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HRSA

Health Resources and Services Administration

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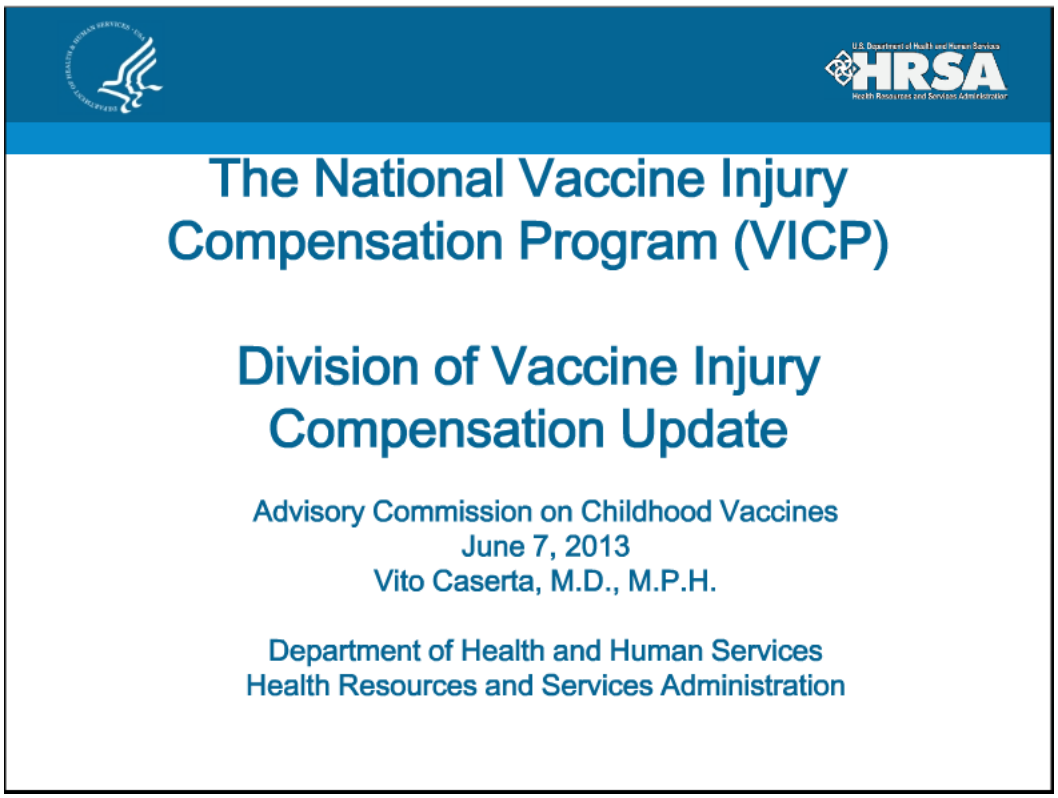
Health Resources and Services Administration

Advisory Commission on Childhood Vaccines

Friday, June 07, 2013

Andrea Herzog

Submitted by: ***Jon Salaveria, Adobe Connect Team***



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Date: Friday, June 07, 2013

Event Coordinator: Andrea Herzog

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Title:	Advisory Commission on Childhood Vaccines - June 7, 2013
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Attendees

1. A Robertson
2. ACCV
3. Allison Durham
4. Andrea Herzog
5. Andrea Jolley
6. Andrew Robertson
7. Ann Pron
8. Caption Colorado
9. Captioner
10. Carole Marks
11. Catharine Reeves
12. Charlene Douglas
13. Claire Schuster
14. Closed Captioner
15. Dave King
16. Ed Kraus
17. Erica DeWald
18. Jason Smith
19. Jocelyn McIntosh
20. Jonathan Salaveria
21. karen williams
22. Kelly Cappio, BIO
23. Kristen Feemster
24. Luis Flores
25. Luisita dela Rosa
26. Marco Melo
27. Mark Ditmar
28. Mary Rubin
29. michelle williams
30. Pat Johnson
31. Phyllis Arthur
32. Stacy Stryer
33. Stephen Marmaras
34. Steve Bende
35. Sylvia Villarreal, MD
36. Tara Kilfoyle

37. Theresa Wrangham
38. Tom Ryan
39. Tom Shimabukuro
40. val
41. ward sorensen

Chat History

N/A

Polls

N/A

Q&A

N/A

Transcript

Please stand by for real time captions. >> Welcome to the 88th quarterly meeting. This meeting is being recorded. I will turn the meeting over into the ACCV care -- chair David King.

Welcome we know it was announced that the ACCV meeting, before we begin I want to do a round the room for the attendees. So everybody can identify who they are, Commissioner or a different role for the commission.

I am David King.

Michelle Williams.

Ed Krouse.

Ann Kron.

Jason Smith.

[Indiscernible]. >> Do we have everybody?

[Silence].

Vito Caserta .

Tom with the CVC.

Vince Matanoski . Department of Justice.

Steve Bend.

[Indiscernible].

Anybody else?

Kristin -- heavenward from Kristin?

-- Have we heard from Kristin?

They are logged in. They are logged into the Adobe Connect.

This is Kristin, can you hear me?

I gave my name and during the roll call. Did you not hear me?

We can hear you now.

Maybe my speaker is not working.

We see death -- Lucita?

We are not showing them on the call.

Well -- when they join we will ask that they be announced and we will -- remark them in assets.

I would say with the number of people including myself, 12345 -- 9 commissioners will qualify as a quorum.

I had to also call and, maybe they will have to figure that out.

Right. Can use and agency let them know that they need to dial in, please?

Thank you.

I will get started then. So a couple of things, we are having a virtual meeting. Be advised as the chair, in the building that I in him, power has gone out twice this morning. Briefly for only about a minute and eight it has come back on. It is currently operating, with a little luck it will stay as such. If that occurs, Michelle I asked that you take over as I dialback and -- dialback in.

Okay.

Lucita, Good morning.

Good morning Dave. I am doing the oh Dolby Acrobat. -- Adobe acrobat.

You will give us a dissertation during the report? Is that correct?

I may refer to Ann , I am not a expert. We will see, we will get the information that we need to get to you.

Right. We are in a virtual meeting and we use a slightly different technology that we have yet Ashe that in the past, so that we can be a little bit -- that in the past, so we can be more collaborative, as we move forward in the environment, we will learn to crawl, walk and then run . We will get better at this as we move forward, we asked for all parties involved, forgive if we stumble slightly. We are in the midst of trying to do something a little bit never

Dave? This is Charlene I use the blackboard cow elaborate for my course, I thought I can speak into the microphone and you would hear me. When Ann talked about calling in, I saw I have to dial in in addition -- dial in, in addition to the utility. I have been here, not able to talk. Thank you.

Wonderful. We are to lightly -- delighted that you are here. So speaking along those lines, since we are virtual, a couple of basic things that we ask you to do. One if you're going to speak, identify yourself so that we know who is speaking when somebody is speaking. Edition only when the presentations are being done, it would be helpful even though many of us can follow online, we do not know everybody is able to do that who is listening in. I would ask that people identify the page number on these slides, those who are listening in, if they have copies of what we are doing, which are available from the website, they are able to know which page we are on. From so I would like us to be able to do that.

Is there anything else? Let me continue with the chairman reports. Request have come in that we are no longer doing fulltext goods of the meetings -- will we provide the audio of the meetings? Under this format

we are capturing a audio of the meetings, they are being recorded and we'll make his meetings available for listening -- is Ann in the room? Streaming or capturing and download talks what type of format Ashe what type -- what type of formats?

They can listen as AMD three player -- MP3 player or something along those lines.

So that will be available for people. Another component is public comments. We have two public comment sense that sections on the agenda, -- sections on the agenda, solely on today's agenda, when people address them that they identify specifically what agenda item they are just -- are dressing. And identify end who they are and affiliation with a organization. At the we have a public comment, that is more wide open and does not have to a dress anything specific on the agenda.

Additional components, sometimes people are unable to be available for the public comment components, the commission will receive public comment in writing. We will not actually read them, they will be in a booklet -- we will not read them aloud. [Laughter]. I would expect every Commissioner to read any public comment that are filed in the folders which they receive in preparation for the meeting. We anticipate if anyone wants to speak to that, any Commissioner, they would be allowed to bring that up and speak to a specific public comments. We will not read every single comment into the record that comes in, one that could open up -- it could take a day depending upon the comments that we get. Be advised we will accept public comments in writing.

Having said that, the other component to discuss is the fact that in the last meeting that we had in the month of March, one of the workgroups that had been asked to be created had to deal with data and understanding the statistics of the data. To be able to analyze this and find out how it could be useful in terms of gathering some information. There was some interest from some of the commissioners, there was no Commissioner that was willing to share that work group. So -- I do not know we can actually have the workgroup if we do not have someone willing to chair. I bring that out to all of the commissioners in case anyone is willing to share a workgroup such as that. If so, let us know. Otherwise I would say, we do not have enough interest from the commissioners and maybe we have the interest but lacking the time, to be able to pursue additional work group as it relates to that area at this time.

Having said that, I would say that -- the chair report is essentially done. I think that anything that I did not cover or alluded to, Vito Caserta you may cover?

Yes.

The chair report is complete. We move on to the agenda item is the public comments, they again are specifically related to any agenda item is on today's agenda. So what asked when we open the line for that, the individual who will be speaking identify who they are, what specific item they are commenting on, then they can make their comments.

We are prepared to do that now. I forget the name of the individual -- Sheila? If you can kindly arrange the public section please.

These press star and one on your phone. If you need to withdraw the comments, press two.

We will take a few moments for the comments to come through. We stand by.

-- Please stand by. >> We are showing no comments at this time.

The public session is closed as it relates to the agenda item and approval to to the March to the March 2013 minutes. Does anybody have any questions, issues, comments as it relates to the minutes that you had the opportunity to review for the March meeting?

[Silence]. >> If there are no comments from anyone as a relates to the minutes, we will it entertain -- we will entertain a motion to approve the minutes.

I move that we will approve the meetings.

I second.

Very good. We will take this to a vote. Does anyone object to the approval of the minutes?

We will assume that everybody is in agreement from the minutes from the March 2013 meeting and they are now part of the record. Thank you.

The next item of the agenda is the report of the The National Vaccine Injury Compensation Program. Vito Caserta will make the presentation.

I will handed over to you.

The morning. We will go ahead and get started with the presentation. White 2 -- why don't we go to slide . We will here from our friends of the justice, Vince Matanoski will do the update Google we will be viewed the statement from the CDC on the DTAP. They have been visibly working to equip the recommendations together and you will see the hard work later today. The update from the members from the FDIC.

Slide 3. A update for the number of petitions filed as a couple of weeks ago. So we are this year -- you know this -- projected we are in a similar range were we have been the last year of approximately 400 petitions for the year. 4 So slide. Is the number of adjudications. Ed -- it is broken down into this missed and total. I will talk on the issue as how we to -- how we break this down later in the presentation. Big Ken -- again the trends is consistent this year with the previous years.

It demonstrates the interest -- the workload that the program -- the Department of Justice and the courts and the HHS has worked with. 5 Okay we will go to slide . This breaks out the compensable cases in two cases that were conceded by HHS and DOJ. Cases that went to the courts and there was a court decision and supplements. As we can see, the elephant in the room in terms of what has been happening in the last few years, most cases get resolved through settlement. I will give everybody a minute to look at the numbers. It is quite far the greatest way of resolving cases. There are many reasons to settle, cases get resolved more quickly, it is a way for the department of justice to deal with increased workload. Everyone walks away from the table somewhat content. So it is a good mechanism that is used to resolve these cases.

It makes sense. Ultimately the purpose of the program is to compensate individuals who may have been injured I a vaccine, -- by a vaccine and to keep the cases out of the civil torts system, so the administrators can do their work and not feel prohibited by the TRP. The program has been successful in achieving the goal. Last few years as far as we know there has not been too many cases -- against many fractures on to civil court. -- Against manufacturers going to civil court. The next slide, amounts paid, the trend is going up, reflects the increased number of cases that are filed 2013 again projected at the end of the year total to be about one of the largest payout years -- more than 2011 amounts.

We are running into the $200 million range the last two years. Slide 7. Looking at the trust funds, the balance currently is $3.4 billion. The revenues from October 1. The revenues from October 1, 2012 through March 31 through March 31, 2013 are $56 million in the excise tax revenue, $30 million in investment on interest for a total of $86 million. Multiplied by 2 that works out to about $174 million which is comparable to what we are paying out --'s -- maybe slightly less over the last few years. There is no concern about the trust fund at this point. Significant activities up 8 on slide. There was our article that came out that was done by judicial watch after sending a request to the department. In essence the article he quitted the number of concessions in the program for HPV vaccine and the amount that was paid out -- indicative of the vaccine is not safe. That created a a lot of international interest, the Canadian immunization committee the counterpart to our advisory to the TDC received a letter in Montréal, there was a -- they read the article and asked, how can Canada continue to give the vaccine? The Canadian immunization committee asked to speak with me, I will speak with them next week. The GAVI alliance, it is the global vaccine initiative that is funded by multiple sources. By the United Nations, Gates foundation, funded by UNICEF, and many other groups. The goal is to get immunizations into Third World countries to spend the type of credible diseases there . They are concerned about this article and I spoke with them. In essence what I explained, to GAVI and they Canadian in this nation committee, -- immunization committee, the share of the cases that the HPV article made reference to is supplements. And supplements we do not concede causation, the court does not attribute causation. It is simply a way of facilitating the claim and disposing of the claim as we said everyone walks away from the table contents.

-- content. It has no correlation to the safety of the vaccine. Again every look back on -- if we look back on --

It appears that you have dropped out.

If I am dropping out more than this, I was silent for a second looking for these slide. If we look at slide 5 again. We can see -- for all vaccines, how the lions share of the cases are settlement and very few of them are concessions on the part of the department. So -- again that is the focus of my answer to those groups. They do not understand the program. And how it works and what it means? So -- the other thing that we are going to propose and ask for the commission's advice, the website currently lists a table. The table only speaks -- it has multiple columns, it tells the number of vaccines, that were filed for injury or death, and the numbers that were compensated and dismissed. The table does not really explain what compensated means. Settlements are included and -- included in the compensation category. What we propose to do, we need to do -- get agency query, -- agency clearance. We will create a new table to add to the website, where we break out the vaccines under the compensable listing, we will break it out into the number of concessions, court decisions and supplements. Similar to slide 5, percentages will have the actual numbers. The total and the number dismissed and the grand total. We will have a column for the number of doses of vaccines attributed to give a perspective as to -- if we received 100 claims how many vaccinations have gone into the arms that have generated the claims. That would add clarity to our website, it will alleviate the problem of a journalist misunderstanding what we mean by compensable. Is easily to see how it can be misunderstood, we do not explain this will. This is a attempt to do this.

I want to alert the commission that we will be doing that. I invite comments or suggestions. There is a shelf I would like to show you. Can we bring this up --

I do not have the updated ones?

With the numbers?

I will keep on going well she does this. Sperm this is -- this is Dave came, when there is no correlation between the supplements and whether or not there has been a injury, I guess -- we do not know that I would think? Even though it has not been conceded, it has been settled. It was not determined by a court case, we do not know the reasons behind the settlement. Do we?

Both sides present their case. Each side has strengths and weaknesses. Whether the court would decide one way or the other is unclear. Both sides believe it is in the best interest to settle. There has been no determination of causation and that is the point.

We cannot say there is no correlation, we simply do not know.

You cannot describe the correlation.

I agree. Rather than saying no correlation, you cannot describe the correlation.

Good point. Thank you.

We will go and get the -- I will continue. Going to slide 9 . Notice of proposed rulemaking for rotavirus, we asked OMD for a exception for it going through OMD. If it is not a major rule under their definitions, it does not have to go through. We are waiting on their decision on this. If they decide it is not have to go through OMD, that would expedite the clearance of the rotavirus rulemaking that is where that currently is. The notice of proposed rulemaking for changes, that is the big table based on the IOM report for 2012. It is most of the vaccines. That is still currently with HSB within HRSA. The priority is to get that moving, hopefully I can be more chill for -- cheerful and talkative of this in the next meeting. -- Talking about this in the next meeting . The process, -- the process for developing and approving notice of proposed rulemaking, and Dave thought I would be good to go over this. After we consulted with ACCV and it preliminary research, the steps that have to be done in order for a rule to go through, the lifecycle -- is -- we need to send the rule through her stuff -- HRSA and get it approved through the agencies. For exam for the countermeasures they want to comment on what the division of vaccine is doing and that sort of thing. Once HRSA clears this, it goes through the department executive secretary that will send it through the department. At that point, IDH and CDC and CMS and all of the sister agencies within HHS have a opportunity to comment on any aspect of the table that they see a need to comment on.

They provide that to us. We then will revise the document based on the comments received. We need to addressed -- address each comments. Then we send it back to HHS, and seek approval from each of the department agencies to make sure we address the comments appropriately. Ensuring that the comments have not generated any new comments. It will go to the office of management and budget, essentially the White House. They request comments from the rest of the department. If the veterans affairs or defense or any other department that provides healthcare, has a interest, they can comment at that time. When we receive those comments, we will vies -- will revise based on the comments and it will get published in the federal register. The public will have 180 guys -- days to comment on any aspect on the proposed rule.

