aware of. I think it is a good point they are making, that it is important to understand vaccines in a lot of different populations.

Some of the things that you have to consider are, it is not necessarily simple to identify those populations. When you say people that have neurodevelopmental issues, if you talk to the autism community there is a whole spectrum of disorders, so how broadly or narrowly do you define the window. What group of people would you consider representative of a larger group of children with autism spectrum disorder?

So I think your comments are very good, and it would be nice to have that information. But part of the issue lies in defining the right population so when you get that information, you know what you can say about that population. If you just were to take people with neurodevelopmental issues and they had very different neurodevelopmental issues, you might be comparing apples and oranges.

So I do think they are making a good point. I just

think in order for any kind of study like that to be good and strong and for us to be able to interpret the data, we have to have the right expertise to be able to understand how to do that trial in the right way.

DR. SALMON: There is another point to consider too, which is that many of these things are studied once the vaccine is licensed and used. For example, the CISA network has an observational study that is being done in children that have metabolic disorders.

So if you are talking about a population that is at increased risk of morbidity and mortality from the disease, it would be very difficult to do a randomized control trial where you said by chance alone you are not going to get the vaccine, because if it is a population that is at increased risk of disease, I think that could be very problematic. However, that is the sort of population that can be studied through observational studies to determine if there are issues of safety among that group, and I provided one example of where such studies were being done.

MS. TEMPFER: I wonder too how to recruit for that kind of study. I think that would be a very difficult population to recruit from.

MS. BUCK: This is just always going to be an age-old problem then. Running clinical trials on healthy children and then extrapolating that out to say that these

vaccines are safe for all kids and all children, is not going to fly. You are getting a lot of pushback on H1N1. Your exemptor rates are going up, and people are saying, look, you can do better and you need to do better to identify kids and any subpopulation of people that may indeed have a susceptibility to an adverse event on this vaccine.

I know we struggled with this a huge amount on the Vaccine Safety Working Group, but this too is an appropriate forum to bring that topic to light. I think H1N1 puts this conversation into every single family in the nation. We are seeing the response back that they need to do better to answer these questions. It is not enough to look at say 600 healthy children and run a clinical trial there and say that is enough to tell everybody that this is going to work well in all their kids.

MS. HOIBERG: What Tammy just asked is, how would you recruit people to allow their children with neurological issues or whatnot to be tested. Good luck with that, because there is no way anyone is injecting anything into my kid, because I am not going to lose her more than I have already lost.

So I don't know how you are going to be able to do it. Can you get a rat to test it on or a monkey like you do everything else? I don't know.

MS. CASTRO-LEWIS: Are we done with questions and

comments? Thank you, Barbara. I believe we have Dr. Gidudu on the line, so if you could please provide us with the update.

Agenda Item: Update on the Immunization Safety Office, Centers for Disease Control and Prevention Vaccine Activities

DR. GIDUDU: May I have the first slide, please? I can't hear you so well. Anyhow, I will be presenting the Immunization Safety update for our office at CDC.

I will highlight three main activities from our office, monitoring the safety of influenza H1N1 monovalent vaccines. The next one is postmarketing surveillance for the bivalent human papillomavirus vaccine, which is Cervarix, which is a new vaccine. The last update will be about continued surveillance of the pentavalent rotavirus vaccine, which is RotaTeq in the Vaccine Safety Datalink.

I will now begin with monitoring the safety of the influenza vaccine. Again, the objective for monitoring the safety are to identify clinically significant adverse events following the receipt of the vaccines in a timely manner, to rapidly evaluate serious adverse events following the receipt of this vaccine, and determine the public health importance, to evaluate is there a risk of GBS and other specific outcomes following this vaccine, and lastly to communicate vaccine safety information in a clear and transparent manner

to health care providers and public health officials and the public.

We are using an established routine surveillance system I mentioned earlier, which I outlined here on the left, the Vaccine Adverse Event Reporting System for rapid signal detection of any potential adverse event of concern, the Vaccine Safety Datalink or VSD and the Clinical Immunization Safety Assessment or CISA for signal verification. On the right are the systems that are enhanced for monitoring safety of the 2009 H1N1 vaccine that I outlined in the last meeting.

