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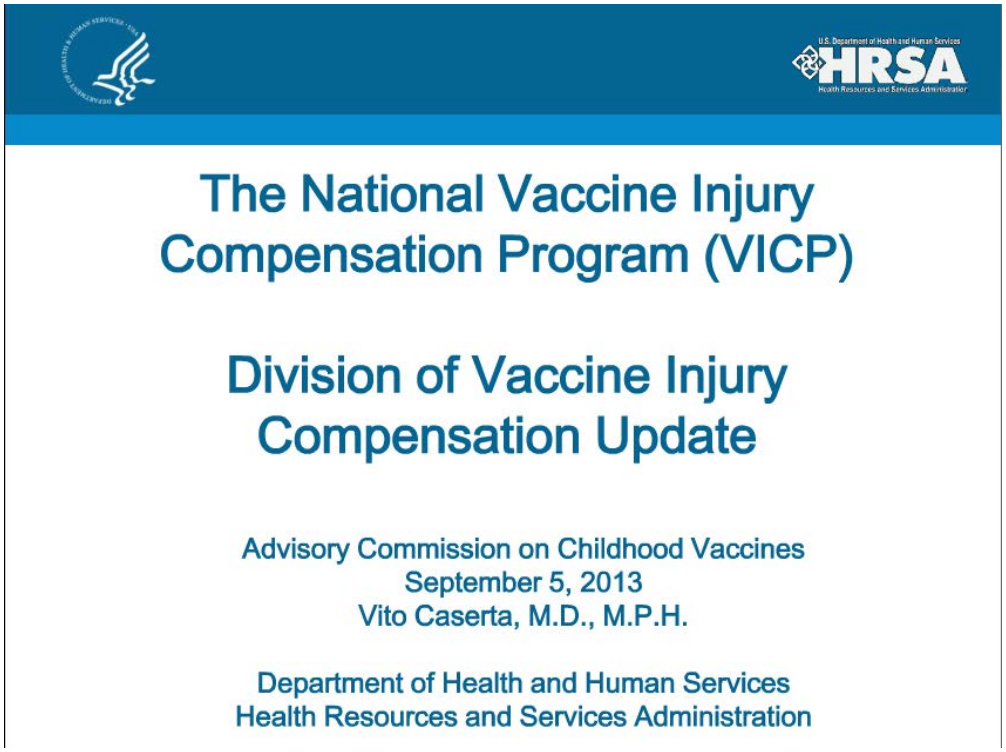
Advisory Commission on Childhood Vaccines

Thursday, September 05, 2013

Andrea Herzog

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



Event: Advisory Commission on Childhood Vaccines

Date: Thursday, September 05, 2013

Event Coordinator: Andrea Herzog

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Start and End Time: 10:00 – 4:00 PM

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Attendees

1. accv
2. Allison Durham
3. Althea Davis
4. Amber
5. Andrea Herzog
6. Ann Martin
7. Ann Pron
8. Anna Kirkland
9. Anne Marie Polak
10. B Shapiro
11. Barbara Mulach
12. Captioner
13. Captions
14. Charlene Douglas
15. Claudia Gangi
16. Darryl Wishard
17. Dave King
18. DawnLoughborough
19. Gordon Shemin
20. guest
21. Heather Pearlman
22. J Reynaud
23. Jason Smith
24. Jocelyn McIntosh
25. Jonathan Salaveria
26. Kristen Feemster
27. Marco Melo
28. Mark Ditmar
29. Mary Rubin
30. Steve Bende
31. Theresa Wrangham
32. Thomas Ryan
33. Tom Shimabukuro
34. Traci Patton
35. Valerie Marshall
36. Wayne Rohde

Chat History

N/A

Polls

N/A

Q&A

N/A

Transcript

Event ID: 2205171
Event Started: 9/5/2013 9:43:36 AM ET

Please stand by for realtime captions.

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Please continue to stand by. Your conference will begin momentarily. Please continue to stand by.

Welcome to the 89th quarterly meeting of the advisory commission on childhood vaccines. At this time, all participants are in a listen only mode. This call is being recorded. If you have objections, you may disconnect at this time. I'll now turn the meeting over to the ACCV chair, Esther David King. You may begin.

Thank you. Good morning to all processes David King the chair of the advisory commission on childhood vaccines. I would like to do a roll call of the commissioners, initially, to start.

There is a terrible echo. You can hear you through the phone, but you are also coming through the computer.

You may need to turn the volume off.

The computer volume.

Shot your speakers off. -- shut your speakers off.

It's off. I don't hear you through the machine out.

All right. So, since you started peeking -- speaking, we will identify you.

Charlene Douglas, Commissioner.

Jason Smith, Commissioner and counsel for Pfizer vaccines.

Michelle Williams, Commissioner, unaffiliated attorney.

Then Kraus, attorney who represents vaccine injured people and I am a Commissioner.

Kristen Feemster, pediatric Commissioner.

Luisita dela Rosa, representing general public -- vaccine injured person. I am a Commissioner.

That counts a total of eight of us. Is Sylvia present at this time? We will proceed without Sylvia.

A couple of housekeeping rules. Just to get us all on the same p age. It's really more of a reminder than anything else. When you speak, and have a common to make, if you could identify who you are for the benefit of everybody on the phone, even though most of us may recognize your v oice, it would still be a good idea to do that, since we are in a virtual environment. Additionally, as we go to the slides, even though many of us are on the Adobe Connect right now, where we can actually see the slides go from page to page, let's run under the assumption, for the moment, that name not be true for all listening on the phone. If that be the case, that would be helpful to identify when you are going to a new slide, whenever you are in a presenting mode. So, we are here, as Julie said for the 89th meeting. I think that from the chair, in terms of my report, it is a limited report. The first thing I really want to do is think the commissioners for the work that they have been doing for the past several years, particularly those who have been most active in the maternal immunization workgroups and the process workgroups over the past year and a half. Because of the effort and time involved and the resolutions that we have moved forward in our prior meetings. I think that we just ought to give a thank you, publicly to you guys for that effort work I also think that it's important that we emphasize that the role of the advisory mission on childhood vaccines is really one of where we are on the frontline, for advising the Secretary of health and human services as to the national vaccine injury compensation program. It provides compensation for certain vaccine related injuries or deaths. I think it's important that we understand that our purpose and focus is around that and it's important for us to remember where the society is on public health, that we would want to vaccinate quite a few people. Let us not forget that in our rush to ensure the health of everyone, that some individuals get injured in that process. Hence, the reason for our e xistence. We are the ones -- when we pass items and put them on the table, that the emphasis being on error on the side of helping those who need the help. I think that from a sales lot -- philosophical point of view, that this commission should be thinking in those types of terms. For those that are injured, or who could potentially be injured, we want to work to make sure that we have been moving in the right direction. That is it for now. During -- at the end of the day, we will bring items up under new business. I will hold off on going into great detail on what some of those items are. One of them would be on the process itself, in terms of how we meet on this virtual versus face to face. I think we ought to at least initiate a more detailed conversation around whether this process allows us to be most effective as commissioners, or if it only allows us to be defective as commissioners. I think that we, as commissioners, should be striving for most effective, not just simple effectiveness. Having said that, I have nothing else to add on the welcome and chair report and am prepared, now, to move to the public comment section. I would've guys anyone who is going to make a public comment, that the public comment, and nationally, that is listed first on the agenda, is only to speak about items that are currently on the agenda. It is not a public format for bringing in new information. That will be

done at the end of the meeting, during the public comment section. The first thing we want to do, if someone has a public comment, is that they state who they are, if they represent anyone and ask the question or make the comment as it relates to something that is specifically on the agenda that we have now. Having said that, operator, Julie, if you could see if there's anybody who wants to make a public comment, as it relates to our agenda items.

At this time, to make a public homage, these press star one. Be sure to unmute your phone and record your name clearly. To with draw your comment, press star to. To be in line for a public comment, leads press star one and record your name. One moment please. The first comment comes from Jim, your line is open.

Good morning everybody. Greetings from London today. I want to thank the Chairman for the opening comments. It something I occasionally talk about and think that that is the important obligation, is to the number people who are injured and that should be, of course, the primary focus. I want to tank -- thank the Chairman for those comments. Also, and looking at the items on the website, I think the staff or putting them there and including the ACCV workbook work that is very helpful. Reports are from June. Thank you for that, since it's a very helpful reminder of what happened in June. Anyway, those reports could be put up the night before. That would aid in preparation for and participating in a good discussion. When those reports are put up, if they will stay up on the website. Occasionally doing historical work. Thank you for putting the information they are, it's extremely helpful as far as the process goes. That's it are now. Thank you.

Okay. Any other comments, Julie?

Yes. The next comet comes from Don. Your line is open.

Good morning and thank you for allowing public comment. I am Dawn Maas Burrill. I'm the mother of three children. To who are affected by vaccine adverse events. I'm calling to represent independent research that's been done to request of this committee, and it looks like it's on the agenda today, some -- I am very glad -- to include some Guillain-Barré syndrome to the vaccine injury table. I'm also requesting that this committee do direct respective vaccinated versus voluntary unvaccinated study. In particular, with maternal immunizations. I'm requesting additions to the table injuries for the future. To include diabetes for him, regressive autism or thimerosal related attractive for 15 years and MMR encephalopathy leading to autism, as well as mitochondrial disorders. All four the table injuries. I'm also requesting that thimerosal be removes from all vaccines and I'm requesting innovation around screening for genetic and metabolic predict there's prior to vaccination of our children. I'm asking you to have education, active educating -- education for VAERS reporting on the clinical setting. I don't believe pregnant moms -- I don't believe a lot of parents know about this and I don't see reporting incentive for pediatricians. That concerns me in regards to the overall process, Mr. Kang, about assuring that vaccine injured children that we error on the side of helping those that are injured. I would also encourage you to have face-to-face meetings open to the public and I look forward to seeing more of the report as they come o ut. Thank you very much.

We will close the public c omment. Are there any moves to change the minutes from anybody?

Since I haven't heard from anybody, Dave King, I have a comment for clarification and it may be that I have misread this. Maybe someone can give me guidance. On page seven of our minutes, down towards the latter third, I guess, it begins with the paragraph c alled, it was noted that the Department of Justice actually determines legislative strategies, so the recommendation is for the secretary to support, not initiate, legislative strategies. Is it true that we are trying to use legislative strategies? Or, should we be using litigation strategy as a word? The prior paragraph talks about support for litigation strategy. I'm just trying to make sure that we use the right words here.

This is Kristen Feemster. This is summarizing, I think for this my correct -- recommendation, we stated that the secretary could pursue either legislative amendment or a litigation strategy. So, I think that this was speaking to that initial mention of pursuing the legislative strategy.

The statutory amendment component?

Exactly. I am looking to make sure that I am not incorrect, here.

The Department of Justice actually determines those?

That's right. The department of justice would be involved with litigation, rather than legislation. That may need to be corrected. If anyone from the Department of Justice is on the line and has comments -- I think that is probably correct.

This is Vince Matanoski. It's correct to say that the carbon of justice would not the determining that secretaries legislative strategies.

That would need to be changed.

So, we need to change those things to say -- litigation strategies, recommendations for the secretary to support, not initiate legislation.

That's correct. It was written that way and, that's correct.

Okay. We will make those corrections to the minutes.

Dave, this is an. I have a comment on page one. Second paragraph on your report. In establishing a workgroup to collect and consider various data, is there a descriptor to what kind of data that refers to?

This was where we were trying to establish a workgroup to collect I consider various data that might become available. I think the data was really -- it stemmed from the fact that we

continually talk about the idea that there is so much data collected for each one of these cases. Was there a way or is there a way to data mine this information in a manner that would protect the privacy of individuals, but at the same time might be able to allow for the discerning of patterns that might help us better understand who might or might not be at specific risk to an injury due to a specific type of vaccine. I think we were unable to establish that workgroup, because we don't have anyone able to assume the responsibility of caring that at this time.

So, is that adverse event data? Or case data? There should be a descriptor in there. It seems very wide open.

[Indiscernible-multiple speakers]

I think we were talking about case data. It's what we were talking about. I'm not sure that it would necessarily be limited solely to that, if someone were managing t hat. It may be -- I don't know that I would want to limit one's ability, but I think that it may be, to some degree, herculean type task. It is not so easy to wrestle this to the ground, is what we have been finding. But, I understand what you are saying. Should we define what that data is? I'm not sure and -- I'm not sure it has ever been completely defined.

This is Ed Crouse. My recollection is, and perhaps the way to proceed it was data from cases that were filed in the program. I think that it is what we are focusing on, figuring out if there was information that would the of use to the public and of interest and value to the public. Some individual cases that were filed in the program.

So, we could -- so, instead of saying various data, we could say various case data or case data? Would that be acceptable?

It sounds good to me. I don't know about the rest of the group.

This is Ed. I'm fine.

I think we should go ahead and make that change. It makes it more specific what we are talking about. Are there any other comments, suggestions, issues?

Regarding the minutes? I would entertain a motion to accept these minutes.

I so move, it's Michelle.

I second it. Ann Pron.

The motion is on the floor and we will call it to a vote. The all in favor -- let me put it this way -- anyone who is opposed, please identify. Please identify.

All in favor, say here here and we will send it as unanimous [Indiscernible].

Here here.

The minutes accepted. Am I within the rules?

[Laughter] You usually don't take the negative vote there could but --

[Laughter]

I will let it go this time.

I'm trying to turn it upside down.

I see [Laughter]

Thank you very much. So, at this time, as we move through the agenda, Dr. Veto Caserta, the division of vaccine injury compensation, you have the floor and welcome.

Thank you David. The highlights of this meeting, we will are from the Department of Justice, as we usually do. They will present a presentation on GBS from the program. Adding GBS to the table is the proposition. We will hear from the workgroups, Luisita dela Rosa and Kristin will respect -- present in their respective groups. There will be a review of influenza vaccine information's events and we will get updates from our members. Slide.

So, the number of petitions filed as of August 13, we are sort of holding pretty steady pattern of getting approximately 400 or so cases filed each year. We are on schedule for that this year, as well. Next slide. The number of adjudications as of August her teen. The number of compensable cases is sort of -- over the past three years, has averaged around 250, to 60. This year it's a little bit higher. Most of these compensable cases are settlements. Slide five.

The categories, in terms of the compensable cases, it's broken out as concessions, or decisions or settlements. You can see the breakout in the numbers, in the past three years. Again, you can see the settlement numbers have increased. Next slide would be slide six. The amount in terms of awards paid. This year, has been a bit of an outlier, in terms of how much has been paid by the program to petitioners. As of August 13, we paid out a figure that we have never seen before, in terms of our history, $215 million. We do have two large cases that are pending payout. So, this number may significantly increase for this fiscal year, before the fiscal year is finished.

Vito?

Dave King speaking.

The fiscal year ends when?

It ends on September 30.

September 30, so that may or may not increased that?

We are expecting at least one claim of about $48 million, that may come in before the end of the fiscal year. There is another claim of approximately $40 million that may or may not. We are not sure.

Okay.

We had to ask Congress, ask OMB for additional funding, because normally we don't ask for this much money to pay out claims. This year, we needed to do that.

Slide seven. At the last meeting, I proposed that we would add a new table to our website. We did accomplish that. If you go to the website, you will see. On the table, it breaks out compensable into the three categories that I mentioned previously. It sort of defines what those categories are. That way, it provides a better view of what we are actually doing, as opposed to just think compensable. That's not really as clear as we want it to be.

[Indiscernible-low volume]

4.2, thanks. If anyone wants to look at it and provide comments about it, please let me know. Slide eight is the status of the trust fund. It's still very healthy. As you can see.

Vito?

Yes?

Dave King again. Earlier, you had said, based on the cases where we might be in an outlier year for fiscal year 2013, and we have the high amount and may have another $40 million, another $43 million or $48 million. You said we needed to ask additional funding from OMB, in light of that. So, I'm not sure -- I know that I don't completely understand and maybe others on the commission don't, as well. If you could explain why, with the balance of $3.4 billion, we would be asking someone for additional funding? Maybe you could help us explain what that process is about, these?

Sure. Although the money is in the trust fund, it's not like a bank account where we can go and withdraw the money whatever we needed. We need to ask permission to with draw the money. We get the money in [I ndiscernible]. In batches. As we spend down, we ask for more. Generally, we are able to get more before we spend down to a point where we can pay a claim, we have to wait to pick claim. -- pay a claim. It's a control of the money, in the sense that we have to request it. That request goes through the Department and goes to OMB and OMB then has to approve that. Then, provide the money to us.

Okay. Rick question. When you say generally, are you able to do that? Does that mean sometimes it's have been where we haven't had the funding when we needed a?

For very short periods of time, it has happened. It did happen with -- with this increase that we have this year. There was a period of a few days where we were really at the very edge of eating able to pay period we held a couple payments for a few days longer than we would normally. It was just a few days and then we got the money quickly. But, it takes time for the process. So, it can happen. Generally, it doesn't happen. It's a rare event, but it can o ccur. Does that answer your question, David?

It does. So, when it does occur, who is really impacted by that?

Well, we try not to impact petitioners here so, we would hold off on paying legal fees, attorney's fees first. Again, it's just a couple of days. If it happens that there was a petitioner that wasn't being paid, that would put more pressure on the system to get us the money more quickly. So, again, even with this instance, I don't think petitioners were affected at all. Attorney's fees were held for a few days as we were sort of seeing the balance Trop and we wanted to have the money to pay the petitioners claims.

Right. But you are saying this is rare and so, not something that we should be managing to? Or, are you saying that maybe we need to look at this process, to see if there's a way to prevent this from occurring?

No. We have it under control. There's really no need. It's simply a process that's in place to sort of control and ensure that the money is spent wisely and that it's monitored. I think that's a good thing.

I don't disagree that it's a good thing to have a check and balance on how the money flows and things of that nature. What we don't want to do, is that people end up in a short position.

We absolutely agree with you. We were scrambling to not let that happen.

Okay.

So, in terms of significant activities on slide nine, we have a notice for the Federal Register to extend the nomination submission deadline for 60 days. I don't think that's been published yet, but it will be published imminently. The rotavirus regulation is currently in the public comment period and that will continue till January 21.

Western, Vito.

Dave King. On the nominations omission deadline, the 60 day extension, we did receive a copy of that in our booklets. Is it just a duplicate of what was already printed?

Yes.

Is the reason we have had the extension because we did not get nominees? Or, is it that the quality of the nominees is less than acceptable or met within the requirements of what we're looking for?

We did not yet nominees in each of the categories that we needed. We did get a nominee from the American Academy of pediatrics for the provider category, but we didn't get nominees and in the other categories.

So, I'm thinking that now might be a time for us to ask questions around it, since the slide is up. But, I am willing to move this to new business, because it makes sense to do so. I will let the commissioners determine whether or not that make sense to do so or not. When we talk about the three individuals, the three voting members, we have a health professional. So, you see you did get a nomination in that area, of back correct?

We did get one, but we would like to have more than one.

Understood. But, we have received no nominations for the general public as the legal representative of -- meaning a parent or guardian. We didn't receive anything as it relates to an attorney with specific affiliation. So, let's back up for a moment. I know we made a recommendation as a commission, to have a member of the general public. It could be of an adult, also was injured. I guess that has not actually become part of the rule you, is that correct?

That's correct.

For the attorney with no specific affiliation, that is just an internal rule, but not really one determined by the charter, is that correct?

I think it is in the charter.

So when I read the charter, what I read, is that we are -- the three members who are attorneys, of whom at least one shall be an attorney whose specialty includes representation of persons who have suffered a vaccine related injury or death. And, of what one shall be an attorney whose specialty includes representation of vaccine manufacturers. So, my reading of that would have it the that we could then have another attorney who is, in fact, a representative of persons who have suffered a vaccine related injury or death, or, it could, in fact, be an attorney whose specialty includes representation of vaccine manufacturers. It doesn't say anything about unaffiliated. It in place dates that we have to have one who is representation of persons who has a vaccine related injury or death and then we have attorneys of home one shall be an attorney whose specialty includes representation of vaccine manufacturers.

Right. Historically we've done it that way for reasons of balance.

I would add do -- argue that the statute doesn't really talk about balance except that in our guidelines, when we put something on the table, that have been outlined, that we should error on the side of petitioners and I would argue that an unaffiliated attorney might not necessarily be what weeks to glue be looking for, but rather an attorney -- but what we should be looking for is an attorney that is representative of persons have suffered a vaccine related injury or death.