The comments -- we review and in consultation we decide which comments to accept or reject. We will explain why in a federal register notice why we will accept or reject a comment. The final rule is developed, it is sense through the executive HHS, OMB will approve and the final rule is put into the federal register and is effective .

I think that Anne is ready.

Can you put this up on the screen?

Well she is for bring this out, does anybody have any questions?

-- While she is for green this out, does anybody have any questions?

How long can it stay at OMB?

90 days to get it back to us. Sometimes they can do this hooker, but usually they take the full 90 days. Wrote this is Dave -- this is Dave King. 9 If we had on slide on the first one the update of the notice. Is there a timeline in terms of what we can expect in the response on the rotavirus?

We can skip the 90 day steps, deal with comments from other departments. We can skip all of that and just go to the step where we can print it in the federal register as a final rule.

The maximum from OMD is 90 this -- is 90 days?

The could be longer depending on the comments. A -- it could be longer depending on the comments.

So we know that we have this 180 days which is about six months. The 90 days is about three months at a minimum, we are looking at a 9 month, it can take significantly longer since the process comes from the ACCV is over one year now. Is there a timeline or project plan is associated with each one of these steps that outlines the expected duration before and -- before it moves to the next stage?

Yes. We frequently can expect just as you say, getting the rules through -- I do not know I've seen a rule go through in less than a year. It seems to take that long. It is 15 or 18 months. The big table, the one is within HSP is one that is complex. That will take a while to work its way through.

A while? 2,3 Years?

18 months to 2 years.

With HRSA it has been over one year?

No Google I do not know it has been that long -- no. I do not know it has been that long. We only started here a short while ago. I'm not sure how long it was sitting before we started. So -- I do not think it has been that long.

The table was first approved in March of 2012?

Writes. -- Right. We need to put it to gather and clear it -- there is a good deal of back-and-forth. The meaning of every word, needs to be clear. And that sort of thing because it takes a while to get a document that is ready to be sent to the department. That is what we are in the process of doing. What has held us up is, -- held us up is, focused on the countermeasures table which is currently in the department. Now we will focus on the vaccine injury compensation table.

From today onwards, with you think the timeframe is before it goes to the next up?

By the next commission meeting, I would be is appointed if it is not in the department.

Okay.

Thank you. >> The table that I asked Anne to get is up. You can see how it is split out , this adds clarity to the data presentation on the website. It is there for everyone to look at and to comment on as we do the discussions today. Mike --

This is Ed Krouse I have a couple of questions on the table and the issue of clarifying -- what can be learned from cases that revolve by settlement?

Actually the table is in two parts. There is the table itself and also definitions that go with the table. That is what has been put up. The definitions define what compensable cases are. Describes what concession is, court decisions and way settlement is. It explains what non-compensable or a dismissed case is. It leaves hopefully -- less room for error and misinterpreting what the program is doing.

Okay. I would like to read -- can we have a second to read this. Can you go back to the text of how you are describing a supplement? ;-).

This is Charlene I would like to make a comment on the table itself. I am pleased to see that you have a column with doses administered. Part of the charge is to reinforce the public that they will be compensated if there is a injury but vaccines are safe and they will be compensated for injury. Although those things are charges of this commission. I think the doses administered is a good column to have, it shows the relationship.

That is -- this is Anne, I do not see the page in front of me any war -- anymore. [Indiscernible].

Just to clarify, the doses administered or distributed?

Distributed.

This is Ed Krouse, two things. One I do not know if it is appropriate to list doses administered or distributed. But to the extent you will list one or the other, it seems to me it should be doses administered. In response to Charlene's comments, in terms of what the charge is at the ACCV it is not to reassure the public about the safety of vaccines. The charge is to be sure that we are a rising the secretary and as a way -- advising the Secretary. and the way that promotes policy. It and and -- and in a way that is consistent with composition programs, it it she's the purposes of Congress and compensating people that have been injured through vaccines.

I like the safest possible vaccine as part of the charge. I am glad that we agreed, that isn't born.

-- That is importance -- important.

Why would you list the vaccines distributed?

Because -- the table needs to have context. The number of doses of DT distributed are far less than the number of doses of influenza that are distributed. To see a much bigger number with blues them -- influenza versus DT. The public and say, why is there a large difference? If there was only DT 1000 doses? That is the answer, because of the volume of opportunity for adverse events to occur. And that context is important.

The data on the doses distributed does not have to be part of the table, it could be a footnote. It needs to be somewhere to give it contexts.

This is Anne, I agree it is a great idea to have the contest for the public to see. The perspective and get a perspective on this.

Thank you.

David King speaking. You have talked about some of this before in the past in terms of distribution. The whole commission has talked about this is patient -- distribution versus administration and how many are actually administrator -- administered is a complex arrangement. It is not reported back in any public formats. My question is, does anyone -- does a manufacturer no how many vaccines -- know how many vaccines to approximate based on number of returns. The number of vaccines actually administered versus distributed?

They considered a that -- that proprietary information . I think SDA is the best to speak to that. I will turn this over to Marshall.

This is Valerie. We are not able to -- to determine the number of vaccine doses administered. We track the lots distributed by each manufacturer. Sometimes the lots go to warehouses and doctors offices, we are not able to track which vaccine is actually administered.

Valerie David King here. Do the manufacturers know the information? Would each manufacturer know how many of its vaccines would be actually administrator -- administrated versus distributed?

To the best of my answer, we do not. We know how many we ship, there are other regulations that they evolve, we do not get access to that information. Just what is shipped.

Okay.

This is Mr., do not some -- do states have a registry, when there is a vaccine don't they have to record? Or somebody would notice? -- Know this?

This is Tom at CDC. Many states have registries, but the quality and completeness -- the completeness of the data is variable. Most registries Hiebert -- target childhood vaccines. You will probably not capture adult vaccines. That is limited, that will give you the data data doses administered. -- Limited data doses administered.

This is Michelle Williams, very fragmented.

This is Dave King. Tom let me ask you, do we know the break down of states that do it by adults and childhood vaccines? With the registry?

That is something I do not know -- there is a group that works with registries. I do not even know what type of data could be made available from registries? They do exist and collect data primarily on childhood vaccines. That are administered. As far as the state of development of registries -- in each individual states. And what type of access -- they may or may not provide to the -- and the level of detail, I cannot answer that. I can check on that -- with the people in the images Asian program to see if -- immunization program to see if that is available.

This is Charlene, before there is consideration of taking off the numbers distributed, from the providers on the panel, I know in public health there are [Indiscernible] to order more vaccines then they will give. Even

in the public health arena, somebody has to pay for it. Using the money and not using the vaccine is a real loss. All I'm saying, the distribution may be the best proxy measure that we have for actual doses distributed. Given that no provider has a interest in stockpiling vaccines that has to be stored properly, that expires quickly, when you think about the shelf life of other kinds of medications . It may simply be the best proxy measure that we have.

This is Anne, I agree with Charlene. It is the best measurement of approximation that we can have it this time. It would seem that with the computer age electronic records, eventually registries can talk to the different records. It is certainly something to look toward in the future having actual doses administers -- administered. At this time it is not available. Distribution is the best approximation.

[Silence].

Dave King. Icily do not think we should remove it from the table -- I do not think we should remove it from the table. I do not know if it is accurate, but what I am hearing that I did not consider, this close approximation may be relatively close because of the fact that nobody wants to stock excess inventory if we can call it that.

In the private sector, it is even worse because they are paying out a park it -- out-of-pocket. They have to be accountable, in the private sector, it is money out of their pocket.

This is Sylvia. The two issues that we have, like Anne is saying, private pediatricians have to have this huge stock it could be anywhere from $300,000 or $40,000 that they buy. In the public sector, I and him dominantly -- I am predominately working with, the states hold back on the inventory. It is difficult for us to get a lot of stock. I can have anywhere from $200,000 of -- or $300,000 of immunizations per month ago it is not mean -- it does not mean that I have run out of DTAP. We have some shortages. For a pediatrician, you put a burden on private versus public eyes to keep inventory.

This is Tom at CDC. I would not get too wrapped up on what is just too good versus event is triggered -- what is distributed versus administrators -- it's manager -- administered. If we had $120 million of flu vaccine and only $5 million of other vaccines, it just provides a general high level picture of what is out there in the marketplace? And distributed to providers and puts the numbers into contexts. You would not be able to pin down how many doses have been administered with the current state of technology. Doses distributed is the best and readily available data to put the numbers into context like Vito Caserta said.

Dave King. Any other comments or questions?

The judicial watch information is included in your binders. The Washington Times stories and -- in sections 8.4 and 8.5 if anyone is interested as to what God is going with this.

Great. Thank you. -- As to what got us going with this.

Great. Thank you.

Are there any other questions, comments etc. for Vito Caserta?

Then I would say, Vito Caserta if you have nothing else to say, I would say. -- Report is complete.

The next report is from Department of Justice . Vince Matanoski.

Would you rather be a Mr. anyway? [Laughter].

I have a great deal of respect for the medical professor.

Aren't you a Dr. of jurisprudence? [Laughter]. Thank you I appreciate you recognizing me to speak here today and I am glad speak . Dr. or not. I will turn to the second slide that I have . If you have any questions at any point, do not hesitate to interrupt me to the extent my -- of my powers, I will address this.

This is a snapshot of coming in -- of what has been filed in the last quarter. This looks at the yearly shots of what we have filed come a the number of cases we have filed. We are on track for the average that trend time -- Vito Caserta derive for the last five years. We will probably have about 400 cases this year. Consistent with the past several years, most are adults, consistent with several years, most of the cases involve flu vaccine.

Turning to slide 3. This is a breakdown by quarter again. Of the petitions that we have had. To summarize what we have here, most of the cases that we had resolved in this period were not compensated or dismiss. They were either not compensated but dismiss. People of those within the -- the bulk of those within the category came Avenue of the -- came out of the autism proceeding. You will see the numbers diminish over time. We worked through a number of those cases at this point, we are now getting to a small number of cases that remained out of the OAP. You will continue to see the number dropped. The cases that were compensated by and large were compensated by settlement.

Turning to slide 4. We have three cases that were dismissed voluntary or -- voluntarily and essentially no judgment was issued. We have been keeping track of this for a number of years because there was a concern way back -- some folks may voluntarily withdraw their cases rather than seeking some resolution through the program. And then go on and file a civil action against the admin or manufacture. We do not see any cases dropped out for that reason. To the extent we hear about any, we do not hear about cases that have been withdrawn going on been filed against manufacturers. Now it's -- now this is essentially what may come to the attention, we do not track that. Of the three cases -- we have no way of tracking it I should add. Of the three cases, want I want to comment on. Although it was voluntary, it is coming back into the program. I suspect that is true with some of the others as well book this one case I want to draw your attention to, they had filed improperly -- a case against a manufacturer or administrator before coming to the program. They filed a claim under the program after they realized their mistake. They did not dismiss the civil action that they had against the administrator or manufacture. So they had a second mistake, they come under the program -- they cannot come under the program when they still have a pending civil action . They withdrew the claim under the program in order to refile after having dismiss the civil action and come back and refile into the program . I think it was refiled two weeks ago.

Turning to slide five ,6,7 . These are all dissemination's provided in the past. You provide these for your benefits -- we provide these for your benefits. I know I have talked to some of these definitions in the past.

This is added -- Ed. I have a question. Your specifically referring to the autism proceeding?

Any case alleging autism. Not specifically out of the OAP. As far as my impression -- Ed, those cases that you see, are all coming out of the OAP.

Does that answer your question?

If a case -- was in the autism proceeding, and it was taken out and an amended. Another theory of causation was advance in the an amended this to this petition, -- amended petition is it a non-autism case? Sprout --

That is correct. A allegation or remaining allegation that the points. That the vaccines cause autism. Any other questions on that?

8 Slide. Slide nine and 10 are slides that you have seen before. They described a process, petition processing and the appellate processing under the program. I will not go over these either since you have seen these before, if there are any questions, I am happy to entertain them. I will be more happy if I can answer them. Turning to slide 11. I reported in the past to the appeal to the Supreme Court in the Cloer case. The issue of attorneys fees in a time barred case. The supreme court issued a decision, they came to the conclusion attorneys fees are available potentially available in a time-barred case. They did not say -- there is no absolute bar to receiving attorneys fees and a time-barred case. The report aspect comes out of the OAP. There were over 1000 cases that appear to be time-barred when they were filed that now potentially could see attorneys fees.

The decision just came out recently as you can see. We have been in discussions with the court I know the potential others -- petitioner's counsel that are also time-barred and now may be eligible for attorneys fees have been in contact with the court to try to come up with a process that is streamlined for addressing -- which cases may be eligible for payment at this point? Each of those cases involve some fact specific development, time-barred, whether or not there is a reason obeys his? -- Reasonable basis? So it could be a fairly -- all parties to the matter recognize and also the courts, recognizes this can be fairly significant resource issue. To address each case separately, so the parties and the courts are exploring ways to get a better handle -- to try to have a process that would be streamlined and efficient for addressing that.

It is still early in the process to know what is going to become of this. I want to inform the commission of the decision and also the events -- subsequent events and efforts to address the second and third order effects if you will of that decision.

We have a couple of cases that were recently decided at the Federal Circuit. I typically address each of those cases because they seem to have more import -- importance as to what happens in the program. The first one Shapiro was a fact dispute between experts . There was not a overall to go way that legal take away from that. It is decided on the facts specific to that case. The one interesting thing about the fax there, it seems -- facts there, it seems from Testaverde -- from testimony that the injury occurred before the vaccine. The injury looked more like if it did not a core -- occur before the vaccine, it was too soon for the vaccine under the theory proposed. Under the theory, or has to be some lag time between administration of vaccine and the injury itself.

figeroa Involves legal issues and they have some impact on cases going forward. This is a case where the petitioner's -- or injured parties the state filed a claim. The estate, essentially be individual had passed away prior to the claim being filed, the estate alleged that the individual in question, that they represent. That -- sustained a vaccine injury prior to death. The individual actually died from a advance or injury that was unrelated to the alleged vaccine injury. They nevertheless filed under the program, climbing -- claiming not for the death but the underlying injury. The way the government read the vaccine act, you can file for eight injury if you are the injured party, you can file if the injured party was incapacitated in some way, minority or mental incapacity. They could not bring the case themselves. In that instance, a personal representative can bring the case for you. If the injured party had died as a result of the vaccine injury, in that circumstance, a estate can bring a claim. That was our reading of the statute based on the plain language. In a 2-1 decision, the Federal Circuit found that personal representative -- the injured claim

survives the death of the ends original -- of the individual. A personal representative can file for the injury alone. There was one judge that descended and essentially viewed the act the same way the government had. By its plain terms it did not permit a claim for a injury to be filed by a estate of someone who died for something other -- than a event alleged to the injury. This could have impact on us in terms of what kind of cases that we see. Because of the act had been it -- interpreted from what was found in Figueroa. We do not know what will happen as a result of the decision.

This last case, a procedural problem with the case being filed by the petitioner. They filed after the time limit for filing the appeal. The federal circuit dismissed on those grounds. We had four new cases filed at the Federal Circuit. I will briefly talk about them. Lelonde Was filed by a petitioner essentially I will call this a fact dispute in the sense that there was conflicting expert testimony. The court found that the government expert was more persuasive and what he had presented on the causation claim. And dismissed the claims that have been a firm federal claim and now it is on appeal in front of the Federal Circuit. I think another sort of a -- disagreement between experts -- one interesting thing out of Isaac. Is the theory that was being proposed by the petitioner. Was a molecular theory that the tetanus vaccine called the injury in question. In support they relied on a case report that was 33 years old. It had been used in a number of cases in the past, it had been looked at by the IOM. In previous IOM reports had been thing to do best to give some credence to the notion that there may be something to the theory. Based on this one case report. In more recent times, the IOM has relook this and look at other evidence regarding the tetanus vaccine and the autoimmune injuries. It has not gone far to say that they think there is a potential link there. The special master found that there was insufficient evidence to find actual causation. The Court of Federal claims judge affirmed this and it is up on appeal to the Federal Circuit. The last two cases which were both bright brought -- both brought by Snyder and Harris. Addressed other cases in the past, talking about that particular gene mutation. The findings by the special master that the gene mutation was more likely because of the child's injury and that the course of the disease was not significantly aggravated by the administration of vaccine. The Court of Federal claims judge reversed -- she heard both of the cases. She reversed in each. They would -- they are now pending in front of the Federal Circuit for review.