The next slide is on VAERS. Again, VAERS is an early warning signal on vaccine safety surveillance. Please note that the website has been updated. Instead of the old pink, it is now blue. As you all know, it is a national passive surveillance system jointly operated by CDC and FDA, and it was established in 1990. It receives over 20,000 reports per year. It accepts reports from physicians, other health care providers, vaccine manufacturers and the public. It is likely for hypothesis generating, seeking signals of potential concern regarding especially rare adverse events that are not detected in pre-licensure studies.

The next slide is again on VAERS. VAERS has several advantages which include being national in scope, covering diverse populations. We are able to detect rare

adverse events in a cost effective manner. Using various methods VAERS can rapidly detect possible signals for further testing and other systems, like VSD. We can assess lot-specific vaccine safety issues.

The limitations are known, which are mainly reporting biases. We have under reporting and over reporting like now with H1N1, which is good. We do not provide information on number of persons vaccinated, and background incidence of conditions in the general population is not well defined.

By November 30, a total of 67 million doses were allocated, and about 60 million doses were ordered, and about 57 million doses were shipped. So these numbers have changed. As of today we have over 70 million doses allocated. Of course, this number is being revised daily. So I have already got a daily update today so we can give you a rough idea of where we were at the end of November.

On the next slide I will now share some VAERS data with you. This slides compares data on seasonal vaccine, which is the live attenuated influenza vaccine and TIV, which is a trivalent inactivated vaccine, comparing it to the H1N1 vaccine, which I am going to be referring to as MIV, which is an LMV for the live attenuated vaccine, by severity and GBS reporting.

The data here is based on reports entered December

1 at 3:30 p.m. We run this data daily. We want to emphasize the vaccine itself as it was projected.

Going through the numbers for seasonal, which is the first vaccine, and then the next column is all reports, and we have fatal, non-fatal serious and non-serious cases, and then the last column on the far right is for the GBS.

For the seasonal live attenuated vaccine, we have so far by that date which is two days ago, we had 506 reports. There were no fatal cases and 38 were non-fatal serious, and the non-serious cases were 468 with five cases of GBS.

On the seasonal TIV we had 4,259 reports; 16 of them were fatal and 241 reports for non-fatal serious cases, and the majority, which is 4,002, 94 percent, were the non-serious cases, and 50 cases so far of GBS. These are all cumulative numbers.

Then we have seasonal unknown, which means that we could not determine which type of vaccines. These were 201 reports. Three of them were fatal, 24 of them were non-fatal serious and 174 were non-serious and three of those were GBS.

So in a grand total we have 4,966 reports in total, a total of 19 fatal reports and the non-fatal reports is 303 and the non-serious is the majority, which is 4,644, with a total of 58 GBS reports.

Coming down to the H1N1 vaccine, the live

attenuated vaccine, we have a total as of December 1 of 1,271 reports. Three of them have been fatal, 55 cases have been non-fatal serious, and a majority or over 1,000 cases were non-serious cases with one case of GBS reported so far.

The next vaccine which is a monovalent IV, MIV vaccine, we have 3,029 reports as of December 1. Fifteen cases have been fatal, there were 159 non-fatal serious cases, and the large majority of 94 percent have been non-serious cases as expected, eight cases of GBS. For the unknown category where we could not determine either of the vaccines of the vaccine, we have 305 reports, one of which was a fatal case and 23 reports were non-fatal serious and a majority of them that were non-serious and two cases of GBS.

So we have up to date a total of 4,605 reports for the H1N1 reports which is close to the seasonal numbers that I just mentioned before, 19 fatal cases, 237 fatal serious and the majority are non-serious reports.

I will move on to the next slide.

MS. HOIBERG: I have a question. When did you start receiving the reports? I understand that it goes to December 1, but when was this begun?

DR. GIDUDU: This is all cumulative since the vaccine was licensed in September 15th. Does that answer your question?