This is Michelle Williams as the unaffiliated attorney representative, I might respectfully disagree. They I make a suggestion that we move this discussion to the process work group? See if we can make some recommendations there and have some thoughtful input in that forum?

Sounds like a good idea.

So, does the Commissioner -- would -- Luisita dela Rosa, is that something you would be willing to take up under the process work group?

We can put that in. It's still part of the process, isn't it?

Yes, it is.

We will do it.

Very good. Then, we will move on.

This is and prompt -- this is Ann Pron. Can you give me an exact date? I'm trying to figure the 60 did extension on August 9, is that what it is? Denomination?

No. This is any. It will be 60 days from the day that is published in the Federal Register. That's probably going to happen in the next week or two. It will be 60 days from the published date.

It will be the same thing that was currently published on J uly 10th?

Yes.

Can you notify when that goes out? I never knew that went out.

Yes. I sure can't.

Thank you.

There may be some minor changes, to it. I'm not certain about that, though.

Vito, when you talk about minor changes, Dave speak -- Dave King speaking. What might they be?

There was an issue to the word related qualified individuals with another commission. There was a question about that. Sort of stock line which comes to us to modify. I'm trying to remember exactly what that modification is. Annie, any helmet? It's not anything important.

[Indiscernible-low volume]

It has to do with the word qualified.

Okay. One other question on the nomination submissions. If you are unable to fill the nominations in the timeframe, where some of us would be under an expiration of our terms, what happens?

We would ask if you would e xtend.

Okay.

We have put some policies in place to help with our recruiting. Annie, would you want to go over what we have done to, sort of, throw out our wider net? We discussed how we could do that and we reached out. I will let Amber introduce y ourself.

That morning. My name is Amber and I'm actually new to [Indiscernible]. I will be helping transition the work that Annie has currently been doing for a number of years. The morning and nice to hear from you all. So far, in terms of the n ominations, we were able to cast kind of a broader net by publishing it on the HRSA splitter account as well as the [Indiscernible] a ccount. Oozing social media as an avenue to disseminate information, as well a s, once the new extended deadline for the FRN is published, we would be casting a broader net by sending out the HRSA listserv.

Thank you, Amber.

Amber, welcome. So, Dave King speaking. Amber, are you replacing Annie? Is that the game plan here?

David, no one can replace Annie.

Well spoken.

Amber will be transitioning into what Annie has traditionally done for the commission. So, the answer to your question is yes.

So I shouldn't break into a we will miss you Annie song.

[Laughter] Always appreciated, Dave.

Annie will remain in the background, as Amber learns the role.

All right. So, I guess we should spell out, as we always like to do, they've King speaking again, regarding the contact information and the building and the like. Because everybody might actually have this information in front of them on the screen and they'd only be listening on the phone. We could kind of read that out.

Sure. I will do it when I get to that slide.

I thought we were on it.

[Indiscernible-low volume]

[Laughter]

All right. Very good.

Okay. So, I guess we can move. But let me just say that at the meeting, Kristin and Anna Jacobs provided a back-to-back presentation from the maternal work Roop and they were very, very, very well received. Actually, Dr. Lauren Steen said it was the best resin Tatian he had ever heard. It was appreciated and I will let Kristin talk about that when it comes that time. Then, the slides that Annie was trigger-happy. Amber will be the contact person and if you need to write to her, she is at the Parkland building, room 11 see. 5600 fishers Lane, Rockville Maryland, 20857. Phone number (301)443-0845. E-mail address aberrian@hrsa.gov. That concludes my presentation.

Thank you, Vito. Does anyone have any questions for Vito?

Yes. This is Ann Pron work is just procedural. Will Amber's name then be on the next Federal Register for the nominations?

Yes.

Thank you.

Okay. Does anyone else have any other questions? Vito, Dave King here. I do have one question. The question relates -- first off -- I want to thank you for what you been doing. I do believe that you still continue to be the acting officer for us, unless you have been fully appointed work have you been fully appointed?

Not yet. But that's in the plans.

Good. That's a good thing. From that perspective.

Thank you.

So, having said that, and you having had some experience, Rome your perspective, because we talked about the effectiveness in the Chairman's report, of the commission, from your perspective, what could we, as a commission, do better, in order for us to be most effective?

Wow. Okay.

This is Michelle. That might be something that Annie might want to think about and may be present at our next meeting?

Michele, I appreciate that. I would love to hear what the don't has to say their.

It would lovably be more affect give if I gave it some thought. Presented at the next meeting, rather than trying to answer off-the-cuff. Is a complex question. Again, to make the commission more effective, we would want to give a really well thought-out answer.

I would ask that we not use the word more, Vito and I ask we use the word most effective. I want to be more, the most effective that we can. I think all the commissioners would agree that they want to be the most effective.

I am coming out of an old total quality management, where each year you try to improve. So, that's why I use more.

Fair enough.

Having read the works, I understand.

Okay. Absolutely I will use the word m ost. I'm just teasing.

[Laughter] Okay.

Okay. I think it's best if I consult with my team, I consult with my attorneys.

I agree. I think shells suggestion works.

Yes. We will present something next time in the cold of December.

That will warm our hearts, though.

Okay. [Laughter]

Thank you. If there are no other questions for Vito, we will move on. We will do the report from the Department of Justice. We have Mr. Vince Matanoski. Vince, are you here with us?

Yes, I am. Thank you. Thank you for allowing me to speak today. It's a pleasure, as always. If there are any questions that come up during my presentation, I would welcome them and be happy to respond. Turning to slide two, this provides our breakdown of the incoming cases for the last three months. No real surprises here. In terms of the overall numbers. They track with what Dr. the third of reported, lovably looking at around the same number -- probably looking at around the same number that we had in previous years of a little over 400 cases to be felt from the fiscal year. The thing that I've noticed that the little different, that you can't see from that number, is that typically during the summer months, it's been my experience there's been a little bit of dip in the number of cases that are filed. It picks up again in September and carries on through. I didn't see that this past year. In the summer, there really was not any flagging in the rate at which cases were being filed. If that remains true, we actually may see a little bit of a bump up in this year's filings, overall, when the fiscal year closes. I will keep an eye on that to see if that trend continues on. Because, it may, essentially, spell that we are going to be looking at slightly more cases being filed over the years. The upcoming years.

Again, in terms of the breakout between minors and adults, if the pattern we've seen -- I've reported on it over the past several meetings. It's still predominantly adults, adult claims that are coming in.

The total adjudications in this period, the numbers are tracking about the same as what you've seen in the past. Where there's been a difference, in terms of the numbers on compensated have tracking about where we've been in the past. Where there's been a do -- difference in this reporting period as the numbers that were not compensated. The last very old, when I reported in June, we had a total of 254 dismissed cases. You can see this period was only 32. The big difference there is the number of cases -- autism cases dismissed dropped this up a pitifully. It was 228 in the last three month period and and it was 19 in this period. What we are coming to, what I believe we are coming to, is the court has worked through most of the cases that were going to be dismissed on the records, as they listed at the time. We got into pretty much the end of those and the remaining autism cases are probably going to be looked at a little more closely, in terms of the petitioners, at least. They are pursuing them a little more vigorously and we probably are not going to see those kinds of numbers of dismissed cases in the next couple of reporting periods. In fact, most of the pending autism cases, I believe, the majority of them, have now been resolved.

Voluntarily withdrawing cases, I'm sorry, I didn't announce the slides. We are now on slide four. It was only one voluntarily withdrawn case during this period. Slide five, --

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This is at Kraus. Before you get into the slide, can I ask a question?

Certainly.

The distinction between autism and non-autism cases, I understand its origins with the omnibus proceedings -- understand its usefulness, I suppose, in the statistics, as to petitions adjudicated during the reporting period. I don't understand -- I think the distinction between autism and n on-autism cases, at this point, is no longer necessary. I also think -- I suspect it's no longer -- it's also, probably, not entirely accurate work I say that, because I know that there are still petitioners who pursue vaccine injury cases, for minors who do have autism. I know that, certainly, strategically, those cases are not litigated as vaccine caused autism. That's not -- that's too broad and problematic a very to establish entitlement. But there are certainly cases where minors have encephalopathy and other alleged vaccine injuries. In addition to that, they have diagnoses are symptoms of autism. So, I would like to suggest that, moving forward, with new petitions that are filed, that the DOJ -- I don't think the distinction between autism and non-autism is appropriate.

Actually, I believe in cases that are being filed now, we do not distinguish between autism and n on-autism cases, as far as the reporting out that we are doing here. That distinction was when -- what you see in these statistics reported are registered nurse who designated the cases as being part of the Omnibus autism proceeding. So, I think that your point, at least in going forward, we wouldn't be drawing that distinction. I think it was just a matter of, and reporting these statistics out in the past, it was a matter of trying to get a better understanding of what you are looking at. If you suddenly saw -- we are having 400 cases filed a year and all of a sudden we had a year of 2500 cases being filed. You needed to have a better understanding of what was driving that change. Going forward, we don't distinguish between them. People who are filing are not filing into designated Omnibus autism case or even designated as autism case, per se. Whatever the injury is that's being alleged, it's just being counted as another case being filed. So, you will probably see this. If this continues, or we aren't seeing very many cases at all, I may just report it out as just a single number there. Does that help?

This is add. I guess so. I guess my understanding, you can't -- maybe I am wrong. You can't file a case in the omnivorous autism proceeding at this point. The away P is closed and you can't file a short form position and create another case under the OAP. If that is the case, I would think that it doesn't need to break down between autism and non-autism. It should just be between minors and adults. Some of those miners cases could involve children who might have autism. But, they are not part of the Omnibus autism proceeding. I understand but you are saying, historically. It was certainly very important and helpful to have the breakout. I just think, moving forward, respectively, and it sounds like that's what DOJ would be doing. Slide to is for the last three months and unless I'm mistaken, I didn't think anybody could file a case in the OAP.

You are right. I apologize. I will take that out. We are not separating them out anymore. That's just an artifact of the way we reported previously. The next time, you will see it, will just be broken out between minors and adults. If we find any other information that we can categorize

that might be of interest to the commission, we will report that. But, you won't see it broken out between autism and non-out to them.

Thank you.

Sure.

This is Ann Pron. I have a question about the compensated cases. I know there are only nine cases conceded, which is maybe a little bit more than 9%. Rather than not conceded. It seems that we have recently, maybe, increased, added to the vaccine injury table and will, again be adding GBS, possibly, to the injury table, as well. Is that what accounts for the big discrepancy before conceded cases and not conceded cases?

You know, I think, just to give you a little context, the number of conceded cases, actually went up is period work when I reported last period, I believe it was five conceded cases and what we were seeing, it wasn't enough that I could tell there was a trend there, and at I believe you are seeing more [Indiscernible] cases, in terms of -- that may be why we saw a little bit of -- actually, in terms of real numbers, there wasn't a big jump. If you talk in terms of p ercentages, it's almost 100% increase in the number of conceded cases between this period and last period. If I were to guess, if you are were to add more tables, this is an educated guess and one that's probably pretty obvious. If you add more injuries to the injury table, you are going to see that number of conceded cases go u p.

It's surprising that it's so low and all the time goes into the vaccine injury table. Already. I'm not in the law field, so I don't have the same perspective.

There are a lot of cases filed that don't allege a table injury. You know, it would obviously -- if all we were seeing were cases that were alleging table injuries, the number of cases that were conceded would be a lot higher. A lot of the cases that are filed don't even alleged table injury. They are not going to be necessarily fitting -- whatever you do with the table isn't necessarily going to affect whether they are conceded or not.

Okay. Thank you.

Sure.

I am going to skip over all the loss three and the levels of appeals, because I covered that before. Again, if there are any questions that you have, I'd be happy to answer them. So, turning to slide 11, to give you an update on what's happening in the appellate courts, we had two cases decided at the Court of Appeals for the Federal Circuit. Deribeaux was a case that we reported on previously. We seen an increasing number of cases alleging that vaccines caused neurologic injuries and when it was examined, when the cases were examined a little closely, it was determined the individual suffered from germ a syndrome, a genetic condition. The cases are presenting interesting medical questions, you cause it appears that the vaccines can trigger

a seizure that is one of the symptoms that unmasks the underlying -- that the individual suffers. Then the question that becomes important for the court to address, is did the vaccine precipitate the neurologic condition or did they make it worse in some way? What has happened, and a number of these gervais cases that have been decided to date, the courts found that based on the evidence, while the vaccines may trigger this first seizure, that then prompts the medical investigation and uncovers the underlying genetic condition, the vaccines did not make the condition any worse, nor were they separately the primary factor driving the child's neurologic injury. So, Deribeaux, like several other earlier cases, the decision by the fact finder was that the vaccine wasn't implicated in the child's condition. In fact, it was essential -- essentially unmasking a symptom without contributing to it. The decision by the special master was reversed by the judge sitting at the Court of Federal claims. When it went up to appeal at the Federal Circuit, they affirmed the special master's decision, finding that the special master was in the best position to judge the credibility of the experts before him or her and that they were in the best position to judge the medical evidence before them. This was essentially a difference standard that was being reinforced by the court. Patarek, similarly, was a question that was before the Federal C ircuit, about what level of deference should be given to the fact finder, the judge that was sitting in this case, the special master, deciding the case. The court found that it was improper that -- improper for the judge of the Court of Appeal claims to insert her findings of fact and not properly defer to the special master, in making the factual findings on the issue.

There's been one new appeal to the Federal Circuit during this period and that was taken by a respondent. It's sort of follows on that same theme that was developed in the decisions that I just reported on. It's the question before the Federal Circuit. What level of deference ought to be accorded to the fact finder, in this case the special master, who is chairing the evidence before them and actually has the witness in front of them. That case is Deobrydev, and it may be decided, not in this three month period, but in the. After that. There were five new cases, new appeals to the Court of Federal claims. All of them are fact-based appeals involving -- all of them were brought by petitioner's and involved some question of the special Masters conclusions regarding either the medical condition that was alleged or whether the medical condition was caused by the vaccine, whether the timing was proper to conclude that it was the vaccine, whether there was another condition that was more likely to cause the injury rather than the vaccine. So, all of these cases involved those sorts of medical issues that now a judge of the Court of Federal claims is being asked review, the special Masters conclusions, with regard to this.

Vince, is that slide 14 were talking about?

I'm sorry. Yes, that is. I jumped ahead to slide 14.

A quick question. You King speaking. I don't know if you know the a nswer. Are all of these appeals? There might be test questions. The first question is, are all of these appeals regarding the same special master?

They are not.

Are the majority of the appeals related to one specific special master?

I don't believe -- let's see -- there are three different special Masters among the five.

Okay. Thank you. It's pretty much spread out.

I would agree.

Turning now to slide 16. On slide 15 you see there are some arguments coming up, if anybody happens to be in the DC area, the arguments are there for them to take a look at. They are public. The public is able to come to support and look at those a rguments. Turning to slide 16, I tried to -- as you know -- I try to synthesize the information that you see in this. Of course, you are free to look through it and draw conclusions. Because there's a lot of information there, there's 77 different settlements that are being reported on, I try to synthesize that to give you a sense of how we are doing, processing wise. That was really the driving factor when we began reporting this. Our settlements moving through fairly rapidly? The last several periods, I assume the same sort of break out, in terms of the amount of time it's taken from the time the petition was filed to the time the settlement was finalized. This stipulation was filed. They are roughly broken down in the following fashion. I'm going to give you the breakout from the last three month period, because that was represented from what I've seen before. About 27% of the cases were adjudicated within a year or less of the date of filing. About an additional 38% were adjudicated within a year to two years. So, a few extended it out another year, you captured another 38%, which gave you 65% of all the cases that settled, were adjudicated within two years of the filing.

If you extended out to another year, so, within three years, you've captured another 18% of the cases that were settled. Where already then up to over 80% or 83% at that point. That had been the trend for the last several periods that I've been reporting. This period, saw a different breakout in this. I don't know whether this is going to continue. But it was a little surprising to me. We had, really, the same number of cases that settle. I think it was 77 last time and it's 77 this time. The exact same number of cases that went to settlement during this period. But, 31 of those cases, 40%, reached a settlement within a year of the date of filing. So, that jumped up Whitey bit. I was wondering, when I saw that, if those cases are within two years moving up a little faster? When I looked at the cases that were done within two years, it added another 34%. So, that tracked about where we had been before. What we were essentially saying was a lot more cases being done within a year. Breaking this out, now, within 1 year we had 40% of the cases. Within two years, an additional 34. Now, where up to 74% and by three years, we had another 10%. So, that got us to 84%. All that being said, within three years, we had the same number of cases, same percentage being settled. More of them are being settled within that first year in this last period. I'm going to keep a close eye on that, or cause I'm wondering if that's going to be a trend that continues. What I have noticed in cases that are being filed, more cases recently are filed with records, or soon after their filed they have records. So, that may be

driving some of this trend, to be able to process cases a lot faster. Also, the court has an initiative that came up with part of a court committee. The petitioners and the respondents participate in an initiative to fast-track certain cases that look like they are good candidates for settlements. That could be another reason why in this last three month period, we saw this jump up in quick processing of cases. Too soon to tell if this is a t rend, as opposed to an aberration. I'm hoping it's a trend and I look at those two factors as possibly driving it, if it is a trend. If you other things about our settlements that may be of interest to the commission.

Of these 77 that were settled, 60 were for adults and 17 were for minor petitioners. So, just as we saw, the majority of the cases that come through the door are for adults. The majority that are settled are also for adults. That's really not that surprising. The number of settlements that involve the flu vaccine, of that total of 77, there were 50. So, roughly two thirds involved the flu vaccine.

That's it for my comments. I'd be happy to entertain any questions you might have.

This is Ed Kraus. Do you know the number? Just a quick unofficial count, but it looks somewhere in the 28, 29 of those flu vaccine cases involved GBS?

I didn't do that. That sounds about right, from my experience. So, we might actually -- if GBS is added to the table, you might see a drop in settlements and an increase in concessions.

Because, GBS was -- it's been a big factor in the number -- a big injury alleged in a number of petitions that have been filed.

Are there any other questions for Vince?

Dave King has a question for y ou.

Certainly.

In light of what was asked of Vito, and the object is really not to put you on the spot, but from your TiVo, -- your perspective. What is it that you see into, that we should, as a commission, do, to make ourselves most effective?

That's -- there are a couple of things that I think of when you ask that question. One is, I'm with Vito. You never can be most. I'm always of the mind that you are always striving to be better. You can never achieve that state of the in most anything. The other is, I have a little bit of trepidation -- whether it's my role to give you, sort of, guidance on what I would think -- and lines of how you do your job. But, it is something that -- when you ask Dr. Concert of that, I thought that might be coming to me. [Laughter]

So, I think it's such an important question that I do think it's one that you really would like to think about before you answer.

So, while initially I wasn't sure and I wanted to hear vetoes answer as I allowed my brain to catch up to my voice, I realized that is so true. Michelle had actually made a good point that we should give you guys time to think about that. I think that we should do that, as well. So, what I'm hoping, is that you could -- at our next meeting -- and it can be at a 30,000-foot level. We could use it possibly for directional guidance.

Okay. I will make this sort of observation. The more I have been involved with this process and the commission, the more I've come to appreciate its value and importance. So, just with that general comment. I think with the question you p osed, and the striving that you have to make the commission as effective as possible, is a good one.

This is Vito. Might I suggest, David, that Vince and I get together, rather than having two separate presentations, we get together and put our brains together with our staffs and with our leadership and do the presentation together? Or, one of us does it?

So, I hadn't thought about that and I am open to other commissioners chiming in here with their thoughts on it. I am of two minds on it. That is, yes, initially, that sounds like a good idea. At the same time, my flag goes up and says, but they come from different perspectives and we might miss something if they give it together. But then I'm not sure that's critical, either. So, that's why I defer to the commissioners and ask the other commissioners what are your feelings on that?

This is Michelle. I think, as long as the content is provided, I'm not sure that it matters if we have one presentation or two. I would let the people that are going to present do it the best way that they think they will be best effective.

Shall, I so suspect that you said that with a smile on your p ace. [Laughter]

Any other thoughts by anybody?

I'm sorry. Is the question whether the Department of Justice should resent separately to answer the question that you posed separately from D VIC? Or whether they should do it as a single report?

