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Advisory Commission on Childhood Vaccines

Thursday, June 05, 2014

Andrea Herzong

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

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Attendees

1. ACCV
2. Adriana Teitel
3. Allison Durham
4. Amy Walker
5. Andrea Herzog
6. Captioner
7. Carole
8. Charlene Douglas
9. Closed Captioner
10. Dave King
11. Guest
12. jason smith
13. Jocelyn McIntosh
14. Jonathan Salaveria
15. Karin Bok
16. Kristen Feemster
17. Luisita dela Rosa
18. Marco Melo
19. Mark Ditmar
20. Robin Auth
21. Theresa Wrangham
22. Tom Ryan
23. Valerie Marshall

Chat History

N/A

Polls

N/A

Q&A

Q/A Done Over the Phone

Transcript

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Welcome to the 92nd quarterly winning own childhood vaccine -- vaccines. Mr. David King.

Welcome good morning thank you everyone for being in attendance. This is David King I am the chair and I will do a rollcall. Why don't we announce ourselves as we go around and we will let it go at that. Someone begin please.

Charlene Douglas ACCV.

[Indiscernible] pediatric nurse practitioner healthcare provider.

Jason Smith in-house counsel at Pfizer vaccines.

Kristin [Indiscernible] pediatric of assistive pieces infection ACCV member.

Sylvia [Indiscernible] member ACCV pediatrician.

Michelle Williams, [Indiscernible] unaffiliated attorney member of the ACCV.

Do we have some other members that are more ex officio?

Tom [Indiscernible] Centers for Disease Control and Prevention.

Anybody else? I guess we will begin the meeting. The record will show that Ed Crouse and Louis Dela Rosa are not yet on the call but that we do anticipate one or both of their arrivals in a little bit. We will begin with the chair report. It is a short report because I believe that some of the information that I might possibly cover will be covered in the subsequent report by Dr. Houston. Just to get the matters out of the way in terms of what we want to do, we would like everybody to identify themselves before talking. I would also ask that the presenters since we have a number of different PowerPoint in front of us, if you could identify the specific PowerPoint for those who might not be looking at it on the website but rather have it on the computers or printouts so that we know the one that you are going to be presenting from so we can move in that area. We would also as the chair, we would like to once again express our dismay over the fact that the meeting is in a virtual environment as opposed to being face-to-

face. The chair strongly believes that this reduces the overall effectiveness and ability to carry out the charter in the most effective way in terms of what we commissioners should be doing and that limits our ability for clear concise communication, recognizing that much communication does not necessarily -- by speaking and listening but by visual and the like and we miss about all those key components as well as any commission that begins to develop a relationship where there is the site chatter, beside talk, beside glance, whatever. I won't belabor the point except for the fact that I do believe that there is no -- I do not accept or believe that the reasons in terms of budgetary have merit. And that is the chair's position and the chairs report on that. We will move on. I ask before -- as we consider the different reports that we here, the different recommendations, in case we need to make some boats and the like, that we think in terms of those who have suffered injury and those who support those who have suffered injury due to vaccines. That we remember that if we have to make a mistake, or an error, that we air on the side of those who have been injured and support those who have been injured. That is the conclusion of the chairs report. So we will move onto public comment on agenda items only. If you would have us understand if anyone is going to make a public comment. I would ask that whoever's going to make it public comment if anybody, that they identify the specific agenda items that they are speaking to prior to them actually speaking to it. And identify who they are and if they have any specific affiliations. Public comment we are ready for.

If you have a remark or comment at this time press star one and record your name. Record your first and last name clearly when prompted. Teresa rang them.

Thank you. I appreciate the opportunity to offer comment on the agenda this morning. The first item -- I represent the national vaccine information Center. I am its executive director. The first item on the agenda but I would like to address is language that the committee will be considering with regard to underlying conditions and genetic predispositions and susceptibilities as it relates to the vaccine injury table. I would remark that's this language should not be adopted into the vaccine injury table. Because it does not acknowledge what the IOM report has repeatedly stated with regard to limitations on epidemiological studies in this regard. People are individuals. And we come with genetic individuality and subset the abilities and predispositions and we may go through our whole life with these risk factors, and they never come together to come to be a disease or condition like lupus, multiple sclerosis, Alzheimer's, Parkinson's. But we know that in every genetics that there our environmental factors at play. Where vaccines -- vaccines may provide a trigger that leads to an outcome, we need to acknowledge that and as the chairman has acknowledged, this system was designed with the intent of benefiting those injured by vaccines. To give them the benefit of the doubt, no-fault mechanism that is meant to be generous. And to adopt such language would negate the very intent of what this whole program is about. There is no large perspective of case controlled study comparing be vaccinated to the unvaccinated. And comparing the morbidities and mortalities and outcomes but also in evaluate the changes of the cellular and molecular levels, changes in the brain and the chromosomal integrity that makes some more susceptible to vaccine injury and death. I really encourage this committee to consider those factors. As they look at the options before them today. Please recall the polling's case where Hannah poling an

underlying condition was aggravated by vaccines. Where vaccines trigger that there must be accountability. We should not pawn them off and say you were destined to have these complications sooner or later and it just happened to be a vexing that did that to you. It's not acceptable. We would encourage the committee to get encourage -- consider these factors is a look at these language. With regard to the vaccine information statements that are put before the committee today. MVIC may general statements of the last meeting with regard to global changes that were needed to reflect the state of the science with regard to the unknown. I am speaking to the Institute of medicine report that this committee has constantly voiced concern over in terms of gaps and vaccine safety research. It's important that the consumer be advised that there are many unknowns, many things we do not understand in the way of faxing injury characterization as they take on the possibility of medical procedure and a pharmaceutical product that carries with it the risk for injury or harm. I also failed to protect and that really is important. In terms of needing to be stated on the [Indiscernible]. There is no public health official or Dr. Who can tell an individual that a vaccine that is administered to them today will protect them and not harm them. That needs to be very clear. I would also encourage that one of the resources that is listed throughout the [Indiscernible] is a vaccine product insert that contains a great deal of information that consumers are unaware of. To refer to it throughout ABIS. Because the consumer is not aware of it. We would also encourage consumers being made aware of the statute of limitations with regard to filing an injury claim so that if there is an injury, they can be eligible for compensation. I will leave it there, and address the rest of my comments at the end of the meeting. I appreciate the opportunity to provide comments today.

Thank you. Are there any other comments?

No other comments at this time.

We will close the public comment on the agenda items section of the agenda and we will move on to the approval of the March 2014 minutes. Does anybody have any additions modifications changes?

I make emotionally accept the minutes as submitted. This is Charlene.

Is there a second to that motion?

I second. This is Christian Easter.

A motion on the floor to accept the minutes. All in favor say aye. And he opposed? Any abstentions? The minutes are duly passed. Thank you. The next item on the agenda is a report from the division of vaccine injury compensation, Dr. Melissa Houston acting director. If you would identify which PowerPoint you will be using.

Certainly, good morning everyone. We will be using the presentation that is entitled the national vaccine injury compensation program division of vaccine injury compensation update. I wanted to review some of the highlights that will occur at this meeting. During my presentation

I will be proposing some clarification to change -- some changes in the vaccine injury table. We will receive an update from the Department of Justice. One of our medical officers will present -- to add diabetes mellitus for measles mumps and rubella vaccines to the table. We will also have a report from the process group review vaccine information statements of updates from the ex officio members. Looking at this table we see the number of [Indiscernible] that among filed with the program as of May 6, 2014. Based on the seven months of data, because the program is based on a fiscal year, October 1 of 2013 through September 30 of 2014, we are projected to have -- 533 positions. That's a slight increase from FY 2013.

Questions? Melissa, do we attribute anything to that?

No, it is not part of -- anticipate that there will be the number of claims the program has been increasing from here to your. I will go back to that slide so we are on track to continue that trend with a slight increase. It is not as great an increase as it was in FY '12 and FY '13 but the trend continues with a slight increase from '13 to '14.

Do we have any -- Dave King speaking. To we have any underlying reason that we may suspect as to why we are beginning to see the increase? It may be a good thing that we are same increase. It could be good or bad. Is there any thing that we can point to or directionally accurate if we were to be thinking that might attribute why we begin to notice an increase in the number of petitions?

I think that you accurately summarized it. It could be the more claims are being filed. Because more people are receiving vaccines. Or there could be other reasons. I know that [Indiscernible] will be speaking more about this in this presentation.

You may be speaking about the reasons why?

Yes, that is correct.

This is Jason Smith. They question related to David's question. Is it related to -- I recall we may have had a discussion about this in meetings past. The influence of vaccine and the recommendation for children. In my -- desiring about Lorna?

What I can say since there is been a universal recommendation we have seen the number of cases in the program increased radically. But that has not been just used to petition for children. Because adults have also -- it is also been universally recommended that adults also receive the influenza vaccine. That has been a large part of the increase in the number of cases that have been filed with the program.

Thank you.

Return to the next slide, we will see that the total number of cases for the past seven months that have been adjudicated have been 246. That's approximately 35 cases that are adjudicated

each month. When we project the number of cases that would be adjudicated for FY '14 that number is 421. Which is a little asked then -- almost half than it has been in the previous year. There are -- there is one factor that could possibly have impacted the number of adjudicated cases for this year. Pretty US Court of Federal claims website there are eight [Indiscernible] in place including a special master. Four of them have been relatively new. That could possibly be one reason why it is projected that it will be less cases adjudicated in FY '14 than they were in FY 14 -- FY '13.

Dave King here. Is that because they are new? Are we saying it is a lack of experience in this that might be causing that?

Not necessarily the lack of experience, but they were staffing up this year. We took some time to have everybody in place and all the full complement of special Masters are in place.

So really what it was is might have been shortstaffed in this area over some of this time is that correct?

That would be a correct statement, yes.

Thank you.

You're welcome. If we move onto the next like the adjudication categories for non- autism claims.

Welcome Lucy to.

Let the record show [Indiscernible] has joined the meeting.

As of May 6, 2014, 140 cases have been found to be compensable. If we project that number out it is anticipated that 253 cases will be found to be compensable. It is projected that 32 cases will be conceded. Predicted that 29 cases would have a court disposition. It is also projected that 109 cases will be phone to be non- compensable and the projected adjudication total would be 363 for the non- autism claims in FY '14. Return to the next slide looking at the award amounts paid as of May 6, 2014. You can see that over $128 million has been paid to petitioner's for attorneys fees and costs. It is projected that through FY '14 approximately 200 and $19 million will be paid to petitioner's and $21 million to cover attorneys fees and costs. Next slide. As of March 31, 2014 the fax -- vaccination trust fund balance was $3.475 billion.

Dave King here. Can we backup? We say attorneys fees and costs we're talking about about petitioner's fees and costs only?

That would be correct.

Thank you.

Looking at activity from October 1, 2013 to March 31, 21406 months, the excise tax revenue, approximately $95 million. The interest on the investments was approximately $30 million so the net income for the trust income -- trust fund was $125.6 million. So I just want to review some significant activities that have occurred within the program. At the program held a second public hearing for the rotavirus NPRM of notice of proposed rulemaking on April 28, 2014. During that time period no additional comments were received. And we anticipate that the final rule for adding rotavirus -- will be finalized. Another significant activity was there was a notice those published the added influenza [Indiscernible] to vaccine injury table. This set of Federal Register notice was published on November 12, 2013. As of that date petitions may be filed for all vaccines against seasonal influenza which was never recovered under the program. It should be noted that all trivalent vaccine tapping covered under the program since July 12,005. This -- significant activity I would like to mention is that the program has been engaged with the GAO study. The study was request by the house committee on oversight and Government Reform and the key questions that they have for the program are as follows. What are the current time frames for processing VICP claims and what factors are associated with longer processing time frames? What changes have been made to the vaccine injury table and what are the criteria for changing the table for the how the funds and the trust funds been spent? And what is known about the experience of claimants? Where filed claims with the program. How has the Department publicized existence of the VICP? A status update of the study is as follows. In March, both HRSA and the Department of Justice had separate entrance conference meetings with the GAO. HRSA is currently responding to the request for information. GAO has met with individual members of the ACCV. Particularly focusing on those specific categories. We have been informed that the GAO has also met with the courts. The GAO has told us that it would like to complete its study in August and a report will be generated thereafter. Are there any questions before we move onto the next portion of my presentation?

The next portion of our presentation we will discuss or propose to categories of table changes that the program is proposing and also clarification to the qualifications on interpretation on the table. As I mentioned previously, all seasonal trivalent influenza vaccine tapping covered by the program since July 1, 2005. At that time, all seasonal influenza vaccines were trivalent. However, Cuadra Valent influenza vaccines became available for general use in the 2013/2014 influenza vexing. Public Law 113 -- 15 was enacted. Explaining to also include any other vaccines against influenza. This amendment ensure that seasonal influenza vaccines are covered under the program. The seasonal influenza vaccine other than the trivalent influenza vaccine was added to this table with an expected date of November 12, 2013. The secretaries now proposing to modify the category '14 on the table from trivalent influenza vaccine to seasonal influenza vaccine. It should be noted that this program does not cover pandemic influenza vaccines. Next slide. The recommendation options are for the ACCV to recommend to modify the category of trivalent influenza vaccine to seasonal influenza vaccine or to not modify the category of trivalent influenza vaccine to seasonal influenza vexing.

This is Charlene Douglas. I have a question. You made the comment that it does not cover pandemic strains and pandemic strains change often. Willis quadravalent vaccine include that seasonal vaccine with H1N1?

Let me clarify. If a vaccine is recommended for regular use during the season, so seasonal influenza vaccine, no matter what strains are contained in a vaccine that vaccine would be covered by the program. That, regarding pandemic flu would be if there is a special vaccine that is intended only to cover for pandemic influenza. That would be covered under another program.

So if we come out next year with something for the Middle East alone, a standalone vaccine, that would not be on the table.

Not if it wasn't recommended for regular it use in the seasonal influenza.

Got it, okay.

Melissa David King here but one could petition potentially if they were injured with that vaccine correct?

If it is a vaccine, this seasonal influenza vaccine and the Secretary has made a declaration that it would be covered that [Indiscernible]

I'm having difficulty hearing you because I'm hearing background noise. If you could please repeat, thank you.

I believe your question was that if there was a vaccine to cover a specific pandemic could a petitioner submit an application to this program. And my response to that is if it is not recommended as part of the seasonal influenza vaccine [Indiscernible] for that particular season it would not be covered under this program. However, if the secretary made a declaration that it would be covered under additional programs, then that might be applicable.

Let's apply this to real world if we can. So that we understand what it is. We have the college and university -- Princeton, we will go to the Princeton case where we ended up bringing in a vaccine for not even the flu but for something entirely different. Is Zach covered under the program if it was given to -- if it had been applied to children?

That would need to be reviewed and evaluated. But what I can say to give you a real world example is the 2009 H one and one monovalent vaccine. Which was not covered under this program but was covered under another program that was administered by the department.

When you say covered under the program meaning for compensation, if someone was injured or not?

That would be correct.

That program was or is?

The countermeasures injury compensation program.

This is [Indiscernible]. I'm looking at the vaccine injury table, number 17. And it says that category now includes all vaccines against [Indiscernible] except for the trivalent which is already covered a number 14.

Yes. So what the secretary is proposing is to combine those two categories. Because cents trivalent would be considered a seasonal influenza vaccine, if category 17 and category 14 were to be combined all available seasonal influenza vaccines would be covered by the program.

It's not a lot different -- it is just moving it around?

That would be correct.

Thank you.

Melissa, what would be the driver for doing that as opposed to letting things be as they are? All seasonal influenza vaccine if there is a feature there are other formulations that are developed that are recommended as a seasonal influenza vexing. They would be covered in that category.

Dave King here. What would be an argument against doing this?

There's no downside to doing this. We do not have an argument against making a modification.

Dave King here again when I am looking at the ACC recommendation options we have two options listed. Is there also a subset under 2 which was do not modify but push to a future meeting to make that decision. Is that an option?

That is always an option.

Dave this is Tom at CDC. Just to use an example. There is now -- seasonal vaccine used to be all trivalent so if three virus strains. But in recent years they have developed a vaccine that has for strains. Now it is quadravalent. And there is even research looking at developing a universal vaccine so a new vaccine. Instead of every time a new seasonal vaccine becomes available, you have to maybe do a separate recommendation. This is just saying we are going to treat all seasonal vaccines whether they are trivalent, Cuadra Valent, and surveillance, whatever is in the future as one category so we don't have to have this discussion every single time. There is no downside. I agree with Melissa on that. There's no downside at all to this.

Good, thank you.

Any other questions or discussions before he moved to the next propose modifications?

This is a end. According to the table here there are no table injuries for influenza seasonal or otherwise? Is that correct?

On the current table. However there been propose changes that have been presented to the ACCV.

That's why I was confused. I thought GBS had been added to that but it doesn't appear there yet.

Correct. In the current table there are no injuries associated with this vaccine. However in the proposed table presented to the ACCV in previous meetings, the proposed changes to add injuries associated with influenza have been presented.

What does that mean that they are not on the table yet? What is a process that hasn't happened?

The rulemaking has not occurred yet.

I see, okay. Which takes a fair amount of time?

It does. For example, in presenting the proposed changes to the ACCV for the recommendation, this is all part of the process.

Dave King here. Can we quantify fair amount of time a little but?

Certainly. We can tell you the process. I can share with you what the processes but there are no time frames -- no specific time frames associated with this process. I believe that [Indiscernible] has reviewed this and previous meetings but I'm happy to do it again. What needs to happen is that there are changes that are proposed to the table. The proposed changes are brought to the ACCV for the recommendation. It is reviewed by the agency. And then after it has been reviewed and cleared by the agency, it is reviewed by the department of HHS and cleared by the Department. Then it is reviewed and cleared by all federal agencies. Then it is published in the Federal Register notice of public comment. For six months. There's a public comment period and then there is a public hearing that must occur. All the comments are compiled. And any changes if any are made. The process goes again. And then the final rule is published in the Federal Register.

Dave King here. So after -- there is no quantifiable trend -- timeframe to do anything until we get into the proposed rulemaking where we have the six months and things of that nature. Is that accurate?

I would be an accurate statement, yes.

This is and [Indiscernible] again. And so do families who are making petitions who have an injury that is under review, is that taken into different consideration? By the Department of Justice?

There are always mechanisms through which petitioners may submit a claim. One is by using the table where there is a presumption of causation and the other way that a claim could be filed is through conservation and fact. And that way the petitioner would need to provide evidence that the vaccine did in fact cause the injury that they are alleging. In practical terms for your question, someone could always submit a claim at any time if there injury is not on the table. They would need to provide evidence to support their claim.

Thank you for reviewing that process. But it seems to me I've heard before something that if it's in the middle of this process and everything is going forward even if it hasn't been published sometimes it expedites the process a little bit. Is that incorrect?

I am not -- can you repeat the question please?

I thought that I understood from some previous conversations that took place that if these injuries are -- to be added to the table or in the middle of this rulemaking process and everything is going along okay without changes and it seems to be -- accepted even though to finalize that this may still expedite the process for a petitioner. To become faded.

At this point in time they are not giving a presumption of causation. There is still a boundary as causation and packed. Until the final ruling is published.

It is very long.

Mr. [Indiscernible] will also talk about some -- may address your questions in his presentation.

Thank you.

You're welcome. Other comments or questions or concerns before I move to the next proposed change?

Dave King here. Along Anne's line of questioning and thinking, just so we have an understanding and this might be something that we moved to a later agenda item on the new or even into a different meaning. But it seems to me that the commission could consider that if we make a recommendation to a change on the table, whatever that may be, that we could also make a recommendation that if we think this makes sense, then we don't think that's people should be fighting opposing and asking people to provide so much additional proof when we believe that -- I think we should err on the side of those who were injured when we believe that this should be added. Just because there is a component where it hasn't needed --

made it to the change it and therefore we might be pursuing with vigor to prevent people from receiving compensation because of a different standard that when this gets approved it might change that standard. I think that that is something that we ought to be having a conversation about.