Turning to the quirks of federal -- Court of Federal claims cases. We had five -- four cases the set of this period. Barnett was a FCN1 case there was a finding by the special master, the evidence was that the course of the injury was not significantly aggravated. The condition of the disease epilepsy was not significantly aggravated by the vaccine. Now that is up on appeal to the core of Federal claims. -- Court of Federal claims. I am sorry that was it killed and affirmed by Judge Wise. LaLonde, I already addressed this, this is a dispute to the experts were the special master and the Court of Federal claims judge found that the government expert was more persuasive. Eisler Is interesting, it involves a case -- that had been settled. There was -- a request by the petitioner following the compensation in the case. Asking for redaction for some information out of the decision. The court denied the request for redaction of certain information out of the decision. The petitioner requested reconsideration before the court had act on the -- alleging new factors. Before the court could act on the motion for reconsideration, they filed a appeal regarding the original decision not to read back the case and that when up to a judge at the Court of Federal claims that granted the appeal fairly rapidly. I believe once it went back to the special master, -- the appeal to reconsider the special master decision. They reconsidered a decision and redacted portions of it consistent with what the petitioner requested.

Graves Is worth mentioning as well, it is a decision that came out regarding pain and suffering. The special master awarded $60,000 in pain and suffering. To refresh your recollection, the total amount that can be awarded under the act is $250,000. The special master awarded $60,000. In awarding this, the special master had in part looked comparatively if you will, over the kind of cases that can come in under the program. And compared the level of pain and suffering, suffering -- suffered by this petitioner. Against some of the other kinds of positions that have come into the program. And then decided, well --

considering that against the backdrop, in part made a finding that $60,000 was appropriate. That was one of the consideration. The court of appeal, the judge -- thought it was impermissible or an appropriate at least legally for him to be looking at other cases and comparing how this case fit amongst the others against a doctor of 250,000 being the absolute maximum that can be awarded. Because the judge found that was legal error, it gave the judge essentially the discretion to then substitute his view of what a appropriate amount for compensation would be. He awarded the full $250,000 under the circumstances.

This can have a impact on what we see in awards written by the court when they decide compensation. What we will see in settlements coming out of the program. The amount of compensation because it may bring it up if you will the amount that you will see being awarded for pain and suffering. Just to offer my own view, I would think there is actually -- there should be some variation if you will, -- at the Congress intended that there be a flat amount awarded for pain and suffering, they would have said that. There should be variation and the special master should look at -- or it seems appropriate for them to look at the relative pain and suffering that a individual suffered. Of course with a ultimately can conclude that would be, would be up to the special master. Where I would type this back into something we were talking about before, talking about the amount paid that was slide 6. Vito Caserta presentation. He indicated the amounts paid over time has gone up. I would look at cases like Figueroa or an early death case that expanded the amounts available in death cases. Or looking at cases like Graves. Part of what you may see, and why as a absolute you will see the amount of money been paid out going up may be attributable in part to the changing case law in terms of the amount of compensation we are finding available for the petitioner's under the program.

But turning now to settlements. I have on slide 15 and 16 there are additional cases that are noted. Appeals that are pending in the federal claims. They have the basic issue involved is noted in parentheses. Slide 16 and shows we do not have any cases pending or oral arguments pending at this point. Turning to slide 17 -25 . These are the cases that have been adjudicated I supplement in this last reporting period. The total number of cases is 78. As I have reported in the past, these cases primarily have been evolved the flu vaccine -- involved flu vaccine in conjunction with other vaccines. If you look, you will notice the single most often repeated injury appears to be

Guillian syndrome. There was a question that came out of the past readings, that the commission members asked if he could tell, how many supplements involved adults and how many involve minors? We went back to find a manageable way from a resource standpoint, we do not track that at this point. We have to go back and look through each of the settlements to take a look at Ein out the information.

What we did, we looked at essentially whether by caption of the case, it appear to evolve a minor or a adults. -- adult. There is a caveat I have to give you with respect to this. It would appear as a minor, as long as the individual is under 18 years of age at the 10 -- at the time the case was decided. It could mean one of the cases involved a child who became a adults while the case was pending. And then the case was listed in their own name rather than behalf of a minor. It can also be, that the case that that was the case that was filed for a minor, but they became a adult. It can also be that a case -- well -- that is a caveat that I would give you with respect to that. Breaking these out, between minors and adults, we had of 78, 66 settlements evolved -- involved adults and 12 involved minors. I also broke out how many involve flu alone or flew as one of the vaccines. 65% of the cases involve either flu alone or flew as one of the vaccines alleged to have treated a injury.'s -- created a injury.

The reason why read reported on settlements is to give you a idea how quickly they were being processed. There was a concern several years ago, that settlements might be taking too long. We have been tracking that now for several years for you. I am pleased to say, that consistent from what I have looked at in the past several times I have reported to you, we seem to be on the same track . Of the cases that you see, I have broken it out to give you some statistics to give you a idea of what this all means in terms of how

quickly these cases go from being filed to settlement . 27% of the cases that you see reported were settled in a year or less of the date they were filed. Additional 38% were settled within two years of being filed. We are up to 65%. If you take it out to three years or less, you add to 3%. 88% of the cases are settled within three years of filing. My recollection, I reported to you last February I think the number was 87% or 88%. Settlements reached within three years of the date of filing.

The three longest cases that we had, there were two actually quite long. 13 and 12 years. Looking back at whatever we see -- we want to see what the reasoning is? Those cases -- each of them, the records were not complete until 2012 . Actually from the time the record was complete from the case, to the time about subtle, is going to be one year or less essentially. They moved along quickly once the records were complete.

Now getting to my last slide. Which I believe is slide 26. A reminder, for me war than anything else, there had been a request that was given to me to address whether it would be advisable to have additional information about settlements presented to the commission in order to look at that, or mind the data for possible indications of vaccine safety. I adjust this back in February -- I addressed this back in February and I have concerns. I have three months to concern -- to think about the concern, they have come into clearer focus for me. I should start by saying, settlements come out of a legal processable, not scientific inquiries. -- A legal process, not scientific inquiries. There is a copy it that is attached to settlements, but also the decisions. The courts are looking at a case, from the standpoint not necessarily of science or medicine, one can conclude a vaccine actually cause the injury. They are looking at scientific evidence, they are looking at that through the lens of a judicial or a legal standard for -- to determine causation was proven. A preponderance of evidence, there are certain factors that are looked at and some are weighted more heavily than others. The court is looking at it -- we talked in the past about -- standard in the prongs that are involved. That is what they apply to determine whether or not they will permit compensation in a case. Settlements proceed out of the same process if you will. So what individuals that are involved in the process are looking at, in part is, what is the likelihood of a court finding? -- Finding causation? That is one consideration of many, it would be wrong to conclude either from a court decision or settlement, that is a finding that has any kind of correlation if you will -- necessarily with a 60 -- safety issue or causation issue.

So I think the chairperson said before, you could not describe a correlation coming out of this. And so with that, the overall idea behind this I think -- you are not going to get the data that you would be looking at if you are looking for safety data. From this. I have some additional concerns that I believe I have voiced before, I again raised them . One is petitioners -- there at -- there are a variety of reasons that do not get to the evidence the hide a case that are behind his settlements. -- That are behind a case that -- we do not know why they choose to settle a particular case. They may know that they do not have good evidence although they put on a good face. Or they may desire to have the case resolved quickly . They do not want to go through the more involved process of having the case heard at trial. There are a lot of factors that go into this, we have no idea of what they are. We been the government.

-- We being the government. Increasingly in fact, we heard the petitioners express a desire for privacy with respect to their cases. In particular in the case has been compensated if you will. The act itself carries a protection of information submitted by the parties. If the information is not found in a decision, the parties -- it cannot be released without the consent of the party involved. We sanitize to the extent that we can, information that we report to you that is not decisional in nature. We try to make it very difficult hopefully impossible to track the information back to a particular individual. Who has filed a case. The more information that is released -- the harder it is to protect the privacy concerns. So I would be very, very hesitant to proceed -- at least very conscience of the concerns in a proceeding further with providing more information.

That we already have. Amongst the information that we have provided, you can tell the vaccine administered, the injury a ledge, and -- the injury alleged, and how long for a settlement . Finally, apart from the privacy concerns, there are concerns about -- I should point out, decisional information is Artie out there . For -- is already out there. For Egypt the cases I reported on, a decision has been reached by the special master. Attached to the decision is a stipulation with all of the information that goes into the stipulation. Including, when there is a case that does not involve concession by the government, in fact the government does not concede that this represents a finding of causation in a case. The government continues to maintain in each of the cases, there is not sufficient evidence to find there is causation.

So -- that is already out there and available as far as what is happening in each of the cases that are settled. With that, I will close my remarks, and be happy to entertain any questions about anything I have spoken about this morning?

David King. Thank you. Are there any questions for Vince Matanoski?

This is Anne. Thank you for doing this, -- this gives a perspective that the majority of folks that are having settlements are adults. And not children although taking into consideration that is the update of -- the date of settlement but not the date of the incident.

I do want -- I did not want to put you on the spot. [Laughter]. We will look at whether we can track this a little bit further out and see if it continues to follow the same pattern. >>

This is Ed Krouse. Vince Matanoski, thank you for the presentation. I was one of the people that was interested in figuring out, what additional information could be provided from the settlements, consistent with the privacy concerns of petitioners? And two, useful for the public to be able to digest what is actually -- sort of coming out of the vaccine compensation program? And to refresh, my reactions -- they have not changed, when you look at a program where we are talking approximately 90% of the cases are settled. The number of actual decisions with kind of robust discussion of medical and causation issues and experts weighing in on possible specific situations were maybe a vaccine has been shown or arguably shown to cause a injury. That is the sort of information that is of concern, and legitimately so of interest to the public. When we settle cases for all the reasons identified, the description is very appropriate. All sorts of factors. So -- on the one hand, I agree with you. We have to be very careful about drawing medical safety conclusions from a case that has settled for all the reasons I think you correctly identify.

I do think there is another side of the ledger. The other side, which I think we still have not -- I am not sure how. Figured out a way to provide as much information as we can to the public about vaccine injuries. So -- you know -- I am struggling with the issue. I do not know -- I appreciate -- pretty much what you have said today, it is consistent on what you have said in the past. That is usually the case, you are very articulate and persuasive on how you present the reasons for caution and providing information from a settlement. Which is a legal proceeding. On the flip side, I remain concerned about the lack of information that could be useful to the public. That gets caught in the settlements process. Gets tracked within the settlement process. As my general comments.

My specific comments, I do remember and recall the reason user to provide us with information on adjudicated settlements is to show the duration of claims. I think that is a useful presentation for us to have because it has very much to do with the efficiency of providing compensation for people who may have been injured by vaccines. Now you have provided it, it seems to me that it would not be difficult or inappropriate or inconsistent with petitioners try to see concerns, to also list -- petitioner privacy concerns, to list the amount of settlement. The information is publicly available with a stipulation with the court. You mentioned petitioners have expressed concerns about the confidentiality of the settlements. Or something about the petitioners consents. They have concerns, they can certainly try to have their names read active,

once the information is available, and on the court website. I see no reason why the department -- why HHS or the program cannot facilitate providing the information, the amount of the settlements? You are correct, the amount of settlement like even for example The Simpsons that the symptoms at ledge, you have to be cautious -- for example, the symptoms that are alleged, you have to be cautious.

For the program, I would think it would be beneficial to provide around of compensation in these adjudicated settlements.

To have -- I am ready to address what you have. Let me address what you have so far Ed. If there are any questions or observations I will also address those. First, generally speaking, as I said, settlements are not a good way to assess the safety in my view. In fact the program and Congress bills in a much better way to do that. And a appropriate way. The IOM for example is one of those. [Indiscernible-static] that is the best way to assess vaccine safety, Lake -- taking a look at scientific and -- scientific information .

I do not dispute that.

I do not think this is getting to be safety issues. As far as the amount that the settlement has, it is yet more information that potentially raises privacy concerns. I do not see that going to safety at all. If anything, amount can be influenced by the gravity of the injury, that the individual had. We describe the injuries there in the information that we provide. Finally, this information is out there . You can look at aggregate information with respect to how much the program is paying out. How much goes out and settlements if you look at this from time to time -- as I mentioned with the case like Graves coming out you may see the settlements amount go up . It is not a reflection at all of the safety of the vaccine, that has to do with what is available. It is not the reflection of the gravity of the injury there, it is with the court found available. [Indiscernible] a case that described amongst your program materials, the court interpreted the vaccine act providing no more than $250,000 for death cases. After this, it additional decisions came out, found that more than $250,000 is available for death cases. Settlements if they are reached in a death case maybe influenced by that Sandy, -- by that finding. It has nothing to do with the evidence or the safety of the vaccine.

Those are some of my brief thoughts about it.

If I can respond, perhaps it is my fault or -- safety and public information or knowledge. I think your point is well made, there are other ways to determine vaccine safety that are far more reliable. Obviously these are scientific and medical questions. I guess my focus is, not so much on the scientific conclusions about safety that can be learned. The ability of the public to have access to information about what other people have experienced in the context of a vaccine injury claim? It does not need to be justified by safety so much as transparency of a program. That benefits I think -- from gaining the public's trust in the vaccine program overall. By providing as much information as can be provided to the public without sacrificing any other interest such as privacy. At least in a way that is not unduly burdensome. I do not think it would be to list the amount of the settlement. You mentioned that the alleged injury provide information, they turned -- they do not provide much. For example the [Indiscernible] syndrome, some people suffer from GBS, six months or later sometimes they are back up and going. There are other people who are permanently disabled for life. Rather than describing the -- what kind of symptoms associated with that person's particular GBS. If you report out this is a case that settled for $1.3 million and this one settled for $72,000 or this one for $30,000. That is information that I think is useful for providing to the public, as you pointed out it is available.

There is no reason to not included on the settlements list. Finally, you have referenced a couple of times the recent decisions like Graves and Figueroa. As to cases that can have greater damages awarded, I do not

think that is relevant to the included amounts. It is certainly possible and [Indiscernible] in particular can result in death cases. I do not know how many death cases that are included in the 78 that we look at. If there are 2-3, there may be additional compensation can -- assuming that a person had a vaccine and died. It was decided that in addition to the $250,000 death benefit, the suffering is also compensable at $125,000. Either way, the total settlement of $375,000 is something I think should be included. Also I have to point out about Graves, you identified it as your own view. It is a case that suggests when you are assessing the damages, is it relative to $250,000 -- available for everybody? I want to point out, I think with the purpose -- it is not clear whether Congress intended somebody for example, injured, suffers for six months or one year. Then has a recovery. It is not clear that Congress did not want -- let me put it this way. Someone who almost dies as a result of a vaccine but then has a recovery. It is not clear did not want that person to receive $250,000 in pain and suffering. Also if somebody for example, has a lifelong vision impairments, following a vaccine. It is not clear that Congress did not want that person to be able to argue that his pain and suffering that the level of $250,000. The only thing we know at Congress It at $250,000. As a positioners attorney, I have no qualms about our green that somebody -- our green -- that arguing that somebody should receive $250,000 -- I consider it to be a. Finally I want -- I consider it to be a cap. Finally with Figueroa, it will not have much of a impact on the program.

Somebody injured by a vaccine, they file their case, and the case has not been filed -- the person suffers let's say a GBS case, they recover. die They are hit by a car and. The estate can still sue or bring the petition under the program and get whatever it is that they are entitled to if they can prove that the vaccine called the -- cause the GBS and pain and suffering. That is a unusual situation, at will not have something that will have a over all impact on them -- on the amount of money paid out of the cases. I am done. I am sorry.

With your permission, with the chairperson's permission, I will briefly give a couple of final comments.

You have permission.

Lawyers can go up -- can fill up every available moment. Laminate -- [Laughter]. My comment regarding damages were in the context of whether the information in terms of the amount of supplements has -- settlements has any bearing on safety. Other than what I was discussing with the decisions themselves, so just to clarify. The -- with respect to Graves and the overall amount, I will observe when Congress came up with $250,000, they knew there were's -- there was going to be a lot of money that goes in the settlement, it can confuse the public more than inform them. I have run out of breath, --

I will relinquish at this point.

Does anybody else have any comments questions or concerns? As a relates to the information has been provided by Vince Matanoski ? Or the comments made sense?

--
since .

If it takes an hour for us to go through the information and have the conversation, that can be the appropriate thing to do.

To be clear on the record, I am not asking. [Laughter]. David, it was well worth going through this and spending the time, even though it put us behind on the agenda.

Okay. If we have no further questions for Vince Matanoski, thank you for the thorough reports. It is appreciated. Prep --

A decision point, we can go to lunch now and have skipped provide the talk this afternoon. Or skip can do it now and have lunch later.

It is not 12 PM yet. Lunch is scheduled for 12 PM. We only have one vaccine injury statement. I am leaning towards pressing on. However, I do think I would take some input -- based upon the commissioners because of the fact there was a agenda published. I do not know of any one has scheduled anything in the lunch hour -- if they have to leave. I will poll.

This is Charlene, press on.

I am fine with pressing on, I would say we do have a guest presentation for the images Asian workgroup at 1:20 PM. -- For the maternal workgroup at 1:20 PM.

We definitely need to press on, I suspect that the allocated time for the process work group -- that might take more than the 20 min. We will not know until we get to this. If there are no objections, I was suggested at Skip we will give you the floor .