I'm not sure that it's broken down white that way. I think there are two different perspective. Vito suggested that perhaps the two sides, and I don't really want to view it as two sides, but the two different perspectives could get together and chat about it with their appropriate personnel. One or both presented those findings to us, as opposed to vetoes group getting tting together and providing two separate. I am of two minds. I'm leaning that Michelle's thinking may have worked just fine on it. I ask what the other commissioners felt on it. I know where Michelle stands on it.

This is Ed. Dave, I think they are different perspectives. They fulfill different roles. Vis-a-vis the program. The Department of Justice. You know, they are representing the government on the other side of these cases. That's their job and a do it well. The DVIC is differently situated. So, they are idea and goals for what the AC -- ACCV needs to be most effective could be different from what the Department of Justice is looking for from an effective ACCV. I would request that we get each entities perspective.

Okay. So, we now have two Commissioner's thinking on this. Are there any others who have thoughts as it relates to this?

This is Charlene. I think it's actually kind of unofficial to think that people -- I mean, I have him in and trust in all colleagues involved in this process. But, and colleagues that work together, certainly, it's not unreasonable to think that they would confer and with think about it. Because, they are addressing the same issue, coming at it from a little different perspective. I don't see -- I don't see any deleterious effect to an overall presentation. The real onus to what the commission needs to do to be more effect of would be a coming together of commissioners and deciding what you see as your role, to be most effective.

Thank you, Charlene. Any other thoughts on that?

This is Ann Pron. I guess I would hesitate to make any strict rule about how they present. I like the idea of Michelle saying, let them decide. Some time, for some quarter, it may be best to combine them and at other times, it may be best to keep them separated like they are. So, I'm not really helping the decision-making. [Laughter]

You are, in fact, helping the decision process. Even though you may not be sure where you stand on it. It's nevertheless good to know that you might the of two minds as well. That's helpful. Anyone else?

This is Kristen Feemster. I think that whether it's a combined -- even if it's a combined report, it still provides an opportunity for both the perspectives to be brought t ogether. So, up their presented at the same time or completely separately, it's still two print perspectives. I agree with Charlene. We are all working towards the same goal, part of our role is balancing our perspectives towards a similar goal. So, I think it makes sense to let them both work out together how to best answer our question about how to be more effect if.

So, does anyone else have any other comments? Anyone not required to make a comment? I will assume by the silence that people have had their speak on it. So, I think that sometimes it's baby steps rather than big huge steps. I think the mere fact that both are willing to address this issue and help guide us or give us ideas and take a look, almost i ntrospectively, and then bring it out to us, I think is a step, absolutely, in the right direction for enabling us to be most effective. With the understanding that it may be and I'd deal that we may be never 100% achieved, but we should certainly die trying. I think that we should move in favor of Vito and Vince, that you guys figure out the way to do it and if it makes sense to all that you speak or

present together and one doesn't, the others there to answer questions, I think we should let you guys make that choice and I think that the mere fact that you are willing to do it, is really a good sign. I think we should just move on in that way.

This is Ed Kraus. I have no problem with that. That was just my perspective on it. I would like to add, a suggestion that we pose the same question to the office of special Masters. I don't know if we are do for our report from them. It would be interesting to hear if they have any opinion or views on what it is that the ACCV could, and should be doing, to be more effective.

I think that is a good idea, Dave King speaking. Vito, is that something you would undertake? I'm not 100% sure.

Well, the special Masters usually are participating in the meeting. I'm not sure if there is anyone on the line.

This is [Indiscernible] Macintosh. On a special attorney at the office of special Masters.

Yes.

I can bring the request to the attention of the chief special master.

I think that would be a terrific thing for you to do for us.

I will do so. I will report back to Dr. Caserta.

That presentation, I think should be separate from the executive branch presentation.

Agreed.

Okay. I think we have a plan of action in the course of moving through it. Terrific. Does anyone have any other questions, comments, before Vince? Thank you so much for your time and willingness to open up to us.

My pleasure.

The next item on the agenda is updating the vaccine injury table to add GPS. Dr.Ahmed Calvo.

Is on meds -- is Ahmed Calvo going to correct me?

By way of introduction, I have historically responded to all kinds of varieties of my name. My friends in high school call me a fit and I responded to a fit for all those years. Whatever you want to call me is fine with me.

We should call you what you want to be called. Anyway, we understand and thank y ou.

Appreciate it there.

Let me jump in and say that I am in new medical officer here at the division of vaccine injury compensation. It's my honor to give you an orientation to a proposal from the division to update the vaccine injury table. With regards to GBS. Particularly, in relation to seasonal influenza vaccines. 10 you hear me okay? My head keeps moving to watch the slide.

From my perspective, Dave King speaking, I can hear you loud and clear.

Terrific.

Slide two, at the top, the objective of my presentation is to seek the advice and concurrent's to the proposed changes to the vaccine injury table. Be IT is a call it for the rest of the presentation. I'd like at the beginning to offer to stop along the way an answer questions if you'd like to do that, or I can sort of power through this really quickly. The purpose of the presentation is to make sure that the committee is comfortable with the concepts we are proposing work please feel free to interrupt me as we go along, because that may be the most efficient way of handling all the details of the presentation.

The overall key concept of the presentation is that these changes are being proposed based on policy recommendation within a sound policy. I will articulate this in the presentation. We want to be clear that the changes are with regards to GBS in relationship to seasonal influenza vaccines, both current and future versions. We want to be concrete about the fact that this is the focus on the proposed changes, conceptually, although we can, perhaps, talk about details of language that may be under consideration. This is really to help you think about the concept. For that, I will orient you a bit about what Sam -- Guillain-Barre i s, first. The rest of the slides, whatever is yellow highlight, that is a key concept. Dion Bari syndrome is really a r are, acute paralysis -- Guillain-Barre syndrome is caused by acute paralysis of the nervous system outside the brain and spinal cord, is one way to think about this. GBS may manifest with weakness abnormal sensations, or abnormal autonomic nervous system function, the voluntary nervous system. The syndrome is generally thought of as an acute demyelinating disorder. That is to say, damage to the myelin sheath of the propeller nervous system cells. Next line.

GBS typically involves ascending we NIST from the toes or fingertips up toward the trunk with or without facial weakness and with or without respiratory failure. Most people fully recover from GBS, but some people can develop permanent disabilities or die from respiratory difficulties. It usually involves respiratory for paralysis of these muscles that are involved in breathing or from complications such as infection or sepsis, superimposed on the acute situation. Of the GBS itself. Next line here slide five, you will see there's a yellow vocabulary. This slide is meant to give you a better feel for the anatomic relationship. It can be really concrete about we are talking about in terms of the syndrome. [Captioners Transitioning]

Where the signal is propagated down to perhaps the next nerve cell. Around the axon there are schwann cells. Schwann cells are cells that create the myelin by wrapping themselves over and over around the long axonal of the nerve cell which is the length thing -- where the signal needs to get to. Looking at this is another picture of an axon coming off of a neuron body. You see these cells that are worked around sequentially. A couple of analogies used to think about this, is the picture on the upper right sort of reminds a few of us of toilet paper rolls wrapped around the dowel of which should be that yellow axon on the far right of the slide think about copper wiring and some insulation wrapped around that copper wire. So, the key concepts here is that the myelin sheath is a series of segments of layers of schwann cells wrapped over and over the accident all the way down ask him and there are separations in between each of the schwann cells, these are known as nodes of Ranvier those are key to explain why myelin is important I will explain that in the next slide so this picture describes another view of the myelin which is the myelin sheath being wrapped around that axon on the far right in the fact that there is separations known as nodes of Ramier and the nucleus of the schwann cells you can see a separate from the axon itself is physically separated from axon. A little view when you see it on a cross cut section what that tries to show is the middle section is the axon itself of the nerve cell right euros -- layers of myelin are wrapped around like a roll of toilet paper analogy I used earlier in the nucleus of the schwann cells is physically separate from the actual nerve axon itself sort of the beginning of the toilet paper, if it was a piece of tape or something you could pull on it. So hopefully I've gotten some clarity around the physical reality of the nerve cell structure

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This will help us with regards to functional analysis. So the function of the myelin which is really important here with regards to nodes is that the structure of the myelin itself helps to skip the electrical signal and there for propagated down the axon a lot faster. In other words neurons that have myelin actually get the signal down the axon faster then nerve cells that do not have myelin. That's true regardless of the size of the neuron itself. In some cases there is some small fibers that don't have myelin and they do the best they can but the fact of the matter is the long axons to control muscles in your legs for example, benefit from the existence of the myelin sheath which helped get that signal faster hence the picture of the kangaroo. To remind us that the signal is being skipped along in a faster way. You want to get the signal down to the next muscle.

So, to try to summarize all of this, the healthy nerve on the left you see a nerve cell in the background, it propagates the signal down the nerve essentially by skipping along as fast as we can with a healthy nerve cells. If the picture in the middle is a damaged nerve cell, you have scarred myelin which there for either does not propagate the signal as fast or does not propagated at all. So demyelination means damaged myelin, the best way of thinking about it

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Now GBS as a whole should be understood as having considered a single disorder by history but really a variety of syndromes whose major variants include an acute inflammatory demyelinating polyneuropathy known as a IDP Fisher Syndrome which historically has been known as Miller Fisher Syndrome because there are two doctors, -- not two doctors just Dr. Fisher going with two last name as his name really should be called Fisher Syndrome in my

opinion. And an acute motor axonal neuropathy and an acute motor and sensory axonal neuropathy. We can go into details about that later in the question-and-answer period, but the bottom line is we think of all of this in the demyelination in all of this included in the literature around how people think about GBS

With regards to the ACCV considerations today, what we would like to help you focus on specifically in the presentation is the key issues. That flu vaccine leakage to GBS could or should be added to the Vaccine Injury Table. What we are proposing, I am trying to do this in English rather than medical or legalese so that we can answer your question in English, if you have questions in Spanish I would be happy to do that as well. And changes are being proposed for policy reasons and we will reemphasize that a little later in the context of the current science status. I thought I would mention a quick factoid, that is to say that VICP to date has actually settled 90.1% of all the flu/GBS claims that have been adjudicated. It is actually a significant alignment already in practice which help us inform our commonsense policy recommendations here

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This slide has -- starts with multiple years this is meant to go to and give you the spectrum that essentially following the H1N1 influenza pandemic, the H1N1 antigen was included in the 2010/2,002,011-2000 pull trivalent vaccine so-called tea IV formulation and we wanted to let you know in fact they are included in the 2012-'13 and impact will be in the 2000 -- 2013-2014 version so that in one antigen version runs the gamut of 2010 through 2009 through 2014 and there for will be an ongoing consideration for the program as a whole.

Actually let me interrupt the 2009 seasonal vaccine did not contain this H1N1 it had an H1N1 but it was a different antigen. So the first year that the seasonal vaccine contained H1N1 is the 2010-2011 the pandemic H1N1

Right. In March, 2012, a presentation was made on behalf of the influenza working group to the ACCV and it discussed a number of IOM findings with regards where evidence was insufficient to accept or reject a causal relationship between the vaccination and the adverse event and there for the context being that it did not warrant a table change back then, I hope panel discussions, including GBSGBS.

Ultimately then, the ACCV in March of 2012 decided to defer on these issues regarding linkage to GBS and the TIV until former peer review and publications were completed and the results available to the public. The history there, a variety of studies include that GBS in the 2009 influenza monovalent vaccine have been published in three large government-sponsored studies published in May of 2012 after the March meeting of the ACCV showed compelling evidence for a rare and small increase in GBS. A new meta-analysis study was published in March of this year which focused on the Association of GBS in the 2009 influenza H1N1 monovalent vaccine showing a small increase of GBS which translates into about 1.6 ask -- 1.6 excess cases of GBS per million people vaccinated. Of note the 2009 monovalent vaccine is not covered by VICP, but it is covered by the countermeasures injury compensation program. Which is also part of this division.

HRQ which is a sister agency to HAR say known as the Agency for Healthcare Research and Quality, developed a new report for the assistant secretary for help that now has been published asking for public comment. That report is not yet final report basically reviewed routine recommended vaccinations, IOM studies and the science of GBS Association with our influenza vaccine leading essentially to an understanding there has not been enough power in the epidemiological studies done to date to resolve completely the science issues at this time

Consequently the current outcome is that we have an understanding of the strength of the evidence in Association is high between the 2009 H1N1 vaccine in GBS but that Post licensure studies report essentially an outcome of mixed results regarding that Association with regards to seasonal influenza vaccine. Including those that contain the H1N1 specific to GBS.

The policy recommendations there for that have been proposed today are for including GBS in the Vaccine Injury Table in the context of the scientific basis not yet been fully resolved. So, we are making this recommendation based on policy reasons as well as the current science in the sense of the status which exists up today. The summation is that DVI see is recommending that the ACCV support the proposed changes to the Vaccine Injury Table. Specifically, the green trivalent influenza vaccine has already the injuries in black, the anaphylaxis, shoulder injury, vasovagal syncope and the appropriate time period on the far right. We are proposing adding seasonal influenza vaccine and adding essentially a D to the injury list namely Guillain-Barre syndrome with the proposed period of three to 42 days

Let me jump in here again, AB&C are not currently on the table, but they were approved for us to move forward at that March, 2012 meeting of the commission so, they are currently in the new version of the table that needs to go through review in the department before it gets published in the Federal Register. So, what is in AB&C is also proposed but from the March, 2012 meeting.

Next slide. With regards to orienting a bit to the kind of deliberations the committee would be working with, the context is statutory authority exists for modifying the table and petitioning the secretary for those changes including petitions from the ACCV and the committee is asked to review the proposed changes because part of the mandate of the ACCV. This includes adding or removing injuries, conditions or time frames and or -- or adding or removing vaccines. One way of thinking about this kind of positions the committee has to think about here, the kind of choices you might pose for yourself namely option one the ACCV concurs with the proposed changes to the Vaccine Injury Table and would like to move forward with or without comments from the ACCV. That the ACCV option 2 does not concur with the proposed changes and would not like to move forward or option three, that the ACCV would like to differ a recommendation on the proposed changes to pending further review which would imply the next meeting perhaps of December 5 of this year.

We would like to remind you of some of the guiding principles that the ACCV has recommended obviously I was not hear back then but in 2006 the ACCV developed recommendations for its

analysis of our revisions in particular the notion that the table should be scientifically and medically credible and that leads into credible is scientifical medical evidence both the support you reject the proposal for change to the table that whenever possible should be done to the benefit of the petitioner next slide. Additional guidance includes the fact that what is to be considered scientifically and medically credible. Heart of it involves if there is an IOM study the conclusions of the IOM should be deemed credible but it does not necessarily mean it should limit the deliberations of the ACCV. For data sources other than the IOM, assessment of relative strength becomes important and also consistency. Consistency across multiple sources of evidence is itself an indication of credibility.

Hierarchical evidence becomes relevant to there are all sorts of ways of doing study all the way from randomized controlled clinical trials to non- peer review of locations many details in the middle but the point is DVI see is help to assess strength of evidence depending on what has been published out there etc. and we will be happy to do that.

Final guidelines include that the committee remained aware of considerations underlying the table that is to say awards to vaccine injury -- injured persons are hoped to be made quickly, easily and with certainty and generosity. Congress intended to compensate serious injuries caused by vaccines. The bottom line is if there is a split in credible scientific evidence, the members should tend towards adding or retaining a proposed injury in the table. The question before you is whether you concur with the proposed changes essentially choice number one whether you do not concur with the proposed changes try server two or whether you would like to differdiffer, choice number three. I would like to finish by essentially trading space for conversation of the whole by asking you what are the key insights on the presentation has generated for you as members or as a committee and specifically we have any questions for the staff at the VAC to help you address your considerations. Thank you for your time and your patience

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Thank you. Bots, comments, questions from the commissioners?

This is Ann I wondered if there's any history or president on anything on the Vaccine Injury Table being changed based on policy in the past as opposed to scientific data because it seems from what we heard from DOJ reports that folks with this GBS that do bring claims forwardforward, even though it is not a injury table, they are usually compensated fairly quickly so that system -- that part is working well. And I just want to start another precedent if it hasn't happened already, that the Vaccine Injury Table has been changed based on policy alone obviously this would save money for the government because they would not have to -- it would just be a Vaccine Injury Table if they could prove that the way it is supposed to be a goes rather quickly and doesn't require much time, as much time.

This is Vito, yes, there is precedent for this in one of the early IOM reports, the evidence for and supple awfully after DVT -- encephalopathy -- dictated that we remove encephalopathy from the table but as a policy decision and under the recommendation of the ACCV at the time we kept it in.

Thank you.

This is Kristen I was wondering -- there is reference to the AHRQ report that is now available for public comment. Would there be opportunity for the ACCV to hear a summary of their findings similar to the report we received regarding the IOM review? Because if there is additional evidence and data that was discussed, that may be helpful in our deliberations.

They will publish that, I think. But are you asking for them to come to the commission?

The IOM report was also published but it was just helpful to have a formal report for some of our meetings we can ask questions, etc..

We can certainly ask I don't know if those sorts of report were part of the contract that the ASA should -- a S H had with AHRQ but we will certainly look into it.

The second question that I have so the study reported, the large studies really focused specifically on monovalent pandemic H1N1 vaccine. Is there any thought that there is response to that vaccine would be any different than the seasonal influenza vaccines that may include H1N1 antigen since it is a new antigen at the time anything that would make us think differently about the study about monovalent vaccine versus the risk of GBS associated with seasonal vaccine? That contains H1N1 along with other circulating influenza strains?

This is Vito again the immune system is a finicky, funny creature and when you add different components, even though one of the components has been shown to do something if you modify it by adding other components the milieu of the vaccine is suddenly different and that may affect the way the immune system reacts to its. So there is a reason to think that even though the monovalent does it, the trivalent doesn't there is certainly reason to think because the monovalent does it the trivalent my also do it but that question hasn't quite been answered yet because the size of the study to find the one in a million increase is very, very large and we did those studies in 2009 because of the pandemic and the emergence of the situation and we found that risk. Incidentally that year the seasonal vaccine was studied by some of these groups that did these large studies and there was no increased risk with the seasonal vaccine in the 2009 influenza season at least not at the one in a million rarity. If there is a one in 10 million rarity the studies would not a picked it up.

But these were similarly powered or -- (multiple speakers) strong evidence.

Bernard Aboba vaccine safety data link -- for example the vaccine safety data link study looked at and found an association with pandemic and did not find an association with seasonal similarly powered. Yes.

This is Tom, CDC. I just -- building on what Vito was saying I also want to mention there was also much more intense level of surveillance during H1N1 and a specific focus on looking for GBS.

So, which is different than we had in the previous seasons so it is always possible that changes in the way we do surveillance may impact the results of our surveillance.

If King has a question so on slide 16 we talked about GBS and H1N1 -- Dave King -- in 2009, and that there were a variety of studies then it says there were three large government sponsored studies published in May, 2012 so, are those three large government-sponsored studies that were published in May of 2012, were they the studies that were done on the 2009 --?

This is Vito yes the 2009 H1N1 vaccine, those were the --

So the second bullet is actually referring to the first bullet? On that slide, is that correct?

Yes

Okay

And this is the enhanced surveillance that CDC sponsored and did for that special flu season.

This is Ed Krause, I have a comment. First of all thank you for the presentation, I thought it was very well done. Second of all, I think it's important that we not imply that there is a lack of scientific support for adding GBS to the table for the flu vaccine. There is different ways, as we know, from the IOM report to establish causation. Epidemiological studies are one way but they are also, as we've been told, of limited value when the reaction is where and we need to keep in mind, for example, the 90% of the cases that are settled by the Department of Justice involving flu vaccine and GBS. Those are cases where someone is healthy, has no issues or symptoms of GBS in any way shape or form, received the flu vaccine and then typically within 4, 5, 10 sometimes 14 days that's sort of the typical, at least in my experience, onset for the GBS. The symptoms come up and so you cannot discount that as the connect us -- mechanistic evidence connection between the flu vaccine and GBS. This is not of no value, there are a lot of individual cases where people are reporting GBS within a time period that would be consistent with an understanding that the GBS was triggered by some kind of autoimmune reaction. So, I just want to -- emphasize that epidemiological studies are of limited value when they show an association, that is certainly important and it is certainly something to pay immediate attention to however, when they don't necessarily show an increased likelihood of the condition, it doesn't mean that you stop and say well there is no scientific evidence or there is not enough scientific evidence so that is my comment and then I certainly don't want to cut off any discussion but, I would be of the opinion that we should, as a commission, we should not delay in voting to approve or voting to recommend that the secretary -- I'm sorry -- that we should vote for the ACCV to concur with the proposed changes to the axing injury table I don't think we should wait until December I appreciate the comment that I think and made about the fact that the system sort of works well now in the sense that 90% of the cases are settled and so do we really need to add it to the table. I can tell you from the perspective of an attorney who represents injured petitioners or injured people, that the difference -- there is a significant difference in being able to file a case that involves a table injury. And so, whereas there is

certainly the Department of justice has been very, I think, conscientious about moving to settlement quickly with flu GBS cases, it still involves significant delays beyond those which would exist with the table injury. With the table injury you can very quickly get into the issues of what the damages are for the individual. Again I don't want to cut off any further discussion, but I for one would be of the opinion that we should select option number one and concur with the proposed changeschanges.