If I could try to understand your comments, the standard -- I am trying to understand your question. Are you stating there would be a different standard of -- applied to the evaluation of a claim?

What I am saying is that if we make a change recommendation, and if it takes time and we all know based upon what we have said that there is no timeline in terms of quantifying until the latter part of the process, which means something could go on for a year, two years, even three years that we as a commission could in fact go on record stating that our advice to the secretary would be that we do not believe that the standard should be held any more, and that we would ask that the Department of Justice not pursue with vigor a category of making people approve certain things when we have already made a recommendation that they shouldn't have to do that any more.

It is my understanding that they cannot make a recommendation but -- they can make that recommendation. And I believe that Mr -- will seek more to have the statute declared -- would be able to have that recommendation -- how that recommendation would plant the current statute.

Right. I'm not sure it would actually play at all with the current statute, but it might be a recommendation that the commissioners might want to go on record for doing. So I think that this is probably a new item agenda or something that needs to be discussed, but this conversation has raised it in my head, and I think that we as a commission are to have a conversation about that. I don't know if others agree here if they think that the chair is off base, but I would be interested in what people might think in terms of should we put this on as a future agenda item.

Any questions or comments or concerns?

The chair has asked the question of the commissioners and the chair is going to ask the question again or if we don't get a response should we assume that silence is acquiescence and agreement?

This is surely. I am trying to be clear. I am heeding the call to air on the side of those injured. These two options before us today, giving -- it is difficult. Giving free reign to how many valence this seasonal vaccine for example has, how does that dovetail with what you are requesting?

It is a difficult question and perhaps it is something that we should take under consideration either through a workgroup or as a commission as able at another point. But I do think that it warrants our attention, because if we're making recommendations but it takes time for these

to be enacted, that we should not only make the recommendation, but we should I think publicly go on record that we believe that sense that is true, our advice to the secretary would be stop people from enforcing a different standard when we have made this recommendation. Why would we not? It seems to me it would slow from a logic point of view.

This is Michelle Williams. Perhaps we should do for this to be process workgroup.

Or the commission as a whole for conversation. I am open to that. [Indiscernible] is the process worker willing to take this up?

I really don't know at this point.

This is what I would like to do than. I think Michelle, I do think that the conversation probably can -- can't occur at the moment so I do think that it is part and parcel to whatever it is that we recommend if we really want to make recommendations and we really need to think -- think through so how do we make it more than a recommendation? We should be saying don't do the other thing then.

If you do that, let me interject and the lawyers tell me out. If you do that, you could leave people who are in the pipeline from litigation in limbo. If a new thing has not been approved and the old thing has been stopped.

The only people that we would leave in the limbo side I suspect is that we would be making a recommendation and this is why we need to move this to as Michelle suggest either to the commission or to the process workgroup or another commission to discuss how we would do that. If we're making recommendations, we should be more than just saying that is our recommendation. We should then say where does that slow, that recommendation?

I got it, I am sorry.

I don't think this commission or any other commission in the federal government will ever have that kind of power. So the process is what the process will be and nobody is going to intervene in that process. The work -- they recommendation that we give to the secretary has to go through three offices in HRSA and then to offices in HHS before it makes it before the secretary. What we suggest does not make it before the secretary. And our saying that we don't like that workaround, we don't like that it takes three offices in HRSA and to offices in HHS before the secretary sees what we want to do, we can do that. Somebody tell me.

If I may say something that may help the discussion, currently for all causation and claims, if the sciences there the recommendation is to concede. It is not that if the sciences present because it's not on the table, there will be a concession. I wanted to make that clear.

This is an again. I apologize for bringing it up like this, but it was surprising to me to see that GBS was not on the table yet. And that's where I think the question originated. I didn't realize it took so long.

Let's ask the question. David King here. GBS is not on the table, but it has been recommended that it be on the table. Are we conceding those cases that have GBS?

What I can say for GBS is that those cases are not being conceited. At this time. As presented is being proposed that GBS be added to the table for policy reasons. But the science, the evidence is not there as yet showing a causal association.

David King speaking. That's exactly the point. I think we do need to have a conversation about this, and what I would propose to do is that under new business later today we make a determination on how we will discuss this piece of the business rather than hold a meeting hostage to it right at this moment.

I would like to revisit it at this time. This is Charlene Douglas.

That's what we will do. We will move it to the end of the day for conversation.

Any other questions or concerns before I move to the next proposed modification? If we can turn to the next slide. Haemophilus influenza type B conjugate vaccine was first licensed by the FDA in 1987 and have been recommended by the CDC for routine use since 1991. The effective date of coverage for the vaccine was August 6, 1997 with no injuries specified. The secretary proposes to modify category nine done the table from Haemophilus indolence of type B polysaccharide conjugate vaccine to Haemophilus influenza type B as a technical change. In order to be inclusive and consistent with the language used that allowed the vaccines to be identified as a [Indiscernible] vaccines.

In essence, to ensure that the table language is the same as the language that allowed an excise tax to be enacted on these vaccines. Next slide. The recommendations options is to modify category nine from Haemophilus influenza type B polysaccharide conjugate vaccines to Haemophilus indolence at type B vaccines or to not modify the category from Haemophilus influenza type B polysaccharide conjugate vaccines to Haemophilus influenza type B vaccines.

This is Charlene Douglas. I don't see anything holding us back from adopted Ms. Recommendation.

David King here just so we understand what we're seeing here. It is worded incorrectly to some degree right now?

Not incorrectly, differently. And just to be consistent with the language that is listed in the excise tax law, it is proposed that the language be modified.

David King with another question. Would that be then consistent with all other phrasing that we have on others with the excise tax law were something is listed hence over here on the table component?

This is what we are attempting to do with this particular category. We're looking at just the category of vaccine and what is covered in the excise tax language and this would -- what is stated in the excise tax language is more inclusive than what is currently on the vaccine injury table.

David King again. Are you saying that if we change this, this will be more inclusive?

That would be correct.

My question is is this consistent with language an excise tax laws where we have the specific language around some of these things. Is that -- is this change consistent in the sense that this would be similar for all the others or would we find that there is inconsistency across the entire table based upon what the language is in the excise tax?

We would have to go back and check but we knew we would be revising the table and since I have started looking at the proposed revisions, that we want it to be more inclusive. To be noted that specific types of Haemophilus influenza vaccines are currently on the table. And the excise tax language is more inclusive of all Haemophilus influenza type B vaccines. And we wanted to make that change. We are proposing that change.

The answer to the question is we don't know.

Yes. We can go back and check for other categories of vaccines.

I will ask the question again, David King here. Is there any downside to this? Any argument against doing this?

There is no downside that we can conceive of by being more inclusive and consistent in the language.

David King again. If eventually adopted would this open up to lasts litigation or type of litigation through the special masters because things would be on the table and we should just move forward with this?

This is Charlene. It seems like there will be lasts for someone to quibble about should they decide to quibble.

That's what I'm trying to -- maybe that's a better way to phrase it. That is based on your thinking of it. I would like to understand Melissa do we believe that to be true across the board? Does everybody think that to be true?

This is and Krause. I am sorry I'm late in in joining the call but I would agree with that.

David King here. Welcome. We do not know what time you join the call. We had hoped you would have been announced. Could you give us an indication of whether you are here for the earlier conversation or not?

I just joined a couple minutes ago and the only conversation I have heard relates to the -- this topic that is on the table right now.

In response to your question it would let all Haemophilus influenza vaccines be covered for the program on the table. If that is clear. One would not have to specify white type of [Indiscernible], they would say they would have a vaccine for the table. And that would be sufficient.

This is Sylvia [Indiscernible]. That would allow anything that is stated as some off was influenza vaccine whether it is polysaccharide or not to be covered. Dave I think that probably the modification would allow more kids to apply for this. Them those specific to that polysaccharide conjugate and I don't know which manufacturer that is. So for future research or vaccines, that would allow more kids to be covered under that umbrella for HIV HIV -- [Indiscernible]

I think that is a positive and this also might drive a different type of recommendation which we will bring up that we all agreed to at the end of the meeting today.

Any other discussions or questions or concerns property if we turn to the next slide, the following slide are meant to share a proposed language clarifying the QA I. This first changes meant to be less restrictive. Currently when we're talking about the and set philosophy definition in the QAI, and set philosophy should not be considered to be condition set forth in the table if it is shown that the and set philosophy -- an underlying condition or systemic disease and parentheses it says such as autoimmune disorder, malignancy, structural lesion, psychiatric illness, dementia genetic disorder, metabolic disturbance, prenatal or perinatal central nervous system injury. And it goes forward. The proposed change is to read and encephalopathy should not be considered to be a condition set forth in the table if it is shown if the encephalopathy was caused by underlying condition or systemic disease shown to be unrelated to the vexing. That would be the new additional language. Such as autoimmune disorder would be removed or crossed out. Malignancy, structural lesion, psychiatric illness, dementia, genetic disorder, metabolic disturbance would be crossed out or removed, prenatal or perinatal central nervous system injury and so forth. That is the change that is being proposed.

This is Charlene Douglas. Does this respond to the public comment that we had earlier that these underlying conditions can be exacerbated by a vaccine? Just tell me to understand because when you say it is to conditions not related and then you said these things are crossed out, Julian these things are not considered or the language is crossed out?

The language is crossed out. The proposed change is in an effort to be more clear that if a condition is shown to be unrelated to the vaccine, that it would be a conclusion. And exclusion. Before just stated that the underlying condition or systemic diseases and illicit of examples, but the clarifying language would be that these conditions were shown to be unrelated to the vexing. And then it list examples of what changes have been shown to be unrelated to the vexing.

David King here. So I understand. Everything that you have read is not actually on the slide is that correct?

No, but I believe that [Indiscernible] sent out the table and the QA test QAI prior to the meeting so that you would be able to refer.

Yes.

This is and [Indiscernible]. I am having a little trouble figuring out which number. There are so many things here.

If you could guide us directly to where we should be looking in our talks, that would be helpful.

It didn't come in the book. It came in the mail yesterday.

What is the title that it came under?

It is [Indiscernible]. Vaccine injury table.

I got it, thank you.

What number under the those interpretations is it? Number two? I still don't see the language.

In the vaccine injury table.

While people are doing that let's ask the question as a relates to how was brought up under the public comment component. Just so we have an understanding. Him there was public comment as it was related to this saying there was not enough research in this particular area in terms of controls or uncontrolled vaccinated people and unvaccinated individuals, and that in the IOM itself there may be some underlying conditions that don't necessarily mean that someone is going to develop a specific disease, but rather they could be environmental and if that is the case, could the vaccine actually cause that injury, or precipitate it to some degree as opposed to where it might never -- and might have remained latent forever, and that it was the vaccine that triggers it. So I think that was what was brought up during the public comment. Do we have any conversation around that to say that is completely off-base? Or do we concede the point that it is possible? Him him --

Was an anything in particular?

It was not a rhetorical question. This do you have an answer to that question? Can you repeat the question please?

Is there any transcript that can repeat it back for me? Let me give you the gist of it. The gist is that is it indeed possible based upon what we heard this morning that an underlying disease or something could in fact remain latent and never impact the individual, but rather the -- but that the application or the administration of a vaccine given to an individual might in fact precipitate or cause a trigger that brings that problem to the surface when -- had the vaccine never been given them I never have happened

Not that we are aware of but I would say that all pieces are evaluated on a case-by-case basis.

Do we concede the possibility that that could occur?

This is Michelle. I think we are getting off into science that is not part of this presentation.

I would say Michelle, David King here, that the goal here is that we would be asked to make a change to the table. And that we change in terms of the wording and the Q&A side of it. We could choose to yes we will do it or we could choose to say no we won't. Or we could choose to kick the can down the road and say we will discuss it and another worker. I think that it is very germane because why would we want to do something that might -- if we concede the point that in fact something is latent and could be's surface to slowly through the administration of a vaccine and not necessarily a person would have it without that, we might want to walk cautiously here.

If I may just clarified that the proposed change are talking about things that are -- that have been shown. There's evidence that shows that these are unrelated to the vexing. And that is the only proposed change. I believe that and just sent out again the proposed -- the language that we are discussing and I would be able to point you directly to the changes that are being proposed.

This is Michelle. I think Dave a question that you are answering is say -- is it a possibility? I don't think that this language is ruling that out. I think what this language if I understand the language correctly, is trying to be more specific.

Again, I would like to clarify that although an alleged injury may not be on the table, claims could still be filed as causation in fact. Even though the table may not consider every possibility that could potentially exist, those claims would still be evaluated on a case-by-case basis.

I think that what it comes down to, David King here, is that there are -- I think that this doesn't -- I think that this could lengthen the process for some. And it may exclude in the sense that an

underlying condition, if one has been able to show that an underlying condition exists, and I think the public comment it was stated that their man fact be underlying conditions that exist. But just because the underlying condition exist doesn't mean it necessarily manifests itself and therefore that the individual might be a perfectly functioning human being as we think of what that term might or might not be. And so the question is that is a possible that a vaccine could precipitate or trigger something that might in fact the latent and never would have surfaced but the vaccine makes it surface but if it's shown that if that existed, even though it never was -- surfaced, would that exclude someone then?

Let me be clear. The current table as the language has an exclusion for underlying conditions already. And I believe that any just some that.

You said that BA e-mail?

Yes, I sent out the color-coded changes for the vaccine injury table.

We need to pull that down and look at it.

That language already exists. What the proposal is seeking to clarify is to say that these underlying conditions have been shown to be unrelated to the vaccine. There already is a risk of underlying conditions. Which would be an exclusion.

If you could help me out here, this is Charlene. Thank you for that clarification. To our presenter. This would go back to assertions that these underlying conditions are exacerbated or can be exacerbated by a vaccine. But as the science, is the absolute science any stronger on that assertion than the assertion that they are not related? It sounds like -- this is being framed as a language change but if not adopted, then we are -- if not adopted, the previous language will still stand. But if not adopted, are we then adopting some assertions that have not been proved to be scientific investigation?

What I want to point out, if everyone has that up, and I can show you exactly what we are speaking of, if you go on the qualifications.

I have still not received it in my e-mail.

This is shortening the specific list of underlying conditions. This is what this language is attempting to do. Currently rainout, it has a list of underlying conditions, and we are attempting to shorten that list. And just state that if there is an underlying condition that has been shown to be unrelated to a vaccine, then that encephalopathy will not be considered to be a conditions set forth in this table.

This is in the fewer exclusion criteria. You have removed some of the specific conditions. And then hear at least the way I am interpreting this, if an underlying condition is shown to be related to vaccination, then encephalopathy is no longer excluded.

That would be correct.

Essentially it's almost widening the criteria for which encephalopathy could be covered. So it is broadening the criteria and it's on Flickr goal is to make sure the language facilitates ease of --

David King here. Has everybody received the new document from any? Could you double check and see that it was sent to me? I do not have it. Nor is it on my server anywhere.

I think I found it in version 8 C on page five.

[Indiscernible] is that what you are talking about?

Further down I believe.

You have a highlighted one do you not?

I don't have that.

Yes, you were. I hate to direct you to the website but it is on the website as well.

And the color-coded component?

The proposed table changes in color-coded version is on the website, yes.

This is an. Is it on page five the language that you're going to change? Because I can't find it in the original version that was sent to us.

You are correct, it is on page five. I cannot find it in the original version that we received which is what stands now. I am a little confused.

[Indiscernible - multiple speakers] these changes were presented to you previously. And what I am discussing our changes to the changes that were -- it is the second one that any sense out that is color corded -- coded. And is on the program website.

I am on the childhood vaccines website. Visit their?

Of the right-hand side.

Tell me the name of it please.

Proposed changes.

I keep getting in and out of the call for some reason. I have not touched any buttons.

I don't have any proposed changes. Please give me a better title. Is it is a summary of the ACCV proposals? Is that it? Where do I find this?

Give me one second. We are having some Internet difficulties here in the room.

I agree with you that it is only for the better. For petitioners. But I guess I'm confused as to why the language as it apparently stands is not thing. As the black part of the document on page five.

David King here. Could I ask we hold off on this until we all have a copy so we are looking at the exact same topic?

This is Ed, I would agree with that suggestion.

I suggest we do not have this conversation without everybody having the exact same documentation front of them.

That could be the other proposals as well.

If we were meeting in person we would be able to run into a coffee machine, photocopy all of this and give it to everybody. Just saying.

If I could ask a question. Has everyone else received the e-mail?

Charlene did.

I receive the proposed changes that a don't have a copy of the table itself. I have been searching.

It was the e-mail sent yesterday, I believe eczema yesterday. There was a whole bunch of documents on it. I believe that document was the last document was to. And then this morning a different document, late yesterday evening East Coast Time another document came out with an update. But I still do not have forth -- I'm on the website and do not know where to go to get this. What you are asking me to go to. So perhaps while everybody gets it together, it would be a good time for us to take a 10 minute break.

I second that motion. So let's reconvene I will give us 12 minutes. We will reconvene at 25 minutes to 12 Eastern daylight time. Thank you. [The event is on a break. Captioner standing by.]

We are a few minutes early. One minute early according to the clock. We will give everybody time.

This is Sylvia. This is quite confusing. We found, we can't look, but we found we are at wits end, it becomes difficult to look at new documents that are produced within minutes. I think it's not fair to the general public either to submit new information that has not had time to be distilled.

We are in agreement but I don't know that we started up the meeting again.

That's okay, that was my opinion.

Thank you for giving it because I am thinking the same way and I suspect that others probably are. We should move this to a separate meeting or to a follow-up meeting. I suspect.

What I do want to say is that all of the documents, the document that we are referring to has been available on the website for many months now. It is not a new document or new information. I wanted to clarify that.

We should start the meeting up again. Do we need to tell [Indiscernible] to open it up or has everybody heard everything we have been saying?

Outlines are listening.

Welcome back from the break everybody. Since we have had a quick brief discussion that people have heard, first off are all the commissioners back on the line?

[Indiscernible] is here, Kristin, Jason Smith, Charlene,

RBC David King.

Sylvia Villareal.

Who are we missing?

Ed. Ed did say he was here I thought.

Ed, did you say you were here? Know he didn't. We don't have Ed, and. Michelle. Charlene,

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Charlene waited in.

This is a him, I get disconnected. I apologize.

Let's run through it again. David King, and, Jason, Sylvia, [Indiscernible], Kristin, Charlene, Ed Michelle.

Ed is back.

And Michelle.

I am willing to give Michelle the grace of a minute here folks. 30 seconds, we are still counting down. I am being a stickler for time. You know how that works. Okay. Fishel have you been able to rejoin us. We will proceed with Michelle not being on the line at the moment. We still have eight of nine commissioners on the line so they core here. Let us pick up from where we were.

Good morning again. I want to apologize for the confusion. I know that [Indiscernible] was trying to make it easy by sending those changes out. They have been on the website for several months. And what I am discussing our changes to the proposed changes that have RD been presented to the ACCV. These clarify language can make it easier by having exclusions for [Indiscernible]. Has everybody found the document that I will be referring to moving forward?

Is the document you are referring to is the proposed changes PDF?

That is correct.

Do so the record shows Jason and Ed I have received your copies of a. I've not yet received the e-mail from any on this.

I'm sorry. I apologize. HRSA seems to be having major connectivity issues to the Internet. We're trying to get everything back up and running. That might be why you have not received it. The other ones got out, I don't know.

This just makes a stronger case for in person meetings.

If you wouldn't mind I will want to go back to what we were talking about before about the clarify language to the QAI encephalopathy. That was found on page five. Section IIA. Subsection A. If people could indicate when they have found that portion of the document.

To indicate that we found it, we should specifically read that it would read an underlying condition of systemic disease such as autoimmune disorder, militancy, structural lesion, dementia, genetic disorder, metabolic disturbance, prenatal or perinatal central nervous system CMS and parentheses injury or is that the area that we should be reading?

That is the correct area.

Melissa, I am confused. I thought the part in black would be what is current. It does not seem to correspond with the current one that we did receive 100.3 vaccine injury table. Are they not the same document?

We're looking at -- you are looking at the current table.

I'm trying to look at the current table and see for any of this languages, such as 2 A.