Jennifer is with me, as we said, we have one to go through today. Essentially has been discussed before with Wolf -- both TB and TDAP regarding the pregnancy which is the reason for updating this. The to vaccine have diverse enough we have to have separate VIS for them and this one is for DTAP only and is for the new pregnancy recommendations. This is pretty similar except that we have switched to the newer format as far as the technical information, it is similar to the existing DTAP . This discussion can go pretty quickly, we can wait and see about that. Prep let's proceed.

Should be go through this -- section by section with Denise -- any comments that you have on each one?

That is appropriate. One don't you just start and we will ask in section 1. We will move it through that way.

This is especially identical I think to the older DTD. The information in this section.

[Silence].

If there is nothing there section 2 is about the DTAP vaccine . There is nothing new in here, probably the wording, we simplify the wording.

Of this is Kristin --

The third paragraph is where we talk about the change in accommodation for pregnant women. Is different from the older one.

[Silence].

This is Kristin I have a question about the fourth paragraph. The issue of -- making sure that caregivers not maternal are also vaccinated. If you are a 60-year-old person in the household with a newborn. It is recommended that you received DTAP. If you received it four years ago -- is that correct? This gets complex. This this need to be something to indicate you can still receive DTAP in the setting of a close contact with a young infant, even if it has been less than 10 years?

This is Anne an 2 paragraph?

Just that you need one, anyone within close contact. 4 Paragraph talk specifically about the dose every 10 years and you can have DTAP as one of those.

You can mentioned that the integral can be reduced?

Yes. In the setting of being in a close contact with a young infants.

We could. Let me add one thing, something that we are trying to do with the VIS they are given at the time of vaccination, trading -- trying to keep them simple, -- [Multiple Speakers] -- is somebody -- unless -- somebody who is not there to receive the vaccine already does not need the information. It is important to know but not important to put on a VIS.

Something proceed if they saw the statement is should be every 10 years wondering if they are getting that that is all?

That can be added in a few words.

Without being can fusing.

Okay. Thank you.

This may not be the right place to bring this up, I know there are a lot of people on the call I know the answer they had been developing a separate vaccine. I have been wishing for as long as you -- as I can remember . Maybe somebody on the committee knows what an idea. >> Does anybody have a understanding of why that is the case and why there is not one?

Out of cure acid the if nobody knows, I will ask around and see if I can find out . >>

Is below are
Oh oh does anyone have any understanding of why that is the case, why there isn't one?

Out of curiosity of no one knows I will ask around and maybe let you know at the next meeting.

This is Kristin. I don't know, it may have happened to you, back the name -- vaccine prevention, the ability to apply the right antigen to put into a vaccine so, in response to that if there is anything in early development development?

This is Steve, we convened -- I mentioned the last meeting of this group that we convened a meeting of all federal agencies in academia and industry on pertussis, to talk about all this. Developing any new pertussis vaccine , reformulating it with the other components or on its own is whether or not that is a necessary given current research of pertussis or any other consideration is probably not something that is going to happen anytime soon. There are a host of reasons for that now the least of which are scientific understanding,
the immune response to the vaccine, difference between a cellular that is replaced the whole cell, any changes in the pathogen -- I am sure you folks can see the mainstream press has been littered with these kinds of stories. So, really understanding what is going on with research in pertussis and any of that is really more about what is going on with this as far as there being a separate product just for pertussis, there does not seem to be an incentive to be one to be developed by anybody. So, especially, given the difficulties with

understanding the biology of the bug and the responses to the vaccine. So, as of right now, there is probably not a lot of incentive to do that.

This is skip, I think also the way people's opinions have been changing about the risk of getting doses of [Indiscernible] too close together too are changing. I believe , current thinking is it is not as risky as previously thought to be yet another reason [Indiscernible] pertussis vaccine.

Anything else on section 2? If not, section 3 at the March meeting, this section is to be called precautions, and based on discussions of the last ACCV meeting we change the heading on all future VIS's to what it is now, some people should not get this vaccine. Again, the technical content is pretty much chemical to the previous TDAP , TIS.

If someone could explain quickly why, and I am sure there is a specific reason for, but why is it not mentioned if someone has severe at her immune condition? Is that something that is for which the TDAP is contraindicated? So why is that listed under top-tier Doctor if -- talk to your doctor if --

I can double check but I do believe it is a contraindication, either in the package insert or from a C-I-P.

As far as I know there is no contraindication for severe autoimmune disease or whatever type -- in fact most of the studies done that look at people with autoimmune diseases they find the vaccines help protect them from the disease itself, more beneficial then theoretically harmful.

Thank you that is why I am a lawyer, not a Doctor.

Okay, if nothing else, section 4 is the risks and basically, I checked and tried to find, if there were any data that different jaded between TDAP as far as risk of adverse events I could not find any difference of this is essentially exactly the same as the previous TTD VIS and we do include the section on syncope which we talked about last time.

One thing that struck me, this is Vito again, when we talk about mild, moderate and severe problems, I think it would be helpful to include when a problem would be expected to occur if the vaccine was associated, another would -- in other words it, get TDAP invalid -- developed a two weeks later, that's not going to be the DTAP whereas they got MMR got fever it would be so different vaccines are different in how they do things so having a time period may be helpful.

Thank you, that's a good point. I will see if we can get the information from our subject matter experts here.

This is Ann Pron how can there is no mention of server here or am I mentioning?

Of what?

Shoulder injury?

We talked about that last time, Tom Shimaburkuro and I said we would work out some wording with that I just have not done it yet, but we will.

So that would be added to this and all vaccines?

I think so, yes. Since that was included in the IOM report as I recall.

This is Vito, the IOM report discussed bursitis, as I remember. They did not go as part as server.

Tom had mentioned that using the term shoulder pain or shoulder injury or something like that might be preferable does because it is easier to understand, a term people would be familiar with.

Sections of five, six and seven , I was going to say they did not change his section six last time we talked about changing the first paragraph of about how we just -- described injury compensation program we made that change in this and it will be the same in future DIS's were we talk about it in a federal program and took out the year it was instituted. Anything? I think you can go to lunch.

Certainly, Skip, we want to thank you. Actually what we want to do is thank you for taking the input from the commission and adapting them to these and future ones so we thank you without.

That's part of our mandate so we thank you for all your comments. It is always a pleasure doing business with you.

All right. Does anyone have any other comments, questions of Skip? Well, since we don't, Skip told us he'd things we can go to lunch so I would say we can probably go to lunch. I would ask that we start up again at the 1:00 p.m., promptly. And, because we do have a full agenda for the afternoon. I am sure at some point people want to go home today. Though, I know that everybody is more than willing to stay and do what needs to be done.

A procedural question, do we hang up and re- dialing?

Great question I was thinking I was going to hang up and re- dialing. Ann or Vito any suggestions?

This is Ann that's probably the best case.

We can close our screens as well?

Yes you can log back on or leave it open, either way.

Great. Let's break for lunch then.

Okay.

Thank you we will return at 1:00. Thanks, goodbye .

[The Advisory Committee on Childhood Vaccines is on a break for lunch and will resume 1:00 EDT. Captioner standing by.]

Welcome to the 88 quarterly meeting of the Advisory Commission on childhood vaccines. This is a continuation of this morning's meeting.This meeting is being recorded. If you have any objections you may disconnect at this time. , not torn the meeting over to the agency be chair, Mr. David King.

Good afternoon everybody assuming you're on the East Coast time so not everybody is I suspect so, good morning to some of you. Before we begin the afternoon session, something based upon the technology that we have, which we are using an Adobe connect, I want to make an announcement to everybody that in addition to the audio being available, when -- in about it weeks time after this meeting on our website,

because of the way this has been recorded, the closed captioning component, which gives a roughly accurate transcript of the proceedings, a few typos in that just because of the nature of the beast, that will begin to flow through that way as well. Are we connected,

Annie? Right here I don't see closed captioning working right now -- yes, I see this now. Nothing is being shared so --

I am working on it. I promise.

In the meantime, we have all commissioners from this morning on the phone with the exception of Michelle Williams, who will be returning to the call in a short period of time. So, the next item on the agenda is the report from the process work group, Luisita are you prepared or ready, we are just waiting for things to, for folks?

Yes, I can read my report myself but what should be on the screen, really is the recommendations themselves only.

Okay why don't you give the report and by that time the recommendations will in fact, suspect be up if not, Annie may have to transmit them to everybody.

This is Luisita, this is our quarterly report for the the process workgroup . During the March ACCV meeting the process workgroup presented a recommendation regarding extension of the statute of limitations. After a brief discussion by the full commission this resolution was supported and passed . During the preparation of the formal resolution, camera overlay notice the recommendations are not provide a date when the provision would take affect . Upon deliberation process workgroup decided to present to the commission and amended SOL recommendation with the provision that it would be effective on the date that it is enacted and applied to all petitions alleging injuries from covered vaccines filed on and after that date. On our subsequent meeting, we continued our discussion of the next recommendation on our list increasing the cap for pain and suffering and death. We agree and support the previous ACCV recommendation that the cap be tied with inflation, using the consumer Price Index for all urban consumers. On the date the recommendation is enacted into law, we also recommend that it be applied to all pending petitions alleging injuries from covered vaccines and to all cases filed on and after that date a table of the production is to assist you in your consideration for the more we also agreed to the following, determining year of benefit amount to be used. For pain and suffering, the year to be used is the year that decision is made. For death, the year to be used is the year of the death. For pain and suffering, and death in the same petition, the year to be used is the year of death. I will present to you right now the formal text of each recommendation prepared by Tamara Oberlin for your considerations. The highlight our only for the purpose of drawing your attention to specific information. I would like to ask a member of the workgroup to make the move for the approval of these two recommendations?

This is Ed Crouse I move we approve these two recommendations.

Do we have a second to that?

This is Ann Pron I second that.

Terrific does anyone have any conversation, discussions, questions as it relates to this?

Dave, I would just -- was just recently voted chair of the faculty Senate I am all into Roberts rule of order you should probably proceed for the record, all in favor, all of those.

Right, but I thought that before I did that --

The last understood does anybody have any problem with that?

So, I guess --

Just the standard thing for the record.

I understand that I wasn't really doing a boat yet I had not called for a boat because the motion was put on the table the motion was seconded once it is on the table and seconded we can then have a conversation, a discussion about it that is what I was encouraging at the moment I had not yet called for a vote. Does that make sense, Charlene?

Yes. That is not how we did it this morning, that's all. That is all I am saying.

Dave, this is to Mira. I just want to be clear that the recommendation should say develop the recommendation and basically I just pretty much type what the workgroup wanted. So, I want to be clear it is not me that's actually developed the recommendations it is the ACCV workgroup who actually developed the recommendations I type them up .

So noted and thank you.

Sorry this is
Luisita all I was dating as you prepare the formal text. I wanted to be clear for the record. [Indiscernible--low volume] developing the recommendation.

It is writing the formal text in the way to present its in acceptable language. And I know this isn't the final form yet because we still receive some kind of -- some editing from Juliet, to make the language more consistent with the original -- with the vaccine act but again, this is still subject to changes anyway.

Luisita, it was actually Andrea,
not Juliet, his submitted some recommended changes and her changes were not going to change, the actual recommendation it with providing information about the reasoning behind it so it would actually change the recommendation you all vote on. It was just basically -- (multiple speakers).

It does not change the recommendation, just the formality of the language.

Yes, she suggested providing reasoning for why we are recommending certain things like why -- why does ACCV recommend potentially where you recommending effective date so that is -- pretty much her suggestion for clarification not actually changing the recommendation any kind of way.

Okay.

This is Ann Pron I have one question it sounded a little vague to me, I reread a couple times I think I understand it correctly but on the first page, the first information in blue, revised amount, pain and suffering applies to all cases ending in this provision case [Indiscernible] did and to all cases only after that date that date the provision is enacted, --

Yes.

I am the only one that had difficulty separating that?

When this provision is enacted , so -- the word that Ben refers to when that provision is enacted.

That's fine if one wanted to just put him in parentheses what that specific thing I mean, I think that's fine too. Dave King , speaking by the way. Any other thoughts? Comments? Discussion? Charlene? May I call it to a vote.

Yes you may, sir.

(laughter) so, we are calling this motion to a vote, all in favor?

Aye.

Aye.

Aye.

Any commissioners opposed?All opposed so the aye's have a all commissioners but one voting aye at this time because the one is out at the moment. Okay, Luisita, do you have any other information to report?

Nothing more at this time. Thank you, Dave, I am there with my report.

Thank you so much. So, having done that thank you and we will move on to the next item on the afternoon agenda which would be the report from the ACCV and NVAC vaccine Advisory Commission maternal immunization workgroups. I believe, Kristen you can tell me are we doing a joint presentation here?

Well, this is Anna Jacobs what the office of General Counsel. The way we were going to do this is I was going to give some basic background for you, and Kristen was going to present the work of the ACCV's workgroup on maternal immunization and then we had a presentation from one of the cochairs from the NVAC workgroup on maternal immunization, Kathryn Torres. That is the order we will going.

That is the order you should go in, feel free to proceed and welcome. Welcome, we are delighted to have you.

Thank you so much, thank you for having me. Is to explain who I am I am an attorney with the office of the general counsel to HHS I provide legal advice to HRSA on vaccine injury compensation program and that means I work closely with HRSA in all of their work with the BI CP and also the DOJ in their litigation of the claims. So, I am here to give you some background information on liability and compensation issues related to maternal immunization that will hopefully assist you in considering the draft recommendations Kristen will be presenting to you. So, we can swipe -- start with slide 2 and go through the point that I will be discussing today. Burst I am going to walk through the statutory provisions and the legal requirement that are relevant for the issues you will be discussing today and then I will briefly address the straight -- the state of the case law in the ICP related to maternal immunization claims. I will touch on the departments interest over the past few years in maternal immunization and then at that point I will turn over the phone to Kristen Feemster and then you will hear from cap mentors on work of NVAC. Let's move on to slide three without further adieu.

So, as you know the way the ICP works is an individual eligible to file a claim first has to file a petition under the BI CP before filing suit in civil court against the vaccine manufacturer or administrator. And, in order to be bound entitled to compensation, a petitioner needs to show that she is eligible to pursue a claim in the BI CP and she also needs to prove by preponderance of evidence it their causation or table injury, and the government has to improve -- proof that basically something other than the vaccine caused the injury. So, on the next slide, for eligible petitioners, that the VICP is the first stop. And, as you know, at the end of the VICP case, the petitioner can say, okay, I expect this judgment and she is finished. Or, she can say she is dissatisfied with the outcome of the claim, rejected the judgment and file suit against the manufacturer work administrator in civil court.

So this requirement to first go through the VICP only applies to individuals who are eligible to pursue a claim. So individuals who are not eligible or were not eligible may file suit directly against the manufacturer or administrator in civil court. If they do file a claim first in the VICP and found in eligible, that means their case should be dismissed. So this question eligibility is important and this is where we need to look when consider immunization of pregnant women . When we are talking about claims stemmed from immunization of pregnant women, we are generally looking at injuries to the mother herself and injuries to the fetus.

With regards to eligibility, the statute sets forth various the permits that the petitioner must meet in order to be eligible to pursue compensation. Eligibility requirements that are most relevant immunization of pregnant women are these on the screen.The first requirement is that the petitioner must prove that the person has suffered such injury or had died received a vaccine set forth in the vaccine injury table where such person did not receive such a vaccine contracted polio directly or indirectly from another person you received an oral polio vaccine. The statute also states only one petition may be filed with respect to each administration. Of a vaccine. We call this the one petition role. So, what does receive a vaccine mean in the case of immunization of pertinent women, it is clear that the mother received a vaccine, but can the fetus be said to have received the vaccine also? And also, does the one petition rule preclude both the mother and child from seeking compensation from the same vaccine administration? On the next slide, drop the program parties have not agreed. The government has taken litigation position that the statute does not contemplate eligibility to pursue in utero injury claims, while petitioners have argued that the statute does allow in utero injury claims to be pursued in the VICP.In every case, though, the special masters hear the arguments and make the ultimate decisions which can be appealed.

Special masters and judges that have addressed these specific questions have not come to a consensus, though. Some have concluded that in utero injuries can be pursued, one rationale being that the term received should be interpreted broadly to include indirect receipt because the vaccine
asked to remedy harm and what rule of statutory construction says that remedial statutes should be interpreted broadly to achieve their remedial goals. Others have concluded the in utero injuries cannot be pursued and one rationale is that the term received must mean direct receipt, because the statute specifies the oral polio exception. And one rule of statutory construction says that the expression one is the exclusion of all others so the expression of one indirect method of received is the exclusion of others.

Now, the one petition rule has not been widely addressed by special Masters, none of the cases we have , however have been appealed to the Federal Circuit so none of the decisions we have our binding. So, this means that one way or the other issue is not settled. The other issue related to maternal immunization under the VICP is coverage of the vaccines. You will be hearing that new vaccines against RSV and group B strep are currently under development and if approved, they could be exclusively recommended for use in pregnant women, but nine children. So the statute authorizing the BAC the specifies that observation is -- compensation is only available for injuries and deaths from covered vaccines a vaccine is close covered when it is recommended by the CDC, for routine administration to children.