Dave King here added, are you putting a motion on the floor?

I don't want to cut off debate so I will put a motion on the floor at this point.

Well, you can put a motion on the floor, Charlene could be seconded, correct? Then we can have a conversation around the motion did we?

Yes have an emotional the floor is what drives debate

That's right, okay. So, Ed?

I would move that we vote for the ACC to concur with the proposed changes to the Vaccine Injury Table and I don't know that we need to make a comment so I will just leave it at that without comments.

Does anyone second that motion?

I second, this is Michelle.

It is now seconded so now we can have a conversation and discussion around this motion to determine whether or not we want to move it up or down so any additional comments, questions? Concerns, issues, thoughts?

This is Tom and CDC. So, I'm not sure what type of language or justification goes with the proposal, the actual proposal to update the table. I'm not addressing the actual proposal, but I would like to comment on whatever language or supporting language goes with that and I guess I will go back to slide 1616. Where there is a statement in their showed compelling evidence and I don't -- I don't really know if -- I mean I think regional people can have differing opinions about how compelling the evidence is -- yes there were three large government studies that showed an increased risk, there also two more that did not show an increased risk and one of those three studies that did a secondary analysis had a nonsignificant increased risk. And actually the author of one of those VSD studies did another analysis, which I will present during my agency update which took antecedent infection into consideration in the risk went away. I know that HRQ has the language in their report about strength of the evidence of association is high, I also think that there is some differing opinion from really the strength of the evidence and how high it is. So, I think if there is language that goes in there up to the secretary with this proposal, I would propose using language something along the lines of the

data or the weight of the evidence supports an increased risk but I just urge caution to use words like compelling and strong and things -- because I think like it was presented on a later slide, I don't think the evidence is really that clear cut and that compelling. So, using a phrase like the weight of evidence supports it certainly would support a proposal but really what I think would be more consistent with what the data are showing

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Tom this is the now. This is why we are putting it in as a policy -- this is a Vito -- four strength of scientific reasons because the data is mixed and the word compelling was referring to just the 2009 H1N1 monovalent -- not the seasonal. So we would not use the word compelling in this rag for this program because the evidence isn't compelling for flu vaccine in general but just as you said, it does support an increased risk and getting back in line with the commissions sort of guidelines, we don't -- we want to put things on the table that are scientifically credible and this fits that criteria

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Understood.

This is Ann Pron. I guess my comment is, a question actually and comment -- this information has just been given to us today and not ahead of time to review or think about? In any way? And that is not usually the way things work or they have worked at least for almost the last three years usually we get the information ahead of time, it comes in a booklet or we get a chance to read it or are reminded that maybe we have a copy of something already that we should view. It just seems to me hard to make a decision when it is just right up front there. And then the second question I guess I have for Vito is, how is it presented as a policy? Policy reason for making the change to the table? Is there any way it is differentiated? Once it's on the table to the table correct?

Once it is on the table it is on the table there's nothing functionally that differentiates it from other table injuries. What we plan to do with this is to go ahead and put it in clearance. Accurately the ACCV needs to provide their input before it is published in the NPRM we could put this in Clarence and get the process started without the ACCV making a decision today. We also plan to present at the December meeting a more finished polished quality interpretation that would go along with this; we're not ready to do that at this meeting so there will be more information coming and of course the ACCV can modify whatever recommendations they make at any time.

Thank you for clarifying that.

This is Charlene, my handset was dying so I got cut off, I came back in. Tom mentioned that he had another presentation this afternoon so can I make a friendly amendment that we reconsider the question at the end of the meeting?

Charlene, this is Tom. That largely addresses the H1N1 vaccine, which as Vito pointed out this is about seasonal although we are kind of using H1N1 --

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It's in every seasonal?

As part of the evidence but that even though that does cover seasonal that is really about looking at that increased risk after H1N1 in controlling for antecedent infection.

Okay I guess what I am getting thrown off in -- again I missed some of the discussion, is that H1N1 is in all seasonal vaccines now but this consideration is just for that year?

No. The consideration is for all flu vaccines. So I guess that is what I thought. And you -- so okay your presentation though you referenced it in your comments, your presentation won't have any bearing on this decision?

That -- Dave King speaking Charlene I believe you're asking the question of Tom is that correct?

Yes

I -- Charlene this is Tom I can't really say that I am just saying that the main finding for that is -- addresses the increased risk for H1N1 vaccine, which is covered by a different program not VICP.

Okay.

Okay. Dave King has a question. Vito, it actually relates to you regarding you had talked about that you would be starting the process whether we decide anything or not or that you could be starting a process. Could you kind of out light than a little bit for us? Please?

I think it is in everyone's interest to move this along and so we would be able to start the clearance process and get further with that because it needs to be cleared through the department and then through OMB, which is essentially the whole executive branch so DoD would comment on it, the VA would comment on it, other agencies other than HHS. So, that clearance process takes a good deal of time. So, we would want to get started with that. Where we need the commissions input is prior to publication in the NPRM which would be after the clearance process so we could differ this decision to December, that would be fine, it it is a little better from our end if ACCV can provide their input now and then revise later if they need to because that way if people ask has the ACCV seen this, does it approved, it better to give them a yes answer than eight no answer

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Or that it is under deliberation?

On deliberations by a CVE -- ACCV?

Rather than save the question was has this been approved or considered by ACCV you would not have to say no you could say it is under deliberation.

That is what I mean, yes, you are right

However, the motion on the table is that we move forward with this now, but I don't want to bring it to a vote until we have the full vetting of the discussion and conversation around this and where we are at. So, I have another question

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Right before you ask let me make one other point clear, that this addition will be part of the larger table that the commission with the changes that the commission approved back in March of 2012 so this will be added to that large table so it will all be in one sort of complete package.

That would then move that entire package as a single unit quickly or as quickly as the rules allow?

It just makes sense to do it that way and there is another option I mean the ACCV could have a special meeting after they've had a chance to review so that is another optional vote I don't know that that is needed.

We don't have to wait until December? A meeting could be called in advance of that?

Yes.

This is in front again. I guess I just -- when we had the IOM information we have plenty of time to review it we got a copy of the draft report before was published and everything I guess I just feel very conflicted about the fact that this happened just today. So quickly. I'm not sure if anybody else in the group is feeling that as well?

Dave King here and, would you feel more comfortable if you actually have the report of one or some of these studies or information to you or the component I believe Kristin had talked about which is the comments or whatever that is being done?

That would be the HRQ study

Yes.

I think it would feel a little bit better. I have no problem with -- obviously our goal is to try to help people as much as possible I understand that because we have considered that in many of our other decisions because the IOM said there was not really enough evidence to accept or reject a causal relationship and it still seems to be conflicting results so far at least even what you just talked about now and the CDC Tom mentioned as well I guess it's just difficult.

Recognize the IOM did not consider the pandemic vaccines, they did not consider the 1976 vaccine that is associated with GBS and they did not consider the 2009 H1N1 monovalent vaccine so they look fully at seasonal and their conclusion was based on the data related to seasonal. The results are mixed as Tom pointed out in that VSD study when they looked at in

light of infection, that the effect from the vaccine disappeared but also the meta-analysis was able to control for infections when they control for infections the effect was still there. So the meta-analysis and the VSB analysis are in complex. Hence the results are mixed. And that is why HRQ concluded that because that is the correct way to see it that the evidence is next.

Dave King here so Vito, in March of 2012 we decided to differ on this linkage until there was a formal peer review and publication was completed and the results of the study publicly available that is on slide 15 so the -- it looks like April, May, two months later the three studies came out is that correct?

Yes.

Is that the only thing that is changed since we made the decision to wait?

In addition the meta-analysis of those three studies in some of the smaller studies came out which was consistent with the three studies and the HRQ report which looked at not just flu but many different vaccines and their conclusions related to flu. Those are the main changes that make it more scientifically credible and that we want to meet that criteria even though we are putting it on for policy reasons.

Right but we did not get a summary of the HRQ report did we?

It is not final yet should be published in final in the next few weeks like the nest couple of weeks it should come out relatively --

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It says it has been published, asking for public comment Dr. --

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It over to finalize once they incorporate the comments they are going to incorporate.

I think that we are -- I think I sense a hesitation on some of the commissioners and correct me if I'm wrong here, that even before the IOM was published we actually had access to review and look at comment might've been been made and things of that nature but in this particular case we may not yet have been afforded that opportunity? Is that -- is that a quick summary of what I am sensing?

This is Ann Pron I have been the one probably spoken to that the most. I guess I also want to say that if we delay until December I mean the flu season has not yet started yet so I don't know that it would really affect -- have a big affect in terms of helping more people being able to get concessions.

The flu season usually starts around October, November it sort of hits its peak in December and January.

Right.

But the season really is thought to start in October.

I understand that but I don't think in terms of -- I don't think people would be petitioning immediately the data got sick echoes they are sick and they have to somewhat resolved that to some extent or a family has to realize there is a problem there. I don't know we would be -- like you said you can start the process on your end and then we can jump on in December, it's not --

We didn't do it that way, that would be fine.

So Dave King again. Let's outline with this processes let's assume for the moment that even if we voted today yes for argument say say we voted yesterday to move this forward and we did not delay until December. What would be the timing though in terms of officially getting onto the table it could still take a year or more is that correct?

Yes

It certainly would not happen during this flu season I mean in all likelihood is that correct as well?

It came because there is a six-month comment period once it is published so no it won't happen during this flu season

So, let me ask a question on this, I do not know who should answer this so I am just going to throw it out there, see if there is any -- if people can help us in our deliberations here and understanding of this. That is if we were not to move forward today realizing that no matter what we do today whether we move forward or not is going to be at a minimum six-month nothing is going to be impacted -- from a legal point of view though does from the justice department point of view from the petitioners attorney's point of view if the ACCV moves forward today, does that in any way used as weight evidence or taken into consideration by Special Masters and the like? About is the question I toss out there.

This is Jason maybe the question is pending, I think I wanted to ask almost the same question in other words your first question is if ACCV does not vote in favor today but decides to wait until December maybe this is a question for Vince, does not delay impact in your view the overall timeframe for adding injury to the table or does the time line that is currently proposed, is unaffected if we waited until December?

This is Vito. It won't affect the timeline.

I'm in Vito, sorry, yes.

It will not. Okay.

Okay so that is a good clear answer to it. Then there is -- so Dave King speaking -- Jason you are correct there are really two questions in my one question so thank you another question then is does that though impact how either the Department of Justice and or the attorneys for the petitioners or the actual petitioners themselves present their cases whether it is delayed or not?

This is Vince Matanoski I am piggyback historically about other proposed changes to the table and where they were in the process and my recollection is that it really didn't impact practice under it in the court of federal claims much I can't recall a real impact obviously when the regulations become final and there is a table change then yes it would not in the interim I don't think -- this is speaking historically, I can't recall there being an impact per se. You can already see from the fact that a large number of the GBS flu cases are being settled that the impact from the standpoint of information out there, scientific information where the medical community is on this, hazards an impact on how cases are being resolved I think that probably has more of an impact than a proposed -- either proposed regulations are proposed legislation when those become law and obviously the court, the parties execute in accordance with the law.

Okay, thank you. So does anybody have any comments or anything?

This is Jason Smith maybe just one quick question is a summary of where we are and again more from a lay understanding of the data that is been presented and I think what I am gleaning from the discussion by the various HCP's represented on the phone that the IOM report that looked at the data, specifically at seasonal influenza and found that there was insufficient evidence to establish the causal relationship between the seasonal flu vaccine and GBS that there has been a great deal of work looking at the question with respect to to H1N1 pandemic flu vaccine and there is some studies that suggest an association, small but statistically significant increase other studies may be less clear of an association between the adverse event and the vaccine and for policy reasons looking at the pandemic data both maybe for and against that the recommendation from TBI see is to include that event on the table based on all the information we have thus far is that may be a good lay summary of where we are is that accurate more to him -- more to and point the data might help me in them couple of months but I want have a fundamental understanding about all of the different looks at the various flu vaccines?

Yes employees that is correct

Thanks, we now.

Dave King speaking. I don't like to bring a vote that isn't going to be -- I don't know that it may -- I don't know which way I can't read without looking at people in the eyes I am unable to tell the nuance of how I think this may go so.

This is Michelle would you like me to call a question?

I don't know that yet.

Okay.

You remember, Dave, that is the role of the chair to anticipate the vote will go the way you wanted and don't take until that time.

[laughter]

Exec sometimes that is in fact what happens. That is not what I'm really trying to do what I am trying to do is save face for the ACCV and I am wondering if the real vote -- I'm trying to find out if there is more of a consensus to move to put this on hold until December or special meeting in between but I think December we have learned from the timeframe would actually work in that in fact has no material impact on anything and if that being the case rather than vote something down I do think from a parliamentary point of view one can withdraw a motion or table it and another motion can be put on the table people vote on that instead is that correct, Charlene?

That is certainly correct that the person who put the motion there has to withdraw it.

Exactly that is what I thought so I am speaking aloud to my thinking because I don't know where things are going and it is not so much I am anticipating the vote but I think that when it shows we vote 820920 things like that it may in fact carry more weight then divided and split votes and I certainly would not want us to be in a position where we voted something down when in fact the only reason we voted it down was because we were asking for a delay I would rather see the motion withdrawn and the other motion put on to review to determine the question at the December meeting but I cannot withdraw the motion only Ed can withdraw the motion and I don't know whether Ed you want -- Michelle you seconded the motion so is Michelle allowed to call the question when she seconded the motion?

This is Ed RFI could make a comment.

We want you to.

Than I have a,.

Great

My comment is I am often being accused of two consulatory and however that is my impulse and I certainly don't want to period on necessary -- create unnecessary risk on the commission I want to restate my position here with the information we have been provided I can see no other responsibility action than for us to ultimately improve and recommend that this be added to the Vaccine Injury Table. I understand the frustration over not having had enough time and

advanced notice I would certainly be open to adding to my motion that we commented we wish we had had additional time to review the information instead of having just been provided with it the day of. I firmly believe that appropriate thing for us to do is to add GBS to the Vaccine Injury Table and we should do it as soon as we can. I think -- and I am -- sorry if I'm repeating myself, this -- it is almost sort of a slavish devotion to the epidemiological studies is I don't believe appropriate you are I think we are failing to understand that there are numerous situations where individuals are getting GBS within an appropriate time period for it to have been caused by the flu vaccine there our many situations where treating doctors all agree an expert medical experts looking at a particular situation all agree that the flu vaccine caused GBS that doesn't necessarily mean it should be added to the table, okay? But it's too not take that into consideration and not understand that the Department of Justice 90% of the time is settling these cases, I am just -- I don't think that -- I think that is a very significant consideration. I think also, and again I am not a medical person but I do represent clients injured by vaccines I have had more than one client to had GBS but would not have been picked up in either of those studies because they did not have a diagnosis of GBS until they came to me and said I believe the flu vaccine caused this neurological problems but I don't have a Dr. Who is running the tests, willing to establish that so I have been involved in helping the individual ultimately get diagnosed or proper medical attention to unearth the GBS diagnosis. What I am saying is I think the studies I am sure are well-designed but I have a hard time believing they capture everybody who in fact has suffered GBS certainly the milder forms of GBS were the ones more likely to have not been picked up the studies are not -- again I have not read them I am sure they are well designed to doesn't change what our purpose is as a commission our purpose is to look up of the people who may be injured by vaccines people who develop GBS following a flu vaccine within three to 42 days for which there is no other obvious explanation should be provided compensation is it possible some of those individuals got GBS not caused by the flu vaccine yes it is possible Congress has said compensate those people anyway because we don't want to miss out on efficiently and expeditiously compensating those people who have been injured by the vaccines. Also I would point out again I don't mean to ramble but my understanding is GBS can also be caused by the flu. If you are looking at people who have received the flu vaccine those people who don't end up getting the flu presumably the flu vaccine has some efficacy so some people are going to get the flu and there for are going to get GBS if you look at people who get GBS, adjust aggregate numbers it could be there is not an increased risk because some of the people who don't get GBS don't get it because the flu vaccine protected them. That doesn't change the fact that the people who did get GBS as a result of the vaccine to be compensated so out is my position I am willing to recall -- withdraw my motion with the understanding that the timeframe will not be affected getting this added to the table but honestly I see no advantage to waiting until December and no set of circumstances under which we would not want to approve this change I will withdraw my motion.

Okay.

This is Michelle my question if it is with drunken we still talk about it?

Good question. Ed, we did not actually anticipate you would go into withdraw it when you said you were willing to withdraw --

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(multiple speakers).

This is at I am withdrawn you but that doesn't mean there can be further discussion. On this topic.

My question is this is Michelle my question is is there any information -- more information we are going to get between now and December?

This is Vito the AHRQ study will be finalized again we are doing this for policy reasons not for scientific reasons so with the study says or downside of must in the future we get overwhelming evidence is not the vaccine which is very unlikely this case -- because you can't prove a negative I don't see anything of significance you will see in terms of studies. In December we will have the interpretation which is an important piece to this and we will present that to you at that time.

I would like to put --

Of course once we have in it in a clean up form we will send it ahead of time before the meetingmeeting

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Okay I would like to put the motion back of the table

Okay. So --

I will second, this is Ed.

[laughter] very good. I will ask the question does anyone have any additional comments, questions or concerns before we put it to if someone calls it for a vote? I will call if I have to.

Not everybody's, did --

Right. Does anybody wish to, to is not yet or does anyone who has already commented want to make an additional comment or consideration for us to have prior to us calling for a vote?

This is Kristen Feemster. Echoing Ann's while I understand this is not necessarily our assessment of the available evidence at least this is the first time I feel like we have made a policy decision so I agree I understand our responsibility is ensuring we support vaccines those that are injured are appropriately and expeditiously compensated but I also want to make sure we are doing this responsibly so would help me at least to what the language is going to be especially since we are making this decision on evidence that supports either side I heard what you said Ed a couple of times the epidemiology isn't helping us ever epidemiology does help to make sure we

understand risk. GBS may be a triple to vaccinations also juvenile to other things I think these studies help us understand where the risk lies. I don't think we want to discount that either it really helps us understand the information we have in front of us. It is hard for me to make the decision right now looking at the information for the first time. I understand we want to do this expeditiously but I personally would like to see how we would prevent this -- present this, we are basing this up on evidence that goes either way outside of the studies that were presented about the monovalent H1N1 vaccine. This is applied to the seasonal vaccine not just the monovalent H one -- H1N1 vaccine not exactly the same one so I want us to make sure we are fulfilling our mission of course I want to make sure we do this responsibly because our goal also is to uphold vaccine safety but to maintain confidence in vaccines so I think that is making sure we support vaccine safety advocacy and doing this based upon that information that we are thoughtful about it. That is all.

Any other comments, questions?

This is Ed I would just respond to that as I don't mean to imply that people who don't want to prove it today are acting responsibly -- irresponsibly attended a little caught up in my rhetoric that I think your points are well made, well taken I also did not mean to imply there was a valiant epidemiological studies I just think the value has to be put into context of what our purposes ACCV in formulating recommendations for the improvement of the program.

Okay. Anyone else?

There is more than one one motion on the floor at the same time correct?

There is one though an amendment can be made to a motion

This is Michelle do you want to make an amendment?

I want to amend that we -- I want to delay the vote is what I really would like to do and I'm not sure that I can do that then?

You can't that would be a subsequent -- I don't think [indiscernible] can do that while we have this motion on the table.