MS. HOIBERG: Yes, it does. Thank you so much, I

appreciate it. So we had 19 deaths from H1N1.

DR. GIDUDU: Yes. I can give you a rough idea of what this number is reported daily. Like, for December 2 we had a total of 139 reports in one single day.

MS. HOIBERG: Thank you. That is incredibly informative, and I really appreciate it.

DR. GIDUDU: Moving on to the next slide, I didn't highlight other systems, but I will mention VSD, and other surveillance system.

VSD is able to monitor vaccine safety on a weekly basis using the rapid cycle analysis, using the appropriate comparison groups. As of November 21 we have 438,000 doses of H1N1 vaccines and we have that break down with 323,000 for MIV and slightly over 100,000 for the live attenuated vaccines that have been administered to their managed care organizations in the VSD. Between October 1 and November 20, up to now, there have been no cases of GBS in the VSD, and one case of anaphylaxis that we have been seen in the persons that have been vaccinated in VSD, which did not defer as compared to the number of events found among historical controls.

VSD is also monitoring other diseases, other demyelinating diseases, peripheral nervous system diseases, encephalomyelitis, Bell’s palsy and other cranial nerve disorders, ataxia and other allergic reactions. VSD will

continue H1N1 vaccine safety monitoring throughout the vaccine season. All the other systems that I mentioned earlier show no safety concerns with the H1N1 vaccine, and I won't go into those details.

The next slide --

DR. SCONYERS: Before you go on to your next slide, I just wanted to ask a question. You had your table with the total reports in VAERS. I understand that there is no denominator there, you don't have any idea, but you don't have a source of total administrations of either seasonal or H1N1 vaccine. But do you have any sort of estimate about the total number of vaccines that have been administered, so what the VAERS cohort represents?

DR. GIDUDU: We are working with another group activity that is coverage the data. We are able to extrapolate some of these rates using the coverage data. I don't have it with me, but we do have data that we are able to extrapolate. But I am presenting absolute numbers.

DR. SALMON: Jeff, I can answer your question in a few different ways. There are a few different sources of data. There are doses distributed and that is how many basically left the warehouse. That is clearly an overestimate of what actually gets administered for multiple reasons. One is it gets time to leave the warehouse and get into somebody's arm.

So early in the program, a lot of what is distributed isn't yet administered. As the program goes on, the percentage overall gets smaller because the time window is a smaller proportion of the overall amount of time. But there are other reasons why distributed doses may not get administered. They could get lost, they could not be stored properly, whatever the case might be.

There is also -- until recently CDC was receiving from states estimates of doses administered. They stopped requesting this because it was too labor intensive, and it is also an underestimate of what in fact is being given because they are not capturing every dose that was administered. So probably the truth lies somewhere between administered and distributed.

The third approach to get at this is to do surveys of vaccine coverage, which CDC is doing through the National Immunization Survey as well as other means. But that also takes time before enough people are vaccinated to pick it up in that sort of surveillance, as well as for the studies that are being conducted.

So there are three answers to your question, all of which are imperfect.

DR. GIDUDU: Thank you. The BFRS data, which is surveillance data and what we are trying to use as proxy. That is the base data we are able to get. Thank you so much.

DR. EVANS: One more thing. Going back to the table, the comment was made that there were 19 deaths caused by H1N1 vaccines. I know that on slide six, on the advantages and limitations, the caveats, one of the caveats that is often seen on the slide is that VAERS is a signal generator, and it is not to be interpreted as proving or showing causation, and that simply because something is reported after a vaccine doesn't mean it was caused by the vaccine.

DR. GIDUDU: That is correct.

DR. SCONYERS: I appreciate your comment. On slide seven of Dr. Gidudu's presentation, she is showing that approximately 57 million doses had been shipped as of the end of November. You are suggesting that the total number administered of course is less than that. Is it half of it? I am just trying to --

DR. SALMON: There are probably people at CDC or perhaps in the states that could give you a better estimate.