And, the secretary outcome of the vaccine in the vaccine injury table through world making with regards to these types of vaccines that are being developed for use exclusively in pregnant women and would not also be recommended for routine use in children, the question is them, how can these vaccines obtain coverage under the program? The interest in HHS vaccination of pregnant women is really nothing new and you will hear more about this from Kristen Feemster and also cap mentors. In 1995 a C-I-P recommended operative women receive an inactivated influenza vaccine to be given at any stage of pregnancy. And in February 2013, but a C-I-P recommended pregnant women received a Tdap booster in the third trimester beach prevented the department people healthy 2020 goals include increasing the percentage of pregnant women vaccinated against seasonal influenza. Also in HRSA's countermeasures injury compensation program which are so much about it provides a compensation for injuries directly caused by the administration or use of covered countermeasures used in public health emergencies such as antiviral medications or pandemic vaccines.

And this program, HRSA exercised its authority under the Public readiness and preparedness act, to promulgate regulations to implement the program and they issued a regulation that specifies that a child can qualify as an injured countermeasure recipient if the child survives birth and is a born with or later sustained a covered injury as the direct result of the mothers administration aureus of a covered countermeasure during pregnancy. So, a few features about this the VICP important to note, the CICP authorizing statute gives the secretary very broad authority to promulgate virtually any regulation for the administration of the program the secretary really makes all the decisions in the CICP whereas in the VICP the vaccine act cases the decision-making with the court and gives the secretary narrow authority to promulgate only specific types of regulations such as regulations the ad vaccines to the table, add, modify or delete injuries and determine the cost of health insurance for purposes of calculating lost wages.

Also the VICP only covers vaccines by CICP covers products beyond vaccines such as antiviral medications that could be inhaled . So, the CICP regulation on who can be a countermeasure recipient is in reference to a broader array of products such as antivirals. And, my last slide, with this recent interest in maternal immunization, HHS has asked the ACCV to look into issues and concerns surrounding maternal immunization. So, at this point, you will have an opportunity to hear how the ACCV subcommittee has approached issues with immunization in pregnant women and of the VICP and then you will be hearing about the NVAC. Thank you.

Thank you. So, Kristen, are you taking over now?

Yes, I am I so apologize I lost my connection, just as you said my name. So thank you,
for moving back into -- maybe with your presentation. Yes, the goal right now is to present the work we have done really over the past year. And given the background Anna has provided regarding the statutory environment, to present our recommendations. So, I will start with my slides. And,
-- and having some difficulty visualizing the Adobe site allowable amount presentation. So, this will be the presentation of the maternal imposition working group draft recommendations and this is really a summary of the report that is being written and is nearly ready for distribution , once we make the final revisions and received input on the ACCV. Slide 2. This is an outline of what I would like to cover today the first is to provide some background regarding maternal immunization and some of the information we considered. To present our charge , I recommendations and of course open it up for discussion. Can everybody hear me well?

Yes.

Yes.

Excellent, thank you. So, slide three so as Anna just presented, the Advisory Commission on immunization practices currently recommends that all pregnant women with a gestational age of 20 weeks or more receive a Tdap immunization tab is a very acellular pertussis immunization during each pregnancy and all pregnant women received inactivated influenza vaccine and in addition to these current recommendations, there are new vaccines currently under development and it is anticipated that if approved they would be proved to be recommended for pregnant women these are vaccines against respiratory virus and group B Streptococcus. Next slide so, the impact of these current and potential maternal immunization recommendations , the two aspects really so one address the increased risk of morbidity and mortality associated with infection and pregnant women especially infection with influenza in pregnant women. And maternal immunization also protects young infants by preventing transmission of these diseases, pertussis, influenza, tetanus and especially Group B Streptococcus, too young infants who are at highest risk for outcomes associated with these diseases because they are too young to be vaccinated. Maternal immunization works in two ways it can reduce the risk of exposure by preventing disease and mothers and also provides protection to the young inventor the passage of maternal antibodies.

So, we reviewed data regarding safety and efficacy of maternal immunization, and it is not that [Indiscernible--static] passes of maternal IgG especially increases towards the end of pregnancy and the last four to six weeks of gestation so immunization towards the end of pregnancy results in a high level of antibodies that can be passed to the infant and current studies also have the maternal immunization benefits the mother and infant and also have not identified any vaccine related adverse events specific to vaccinated pregnant women and their infants. These are for vaccines routinely recommended for the general population.

And as an aside there are references provided at the end of my slides . But, what are some of the key city outcomes that are considered in the study of maternal immunization? Primarily referred to teratogenicity as well as growth or functional impairment or impaired viability due to in utero exposure to a vaccine. It should be noted many of these outcomes are ones that occur at high rates in the general population, with some estimates here for outcomes including spontaneous abortion, preterm birth, small for gestational age and birth defects. This is in the general population regardless of vaccines received. And, we do know there is no evidence that inactivated virus or bacterial vaccines or toxoid present a risk to the fetus for these or other outcomes .

And the last safety information I wanted to present, we know that the risk associated with inactivated vaccines regarding live virus vaccines there is a theoretical risk that administration of a live virus vaccine could result in transmission of vaccine virus to the fetus and as such live virus vaccines are contraindicated for it ministration to women prior to conception through pregnancy and there are no live virus vaccines currently recommended for pregnant women. However, there has been no evidence of fetal infection or malformation from pregnancy registries if a live virus vaccine routinely recommended to the general population are inadvertently administered during pregnancy.

That primarily summarizes the background information we have reviewed. So, given the benefits and opportunities related to maternal immunization, the successful implementation of these recommendations will require that women and healthcare providers check the safety of vaccines during pregnancy and we also consider it is therefore very important to ensure that the current safety assessment and monitoring processes can effectively define, identify and respond to safety issues. And that the vaccine interesting -- vaccine injury composition program is available from others in infants when vaccines are administered during pregnancy. Given all of that the maternal immunization working group was convened in June of last year to address the need for the VICP to address the evolving recommendations for vaccination during pregnancy and we met both in person, initially via conference call, everyone to two months to discuss and develop recommendations related to four charges I will present in just a moment.

We also have developed a collaboration with the national vaccine advisory committee, maternal immunization working group and we will hear from their working group shortly and also an opportunity to go and present draft -- draft recommendations to their NVAC as well. So, representing our draft recommendations today for discussion and we will submit a final report. So, now I will summarize our charges. And, we have four. So, the first charge focuses on eligibility for compensation for injuries from vaccines that are not currently covered by the vaccine injury compensation program. This speaks largely to -- likely approval of RSP and Group B Streptococcus vaccine that would potentially be exclusively -- if approved would be exclusively administered to pregnant women. And under this charge, [Indiscernible] to provide information to the ACCV regarding eligibility for compensation by the VICP for injuries from vaccines recommended for or sometimes given to pregnant women if they are not recommended for routine administration to children. And therefore not currently covered and summarized some of the legal issues related to the current statues for this. And to identify the pros and cons for covering such vaccines and providing compensation for such injuries under the VICP. And then based upon the discussion develop a draft ACCV recommendation for the secretary.

Our second charge focused upon eligibility for compensation for injuries and infant and from covered vaccines received by the mother both in the was in your new and diverse charge goal to provide information to the ACCV regarding the eligibility to present the pros and cons for providing compensation for such inverted -- injuries and develop draft recommendations. And here is the main issue, while the mother is the recipient of such vaccines the group considered eligibility of those live born infant. -- the live born infant. So the last two charges are detailed here , charge three, we also wanted to provide information to the ACCV regarding the safety monitoring infrastructure and might of expanding recommendation for eternal -- maternal recommendation. And lastly we wanted to review ACCV membership guidelines to consider inclusion of individuals who provide care to pregnant women. In order to include that expertise on the ACCV , to reflect changes in the the VICP. As we explore this charges the working group reviewed data from a variety of sources we reviewed available data about mechanisms of action, safety of vaccines administered during pregnancy, we reviewed available data from pre- licensure trials as well for the and Group B Streptococcus vaccines. We reviewed the current vaccine safety infrastructure, we also reviewed the activities of the maternal immunization working group from the NVAC and also review the current statute guiding program activities in order to determine how to best make a recommendation. I will now present our draft recommendations after all of that background and so as I present these recommendations, the form that will follow this will follow these four areas so the first, to summarize the benefits and challenges of expanding coverage region degradation to provide the actual recommendation .

And look to potential approaches to pursue these recommendations in light of the current statutory framework within which we are working and then to review the benefits and challenges related to each approach. Soper charge one the compatibility of in utero injuries from vaccines not currently covered. So first the working group released -- explore the benefits and challenges related to potentially expanding the program to include coverage of vaccines that are not currently covered and the benefits that we highlighted are as follows. The first is that it does match the abolition of the vaccine injury compensation program national immunization program as well.

Secondly, it does provide public reassurance that injuries from you vaccines recommended for pregnant women may be pursued under the VICP period and lastly , that this would address barriers that the vaccine industry may face regarding liability to foster vaccine development and also ensure an adequate supply of vaccines. The challenges we consider included potential administrative cost to the VICP. Spanning coverage , additional excise tax on new vaccines and additional resources drawn from the trust center for claims for expanded coverage and lastly public perception perhaps as the government is pushing more vaccines, by expanding coverage as well. And as we consider these challenges important to emphasize is expanding

coverage is not equivalent to making a recommendation for a new vaccine and it is important to emphasize the potential benefit to the public as well to the protection of pregnant women and young infants. So after the discussion of the benefits and talents -- challenges related to expanding coverage, we would like to suggest the following recommendation. And, that is on the next slide that follows the ACCV recommends that the Secretary work to expand coverage under the the VICP to include vaccines that are recommended for categories other than children such as pregnant women and not specifically recommended for Britain administration it shall deliver, the Secretary take whatever steps are necessary within her legal authority to attain such expansion. So we opted to leave the Avenue of pursuing this charge up to the Secretary because there is more than one potential avenue to consider. The two primary approaches that we considered for this charge are as follows and so the first is a statutory amendment . And this reflected information and -- Anna provided as well, the Secretary could propose legislation through the a 19 process which would explicitly include language to expand coverage to vaccines recommended for categories other than children, i.e. pregnant women. And pros are benefits that there would be a definitive path, however the drawbacks that one, it could take a significant amount of time and may not come to fruition and additionally the Secretary may have little control over the ultimate statutory change.

So the potential avenue the Secretary could consider is administrative rulemaking to adopt a broader interpretation of the current statute so that changing the statute this would be rulemaking through broad interpretation of the current statute and this way, considering interpretation of routine administration children to include administration of vaccines to pregnant women because such a pregnant population make with individuals in the pediatric age range. Additionally an infant could be considered the beneficiary of maternal immunization through the receipt of maternal antibodies. So for these two reasons,

this provided an avenue for broader interpretation of the current statute, the pros of this approach that it is expeditious and would also provide flexibility for the be VICP to adapt to changes in the immunization program. And

the cons we considered as it would also set precedent for inclusion of other vaccines recommended for individuals other than children and this could require significant changes in program operation and expenditure of resources. Continue to include other vaccines as well.

One important caveat I think for consideration by the ACCV related to this approach is that this approach does require that a broad interpretation by the Secretary is legally permissible and consistent with the congressional intent of the statute. Moving on to charge 2, so this relates again to compensability of in utero injuries from covered vaccines and here is where we considered live born infants as eligible individuals. So, our discussion of the benefits of challenge of expanding coverage or are really similar to charge one,

didn't want to listen again here but did want to provide some discussion of -- regarding live born infants as an eligible individual. So, our focus upon live born infants as an eligible individual is based upon the following considerations. The first is the term clearly defines the infant as a separate individual from the mother and therefore should be considered a separate injured individual. Secondly a fetus is dependent upon the mother and it is difficult to separate injury to a fetus from the mother and thirdly miscarriages and/or stillbirth do not prevent the same challenge or liability as injury claims as can be pursued as the mothers claim.

So the suggested recommendations for charge 2 is as follows. That is that the ACCV recommends that the Secretary should support eligibility to pursue compensation for injuries sustained by a live born infant whose mother receive the vaccine while the infant is in utero. In order to further her support we recommend that the Secretary take whatever steps are necessary and within her legal authority. A few options that the Secretary may wish to consider, this is similar to charge one, statutory amendment pursuing administrative rulemaking and then also a third approach that applies to discharge and that is a litigation strategy.

So statutory ammendments , similar to charge where the Secretary could propose legislation through the A 19 process which explicitly includes language here that would specify eligibility of live born infants whose mothers received a vaccine while the infant was in utero. And again, the pro of this approach is it does represent a definitive path and again drawbacks is this could take a significant amount of time and may not come to fruition and the Secretary may have little control over the ultimate statutory change. The second potential avenue or approach is the administrative rulemaking to adopt a broader interpretation of the current statute and its broader interpretation would be based upon the consideration that and then directly receive a product of maternal vaccination through passage of maternal antibodies so they could be considered [Indiscernible] until the vaccine. The benefits and pros of this approach are again that it would be expeditious and provide flexibility for the VICP to adapt to changes in immunization program, additionally we discussed issuing a rule as public and present a formal statement which may provide reassurance to the public as well as vaccine manufacturers and immunization program administrators.

And the drawback of this approach it is nonbinding and the court, because primarily because the court is the final adjudicator of claims. Again, here the important is this approach also requires the Secretary have the authority to issue such a regulation. The last approach is a litigation strategy. And here, the two potential avenues one would be to seek a binding decision in the US Court of Appeals for the Federal Circuit by initially communicating a position to extend eligibility on a case-by-case basis. The court makes ultimate determination of eligibility if this is appealed to the US Court of Appeals could yield a final decision that would set precedent. A second litigation strategy would allow petitioners to pursue in utero injury claims, and proceed to education of

that marijuana resulting in a binding Federal Circuit decision.

So the pros of these approaches , the first litigation approach would be binding if there wasn't until up to the US Court of Appeals to the Federal Circuit. And the second approach would allow pursuit of claims in the current program and a special Masters would determine eligibility to this case and the convert approaches the binding decision would acquire -- require a case and multiple appeals limited time especially for the second approach special Masters they fight against eligibility so the Secretary would have able to dictate how the court may determine eligibility but the Secretary could present her opinion. To summarize for charges one into this is a lot of information, the working group suggests that ACCV recommend the Secretary one, work to expand coverage under the the VICP to include vaccines that are recommended for categories other than children such as pregnant women and not specifically recommended for routine administration children and two the Secretary support eligibility to pursue compensation for injuries

sustained by a live born infant is mother receives a vaccine by the infant is in your. The Secretary may take whatever steps necessary within her legal authority to achieve these goals and consideration either supporting a statutory amendment pursuing administrative rulemaking or supporting a litigation strategy. Each approach comes with unique benefits and challenges we also suggest recommending that the Secretary solicit input from a variety of stakeholders including the public, vaccine manufacturers and immunization program administrators.

Kristen? This is Anna if I could backtrack and not the important caveat about the litigation strategy option? I just wanted to add that litigation strategies, at the end of the day, are made by the Department of Justice. The Secretary of Health and Human Services does not make litigation decisions. And, so, that's why this decision is worded that the Secretary would support litigation strategies. It is sort of akin to those statutory amendment option the Secretary does not have the authority to amend a statute Congress has the authority to do that all the Secretary can do is support an amendment.

(multiple speakers) communicate her opinion -- not make the decision. Thank you.

Sure.

This is Ann Pron, can I had such a suggestion about the previous slide, charge?

Yes, of course.

And recommendations of the Secretary to support eligibility to support compensation for injury sustained by live born infant, the mothers received the vaccine that's whether not currently given to infants? I mean the first one sort of spelled out (multiple speakers).

The second chart refers to covered vaccine.

Doesn't say that FYI.

I apologize for that, the charge I think the text of the charge -- says that.

Okay.

Any other questions before? That was a lot of information -- before I can [Indiscernible] charge three is to provide information regarding vaccine safety monitoring infrastructure so monitoring for safety events during pregnancy does take place through a variety of avenues including the vaccine adverse event reporting system, pregnancy registries maintained by vaccine manufacturers and also through active surveillance the the vaccine safety datalink. There is also a recently established system called the vaccine and medications in pregnancy surveillance system that prevents perspective and [Indiscernible] study safety exposure to vaccines and medications during pregnancy and there is a link to a website there that explains in more detail what they do but there are multiple avenues for ongoing surveillance of safety of vaccines administered during pregnancy.

There are also several recent studies and reviews that explore the use of the current vaccine safety monitoring tool specifically for maternal immunization. And, provided some of those references at the end of the slides presentation. Charge for regarding ACCV membership. The working group considered as the immunization program expands, it is important to ensure that the appropriate perspective and expertise is represented within ACCV membership. We therefore suggest recommending that the Secretary consider having an obstetrician with maternal fetal expertise as one of the health professionals under the current ACCV charter .