Can I ask, this is Jason Smith, who made the motion and what is the motion that is currently pending?

So Ed made the motion, he withdrew -- second about Michelle, and withdrew the motion and Michelle Rhee made it I am okay with the two of you and Ed seconded it kind of explaining to everybody what specifically that motion is which I do believe is, maybe all we phrases everybody has it that we move forward with the proposed change to the Vaccine Injury Table so we concur and say let's add this to the table. That is essentially what we are saying

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This is Vito, to marriages whispered something in my which is important this commission approved the rotavirus change in the reg that just is currently in public comment and when we wrote that reg, came to the commission providing for both vaccines on the table was also a policy call. Because the evidence in the United States was not there but subsequently the evidence is there so it is no longer really a policy because evidence for more likely or not causation has been published. So to say this commission has never done anything on a policy I think is not correct.

Thank you. So my question goes back devices singly capture the motion, Michelle and at that you both -- Michelle and Ed -- that you both one of the table.

This is Ed you did I also suggested perhaps that we have -- make a comment the comment is that we wish that we had been provided with more lead time to consider this issue but we certainly concur with the proposed changes. It doesn't have to be part of it I would leave that to Michelle

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And I propose the friendly amendment then to the current motion? That Michelle had and that we revisit this issue if there is evidence between now and December? That would change? This decision?

This is Vito I think you can revisit this at any time. You don't need to limit yourself between now and December if something happens in March and you wish to revisit that is within your prerogative.

Okay.

We can revisit -- Dave King speaking -- we can revisit any issue we so choose and read look at any decision we have made if we choose as a group to do that. Is that correct, Vito, what you're saying?

Yes

Okay. And, Ann is that satisfy what you are thinking?

Yes I guess the time I'm as would point in our do the same whether we approve it today or in December or the same thing if we approved it today I'd of course if we did not put in December that would -- I don't know if that would affect the timeline or not? I don't think so doesn't some like it would

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It's very unlikely to affect the timeline the only issue is someone may balk in the clearance if the ACCV in fermata is not on it but I doubt that would happen because we would be able to explain the situation.

Okay.

Okay. I do think we probably had enough conversation on this so I would ask one more time does anyone have a comment, question, concern? Anything? I have given a pause either no response, nobody jump in and so we will call this question to a vote. I guess I will just call is out everybody's name now and we will -- tell me yes or no I am going to use the ACCV members list and I'm going to go in reverse order of how the list is. On our sheets. So Ed? Yes or no.

Yes.

Charlene? Yes or no?

No.

I did not hear that? That did not come across yes or no?

No.

Kristen?

No.

Michelle? Yes or no.

Yes

Lucy deck?

Yes.

Jason? Yes or no.

Yes.

Ann? Yes or no.

No.

So we have -- eight of us here as tear I am going to go yes, -- chair -- without my vote yes still carried 2- 3 so -- 4- 3 so 5- 3.

.you only vote in a tight?

Yes I guess technically the miss will now my sentiment [laughter] the motion carries.

This is Ed. Is there a way to note that those who voted against it if this is a correct reading those who voted against it that they voted against it because they felt they had not had enough time to consider the proposal?

The comment -- this is Michelle -- the resolution was identical to yours so it does say that we did not have enough time but I don't have any problems with the comment you are suggesting we have but I would defer to the people who voted no.

(multiple speakers).

You were lost we could not really hear what you said?

I agree with the comment you made Michelle I agree or Ed made, rather.

So do I, this is Charlie

Yes, as do I, this is Kristen.

So I think we should make Dave King speaking we should make note of that fact that no votes were based primarily on the fact that not enough time before the vote was called in terms of what they wanted in terms of information and the like I think that is a fair thing to put in there .

This is Vito. I apologize for the lack of time but I did that intentionally and I wanted to move this as quickly as I could and knew I sort of have the backup position that this could be deferred to December but I wanted to make this all part of one package and doing it this way works best for us.

So Dave King speaking, Vito, in the future should something like this occur is there a way, we would certainly want this to happen, that the information be disseminated to the commissioners both about what it is we are going to do and evidence to either for or against it, maybe both, be provided in advance of the meeting and certainly we would want to go more than just a day in advance if we could. We want to give them time to disseminate, go through and look at and think about it?

We we'll a note of that for major decisions like this that we would get it out as quickly as we could

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When you are thinking you are going to bring it and try to get it on the agenda, since that probably occurs a good month in advance, it would make sense to get the information out them?

Right.

Okay. Then I think it is according to the agenda it is time for us to break to lunch folks.

You think?

No doubt in my mind [laughter]

When do you want us to come back?

Normally we do a one-hour we certainly extended ourselves to almost 12:50, not quite. It's 1:30 to quickly to come back for folks?

That is good.

That is fine

Why do we do a 1:30 return from lunch.

Great.

Thank you.

Thank you.

We will all dial back in?

[Captioners Transitioning]

[The ACCV teleconference is on lunch break and will return at 1:30 ET. Captioner on standby.] ave King speaking. We are resuming after lunch and the first item on the afternoon agenda is the report from the process work group. Luisita dela Rosa, you are the chair. We will take your report, please.

This is Luisita dela Rosa. I will now read my report, which was hastily written in the middle of the night there are misspellings and error's and grammar. You just have to bear with me. The process workgroup managed to have just one meeting this past quarter. We have scheduled meetings for July and August, due to circumstances beyond our control they were not held. No comma time could be scheduled after each cancellation to have the teleconference for the month. During our meeting yesterday, September 4, we reviewed what we have accomplished since the inception of the process work rope in June 2012. We have been able to put together three recommendations to the Secretary that affirmed the previous commissions recommendations. The full commission approved all three. The first was the recommendation to the secretary to consider a vaccine injured adult or his or her representative as a member of the commission representing the general public. This recommendation was already submitted to the Secretary prior to our June 2013 meeting. The two other that the recommendation to extend the statute of limitations and the recommendations to increase the cap for pain and

suffering. Both of these recommendations will be presented to the Secretary, I believe after this meeting. Between this meeting and December. Mr.King reminded us that recommendations are to be submitted individually to the secretary, so that each one would get the full attention it deserves. Dr. Caserta promised that he would keep the process workgroup updated as to the progress of this recommendation submitted to the secretary. We also discussed the direction we need to take for our future meetings and we decided we would proceed as we have originally intended, that is to continue to examine the remaining 2009 recommendations. We also expressed some grievance about the virtual nature of the meetings. Doctor Concerta and Tamara Overby, explained the current Federal government travel policy to us. The hour was up in the meeting was adjourned. That's my report.

Thank you, Luisita. Does anyone have any questions, comments, or anything further for Luisita?

Luisita, I think that already this morning we have added something to the agenda for the process workgroup to consider. I know that under new business we were going to talk a little bit about the virtual nature of the meetings. That might also get referred back to the process workgroup, I s uspect, although we may want to air a few comments about it. Are you okay? Can the process workgroup handle that as an issue?

I believe we could figure out a way to recommend anything that we feel would help the commission, because as long it's, -- as is part of the Ysidro stuff that affects our ability -- procedural stuff that affects our ability to work as commissioners.

Okay. Good. Should we talk about -- so, Luisita, I am asking you, but Vito, I am also asking you whether we should be having any conversation around the travel policy as it relates to us not getting there? Or, do you want us to hold that off to business at the end of the day?

I am fine with that, as well, to be honest with you.

It's up to you, David. It doesn't matter to me.

I think of that is more is an internal issue as it relates to the commissioners, themselves. I'm thinking that we should move o n, because of the over time during the lunch hour and it will help us get more back on a schedule. We have folks, I'm sure, what taken time out of their is the days and have commitments that allow us to be able to hear from them before any of them has to leave or anything like that. If no one has objection to that, I would like to move in that direction. Luisita, are you good with that?

I am good with that.

Great. Thank you so much for your report. The next item on the agenda would be the report from the maternal immunization workgroup. Kristen, if you could give us your report.

Yes, I can. I am just starting now. The maternal immunization working group has not formally met since the last ACCV meeting. But, we did, as you can see here, draft at formal and final report of our recommendations, based on the feedback we received at the last ACCV meeting and the final wording of the recommendations that we voted upon. The report was distributed to everybody this morning. I won't read through them. They've been in the minutes. I think everyone is familiar with the recommendations that we agreed upon as a commission. As Vito referred to earlier today, both myself and Anna Jacobs did have an opportunity to go to the June meeting to present our recommendations. I do have just a little bit of feedback from that. The report was well received. The group especially appreciated our presentation of the legal framework for our consideration of recommendations. Also, or discussion of the pros and cons of each approach that we suggested and, is tanning suggesting a range of approaches that the secretary may take to expand the coverage to include maternal immunization in the compensation program.

One specific point that was presented by some of the members of NVAC, because we were talking about expanding coverage of vaccines that are not currently recommended for routine administration to children, and whether or not we should, as a commission, also consider adult immunization, in general. And, consider other vaccines such as those that fall into this category recommended for adults that are not rich in the for children.

I said that I would bring this back to the ACCV and see whether or not this is something that perhaps the process working group would consider taking up or whether we would want to consider, as a commission, forming another working group related to adult i mmunization, in general. The vaccine program continues to evolve. So, that really concludes my reports. Our recommendations have been included in formal recommendations to be presented to the secretary and we look forward to updates regarding the [Indiscernible] of those recommendations. Again, I really think the working group for their input and insight, and the ACCV, in putting together these recommendations.

Great. Thank you. All the workgroup chairs really have done an outstanding job. Does anyone have any questions for Wriston? Comments, -- Kristin? Comments, suggestions?

This is a mammoth report. This is Ann Pron. This is amazing. Very nicely done.

Thank you very much. There was a lot of input from the office of General Counsel, especially with all of the -- the description of litigation strategies, statutory potential, statutory approaches. This really was a group effort.

This is Michelle. I would like to commend both Luisita and Kristin for their tremendous leadership. I know it's already been said. I want to second it. I've been on meetings -- both meetings -- both workgroup m eetings. It's really been an outstanding effort.

The chair obviously concurs. Kristin, Dave King here. I've a question. So, you had talked about the other item that you may possibly it would need to coalesce, either as the condition as a

whole or assigned to a workgroup. Can you make sure we are all in sync and didn't pass by that there?

As we discussed the specific recommendations, particularly the charge regarding expanding coverage to include -- a group of pregnant women that would not be recommended for routine administration to children, and whether or not we would consider expanding coverage for all -- any vaccine -- adult vaccination in general. Any vaccine that would be recommended for routine it in a straight into individuals other than children. I think this came up a little bit in the wording of our recommendations when we presented them in June. I think that our initial wording was a little more general and to expand coverage to vaccines that were not really keenly recommended for children. We voted on some changes to make sure that we were specific about vaccines recommended for pregnant women. Because there are vaccines in the program better recommended for for routine administration, that are for adults, the suggestion was made that we may consider making recommendations to the secretary to expand the vaccine injury compensation program to include adult immunization, as well. Also, it's a reflection of high proportion of claims to the program that come from adults. I know this is primarily from vaccines that are covered, but that was the suggestion that was made by NVAC.

Okay. Yes. I know that -- so, we cover vaccines that are administered to children, but that doesn't exclude that they only go to children. They can, in fact, be given to adults as well, which is where the injuries come up your what you are suggesting is that we focus in on something that might just be recommended for adults and not necessarily for children, is that correct? Act correct. If we are considering expanding external immunization, that group would be recommended for pregnant women and not recommended for children. We also want to can that are the addition of other adults vaccines not recommended for routine administration and children. Vito, you were also there. You can, perhaps, concur or provide any input.

I certainly concur. We had discussed that issue and we decided not to go there, in order to make the recommendation more narrow and, therefore, more likely to succeed.

Yes.

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that now we're talking about setting up, possibly, a separate workgroup or undertaking it as a commission as a whole or something like that, to address this other issue. What I'm trying to understand, is that going to go beyond the scope? Or, is it something that we, in fact, can embrace?

I think you can embrace it. I'm looking at Andrea and I think she is shaking her head yes.

Even though it would be -- even though we are focused on the vaccines given to children, even though adults can also receive those vaccines, what we are also suggesting is that we possibly take a focus on vaccines that are given to adults exclusively, and not to children, except, I guess to some degree, in the case of a woman was pregnant, are we, in fact, giving a depending on

how many weeks she is, that maybe impact their, right? I'm looking for guidance as to whether or not we are going further out than we should be, because it's not within our domain of play.

This is certainly different than talking about maternal i mmunization.

Yes.

So, commissioners, we can hear from you, as well. What's your thinking around this? At we are looking for guidance. I know that we are thinking that, yeah, we probably can. Is it really something that's going to end up causing -- we will spend a lot of time and -- you guys are not allowed to talk about that, it's not really part of your charter?

This is Ann Pron. I do think it's worth looking into. See what the cost would be. Certainly that would mean there would be tax on all those adult communications, which is add to the fund as well as payment paid out. Right now, we have a large number of adults, probably the largest vaccine -- distribution is flu vaccine. Certainly, as we know, that's where we are getting a lot of claims from adult. Adults injured, flu vaccine. That happens to be one of the childhood immunization schedule. It does seem -- that, and certainly the pregnant woman receiving vaccines does seem to mean that we are already including adults and some vaccines. I guess the total numbers of other vaccines given to adult would then need to be figured out.

Well, this is Vito. Of course, where talking about routine administration for adults. So, the vaccines that could be in that category that we currently don't cover are the shingles vaccine and the polysaccharide pneumococcal vaccine. So, I think we cover everything else. We do cover the high dose Marisela -- I'm sorry -- influenza? Even though that's not routinely recommended for children, they the excise tax cut passed, it included it. So, it is covered. But, my point being, the only two vaccines that I know of would be the polysaccharide pneumococcal and the shingles vaccine.

They would not be part of our discussion.

Those are the ones that we are talking about, of we wanted to go to adults. That currently would be added. We cover everything else.

Do those two vaccines -- they are not given to children, those vaccines?

No.

So, does NVAC cover them?

NVAC covers all vaccines and they are sort of under their umbrella, in terms of their discussions. Yes.

They cover all and we cover children?

Routine children.

To my all, pneumococcal vaccine can be administered to children, but not part of the routine schedule.

Right.

Okay. So, go ahead. Somebody is going to say something?

That's all right.

No, I'm okay.

I recognize this would require statutory change. Congress would have to act to expand the program to adults.

Is there a way to calculate the burden of what that would mean for the program?

I guess the short answer is yes.

Wouldn't that be done -- excuse me, this is Michelle Williams. Wouldn't that be done as part of what they would have to do for Congress?

Yes. There will be a cost burden estimate, as part of that.

Right. I guess that comes out of the Congressional budget office of the OMB or somebody, right?

I'm not sure. Camero, would you know?

It right even be our office.

Ultimately, it's OMB.

[Indiscernible-low volume]

Certainly from DOJ.

So, is this something we should move to new business if we want to start this up? Or, how does the commission want to proceed with this?

This is Ed. I think we should move it to new business. Whether or not we want to proceed with recommendations along the lines of covering the couple of vaccines that are currently recommended for adults, but not routinely given to children.

Okay. I'm good with that.

Okay. Having said that, Tristan, thank you so very much, if no one has any other questions for you.

No problem. You're welcome. Thank you.

Next item on the agenda are vaccine information statements. Skip Wolfe?

Suzanne Johnson is with me. She is beginning to work on VIS with us.

Welcome, Suzanne.

Thank you.

You all have the very brief Word document that I sent out just a few days ago that starts with problems that could happen after any v accine?

I believe we do.

I wanted to start with that work the issue might come up while we are talking about flew VIS. I thought we might as well talk about that first.

Can you bring that up on the screen?

It's problems that can happen after any vaccine. Brief fainting spells connection, shoulder pain, --

Maybe. We will see how good I become at this. I don't know.

We are so confident in your ability.

[Laughter] Let's see.

Is Amber watching you do this?

Yes, she is. I think I did it.

You see our faith?

Exactly. We knew we could.

Annie, you are simply the best.

Perfect.

Skip, it is in front of us all, now.

The genesis for this was, I think it was a March meeting when the issue from the IOM report about deltoid bursitis came up. We already had a statement about sync of the. It occurred to me when I was working on another VIS that these three things are not vaccine specific. The fainting spells and the severe shoulder pain or deltoid bursitis can happen after any injectable vaccine, apparently. Anaphylaxis can happen after every vaccine. It occurred to me that for each vaccine we should have a subsection under the risks that would this these three things and with the heading similar to this saying they can happen after any vaccine. I wanted to get the commissions open union on that and also comments on language.

Dave Kings bee sting. I'm just trying to -- I know that at our last meeting, you and Tom will work on wording. Is this bad wording?

I asked Tom about it and Beth who works for Tom. . The wording is my own. We had discussed it a little bit. I believe that the last meeting or the March meeting when this came u p, the idea was to use the term shoulder pain and stead of deltoid bursitis, because it's more of a colloquial term that people would understand.

Agreed.

Skip, this is Tom. I would maybe take severe out of i t. That is subjective. Severe allergic reaction, that's a medical thing. I would just say shoulder pain and temporary loss of motion.

Okay.

This is Ann Pron. I like the fact that you have the fainting spells can happen after any medical procedure, because that sort of levels it out a little bit. Any shot is really -- even if you're getting it from an antibiotic or something. The only thing that's a little bit confusing is, if you field do the or have vision changes or ringing in your ears, tell your doctor. It doesn't seem to put that in the timeframe. I I guess that just could be rethought, how you might want to were that. If you start to feel dizzy or have vision changes.

While you are still in the doctor levels?

I guess that's what it means, right?

Yeah, okay.

Skip, this is Tom. What if you just said, like after that first sentence, brief fainting spells can happen after any medical procedure, including vaccination. These are often preceded by dizziness, vision changes and ringing in the ears.

Yeah. I like that.

Sounds good.

Okay. Good. But that next and then have sitting or lying down the last sentence?

Yeah.

Okay.

Great. Sounds good.

Okay. In theory, we are in favor of including this section? If we have more minor changes to the wording, we can work on that later. If we are in favor of this, in theory, I will start rooting it into all the injectable vaccine V IS. Of course, anaphylaxis will stay in all of them.

Skip, this is Vito. The second bullet, are you proposing that it reflects b ursitis? Or are you proposing that it reflects the sore arms that are common after vaccination and is appear after 48 hours?

This would be bursitis. Is very different timescale we should add to this, you you think?

Well, the word temporary, then, may not be fully accurate. Some cases of bursitis become chronic.

Would taking out the word temporary make it sound too dire? Maybe not. I don't know if we should add more language to say temporary or possibly permanent.

This is Tom. Skip, I am actually seeing another problem with this. It kind of depends on how people interpret using and. What if you say something like, persistent shoulder pain and loss of range of motion in the arm. Instead of shoulder pain and. People may interpret that as, of course I've got shoulder pain. If you say persistent shoulder pain and loss of range of motion, it implies that it him thing different than a typical injection site reaction, unless people feel otherwise.

Okay. That's fine with me.

I agree with Vito. Is can become -- the loss of range of motion can become permanent. You never achieve -- you may never fully achieved what you had before.

Yeah. I don't remember from the IOM report, how common in the -- is this?

I don't know how common it is. I don't think it's uncommon, t hough.

Okay.

I think, Dave King speaking, I think some of it occurs because the spot where people inject or how they inject. If people are at the same level or sitting down when they're giving it rather than someone coming in from the top of the shoulder. If I'm not mistaken, that can really impact whether the like the hood of this or the possibility of it is good or not.

That was part of the discussion that I had with Tom and Beth, whether it was actually a vaccine injection error problem. Apparently, we are not sure about that.

It usually is. But, the bursa can come down low in some people, unusually low and even if you injected correctly, you can still hit it.

Okay. It's kind of irrelevant as far as the statement goes, but we will make those changes. Jennifer just joined us by the way.

Welcome, Jennifer.

Okay. Unless anybody has more comments on that, we can move on to the EBIS, themselves. We just referred -- review these in March. The reason for doing it again so soon, and the ones that you have their, the ones that are currently published for this season. The reasons we are viewing them so soon, there are still using them, but we've reached a point where, partly because we've taken out some of the specific stuff that might change often, and because I think the recommendations have solidified enough that we may be able to finally get a flu VIS's that we can use for more than one season. That's what I'm hoping for. The reason you are reviewing and again is because we are trying to take as interim and make it final.