DR. SCONYERS: I am looking for an order of magnitude relationship between the reports to VAERS and the number of doses administered. I'm not looking for anything more precise than rough order of magnitude.

DR. GIDUDU: Because of the high demand, I think for the H1N1 it is higher than the previous. It should be somewhere closer to what has been distributed because the

demand is still very high.

DR. HERR: My question would be shipped to who? Are they shipped to the states for the states to distribute, or are they shipped to the individual practitioners or health departments or hospitals to distribute? Because if there are a number of middlemen in the way, that ship number is going to be a lot different.

DR. GIDUDU: It is shipped to the states. The numbers we have are to the states.

DR. HERR: So the number getting out to the public is a lot different.

DR. SALMON: If I could make one other comment, just to exemplify the point that Dr. Evans made about reports to VAERS and how one wouldn't want to interpret them as causality.

For example, one of those 19 fatalities was actually a car accident. So anything can be reported to VAERS. The details aren't in the public use data set. It is possible for example somebody fainted and they got into a car accident. I just use this as an example.

The real point I am making is that this is a system where anyone can report anything. Serious reports such as deaths are investigated thoroughly by both FDA and CDC as well as the state health departments. It is just important that people don't misunderstand these data to think

that they mean that it was caused by the vaccine.

MS. HOIBERG: I realize that, Dr. Salmon. I realize that. You don't have to explain that for my benefit. I know you are doing it for the general public, but I understand that.

DR. GIDUDU: Most of the patients -- it takes awhile to get all of this back. Most of these patients had a lot of comorbidity. There are very ill people and some of them had accidents, and most of them had explainable causes of death.

DR. SCONYERS: Let me take a different tack. Can I request that as a follow-up to this presentation we get somebody's best estimate from CDC about the total number of doses administered as of the date on which this table was prepared, so as of December 1, just an estimate?

DR. GIDUDU: I can try to get you that, sure.

DR. EVANS: What they will give you from CDC, they will give you estimated doses distributed. That is something CDC does track, but they cannot make any reasonable estimate. Maybe H1N1 will be an exception to the rule, but they really don't make those kinds of estimates. AT least they have not in the past.

DR. GIDUDU: It is very difficult to get the actual estimate for doses administered. We are able to give you the doses distributed.

DR. SCONYERS: Raw numbers without rates are just meaningless.

DR. EVANS: It is a very reasonable question, Jeff. The problem is to answer the question is very hard to do.

DR. GIDUDU: Shall I go to my next slide, please? Let's go to slide number ten, which is the post-marketing safety surveillance for the Cervarix vaccine.

Cervarix as many of you know is manufactured by GSK, and it is approved for use in females 10 years to 25 years of age. The next slide shows the general template for monitoring safety of new vaccines. To begin with a summary of pre-licensure safety data that are largely identified from Phase III clinical trials. Then a review of any of the available post-marketing data. We have a VAERS monitoring plan and a VSD plan, using key outcomes for VSD using their rapid cycle analysis or any other planned studies. Identification of key case definitions is usually done, and identification of candidate CISA protocols for special studies as needed.

On the next slide, again for VAERS, we have aggregate summaries for VAERS reports that will be evaluated for reporting patterns and potential signal identification, reports of serious adverse events including deaths and other medically important conditions will be reviewed in detail.

For VSD, which is a collaboration between CDC and managed care organizations in the U.S., have an annual population of over 9 million with an annual birth cohort of over 90,000. The main advantages of having a well defined population, which is computerized and linkable to administrative data files, which is a powerful tool for controlled population-based studies.

The next slide, rapid cycle analysis is an alternative to the traditional post-licensure vaccine safety study methods, which generally take years to complete. An analysis of pregnancy outcomes after vaccination will be done.

The next slide, we will evaluate the other pre-specified conditions and associations identified from Phase III and Phase IV studies and also a review of literature as well as VAERS. Final outcomes are under consideration but will include GBS, VTE and stroke as well as syncope.