The next ACCV charter said the commission should be composed of nine over three members were help -- professionals [Indiscernible] US government who have expertise in the healthcare children, epidemiology, etiology and prevention of childhood diseases and adverse associations -- adverse reactions associated with vaccines of whom at least two should be pediatricians. So the current charter it appears that this recommendation be pursued. The next slide, 20, so this concludes the presentation of our draft recommendations I would like to acknowledge all of expertise and input and hard work of maternal immunization working group and other members of the vaccine injury compensation program who also have supported her work and provided expertise. Thank you all very, very much and especially to Anna for ensuring the legal context was appropriate , thoroughly described and all the language was accurate.

Thanks you, Kristen for staying on top of the potentially volatile but important , new initiative in bringing all the disparate places together into a new hole.

Charlene?Did you identify yourself?

That was Charlene.

Thank you, Charlene. And slide 29 and 30 I do include the references will we utilize in the report. That is currently under -- currently being written. So, with that
-- will first open to discussion and also request a motion to accept the recommendation unless there is a request for additional information or revision?

So, Dave King speaking, Kristen, that was a terrific job, well done to all the members who worked on that, you really -- you have my name on that last slide but I really did nothing to make this work but thank you for -- just thank you for your efforts here, and everyone else who worked on it. But, '-apostrophe in terms of how you want to pursue this. Do you want to pursue each one of those of the separate? Or, do you want to do them all bundled together?

Perhaps we should do it each one separately? Date each are going to stand on their (multiple speakers).

That is kind of my thinking that they are indeed, since they are separate, and might be easier to just discuss each one as a separate component and, do you want to -- so, I will let you then figure out how to move forward without.

Okay, so, in that light, actually, would be helpful, before we discuss , to hear the presentation from the NVAC maternal immunization working group?

This is Anna I think it would be helpful.

I agree, I think it would be coupled visible provide a broader -- broader context regarding all the activities and immunization program national immunization program related to maternal immunization.

So Dave King here, let's do that then.

Okay.

[Captioners Transitioning]

I am Dr. Catherine Torres and I think all of you for inviting our group to present today. At the overview of the national vaccine advisory committee and the maternal immunization working group. I believe you should have the slide or have them. We will go through the second slide, the importance of maternal immunizations. We know with maternal and neonatal tetanus, mortality rates are extremely high in developing countries especially where there is inappropriate medical care. We know that hygienic delivery and core care practices in immunizing also tetanus has led to 93% decrease in neonatal tetanus since the 1980s. But we do still see some neonatal tetanus in the United States because there are some moms who are not vaccinated and choose to have homebirths and do everything very natural. So we do occasionally do see neonatal tetanus. Influenza, we know there is high morbidity and mortality rates that have been associated among pregnant women with influenza are and the pandemics of 1918, 1957 and recently 2009. Pregnancy is a significant risk factor for increased illness and death and pandemic flu. Maternal immunization vaccination has -- documented benefits to both mom and the newborn. Pertussis, infants less than three months of age are particularly vulnerable to severe disease and death because we don't start immunizing them until age two months and we also -- they need to have at least two doses of the cap to be effective. As a primary strategy to protect infants until they're old enough to be vaccinated. We know that maternal immunization is a test to protect the newborn. On slide three, healthy people 2020 which

most of you are an error of. I think is start with healthy people 2012. But we know that this is an initiative led by the assistant secretary which focuses on a 10 year plan of health objectives. Goal 1.6 to reduce cases of pertussis among children under the age of one and goal 12, it is to increase the percentage of pregnant women or vaccinated against seasonal influenza. Recently in February of 2013, the advisory committee for immunization practice which is known as the ACIP recommended that women receive a T Depp booster. The ACIP recommended to all pregnant receive inactivated influence of vaccine and the dose can be given at any stage of pregnancy. Pertussis, what we know today is 2.6 women are vaccinating with TDA P and 53% of women with influenza during pregnancy.

On side floor, the national vaccine advisory committee. Formed in 1987 and it's a federal advisory committee that advises it makes vaccine and immunization policy recommendations and to the assistant secretary of health in his or her testing of the director of the national vaccine program on matters related to program responsibility. It studies and recommends ways to encourage the availability of adequate supply of safe and effective vaccine in the United States. It recommends research priorities the director should take to enhance the safety and efficacy of vaccines. It advises the director in the implementation of the national vaccine program responsibility and the plan. That identifies annually for the Rector the most important areas of the government and nongovernment cooperation related to the national vaccine program responsibilities and implementations of the plan. It convenes working groups that recommend -- stakeholders such as academics and Effexor's health industry, healthcare providers, consumers, nongovernment organizations, federal -- and local Department of Health. The next slide -- I wanted to show you the reporting structure of vaccine and immunization related HHS Federal agencies. We are little different than you, you report directly to the Secretary and the national vaccine advisory committee reports directly to the assistant secretary of health. As you can see the advisory committee on immunization practices reports to the director of CDC. Next slide. The charge for the maternal immunization working group has become to parts. Part one was to review the current status or current state of maternal immunization in existing best practices, and to identify programmatic areas to the implementation of current recommendations related to maternal immunizations. And make recommendations to overcome these barriers. In the second part are to identify barriers to an opportunity for developing vaccines for pregnant women and make recommendations to overcome these barriers. Both of these are going to be addressed separately, currently the maternal immunization working group is on par one. The approval process, NVAC will accept the charge and it accepted the charge in the formation of the maternal immunization working group of June of last year and the maternal immunization -- began working in August of 2012. What we see are the potential synergies between the ACCV and NVAC for dancing maternal immunizations. The maternal -- the NVAC maternal immunization working group has been in close communication with the ACCV in developing discussions and recommendations. So why NVAC? There's a lot of uncertainty surrounding maternal immunizations and vaccine liability that may create barriers that limit obstetrical providers willingness to administer important immunizations during pregnancy. There are uncertainties surrounding maternal immunizations and vaccine liability that create barriers even to the development of future vaccines that have the potential to greatly improve newborn health. The consensus among multiple advisory groups is that this will be -- an important issue and it sends an important message to HHS and others and helps build solidarity around the proposed recommendations.

Next slide. This is a slide of who our members are. And who the different experts that participate and liaison representatives and the difference staff. We have quite the group and have kept -- a great group to work with and have kept us will informed to present some great recommendations. The next slide is our working group process. We have an inaugural meeting in August of 2012. We meet about one to two times per month by phone, and we would have presentations by different subject matter experts which would then followed by group discussion. A total of 13 presentations on maternal immunization topics which included epidemiology, patient barriers, provider barriers, vaccine financing and vaccine liability. We looked up public financing. We looked at development of vaccines and the use of pregnant women. We looked at

regulatory considerations and one of the most important things is communication. There've develop recommendations for presentation to the NVAC. And then we will develop a white paper that provides background and rationale to the recommendations. One of the things that we really focus on was to improve our providers of maternal care. And as you can see, it's just not OB/GYN. Their family practice docs and certified nurse midwives and advanced practice nurses and physician assistants. As always, the pediatricians and neonatologist get involved when families are part of the cocoon where dads or grandparents want to be immunized and they can sure -- and make sure that all children are immunized especially when it comes to pertussis.

Our recommendations fell into five focus areas. The first was to enhance communications directive is safety and effectiveness of all currently recommended immunizations during pregnancy as well as future vaccines. The second focus area was to focus on comprehensive efforts to maximize obstetric provider recommendations and administration of all recommended maternal immunizations recommended for this population. Third, we wanted to focus efforts to improve financing for immunization services during pregnancy and postpartum because we know that it's not just buying the vaccine and giving it to my you have two storied, make sure its documented correctly, and that providers have to have the ability to finance those procedures and also be reimbursed for those things. Support efforts to increase the use of electronic health records by maternal care providers to strengthen the immunization information system and vaccine surveillance systems for pregnant women so we can see how effective these vaccines are as follows to make sure that people are being vaccinated. And five, recognize and address current vaccine liability barriers to optimize investigations and uptake of recommended and future vaccines during pregnancy. The maternal immunization working group recommendations align with goals two, three, and four of the national vaccine plan. There are five goals in the national vaccine plan. We look at three of them. To enhance vaccine safety, to support communications to enhance informed vaccine decision-making, and to ensure a stable supply of access to and better use of recommended vaccines in the US.

Our next steps. In June -- next week we will present our draft recommendations to the national vaccine advisory committee for discussion. The recommendations will be revised based on the committees feedback. In September of 2013 we will draft recommendations and draft a report and this will be presented to the full NVAC for deliberation and vote. And in the fall, hopefully by the fall, for sure by the winter of 2013 we are going to proceed with the third component of the charge, which is to begin analyzing barriers and opportunities for developing vaccines specifically for the use of pregnant women. Such as group B strep or RSV. and the recommendation are to follow. At this time, I cannot present our recommendations because they have not been presented to our committee but once they are presented to our committee, then not we will again get feedback to the ACCV through those members were present on your committee. I want to thank you for the opportunity to present and it's been great to work with both groups and to hear the things you are working on as our leadership has worked with some of your leadership and I think we will put together some great recommendations from both committees. If you have any questions at this time, there are several people on the call that can help me answer any questions.

Thank you. Are there any questions for anyone? David King speaking.

This is and -- I have lots of questions. It's a lot of information. I'm just not sure I heard it prickly. The recommendations for group B strep and for respiratory syndrome virus for pregnant women is for each pregnancy as well?

That I don't -- I don't know where they are with that. Those are still in the developmental stages and so the ACIP is not -- has not put out any recommendations because they think they are still in the research part of it. Am I correct Jennifer?

Yes, that is true. Those vaccines are still under development, and so until they are licensed them there won't be any way to say with ACIP recommendations or how they will be treated during pregnancy. We just don't know yet.

Thank you. I think it was addressed in one of these presentations, but I know from the past, sometimes it's difficult to get OB/GYN's to give out HPV vaccines. Just wondering how you're going to approach them with the -- and that is covered under the vaccine compensation program and we will hit them with all these others for pregnant women. Just wondering how that's going to be executed.

I think we have really looked at communication and how information patients get or providers get sometimes. They're not well informed. Making sure that they are getting will informed information. Also making it accessible. Part of the problem with HPV was the cost. Of HPV. And then people were very worried about infertility, there was a lot of scare among the problems with HPV. And I think we have given a lot of HPV in the United States and now we are able to look at some of the true side effects from HPV. And some of those there really never existed. I think it's just putting together better communication plan for providers, as well's making sure that they are being reimbursed for giving me vaccines.

This is Steve just to add onto that, clearly are raising a good point and this working group and also you are -- will hear later, not to steal some of my own thunder here but later on when I give the update, I will be telling you about HPV working group that is formed and NVAC and one other charges is to create days increase rates for adolescents. How that will happen communication strategy for -- are being chewed on and hopefully we will have firmer plans to tell you about in the future about specifics.

Great. I just have one more comment. I guess it never occurred to me until I heard Kristen's presentation that one way to get the immunization some cells may not be manufactured unless it will fall under this program. Because they don't want to take that risk of liability. That makes a lot of sense and I hadn't put those two together until I heard your presentation. Thank you.

It certainly speaks to the role of the program, and sustainability of the vaccine program in general.

Rate, thank you.

Kristin, how do you want to proceed? Take each one of these one by one?

Yes, let's do that.

Can we get them placed upon the screen and will you be able to do that?

First we will look at the recommendations for the first charge. Slide 16. Similar to what we did for the process group, draft recommendation. Request day -- to consider the recommendation. And then we can open it up for discussion?

You want to start with charge one or which one do you want to start with?

We will just go one, two, three, four. Charge one is on the table.

I believe it is currently on our screens. Someone should make a motion.

And someone from the working group make a motion?

Move for approval.

This is [Indiscernible].

Thank you, that is the move to approve. There is a second on the table.

I second. This is Charlene.

We cannot discuss this and then we can bring it to a vote.

This is Ed Crouse. I think that the recommendation makes tremendous amount of sense for all the reasons that have been explained very thoroughly and carefully in the last hour. And I like how it is worded. I think it provides wiggle room for the Secretary to figure out the best approach. And stays focused on accomplishing the goal -- goals that are important to accomplish.

Does an oil 70 other comments? If not I will this bring -- progress to a vote.

It's only upon rereading it now that this would also been open up coverage for herpes zoster vaccine and other vaccines that are not given to children. Is I correct? It doesn't say --

We talked about that. Because we don't specify just pregnant women. For categories other than children. And in that way it allows us to be flexible related to the evolution of the immunization program in general. I don't know if you want to speak to that as well. But that's -- we decided to worded in this way.

The comment was correct. It would -- pending coverage of categories of anyone other than children and so it could include the vaccines that you mentioned there, and Kristin did a really good job of going through the benefit and the challenges of that's, and one of the challenges is that Congress intended the program to provide compensation for vaccines that are recommended for children. And of course we know that this coverage is injuries to adults as if they receive those vaccines as well the Congress did set those parameters, and of course, one of the options that we -- that the group mentioned is that the secretary could seek a statutory amendment that would expand those parameters. But if those parameters were extended and more vaccines would be added to the table, that's a big administrative cost to the VICP. Congress would have to work through additional -- to add excise taxes to the vaccines, and they may or may not be wild about having to do that. And it is more of an administrative -- it could be an administrative burden on HHS, DoJ, and those are the things the group talked about.

This is veto. An important question I have is the commission considering routinely recommended for other groups or just recommended for other groups? There is a difference. Routinely recommended would be for vaccine like the zoster vaccine for the tallies -- polysaccharide numeral cockle vexing which are both not currently covered by the program but they are routinely recommended for geriatric appellations. Other vaccines are recommended just for specific situations like travel vaccines or -- if one were to be bitten by a raccoon and you get a rabies vaccine. We need to be clear what we are asking the secretary to do.

This is Anna. I can speak to that. The report goes into this in more detail and you will be receiving the report, and the report does explained that the suggested recommendation that the secretary would work to expand coverage and include vaccines that are routinely recommended. The answer to your question will be yes that's what it supposed to be. That is probably just an oversight. That word should then be added to that recommendation there.

Then it is the intent of the commission to recommend not just for [Indiscernible] but also like the geriatric population?

That was what came out of the workgroup.

Okay.

Other objections to that broader target rather than specifically targeting pregnant women?

This is [Indiscernible], I would support more easily if it was for pregnant women. I think that we need more time to consider whether we are going to include -- from pre- birth until death.

That's fair. That is fair enough. The justification of everything we reviewed of the -- I think as we were considering the wording we were also thinking about the fish including some flexibility and recommendation itself, but that's a good point. Is not based in the same [Indiscernible] data review.

This is Ed Crouse. I think that it is a very important issue that we should take up, about encouraging -- about potentially making a recommendation for the secretary to expand coverage under the VIC to include categories other than pregnant woman, that I do -- I think in this point is a good one. That since this is specific to maternal health, or maternal situation, I think that we should agree that we will take up this issue of a broader recommendation about expanding the act to include things like [Indiscernible] and other vaccines that are routinely administered to non- children. I think we could take of for example in the process workgroup is one of the recommendations. I don't want to make work for our workgroup, but it seems to me it would fit within the purview of what we have been considering in terms of [Indiscernible] recommendations.

This is Dave King. Lewis [Indiscernible] how do you feel about that?

Do we have the data? To consider when we go into this particular area? They have all the information on the pregnant women but do we have the information for the -- any other groups?

It is obtainable.

That would be up to the workgroup to do.

I guess one more thing to do. We still have several more years. Before I get out of this.

If you believe the work process group can handle the workload, then I would say -- to that workgroup. That specific issue. And Kristin with that then allow for this to just be focusing on the maternal to pregnancy component of it?

Yes. As I look -- we're talking about in utero injury so it does already -- if we want to consider a vaccination separate for vaccinations from pregnant women it does allow us to do that. And we can change the wording.

This is Anna Jacobs. One thing you could consider doing is revising the wording of that recommendation so it could state the ACCV recommends that the secretary work to expand coverage under the VICP to include vaccines that are routinely -- recommended for pregnant women.

Including vaccines that are not specifically recommended for routine administration to children?

That is perfect.

That's an amendment to the original.

That would be an amendment to the original motion. We are going to assume that -- doing need to go through the formality but if we want to -- Charlene would you like the formality of this?

It's a friendly amendment, it can be made as a friendly amendment so if Kristin accepts it, then it's accepted.

Kristin will you accept that friendly amendment?

I will excepted from the amendment. If there are no objections from the workgroup I will accept the friendly amendment on behalf of the workgroup.

No objections.

As the cherry think we should bring this to a vote. All in favor of the amendment as proposed with the friendly component incorporated into it, say aye.

Aye.

All opposed? I know that there are not commissioners but I think that they are still in need [Indiscernible] Michelle have you been able to rejoin us? Then it will be a vote of 820 on that.

Thank you everybody. Let's go to the recommendations for church two, slide 20. I know we need to add a -- to make sure we indicate it is a covered vexing. And that is in the actual recommendation. Mayor requesting motion to approve this recommendation?

There is a motion on the table. Has anyone seconded it? Anybody?

I will second. This is Charlene.

You can second even if you're on the workgroup. Don't have it up for discussion. Is there any discussion around this?

What is the wording you said you would change?