These include a lot of the changes that we talked about back in March.

Skip, Dave King. What you are also saying is what we just looked that you are trying to put on here as well, correct?

Yes. Not this season, but for the final one.

Correct. Let's look at the end of act dated one first and you can give me any comments you have I let what you see.

Section one, why get vaccinated? It has not changed a whole lot from the one you saw before. A couple of the changes that you suggested have been implemented here.

I think people are reading it, skip.

Okay.

It's not really significantly different from last time.

This is Ed. In section two, the statement that studies have shown that the Marisol in vaccines is not harmful. -- the Marisol in vaccines is not harmful. It might be more accurate to say that studies -- to the extent -- to make the point that you are trying to make, studies have not shown thimerosol to be harmful, rather than showing them to be not h armful. It's a new ones.

I appreciate the subtlety.

Incidentally, one question I have. You think we ought to keep the paragraph about the high dose flu vaccine? After we put that in, every time I look at that, I think it looks out of place. Since the VIS is going to be given to people who are already there getting the vaccine, I just wonder if that's even useful to have that paragraph in there about the high dose. It's something to think about.

Well, perhaps it doesn't belong in that spot. If you wanted it, maybe it's under the why get vaccinated component. That might be where you put it. I don't know, I do not know whether you need it or not, either.

Skip, this is Tom. Given that it's so relatively new and somewhat unknown, I am okay keeping it. I'm okay with it there. I don't think it does any harm or or causes any confusion. If somebody were to get this and read it before they got a vaccine, maybe they might ask the provider if they have this.

That was the rationale when that first came out that somebody over 65 might not know about it.

We are only in the fourth season and the uptake hasn't been superhigh. It may be of some value to have it there, and I don't think it hurts.

I was worried it might be getting close to an endorsement. It's not really. It's just telling people that it exists. Packets no more of an endorsement that's what's in the racks, anyway.

Skip, this is Jason Smith. Just purely editorial comment on that point. Just for suggestion only. The high dose. Up, perhaps if you moved it after the explanation of inactivated and then attenuated, what you are also saying, there's another vaccine out there for adults 65 and older, ask your healthcare provider. Just maybe more in context than hanging out at the end.

That's a good thought.

This is Jason Smith. I think it's a very well-written, easily understood, nicely organized list.

Thank you very much. We had to lobby hard with our flu experts. With some of the new vaccines that are out, the recombinant vaccine and the cell culture vaccine, there was even talk of having separate VISs for them. We had to argue, from a patient's point of view, basically, a shot is a shot and they are not going to split hairs whether it's recombinant or inactivated or cell culture. If any of you were thinking along those same lines, that was our rationale for not doing that. From the patient's point of view, it a flu shot, regardless of any of the nuances that mean a lot to epidemiologist's.

Skip, this is Vito. The first paragraph in the second column on the first page where it says flu vaccine is recommended every year children's months should get to the -- to those of the first year they were vaccinated. I think you need to say the first year they get vaccinated with flu.

Good idea. Thank you.

I don't remember the latest recommendations, but at the child this age got of -- got one flu vaccine but didn't get the second, the subsequent year they still need two, right?

It depends. There is a fairly complicated algorithm.

Right. You are not covering that, either, with that paragraph.

We are not. But, the accompanying guidelines for providers that will be posted along with the VIS has that algorithm and that information. The provider, the one who has to know that, will have that information. The patient will only get it if they ask about art or if the provider decides to tell them about it.

I agree it's not necessary to put it there. You don't even put that they get a half dose under three. Under three years of age, the dose is different. It's so complicated, the algorithm and changes from year to year and might eventually go away.

The discussion you had about adding GBS after flu vaccine to the injury table, how did that go?

[Laughter]

Never mind, forget I brought it up. [Laughter]

It went well. I think -- the reason I brought it up, is the statement we have here under section four, the last bullet at the bottom of the first column there, I think it probably covers us regardless of what you decided here.

I think it's perfect.

Okay. Good.

Anything else on the i nactivated? Or are you still reading through i t?

Skip, this is Tom. What's on the barcode?

All that is, is because the law requires people to record the addition date and the name of the VIS in the patient's record. All that barcode was is allow them to skin that information instead of entering it by hand.

I got it.

One thing, an idea Jennifer came up with, eventually, it might be nice to be able to allow patients to have enough information in a bar code that would allow patients to scan it with their smartphone and it would bring up more detailed information, if they wanted, which sounds like a pretty neat idea.

That is far down the road, probably. The limited amount of information we have so far, said just that providers aren't using the barcode that much to do that, at this point. It's there if they need to.

Given how ubiquitous the use of those codes are, I don't have a smartphone line, slides open and slides closed. But, that should not be really difficult to do.

I wouldn't think so.

Everybody does it. You can slide something off a bus and get information on the next sale.

I think that is really an exciting, potential use for those.

[Indiscernible-low volume]

Yeah. And the average kid can probably do it themselves. The average 4-year-old can p robably.

[Laughter]

Are we looking at -- should be moved to the live version? Or are we on it, already.

If we are ready to. The second one, second one is exactly the same. Sections five, six, and seven are exactly the same. Two, three, and four are different in the live.

This is Kristen. On section test, the statement that gives the Ainge range to be given -- would it be better to move that up just a little bit? Maybe after flu vaccine is recommended every year? Maybe after that statement? Or, as a description of the v accine?

Okay. Let's see.

After the paragraph where it talks about children through age eight, put it under their you mean?

Yes.

Okay.

Do we know what the different vaccine options are that are recommended? This one is for a certain age g roup.

Okay.

That's pretty important, just move it up a little bit.

Okay.

Skip, this is Vito. Under number two, the second paragraph, new paragraph just one line, the last sentence, the virus in the vaccine has been weakened so they can't make you sick.

Yeah.

I don't think you can say that.

I didn't like it either. I think our flu people told us to do that. I will be happy to pass along that you agree with me, that we should soften that'd open.

The vaccine causes sinusitis and upper respiratory. It can make you sick.

Yeah.

A more accurate thing, it can't -- well, it can't make you very sick with the flu or something like that.

Theoretically, it could give you a mild case of flu.

It could give you a mild case of flu, right. I think that is overstated.

I think the way we had it in the last VIS was doesn't. At that time, and maybe even now, there's no evidence that it does. Which is a little milder than c an't.

Even though it still could be misinterpreted, I suppose.

Right. Many people would consider a sinus infection being sick.

Yeah.

We should confine it to giving you influenza, I guess.

Even that, I'm not sure you can say.

No, I don't think we should say can't. I think we should replace make you sick with give you flu, or something like that and then replace can't with something a little softer.

Or you could just leave it with the definition of [Indiscernible-low volume]

Could you all hear that?

[Indiscernible-low volume]

The virus in the vaccine has been weakened, period. Does that say too to little, do you think?

I think it might not say quite enough. Probably one of the biggest errors to sensibility is the concern that the vaccine does give you influenza infection. I'm sure you saying -- I'm sure you're saying that the exposure would give you the immune response. But I guess it depends on how that's going to be interpreted. That's a little bit different than having a severe influenza infection or even a moderate infection. So, I'm guessing that the idea that we are trying to submit is it's not causing -- it's not supposed to be causing acute influenza infection.

I guess that's the point we want to get across. You are right. That's one of the main objections we hear of flu vaccine. Everyone thinks it give them flu. I will try to work on the wording to make it more accurate.

This is Luisita. I'm wondering whether you should say it's weakened enough -- weakened so that it can stimulate the immune response, but to help you get protected.

That's what it does.

Yeah. That still doesn't get to the idea that it's not likely to cause flu.

But if you say it doesn't cause flu, but what's the sense of getting the vaccine if you are not -- basically, the vaccine is to stimulate your immune response so you are ready to fight the real f lu.

Yes.

Which is all around you.

Skip, this is Tom. You need to find a simple way to say it's cold adapted for upper airways but one cause severe lung disease. [Laughter]

That's not being helpful. [Laughter]

I use the term nasopharynx, too? [Laughter]

Skip, the inactivated flu vaccine, obviously, people don't get sick from that. It's not a live virus. So, you don't have to say anything there. But, maybe you shouldn't -- I mean, if it can make you sick, why don't you say something may experience mild symptoms or something like that. If in fact it can make someone s ick, just say -- put a statement in along with what Luisita has s aid, which is, it is your immune system at work.

Okay. That's work on that.

[Indiscernible-low volume]

This is Ed. I have a suggestion. It's a bit of a new ones. How about, the virus and the vaccine has been weakened so they won't make you sick.

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that still doesn't seem to work very well. There is a reason why the vaccine program is in existence, it does make very small percentage, very, very sick.

That works. You are saying that's the reason it was weakened, as opposed to the fact that it doesn't make you sick.

Correct. I'm not saying it can't, I'm saying the reason it's weakened, is so that it won't.

That's a thought, too.

It's certainly still possible, as is pointed out elsewhere in the VIS. Some people will get sick. The reason it's weakened is so you won't get sick.

Okay. These are all --

Very, very sick.

This is Ann Pron. And section four, you say that could be severe problems and you just have severe allergic reaction. Is that the only severe problem? You are telling them to look for behavior changes the number five.

That's standard wording on all VISs.

Behavior change? Gosh, I never knew that before.

They added it a few years ago. I can't remember if it was because it came out of the ACCV meeting are not. It hasn't been there for that many years.

Okay.

I think that severe behavior changes not necessarily what we think of as behavior change. The play that the child is -- looks not the same. They look a little odd to us.

I think we left it intentionally vague to error on the side of caution.

I guess, and part four, where we say it does not cause flu, we need to change that. The second paragraph under section four, where we say in bold letters does not cause flu, we need to either take that owner make a similar change, like we did under section two.

I have a question. How can a virus, if it is in a strong, healthy state, that causes flu, will not cause flu when it is in its weakened state, it's still the same identity. Just Verlyn's of a virus we are looking at. If they show signs -- mild s ymptoms, it would still be flu symptoms, wouldn't they? Except they are very mild. You can even ignore them.

Yeah. I guess without getting into all adapted and heat sensitive, it's hard to explain that in a simple way.

This is Tom. I think, like a clinical diagnosis of flu, I will defer if there's clinicians on the call, would be you'd have to meet certain criteria like fever, cough, whatever. Having runny nose and a low-grade fever would not necessarily -- that wouldn't be a clinical diagnosis of flu. But, I mean, I know we are splitting hairs. But, I think that's where that's going. I agree, if you say will not make you sick, it's probably a better way to put that. He cause, you are getting a subclinical infection in upper airways. With an attenuated virus.

Right.

So, instead of will, tom, do you think should and should not make you sick?

Or, won't. How about won't give you the flu?

The vaccine has been weakened so that you will not get the flu.

I'm okay with that one. I'm okay with that.

Is it true you won't get the flu from it?

If you are talking about the clinical case definition in the lower respiratory tract infection, that is true, because that is the difference in having virus replicating your upper airways. Technically, that would be true. The definition of influenza.

This is Michelle. It seems like we're talking about two different things. You will not get the flu from the vaccination, you will not get the flu because you took the vaccination.

The point we want to make, is that getting the vaccination will not give you the flu.

You are not going to get a clinical case of the flu.

I would say getting the vaccination will not give you the flu.

Would getting the vaccination protect you from blue, it's basically the reason for vaccines. Protect is probably better than would not give you, if you are --

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It's two different things.

If you say the weakened virus will not give you the flu, I think that's accurate.

Okay.

Good.

All right. We've got enough suggestions to work with. We will try to put something together that will solve that problem in the next edition. Back okay.

Okay.

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skip, anything else?

I think we say thank you.

Suzanne and Jennifer, as well, right?

It's been a pleasure, as always. We should have more to review for you next time.

Great.

You have given is that in vacation thank you very much.

Thank you all.

We should reflect that Cheryl had to leave at 2:27.

So, the next item on the agenda is the update on the immunization safety office centers for disease control and prevention vaccine activities, Dr. Tom Shimabukuro. [Captioners Transitioning]

I am working on my own PowerPoint,.

It is loaded on our system I can see it on my screen

Moving to slide 2 I will cover the June 2013 advisory committee on immunization practices meeting summary indications updates and go over presentations the -- there were a lot of sessions with safety presentations, a lot of material presented, I am going to cover this at a high level if people are interested in accessing the actual presentations they are available at that website and other sites will provide the exact link and if you are interested in watching the actual meeting you can click on the Live Meeting and I discovered they are actually available on YouTube too. You can actually view the entire meeting and sessions either there or on YouTube.

Moving to slide 4, I will cover selected sessions where there was safety data presented and I will start with human papilloma virus vaccines session. And the main presentation their of interest was the Merck pregnancy registry for Roger Valent HPV vaccine exposure during pregnancy from June 1, 2006 through May 312012 presented by Merck. The main points for this presentation were that part is still is not recommended -- Gardasil is not recommended for use during pregnancy however inadvertent exposures may occur through error or it ministration to an individual who did not know they were pregnant at the time. So the pregnancy registry was part of regulatory commitments with FDA and other international regulatory agencies. It included data from over six years of surveillance which we are were sharing with respect to the safety after pregnancy exposures and the rates of spontaneous abortions, fetal death and overall congenital anomalies compared favorably the background rates. Moving onto slide five, the HPV session continued so this presentation (multiple speakers) -- this is Ed curious the way you expressed the inadvertent exposure. Is there another -- other than a person being given the vaccine, HPV vaccine who was not aware that they were pregnant at the time is there another way that someone would have an invert exposure to HPV or is it the only way?

It could be an error, that --

What is the other kind of error that could result in somebody -- a pregnant woman getting HPV vaccine?

I guess there is three things that come to mind. Number one it was known the person was pregnant and they got the vaccine in error number two they got the vaccine and later found out that at that time they were or were likely pregnant so they did not know at the time and of the third is there is the possibility that a provider could use it off label, but it is not approved or recommended in that case

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Okay, thank you.

I am on slide five now. So this data was presented because the Merck pregnancy registry for Gardasil is scheduled to be discontinued and the rationale is the registry fulfill the regulatory obligation of five years it is the largest vaccine progressed -- pregnancy registry the date of the data indicated no clustering of malformations, no identified patterns of birth defects and overall rates of spontaneous abortions, fetal death and congenital anomalies were at or below background rates and the continuation of the sick registry will not significantly increase power to detect adverse pregnancy outcomes that goes back to the second bullet, the largest partners -- pregnancy registry to date. Moving onto slide six the rotavirus vaccine update on intussusception and actually Vito briefly touched on this when he said the data on rotavirus vaccine and intussusception subsequently came out this was the sessions -- session where this data was presented -- presented NUC the three presentations which were given during this session one was rotavirus vaccine and intussusception in the vaccine safety data link then monitoring of intussusception after rotavirus vaccine, United States vaccine adverse reporting system 2006 through 2012 risk of intussusception after rotavirus vaccination results of a prism study that is in FDA surveillance system moving onto slide seven the continuation and there is intussusception and rotavirus vaccines in Australia, so the Australians came and presented at the 80 -- at the ACIP meeting during the session and finally, there was a summary of intussusception risk and rotavirus vaccination in the United States. Those links go directly to the individual presentations presentations so the take-home message from all of these presentations together was that a small access risk for intussusception was detect the following RV5 which is RotaTeq and RV1 which is ROTARIX impose partnering surveillance CDC continues to recommend all US infants following age of precautions/contraindication criteria, receive rotavirus vaccine and the benefits of RV5 and RV1 outweigh the small risk of intussusception.

Moving onto slide eight, there is a safety update at the influenza session and the presentation there was and of season update 2012-2013 influenza fixing -- influenza vaccine safety monitoring the take-home points during this presentation were that no new safety concerns were detected for and activated or live attenuated influenza vaccine during the 2012-13 influenza season. A review of pregnancy reports in VAERS for the 2012-13 influenza season identified no unusual patterns and not safety signals or elevated risk was observed for febrile seizures in young children following in activated influenza vaccine for the 2012-2013 season in the communications update I will touch -- elaborate on that last bullet there. Moving onto slide nine

Is a couple communications update with links if you are interested in accessing those the first is titled seasonal flu update summary of 2013-2014 influenza vaccine information. That is a general at date on flu vaccine for the upcoming season and some plans for monitoring and that is on the VAERS website. The next update was febrile seizures in children following vaccination with influenza vaccines, 2012-2013 influenza season available on the CDC website. This updates old information that was previously on the CDC website so as you remember in 2010-2011, CDC and FDA detected a safety signal for febrile seizures following influenza vaccines and further investigation in the BSD indicated there was increased risk for febrile seizures in young children following influenza vaccines and this risk was increased when influenza vaccines Word ministered with pneumococcal conjugate 13 -- vaccine. A risk was observed the following season 2011-2012 so essentially we had -- we observed similar findings the following season compared to the initial season we had the signal and last season, we did not observe any signals or increased risk in our monitoring. This update just runs through that information. We don't know exactly why that is although we do know that there was a change in the formulation of influenza vaccine this past season compared to the previous two.

Moving onto slide 10, just a general seasonal influenza update available at the CDC website, that is not a safety related update, then there was a press release and a press briefing conducted by the CDC director, on HPV vaccine and that just covered the safety and effectiveness of HPV vaccine and talked about the low coverage rates that we are currently experiencing in the US and some potential reasons why. Moving onto slide 11 I will just go over some selected publications the first one is by Dodd at all international collaboration to assess the risk of Guillain-Barre syndrome following influenza A H1N1 2009 monovalent vaccine. And the findings for this study were the international collaboration to evaluate serious outcomes using a common protocol it is feasible he used pull data from multiple countries and Europe and they found that they detected in increased risk of GBS following H1N1 influenza vaccine and the significance and consistency of the findings support a conclusion of an Association between H1N1 vaccination and GBS. And they finish up by saying that given the rarity of the event the relative incidence found is not provide evidence in contradiction to international recommendations for continue to use of influenza vaccines.

The next study, carb on the at all in activated -- adverse obstetric events, in this large cohort influenza vaccination during pregnancy was not associated with increased risk for medically attended adverse of the trick events that really adds to the body of literature that influenza vaccination is not harmful in pregnancy. Moving onto slide 12 Iqbal et al. number of antigens in early childhood vaccines and nervous at -- neuropsychological outcomes at age seven-10 years this is a reanalysis of an existing vaccine safe to dating think -- data link which was initially used to look at the relationship between thimerosal and neuropsychological outcomes this with the number of antigens or immunologically active components and the finding was no adverse associations between antigens received through vaccines in the first two years of life and neuropsychological outcomes of later childhood. The next study is a pretty significant study, Greene et al, grant -- Guillain-Barre influenza vaccination and antecedent respiratory and gastrointestinal infections a case in an analysis in the vaccine patent -- vaccine safety data link

2009-2011. This is the same author and really the same group that did the VSD study on risk of GBS after H1N1 vaccination they went back and looked at some additional data and what we know is a respiratory infection and gastrointestinal infections are known risk factors for GBS. They went in and attempted to adjust for antecedent infection or infection with a respiratory illness or G.I. infection and looked at how that impacted the risk after vaccination and after adjusting for antecedent infections is not evidence of an elevated GBS risk following 2009-2010 MIB H1N1 vaccination pandemic H1N1 vaccine and 2010-to those 11 TIV influenza vaccines

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So, there was an increased risk detected for GBS following H1N1 vaccine and the vaccine safety data link when these investigators were back and adjusted for and antecedent respiratory or G.I. infection that increased risk went away and they did not observe one for 2000-to those 11 seasonal influenza vaccines. And moving onto slide 13 McCarthy fertility rates and up patterns in vaccinated population this is the VSD study the authors concluded VSD mortality rates demonstrate a healthy vaccination effect with rates lowest in the days meeting the following vaccination most appear in older age groups translated this means that individuals who receive vaccines actually have lower mortality rates than those that don't this is sort of a well known phenomenon healthy vaccine affect people who get vaccinate -- vaccinated is hypothesized they may be more healthy and there for less likely to experience outcomes like death. So the VSD mortality rate is lower than that in the general US population causes of death are similar so really vaccination does not increase risk for death and certain risk period that they looked at and the final is that CDC MMWR human papilloma virus vaccination coverage in adolescent girls 2007 through 2012 Post licensure vaccine safety monitoring 2006-2013, United States. In the communications update the press release and the press conference that was really in response to -- nonresponse -- accompanied the release of this MMWR so similar message really despite the availability of safe and effective vaccines and ample opportunities for vaccine delivery in the healthcare setting, HPV vaccination coverage among adolescent girls felt increased from 2011 through 2012

-- failed to increase -- so that is all I have, I will be happy to answer questions.