The next slide, I will now turn to continued surveillance of the RotaTeq vaccine safety on the Vaccine Safety Datalink population. This map shows you the VSD sites across the country, as well as a collaboration between CDC and eight managed care organizations shown here.

For the next slide is on the study objectives for the VSD study, which were to monitor for increased risk of intussusception during a 30 day window after receiving the

RotaTeq vaccine, and to monitor for increased risk of other pre-specified adverse events following receipt of the vaccine.

The major findings include five cases of intussusception within 30 days of the RotaTeq in the computerized data. This did not exceed the expected number of cases, and there were no cases seen with seven days of vaccination after over 200,000 doses of vaccine administered.

Only two cases were validated after medical review of records. Neither case occurred following dose one and the results provide no evidence that RotaTeq vaccine is associated with an increased risk of intussusception or other pre-specified adverse events.

Next slide. Using the maximized sequential probability ratio test, which is one of the statistical methods done in VSD, there is no signal that was detected in VSD.

Next slide. There has been continued surveillance for intussusception occurring in one to 30 days and one to seven days risk windows after RotaTeq vaccination, including all the eight VSD sites. The exposed population were in children who received any dose of RotaTeq with or without other vaccines from age 4 through 34 weeks.

The concurrent comparison group was children who received any immunization in the same age range, and the

study period was from May 2006 through October 2009.

Next slide. So in summary, the results provide no evidence that RotaTeq vaccine is associated with an increased risk of intussusception in 1 to 30 days or 1 to 7 days following vaccination.

The next slide is some of the resources you could use. I would like to thank my colleagues listed here. Thanks for listening to me. I am sorry I wasn't able to come.

MS. CASTRO-LEWIS: Thank you so much, Dr. Gidudu. Are there more questions?

DR. SCONYERS: In your presentation on the RotaTeq intussusception analysis you have a table, the Poisson SPRT results. There is a column in there that is captioned RR. What is RR?

DR. GIDUDU: That is relative risk.

MS. CASTRO-LEWIS: Thank you so much. If there are no other questions, I am going to request for Dr. Gruber to come to the table.

Okay, so is somebody there for Dr. Gruber to do her presentation from the FDA? We have Theresa Finn in place of Dr. Gruber to do the report from the FDA.

(Pause to arrange presentation.)

MS. CASTRO-LEWIS: We have Theresa Finn in place of Dr. Gruber to do the report from FDA.

Agenda Item: Update on the Center for Biologics Evaluation and Research, Food and Drug Administration, Vaccine Activities

DR. FINN: Thank you. I am standing in today for Marion Gruber. I am in the Office of Vaccines and Special Biologics at FDA. Marion asked me to give you an update on FDA's vaccine activities.

I think at the last meeting in September, Marion gave you an update and noted that we had approved four vaccines to protect against pandemic H1N1 disease. The manufacturers of the vaccine were CSL Limited, MedImmune, which is the live in intranasal vaccine, the Novartis vaccine and the vaccine manufactured by Sanofi-Pasteur.

On November 10 of this year, FDA approved an additional vaccine to protect against the pandemic H1N1. This is the vaccine that is manufactured by ID Biomedical and distributed by GlaxoSmithKline. It is based on the Flulaval manufacturing processes. This vaccine is approved for the use in persons 18 years of age and older.

Moving on a little bit to seasonal influenza vaccines, on November 10 also, FDA approved Afluria. This is an inactivated bivalent vaccine manufactured by CSL. The approval was for use of this vaccine in children 6 months through 17 years of age. It had previously been approved for use in adults 18 years of age and older. It is available in

single dose preservative-free prefilled syringes and in multi-dose vials that contain thimerosal as a preservative. The approval of this also expands the use of the H1N1 vaccine manufactured by CSL for us in children six months of age and older.

On November 27, FDA approved Agraflu. This is an inactivated seasonal influenza vaccine made by Novartis for use in adults 18 years of age and older. Since it is seasonal it is to protect against influenza types A and B. Agraflu is not obviously intended to protect the H1N1 influenza virus.