You had asked if this was for a -- only covered vaccines or any vaccines given to pregnant women? It a referred to covered vaccines for recognize that's not what the recommendation says on the slide. That's all.

This is Anna. So the recommendation would be changed -- it is on the end of the third line, it would say received a covered vexing. That would be that change.

Exactly.

That would be a friendly amendment again.

That is the intent . The charge is about compensability of in utero injuries from covered vaccines. Yes, that would be a friendly one.

Okay.

Any other comments? I think we will bring it to a vote. All in favor say aye.

Aye.

All opposed? This again is eight to nothing. We were move on to charge three.

Moving right along. Charge three, really was about providing information. So this is slide 25. Do I move to accept the information is provided or see whether or not additional information is requested?

You did not propose a recommendation.

There is no recommendation so I don't know that we need to vote on anything.

Charge number for which is slide 26. We recommend the secretary consider having an obstetrician -- maternal fetal expert piece.

You're making the motion.

Yes man move that we were approve?

A second?

This is Sylvia I second.

Any discussion on this?

This is Anna Jacobs again. I just wanted to add that the workgroup also considered that the obstetrician could also fit into the category of one of the members of the general public. So the recommendation -- pardon me, I am pulling up the report right now. The report states that the ACCV recommends that the secretary consider having an obstetrician with maternal fetal expertise is one of the health professionals or members of the general public. I can just provide further explanation.

Before you do, there is a recommendation -- Dave King speaking, that had already been passed regarding the general public, and it had to do with an adult who had been vaccine injured or taking care of a vaccine injured adult. And since I recommendation has already been made by the commission, and the statutory component is that the other two -- be related to vaccine injured children, I'm just tossing out there, is there room for this to be able to be done in light of what the mission has already recommended?

I had brought that point up earlier. There is room instead of --

Charlene is this you?

Yes. This is Charlene. We have a couple of pediatricians on the providers -- for people who work with children, I don't know if there is any statutory limitations on what the specialty of the providers are.

I believe there is room under the health professionals for this. When Anna talked about the general public one, that's where the antenna one up and I said we're Vardy done something that relates to that. Under the health professional one I think -- if you thought they may have room.

This is Christian. Kristin. The requirements for the -- so that we shall be pediatricians but could be an obstetrician. This is why I specified health professionals. Re: a member of the general public it is true when we initially wrote the recommendations for the report, we -- including both options. But Charlene had also raised the point that we had recently approved a recommendation to use one of the general public -- for -- so we would have that is

I represent the nonphysician providers and I happen to be in pediatrics, pediatric nurse practitioner. I doing that then you remove any one of the health professionals other than the physicians.

That is a good point as well.

Is very statutory language that two of these healthcare providers must be physicians?

I wondered does that mean MMD, is adjust anybody with pediatric expertise? We can look into that? Because the pediatric healthcare provider -- means a pediatric healthcare provider.

I am looking at the charter. And under that section where it says the commission shall be composed of the following. Dave King speaking. Nine members appointed by the secretary as follows. Under subparagraph A, it ends with the phrase -- it starts with three members of our health professionals the has -- ends with the phrase of whom at least two shall be pediatricians.

The question is whether or not pediatricians is strictly defined as someone with and M.D. or pediatric healthcare provider who could be a practitioner?

When you think of the word pediatrician want to think of? Dr. Or someone else who might work with children?

And our pediatric practices we both have M.D. is and MC's for considered it very careful positions.

As a member of the public I think of it as a doctor but it could be that I am thinking incorrectly here. You're closer to the professional side with the night. It may be that if you have heard of both, there may be room.

I suppose it depends upon how much latitude we have. We know exactly what the intent was? Can we still make the -- or do we just need to clarify?

This is Anna Jacobs. At the recommendation is that the secretary consider. And obstetrician. Because at the end of the day the secretary will interpret the statute and the scope of the charge the secretary will decide what it means and whether she can fit individuals of certain categories. And so what the ACCV would just be doing is to recommend that she consider it. The ACCV doesn't have to say here and determine what the statute means.

I agree.

It could be a --

The wording though is as we see on our screens, is that what it means? The secretary consider having an obstetrician with maternal fetal expertise as one of the health professionals under the current ACCV charter? Is that what we are saying what the

Yes, that is the wording.

The slide does not match up with the report. I think --

We may need to amend the report them.

The report is right.

But I don't think we can suggest -- I don't think we have a general public slot at this point because we have already voted on a recommendation to have one of the general public spots be an injured adult, vaccine injured adult and the other two must the parents of children correct?

That is correct. And so what would be happening here is that if we were to recommend that it include one of the general public, I think that we would be inconsistent in our logic flow of what we are requesting.

This is [Indiscernible]. Has that recommendation already gone forward to the secretary?

As far as I know, it should have.

The ultimate thing that we are saying is I think that we want the commissioners to be thought through from a number of angles. I don't think it's redundant to say as either member of the general public or a health professional, because as I am hearing from -- Anna said that -- it's ultimately -- the secretaries going to make that decision and we are saying to her by doing all these different things that we don't know that the membership right now is consistent with the population that seems to be covered to receive .

Provide latitude to the secretary to expand memberships .

We can have that wording back.

This is Ed Crouse. I don't want to digress but I would rather -- I agree with Dave -- Dave King's comment. If we are now making a recommendation that -- it does conflict with what we recommended previously, I think it's very important that there be representation on the ACCV of a person -- of a vaccine injured adult or someone who has taking care of a vaccine injured adult. That is the only slot that would be available. I don't want to undermine that recommendation. On the other hand, I fully understand the wisdom of recommending that someone with maternal fetal health expertise be considered as part of the mix of the medical providers. But I don't want to prioritize that above having a vaccine injured adult.

This is Dave King speaking. And obviously I am in agreement with you. So my recommendation and Christian, you can choose to go with this or not, is to go with what you have on the screen. And get support. Otherwise I don't know whether you really want us to bring this to a vote right now.

If we don't vote on it now -- without changing this charter, it seems like this is our only --

I would vote on it without putting in the general public. I would change the report, not the resolution.

Are you comfortable doing that?

In the end is something we need to be and it won't pass any more think about another approach. Bring it -- we can bring it to a vote. I'm not sure we have another way to present it without suggesting that one of the general public spots also be considered.

I am confused. What I'm looking at is that it is one of the health professionals.

That's correct.

Not one of the general public.

I'm saying there is not another -- this is the only way to do it unless we present what we have written in the report. Which is to consider other one. Which presents a conflict for some but not for others. There isn't any other way to achieve changing the -- membership under the current charter.

What is it that we are voting on?

Let's but what we have written in front of us.

This is -- I want to propose [Indiscernible] for others but in reality, I don't know what the numbers will be for pregnant women. But we have a lot of numbers of adults right now. The other issue for me is should there be professional health, and certainly an obstetrician maternal fetal health is pretty narrow in that regard.

That's an important point as well.

That's one thing that somehow to me the whole composition of the commission --

Do we need to potentially consider addressing this charter? We are limited. If we would like to include all of these perspectives.

In lieu of the numbers -- in terms of -- in terms of the settlements and everything else. I think the board -- the program is moving further and further away from being just a children's program. I am not saying this isn't a good idea, but I'm saying -- I just think that the whole structure needs to be looked at. In lieu of of the program is working now in 2013 as opposed to how was in 1986. I know that is not what is up here.

Christin do you want to move forward with a vote? I don't know whether we are love to entertain a motion to table or anything like that. Charlene as the reportorial expert do know what we are allowed to do here? May be Charlene is looking it up.

I'm sorry, I had my mute button pushed him sorry, I was talking. What I was saying -- is that I just got elected to be posted and I am not to duplicate. But tabling it I know will not address Christians concerned.

Tabling it will not address Christians concerned but tabling might allow people to think this through more detail rather than giving up or down vote right now.

To consider whether we need to -- look at the charter or try to work within --

Right. Unless you want to move forward with it as is currently worded. But I think that and raises -- are we too narrowly focused? I think there a lot of issues. But the work -- did they workgroup cover all of those issues?

Our focus really was considering one aspects of the program would -- support successful in the limitation of maternal immunization recommendation, so we really focused upon what kind of expertise would be helpful to have on the ACCV related to maternal immunizations. And what we can do within the current charter. So we didn't have extensive conversations about -- whether this would preclude our ability to have -- internal medicine provider for example.

Okay.

Unless I am -- we didn't really --

We did bring up the issue. This is surely. Would bring up the issue about the public members but until this conversation I did not realize that there was statutory language is said to have to be pediatricians. I thought it said physicians.

This is Vito. There is a specialty that is a pediatrician but also internal medicine. A four-year residency. One thing the Secretary could do is look in that population for folks who would be interested and who are qualified. And I would cover a broader range than just to pediatricians. That is just another thought. That the commission could suggest or -- to increase the adult scope on the physician side -- composition of the ACCV.

Did you repeat that? What did you call that? The Mac med peds.

Med peds.

We'll training and internal medicine and pediatrics.

They still think from the working group perspective that it is important to include someone with expertise in maternal fetal health. It's hard with our overall package of recommendations.

This is Ed. What if we just left it this that of saying obstetrician we say the secretary consider insuring an individual or health professional with maternal fetal expertise. Make it broad enough that it doesn't conflict with our earlier recommendations, but that it conveys a sense that it is important that this expertise be included in the mix of qualifications.

I would say healthcare professional with obstetric expertise. Maternal fetal could include a neonatologist.

That is true.

I would be fine with that articulation. This is Ed.

With that Ed, with that articulation that Vito provided but really what you are suggesting, would that be considered a friendly amendment?

Yes that is a friendly amendment. I think it does provide a little more flexibility that is a family medicine provider -- I think this is a good approach. signals that we need to expand membership expertise. I like it. Friendly amendment.

From a moment accepted. No further discussion, I think we should bring this to a vote.

Can someone repeat the --

Yes I think that is a reasonable request.

Be friendly amendment is to change of wording to consider having a health professional with obstetric expertise or -- expertise in absurd tricks is one of the health professionals under the current ACCV charter. Is that correct?

Yes.

Okay . Let's bring it to a vote them.

The friendly amended --

We have that motion.

I'm sorry, we do.

All I'm doing is bringing it to a vote. All in favor?

Aye.

All opposed? We are still eight commissioners is that correct what the

Yes.

Not on. One is not here. Okay. Very good. Will done. And really to the commission as a whole, and helping fine tune that and make it workable resolution.

Thank you so much everyone. Let's move on in the interest of time. We have the update on the immunization safety office, Centers for Disease Control and Prevention, that would be Dr. Tom -- Dr. Tom Shimabukuro. Are you prepared?

This will be a pretty short update. The Advisory Committee on Immunization Practices is meeting in a couple of weeks. So I don't actually have a presentation to give on the outcome of that meeting. But for the next meeting I will. I will give you a little highlight on that. On slide two, the topics presented today at the June 2013 advisory committee on immunization practices, meaning preview. I will talk a little bit about CDC's avian influence -- response and then go over some recent selected publications. There are a lot of -- the June 2013 ACIP meeting, there will be quite a bit of safety presentation or some presentation given at this meeting. There's a Japanese encephalitis vaccine session during which time the safety and immunogenicity of Japanese encephalitis vaccine in children will be presented. The General recommendations on immunization working group is going to have a session and they will be discussing preventing and managing adverse reactions. There will be a human papilloma virus vaccine session. During the session, Merck will discuss -- discussed the registry for Quadra valent HPV vaccine that they a pet maintaining. Just to let you know if you want to look at the draft agenda, it is at that link on the bottom of the slide. You can get the entire agenda. Moving onto slide four, there will be a rotavirus vaccine update on [Indiscernible]. This will be a pretty extensive review. We'll include data from the vaccine safety data

link. Vaccine adverse event reporting system. The Post licensure rapid immunization safety monitoring system which is and FDA system. And also a presentation of Australia surveillance data. During the session there also be a summary. Of the risk and benefit -- in the United States. And finally, there will be an influence a session during which time there will be a vaccine safety update for the 2012/2013 influences session. I will be giving that update.

Moving onto slide five, if you have been following the news for the past couple of months here, you are aware of of the adhesion of one of break in China and in response to this in early April CDC activated to support to support avian influenza and if you're interested in learning more about [Indiscernible] influenza and what CDC is doing about this, you can go to this link. It's a webpage, frequently asked questions at the link you see there in the second bullet. And what I am presenting on this is all publicly available information that I've pulled off of CDC's website. And just to let you know that HHS and its partners are taking steps to develop candidate vaccine viruses and are planning on vexing clinical trials. CDC specifically is working on developing candidate vaccine viruses for the vaccine manufacturers. I want to say that these are routine activities that CDC and HHS and it partners take whenever a novel -- whenever a virus is detected. Typically the CDC lab will receive specimens, and they will develop these candidate vaccine viruses which they will distribute to the vaccine manufacturers for making candidate vaccine lots four vexing clinical trials. A similar thing happened last season one the variance was detected. In a relatively small number of individuals. Primarily visiting -- who had contact with animals a lot of them out these County fairs. These are fairly routine activities for CDC and HHS in response to detection of novel influenza a virus. And these candidate vaccine viruses could be used to manufacture vaccines if one is needed. If you want additional information, you can access CDC's website at the link below. Moving onto slide six. I will go over several recent publications which have come out since the last time I spoke to. Dr. DiStefano was the immunization safety office director. Just cannot with a paper, increase in exposure to anybody stimulating protein them polysaccharides in vaccines is not associated with a risk of autism. And what the authors did here was do a secondary review of a data set that was used previously to look at they Marisol in autism. They looked at the exposure of antibodies stimulating protein them polysaccharides. these are the substitution -- substances which stimulate an immune response. They look at the total load of these antibodies emulating substances during the first two years of life. And that is really -- summing up the number of these proteins and polysaccharides in the total number of vaccines. The load you're getting in the first two years of life. And their conclusion was that exposure to these antibody stimulating proteins was not related to risk of autism spectrum disorders in children.

This is Ed. Just a quick question. What was the control group?

I have the abstract in front of me. They are looking at children with autism -- this is a vaccine safety datalink study. There identifying children with autism in these managed care organizations and then the controls were children that were matched, children -- matched by birth year, sex, and in the specific managed-care organization. By the specific VSD site.

Okay, thank you.

Another paper that is come out saying -- Post licensure surveillance for prespecified adverse events pneumococcal conjugate vaccine in children. As most of you know, the US switched over to PCV 13. Back in 2010. Previously we were using PCV seven and went to PCV 13. This was comparing the two vaccines. Retrospective comparison. And the take home from this paper was compared to PCV seven vaccine, no significant increase risk of prespecified adverse events was identified. And some of those prespecified adverse events were federal seizures, urticaria, neurotic edema thrombocytopenia, anaphylaxis, encephalopathy. There was -- an elevated relative risk for Kawasaki disease in the zero to 28 days following vaccination relative to PCV seven. But it was not statistically significant. And authors concluded that this

possible Association between PCV 13 and Kawasaki disease may warrant further investigation. Moving onto slide seven. Was unlikely to report adverse events after vaccination to the vaccine adverse event reporting system. And knowledge attitudes and behavior study of primary care physicians. A providers. The take-home was a primary care practice area and familiarity with adverse event were significantly associated with the likelihood of healthcare provider reporting -- which intuitively makes sense. The next paper, trivalent inactivated -- vaccine and spontaneous abortion. This was a vaccine safety datalink study as well. And looking at spontaneous abortion in women age 18 to 44 years, and the take-home message from this study was authors concluded there is no statistically significant increased risk of pregnancy loss in the four weeks after seasonal and activated influenza vaccination. Compared to those that did not have the exposure to influenza vaccine. And the final paper on page eight -- rotavirus vaccines reported to US -- 2006, 2012. One of the presenters and into succession that I mentioned previously at ACIP. She will be presenting the results of this paper. This was a study looking at reports -- and doing some analysis to look at clustering of reports. Really when does the onset -- onset occurring after following receipt of rotavirus vaccines. And she noted persistent clustering of reported and subsumption events, three to six days after the first dose of Robotech vaccination. And concluded that the clustering could translate into a small increased risk of deception which is outweighed by the benefits of rotavirus vaccination. And I just want to say that I think the next time that we have the ACCV meeting there will be a lot of information for me to present about subsumption. There are two other studies that will be presented, a vaccine safety datalink study and then a prison study by the FDA. There will be more to come on this issue at future meetings. That's all I have. Be happy to take questions.

Does anyone have any questions for Tom?

Dave King. I have one quick question. I probably should know this answer. On the -- is that -- at a requirement for someone to report that or is that all voluntary? There are requirements, so manufacturers are required to report adverse events that come to their attention. That is somewhat -- that's a little different mechanism than provider and public reports that manufacturers have reporting requirements that are set by law. Providers are required by law to report events that are on the table of reportable events. And also, I believe required to report conditions which are listed as contraindications in the package insert. So there is mandatory reporting both on the manufacturing side and on the provider side for members of the public. It's completely voluntary.

Got it, thank you. Any other questions for Tom or comments? There being none, thank you so very much. I appreciate it, and we will move on. We held that the update on the infectious diseases, national Institute of health vaccine activities. Dr. --

Claire Schuster should be on the line.