If you look at the proposed changes that are on the website. That was trying to facilitate discussion by sending it by e-mail. That is the document that we are looking at.

Melissa, I think what an is saying is that she is looking at both documents and doing a comparison and this finding is inconsistent.

It doesn't exist in the current one. In this format. That's why we're looking at the proposed one that had been presented. And we are just trying to propose additional clarifying language to what has been presented to the ACCV already.

What is the current one? What you are asking is that we change from what the current one is.

No. I am asking about -- asking us to review the proposed changes that were already presented to the ACCV. We are proposing additional changes to the proposed changes.

David King here. One where the original proposed changes given to the ACCV?

March, 2012.

What is black is also new? It says online green wordings are deletes and blue wordings are additions. I have sections in black but I thought that would correspond to the current table as it stands. Is that not correct? Maybe somebody else could help me out.

We understand what you're asking. I think that people are just formulating an answer.

This is Kristin. I see the capital letter a under the desk in black it does state the language that you are proposing to be clarified.

That is the language we are proposing to be clarified and on the slide, in bold and underlined is showing the additional language that would be added to clarify, and I am orally telling you what exclusions we are proposing to remove.

I think the confusion is because we're expecting to see the green indicates removal, that this text would have been in green. But these are the old, these are the original changes and so this text does not show these additional clarify languages. And language changes.

Correct, that would be on the slide.

But it's black, it does not seem to correspond to the current table as it stands. Or am I just -- was the whole table you raised and re- done? The things in black were also additions?

Dave King here.

We are looking to compare the current table and what has been proposed.

This is [Indiscernible]. I think what she meant, the black ones are what are on the table itself right now.

I can't find that and what we have.

This is Dave King. Everybody, I believe that this section of the meeting should be pushed to another meeting. It is too confusing for the commissioners working in a virtual environment to homeless. We don't have anybody next to us to say this is the page you should be looking at. This is this one, that is that one. This conversation should not happen in this format. It is too confusing for the commissioners. I would like to get a sense of the commission if you agree with me on that.

In this document you are referring to be put up on the screen?

I would agree with Dave's comment. I am feeling confused and I'm hearing that other commissioners are feeling confused. I don't remember having an issue on the agenda where we got -- unable to all be on the same page. At the very least, I think we should move on because the clock is ticking and I think we should probably deal with this issue at either a later time or at a subsequent meeting.

Do we mean for all the propose clarifying language? We talked about two that we thought -- sounded reasonable. Clarifying language to later time

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That is a good question. And they leave it to the commissioners to make that decision.

I think we should take votes on those issues just to give this particular meeting a sense of work done.

I agree with that.

Dave King speaking. I don't know that we should drive to get a sense of work done if we are not sure of things. I don't know

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This is surely. That's with the vote is not on this issue. For certain, but there were two things --

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That without we had a good conversation on.

Even without travel money, meetings cost something and there should be work done.

Dave King here. I would argue that work is being done, even if it is not necessarily the work that we might hope to have done.

But if there was consensus on the first two issues, this is Kristin, I would vote for at least moving forward with those because if it is clarifying language that could help make the table more efficient, then it would be nice to be able to move forward on that while we have an opportunity to spend more time on this issue.

This is a.m.. That would be the first two bullets. The one about seasonal influenza at vaccine and him off list influenza type B vaccines. Do we need a motion?

And make a motion we end up those two changes for seasonal vaccine and for whom off list be -- him off the list be.

This is Michelle I second.

We have a motion on the table. Let us go back and reviewing make sure sure that everybody understands what specifically they are. If we go back to the slides I believe it would have been slide 12 and slide 14. Melissa, do correct me if I am wrong.

You are correct.

Okay. Those are -- what we are talking about is doing recommendation number one on both the slides 12 and 12 -- 14.

Be proposed on 12 and 14 the recommendation options are 13 and 15.

All right. Rate. What we would do is the second bullet is what we are proposing to modify on slide 13 I am reading right now category nine from I can't even pronounce this properly. You guys know what it is. What is the other slide 11 and slide 13. The proposed table change seasonal influenza vaccine and the other one is to modify the category nine. Before we -- we can have a discussion on this. Even though we have had quite a bit as long as it relates to the topic at hand proposal on the table. Does anybody have any questions as it relates to that.

No.

So then we will bring this to a vote. The vote is to -- just so we are all clear, the vote is to make the proposed table change that is on slide 11. Which is on the seasonal influenza vaccine, and slide 13, which is the second bullet to modify the category nine. Those are the two, all in favor? Say I. Any imposed? Any abstentions? That passes.

Mr. King if I may make a comment in response to the query about the black language in the proposed changes PDF document. That is the original language. However, the numbering has changed from the current table, so I would have to point you directly to where the original language is in the current table to the proposed table which could be confused. It is correct that the black language is unchanged but if you're looking at the proposed table if it -- it would be easier for everyone to follow the same document.

Melissa, what we have agreed is that we are going to table this and move it to a separate meeting.

Sure. And I wanted to clarify an address the question and then the other thing I would look to say is that moving that to another meeting would just mean that these proposed table changes would be waiting for your recommendation before moving forward.

Are you able to give the correct numbers than of what is black on the proposed changes document?

Sure, I can do that.

Dave King here. The chair is not comfortable with this in this environment. And I think that we have a sense that the other commissioners were not comfortable either.

I understand and I am not disagreeing with whatever the decision as but I wanted to address the concern about the black language, about her not being able to find unchanged language in the current table and what I am trying to say is that it is there but because the proposed table is numbered differently it wouldn't be an exact number. That is why we were looking at the proposed changes table and not at the language in the [Indiscernible] table. I wanted to address or concern and whatever the commission decides to do, I am not arguing with that, I just wanted to address the concern.

Great, thank you. Do have any other slides in your presentation?

No, they were all about the proposed clarifying language and whatever you decide to do just know that while we are waiting on the recommendations that the table will still be in the division and won't be --

This is Ed. And maybe we can address new business whether we want to try to schedule a meeting before our next regularly scheduled ACCV meeting to consider this change.

We could certainly entertainment under the new business. I see no reason why that cannot be done.

This is and for clarification then this version 8 C has not moved out of the department at all at this point.

That would be correct.

That is over two years.

Thank you.

When you say it has not moved out of the department you mean HRSA.

That would be correct.

We might have great-grandchildren by the time this is in place. Melissa, you did have something on [Indiscernible].

This is all part of the clarifying language so it would be the same thing, we would be looking at the proposed changes document that I can share with you the additional clarifying language. That we are proposing to add. It would be the same issues that you are experiencing. One thing that I could suggest is that if after lunch, if our activity with HRSA lawyer we could have the documents upon Adobe connect then I am able to point to exactly where the proposed changes are. We have other items on the agenda ready. We will have to play that they are. I was expect we would move it to the latter part after we cover the other agenda items.

A copy of the table injuries we received as an attachment to our e-mail. Vaccine injury -- that is not the most current version. Maybe that's why the language doesn't correspond. To the black part of this other one. I'm just asking, maybe that can be checked during the lunch hour.

The current languages at the same but the proposes numbers differently. Corresponds to C or I I in the current table. But the language would be the same.

I will rest for now, thank you.

Thank you. Undercurrent course of speed, I think that -- Dave King speaking, that this -- we need to do this in an in person meeting. There is too much potential confusion and issues around understanding that might be better done in a manner that fosters the clearest communication. Let us move on. I think the last slide is typically read aloud. So that everybody -- for those who are on the phone if they cannot see or can see the web they would get this particular information was has to do with the dishes somebody wants to make it public comment and participate in commission meetings.

Thank you everyone for your time and attention this morning. If anyone would like to make a public comment or participate in future commission meetings, please contact [Indiscernible] at Park long building room 11 C -- 26. Rockville Maryland. Or call her cover 301 [Indiscernible]. She is also available by e-mail at [Indiscernible].

I think the phone number was 6634. Maybe it is just my connection. Melissa thank you. The next item on the agenda. I need to talk to commissioners here we're approaching the noon hour. And we have Vince Matanoski from the Department of Justice to give the report from the Department of Justice are you ready to do that or would you prefer that we picked up after the lunch hour

I am ready. Mr. Chairman.

Commissioners are you open to this? I am to.

Sylvia, let's proceed.

Vince, bring it on.

There is no way possible that a lawyer could get us back on schedule, that's for sure. But I will do my best to be brief here. I will start my presentation entitled Department of Justice June 5, 2014. Moving to the second slide this is the total number of petitions that were filed in the three-month here.

[Captioners transitioning; please stand by.]

-- that we are seeing for this fiscal year over the historical number of cases that we see. I know there was question about what might be some of the drivers for that. I will address that in a moment. Looking at the slide in this class period we saw 122 cases filed looking back on what we had in the first period of this fiscal year and projecting out. We are showing the same pattern that was seen by Doctor Houston and we are on track for 530 cases this year. Historically there've been about 400 per fiscal year running back to about 2009. 2013 was a year where we saw a jump to 500. That represents 25% increase in what we have seen. We all still running most of the cases being adult cases. You can see in this past period that 82/122 were a dull cases. That is a percentage and is less than what we have seen in the past couple of meetings what we were reporting this. It was generally running about 80% adult cases and 20% children cases. It's too early to tell whether there is another shift in place. Time will tell whether that is an emerging pattern where we are shifting to more children cases than we've seen in recent past. I've looked at data that we have. With looked at the cases that come in and what's being alleged. Was filing them in terms of the law firms for example. And I tried to figure out what might be driving the sustained 25% increase in the number of cases. I will preface these comments by staying -- saying you should never look at cases filed here as a surrogate for what might be happening with injuries to people as a result of vaccines. This is not a substitute for good surveillance or good scientific research about what injuries could be associated with faxing. -- vaccine. It might tell us about whether there is good case ascertainment for example or how well the program itself is being received by the public and how well they know about the program. Looking back at what we saw happening in the last year and a half there has been a number of cases that are the flu GPF cases that of increased. I looked at this recently over the past couple of years to see what the breakout of those kinds of cases were versus the total number of cases we received. It seems to be that the flu GBS and the server cases are driving this case increase. Other types of injuries associated with other vaccines haven't increased a lot. So it seems to be this awareness if you will of these potential links that may be driving our case numbers up in the program. It looks like it will be sustained. As you know there has been a lot of information out there because of studies that were published in because of the IOM and because of the work here at the ACCV about proposed table changes that could be influencing

the pattern of cases we are seeing file. Another phenomenon that I have observed is that the lawyers that are bringing the cases are -- we're seeing expanding number of law firms that are bringing the cases. So in years past there have been the majority of the cases that were filed by a relatively small number of firms. Now we have a great variety in the number of firms bringing these cases. I think we might be seeing an effect in some cases the Internet age. More information that is out there for consumer. More outlets for consumer. To find representation to bring their cases. Those seem to be from what I can find to be the drivers behind the case increase. I am expecting this case increase to be sustained at least at that 500 or more case a year level which then raises some questions about resourcing to make sure that the program is positioned to get those cases and those petitions processed in an expeditious fashion. So that is something that we keep a close eye on. ROE resourced and staffed properly. To move these cases along. Turning to slide three, the total number of cases in the reporting period -- we had 130 cases adjudicated. If you compare that to the number of cases that came in there are 122. Of course is not the same 122 that got adjudicated this period. Those 120 they got adjudicated are from years past. I keep a close eye because you obviously want to see as close as possible at least as many cases adjudicated as there are cases coming in. Otherwise you are continuing to see the number of pending cases expand. And I was gratified to see that we were close in terms of the number of adjudications to the number of cases coming in. The last meeting I reported that we were about 13 behind in terms of the number of cases adjudicated. So getting closer to being -- odyssey you would wanted to be adjudicated then coming in so we could work on the pending cases but at least keeping us at the same level is gratifying. Moving down to the cases conceded by -- cases not conceded by HHS there were 67. 64 of those were by settlement and we've talked about this in the past. A lot of cases that are compensated but not conceded are compensated via settlement. I want to talk about this a little bit more depth because of the question that came up about proposed changes to the table to add blue and Serva and concerns about the length of time it takes to actually see those table changes become public. And what happens in the interim. As a practical matter let me take a step back. Let's talk about Serva. If there is good science that is driving a table change that let's say there are several studies that are done and it shows shoulder injury related to vaccine administration. As causally connected to vaccine administration. That might be the driver and probably will be a driver to make a table change. Adding Serva. Those types of cases while the table changed his pending. Were ones where there is good scientific evidence of actual causation. So they would be conceded. But a table change may go beyond what the science has proposed for has found and be a little more generous. Let's say the science said that Serva occurs within 24 hours of vaccination. And that's the only study that was being looked at. So then you had good science for that but maybe the table said if you have it within a week we are going to consider this cases compensable. What will generally happen with that is those types of cases and that being candidates for settlement. In the interim before table change is in place. Flu GBS is another category of flavor of what can happen. Flu GBS is being proposed for addition to the table and not because there is necessarily good science but for policy reasons as well. There are some policy drivers behind adding flu GBS to the table. That is being considered. In the interim there's been a lot of talk including public talk here at the ACCV that is put out that flu GBS is considered for addition to the table. The secretary has an active yet but it's under consideration. The IOM looked at this. They're different studies that have looked at this question. What happens as a

practical matter is that those cases then start becoming candidates for settlement. And my later part of my presentation I have slides and I will look -- i think it starts at slide 11 where we go through the adjudicated settlements that we had this period and it talks about in the slides -- it shows what the vaccine was and what the injury alleged for that vaccine was. I quickly went through that while the discussion was going on about what happens in the interim while the table changes pending. And I added up the number of cases that were strictly flu GBS cases. There were 31 of them. So you can see that what happens as a practical matter is as this is moving its way through the administrative process the judicial process is already taking these things into account. The petitioners and their Council no they have it case that is likely compensated in some way and this cases move through the settlement. The question becomes one of our they adequately compensated and as the evidence is stronger, or you are moving closer to the completion of a case being added to the table, one can see that the petitioners are in a much stronger position in that settlement discussion and as the amounts of settlement go up. So it's a process that occurs over time. But to address some of the concerns that you rightly raise about what happens while we are all pondering this and waiting for this to take place and we know there's a fairly involved process to get that to completion where there is actually a public change, an official change to the table, while the digital proceedings -- judicial proceedings take care of that in some way. Because of the nature of how we proceed in court.

This is and Ron. Thank you for clarifying.

I have a question. Dave King. I thought I heard you say and clear me up if I mistaken in my understanding of this, is that let's just say we have a case where we on the commission might recommend a change to the table. And that has to go through its process. And that the earlier in the process the less positioned are the petitioners who might say but that is what happened to us as opposed to as a goes through the rest of the approval process and data becomes more likely. Did I hear that correctly? And that might impact the dollar amount?

I think the thing that most affects how strong a settlement position is in is how much evidence they have. The basis of their scientific evidence for an injury. We know there is mixed evidence on flu GBS for example but there is some. Some that folks have looked at indicating with respect to -- i believe it was the H1 and one strain. There have been a signal there that there might have been Association. The strongest driver for the amounts will be the evidence that petitioner has. But as the secretary was the one who proposed the table change for flu GBS. As that is made public obviously there is a stronger position that the parties are in -- in terms of the settlement posture. So that can influence and I was anticipating next questions because it seems to me that is the logical next question is are the amount of settlement -- how does that compare. I think you see over time as there is more evidence developed and more acceptance of this as a potential table entry that you see the amounts settlement go out. And in fact that also influences how long settlements take for example because the negotiations can be a little bit more involved when you are talking about these changes in settlement posture.

Does that help?

I think what it tells me is that there is nuance to all of this.

There certainly is. It is an evolution that occurs. I've seen it happen with the other table changes over time. What you eventually see is with the table changes it is a like there's a night and day difference. When the table change takes a back. The day before the table change the contact someone got zero and the day after they got $500,000. That deep -- that you do not see because this process -- the judicial process is taking into account what is about to happen or likely to happen.

I think you've answered the question. Thank you.

Moving ahead to slide four. We are running about the same I think. Voluntarily dismissed withdrawn cases last time so there is no difference there. I'm going to -- i'm not going to talk about each of those slides with decided cases that briefly talk on slide 5 that there was Tim then it's which was the damages case. It was a death case involving a child. The issue is whether the child was authorized or whether the petitioner was authorized to receive future lost wages sufficient to the other death benefit compensation that the state received and that finding as a federal circuit was they were not entitled to future lost wages. The petitioners filed an additional [Background Noise] and the Supreme Court asked for the respondent file in opposition to that. The Supreme Court has an active yet to decide whether it will hear the case. That is pending in the Supreme Court. There were two recently decided cases of the Federal Circuit and one was price -- i'm sorry, slide 6. One was Price versus HHS. That was a case where the appeal itself was filed late. The case had been voluntarily dismissed by the petitioner about a year or so -- about a year after the petitioner had dismissed this case he sought to have the judgment withdrawn or vacated. The special master decided not to withdraw that judgment. Issued a decision. To that effect. And the petitioner was -- had 30 days to appeal that and did not appeal that petition in time. Did not appeal the decision in time. To the Court of Federal claims. The Court of Federal claims decided that because the appeal was late it wouldn't -- they would deny the appeal. The petitioner then filed an appeal to the federal circuit again. The petitioner had 60 days and the petitioner was again late filing the appeal. The Federal Circuit said it was going to deny bare appeal for being late. So that the procedural case. It's not dealing with substance. [Indiscernible] with the other case decided by the Federal Circuit. That was a fact based appeal where there had been an allegation about whether the individual had vaccine related anti-electric shock. There was a finding that the individual did but they condition resulted -- resolved itself without any lasting effect. It didn't affect the petitioner for more than six months as required to be able to file a petition. The special master dismissed the case on the grounds. The court of federal payments -- claims agreed and upheld it. The federal circuit has agreed that that. That is all I will be briefing today to try to get back post the schedule but I'm happy to entertain any questions you might have.

Vince, you don't have to try to keep us on schedule. If it makes sense for you to provide information on the other slides you have you should do that.

I appreciate that. I did go through them because I wanted to look and see if there was anything that I thought was of sufficient importance for the commission that I would cover it. Certainly the what -- the new cases that were filed there will be the opportunity to cover those with their decided. And I looked through the cases that were recently decided and didn't see any that jumped out at me. Other than one to give you -- i guess I would cover for this reason and because you had a question about flu GBS and what happens in the meantime. There was a decision that came out where flu GBS case had been denied and the shows you that even when something is added to the table this case would also be one that would be contested because there was evidence of another factor involved for the GBS. There was a respiratory infection and there was good evidence that that was the cause of the individuals GBS. That's the case that -- i will quickly mention it by name. That was the Tompkins case. That case -- i only put that out because that case regardless of whether flu was added to the table or -- dbs was added to the table that case would've been contested no matter what because of the strong evidence that there was another cause associated with the injury.

Vince, this is Ed Kraus. You said Tompkins because that one -- the parenthetical afterwards says jurisdiction.

I think it was Tompkins. I'm sorry if it says jurisdiction after the parenthetical. I might be missing some nuance to the case decision that involve jurisdiction. But -- i am wrong. I'm sorry. There was a jurisdictional problem with that case. That case was -- that individual -- no, I'm sorry. I'm confusing the case with another one just filed where there was a jurisdictional issue involved because it was a government contractor. Who received the vaccine overseas. I believe that Tompkins is a case that involved an entitlement question about what the primary cause of the individuals GBS was. And I apologize if the parenthetical is throwing us off on that.

Vince, Dave King here. On the pending cases under the appeals by respondents -- is that an appeal that you are making where you didn't agree with what was decided?

That's correct. One that is up there at the Federal Circuit -- i'm turning to slide 7.

I was looking at the newer case.