With this approval, the influenza vaccine capacity for the U.S. both for the seasonal vaccines as well as vaccines for flu pandemics has been increased. I should mention that Novartis manufactures another US-licensed seasonal influenza vaccine called Fluvirin.

On October 19, FDA approved a supplement for the use of Fluarix, which is the inactivated seasonal vaccine manufactured by GSK for use in children three years of age and older. Previously Fluarix was approved for use in adults 18 years of age and older. So it has been a busy time.

Moving on now to HPV vaccines, the human papillomavirus vaccines. On October 16, FDA approved Cervarix. This is a bivalent HPV vaccine manufactured by GSK. It contains type 16 and 18 HPV. It is indicated for the

prevention of cervical cancer, cervical intraepithelial neoplasia, CIN grades two or worse, and adenocarcinoma in situ, as well as CIN grade one caused by HPV 16 and 18 in females 10 hrough 25 years of age.

On October 16, the same day, FDA approved the use of Gardasil for use in boys and men 9 through 26 years of age to prevent genital warts caused by HPV 6 and 11. You probably know that Gardasil was initially approved back in 2006 for use in females 9 through 26 for prevention of cervical cancer and precancerous genital lesions caused by 6, 11, 16 and 18.

We currently have a number of products under review. These include a vaccine for a meningococcal conjugate vaccine for prevention of disease caused by *Neisseria meningitides*, as well as a pneumococcal conjugate vaccine and a seasonal influenza vaccine.

The latter two, the pneumococcal conjugates and the seasonal influenza, were presented at the most recent advisory committee meeting on November 18 and 19.

Prevnar 13 is a pneumococcal conjugate vaccine. This is manufactured by Wyeth, which was recently acquired by Pfizer. Wyeth already manufactures Prevnar, which is a 7-valent product. So the committee discussed and made recommendations on the safety and the effectiveness of the 13-valent pneumococcal vaccine.

The intended use for this is to use in infants and toddlers as a four dose series given at two, four, six and 15 months of age.

DR. HERR: Is this to replace the Prevnar 7?

DR. FINN: That would be the ultimate aim, yes. Also on November 19 the committee discussed and made recommendations on the safety and effectiveness of FluBlok. This is a recombinant seasonal influenza vaccine. It is made in insect cells and manufactured by Protein Sciences. The manufacturer had requested use of this product in persons 18 years of age and older.

That was all I had for an update.

DR. SCONYERS: So did you say that the cell-based vaccine was approved?

DR. FINN: No, I said it was presented and discussed at the Advisory Committee meeting. No decision has been made on approval at this point in time.

DR. HERR: Doctor, can I ask you a question? Going back to the H1N1 vaccine, what vaccine is specifically made besides FluMist and one of the newer ones you talked about for children age three?

DR. FINN: For three and up we have --

DR. HERR: Because Novartis is four and up and Sanofi is 6 to 35 months.

DR. FINN: Sanofi is six months and up.

DR. HERR: It is 35.

DR. FINN: Well, 2.25 mL dose is for the 6 months through 35 months, and then the 0.5 mL dose is for 36 months and up.

DR. HERR: Because what is being distributed is the 6 months to 35 months and the 4 and over.

DR. FINN: No, the Sanofi product, the .5 mL dose of the Sanofi product can be used in children three years and older.

DR. HERR: In unit doses?

DR. FINN: They are available in -- the .5 mL dose is available in the prefilled syringe with a pink plunger and the .5 mL dose is available in a prefilled syringe or in mono-dose vials.

DR. HERR: We are not getting anything to cover that three-year-old.

DR. FINN: It is supposed to be available. The other one which is approved for three and up is the last one I talked about, which was the CSL product, which is their H1N1 vaccine. And just recently we approved the supplement for use of that product in children 6 months of age and up.

DR. SCONYERS: Earlier before you were here we had a question about the decision about strains for next year's seasonal influenza flu vaccines. When will that decision be made? What will happen, do you suppose, with the H1N1

circulating strains.