Tom that was a lot of information to throw at us, Dave King here, that was good. Does anybody have any thoughts, questions?

This is Ed. I just wondered what it he inconvenient or a problem to provide us with links or copies of the articles that you cite? In your report, Tom?

Yes, I can do that.

I guess I will send those to --

Yes that is what I would do.

Thank you

Really, it should go to amber

So, we have your presentation? And he sent it out already? And those links are in fact live I'm just opening a --

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I think he was talking about -- Ed was talking about the actual selected publications.

Okay

I can work on getting those papers although Ed, and anyone else on the call, if you go into PubMed and cut-and-paste you will get the abstract of the paper and in some cases you can actually access if they've been publicly posted you can access the actual paper but I will try -- but not all of the full papers I don't think --

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Thanks, Tom I realize that that is why I don't want to make extra work for you now you can get the abstracts and sometimes though it is more difficult to get the actual articles or the full text of the article. I just wondered if -- I don't want to make extra work but if it is easy to include, just as a routine matter, links or copies to the safety reports that you provided, just would be of interest to me

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It is not that much travel, Ed

Thanks, Tom.

This is indeed oh, one thing we used to do in the past was as we were doing our work and saw literature that got published, we would include that in the commission book. Would've the commission find it helpful for us to continue that? I think we stopped just to save trees and a previous commission wasn't particularly helpful but with the question Ed had of getting the actual papers is that something we could do as a routine as we sort of monitor the literature.

Vito, we include some articles in the workbook, so just depends on what we find or if something comes up that is interesting, I will let Amber now.

What I am talking about is I haven't actively send articles to you or -- when I see them and read them. I think it would probably be wise to do that if the commission wants us to chop down more trees

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We love trees being chopped down, Vito.

Okay, I see that.

It actually we don't really love them being chopped down but managed forestry actually is not a bad thing. But aside from that why not send them to us electronically? And then those who

choose to print can and those that want to read on the screen or reader or something, a tablet will be able to

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I generally could do that, yes. Not every paper is available electronically or is fully available electronically but I can do that, yes

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Okay

(multiple speakers).

What I can do is get the mailing list of the Commissioner whenever I see something or read something of interest I will send it. Does that work?

Sounds great.

Sounds great.

It does. I think it does. Will okay --

This is Tom I have to check out and about 10 minutes but Dr. Dr. Pedro Moro will be coming out when I get off.

You mentioned that had happened is any have any comments or questions for Tom or suggestion? Tom? Sounds like no thank you so very much for the report you gave there

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My pleasure

Okay. We will do the update on the Institute of allergy and infectious diseases, the National Institutes of Health vaccine activities and I believe it is -- (multiple speakers).

Actually Barbar Mulach, Claire is off today for the George holiday. Hello?

You know we probably should've thought about how this is scheduled, at one point therethere.

We were kicking ourselves up the side of the head figuring out how this happened so now it's slipped past us.

We neglected to look at a calendar but anyway it happened, happened, we are here

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I hope that's okay I am very pleased to be with you this afternoon.

Arbor we are delighted to have you with us please proceed.

Thank you so much. So I just have a couple of updates for you I am happy to answer questions and I also have links for a couple of them if you like I can follow up with an e-mail with links with additional information should you be interested. First and foremost I want to let everyone know we are continuing to work with other federal agencies trying to advance age seven and nine influenza vaccine so in the coming months will be looking to do some clinical trials as well industry and other agencies trying to determine if it is needed what we would be able to do to be able to predict -- protect people in the event H7N9 becomes a problem we can provide updates of those become available but you might be seen some of those in the public in the coming months as well.

May I interrupt? This is Vito. The H7N9 is not covered by this program, by the vaccine injury compensation program that is a pandemic vaccine for a pandemic virus if it becomes pandemic because that would be the concern but it would be covered even clinical trials would be covered under challenge -- countermeasures injury compensation program thanks.

Okay. The next item I wanted to let you know that recently a Phase I clinical trial was conducted at the NAI the clinical center studying an investigational malaria vaccine it was very early Phase I study but it was quite interesting that in a small subset of patients that they were able to produce protection against a malaria strain so there is still some complications to those studies but the vaccine is known as PFSPZ and the company we are working with is Sonaria there is positive initial data we are hoping that will be a stepping stone toward actually moving towards a better way of protecting people against malaria. Look forward to additional studies of that in the coming months

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Thirdly, I want to let you know about it vaccine that NIH and Barta have been supporting for a while it is a smallpox vaccine called Invonex, the company is the very a Nordic. We've been supporting a lots of efforts as you may remember early smallpox vaccines before smallpox was eradicated there were some side effects and concerns about that so the newer vaccines are meant to be safer for people particularly with weakened immune systems such as atopic dermatitis, HIV and other things. On August 7, 2013, the European commission granted marketing authorization for this vaccine Invonex and it was approved for active immunization against smallpox disease for the general adult population including people with weakened immune systems. So these studies have been going on for a while and this vaccine is also currently in that US strategic national stockpile for emergency use and immunocompetent -- immunocompromised individuals I wanted to provide if you updates with regards to genomics it interesting stuff in the news lately I thought you guys might be interested in. Some of you may be in familiar -- familiar with the story of Henrietta lacks and in March the genome for the cell line was published and posted on a public database the concern with that was that having this information in the public domain could've revealed unwanted information about family members for Henrietta and so NIH worked with the family of Henrietta in order to come to an agreement about how the information can be used for cell lines for people doing research that could also protect the families concerned so this is something is going to come up increasingly as our ability to do this kind of research and understand full genome ethical issues associated with it and I think NIH felt really compelled to be compelled and responsible that to make sure

we are protecting family members as well as research to advance all the science conducted with this very important HeLa cell line so there isn't any age directors blog and also a nature comment and I can send you links to those of you are interested in reading more. And related to that actually NIH announced a new program where we are going to support information gathering to see if secrecy of newborn genomes can provide useful information beyond what is currently understood period newborn screening programs. Is is a pilot as part of the pilot three new awards have been made and basically through these awards, genome sequencing and analysis will be conduct did but also research related to patient care and thirdly looking at the ethical, legal and social implications of using genomic information in the newborn period

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So it's really about understanding as we go forward the implications to better understand the help of those newborns but also to protect patients as we are gathering this information I think in the coming years it will be very interesting to see how this plays out everybody talks about personalized medicine and genomic sequencing but realizing the ethical issues that are associated with this. The three awards were three awards for me to Brigham and Women's Hospital in Boston, children's Mercy Hospital in Kansas City Missouri and University of California San Francisco. Again we can provide updates as new data comes from these new awards. Lastly I want to let everyone know the NIH partnered with the Smithsonian Institute to come up with a state of the art exhibition about genome science. This is called genome unlocking life's code opened Friday June 14 at the national Museum of national history -- natural history -- the celebrate the tenth anniversary of the human genome projects completion as well as the 60th anniversary of the Watson and crick discovery of the double helical structure. So this will be available through the Museum of Natural History through September 2014 and it will travel throughout North America for about five years after that. It sounds like it is really exciting, meant to be interactive and look at a futuristic environment and think about the revolutionary nature of genomics. I think this will be an interesting exhibit hopefully it will get Prost played throughout North America so people throughout the country can see the latest and greatest in genome science. That is my update I am happy to provide answers to questions.

Anybody have any questions for Barbara? Okay do we need links?Is that something you can provide, Barbara?

I would be happy to provide the links you said to Amber?

Yes Amber can forward them to the commissioners

Certainly, we will do that

Great thank you very much for your time.

Any time

Next on the list, update on the center for Biologics evaluation and research FDA vaccine activities Lieutenant Valerie Marshall

Hi.

How are you? Welcome.

Thank you. I have a brief update on some FDA approvals for vaccines. In June, 2013 FDA approved supplements for the 20132014 United States formulation of the following influenza vaccines [indiscernible]. On June 72,013 FDA approved a Quattro failing influenza vaccine which is manufactured by Sanofi for use in persons six months of age and older. On August 1, 2013 FDA approved a supplement to expand the age indication of [indiscernible] conjugate vaccine to children two months through 20 months -- 23 months of age. This vaccine was previously indicated for children 2-10 years of age for adolescents and adults 11-55 years of age. On August 16, 2013 FDA approved a supplement to expand the age indication of trivalent influenza virus vaccine which is manufactured by GSK the children three years to 73 years of age the vaccine was previously indicated for adults 18 years of age and older. On August 16, 2013 FDA approved a supplement to the Biologics license application for [indiscernible] to approve a Quattro failing to influenza virus or regulation for persons three years of age or older. This concludes my report I will be happy to provide links as people are interested in those.

Why don't we just provide those links and that way we have them. Is that okay?

Absolutely

Great. Does anyone have any questions or Valerie? Comments? Then we will move right along. Valerie, thank you so much

Thank you.

The next item is the update from the national vaccine program office Dr. Steve Bende

Hi everybody thank you. I just wanted to let you know just give you a minute here to tell you about the meeting coming up next week, next Tuesday and Wednesday. It is a very special NVAC meeting it is the 25th anniversary so it will be a historical overview given reports from previous chairs and previous NVPO office directors and it is so special that deputy HHS secretary Bill Corr will be attending addressing the group as well. Just to highlight some of the things on the agenda, some of these things will resonate with some other things we been talking about here today. First of all there will be a review of helping people 2020 goals and one of the issues that continues to occupy the assistant secretary and NVPO are that of adult immunization. Adult immunization lags behind, as you all know, there is a task force that we have been running from our office that -- to bring together external entities as well as government agencies to see about ways to intervene at the provider level, patient level and others to come up with mechanisms to improve adult immunization rates.

Another session will focus on the Affordable Care Act or ACA. That will have a lot to do with improving adult rates, among other things of course, but the ACA through the marketplace plans and other plans must cover preventative services without charging patients co-pays or core insurance and this is true even if patients haven't met a yearly the dockable -- coinsurance -- this is being looked at as something that is very much improved to knockdown the economic barriers that influence especially adult immunization. Further another issue that is going to be addressed at the meeting is that of immunization registries. There is a big push for that and recommendations will be presented by the adult task force and I will just read them real quickly to you. With regards to providers all providers will be asked to incorporate into routine clinical care assessment of their adult patients immunization status and recommend needed vaccines to the patient and caregiver. For non- immunizing providers primary care providers will be strongly urged stock and provide all recommended vaccines and providers facilities who are unable to provide certain immunizations will be asked to assess whether their patients are up to date on recommended vaccinations and strongly recommend those vaccines and refer patients to providers who can administer them

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Providers who immunize, all providers who have a role with the primary source of health care for patients will be asked to stop all recommended vaccines for adults, standards for all providers who immunize adults include ensuring professional competencies, knowledge of vaccine recommendations, means assessment, administration, storage, handling, documentation and communicating information about vaccines to the patient's medical home. Professional healthcare related organizations are going to be asked to support the overall immunization improvement activities through multiple channels including supporting education of their members providing of course to facilitate immunizations developing methods to assess and measure coverage rates etc. and public health departments are going to be asked to provide services that adhere to the public health devotionals and ask them to him here to standards of the profession and the public health also has an additional role in assessing immunization program needs an impact of vaccination programs broadly.

Very big push in adult in innovation and again you heard this for me in the last couple of times giving updates on what's going on at NVPO but adult immunization continues to take up a lot of our effort. Seen that this is the beginning of the flu season there is going to be a session on flu. We have already heard multiple times in today's session about the importance of communicating among other things the various options for vaccines and there'll be a discussion about communication plans from CDC so I will go into that too much because a lot of those issues we touched on today. There's going to be a session on viral hepatitis in action plan has been released focusing on healthy people to those -- Healthy People 2020 goals. As you know hepatitis a and B are preventable by vaccines if there's not a vaccine for hepatitis C but the new 2020 goals for viral hepatitis from the new action plan are going to increase from 33 to 66% the force of folks that are aware they are HPV status increase from 45 to 66% the proportion of those aware of their hepatitis C virus infection status and reduce new HCV infections by 25% 1180 mother to child have the tightest be virus transmission.

We heard from the maternal working group today for ACCV and as was mentioned there has been a nice linkage with the NVAC maternal working group they are going to be giving an update -- on their deliberations and plans and there will also be an update in that session from the CDC on T gap coverage which as you know is recommended for maternal of administration. Another Healthy People 2020 goal has been human papilloma virus vaccine coverage and as was reported earlier that coverage is lagging in HP 2020 goals are movement towards those has stalled so there is a working group for HPV and they are going to be discussing how to improve those. Lastly there is going to be a session on the global working group about to prevent their recommendations to NVAC for a vote and I will say one more thing the report Vito was mentioning with regard to seasonal flu and Guillain-Barre the AHRQ study the NVPO commission a study to HOK we expect that there is a final version of that upper, now is a draft as we go said it is going to be massaged further with -- based on peer and public comments we are accepting not a hard to get there probably sometime in early to mid-October when we expect the final version of that to land. If anybody has any questions I would be happy to take them that is what I would have for today

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Thank you does anybody have any questions for Steve? It would appear you are off the hook. Well done, thank you. Next item on the agenda is the public comment Julie we will need to open the lines for anyone who has a public comment to make their is an advisory commission on childhood vaccines

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Thank you at this time of the would like to make a comment please press star one, one moment please.

I wanted thank you for the meeting today and say I wondered if ACCV has proper legal jurisdiction over adult vaccine since you are set up by the 1986 childhood immunization act I would request that you look into whether you can take on the adult immunization oversight and in addition I want to raise concerns for pregnant mothers and the procedures that you would use given a vaccine injury of a pregnant mother and the impact of that on the unborn child. I am sure there would be many procedures that you would need to work out for vaccine injury. And how to even diagnose that and have some concerns over thimerosal continuing to be the flu shots administered to pregnant mothers in particular and if you read the study very carefully, there are indications progress of autism uptick from that study. In your vaccine information sheets it is an accurate to say that there is a body of scientific peer review literature that shows thimerosal in vaccines -- it is harmful and eight use the state on the VIS that studies have shown that thimerosal in vaccines is not harmful but that is on the influenza vaccine information sheet for the inactivated flu vaccine and there are over 600 studies that show that there are problems with thimerosal and the Mercury in the thimerosal can affect portions of our population. So, I would request you take another look at your VIS on that particular sheet. And, to be safest, pregnant mothers should be informed that there are risks for having thimerosal in their shots and the recommended that they get the shots without thimerosal. A couple of her comments today -- other comments -- in the Merck of being responsible for the pregnancy vaccination registry, it just seems like a conflict of interest from the public perspective concern that you are asking the industry to self regulate and there is no

accountability who will take over those registries with regards to the Gardasil shots. Last I am very, very pleased that you voted for including GPS on the table of injuries. I think that is a huge move forward. I think you can be very innovative now and get some antidotes going in our culture of vaccines in this country and have some clinical inroads that will be very, very important for those showing up in emergency departments having these types of reactions so congratulations I am concerned that three people voted no from your commission number one that they did not seek out to be responsible for signing -- finding out ahead of the meeting what was going to be going on in today's meeting and number two that they would not align with the 1986 childhood immunization act which airs on the side of policy that says we shall look out for vaccine injured children so I am really pleased that pass today and thank you from the public.

Mr. King this is Pedro Moro from the immunization safety office I just wanted to let you know that [indiscernible] had to leave I am taking his place right now

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Thank you very much I appreciate that. We will have the minutes show that occurred. Thank you. Any other public comments?

Your next, comes from [indiscernible]

Thank you. My name is Teresa rang them I am the executive director of the national vaccine information Center the mission of which is to reduce vaccine injury and death through public education and to defend the informed consent ethic in vaccination practices. Appreciate the opportunity to make a comment today. First I would like to think the commissioners DTIC and the DOJ for the thoughtful discussion on PBS being added to the vaccine injury table I believe the comments made by Mr. Krause in terms of the limitations of epidemiology and the settlements made by the VICP for GBS for in support -- for influenza vaccine are key concepts that support the addition to the table I think it's reassuring to note know of directions to this edition should be read into the no both passed by commissioners in these no both are more a commentary on the lack of time given to review the additional request. Thank you for keeping generosity and compassion central to these discussions

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My other comments today focus on the need for a higher degree of transparency in reporting the activities of the federal vaccine injury compensation program. Recent additions to the data and adjudications reports of vaccines distributed against a number of petitions for compensation tells an incomplete story. This report does not include the number of vaccine reactions reported to Ann for the same time for me -- the majority of vaccine reactions go unreported -- reported two VAERS -- in addition there's no mention of the likelihood of the lack of public awareness regarding the VICP impacts the number of claims submitted for compensation. Now, it was only a few years ago that the ACCV authorized outreach -- an outreach project to raise public and it -- public awareness. The absence of this contextual information appears to undercut the seriousness of vaccine injury and death which is the relevant focus of the VICP and the commission this report would benefit from the inclusion of this information as well as information regarding published and unpublished awards. We would ask the commission to consider these reporting additions. Additionally, MDIC again encourages

the inclusion and/or combining of existing reports that would meaningfully communicate award amounts made for each vaccine with alleged injuries and outcomes by year. This information is communicated to the ACCV during the regular course of the meeting, we have various slides presented by the department of justice and the division of vaccine injury compensation. All of which is done without violating individual privacy. In short this information, to a very great extent, is already public but requires one step through ACCV meeting documents. The public should not have to sift through and compile their own reports to understand the nature of compensation made by the VICP. With regard to the vaccine information statements MDIC notes the law provides VIS revisions must be done in collaboration with parent organizations. The March ACCV minutes do not reflect the discussion or the fact that MDIC was specifically mentioned in this context and assisted to request and these revisions we request the record be corrected in this regard. As the commission reviews revisions we encourage the commission to recommend inclusion of information on the statute of limitations an effort to decrease the number of claims dismissed for exceeding statute limitations. For each VIS under review we would also encourage the inclusion of language regarding deficits and research on the asking risks as they apply to many of the most commonly reported reactions as noted by the IOM. Information on whether or not the vaccine is covered by the PIC should also be more explicit in each VIS. Current revisions under consideration appear to claim -- contain a blanket statement that certain vaccines are eligible for compensation. As many on the phone are remember the day vaccines can cause injuries that financially ruined families as consumers consider vaccination they must know in advance when they must bear the financial burden of low -- alone. The inclusion in the VIS processes in keeping with the authorizing legislation to provide information on the risks of vaccinations to the consumer prior to vaccination. In closing we like to thank the commission for providing on the website a historical overview of ACCV previous reclamation to the secretary since their inception. It is not an sick -- some of the recognitions of the same recommendations under consideration today. The public would benefit from additional information regarding with recommendations to date have been acted upon which have not as well as the number of times a recommendation has been requested. The website also contains only one response to data from the secretary. To the ACCV on recommendations. We would request that all responses be posted to the website. Thanks very much for the opportunity to comment.

Thank you. Are there any additional comments?

One more comment Jim Moody your line is open

Sir, please check your mute button. Your line is open.

Hello? Can you hear me?

We can hear you now

Okay, thank you very much. Thank you Mr. King and members of the committee and the opportunity to make comments. I would like to specifically acknowledge the work of the staff

and Dr. Can search in bringing forward the quick recommendation on GBS. On policy and certainly to include that in the vaccine injury table that is appropriate and thank you for the quick action. Also want to complement the chairman on bringing forth an agenda item for a sort of self-critical appraisal of ACCV's role and in that regard the focus on sections three and five of the charter which concerned the need for ACCV to make recommendations on research. That is consistent with section 27 of the statue which requires the secretary to do research to reduce the adverse events in childhood vaccines. That research begins with baseline data on unvaccinated children. So it specifically request ACCV take up the study unvaccinated children as an agenda item, it has been identified as a gap by everybody from CDC to NVAC the most recently IOM the gap must be filled ignorance is not a substitute for science secondly, I briefed ACCV before a couple of times on the fact the government apparently directed the IOM adverse panel not to study the Mercury literature in making its recent report and recommendations. I would specifically ask that the identified as an ACCV agenda item because that denies the program on the public the knowledge necessary to make its case on mercury as a potential cause of autism and other adverse events. Thank you very much.