We've already briefed the other one previously. Paluck Was a case where it hasn't involved procedural history. It was in front of the special master on an issue of whether the vaccine -- the individual had a mitochondrial disorder and there was a question about whether or not the condition of the individual had was Denovo caused by the vaccine or whether the vaccine significantly aggravated the underlying by mechanism of acting -- of activation in conjunction with the underlying mitochondrial disorder caused the condition. The case was decided by the special master found that the -- there was not sufficient evidence for him to conclude that the -- that there was actual causation for the injury in that instance or significant activation of the underlying case. That went up to the Court of Federal claims and it was reversed and remanded back because there was some question about whether or not the petitioner had adequately had an opportunity to address the significant aggravation aspect. The case had been -- the

special master question whether it was probably a significant aggravation case. Made some findings on that but the Court of Federal claims send it back and said this needs to be looked at further. There was a hearing in the case. There were a number of experts they came in and discussed the significant aggravation aspect. I'm trying not to confuse the many cases I have here. It went back up to these special master and they found that the person was not entitled to compensation. In a lengthy decision. It went to court of Federal claims. The judge essentially -- the judge reversed and substituted his own factual findings for those of special master. And it's really that issue about whether that was appropriate for the judge at the Court of Federal claims to be doing whether he had given the appropriate level of deference by law to the facts by the special master. That is driving the notice of appeal in that case. A brief hasn't been filed. We've noticed our appeal but it is not at this point briefed in front of the Federal Circuit.

Thank you.

Are there other questions?

I'm hearing none so I will step down now.

Actually I will ask one question before you go and that is we've moved to conversation around new business and it may end up being in the -- it may actually get moved to a committee or workgroup or move down to a different meaning that it really has to do with when we make a recommendation should we -- what is your opinion of us making a recommendation on whether one should be pursuant with bigger those types of cases.

Obviously that recommendation is -- directed to the secretary of health and human --

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Correct. We are just asking how you feel about us doing things like that. I'm asking for an opinion. You don't have big give it if you feel uncomfortable. I will let you off the hook.

It's not really a measure of being uncomfortable. Attorneys always have opinions and they always want to talk. I'm not sure what impact it would have necessarily in -- i'm thinking in terms of the judicial proceedings. From where I sit what I see is when the secretary or HHS and the commission have made a recommendation to have a table change, things start happening as a result of that. And I haven't really witnessed a vigorous defense of cases that are currently being considered for addition to the table. That doesn't mean that there aren't going to be cases like the one I talked about where there is good evidence that there is some other reason for the injury. And those might be defended. Or there might be cases where the timeframe is not right. It's either too soon or too late or there might be question about did they really suffer the injury or not. Is a really GBS versus another condition. Those things might end up causing a case to be looked at closely for defending and or maybe if it does settle in my not settle as much money as the case that more closely was tied to the table. The proposed table change. But it seems to me that in a lot of ways things start happening before you actually see it in black-and-white on the table. And the big driver on all of this seems to be the research that is done and what comes out of that. And then when it starts being -- that seems to be one of the

reasons why things get proposed. That is stating the obvious. The time frames or the way the entry looks might be more generous than what the studies say. So the table might extend that beyond what the science is. But we start seeing in the court cases -- it's not like it's happening in a vacuum. It's happening in a vacuum -- it ends up having an impact.

That's good input. Just to follow-up on that. Dave King speaking. So sometimes -- i gather that sometimes the recommendation on the table might in fact be more generous than the science my necessarily want. That's possible is what you are saying.

Correct.

But was it not the intent of Congress at the time that we would air on the side of those injured and that therefore we should be moving more likely towards settling this type of cases even if it might be a little bit more generous then the science supports?

Going back to when the table and when Congress was first looking at it, I don't think there's a yes or no answer. But I think -- i think the answer in my view and this is my opinion. Congress when they first did the table they had different thought in mind and that was they weren't sure what was going on. But they said we really want to act now and give it our best guess about what goes on the table. And so they came up with that original table with that idea. We know this is not perfect. But this is our best guess. And so that is what they came up with. Then they charged the secretary with the job of maintaining the table thereafter. And they did tell the secretary here are the rules you should use when you look at how you maintain the table. One of the tools is various scientific bodies to take a look at four information about what vaccines are doing. So I don't know I would be able to say that that Congress had it in mind that you would air on the side of being more generous but I do think the table with that pedigree for the table -- you would say that the table is more than just -- it doesn't necessarily have to be just strictly what science has set and I think that is already being reflected by how the HRSA in terms of its proposal to you and where it seems to be going with blue GBS that that is already an approach that's being taken by the HRSA at least. They said this is not -- if we were to go by science we wouldn't be making this recommendation. So is beyond that. So a long way of saying I think the pedigree of the table isn't totally based in science and so there's room on the table to be more generous. Than what you would necessarily have in science. But looking back to what Congress was doing back when they first started it they pointed the secretary -- they charge the secretary with maintaining the table and pointed her in a particular direction. But again this seems to be room within that construct to take into account or than just science.

I believe there was actually. I guess I need to go back and review the legislative history but I believe that I got the sense what I was reading that that it was more that the intent was we need to help those who might be injured and it's not necessarily all about the science. And I think that was really part of the intent. So if that is the case I sometimes wonder if we push the science piece to hard at times particularly when it injury might be on the table.

The difference between actual causation and a table injury. It does seem that there is room -- actual causation is going to be evidence-based. The table doesn't necessarily -- there's room in the table to take into account other factors. And certainly there is legislative history to the effect that their pronouncements that the program was meant to be generous. One may interpret that as generous in compensation awarded to those who establish their entitlement to compensation. Or one may interpret it as it meant to be more generous and how you establish entitlement. And I'm not in a position to tell you what Congress intended when they said -- made a pronouncement. But I would say that actual -- one might -- one must look at actual causation differently because that will be driven by evidence and there are ready in place decisions that say what that evidence has to be. That has to be reliable. It can't just be -- the statute says it can't be on those claims that the petitioner alone not backed up by evidence. There are certain parameters we do operate under with respect to actual causation cases. The more we talk together I think we are in agreement. I don't think there's a big difference between what I'm saying now what you are saying.

There might not be. You might be right on that. I don't know and I guess I may go back and look in more detail on the legislative history and see maybe they made more directive approach that we all have interpreted overtime.

Or at least bring it to our attention. Something to think about. -- obviously one can ask if all that's on the table is what you can proven the case and the table is serving to be a shortcut when something is are ready establish. As opposed to being a policy document as well. That is I think with respect to blue GBS we see the table moving to more of a statement of policy decision. By the secretary if that's the way it goes. Of course that has not been adopted yet.

Right. Okay. Does anybody have any questions?

Thank you.

Thank you Vincent.

So we probably do need to break for lunch. I would ask the commissioners -- we normally have an hour but I'm looking wondering if we can shoot for 1:30 PM return.

1:30 PM Eastern daylight Time.

Sounds good.

Let us reconvene at 130 Eastern daylight Time. We are on a lunch break for now. Thank you everybody.

[Event is taking a lunch break and will reconvene at 1:30 p.m. EST]

Thank you everybody. We are continuing with the 92nd quarterly meaning. We're in the afternoon session. The first item on the agenda is Doctor Mary Rubin and the item is to petition to add Diabetes Mellitus as an injury for the measles, mumps and rubella vaccine. Doctor Reuben, we will give the floor to you.

Thank you. Hello. Or good afternoon good morning. My presentation is titled the national vaccine enter compensation program and vaccine and diabetes mellitus. If you are looking for this slide set. Briefly this is coming in front of the ACCV because there has been a public petition received to add Diabetes Mellitus as an injury for the MMR vaccine in the injury table. According to the statute any person including be advisory commission and childhood vaccines -- i am on slide three. May petition the secretary the proposed regulations for the table. And less clearly frivolous or shaded by the commission any such petition shall be referred to the commission for its recommendations. Following a receipt of the recommendation of the commission or 80 days after the date of referral to the commission whichever occurs first. The Secretary shall conduct a rulemaking proceeding on the Mattis proposed the deposition published in the Federal Register a statement of reasons for not conducting such proceeding. Slide 4. Before I delve into the summary of the current science I'd like to briefly define Diabetes Mellitus although it is a common disease that most people know what it is. But there are two types of diabetes mellitus. Type I diabetes and that is one of the most common chronic diseases in childhood. It's caused by insulin deficiency following destruction of insulin producing pancreatic beta cells. This is an autoimmune disease and it has a T-cell mitigated destruction and marked by presence of pancreatic [Indiscernible]. Absolute in -- insulin deficiency and you may have heard it referred to as insulin-dependent diabetes. There is also type II diabetes mellitus and this one is characterized by hyperglycemia and insulin resistance and relative impairment in insulin secretion. It has strong association with obesity and the difference between type I and type II is that is not mediated by antibodies against pancreatic [Indiscernible] cells. The petition did not specify which type of diabetes [Indiscernible] so I will go over -- we did look through what current science has provoked types. There have been many studies evaluating the risk of diabetes mellitus between MMR vaccine and type I diabetes.

Including reviews of [Indiscernible] the 2002 IRM reports completed literature that rejection of relationship between multiple vaccines and increased risk in type I diabetes. There have been multiple studies as I mentioned and in 2012 IRM report had reviewed the studies up to its current studies that have been published until 2011. After their review the 2012 IRM report completed that the evidence favors rejection of eight cross -- causal relationship between MMR vaccine and type I diabetes. Specifically, the IOM committee had a high degree of confidence in epidemiologic evidence that these studies consistently report a knowledge Association. Also be committee assess the mechanistic evidence regarding an association between MMR vaccine in type I diabetes and as lacking. After the 2012 IOM report has been published there were other studies after the studies that they reviewed in 2011. There was a collaboration report that -- i'm on slide 5. Reviewed MMR vaccine in children and the goal was to assess the effectiveness and adverse effects associated with MMR vaccine in children up to 15 years of age. They reviewed and assessed studies in the central registry of the control child. The conclusion to type I diabetes and with MMR vaccine is likely to be associated with type I diabetes mellitus.

In slide six there is a study of 2012 by [Indiscernible] and this was to evaluate whether vaccination increases the risk of type I diabetes in active components U.S. military personnel. It was a retrospective cohort study among active U.S. military personnel where they identified type I diabetes from 2002-2008 an estimated the risk ratio. The result was of no increase the rest of diagnosed type I diabetes in any of the study vaccines. Including MMR vaccine.

Regarding type II diabetes mellitus there hasn't been any -- there were no studies regarding MMR vaccine and type II diabetes mellitus.

Slide 7 and 8 list the articles that have been included in the IOM and the additional studies. I believe it any -- annie sent this to you.

On slide 9, this is coming in front of ACCV for recommendation to see what the options were recommendations would be. With the ad MMR diabetes mellitus to the Vaccine Injury Table or not add MMR diabetes mellitus to the Vaccine Injury Table.

I opened this for discussion.

This is with Cetip. When I was researching the [Indiscernible] vaccine a long time ago I did run into an article that said that immediately after mumps outbreak there is usually a rise in diagnosis for diabetes. Would that be considered Association?

That is a complicated question because for the most part that definitely has a temporal relationship but that doesn't necessarily mean a causal relationship because they could be other factors. It depends. When we did go through the research we did research for measles vaccine and mumps vaccine and rubella vaccine and the MMR. The IOM did the same thing.

Again the moms is known to --

The mumps virus. There could be a mechanism but it's not necessarily that the vaccine -- although the mumps virus vaccine is alive virus so far there has not been evidence that the mumps vaccine itself causes diabetes mellitus.

Okay. Thank you.

Any other comments or questions flex

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It would appear not.

Mister King, I would like you to -- for you and the committee to discuss if you would like to add MMR diabetes mellitus to the vaccine injury table. We were asking for your recommendation.

So that the question I have is the driver for this was from someone from the public.

That is correct.

This is Ed. The petition was submitted to HRSA in -- to make this table change. Was there any medical literature or medical evidence or epidemiological evidence submitted along with it or was it just a request to add it to the Vaccine Injury Table?

It was just a request.

So there was an e-mail that was sent on April 9 and it was sent to the go and I was copied. I followed it also. All they said was they believed that their child had been injured by the MMR vaccine. If you look under -- looking your book under terms seven you will see it. The question is this a statement in there that says that Merck lists this as a possible adverse reaction to their MMR vaccine to the product insert which they said was attached. Is that an accurate statement?

We also have a copy of the Mark Mac MMR -- merck MMR.

That was submitted along with this e-mail. I didn't make that connection.

The Merck product insert reports everything that people report that is happened. That has no scientific or causal basis.

This is Sylvia. If you look at the Merc insert page 7 it says endocrine system under adverse reactions. And it mentions diabetes mellitus.

By name.

This is Kristin. It lists the beginning of that section that these are adverse reactions listed in decreasing order of severity without regard to causality. So is stating that these are all things that have been reported during trials. So it is a listing of everything reported. Without an evaluation of causality. Is there an obligation to list everything reported in the product insert?

I think so, yes.

But it doesn't tell us in decreasing order of severity but it doesn't tell us what the severity is actually. So we don't know -- we don't know -- always know this has been reported.

It doesn't tell us anything of causality.

It says this is an adverse reaction that was reported.

This is Ed. I would speak to the issue that the proposal is to added to the Vaccine Injury Table based on the IOM study and the presentation that we have been provided with. I don't see basis to create a presumption of causation at least in the medical literature. I would point out or remind everyone that it doesn't mean that a person couldn't pursue a causation in fact case in which they alleged the diabetes was caused following -- and MMR vaccine. I think it seems almost as though this is a procedural obligation on HRSA to present this to us. And I'm not seeing anything that would make me think that we would need to look beyond what we've been presented with. I think we can probably comfortably say that there is no supporting medical literature or scientific evidence to create a presumption of causation for diabetes following MMR.

Dave King. Jason, how would -- i don't know if you can answer the question but --

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I may not be able to.

That may be what I'm thinking. I think it would be speculation.

It is on the Merck product insert and then it would be. I would hesitate to speculate.

I agree with you.

Mister chair, this is Sylvia. I move that we use the information to submit by Mister Krause go to ACC -- accv recommendation M to -- number two. Does not meet the causal obligations.

This is Charlene Douglas and I second that motion.

Is there any discussion on this motion?

We will call the collective.

All in favor of the motion as submitted which is essentially number 2 on slide nine say I. All oppose? Any abstentions? It passes.

And I would assume then any and Melissa what ends up happening is with the reason in and the reason being that there is no evidence to support it.

That's correct.

Great.

Thank you.

The next item on the agenda is the report from the process workgroup. Lucita DeLaRosa.

I will read my report. I submitted it before handed you should have a copy. The process workgroup was able to meet by telephone on May 8 and the meeting focused on two items that were brought up during the March full commission meeting. The items are the presentation of the statistical data on vaccine cases filed in edge you could dictated -- adjudicated over the years. The commission can gain support to move the recommendations that have been presented to the secretary forward. The summary is as follows. Data mining. The group discussed they were proposed by mysteries their rank him and how it differs from the information already available in the HRSA DVIC website under the heading data and statistics that is updated monthly by the division. After a lengthy discussion we came up with the following. It was decided that miss [Indiscernible] would be invited in a future process workgroup meeting probably in July or August to provide us with the thinking behind the request. She could also provide us insight as to why she suggested a new table and who are the most serve the by the information being requested in the new presentation. Studying the proposed table table the level of detail being requested under this section not compensable, for example, exceeded the statute of limitation, incomplete claim, withdrawn, dismiss for other reasons, can only be determined by reading individual files and the DVIC is not doing that. Also noted is that all decisions are published in the Court of Federal claims website in so far as the main vaccine cases concern. Lawyers these are usually not published about entitlements are published information. Other search engines that access court information can also be used to search details of different cases, especially older cases, however the records of most of the newer cases that are decided be a proper settlement do not offer details. Also pointed out is that when a potential claimant request the assistance of a vaccine lawyer to file a petition that exceeds the SOL, the vaccine lawyer would not take the case and so would likely not reach the court system.

On the second topic, how the ACCV can gain support and moving its recommendations forward. The group discussed how the commission can move this. That were formulated and presented to the secretary. For the discussion we focused on the SOL. We have a strong sentiment that is a whole the commission should expect a response from the secretary specifically the secretary stand on the recommendations made by ACCV, beyond acknowledging the receipt of these recommendations in her office. Says there are two types of recommendations made, the first one those that can be acted on internally at the department level and those that require legislative changes, that is workgroup wants to have the commission had a discussion on how we can create movement that would help to get the recommendations without stepping out of bounds of our capacity as an advisory body. Especially the recommendations that would entail statutory change for their implementation. As a start, members of the ACCV already represent the different stakeholders and the representatives of the different departments sit on the commission meetings. This discussion is included as an agenda for the June ACCV meeting to enable the commission as a whole to see the different points of views. Some reasons for exceeding the SOL were enumerated during our meeting. Lack of awareness of the program despite the information provided by VIS about it. Either the VIS was not read in full initially or by the time the information was needed it was already forgotten. Reliance on the statement of the healthcare provider as to the cause of the problem, sometimes the potential claimant receives an outright denial that the vaccine could be the cause. Sometimes a lawyer

approached by potential claimant tells him or her that he or she could not be helped. That is the case has no merit. Parents or caregivers are too busy dealing with the aftermath of the injury to realize the passage of time. There was also a brief mention of revisiting the issue of public awareness of the facts and -- vaccine injury compensation program. That is it. For a one-hour discussion.

[Laughter]. Why don't we have a conversation around some of these things. If I may jump in Lucita, in our minutes for this meeting that were put this morning, on page 7 part of this was talked about in the sense of the area on hearing from the different potential stakeholders in the like around the statute of limitations. It appears to me that the consensus was is that we would develop and work on that agenda item for the September meeting because it was suggested that this would be something done better in a face-to-face environment. So I turned to Melissa for a moment. Melissa, will September meeting be in a face-to-face environment quick

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It is scheduled to be face-to-face.

Okay. It is possible we could set this up for that and developing -- in fact, if people look on page 7 you will see this a paragraph that begins with Jason Smith and moves on through. And then that [Indiscernible] suggested a small group development list of appropriate witnesses. I think we'll use the word witnesses in". And then Ed Kraus suggested the process workgroup my be the appropriate group to develop that list and that because it might be more effective in face-to-face as opposed to what teleconference we would target the September meeting. I would say this is something that is probably a work in process that either July or probably the July were process group meeting because we need to give people time to get it on the schedule if they're going to speak. We would invite folks in I would think. Does that make sense? How you feel about that?

It's okay as long as we get going with our meetings. Is difficult to get people all on the same time. That is why so far I will go one meeting a month and we haven't been able to meet it because of the difficulty of getting everybody. All lined up.

So, we do have time right now. We could have some of this conversation right now. On the agenda it would appear that the process workgroup was going to hold the agenda for from 2:58 PM. It is only get a few minutes before to PM. The commission can meet as a committee of the whole and as the process workgroup committee Dashwood group will talk about this. We could do that. And get input from everybody on how best to go about it. I think Ed, we talked about different groups that might come in and petitioners far might have a suggestion. The Department of Justice might have a suggestion. So how do we make this happen?

Dave, which part -- this is end. Which part of this proposal are you talking about quick

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The second component right now which is the statute of limitations and having a more in-depth conversation and discussion around that.

Thank you.

We try to figure out how is the best way to go forward. Lucita is concerned we may not have time to put together in the process workgroup because of the scheduling difficulties and I can empathize with that particularly in the month of July and August.

[Captioners Transitioning - Please stand by]

Does anyone have any suggestions on how we could successfully execute on this property

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This is Ed Crouse. Those of us were on the the process workgroup, we have had some discussions about this but we were I think wanting to hear from other folks, other commission members about it.

This is Michelle, maybe the sub group -- a subgroup of the process group could collate request and collate thoughts from the other committee members. Other commission members. And rather than have meetings, just do it on paper.

In other words, people would direct an e-mail or missive to people just aligning their thoughts as to who might be appropriate people, why you should be invited for a more in-depth conversation around the statute of limitations. Is that what you are suggesting Michelle of the

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Or if you have comments about the issues. Maybe there could be one person from the process workgroup designated as the statute of limitations person. To coordinate. Either on paper or in the end.

Any other thoughts property

This is Kristin. That some like it might be a good way to proceed because then people can take some time to think about the specific questions and how to respond. Sounds like some of this will take a little bit of thought, this just might be a way to more easily facilitate sharing thoughts and ideas. That we can then talk about.