DR. FINN: In September of this year WHO already made the decision for the Southern Hemisphere that the pandemic H1N1 would be included as one of the strains of the seasonal. The decision for the Northern Hemisphere hasn't been made yet. The recommendations for the Northern Hemisphere haven't been made by WHO. Those recommendations will be taken into account when FDA meets. We have our Advisory Committee meeting, which occurs in February next year, and that is where the formal decision for what goes into the vaccine will be made. But that is of course done in consultation with CDC; we are doing ongoing surveillance.

But that is not to say that -- this is an ongoing process that occurs every year, and manufacturers are always working on this, and can usually anticipate what will be distributed.

MS. HOIBERG: So they are going to fully investigate whether or not the H1N1 cancels out the seasonal influenza or vice versa? There has been a lot of controversy about that.

DR. FINN: I'm not quite sure I understand the question, but I am going to answer what I think might be the question, which is whether it would be – well, actually, I'm not sure I can answer the question.

MS. HOIBERG: I heard that when you give the two

shots -- and I can't remember clearly whether it was the H1N1 in conjunction with the normal seasonal influenza flu, that they cancel each other out, they don't work well together. So you are not really vaccinating against anything.

DR. FINN: You are talking about vaccine interference.

MS. HOIBERG: Yes.

DR. FINN: Yes. NIH is doing studies to look at that. I have not seen the data, but I have heard that -- maybe somebody else can speak to this.

DR. SCONYERS: She said her presentation would make more sense coming after yours. 11:12

DR. MULACH: I think the issue is we talked about the interference issue with the inactivated vaccines, and then the question came up about the live attenuated vaccine and whether or not you could take the live attenuated vaccine simultaneously or live attenuated with inactivated. As far as I know NIH was not doing studies with the live attenuated vaccine. So the question is, how do we know whether or not you can get the live attenuated vaccine with other vaccines at the same time?

DR. FINN: Right, and I am not aware of data that addresses that specific question, but I do know that NIH is doing studies to look at the inactivated, administered together or separate, to see whether there is a difference.

MS. HOIBERG: Why isn't the live one being tested? I guess that is what my question is. That one doesn't seem to be being tested along with given in conjunction with other vaccines. I don't understand why that is not being looked at.

DR. FINN: I don't know why it is not being looked at.

MS. HOIBERG: Is there some way that we could find that out and you could suggest it? Don't you think it is important?

DR. FINN: Yes, it is an important question. We will speak with NIH to see if they can do that.

MS. HOIBERG: Thank you.

MS. CASTRO-LEWIS: Any other questions for Dr. Finn? Thank you so much. We kind of rushed you in, but thank you so much.

I have a couple of issues. We have finished with the main part of the agenda, and we are a little bit ahead of time, so there are some other items that I think we need to take care of.

One, I would like to ask Jeff and Sherry to prepare a summary of what happened with their working group, what was discussed -- this is just for the record -- what was the discussed, what conclusions you came up with and why the recommendations. Something very little just for the record,

is that okay?

DR. SCONYERS: Sure.

MS. CASTRO-LEWIS: The other issue that we need to discuss is the election of the new chair of the ACCV. It is that time again. Not today, but what we think we could do is create a nomination committee after this meeting and have the election conducted in the March meeting.

MS. HOIBERG: Are we going to have the new members in place by the March meeting?

DR. EVANS: I don't know for sure, so I think we have to operate on the assumption that they will not be there for the March meeting at this point.

MS. HOIBERG: It would be awfully unfair to ask the brand new members to vote for someone they have never seen in their life.

DR. SCONYERS: That is true. What has happened over the course of many years is that the election has been in December of new officers, and new members have come in in March. But the cycle has been off now for the past couple of years, so we have to proceed not knowing whether there will be new members or not.

MS. CASTRO-LEWIS: With that I think we can proceed. I do have a suggestion, but you can comment on it and see if you agree with it or not. I would like to suggest to have the members of the Commission that are soon leaving,

which are Jeff, Tammy and Tawny, to be the nomination committee. I will leave to you how you would like to proceed and to provide us with some kind of a nomination at the next meeting, and then we will have our election. Does that sound like a plan?