Claire are you ready? I don't hear Claire.

Claire, check and make sure your mute button is not pushed. This is Charlene.

I am not showing clear in the conference unless she is in a room with another speaker.

We do show her as a participant on the attendee list.

Let me check, one moment.

That participant list --

This is clear. Can you hear me now?

We can hear you, welcome.

Sorry, problems of the mute function. Sorry don't have slides. I will go through a few updates that may be of interest to the group. I would like to start by talking a little bit about our activities in age seven and nine influenza. Working with other federal agencies to assess the threat of H7N9 in response to this new virus. We are currently responding you research on H7N9 including genetic sequence analysis and surveillance among poultry. Where also supporting a generation of vaccines strains am planning for vexing clinical trials. The trials are expected to begin this summer, and key questions include vaccine dosage, looking at one versus two doses, and whether adjuvants will be needed. I also want to mention a few recent papers that of come out on novel influenza vaccine approaches. One is by [Indiscernible] and that was published may 22nd. This paper describes how scientists have designed experimental influenza vaccine be chairing the protein keratin which can self assemble into nanoparticles. In the study Sarah 10 was fused with a protein found on the surface of the influenza virus and the protein is known as hemoagglutinin. This novel vaccine approach generated a more potent immune response and broader protection than currently licensed seasonal influenza vaccines when it was tested in mice and ferrets. And represents an importance moving toward the universal flu vaccine. If you're interested in reading more about the study we do have a press release posted on the website. Another paper by [Indiscernible] was published in science translational medicine on May 15. And this was a paper written by a -- supported international researchers looking at new ways to generate influenza vaccines using synthetic genomic tools and technologies. The team demonstrated that in just four days and four hours, they could accurately construct synthetic vaccine viruses for use in influenza vaccine development. And this work was supported by the biomedical advanced research and development Authority that Novartis foundation and naiad. I also wanted to mention the rotavirus vaccine study that was conducted in India. A new rotavirus vaccine consisting of a strain that was isolated, manufactured, and tested in India with support from naiad and other partners. The government of India -- Biotech announce positive results from a phase three clinical trial of Robotech. Phase three trial began in March 2011 and enrolled more than 6000 participants across three sites in India. The vaccine significantly reduced severe rotavirus diarrhea by more than half, 56% during the first year of life with protection continuing into the second year of life. Based on the studies successful finding infants in India will gain access to licensed vaccine and significant production against severe rotavirus induced gastroenteritis. The vaccine was developed over many years, three public and private partnership involving many partners including DBT in India, Biotech, CDC, Stanford University, school of medicine, Bill and Melinda Gates foundation, research Council of Norway, United Kingdom Department of international development. We also have a statement on our website by Dr. -- about our involvement in the vaccine success. For my last update, I wanted to let the group know that -- is sponsoring workshop today on staff vaccine development. And the vaccine is being held in Rockville Maryland and titled overcoming challenges and Staphylococcus aureus development. Government academic nonprofit and industry stakeholders to address challenges in the development of staff vaccines is lost to to discuss recent developments and possible solutions. Thank you.

Thank you, we appreciate it. Any questions or comments for Claire? Then we will move on. Will do the update on the Center for biologic evaluation and research FDA vaccine activities and that is Valerie Marshall.

Yes, this is Valerie. Can you hear me?

In May 2013, FDA approved a supplement to Japanese encephalitis -- absorbed to extend the age range to include infants, children, and adolescents two months to less than 17 years of age for active immunization for the prevention of disease caused by Japanese encephalitis virus. There are no reports of infection

occurring in North America. Residence -- [Indiscernible - low volume] endemic regions. FDA and NIH totally held eight transportation therapy workshop on may second and third exchange information with medical and scientific community about the regulatory associated with microbiota for transplantation. This is the process of transplantation of fecal bacteria from the healthy individual to a recipient is treatment for patients -- Clostridium difficile infections all sorts of colitis another orders. For safety and efficacy are regulated by the FDA. Currently, people participated in HHS department meeting Dr. -- the assistant secretary of health on a pertussis workshop held on March 6. Discuss clinical development of pertussis vaccine and presented its baboon animal model which is developed to address some of the scientific apps and knowledge regarding pertussis. As was mentioned by my colleague, FDA is engaged in H7N9 preparedness activity. All the risk to people in the United States continues to be low, because of the pandemic potential, FDA along with CDC NIH and the World Health Organization are taking proactive steps in the event that the virus becomes transmissible between people. FDA's developing clinical protocols in conjunction with NIH to determine the optimal dose and is actively engaged with vaccine manufacturers on regulatory pathways to for the development of pandemic vaccines. FDA's also preparing reagents that will be needed to help manufacturers produce pertussis vaccines. That concludes my report. Thank you.

Thank you. Does anybody have any comments or questions for Valerie? If none, we will proceed on. Thank you Valerie. We will have the update from the national vaccine program office. Dr. Steve Bende.

We heard your voice earlier today. We get to hear it again.

Thank you. What I would like to highlight, next week as you have heard from our maternal immunization presentation there'll be and NVAC meeting, national vaccine advisory meeting this coming Tuesday and Wednesday. The topics will include adult immunization. The H7N9 situation. A report from the IOM on childhood immunization schedule which I mentioned to this group last time. Reports from our global immunization working group, maternal immunization working group. The first report from HPV working group. And also report about the pertussis meeting that you have heard about and influenza Affordable Care Act on immunization especially adult immunization. Let me go through some of those very quickly. Adult immunization the assistant Secretary for health has been very interested in this -- increasing adult immunization rates and recently a meeting was held in Atlanta CDC on May 14 through 16 bring together federal nonfederal partners in this effort. The NVAC published recommendations on adult immunization back in 2011 and public health reports, following the 2009 pandemic flu response, the assistant secretary for health has chaired an interagency task force to increase seasonal task force coverage. Significant increase for kids, pregnant women and reduction in disparities but difficulties in improving so coverage for adults and so as a result, this working group was focused on increasing those and now of late, this task force has been expanded to include all its health immunizations. Not just flew. And so this foundation has been laid and efforts are guided by the task force and healthy people 2020 goals and again, this is a very active area for and VPL and the Department General. It brings together folks from CDC, CMS, HRSA and all across the government. And partners on the outside as well. As far as ACA goes, the focus has been on the Affordable Care Act as its advice to encourage better vaccine uptake by adults specifically . The law requires all ACIP recommended vaccines be included in new health insurance plans with no co-pays at no cost sharing. As you can imagine there are a number of issues to work through with this. And so we have focused some attention on that internally and we are staying connected to the office of health affairs to try to see what we can do --

As far as pertussis, you have heard a number of times on this particular call today that [Indiscernible] convene a meeting back in March to bring together industry and academia and government to talk about the emerging pertussis issue. And again, no conclusions were made except that to keep monitoring this more epidemiology is needed. Or broad understanding of the science behind the infection and behind the response to the two kinds of vaccines that are used and to flesh this out further. Stay tuned for this. This is

getting a lot of attention of the highest levels as well. As far as H7N9 preparedness, I'm not sure this group is aware, but -- coordinates a task force called interagency immunization safety task force. Which coordinates connection between all government agencies involved in vaccine safety monitor. FDA's CDC NIH as well, but also the DoD, health service and others that do vaccine monitoring or monitoring of health outcomes and adverse event if you will. And so in the wake of the 2009 pandemic, this group was formed to ensure that there was very consistent and engaged -- discussing connection between all the agencies. And that would continue under -- in the event of and H7N9 vaccination program. Also on the agenda for the meeting is there going to hear -- last time I told you that there was a report from the IOM on the safety of the childhood immunization schedule. It turns out that for logistical reasons -- reasons they were not able to shop. The IOM is coming this, they will talk about that report and if you'll recall I mentioned that it said that the childhood schedule -- the evidence is such that it would be beneficial for parents to keep immunizing their children. It would be unethical or otherwise to do broad randomized clinical trials to study the safety of the schedule and not vaccinate cohorts of kids and also, that and the studies should be conducted within the safety systems but they said are equipped to do so. For example the vaccine safety datalink that you heard from -- is ample system to address any type of concern that might arise. And they also admonished that there should be -- any kinds of issues about safety in the schedule should be addressed based on epidemiology and hard science and biological plausibility. They are going to talk about that. Another thing I would like to bring your attention to that I will be talking about this group's next meeting is the IOM is performing four -- funding the IOM to prepare a prioritization tool. When thinking about which vaccines to develop next and how to prioritize that you can imagine different stakeholders having different perspectives and so they are developing a software tool. That will be available at the head of September. And it contains about 29 different parameters that can be weighted by the user ranging from demographic data to specifics and serve as a centerpiece for discussion among disparate stakeholders to talk about how to prioritize vaccine development. Stay tuned for that. Like I said, we will be hearing from our global immunizations working group. That group is reviewing the role of HHS and global immunization efforts and will recommend how HHS can best continue to contribute to these efforts. Consistent with the newly established group global health strategy and goal five of the national vaccine plan. They're work has included reviewing how global immunization programs have affected the global populations and US populations. Reviewing global goals and ongoing initiatives related to global immunization and highlighting areas of global immunization programs that could benefit from HHS efforts. This work is ongoing and again will be part of this coming Tuesday and Wednesday's agenda. You heard about the maternal immunization working group are ready today so I will not go into that. Also a hesitancy working group that is just want and is beginning it's work. The healthy people 2020 objectives include producing illuminating or maintaining elimination of vaccine preventable diseases as well as maintain effective vaccination coverage levels for childhood vaccines, vaccination coverage is at or near historically high levels, evidence suggest that nearly 12% of parents refuse at least one recommended childhood vaccine and 30% delay one or more and exemptions obtained for personal reasons from school immunization requirements have been increasing. Children with exemptions our offer -- often clustered geographically where populations are at risk for outbreaks of disease. Vexing confidences one of a number of factors that affect individual and population level willingness to accept the vaccine. Basically, recognizing that immunizations are given across the lifespan and are likely to be important differences in vaccine acceptance at different stages of life the assistant Secretary for health is initially charged the NVAC to report on how confidence in vaccines impact optimal use of recommended childhood vaccines in the US including reaching healthy people 2020 immunization coverage targets. Focus of a report from this working group would include determinants of action vaccination acceptance among parents, HHS should be doing to improve parental confidence in vaccine recommendations and how to best measure confidence in vaccine and vaccination is to inform and evaluate interventions in the future. You'll also be hearing next week from HPV working group. I could go into -- read this entire charts but in the interest of time, low vaccination coverage levels for HPV in adolescence have been exhibited to many factors including cost, missed opportunity, strength to provide a recommendation and parental knowledge and attitudes. National

vaccine plans dates the need to ensure access to a better use of recommended vaccines in the US. And so the assistant Secretary for health for the specific vaccine is asking the NVAC to review the current state of HPV immunization understand the root causes for the observed uptake and to identify existing best practices all of the goal provide recommendations and how to increase use of this vaccine in young adolescents. I think that just about covers it except I would like to note that there has been a solicitation made in the Federal Register for new members of NVAC subject that. And I think that is closing sometime in the next two weeks. If you are interested, please take a look. That's it.

Thank you very much. Steve, you were the last main item and presenter on the agenda. We're now going to open it up to public comment. Sheila, you're the moderator property

Yes.

You can open our lines for public comment.

To contribute a comment press star one on your phone and record your name unprompted. To withdraw your common press star 2. It will take a few moments for the comments to come through. Please standby.

Wayne Roti.

Thank you, good afternoon Mr. Chairman and commission members. My name is Wayne Roti parent of a vaccine injured child. During public comment segments of previous ACCV meetings, I've been advocating for the ability of the general public for those who cannot attend to submit written comments that can be placed into the record. I urge you to examine this process. But my main, today is centered around the documents that Dr. -- presented earlier today. A document that proposes a link to the vaccine dosage administered in context with petitions compensated and/or dismissed. It is my opinion this is an attempt to minimize the number petitions to make vaccine injury even more rare than it actually is. We currently have difficulty understanding the -- data as it relates to the number of actual injuries. Some studies report the data represents 1%, 5%, or up to 10% of the actual injuries. We do not know how many people actually could file a petition with the program versus the number of injured parties him that may approach attorneys versus the actual number of petitions filed. This document as proposed by Dr. -- should be more about petitions filed as compared to compensable or dismissed cases. And another document could be created a vaccine dosage administered compared to the data. Thank you for your time today.

Thank you. Any additional comments property

Teresa [Indiscernible].

Thank you. I am the Executive Director for the national vaccine information Center. I want to thank the committee today for the opportunity to offer public comment. The only comment I would really like to make today is regard to the report on the additional table. The subsequent discussion on data mining. And providing some transparency with regard to cases that are settled, and the amounts they are settled for four what injuries and so on. I believe strongly that this is a public trust issue. It's a transparency issue. To public has a right to know what types of compensations are being made. At the same time, we very much respect the concerns from privacy. However, I think this could be broken down by vaccine, by injury award, per year, and greatly respect privacy. I know that the information is available but you have to know where to look and I don't think it should be incumbent upon the public to have to sort that out. That should be a matter of public information. I think that there is a way to do it but perhaps a lack of well to do so. With regard to concerns a misleading the public or the media by providing such information and that higher level of transparency, I think that it's very easy to put information out on the Internet to provide a glossary

of terms much like you see during your meetings explaining exactly what his settlement. What do these terms mean? And by providing that information, as well is that award information and providing that higher degree of transparency, it goes directly to public trust. I would encourage the committee to consider those factors and to revisit that subject. Thank you for the opportunity to comment.

Thank you.

As a reminder to contribute a comment, press star one and record your name. We are showing no further comments at this time.

We'll close the public comment section. Thank you. Is the chair I would like to make a comment. Based upon one of the public comments that was made, I want to reiterate that any I need you to correct me if I'm wrong but that we will be having -- we will take public comments in a written format, after our meetings and we will allow them to be inserted into the folders that are distributed to the commission members and if a commission member upon reading that comment wants to have a conversation about it or bring it up, they have the ability and right to do so as I correct?

Yes.

We will be taking the public comments. Future agenda items and new business. Any specific future agenda items that someone would like us to put on an agenda so we can specifically cover? Him

This is [Indiscernible]. I am not sure whether it is ready for an agenda item, but I know that you charged the process group with looking at adding the elderly as a population covered by the program. Those with chronic illnesses as well. Who would receive the -- and then the elderly who were older than 60 that would receive the [Indiscernible] vaccine. I don't know whether it's appropriate even for us as a commission to review the charter it is and make some comments about how the charter was set up to -- for childhood vaccines and now expanded. It seems to me that some kind of comment would be worthwhile.

Dave King here. I with ink that if we wanted to talk about the charter come rethinking specifically in any particular area of the charter such as the membership?

In general the program -- even the name of the program is for childhood vaccines. It's really not just for childhood vaccines anymore. Even though my heart is with the children. boy take care of. But it seems to me that we are taking care of more adults into the program. And really all the vaccines now are on the childhood schedule except for the two that I mentioned. For routine vaccines. I guess I just feel conflicted about it at times. I know we have brought it up and I know the issue is still to protect people. Of any age, really. But the charter doesn't reflect that.

Dave King here. The description of duties certainly do talk about the childhood vaccine and things of that nature but it also talks specifically about changes in the vaccine injury table. Might it be that just the name, the advisory mission on childhood vaccines is really what is throwing -- causing the issue or concern or dissonance.

There may be. It just -- issue of perception of it. I know it has changed. And that is great but I'm not sure what it is actually.

We should refer to ourselves as the commission. Does anybody have thoughts on this? I don't know what we can actually do. Vito, I will call upon you.

The problem is there are a lot of commissions.

Currently we cover childhood vaccines regardless of the age of the person who received it. Until the obstetrical vaccines get included, we are still talking about childhood vaccines. That are also given to adults. So I don't see that problem yet. But when or if we expand then certainly it would be prudent to have the name reflect what we are really doing.

That is a good explanation. I have to get my head wrapped around that. We do cover childhood vaccines.

That happened to be given to adults and has to be recommended for CDC administration to children.

Thank you.

Any other future agenda items and/or new business the the?

I have contact with Kristen right now, I am a member member -- the NVAC liaison, a member of the vexing hesitancy group and we are meeting here in DC the afternoon of Monday. Kristen, I see your name as presenting to NVAC on Wednesday. Did you plan to attend?

I believe Kristin has left the call.

She can report -- Vito, I'm going to call your office right after this meeting them.

Okay. Do have our number?

I have any summer. Everyone has Annie's number.

What I would say is that if there are any -- if there are no other agenda items or ideas for new business to bring before the commission at this time, I am sure that we will solicit ideas during the course before our next meeting for any additional items. And things of that nature. The worker may come forward with something as well. Having said that, I am ready to entertain an adjournment. Do we have a motion to adjourn?

Motion to adjourn.

I second that.

So be it. All the eyes have it. Everyone have it -- everyone have a good weekend.

That concludes today's conference. Thank you for participating. You may disconnect at this time.

[Event Concluded]