Okay.

Maybe the three lawyers on the commission could spearhead this for you all. Recognizing that I can't see anybody spaces to know if they are rolling their eyes. [Laughter]

We'll said Michelle. Jason and add, as the other attorneys, how do you feel about Michelle's suggestion their property

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I am including myself.

That is good to hear. This is Jason. I am fine with it. I think it would be a good idea if we are going to do that so there is clarity it is a little difficult over the phone, but Michelle add and myself can get together following this meeting so we are clear on what some of the action steps are going to be and accountabilities following the meeting so it doesn't slip. Being one of the accountable people, we will just meet and be able to be sure who does what.

That is fine.

That is an action item that has come out of this. Good. And then you guys will give us a recommendation on how to move forward, is that correct property

Yes.

That would be the overall objective, yes.

That would be the goal.

I think that is something. Let's go to the first part. Luisita, I can't see -- can someone move the process workgroup to the first page please what the than the second -- the first part there is just something that should be part of the July or August meeting. Is that correct Luisita?

Yes we can find out.

Right. I know it can be difficult. It might be -- June is already upon us. We are in the midst of it. There should at least be one meeting I would think that the group could have one meeting to dissect and work that through. Annie you put out a polling on it until you property

Yes.

Will you encourage Teresa Wrangham in Nepal?

Yes.

We will let you take care of that piece and then we will all try to drive to a consensus on what might be a good time. I see no other way to go about doing that. Luisita, does that make sense to you?

Yes. Anything --

Does anyone have any questions for Luisita and the process workgroup?

No.

Did everybody drink their read all after lunch?

It will take more than that.

The good news is the we're going to move to the next item on the agenda and we have always known that it is a robust time when we talk about the vaccine information statements. Skip Wolfe you are on. Is skip here?

This is Tom. Let me call him and tell him we are ahead of schedule.

Let us do that. Since we are slightly ahead of schedule on that, should we jump the schedule or -- while you try to reach him. Is Barbara Mulach available to give her report?

Hello.

While Thomas reaching out to skip, why don't we get your report on the update on the national Institute of allergy and infectious diseases.

Happy to do that. Just a couple of updates for you. I believe you should have slides as well. To start, I wanted to highlight a recent study that was published that is an ID supported and that was studying pregnant women receiving TDA P vaccines. This is recommended but we were looking to gain some additional information about the mean response and the safety in women in their third trimester of pregnancy. And the results came out. In the Journal of the American Medical Association recently in the publication is listed there. We found the vaccine to be safe and to induce an immune response that could be seen in the newborns and in the mothers. Again, that is supportive evidence for the maternal immunization recommendations we have. Secondly, I wanted to highlight our movement towards personalized medicine. We are continuing to look in many different ways at different immune responses that people get when they are receiving a vaccine. And a study in slide three, we have an intramural investigator who is looking at immune responses both before and after people would receive the 2009 H1N1 vaccine. That was a new vaccine and people have not been exposed to H1N1 before it was an opportunity to see what was going on in the immune system both before and after and they collected huge amounts of data so one of the terms you will hear from NIH a lot is the data. Where you collect a lot of information and then the challenge is to figure out what it all means. And so we're moving in the direction of figuring out what all of this information means, and trying to really hone in on what it is that makes for an effective immune response and then to be able to tell him individual people whether or not it works for this type of person or that type of person. And trying to identify those factors both genetic and environmental. This is a step in that direction and they were able to hone in on a few different immune cell types that were predictive of a level of antibodies to the influenza vaccine. Again, this is basic research, but it's really exciting where we are going with all of this. We have a couple of different programs that are doing similar things. Where hopeful that in the future we will be able to really understand how people are protected by different vaccines. This is one of the steps in the way of doing that. The link is there to the article and then the papers if you are interested in more

information. Slide four, we wanted to recognize one of our very successful programs the centers of excellence for influenza research and surveillance. This is a program that we have had since the mid- 2000 and we re- competed the program and our awardees are looking at a lot of different things. They're looking at development of better and more protective influenza vaccines with the ultimate goal of moving toward a universal flu vaccine. What we call so we wouldn't have to vaccinate every single year, we would be able to give a flu vaccine and it would be more broadly protective. Other people are looking at surveillance across the world and so these awardees have collaborators in many different countries and you can see on slide five read points on some of the areas where we have collaborations. The idea is to look at the avian influenza and the migration pathways and the fly ways and to be looking to see what flu is circulating in different parts of the country and to anticipate when the flu might be coming into human populations so that we can do our best to limit the impact of those new flu strains. To avoid a future pandemic. They're doing a lot of really great research to develop better vaccines and a lot of basic research to better understand how the viruses are evolving and what we can do to limit the impact in the human population. And the last slide I wanted to highlight a few of the different meetings that are ongoing. We are collaborating with FDA on a vaccine meeting to be held on June 19 and 20th. It's called common barriers in vaccine research and development. The idea is to get at what are some of the limiting factors that keep us from getting license vaccines into the system and what can we do to make that better. We're looking forward to that meeting. We have a couple of different meeting reports. One on our website that talks about a consultation on dengue vaccine. Are Staphylococcus aureus vaccine meeting summary report. So again, these are places where we've had meetings and we've identified some of the issues and progress and really trying to tease out what the issues are and trying to move the field forward in terms of the science. Hopefully that means more exciting research and activities are coming out in the vaccine world. In the coming years. That is my report and I'm happy to answer any questions.

This is Luisita. Is the conclusion that you are presenting a result of this study consisting of 48 women?

This is meant to be an indication of what we have learned about vaccinating those women and what the immune response and what the safety and those women are. It's not meant to be a comprehensive indication for all women but again, it's gathering more information about what we know about the immune response. They are always monitoring all women who are getting vaccines but this is a way to look more clearly at what kind of immune response they are creating so that we better understand that it is causing some antibody response that would make it worthwhile to vaccinate. Does that make sense?

You have at least on the maternal vaccination program the clinical trials. Do have some idea of how many are registered for this trial?

This was a small trial. We have several trials we've been doing with TDA P vaccines. Where they were looking more closely at the immune response. This is one small trial.

Your statement is simply that the trend looks like it is protective.

Right.

Likely. I just want to make sure that this isn't a part conclusion if it is not.

No not basing full conclusions on a small number in that way.

Thank you.

Any other questions or comments?

This is time and TDC. In that study, did newborns get tested for antibodies?

Yes, they did.

Okay.

Do want me to send you the paper?

I can look it up, thanks, that is fine.

They did look at the newborn antibody concentration.

Okay, thanks.

Any other comments or questions?

This is an. For the same study did they determined that the safety for the newborns was good property

Yes, we didn't see any safety concerns in that study. It's a small population, so taking that under advisement. Yes.

Thank you.

Anyone else? All right then. Barbara, thank you so very much.

Any time.

Tom were you able to get through to skip?

He did and I am on.

Skip, you are on.

Hi. I think Suzanne should be onto. She is calling in from home.

Hello Suzanne?

I told her a minute ago. She might not have time to join us here at that she should be.

Okay. Do you want to give a preamble first?

Not really, we've all been through this.

Let's get to it.

We have three to review, two for HPV which are pretty similar except for the first couple of sections. And then the multi- vaccine which might take a little longer. People have been asking for that one.

In our books, we will find it under tab five.

We can do it in whatever order you would like to.

The first one starts with Gardasil. Why do we start with Gardasil.

I don't have any questions to start out with. There are a couple that may come up with as we go along but when we start with your comment? Starting with the first section. These have been reviewed by our HPV people by the way. And then some of the wording came from him. Anything in part one?

Yes, this is [Indiscernible]. I had a question. That is for sense. The vaccine you are getting, by human papilloma virus. Would be helpful to specify which type? Of all types of human papilloma virus -- it would prevent all types?

I'm not sure if that is too nuanced for a lot of patience. We avoided getting into different types for that reason.

This is Suzanne. I am online.

Suzanne, welcome.

Thank you.

If we say prevents cancer, I don't know if we're afraid that that implies that it means all cancers caused by human papilloma virus. We could add the word some there without getting into specific types.

I think it would be helpful. That was my first impression when I read it. If they would think that is [Indiscernible].

This is Ed Crouse. That was my comment and concern as well that it implies that a prevents all cancer caused by HPV. Which it doesn't. I think it's important to add some.

That's an easy fix.

I will most. In the later sections you say 70%.

This is Christian. I was going to suggest the same thing. Say many cancers or most.

Is that accurate? Prevents most cervical cancers.

In total, maybe many cancers?

I don't think a prevents most.

Close to 50% but I don't know if we know for sure. More than song.

Many?

Yes.

Okay, good.

This is an. I am still in section one. The line that my parents see the most is HPV infection comes from sexual contact. That's why they don't want their kids to get it because they're too young they're not having sex and in their minds they will never have sex but that is the parents perspective. Somehow they could be buried into the second may be HPV is an infectious disease or most people will become infected at some point in their life and the next sentence could be comes from sexual contact. It is just out there and that's always the first thing they see and hear, and they know it ahead of time but we are trying to downplay that a little but because we want them to get immunized before they are sexually active. But the parents don't get that connection there.

I agree, my own inclination is to also stress that it's important to get it before you are exposed. Which we downplay in this version. I think our HPV epidemiologist for some reason wanted to do that. But I would be in favor of making that more prominent. The importance of being vaccinated before you are exposed.

Absolutely. Like it or not, parents have to recognize their kids are going to become sexually active at some point in their lives.

That seems to me to be a strong argument. Implying that your kids are not active now but let's vaccinate them before they are.

The clinicians on the line, this is Charlene. I teach my students and I've used it myself, that I just say I fully understand your commitment to the sexual contact outside of marriage and I am certain that your child will adhere to those values in your family. The problem is you have not raised a partner.

That's a good point.

You are batting her health on the behavior of someone you did not raise.

Maybe instead of putting that in the VIS itself --

That is for bridge for clinicians.

That is good.

We will try to emphasize that and also try to downplay the the phrase about sexual contact.

This is Luisita. With the preliminary sentence saying that the HPV vaccine is preventive for some of this stuff.

That's good. There to the idea protective. Nobody should actually watch their own kids 24/7. It could happen.

I still think a lot of parents don't like to admit that the you are right.

If you have that sentence that it is a preventive measure. The impact is talking about sexual contact.

Stretch that.

With Gardasil prevent -- preventing penile warts on the males is that correct or incorrect?

Was a genital ramped. The section underneath there. Underneath that we say genital warts for both.

Can you put it as a bullet? You tend to skip something that is not enable a point.

That would be a holdover from the way we were did it before because I think we had cancer and then opening. And separate genital warts because it was may cancer but now we change that.

That becomes very critical for us. You have males and females. I think you should put it as a bullet. That's easier to see.

The boys really go for that one.

Got to keep it pretty.

More persuasive than anything else. Anything else under the first section of the in the second section. We simplified be what are epidemiologist wanted to put about the schedule. They wanted to add more details about the ages. So here we say, can be given from age of through age 26, they wanted to include specific information for MSM. Which is slightly different recommendation. I thought that was too much information and let the provider from that can be done. I think that's good enough. But they told told the epidemiologist I would get your opinion on that. In other ones, they wanted to say it is routinely given for men of through age 21 but MSM can get it through age 26. That seems like more nuanced information we needed there.

This is Christian. I think this looks good. If you include MSM is love your talk about sexual activity. This is the recommendation. 411 to 12 and catch up through 26 or 21.

I had originally had it even simpler than that. It is routinely given at age 11 or 12 but can be given as early as age nine and as late as 26. To expand on that a little but. As a matter of fact, some people even wanted to leave the routine schedule -- we did leave the routine schedule off. In this version. We don't say how many doses. I also wanted to get the commission's opinion on whether we had to say it's routinely recommended as three doses. Or if we think that doesn't matter.

This is an. I think you need to say it somewhere on here, because people don't finish the series.

I think you're right. People want to know even though realistically it's not needed at the time you get a dose to know how many other doses you need. It's something we do another VIS and it adds a couple of words. It is not a big deal to add it here. There's nothing else under section 2. Let's move on to section 3. This is the contraindications and precautions. One thing that I think we discussed at the last meeting was if there is a common allergen to go ahead and add that instead of just saying if you have any severe allergies tell your provider. And then if there is something that people may know that they have an allergy to, in this case, East, go ahead and attic. We added that here. If you know of any severe allergies including a severe allergy to yeast to remind people about that if they happen to be aware of it.

It is interesting that you said provider even though it is Dr. Here.

We are still trying to make that switch.

You then -- David King here. You have severe as life-threatening defined on the first bullet under three in parentheses. Is that what we mean property you have it again defined in 2. But then in the other part you don't actually have it defined their. Are we to assume everyone knows it is life-threatening by then?

For that, I think maybe they don't know it is life-threatening but if they know they have an allergy, I think we would rather have people tell their doctor about an allergy that may not be life-threatening and let the doctor decide whether they are going to vaccinate. In fact, this is something else that occurred to me. If we are using a term severe and then immediately defining it as life-threatening do we need to say severe? Can we just a life-threatening and leave out the word severe in the first two sentences? What to think about that while the

I like the redundancy to some extent.

Okay, that is what we've always done. There's no harm in leaving them in there.

What does the rest of the group think?

How do you define severe brief besides life-threatening?

For this purpose that's how we define it. We could say anaphylactic. A lot of people won't know what that means.

Would it be -- parentheses in there would it be a severe or life-threatening allergic reaction? There many severe reactions but the do not need to be life-threatening and severity.

That's another thought.

David King here. Luisita, I think you're accurate on this. There could be a lot of severe allergic reactions but not every severe reaction is life-threatening.

We want it to be severe and life-threatening.

Do you?

We want to know if it is. We can make that change. Anything else under number three? With that pregnancy and the standard Prakashan for a mild illness. How about the risks section?

I want to back up to that last two sentences there. Probably. That seems vague.

Because it is a precaution, and it's not a contraindication. Depending on how -- depending on the nature of the acute illness. There may get it or the combination of the nature of the illness and the risk of the patient getting HPV. The provider could decide to give it or might not. It really is probably.

For both the mild and moderately or severe?

Yes because we leave that up to the -- yes. Because in either case it is a precaution. Not an out right contraindication.

Thanks.

Anything on risks in section four? We've added as we are to all vaccines now we are adding the problems that could happen after any vexing. The shoulder pain, only for injected vaccines.

David King here. Last time we met, there was a robust discussion on the idea of death and the like.

Yes. So -- we haven't made a decision on how to do that yet but our legal counsel, we talked our legal counsel about it and he agrees that we should say something about death. We haven't decided exactly how to do that yet. If you've got ideas we will be happy to entertain them.

I don't know if you and Tom ever got a chance to chat about that at all.

No, we haven't. But we will, before we -- before this gets published.

This is Tom. You have a sentence come up that second sentence. Serious side effects are also possible but are very rare. And then you have underneath the bullets no serious problems have been associated with HPV vaccine and then the last bullet you have severe allergic reactions from many vaccines are rare. But can occur. Aren't you contradicting yourself? Do you even need that bullet? Do need that sentence that says no serious problems have been associated with HPV vaccine? There probably are cases of anaphylaxis that are causally related. It just seems like you are contradicting yourself. A little bit.

Yes. I guess that grew out that if there have been reports of serious problems, we list them. He may be right. Him very mentioned anaphylaxis. You may be right.

I think you could delete that sentence. Because you are just saying that anaphylaxis can occur, severe allergic reactions can occur but it's very rare and leave it at that. Because my understanding, that is the only serious adverse reaction at least the evidence has -- there's evidence that it could be associated with HPV vaccine.

Thank you, that's a good idea, that makes sense.

This is Ed. My concern, I'm not sure how it can be addressed is there are many reports of serious adverse events following the Gardasil vaccine. And whether or not causation has been established for those reported adverse events is a different issue. But it certainly -- at least my understanding, if you go to the vaccine adverse event reporting system, there are a lot of cases where people are associating serious adverse reactions with HPV. And I don't know how that is supposed to be acknowledged or if there is a way to differentiate between the reporting of adverse reactions and the fact that -- in my view a lot of the adverse reactions that I've been reported, it's not clear. We don't know yet. The science is still unfolding and the cases are still moving forward as to whether or not causation can be established. When I am looking at this, as our job or at the federal government wants to make sure that the risks of the vaccine reaction are clearly set forth. It doesn't seem -- it doesn't seem to address the fact that there is a lot of conditions and reactions that have been reported. It is still a fairly new vaccine. Not sure how that fits in.

Tom will know better than I whether there have been any of those reports that have been established as having been caused by the vexing. One thing we could do if that is not the case. If there haven't been any of there -- definitely associated with the vexing. That something else we could put in the provider materials to explain the difference between a reports and something that we know is causal.

I guess my question is a little more fundamental than that. For with those cases -- where would be proof or evidence of causation the? Foreign adverse reaction, or a bunch of adverse reactions that were reported in 2011 let's say. Where would one look to that? I think there is ongoing observation and study and evaluation. And in some cases litigation about whether certain conditions are adverse reactions to the Gardasil vaccine. But I'm just trying to look at these VIS statements sometimes with a fresh eye, not just another VIS statements and so I know that there is a protocol and an approach for how things are set forth, but I am thinking about the concern that this is a relatively new vaccine in terms of understanding what are the potential adverse reactions, and maybe it's important to point out that there are adverse events that are -- that have been reported or again, I am not saying that there should be and efforts to presume causation just because of temporal proximity from vaccine and then a condition, but I think it's important and honest to put it out there that there are a lot of people who have -- when I say a lot it is still rare. It's not as though there are no serious problems. I don't see how that is true. You might be true to say that Sears problems that have been reported as associated with HPV have not yet or haven't been shown, established to be causal. I'm just not sure.

This is Tom. If that statement were changed to no serious problems have been causally associated with HPV vaccine that would be a more accurate statement. But I would recommend just deleting that. As far as -- as far as talk about [Indiscernible] and the VIS, I don't know if that is -- I don't think that would be a good idea. There are all kinds of -- they accept any report every temporarily associated vaccine adverse event or any report at all without any judgment on causality and although this is a new vaccine, it's actually been studied a lot both in the US and a lot in Europe, and my understanding is that the only causally associated adverse event

that has been associated with HPV vaccine is syncope. And, I think the anaphylaxis is just generic to any vaccination and that is more looking at mechanistic evidence than epidemiologic evidence. But it's only syncope that has been causally associated in epidemiologic studies. I just recommend getting rid of that sense.

What we usually do for VIS is an adverse event is being -- then we headed to the VIS. What we can do. I suggested before is that some language to the provider materials. To give them something to discuss with patients were concerned about that. Who may have heard about the -- reports. And it can be a providers responsibility to explain how it works and how reports don't necessarily mean causation. The jury may still be out. Rather than trying to explain all that under VIS itself.

This is [Indiscernible]. We will be studying this issue a lot. And first of all I don't think -- I think it's only 30% of clinicians report to [Indiscernible]. Most of them don't understand how the system works. Especially with HPV. So I don't know if it would be doing us a disservice by adding associations that are not proven. I don't think that would be smart. Going back to how the system works, the insurer you know it better than me but it is just a database of complaints. Anything and everything that has been shown after you get vaccination to prove that something -- you go to the vaccine safety datalink which is the database. It's an active study with a lot of different networks within the US who studies the causation of that affect. So far nothing has been reported. With HPV specifically.

And once it is, then [Indiscernible] would pick up on that and incorporate it into their recommendations.

This is Tom. I am realizing that I only talked about anaphylaxis and syncope but I think [Indiscernible] is also something that has been well established, that there is a causal association with service. You've got those covered there. Under problems I could happen after vexing.

Incidentally, I just picked up the third VIS we will be looking at the multi- vaccine and we do have a statement about death in there which we will get to where we get to that but I will read it to you know and see what you think about it. After laying out the specific problems we say as with any medicine, there is a very remote chance of a vaccine causing a serious injury or death.

This is Luisita. Can you clarify the difference between the word side effects and problems?