MS. TEMPFER: I can do it.

MS. CASTRO-LEWIS: What about you, Tawny?

MS. BUCK: Sure.

MS. CASTRO-LEWIS: Jeff?

DR. SCONYERS: You bet.

MS. CASTRO-LEWIS: So we have the committee ready. Any other questions; any other comments? Anything in relation to today that any of the Commission members would like to do?

Now it is time for our public comment, which is included on the agenda in order to provide feedback to the program and to the ACCV. We are opening the floor to the comments at this time. So operator, if you have anybody that would like to do comments, could you please connect us with them?

Agenda Item: Public Comment

MS. WRANGHAM: Theresa Wrangham. I am with Safe Minds. I want to thank the committee today for the opportunity to comment. I also would like to acknowledge the work of the NVAC on task one and reviewing the CDC's ISO

agenda and you work on task two.

I agree with Dr. Salmon that that work should not gather dust on the shelf, but be used to increase vaccine safety, and more specifically to encourage understanding of biological mechanisms of injury and gathering basic safety data that is not encompassed in the CDC's ISO agenda, particularly as it pertains to medically susceptible populations.

Additionally, I would like to say that vaccines benefit the cost as well as the range of adverse events. It is widely acknowledged that adverse events are rare, as well as the impossibility of a perfectly safe vaccine. However, the magnitude of the benefit to society attributed to vaccines is often dwarfed by the recognized adverse events.

We believe that the 1986 mandate for safer childhood vaccines very clearly provides that adverse reaction reporting be made public. The recent public engagement on the CDC ISO in H1N1 has made it very clear that the public continues to have safety concerns. Many of them are legitimately based in the NVAC review of the ISO agenda. There is a continued rise in exemptions due to these concerns, so statements are being made suggesting that non-disclosure of a word, which vaccines have caused injury and what type of injury coming through the Vaccine Injury Compensation Program, that they shouldn't be made public,

which seems to be illogical to us. We believe it is part of informed consent, that the public should know this as well as being aligned with the 1986 mandate. Certainly trust is earned and you cannot earn trust without that type of transparency.

Additionally, if I heard the information correctly today, I believe it was stated that 90 percent of cases are litigated for settlement. I believe that these type of cases have no information available to the public in terms of which vaccines cause injury, the nature of the injury, or the amount compensated. I think the public has a right to this information and again it goes to transparency that has already been raised by this panel. We would like to see that corrected.

In closing, I would say the information that was offered today on H1N1 VAERS reporting, that is a basic database. I am wondering why there wasn't a report given with the same cutoff date of November 21 matched to the administration data of the vaccines to give us more meaningful information on rates of possible injury, death and so on.

So again, I would like to thank the committee for the opportunity to comment, and would certainly advocate for a higher level of transparency when it comes to injury and treating injury as seriously as we treat public health with

regards to the vaccination program.

MS. CASTRO-LEWIS: Thank you so much for your comment. Operator, are there any other comments?

OPERATOR: Once again, if you would like to make a comment, please press star one.

There are no further comments at this time.

MS. CASTRO-LEWIS: Thank you so much. With that, it is 4:20.

MS. BUCK: Magda, can I say something before you adjourn?

MS. CASTRO-LEWIS: Yes.

MS. BUCK: If the meeting is adjourning early, and as people are following our agenda and planning to do public comment at five, and they log on to find out that we have adjourned and they can't, can I suggest, is it possible for us to call for public comment at the start of our meeting tomorrow to pick up anybody who may have wanted and missed the opportunity tonight?

MS. CASTRO-LEWIS: I don't see a problem with that. We will reconvene tomorrow at nine o'clock, so if there are people that come later on and ask for that, it will be okay.

MS. BUCK: Okay, thank you.

MS. CASTRO-LEWIS: Thank you so much. With that, the meeting is adjourned until tomorrow at nine o'clock.

(Whereupon, the meeting was recessed until Friday, December 4, 2009 at 9:00 a.m.)