Do homage to him about one that one property

My understanding and Valerie can correct me if I am wrong, a vaccine adverse reaction, the term reaction implies that some inherent property of the vaccine caused the health problem. The vaccine adverse event means that the health problem happened after a vaccine. So an adverse reaction is an adverse event. By definition, there is a body of evidence that suggests that is a causally related event where the vaccine adverse related event doesn't make any

statement on causality. Adverse effect an adverse reaction are really the same thing. I think side effect is often used synonymously with adverse reaction or adverse effect. However, side effect I think in the regulatory world could also be a good thing. So it's better to talk about an adverse reaction or an adverse effect as a causally related health problem for as an adverse event is a temporarily related event. To sacrifice?

What about the term problem? We have traditionally use the term problem. I think as -- and set of reaction.

I mean that is probably more of a plan language.

It is. In your opinion can they be used --

I think it's okay to say health problem after a vaccination. That is the same as a vaccine adverse event.

I think people would understand that. When we get to the [Indiscernible] we can revisit the statement about death, but we didn't added to the HPV ones because it wasn't on there when the subject matter experts reviewed it. But we will -- once we decide on the wording we will put that on all VIS.

Are we still going for suggestions that we delete that symptom there's no serious problems have been associated with HPV? Are we still working on that one property

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If you have an opinion on it, we would be happy to hear it.

It's either you say it immediately after the serious side effect, and not under the mild or moderate problems. Maybe combine those two sentences into one. Something like although no serious problems have been associated with HPV, serious side effects are still possible. But are rare. With that be a better approach?

You are talking about the last bullet?

Number four. Immediately after --

Serious side effects are possible but very rare.

You say you have serious side effects also possible but are very rare and after the bullets you have no serious problems have been associated with HPV vaccine. Would it be better to combine those two sentences in such a way something like although no serious health problems have been associated with HPV vaccine, serious side effects are still possible.

I wanted to leave that thought in there. That none have been associated with HPV vaccine although I believe Tom is lobbying to redo that.

We combine those sentences in such a way [Indiscernible]

David King here. When Tom talk 12 to get the wasn't sure and I think I get it where you combine the two sentences, but I want to ask the question, which is the vaccine information statements is meant to inform people. It is not meant to sell them I don't believe I'm getting the vaccine, is it?

So on a look at no serious problems have been associated with the HPV vaccine, I guess it could be a piece of information that I'm wondering if it is really designed to sell people -- tell people it is okay to get this faxing. And maybe it could be removed and you just have serious side effects are also possible. But are rare.

It is informative.

But is already stated is a not?

I agree and I think that was Tom's point.

At first I wasn't sure but now that I'm thinking it through it is just meant to inform so that people know what it is what they are doing. That is really what it is. So that people can make an informed decision as to getting a vaccine or not getting a vaccine. That is really what the vaccine information statement is about. Correct?

It is not a consent form, but it is to inform them about the risks and benefits.

So they can make a decision.

Yes.

ICB point, and I think it is -- it would be better without that statement I believe. It's a little redundant the way.

I would agree. This is Ed Crouse. I have other issues and problems with -- but I do think that at the very least that should be removed. No serious problems have been associated with HPV vaccine.

Okay. If there is something else under number four, five, six, and seven have not really changed since we have reviewed them for other vaccines. Under number six, when we're talking about the compensation program, last time we talked about adding a sentence or a clause talk about the statute of limitations. Let's talk about the statute of limitations. We did not add your because we have not decided on the wording at. But when we decide how to word that, we will add that to all VIS. Veto are you there?

I did see the section I was added per the discussion that we have the last time.

I don't think we had specific wording for that did we?

We didn't suggest specific wording.

To add that idea.

Right.

We were still -- it is not on here but -- we did put it on there. Is that wording okay?

That is okay with me.

David King here. I was looking at that and I wrote a note on it. Why don't we identify what that time limit is? Why wouldn't we just tell everybody what the specific time limit is which is if I am not mistaken 36 months from the time that the -- when first symptoms are exhibited or when the shot is given? At do you know?

Manifestation of first symptoms.

I think we should put it very specifically what it is.

That's the same for all injuries?

We would recommend that the VIS is not the best place to put exact information because it is [Indiscernible]. Perhaps if you wanted to include that in the provider information is the provider may be the first one to provide additional information because it's a little bit more nuanced.

David King here. Helpless understanding he wants. If it is 36 months after -- that the statute of limitations expires after a symptom first manifest itself what specifically is nuanced their floppy

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It is different for death cases, different for injury cases.

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24 months for death cases.

Maybe we should outline the mall. To me the vaccine information statement if we talk about the compensation program on there. And why not give -- one of the big problems from an anecdotal basis that we begin to see because there is no real way to capture this information. But it is part of the conversation that we have been having now for several years, and prior to us being on the commission it was discussed. Which is the actual statute of limitations. And that people file or want to file after the statute of limitations expires but they're too late. And so an attorney will say I'm sorry, it's not going to fly, I can't take your case. Why would we not have

this information on the vaccine information statements so that they can act on it if something adverse were to occur?

Two more comments about that. I know that the onset of first manifestation is something that is decided by a court. One of the issues that is nuanced. And then the other thing that has come up is when you say there is a time limit, there may be some more urgency if someone experienced an adverse event to look into how does this apply to my case? Versus if we say that it is 36 months, they may not start looking into it into way down in the line and there may have been the issues like when did the first manifest come in to play. And then it went through them. Those are some of the things we were thinking about by leaving at the way that we did at the time.

We do refer to the website where I presume people can find all of this nuances.

Here's the drill on that. Let's talk real world here and what really happens. David King speaking. It may be different for a parent of a child versus an adult. But it may not be. Somebody receives a vaccine. There is a severe allergic reaction to the vaccine. They are in response reactive mode. And bear entire -- depending upon the severity of the reaction, their entire focus is on something entirely different other than this. They may not remember in either case, but I suspect that if there was a delineation and if we were to put it in a bullet form of what specific timelines are and maybe we put it in the beginning that in both cases, these are the timelines that apply. That that -- that somebody might remember that as they're moving forward but to say I need to go to the vaccine compensation website or do things like that. It is not -- I think we need to get as much information to people in advance. As possible. Because it's a vaccine information statement which is meant to give them as much information as possible. So I argue that the idea of withholding information is not a good idea. Then we should put it -- let us assume that people are smart enough and intelligent enough to make decisions when they are provided with information.

Certainly.

This is Luisita. I wonder if anywhere in this letter, in this VIS is a statement that says skip this information for future reference. The tendency is to look at it read and roadway.

Hopefully if they did keep it they remember where they kept it.

I think the studies of the list that is there's people throw it away they don't even take it with them.

They may take it and drop it in me -- on the well. For they have a file of that they created and a couple documents in file.

Not even a single hint of a suggestion that they should keep this for future reference. It will never occur to them for Ms. People who do not have it filing paper, will not even consider keeping it. Would be helpful if we do that?

I like the idea. David King here. That is not a bad idea. Lisette. You are speaking now. Also and we didn't capture that your thoughts are so please give a few input.

Mike Cameron's were not mentioned in wait to redirect people where they could get the most information that would be beneficial to them. On the VIS statement. But that is [Indiscernible] for complete information that's available on the website. We want people to have a reference for that.

Melissa, David King here. I did not mean to imply that you might have been thinking that way. If that came across a way that is not something that I would have meant to imply. It was more of a blanket statement that the more information we can have the better as opposed to an actual deliberate act of trying to pull this information. I don't think anybody's doing that.

I am not sure that is even 100% true. One of the problems we face with VIS is including enough information to tell people to know what they need to know but not much information it's going to make it difficult for them to read. There is a point where telling them where to find information may be more useful than including it because it's just going to make the VIS more cumbersome to read.

I'm not sure whether -- exactly where we cross that line in this case.

The law says regarding the compensation program, it just says that we have to inform that there is a conversation program. We are already doing more than we have to. And a sense, the more detail you put on VIS the more you are ensuring that people are not going to read it.

I have a suggestion. This is an. I think that where the statement is as there is a time limit to file a claim for compensation. It may not be seen. I think if you put that not as a bullet but as the next paragraph, a single sentence. Even now I know I paragraph should contain a single sentence. Like that information. In general.

This of course is not the final format. That would be easy enough to make that its own paragraph. If we want to.

I don't think people see that right off. There's too much else.

You are right.

David King here. Shall we do some out-of-the-box thinking for a moment? What happens if we reverse the whole vaccine information statement? What happens if you were to start with how can I learn more? And then you were to talk about that there is a national vaccine injury

compensation program, and that will there is not a great chance, there have -- there are sometimes some risks associated with it and you end it with why should you get vaccinated?

I don't know, what do other people think? That doesn't seem like a very natural progression to me but see what everybody else thinks.

That would scare clients unduly.

My get them to read it though.

No. They will read that and leave. Not read that and be enticed to read others.

I did say it was out of the box thinking.

It is out-of-the-box.

I do have a comment about that. If you wanted to say more under number six, this whole number 56,007, if they are indeed the same for every vaccine, it could cut down the number of papers that you give people and maybe with every vaccine. I know the other side of that is a could get omitted. Sometimes when people make copies the VIS comes August 2 separate pages and page two is submitted already. So there's a lot of pros and cons.

That's a thought. We have considered things like that. I would have to see what our legal counsel says about that. Whether people think that is consistent with the letter and spirit of the law. It is something we have considered.

I will continue with a little bit of the out of the box thinking. David King here. While it may seem intuitively to be backwards, the fact of the matter is if you are in a medical provider's office, a doctors office or wherever one might be, they idea of why get vaccinated, you are already considering the vaccination. Otherwise you wouldn't be given the document to begin with. Since we already know that people are thinking about getting the vaccination, why would we not -- rather than hide it at the end and hiding might be the wrong termination why would we not if we are trying to inform people, informed people because we have art agreed that the vaccine information statement is not a vaccine selling statement.

As a vaccine information -- it seems that the important information if it was coming with the recommendation, this is what your child or you may be do for, this is why the recommendation is being made. This is the benefit of vaccination and the risk of vaccination and this is what is in place

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Exactly. Why not start with the risk first?

I think when you're deciding, from a clinician standpoint or a parent standpoint, when I am deciding whether or not to accept a recommendation for my child the first thing I want to know

is why does my child need this vaccine? That would be the most important information I would like to know about. And then after I understand why, then I would want to think about the downsides and what I could do about it. I think starting already, it seems like -- I think that it is -- it's more helpful to open conversation with this is why this is a recommendation. This is what I want to hear. Why it is important. And I think that opens up a more natural discussion with parents. When you're using the VIS cause it often well come up. I don't work in a primary care setting any more but I know when I take my kids in as soon as we are put in a room, as part of the recommendation, so a parent may not are to be think about yes I'm already considering vaccinating you at this part of the recommendation. As a communications tool, I think it's important to start with vaccination itself. Before presenting these other programs. I also think that the point was raised you're asking the provider to start talking about this program with VICP and so you would want to make sure that everybody felt comfortable talking about that. There may be a lot of questions about that before you have a chance to talk about the vaccine. This is Kristin by the way.

Okay.

I would concur with Kristin statements as I think of other kinds of information. And how very scary most consent forms are. This is not a consent form but how very scary consent forms are. It is if truly the first sentence was you can die and it is not our fault. Would just not be helpful.

It seems by putting up first we're implying that might be the most important thing on the form and I'm not sure if it is. It is something you hope you don't have to think about that that you may.

I will pay with -- I'm okay with everybody's thinking on this. I thought that sometimes we should rethink what we do.

It certainly eight -- it sounds like -- it is similar talked about how to make sure this information is noticeable and available. But I think you will have to keep thinking about the whole contacts. It is a communication tool but vaccination in general and this is some part of it.

The way it is organize now is chronologically correct. You talk about the vaccine and you talk about contraindications any talk about possible adverse effects and what happens if there is one and what you do afterwards. Chronologically it's in the correct order now. That's the right order to have them. I appreciate your bringing that up, Dave.

Okay. Thank you.

Anything else on Gardasil? The server acts is pretty similar but there are a couple changes since it is a different vaccine. Were only talk about cervical cancer with this one. We only talk about women. Talking about section one.

The approval is it also for prevention of vaginal other genital cancers

Our subject matter expert, just want to talk about cervical cancer. I believe the two types that are in here are mainly cause the cervical cancer and less so or not at all for the other cancers.

I wasn't sure, I thought it was one of the indications. I wasn't sure about Cervarix

The indications if you're female are the same. Sections wanted to are slightly different in that way. Section three is the same. Except yeast, there is no Eastern Cervarix so we left off that. And the adverse reactions in section 4 are different. Other than that, it is identical.

This is Luisita. You would make the changes suggested in the first VIS?

The ones that apply, yes.

Okay, thanks. If there's nothing else on that maybe we ought to move ahead to the [Indiscernible]. I don't know how much -- we're starting to run over as far as time goes.

Not to worry on that. Let's do what we are supposed to do.

We're making some changes in this because of a couple changes and recommendations, mainly for rotavirus. We also made is -- it simpler this time than the previous versions. The VIS. The information in here should be the same as the information on the individual VIS. The questions might concern how we've got it laid out. What we have decided to include, obviously we couldn't include everything that we include on the individual VIS. Try to include the information about the diseases. The contraindications and precautions and the adverse events to make sure we include all of those. So if we could just started beginning, our people okay with the introduction saying that the baby's first vaccine, these are the -- some of them have doses that can be given later. Provider checks off which ones are going to be given that day. And then there is a -- in the section we talk about each -- in the first section each disease and in the different section each vaccine.

Section one why get vaccinated? it's a description of the -- of each disease that these vaccines and complications to them. I'm trying to see if I have any specific questions for the don't see anything. There anything in the first section on why get vaccinated?

This is Sylvia. Did you do -- the reason you put this together was a consumer input on helping moms with the first baby shots is that right? I can imagine what a parent things we're looking at this. I need the fundamental reasoning for putting this together.

The reasoning was because so many of these vaccines are given at the same time, it allows a parent to get one document instead of age documents. And it's probably because as we talked about before, several sections are identical. In this case they only have to read that stuff once. Is set up several times. When we first did this it was just a thought and without that might be useful. It turns out this was extremely popular. I've been getting daily messages saying one is

anyone going to be out.People like you for that reason. One document instead of several. Even though it does contain a lot of information.

The consumer has seen this as good to put this altogether? It is a problem for us clinicians that these first shots are quite overwhelming. And that's all I needed to know, that it was being accepted in different languages and people were reading it and getting the information they needed. Thank you.

As a matter fact, we are getting requests to do one for adolescents also. So we're working on that.

I would add four to six rural visits.

And that, yes.

Four to six, that is included in this one. The vaccines that you can get from four to six. We include those doses on here. You can use us all the way up to six years.

Skip, Dave King here just a quick question on diff area. Prior to the vaccine it says 50,000 people die in the United dates each year. Do we have the number of how many will die now or is it just zero?

This is Charlene. What happened?

I don't know what happened.

Skip? I think you lost him for a minute.

We are still here.

It would appear that skip is not on the line. He's never -- have enough of the ACCV.

Is Annie on the call?

Yes.

I would be willing to take a stab at that, just ask your question again.

On the diphtheria? On a statement it says about 15,000 died prior to the vaccine but now that we have the vaccine my question is how many die on an annual basis?

I don't think anybody has died in the US but certainly when I went to Russia I had to get a tetanus booster for the diphtheria coverage. And not the tetanus. But immunity is over 80%. As

long as everybody is vaccinated, the data from all of these diseases should be zero. But that's the crux there. As long as everybody is vaccinated.

I recognize. I am wondering what the answer was.

I can tell you for certain, diphtheria is alive and well in the world.

But in the US.

We haven't had an outbreak but then again we didn't have an outbreak of measles until the rate of vaccination dipped so low. If this tips somebody can come visiting from Russia and there you have it.

This is Ed Crouse. I was just dropped so I missed it.

You were dropped?

There was a uniform of drop edge.

And skip.

You know in a face-to-face meeting we never would have dropped you.

[Laughter]

Thank you.

[Indiscernible - multiple speakers] is the operator --

Still standing by.

A number of people have dropped off the call through what we believe to be no one --

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We are currently researching the issue at this time.

Will those folks be dialing back in?

I was -- this is Ed Crouse, I was able to dial back in. I was on hold for a minute or so. It wasn't immediate.

Since we are waiting for skip we will give him the minute or two. We will assume he is trying to dial back in. And Suzanne for that matter. She must have dropped as well.

This is Tom I got dropped but I'm back on.

It was like one section -- what happened?

Technology.

We have been hacked. [Laughter]

We don't know if any other [Indiscernible] has dropped.

Are there any HRSA people on this call?

Everyone from HRSA is still on the call.

This is truly our meeting.

Except we're missing -- is there anyone -- we know add to got dropped. Any other commissioners dropped?

I haven't heard from Jason. Are you still on?

Yes, I have not dropped. I have been here.

Let's do a rollcall.

Charlene, and, Jason, Sylvia, Luisita, Michelle, Kristin, and Ed. We are on has skip come back on again.

We have e-mailed skip. That he is not on the colony longer. I don't know.

You may not be looking at his e-mail.

I think I got cut off. This is wonderful somebody has any comments.

That's not why happen.

That will never happen and the question when he got dropped off the line had to do with affect that in diphtheria it says 50,000 people died each year in the us prior to the vexing. My question was, need die now that the vaccine is in use.

I can tell you in a second. Almost none. We've got data up through 2011 and the less death was in 2003.

What is the level of vaccine coverage for diphtheria in the country?

That is Charlene asking. .

DTP which includes DTP for four doses it is 84%. This is 2010.

Do you want to put anything in there on diphtheria?

No.

He didn't hear -- this is Charlene. He did not hear the original issue of 15,000 people died before we had a vexing. And my response when you're dropped was I know that did the area is alive and well in the world. Because our levels of coverage I don't think anybody is but as soon as we say that. And well be people -- it's been about two years. There is been a case and that was in 2003. .

The last paragraph after number eight and -- these are much less common than they used to be thanks to generations of parents. Comeback if we stopped vaccinating. I wonder if something like that could go on the front page.

Yes.

That's a good front page statement.

The second paragraph of those 200 number eight.

It almost makes sense to put it on all of them, but --

This is Ed Crouse. I don't like that language. I don't like that paragraph. I understand the intent behind it, but I don't -- I think the one point that is legitimate to make is that it is -- that keeping vaccinations just because diseases have been significantly reduced by vaccines in the past, for that to continue to be the case, vaccine rates need to stay at whatever rate it is that they need to stay her. This to me is the kind of statement that is -- to me it is persuasive language. I think it's also -- it implies that parents who will -- in all situations, parents who don't get their children vaccinated, that that is not a legitimate decision to make. I have all sorts of problems with that. That is just me.

Dave King here. Generations of parents is some wording that I would have underlined as well that I have some questions around that as well.

This is Charlene. We are true, we're facing the largest amounts of measles that we've had in a very long time because people are not vaccinating. That is simply another view. And when we dipped below 80, it is going to spread through the population no matter what disease it is.

I guess the question is, is this persuasion or information?

I guess it depends on what we mean by the word [Indiscernible]

What if we left that part off? These diseases are much less common than they used to be and live off the rest of the sentence?

This is Kristin. Even a disease that disappeared will come back if you stop vaccinating.

That would be a big improvement. From my perspective.

Okay. And that is simply stating the fact.

Without applying a value.

Okay.

Wherein the front would you put that? I have no problem with dropping a part of the sentence either. I just really like the spirit of disease is returning. [Laughter]

That might have come out wrong.

Sorry.

You like these spirit of diseases not returning. Clearly what you meant.

Now we go from the checklist of the vaccines straight to the description of the disease is. So would we put -- would you consider putting that statement in between?

Dave King, the following diseases are much more common than they used to be but if -- all diseases will come back if we stop vaccinating. Something along that type of wording.

Even though we have just proved to other statements that might be considered for revisions of future VIS.

I'm sorry?

Including a statement like that, these diseases are much less common but even a disease that almost disappeared, that whole paragraph there is a statement that might be considered to go on most of the VIS statements. In particular right now people will read that because it is measles outbreaks.

Most of them -- I will have to double check but as we update them I think most of them will include a statement -- a specific statement about the vaccine that is covered by that VIS that will be analogous to this.

But it should go front position.

We should put it in the same position in everyone.

[Captioners transitioning; please stand by.]

Does that seem like a reasonable way to describe the vaccines?

In a table form? There certain things that people want to know about each one. How many doses, the ages and some artifact that people ought to know about.

Dave King. The three or four or 203. It's not 100% some get a three? Some get a four?

Other information. There are two different vaccines.

I see it.

That's one of the difficult things about including how many vaccines in one thing that you have to explain that.

The sentence -- the paragraph underneath that table -- the combination -- is that clear to people per --?

Do we have evidence -- dave king. Combination of vaccines that are safe and effective as the individual vaccines quick

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I think we do. Tom?

I believe so. I can't think --

Basically when we say save I could plug the word equal. So are combination vaccines equally safe as the individual vaccines. Or are they safer.

This is Sylvia. Tom, we had discussed -- this probably doesn't cover it. The MRV for a one-year-old probably causes a more seizures with beaver. And I know it's not there but you do have some combos they go for four and Sixers years -- for six-year-old's which is the MMB. That would be the only thing and you don't mention it. I will to shut up with that one.

Is not covered on this.

It is a common end of the statement. All combination of vaccines. Mentioning an exception for vaccine is not on here seems kind of weird also.

I realize that but you lumped four and six-year-old shots on their and not mentioned the MMR be. You are covering vaccines up to six months and not up to one year of age.

We are also considering another multiple one for the one year vaccines.

All right.

Actually the MMR and MMRV -- this is Tom. The evidence there is clear. I was looking at this table trying to remember what are the combinations like 10 to sell and [Indiscernible]. I don't have the data. There may be side differences it -- in fever or local reactions. As a general statement that is true. They are as safe and effective.

There's no dramatic differences between the individuals and combinations with these vaccines.

Dave King. You are talking about the specific six that you've outlined? As the combination. Not what Sylvia talked about.

No.

Is there a way for you to refer back to V6 or something.

We can do that. That way we exclude MMRV.

Okay.

After I was cut off, when you could hear me, I was talking about the next section about contraindications and cautions. I'm sorry you missed that because it was eloquent. [Laughter].

Basically I said the -- this is on page 3 I guess. Under some children should not get certain vaccines. The three universal percussions are the first three bullets and then underneath that I listed specific vaccines. And instead of saying this is a per caution and this is a contraindication just say talk to your doctor because they will decide whether the vaccine should be given and not the patient. The patient task is to tell the doctor if any of these conditions exist.

Skip, one second. If it's a child is it not the parent that determines whether the child get the vaccine another doctor quick

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Yes. Well, it would be the doctor decides if there is a contraindication or per caution.

But the doctor doesn't decide. It's the parent.

They can decide who doesn't get it. I guess that's point.

A hearing can decide that as well. -- a parent can decide that as well.

The doctor can recommend who should or should not get it and the doctor still cannot make a decision unless someone says to them I give you the authority to make that decision. Otherwise the decision resides with the parent.

That's a good question. Should the parent -- be able to say even though my child has a contraindication I want them to get the vaccine anyway.

I think the doctor would overrule in that case.

I hear both sides and I'm wondering if you just want the language to reflect [Indiscernible] has a role in the acceptance process.

Really it had more to do with skip that made a statement that [Indiscernible] that I was stopping. A parent -- the now you are saying it's possible we should have the parent has a role in the decision process.

I think we don't even talk about the decision here. All we say is tell your doctor if these conditions exist and then after that it's up to the parent and the doctor to decide.

This is Anne. I speaking up the nurses here because many times children come to the office and it's not quite enough weeks between doses so they're told to come back in a week and they may just see the nurse. And there may be no provider other than the RN who then has to as the screening questions. So it is in -- it's inaccurate to say talk to your doctor because you need to talk to whoever will be giving you the shot. It could be an RN.

We might change that. The reason for putting Doctor in there is that we have been told for years that patients understand the word doctor even if the person talking to them is not a doctor. That's the term they like to hear. We've gotten so much pushback from providers who are not doctors about that that we may have to change it back to healthcare provider. People interpret that is being their insurance provider. If we say provider we have to say healthcare provider and hope people know what we are talking about.

This is Charlene. With the changing landscape of healthcare more and more people giving children vaccine will be nurses and nurse practitioners.

As long as we are sure that people know what we are talking about when we say healthcare provider that's okay. The thing that we have been told before is that people understand -- when people see doctors they don't care if you're talking about a Doctor or nurse or medical assistant. They interpret that as the person they are dealing with.

Dave King. You could talk to your doctor/and/or healthcare provider or doctor/healthcare provider.

There has to be a way to put that in there.

Doctor or nurse.

And we immediately start hearing from nurse practitioners who say it is a nurse you have to say nurse practitioner. Then we have is a pharmacist. We can't list every person who could give you a shot.

With the person giving you the shot.

For flu -- we talked about that. There were so many different people get those that we did go to using that term. It could be almost anyone.

Why can't we use that here?

It's a lot of words.

This is Sylvia. With some of the other [Indiscernible] you might want to do stop and say -- this is under the category of certain children should not get vaccines. Then if you did instead of talk to your provider just say stop and then underneath they polio say it says don't give it if you have these problems. So then they will have to stop right there instead of talk to -- just stop. Don't get the shot if.

But some of these are contraindications and summer percussions.

-- some are precautions.

So it's not always a contraindication.

Maybe all of these are.

Skip, I wouldn't give a baby any counter indications and I don't if I have any child with the -- child with developmental to play -- developmental delay. We are not going to go there.

That has a contraindication. If these are all contraindications we can do that. If any Arbor cautions -- if any are percussions we can say that. I will double check. Tom, do you remember. Is a child who had [Indiscernible] -- is that a contraindication for a vaccine? I think it's a precaution.

I'm not sure.

I will double check these. And see if they are contraindications.

My phone ran out of battery. This is Anne. I miss the conversation from when Sylvia started to talk.

Anne this is Sylvia. I wanted instead of and I agree with you as far as the nurse and nurse petitioner -- but there has to be a place and skip and Tom will look at it whether you can say right above the [Indiscernible] stop and they have to inform somebody that if the child has had any of these conditions. I'm a clinician and I don't get vaccines if they have these counter indications.

The purpose of doing it this way is this is for the parent. We are telling the parent what to do. You need to tell your doctor if your child has these conditions.

My statement was we do the stop sign that.. Don't give the vaccine to the parent if they've had these [Indiscernible] all the weight the PCB.

That is the provider decision. The parent decision is to tell your provider whether these conditions apply to your child. In a way it's irrelevant to tell them because your doctor will tell this [Indiscernible] because that is what they will do anyway. There's a way to try to keep it as simple as we could.

Okay.

Also after I had been cut off I moved onto the next page and said the adverse events listed should match those on the individual VIS. I will make sure they do before it gets published. That is something we can't summarize because we have to list them all.

Compensation program and how do I learn more of the same. Although this is the one I have mistakenly thought not added this section about statute of limitations. It was this one we didn't at that that we will. -- at bat but we will.

This includes death.

Yes.

Do we not -- do we know what numbers are for how many children getting anyone of these vaccines here have died? Out of doses given?

I don't know how -- that is something I always wish I knew and I don't think anybody has a very clear idea of how many reports of death turn out to have been associated with the vaccine or how certain we are that they were. As far as I know it is rare that it's hard to get specific numbers. Tom, is that correct?

Yeah. I'm trying to find -- we are preparing a document on death. I think it's in the handfuls of cases of anaphylaxis or people with pre-existing him you know compromising conditions that

God -- that got live vaccines. And they didn't know they had these conditions. It's a very small number of individuals where there is been -- has been conclusion about causality.

It is nuanced because it may have been because of an error. In a way it is misleading.

Why are you including it? Has this been recommended by the legal department?

Yes, because it is a possibility. It would be sort of withholding information if we didn't mention it's possible.

Now they will have to tell kids that they go to school they can die.

I agree with Kevin that we do have a responsibility to not [Indiscernible] the fact that it could happen.

Tom, I will be interested to see that document because it would be nice to include general statement was some sort of number if we can on all VIS to say it is rare and -- whatever we can say. It would be nice to say how uncommon it is.

The focus of this document -- skip, we get questions about this quite a bit. And so we decided to do a prepare for Mark so we can refer to that. It is almost -- is less about numbers are more about conditions. And a person can die from anaphylaxis if they don't receive prompt treatment. It's a possibility. A person with skid or other him you know compromising condition that they didn't know about get the live vaccine. GB after [Indiscernible] -- there may have been some deaths associated with that. But I think the focus of our responses less on this many documented numbers. It's more about these are some of the conditions and it's exceedingly rare. The benefits of vaccination far outweigh the risks when it comes to the possibility of death from a vaccine.

Maybe a general statement like this is the best we can do under the circumstances.

As a clinician I can see a parent saying that and wanting to know what is it. Isn't one in 1000 or one in 10 million.

Maybe we can include something on the provider materials to help them answer that question. Rather than put it on the VIS.

This is Ed. Unfortunately the point is we just don't -- we are not that sure. We're sure it's very rare. But we don't have in place everything we would need to from a science and public health standpoint to say with any certainty that it's only one in 1 million.

But we could do what Tom suggest and say when it does happen these are some of the reasons.

Yes.

This is Kristin. It may help to provide some context because I could imagine a parent asking what is the risk and also how is -- how can the vaccine cause death. It sounds like other reported cases related to a -- a different adverse event. Like anaphylaxis. Or having them you know compromising condition. It was a like the injection was given and then death ensued. It was related to a complication. Or an adverse event. I know we can't provide all of the detailed but maybe there is some qualifying statement you could provide.

Maybe put it in a different place. Maybe we could put it under if there is a serious reaction, what should I do.

We tried putting it at the beginning of the section on adverse events and try putting it at the end. I don't know -- i don't know the best place frankly. I hate to put it at the end or the beginning. Because those of the two positions that people will remember.

Dave King. I have two things to talk about. The statement as with any medicine there is a remote chance of vaccine causing death. What I will put that directly underneath the bolt national vaccine injury compensation..

That's a thought. That's one idea. I have one other component which is under DTE be vaccine. Under serious problems where it says long-term seizures back -- these are so rare it's hard to tell if the problems were really caused by the vaccine. It seems more like an editorial opinion.

Dave, this is Tom. That is similar to death where you do epidemiologic studies looking at death after vaccine and the rates are similar in vaccinated versus unvaccinated. And the causes of death are similar. They are lower in vaccinated people but we think there is a healthy effect. And I think the same for the acellular pertussis vaccine. This is so rare and this is such a rare event then epidemiologic studies you can't -- you are not powered to find -- to detect a risk.

That's a hard concept to get across. I am not really happy with that wording but I think it is something we need to say.

People don't get vaccines get the same conditions and it's hard to separate the baseline from what may have been caused by vaccine.

Maybe we should say these reports are extremely rare. That would be the fact.

Because you might find others who argue that no, that was caused by the vaccine. And it might be a doctor who says that. On the side of a petitioner saying I'm the expert and I say it was caused by that. And you might have a disagreeing Doctor on another side of the case saying it. So rather than having an editorial comment which is hard to tell just simply say these reports are extremely rare.

We could do that.

The point is -- this is Ed. We talked about this before. The difference between things that can be proven through epidemiology and things that can be shown to have happened based on mechanistic evidence in the particular circumstances of a case with an expert in treating doctors saying the vaccine caused this injury. That doesn't -- even in those cases if they are rare enough if you do a study you will still not pick it up in terms of epidemiology. You won't show an increased risk. It doesn't mean the vaccine didn't cause it. At least for purposes of how causation is defined under the vaccine act in that particular case.

I think it's a problem of not knowing -- if we don't know the mechanism by which the vaccine might have caused it it becomes an epidemiologic decision. Which is -- for one individual case is difficult to prove.

I think you should just say these reports are extremely rare. And call it a day.

This is Tom. I think -- for a lay audience that may not fully understand statistical power and the ability to detect the risk after exposure for really rare events -- if you say these outcomes and these conditions have been reported following [Indiscernible] vaccination these reports are rare. It may be misinterpreted as an acknowledgment of causality. If you say anaphylaxis has been reported following vaccination although it's rare -- we know that anaphylaxis can be causally related to vaccination. Without qualifying saying -- without any qualifying language after these reports are rare -- i think a person could be left with the impression that there is an acknowledgment that there is a causal relationship between those outcomes and DTA be.

Leaving the statement as is there so rare that it is hard to tell which would imply that it might be possible to tell. I would argue the same case with you.

I thought about saying and possible but that seemed to unequivocal. I think the problem is that we net -- when we see reports we know what we are talking about that most patients by Tom implied will see reports and leave cause.

Here you have listed serious problems. You say long-term seizures, coma, and permanent brain damage have been reported following DTaP vaccination. He said that has been reported at it may be -- in the statement before it all is of childhood vaccines have been associated with the following additional problems. You are saying these problems exist. And then to me it's an editorial comment to say it's hard to tell if they are really caused by the vaccine.

This is Chris. I don't know if it's an editorial comment. It sounds like based upon what we know that it is hard to tell because the reports is so rare. Is a possibility of causation and there is a possibility of no causation. So I don't know if that is an editorial. It seems like it is classifying what we know. It is true, it is different than anaphylaxis is a serious problem which is rare. At least that is my interpretation.

I think that if we use the statement these reports are extremely rare or are very rare whenever I put a period and eliminate the rest is still says what you want to say.

Or -- this is Ed. It would be more accurate to say these reports are so rare that it is difficult or impossible to determine if any child is -- has an increased risk for these conditions following vaccination.

Is that similar to what is stated?

The problem I have with this is it is implying -- and maybe it is the petitioners lawyer in me but it's implying you can show that a vaccine -- that an injury was caused by vaccine unless you have some epidemiologic -- epidemiological study that shows an increased risk. I just don't think -- that is certainly not what is envisioned by the vaccine act and I know we are not litigating cases under the vaccine act in that the EIS statement. -- vis statement. Trying to have a consistent conception what we're saying is these are conditions in some cases that have been reported following a vaccination and in some cases they have been -- the vaccine was found to have caused this condition. It doesn't mean that until there is some epidemiological study that establishes an increased risk, that it is never going to be shown to have been caused by the vaccine.

This is Christine. I'm not disagreeing. The language you just [Indiscernible] sounded similar to the language that is there. I understand the distinction.

I'm sorry. I get what you are saying.

I think because of that I think maybe Dave's suggestion is the one that makes more sense to say that these reports are very rare.

And leave it at that. I will say eyewitnesses the back -- i would suspect there are doctors who are working with petitioners and are stating that it was caused by that possibly. And while there may be other doctors who say their warrant -- there aren't. Why can't we just say these reports are very rare and let it go at that. What is the hard part about that.

I guess the reason for including that is the fact that people are going to see reports -- people are not going to distinguish between a report and a causal. They will see reports and they know the vaccine is a cause. They will say these reports are rare and with these reports these vaccines cause this but they do it rarely.

So with the wording you have to I will go back to what I said earlier witches these reports are so rare that it is hard to tell if the problems were caused by the vaccine. Hard to tell. It isn't the word impossible. It implies that it's possible to tell. Are you saying it's possible to tell?

Probably not.

So I think the thing to do is to simply say -- why did you say this is extremely rare. Forget reports. This is extremely rare. Period.

Tom?

That is a totally accurate statement. These reports are so rare that it's hard to tell if the problem that is really caused by the vaccine. Look at the [Indiscernible]. Serious problems. In that case we have good evidence that rotavirus is causally associated. With intussusception for seizures, permanent brain damage, we don't have evidence that there is a causal association between those and DTaP. If they read the DTaP and read the rotavirus one where they're talking about serious problems and talking about rates somebody could think those two are equivalent -- the serious problems for DTaP and the serious problems for rotavirus are equivalent statements but they are not.

You might be right but you have more data around one than the other. Let me ask you is the statement this is extremely rare -- that's an accurate statement also, is it not?

It is that it is less complete than the full statement. It is an accurate statement.

I read that last statement as having a built-in bias. That's how I read it.

Dave, I would respectively say that's a limitation of an epidemiologic study to detect a risk for really rare event. That's a limitation of the data.

So I would then say let us err on the side of the injured and not have it in their. -- in there.

This is Lucita. Isn't this rare condition listed as compensable in the table quick

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I think they are.

If they are that means if the the IT says if this happens it is compensable so therefore it's possible it could happen.

It if it could happen but it doesn't mean it did.

I think compensation --

The fact that it is listed mean someone has filed a petition on this vaccine and on this particular injury. Otherwise it would not be listed.

This is Ed. Let me ask a question. I can find a case that has been decided where there was a ruling that a child with a seizure disorder a long-term order -- disorder were permanent brain damage -- that his condition was caused by that DTaP.

There are decisions that exist in the Court of Federal claims database. I understand that anyone decision is just a decision and that particular case and we are dealing not with scientific certainty by dealing with a standard of proof that is more likely than not. But that is what is set out in the act. And I think this is where we have this tension between scientific people and medical people saying we don't know for sure that the vaccine caused the injury. But for purposes of the vaccine act and the vaccine compensation program we are saying that if you can prove that it's more likely than not that the vaccine caused your injury then we will are going to say the vaccine caused her injury. And in part it's a policy decision. Because vaccines are given to healthy people. Unlike other kinds of medication. It gets a little philosophical here but I think at the end of the day we are better off being clear that these are problems and they are reported and they are very rare. And if we are going to try to be anymore helpful or accurate in describing how rare and the difficulties in proving causation I think we get ourselves into a lot of murky waters.

Skip, what is it say on the DTaP VIS?

Hang on.

I think it says the same thing but just a second.

These are so rare it is hard to tell if they are caused by the vaccine.

We should change that one also. Dave King speaking.

It's a subtle nuanced concept that's hard to get across in a simple way.

This is Ed. How do the medical people on the commission -- how do you feel about this discussion? Are we getting too far afield?

Sylvia? As a pediatrician.

I just went to court on this yesterday.

The families will have to know that in extremely rare cases and we're really talking about DTaP and in the old dies -- old days we are talking about DTP you can get death from this toxoid. So you guys are in the weeds and you are sort of looting -- losing me because I don't talk too much. So I don't know where we are going. We always have to say to them that vaccines causes side effect and it can cause seizures. And in some children who have these seizures it can cause them to stop reading. So that ends up being a translation your baby could die because of this vaccine. So I always want to air on the side of the injured child. Not me or my lawsuits or anything. To answer your question, when I have the forms in front of me and in fact I'm reviewing, at the end of the VIS it says these are so rare I would just say this is where we are uncertain that the vaccine caused the death. And when I go to court I said that. And this was an injured child. I don't know -- let me finish with Ed. Ed is asking an important question and so is

day. Ed is a lawyer and Dave is the dad. We have to be able to say to families and that is what you have with these baby vaccines. This is the hardest time when you start putting them together. And so I had to look at your logic and your logic is death is a where outcome.

Death can happen with this vaccine. Rarely. Rarely this happens with this vaccine. I don't know. And I have to talk to families about this all the time.

Sorry.

That was very helpful.

Is obviously a tough area. We will think about possibility of changing this. If we are going to associate adverse events with compensation let me ask when a parent is compensated for a vaccine injury, are you saying it was definitely cost by the vaccine or we are giving you the benefit of the doubt?

This is Melissa. If the case is not completed but there is a decision to either compensate the case or if there is a court decision for the case to be settled it was a statement stating that the department did not concede that this was a [Indiscernible] injury.

There is language in both of those instances that state that the respondent does not concede.

So you're not saying unequivocally --

This is Ed. Melissa, I think you're may be confusing folks a little bit. If a case is settled by a stipulation absolutely you are correct. There is a statement in the stipulation that says respondent denies that the vaccine caused the injury. Nevertheless of the parties agree to this. I'm talking about cases that are contested that end up going before a special master and the decision is issued finding causation. It's true. It only goes before the special master and his litigated and the hearing is being held because respondent denies causation.

I'm sorry, Ed. Even when it's contested there is something in the decision that would make the respondent not concede.

Of course. You would never have a hearing in a case where it is conceded. I'm pointing out that there are decisions in the history of the vaccine compensation program in which DPT and DTaP have been found to cause death. And/or long-term seizures. I know that respondent contested it but ultimately under the act if a judge or a special master where the Court of Federal claims if it goes up on appeal decides whether or not causation -- whether entitlement has been established by virtue of the evidence presented by the petitioner.

Yes, I was trying to address your question about if a compensation has been awarded that it has been shown that causation was found. I was trying to address that question.

I apologize. In 80% of the cases or it's only cases that are conceded which we saw -- is usually somewhere between three and 10% of cases that are conceded each year. That is the only one where everybody is occurring where there is causation. Otherwise the majority of cases -- there's no agreement about causation and in other cases they go to a hearing and a judge is the one under the program who decides whether or not causation has been found. And it's a legal standard and not a medical certainty standard.

Dave King here. Skip, you have our input.

I was going to say the same thing.

There's no point in continuing. You got plenty of input to figure out what to do.

We will give you some guidance.

We will do our best.

This is Tom. Before we leave, I just scribbled something down. Just tell them if you think I'm restating the same thing in a different way or if this is substantively different. If you say something like in these whereas this is the contribution of the vaccine to the condition is difficult to determine. To you, is that saying the same thing or is that different?

Say that again.

It would be long-term seizures etc. have been reported following the -- dtap vaccination. In these rare instances the contribution of the vaccine to the condition is difficult to determine. Is that any different?

I'm not sure it's different but I think you are trying to move slightly different. And say maybe you're onto something because you could add one word and there were so. Rather than -- i would almost suggest you put in can be difficult as opposed to --

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Yes.

Tom, could you e-mail that sentence?

If I can read my own writing I will do that.

Okay.

Thank you.

I think that might sound better. We have to see it but I think we're moving in the right direction along that thinking. That's good, Tom.

All right. Anybody else have anything to add?

If not, thank you as always for your comments.

Thank you, skip. We appreciate you giving us the time.

People don't believe me but these meetings are fun for me.

We believe it. Otherwise why would you do it.

Torture.

Thank you.

We have a couple more items to cover on the agenda. But it is for 16 PM and nobody has taken a break. Do I dare give everyone a break until put 30 PM and we drive the closure after that?

I think we need to do that. People need to get up. So let us resume the meeting at 430 at 4:30 PM Eastern daylight Time.

Dave King is back on the line.

Sylvia is here.

Hi everybody.

Jason.

We will give it a few minutes.

Kristin? Michelle?

It is not yet 4:30 PM. I will give them another 30 seconds. I think we should begin to move forward.

Operator, our lines are still open?

Yes.

I will suggest we continue the meeting. The next item on the agenda is a Valerie Marshall. Can you give us your update?

Sure. In January 2014 the FDA approved three supplements to the Biologics application for pneumococcal valent conjugate vaccine which is [Indiscernible] 13 to include text in the U.S. prescribing information for the use of bread now 13 and HIV infected adults greater than 50 years of age greater than or equal to 50 years of age preterm [Indiscernible] less than 35 weeks of gestational age, and children and adults not [Indiscernible] age 6 to less than 18 years of age with sickle cell disease. In March 2014 the FDA approved a supplement to lower the age indication [Indiscernible] which is tetanus toxoid diphtheria and a cellular [Indiscernible] vaccine absorbed. From 11 to 10 years of age. In March and April of 2014 the FDA granted breakthrough therapy designation which is an expedited review program to Pfizer's candidate Tybee vaccine and Novartis type the meningitis vaccine. In may 2014 the FDA approved the supplement to that the LA for rotavirus vaccine live ortho which is [Indiscernible] to include a summary of post marketing surveillance data suggestive of an increased risk of interception in the seven days following does to of redirects. In may 2014 the FDA issued an update to previous FDA communications which describe increased reports of seizures following vaccinations. During that 2010, 2011 influenza season. Results from FDA present study demonstrated no specific it -- association between the vaccine and seizures in children during the 2010 the 2011 season. In June for testing for 2014 the science board to the FDA discussed and made recommendations on the draft report from post marketing CD review subcommittee. This concludes my report. Thank you.

Thank you. Does anybody have any questions or comments?

Valerie, thank you.

The next item is the update from that vaccine program office. Karin Bok.

Hi. Thank you. I would like to introduce myself. I am Karin Bok and I'm the new vaccine safety specialist at NVPO and I will be joining you on the future meetings. I believe you already received the report from the last [Indiscernible]. We will have a new meeting next week. This document being discussed that might be of interest to ACCV. It is called reducing patient and provider there is to maternal immunization. We have a working group in NVAC studying how to increase the uptake of maternal immunization. So when we put these reports out for public comment there were several organizations that commented of interest to ACCV. I would like to read you a few of them. The first one is from the group B support organization. They say that they have the concern of health providers with obligation with adverse outcomes experiencing it directly or indirectly as a result of vaccines may be a barrier to health professionals in maternal immunization programs. These concerns need to be addressed. Openly and clearly. That was one comment. The American Academy of pediatrics had to say that the vaccine -- to the vaccine injury compensation program as long as -- is longtime supporters of the injury compensation program, the American institution of pediatrics commence the recommendation number five which is recognizing and addressing current vaccine liability barriers to optimize investigations and future vaccination nation -- integer vaccinations during pregnancy. We suggest to broadening the eligibility of the VICP to include injury intrauterine role to be appropriate. It is important that that the ACP defined outcomes related to vaccines. As you are

aware, these have been cases of experience and research that have guided the compensation determinations in VICP. To our knowledge currently we are unaware of any specific adverse outcomes that are related to prenatal vaccines. We urge the commission to take this into account. Also something to say. Buyer wishes to to take this opportunity to ask express does to express its in journey program which has been the cornerstone of our conscious vaccine program since the creation nearly 30 years ago. That the ACP has been vital to continue vaccine development. So they also support recommendation number five which encourages the [Indiscernible] six -- secretary of health to work with health resources and services administration to address the issue of in utero injuries following immunization within the VICP and further recommends the [Indiscernible] support this issue in terms of allowing such claim to be pursued under the VICP and in favor of providing federal liability protection to vaccine manufacturers and administrators.

There was one last comment. From the national vaccine information center. They said that due to lack of enough credible scientific data regarding the safety and FDA's [Indiscernible] of women during pregnancy the national vaccine information center does not support giving vaccine manufacturers or vaccine providers the liability shield under the federal vaccine injury compensation program. So that was their point of view. And then nova back -- Novavak said they have a strong record the recommendations and the [Indiscernible] issue of in utero injuries. Allegedly incurred following maternal immunization within the VICP. You see that the subject here is common among all the public comments. This report will be voted and the final version will be ready next week or the week after that and I will be happy to circulate it among ACCV members. If you have any questions I'm happy to answer. Thank you.

Thank you and welcome.

Does anybody have any questions?

Karen, that report you are going to circulate -- does Karen give it to you and you send it to us?

Yes.

Perfect. That will work out. Karen, thank you.

No problem.

The next on the agenda is Doctor Tom Shimabukuro with the center for disease control.

You have our undivided attention.

Thanks Dave. My slide is titled immunization safety office updates and it is the one with the blue background.

I'm on slide number two. Today I will give a recap of that February 2014 advisory committee on immunization practices meeting. I will give you a preview of the June 2014 ACI meeting and go over selected publications. For the favorite the 14 ACIP meeting as far as those in the influenza section there was about to accept the updated -- to accept to update the 2014, 2015 seasonal recommendations based on the same recommendations for the 2013, 2014 season. That's a routine vote. And for HPV vaccine they accepted the update the ACIP HPV back when -- recommendations to consolidate recommendations for males and females and [Indiscernible] recommendations where appropriate to harmonize wording and to add a section on history of sexual abuse or assault. And those presentations and also the live meetings if you want to watch the sessions are available on that website on the bottom. Slide four. In the influenza section the immunization safety office gave the presentation interim in [Indiscernible] safety updates via the [Indiscernible] forms of vaccine and in activated influenza vaccine in persons less than 18 years of age that included [Indiscernible] and vaccine safety datalink. There are no new safety concerns detected for Roger Valen LA ID part of agent ID or trivalent during that 2013 2014 influenza season in persons less than 18 years of age for the data we had up to that point which actually includes most of the data because most vaccination occurs prior to the end of December. And there was a comparable safety profile for Roger Valen LA ID versus trivalent LA ID and Roger Valen ID versus trivalent ID in persons less than 18 years of age. Just to remind you LA ID 4 replaced 3 this past year so there was a complete switch from trivalent Roger Valent so that comparison was the season versus last season for LAIV. Then for inactivated influenza vaccine there is a small number of -- a small amount of IID being used but most inactivated vaccine is still IID 3 so that was an in season comparison. So looking at the Roger Valen formulations versus the trivalent formulations. The preliminary data in persons less than 18 years of age are that the safety profiles for the project Valen vaccines are similar to the trivalent vaccines. And another presentation LAIV versus IIV in children aged 2 to 8 years old. This was an evidence review. The key findings for this presentation were that LAIV maintained higher efficacy then IID for lab confirmed influenza and Knarr Titus media. There's a difference for medically attended acute respiratory illness. There's no evidence for increased risk of medically attended wheezing were serious adverse event for LAIV versus IIV. There was evidence for transient increased risk of mild fever after LAIV versus TIV during one influenza season. And both of these presentations were to inform the discussion on a possible preferential vote for LAIV versus IIV in young children, to the eight years of age. Whether evidence it is a more effective vaccine than the inactivated vaccine.

Slide five. There is a presentation on the safety of TD AP in pregnancies. We are doing as we continue to monitor following the recommendation to give Tdap vaccination in pregnancy. There are no new or unexpected safety concerns noted among pregnant women who receive Tdap or their infants. However the ERS received fewer reports of revenue received fewer voted -- fewer doses with special emphasis on repeat doses of Tdap.

Slide six. We also presented the results of a vaccine safety datalink study on safety of Tdap and pregnancy. And the key findings were receipt of Tdap during pregnancy is not associated with increased risk of adverse birth outcomes. There is a small increased risk for chorioamnionitis in persons vaccinated with Tdap in pregnancy versus unvaccinated. The chorioamnionitis merit

further investigate a. The data does not allow for valuation of many important chorioamnionitis risk factors. The magnitude of the potential risk for chorioamnionitis following Tdap vaccination pregnancy was small and the risk was around 1.2. The risk is largely attributable to differences in rates in one particular year 2012.

Dave King. Can you define chorioamnionitis for us.

I'm afraid you would ask that. Infection of these membranes -- maybe Kristin can explain a little better what Coram man may not is is. It's an infection of these linings that hold the developing fetus during the pregnancy.

So is it around the fluid -- can we think of it in those terms?

Yes.

That's a fair -- yes.

I think the last bullet is the most important here so with Gloria Minogue and midnight is [Indiscernible] is an increased risk for preterm birth. It is a risk factor for preterm birth. Although we saw the small increase risk for [Indiscernible] following Tdap there was no associated increased risk for preterm birth. Detected in this study.

So can I ask -- this is Anne. Is that the only risk with chorioamnionitis? Is there risk to the fetus from other?

For the outcomes selected there was not. Preterm birth small for gestational age no increased risk.

I would have to review the paper. There were several outcomes but the big ones that they were looking at were these preterm birth and small for gestational age.

Slide 7. In the HPV session, there was a review of some of the epidemiology of HPV looking at HPV type attribution and HPV associated disease in the United States. So for cervical [Indiscernible] grade 2 and three lesions approximately 50% is attributable to HPV 16 and 18 and those are the types that are in the vaccine both in the bio Valent and the Roger Valent. And 25% were attributed to five additional types in the investigational Valent vaccine. For HPV associated cancers, approximately 62% were attributable to HPV 16 and 18 and approximately 11% attributable to the five additional types in the 9 Valent vaccine. The 9 Valent vaccine clinical trial were presented by Merck. There be LA is under review and they expect licensure in 2015.

HIV-associated cancer. This is Kristin. Does that refer to all anogenital cancers or what was included quick

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I believe it was cervical. But I will get back to you on that. I have to review the paper more in-depth and get back to you on that.

Thank you.

Review the presentation and get back to you on that.

Slide eight. Coming up for the June ACIP meeting in a few weeks there will be several presentations at the influenza session at a couple of presentations at a standalone vaccine safety session. With influenza session there will be Bactine safety updates for the 2013 2014 influenza season. That's a standard and it's easy review. There will be a presentation on assisting people rates in children following [Indiscernible] forms of vaccine and inactivated forms of vaccine. And then LAIV and IIV safety evidence review. The vaccine safety session there will be two presentations. One is a prison study and Valerie preview that one. This is looking at grand mal seizures after influenza vaccines. And the post license safety monitoring system during the 2010/2011 influenza season. Seizures following administration of multiple vaccines, a Bactine -- a vaccine safety datalink study. These are follow-up activities to the 2010, 2011 signal fourth seizures and young children following trivalent inactivated influenza vaccine and pneumococcal conjugate vaccine. And just -- to let you know the agenda is available at that website below and you can I -- you can watch the ACIP meeting live. You need to go to the ACIP website and click on the links that provide meeting and you can watch the sessions if you wish.

Moving onto slide nine. The first study timely versus delayed early childhood vaccination and seizures versus Cambridge. The investigators found no increased risk of post vaccination Caesar in and -- and -- seizure in infants. In year two, delaying MMR vaccine past 15 months of age results in a higher risk of seizures. The strength of association is doubled with MMRV vaccine. The findings suggest that on-time vaccination is as safe with regard to seizures as delayed vaccination in the first year of life and that delayed vaccination of the second year of life is associated with post vaccination seizures than on-time vaccination. I will take time to explain this publication. What the authors were really looking at was does delaying vaccination protect a person or child from seizures and we thing most of the seizures are febrile seizures. Delaying vaccinations are using an alternate vaccination schedule during the first year of life has no effect on seizures. However when you move into year two so you are looking at 13 -- the 12 month or 13th up to 24 months in the second year of life delaying MMR and MMR vaccine puts it -- as a child at risk for febrile seizures. The reason for this are that febrile seizures are pretty uncommon in infants during the first year of life. The risk of a febrile seizure increases as you move into the second year of life and it tends to peak around 18 months of age and then gradually decreases. As children get older. If a child is delayed in getting MMR and MMR vaccine which we now -- which I know are associated with increased rest -- risk of febrile seizures if you delayed that past 15 months you are moving into that period when child -- children are naturally at highest risk for febrile seizures. That is where you seeing this effect that if you delay getting MMR and MMRV you have an increased risk of seizures as opposed to giving those vaccines during 12 to 15 months.

Dave King. Tom, a child who based upon when the parent and the doctor confer and say the child is too sick right now or exhibits some signs that are we should delay on getting this vaccine so [Indiscernible] if then when it's time and their past that 15 months of age so at that close to the 18 month where it peaks, would they be better off to wait or is the risk so high of developing this that you would still want to give them the vaccine?

In that situation I don't think we have information that could answer that question. Delaying a vaccine for medical reasons -- for legitimate medical reasons -- i think it's a decision best left to the provider in consultation with parents. This is more about voluntarily delaying vaccines.

Maybe [Indiscernible] what I was trying to get at is I understand that sometimes people do delayed and sent time people voluntarily delaying and sometimes it's involuntary. It makes sense they delay. My question to you is based upon your research with the research that is been done here and he said that it peaks at 18 months if it turns out that they could give them the vaccine between the ages of 15 and 18 months but that if it peaks at 18 months does that mean in general at the month in 21 months and 22 months they would be less likely. Would they do that are to wait been giving it at the peak period of 18 months?

You are asking if a child has a delay of vaccine during 12 to 15 months for whatever reason would they be better off waiting even longer when the risk of febrile seizures naturally begins to decline. Again, I don't think there is evidence that -- there's not data to answer that question. But I will say that when you delay vaccines -- there are risks to giving MMR and MMRV during that time when children are naturally at highest risk for seizures but there is also a risk of not giving MMR vaccine because you are prolonging the window that they are susceptible to measles and mumps and rubella. I don't think we have data to answer that question but I think that has to be a decision a provider would make based on his or her risk-benefit assessment of that particular case.

Okay, thank you.

Slide 10. The next publication. Haber and Post licensure surveillance of trivalent live attenuated influenza vaccine in children aged 2-18 years, this was a standard analysis looking at reports of LAIV 3 and no new or unexpected adverse event patterns were found. There were reports of LAIV administered to persons for whom it does not recommend such as children with a history of asthma or active airway disease or indicating that ongoing monitoring are needed.

Slide 11. Nail way versus safety of influenza vaccination during pregnancy. This was a review of two studies and no associations between inactivated influenza vaccination and gestational diabetes and hypertension preeclampsia or [Indiscernible] were observed in cohort. When considered as a holding steady should further reassure women and clinicians that influenza vaccination during pregnancy is safe from others. -- foremothers.

Norton and maternal influenza vaccine and risks for preterm or small gestational age birth. This looked at receipt of trivalent inactivated influenza during pregnancy and it was not associated

with increased or decreased risk of preterm or small for gestational age birth. The findings support the safety of vaccinating pregnant women against influenza during the first, second, and third trimester's. It suggests that a nonspecific protective effect of the influenza vaccine for these outcomes may not exist.

That is the end of my presentation. I will be happy to answer questions.

No questions. Does anybody have questions or comments?

No.

Tom, thank you. Always appreciated.

You are welcome.

The next item is public comment. So operator, we can open the lines for public comment and allow people to make comments.

If anyone would like to make a comment press star one and record your name.

There is a comment from Theresa [Indiscernible].

Good afternoon. My name is the recent [Indiscernible] and on the executive director for the national vaccine information center the mission is to prevent vaccine injury and death of public education and to defend the [Indiscernible] and vaccination policies. I appreciate the opportunity to comment today. I like to thank the committee for their careful consideration of language clarifications to the vaccine injury table recommendations made by the commission and March of 2012. DIC is requesting eight copy of this recommendations as they relate to this topic and these presentations and e-mails that were distributed to the commission yesterday do not appear on the website for public access. We appreciate consideration under the request. We would reiterate that people or individuals and genetic disposition and susceptibilities are risk factors that do not necessarily manifest into medical conditions during one's lifetime. So we put risk factors do not predestined individuals to and associated medical condition. The ability of environmental factors to trigger or exacerbate underlying conditions must be considered individually. And where vaccines have been found to trigger or exacerbate these predispositions susceptibilities for claims filed within the VICP compensation must be granted. In addition the IOM has stated the limitations of epidemiology in relation to susceptibility and stated that most children who experience an adverse reaction to immunization have a pre-existing susceptibility. Some predispositions may be detectable prior to vaccination and others at least with current technology and practice are not. We would also note the statement made during the meeting with regard to [Indiscernible] immunity and vaccines was not accurate. The CDC a knowledge is that immunity is a situation in which through vaccination our prior illness a sufficient portion of the population is immune to an infectious disease. With regard to the EIS revisions consumers are entitled to understand that

vaccines are not risk-free. Consumers must have accurate information to confirm decisions even when that means they need to delay or decline in one or more vaccines. Parents and individuals are the decision-makers and vaccination and not vaccine providers. A vaccine providers world under the federal law and the informed consent act is to inform vaccine risks and benefits so the decision maker the consumer can make voluntary decisions that include excepting, delaying or declining one or more the vaccines. The federal law that requires that the EIS to provide clear and accurate information to consumers on bass scene receive benefits which state the vaccines carry risks.

[Event has exceeded scheduled time. Captioner must proceed to captioner next scheduled event. Disconnecting at 5:03 p.m. EST]

The risk of injury and the risk of death. Additionally we know the following with regard to the EIS and statements that it could benefit by. That the ISS met Schroeder today than in the past and is consequently more limited in conveying risk and benefit information. The law doesn't require that providers go over the VIS of parent or that parents greeted and contribute to it not being read, save the way. This possibility is not a valid reason to limit the information provided in the VIS. We would encourage visiting the links of the VIS today.

[Event Concluded]