Thank you. Are there any additional comments?

There are none at this time

Than the public session is closed. We will move on. On the agenda we have future agenda items and new business. Seems to be a lot of this today. Does anyone have a priority on how to begin here? So I will just kind of run down what I have listed here. One of them being the virtual meeting and the effectiveness of the virtual meeting I think that we have agreed that we are going to move this to the process workgroup but I think that it would behoove the process workgroup to have some understanding of how people think about what this is prior to the first session we worked on it. So, I think that we ought to spend a couple minutes or not -- I don't know if it has been 30 minutes but I think we can spend five minutes or so here kind of fleshing out how we view this virtual meeting environment versus the face-to-face meeting and whether or not the virtual meeting is as effective as that or whether it is not as effective as face-to-face. And I think that it speaks to Vito, some of the travel budget issues which perhaps, might be worthwhile for you to explain, since we know that the travel budget is technically funded from the program itself which has $3.4 billion, but that is not the way it actually is exercise. So, Vito, you might be able to give some guidance in that area?

Sure, David. What is happening, is there is a government wide movement to restrict travel. For government employees. And whether a program has the money or not is irrelevant. The amount of travel is just being restricted and we are not permitted to travel or to travel people such as the commission unless we can really strongly justify it. It is really not a budget issue -- it may ultimately be a budget issue in the government attempts to become more effective and efficient and in that way save money but that's is really the source of the issue about travel is that it is governmentwide and an attempt to become more efficient. Did I answer your question, David the jewelry going to anything else?

That is -- so actually I -- what you're saying that it is not really a budget issue but that rather it's is an efficiency issue will of the limiting travel and that might impact -- I would argue from my perspective that the nuance of conversation, the discussion in the hallway, the face-to-face communication, the sit down at lunch, all of the big human interaction that is the key and critical in -- an essential for good forward progress is eliminated under the virtual meeting environment as we have currently structured and so while it may be efficient I think that it hampers the effectiveness of the group.

Just to be fair, the other side of the coin it takes a lot of time for people to travel so some folks may need a day before and the day after in addition to the day of the meeting when you are sitting at home or in your office in front of your computer and someone says something that you are not quite sure is correct you period very easily look that up so there is sort of effectiveness efficiency improvements as opposed to being at the desk as opposed to being here --

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You know I'm not disputing efficiency I am arguing about the effectiveness I don't view them as the same

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The arguments you have made and are making now have been voiced. I tried to bring those human elements into the discussion and it did not get me anywhere. In terms of affecting my chain of command in a way that would make them more sympathetic. I did all that I could to sort of reserve one meeting a year, if we needed, and we are thinking when we bring on new commission members that would be the time to exercise their travel again there is no guarantees with the way the sequester is and how things are sort of evolving and unfolding. But again I would make those arguments and do what I could to let that meeting happen in person when it comes that time

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So I would think then -- on our charter statement where it talks the estimated annual amount and budget that we have there we probably ought to take away the $63,000 estimated for travel and just leave us with what the compensation component is for the commissioners? As currently structured 4 times a year.

As I said we -- I've worked hard to reserve one meeting a year if we need it to travel folks so it would be the total amount necessarily.

Who is -- who determines need? If we needed? Thank you we would have to justify it so that justification would go up the chain of commandcommand, ultimately to the administrator of the agency.

[Indiscernible--low volume]

This is Ed Kraus. I have a question I am a little confused about what you had referred during the process workgroup to sort of -- I think you used the term Bureau you referred to an overall

travel budget for the Bureau and I wasn't clear who else is -- for whom is that budget responsible in terms of commissions and boards and travel?

The way the agency is structured as you have the agency which is HRSA and it is broken up into different bureaus Bureau of Primary Health Care, Bureau of maternal and child care, Bureau of health professions, are Bureau, and then below the Bureau is the actual division so the vaccine program falls into this division of vaccine injury compensation what I had said was the travel budget before these travel restrictions came into play was approximately 75 to $100,000 a year. It was dropped down to $25,000 for the whole euro. So it is significantly restricted from where it was before.

Dave King here so the travel budget of total typically was 70 some odd thousand dollars.

So it is sort of a cap for the Bureau to be able to spend on travel.

So according to the estimated annual operating cost that really are compensation travel for members is approximately 84,000 so if there was a -- so are you saying that we had the bulk of all of this?

You had a large piece but some of those numbers is not just travel.

We could easily multiply by nine the daily compensation rate and multiply that by 4, deduct that amount and we would come up with an amount roughly in the area of travel of $63,000 in travel is what we would normally have and if it was 75,000 for the overall Bureau then we would've had 63 divided by 75 whatever that percentages of that travel budget.

Dave, we have calculated that in terms of the real numbers when we are actually doing the requisitions and the payments the meetings cost about $10,000 each to travel the commission members.

About just travel alone or is that just --

That includes per diem.

[Indiscernible--low volume]

Okay so actually mine is a more aggressive and higher number for that you are actually more conservative in your number.

Right.

I have a travel budgets that we probably spent roughly -- I am including -- I'm not including per diem of 63,000 set aside for travel.

Right but what actually historically spent the recent commission meetings in person was $10,000 per meeting.

Right that would be $10,000 for meeting times four would be $40,000 I've actually calculated $23,000 more.

Right.

What you're saying is actually significantly less than what I am thinking it is.

Right.

I would then argue again why are we not meeting in person?

Because the Bureau has a $25,000 limit and if we travel you that would almost take half of it. So, it's -- just being restricted, David

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So I guess it then comes down to what warrants us to travel and what does not since we are trying to save it for the Bureau. What in the Bureau takes precedence over the advisory commission on childhood vaccines?

There are many different programs and the Bureau one of the programs is Hansen's disease and outside New Orleans Louisiana there is a center in Carville that's is devoted to Hansen's disease. So you need to travel people back and forth when you're part of the same organization. I need to go to CDC when they have the ACIP meeting. There is -- that kind of travel for each sort of program has to deal with. But even with us, travel is very restricted that is the only thing I am even asking the travel for if a doctor want to go to the medical conference, travel can't be something not local because we won't pay for travel.

Understood but I guess when it comes back to those is it seems that the thinking has somehow become clouded because of the fact that those other components are in fact budgeted a different way then the advisory commission on childhood vaccine we are budgeted directly from the program funds.

Well that would be true with the other programs as well --

They are funded through the program funds?

Yes.

Do their own program funds not our program funds.

So if we are funded to the program funds then we have -- I don't know what their status is in terms of what they have by now we have 3.4 billion -- to the 4 million -- I guess we are going to

talk until we're blue in the face your I'm going to turn this over the commissioners and asked the commissioners are we fighting a battle that is not worth fighting or is a question of do you believe that we would be more effective if we at least not once or twice a year face-to-face? Because maybe I am in the minority and I don't have commission support here so let me put it out there unless find out. How does the commission feel?

This is surely I am certified in online education. So a lot of my life is online. I can tell at the beginning of this particular meeting there have been meetings that went on to just the framing of why we are here, it did not happen in a vacuum. After our vote there was some e-mail back and forth as we checked in, people checked in with how did that come across it actually was more than one person how did that come across how is that received and these are people on the same and different sides of the fence. So, that works for me, that was still in tact for me, I come out of that discussion as someone who was not in the majority, still feeling heard and respected. I had the personal check in, I get the screen, I am good.

All right, that is good. So Charlene you think that the effectiveness is not diminished through the virtual meeting process, is that correct?

Not for me it is not.

Good that is what we need to know. Do -- so let's find out whether or not others feel as Charlene does because if they do to be honest with you, we know if I find myself as a single person, probably other battles were fighting than this one if it doesn't make sense? So let's talk about it.

I will weigh in I'm in my comments of the process for group I feel that we are not nearly as effective as we could be if we were able to meet in person the frequency of meeting in person can be debated but to not meet for an entire year I think tends to put us into a different sort of frame of mind about whether -- how we operate as a commission. I think that meeting in person at least once a year is imperative for us to have any I think is sort of sense of common mission. I also think that the justification budgetary sort of explanations we received don't -- they leave my very dissatisfied. When government employees decide to restrict travel for government employees that is one decision they make and I probably might well have my own personal opinion on whether that is wise or whether that is justified but when you have a commission where you are appointing people to participate for a period of three years you are asking them to volunteer their time and basically be available for four meetings yes, I do not enjoy the travel, it is inconvenient, I have children when I traveled to DC for one of the meetings I miss at least two full days of work however when I was asked to serve on the commission I understand that was part of my commitment. I think that when you delete the meetings to only telephone, virtual settings you have -- you really diminish the value that individual commissioners can feel in terms of their own contribution and I would strongly echo David's comments about the conversation, the caucusing, the idea sharing between members of the commission and the ex officio members and all the other individuals including the people who would choose to be present from the community who would come and give testimony if

they so chose during the public comment I mean we are already a sort of virtual commission to begin with because we are nine people from all over the country but one thing that could help tie us together or one thing that Titus together was meeting in person four times your add period will we need to be in person I don't understand why the travel budget doesn't support at least once a year that is my view.

Others?

This is the no man just state something? -- this is vetoed -- may I just ate something I'm not sure what Edmund government employees telling me this is of the highest levels. So it is not at our bureau, it is not enter agency I don't even think it is that the department because the Department of Justice has significant travel restrictions, the court isn't traveling they are having all their hearings just about all their hearings in Washington it is government wide. It is not an employee telling another employee this is of the highest levels.

Okay.

I understand that I didn't -- I still think they are government employees I mean if you are -- but they are high-level government employees I understand that.

Right I think there is sort of elected government employees --

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Elective employee seem to be able to travel they have not diminished that so anyway are you going to speak?

I also supports at least one meeting a year face-to-face and I have to say that the latest cohort -- I am not sure how we go by year or something 2015 group -- I don't feel that I know them as well the other two groups I do because we have met a number of times face-to-face I know a little bit about their lives it kind of helps me have report when I'm on the phone I kind of see the picture who it is and that's easier for me to negotiate I guess for issues that are less easy. To put that way. So I would support one meeting a year as a minimum and we don't know when the next group will be coming in because already the nominations process is somewhat delayed.

Thank you.

I would love to hear from each commissioner on this so that it gives us a basis for thinking of what we ought to be doing here.

This Kristen I would also supports in person meetings at least once a year because I do think it contributes to underline, ruddy or understand where each of us are coming from which does make a difference since we all bring different perspectives to the table I mean I agree certainly we did have a productive discussion today even though our vote reflected some differences in terms of how we are feeling about making this today we -- everyone was still able to

communicate what they were thinking and the reasons behind their voting. There was an e-mail exchanges but it's hard to know whether or not that was because these are -- because we had met each other before or it felt like we knew each other now one of two -- well enough to share perspective even if they might be different so I think it's helpful to have a person meetings whenever possible to contribute to effectiveness. And I think other groups related to the immunization program are able to me in person and are there differences in terms of funding streams or how are these decisions made? Compared ACCV or are some groups able to me in person others not? Or are the restrictions across the board how does that work?

It's across the board. Kristen said she believes others are able to meet is that accurate?

[Indiscernible--low volume]

Others are able to meet I know the division of transplantation they have a large commission that is just as restricted as we are

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AWSS a large commission Kristen specifically when you say you know others are able to meet.

Are NVAC meetings -- they are in person correct?

Vito? Are NVAC meetings in person?

And back -- NVAC meetings have been and are in person I don't know Steve can you speak to the restrictions of the level of the ASH?

The level of what?

The assistant Secretary for health? The parent organization for NVAC is the assistant Secretary for health and the national vaccine program office is within that so Steve works in the national vaccine program office.

Part of HRSA or no.

(multiple speakers) they are not in an agency it is separate from HRSA

It is Tom, I am back on.

Thank you. Please have the minutes make note of that.

So, ditto, I guess -- I really can't speak as to why NVAC meetings are still in person, I can assure you though that the restrictions -- the government wide or certainly departmentwide restrictions in at least very watchful eye on travel are government employees is just a strict. We

are being -- where we go is been watch her closely and it is not like business as usual these days. While the general travel restrictions Vito speaks of the government employees to conferences etc. is there I can't speak to why NVAC is meeting in person so.

Right but even NVAC is affected because people from CDC and other places that aren't in Washington that normally go to NVAC many are not going because they can't travel.

Understood that Vito we can see the argument that we should be not be getting together or unable to meet if we find that NVAC is able to meet.

Well I see the inconsistency but as I said I have been pushing for at least one meeting, I have been holding the in my back pocket one meeting per year for when we have new commission members or if some issue comes up that would require us to work together in the same room so I don't want to use that meeting per year until we have new commission members because what we really want to do it then.

This is add the last meeting we had in person was one?

I think it was September of 2012.

Week on a year without a meeting (multiple speakers).

(multiple speakers) a year and a half without.

I'm not following that entirely if you are holding in your reserve the ability for us to meet once a year in person I mean it seems to me we should be meeting in December.

We haven't had -- there was an agenda items that dictated we should get together so --

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Vito you are missing the point it's not the ended the items in an of itself it is the human interaction, the nuance of human interaction that doesn't always occur on the agenda items that can occur in the idea of ideas getting across as you walk down the hall, my goal on a break, eat our lunch, those -- where there is a gel what people have universities. That is why they bring minds together and foster a conversation what we are saying here is the conversation is being limited to some degree based upon the method that we are using to meetmeet.

I fully understand what you're saying David and I make those arguments because I am not happy with having this view face-to-face meetings so I've been arguing the same point I know them.

Okay well we could continue to talk until we're blue in the face here so two people we haven't heard from I would like if we could hear from and that would be Jason and Luisita.

I agree face-to-face guess is a lot of information because body language does give us more information than the spoken word. So we could assess when someone is actually having issues and could not exactly what them at that point so the chairman for example you can address that person directly and figure out what is going on so to speak and we will all be able to speak our minds as far as issues are concerned. I agree it is difficult for me absolutely very difficult for me to travel because what ever little per diem or whatever I am supposed to earn for being and ACB Commissioner I pay more for how wanted take care of my daughter so I really spent more my -- this really is truly volunteer work for me and I am the one who actually has to have a day before and the day after staying in the city because I am all the way from the other end of the country the timewise virtual meeting is advantageous for me that the human contact I stumble isolated so speak and I really barely know anybody because I only have been there for two or three meetings but I barely know anybody really.

Okay.

I agree I would rather have a face-to-face meeting because it does give you some feel as to how we could work together.

I would definitely raise this with her leadership as I have in the past I don't know they have much room to wiggle with this.

Understood.

Jason?

You are talking about the other government avoid attending ACCV meetings and they may not be able to attend but how about the commissioners having to be altogether and listening to everybody else giving the reports? But the commissioners themselves are there and you guys are already there?

Right on not talking about folks like Tom at CDC who would need to travel I mean that would be up to his agency but I suspect he probably would do it via telephone. we may be able to travel I can go to a C-I-P but I missed a few meetings because they would not let me travel.

You not dialing?

Did you dial in.

No I was busy and I was working on other things I did not dialing.

Jason can we hear your thoughts place.

Real quick same sentiment Live Meeting to me are always preferred I know where Vito is coming from working for a company where we have to be really cognizant of our travel budgets

and we have been forced to try to adapt as best we came to make do with doing things in the room old-fashioned again when you are used to doing them a certain way change is always difficult but I find meetings like the Dae quite frankly when we have an agenda with one day worth of items on it to the point traveling it is sometimes better to me to do it remotely I understand budget pressures that seems based on some discussion we have recruiting new members is always going to be commission members is going to be tough and part of going back to I decided to move forward with the nomination of membership it was meeting colleagues around the table with everyone's different perspectives and that dynamic when you first get together that I think you have a productive commission and if it is in perpetuity where were always doing on the phone I think you are going to lose that again as you are suggesting maybe that once a year when you have new members because without it I just think the functioning of the group on the phone when you don't know who the people are not the most people and makes the conversation work a little more difficult -- I am supportive, I'm willing to to the way we are doing it I think it's getting a little better every time but I do think on a periodic basis we should get together but with an agenda that justifies the travel budget.

Right thank you that's helpful.

So Vito would be helpful if the commission were to pass a resolution inform the secretary we believe that the lack of meeting face-to-face is impeding our effectiveness and that wall were not insisting on four times a year face-to-face meeting we believe the current frequency of face-to-face meetings is not allowing us to be as effective as we might be able to be?

We have direct access to the secretary getting that -- those sentiments to her in that way would be a good thing if that is what the Commissioner wants to communicate.

Would be helpful to you?

Well it would be helpful to your goal and it would be helpful to me in the sense that it would assist with that goal becoming more of a reality but so it is your call whether or not you address the secretary with this issue it can't hurt and it would likely -- she would give it some attention.

So as chair I'm inclined to think that we ought to direct us to say something to the secretary via a missive to her outlining the fact that we believe that we ought to be meeting a little bit more face-to-face than we currently are. We don't have to say we need to meet four times a year or whatever so I think we need to put something together but I don't think that I have the authority to move forward without without us actually passing some level of a resolution to that effect. I don't think the chair write a letter and says that.

There can be a document drafted that everyone has input to and get circulated and allows for input of all the commissioners

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I would move that we empower Dave the draft -- I move that we communicate as a commission the sentiments that we just discussed here about the lack of effectiveness that stems from not

having any in person meetings and I would point out again we are not having once you're in person meetings at this point at this point we are having 0 in person meetings a year. Putting that aside, I would move that we have Dave take charge of drafting with the assistance of November is appropriate, a letter to the secretary expressing our concerns that our effectiveness is somewhat hampered by the inability to me in person at least once a year. -- to meet in person and that the language can be we can all have input on the language

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Right you need to list the justifications, the nuance of conversation the face-to-face body language that you are missing been able to learn about other people when sitting at lunch and these are the people you are working muscle all these justifications need to be laid out in the letter.

Absolutely.

And my understanding Vito that we do have provision for once a year meetings. I would suggest we not use that provision for the December meeting because December can get dicey I mean if there's time to do an online meeting it is December but didn't you say you have made provisions for want to your meetings?

Right let me be clear when I say once a year what we are talking about is the fiscal year so the fiscal year runs from October 1 through September 30.

So we have and that this year than?

We haven't but we didn't really have a strong reason to meet we had agenda items I could be easily handled on the phone albeit not as well but easily handle on the phone. I was holding that in reserve so when I do ask it will be more likely to be approved.

We have a change of the guard in March yes?

We have a change of the guard before that except we may not have a guard to change.

[laughter]

We a change of the guard officially scheduled there are a number of -- am I right Vito? Is a new goes off in March?

Potentially we may ask you to stay.

Our first meeting Charlene was March of 2011 right?

Our last one will be March 2014.

Then it would be yes.

That's three years as a?

Three years

That would be three so if we've met on the 11th, 12th, 13th -- maybe it was the template we came on? March 2010 to March 2011? No it was March 2011 so 2012 was one year 2013 we've done that your three we were at the March meeting so technically our last meeting should be December 2013.

Yes.

That should be the last meeting for me, Charlene and Fort Michelle --

I'm not ready.

You're right (multiple speakers) so it is Michelle Ann and me, David the party way.

And other people before I stayed on I think maybe even up to one year it was a while they hung around but but nothing personal.

But they did go to face-to-face meetings we don't know they would be willing we don't know what they would have been had enough of a survey.

Were they voting members of the time?

Yes

Yes because no one filled their shoes no one had come in and taken over.

It took two years I know to get the nomination approved for there was a change in [Indiscernible--low volume] it ministration something.

We think it would move a little more quickly but we really don't know what distractions will occur in the political environment that would prevent people from putting people -- there are loads of improvements -- appointed positions throughout the bureaucracy that are unfilled I mean of the fact so who knows okay. Do we need a motion to do what we just add put on the table? That was a motion?

That was a motion.

We need a second.

I second (multiple speakers).

It has been seconded by Jason so let's call to -- any discussion? I think we probably talk it through? Having talk it through let's bring it to a vote I will not do the negative I will do -- (multiple speakers) all in favor say aye all opposed say nay any abstentions? None the aye's habit we know what we need to do.

David we've been together the first draft.

I will on will be on a long plane ride at the beginning of next week perhaps I will begin to type it out an e-mail to you from my destination.

Sounds good.

It will be trust me a draft adversely you will need wordsmithing and the like. Any additional -- business? That we may want to talk about at this moment?

This is Ann I have one thing I would like to bring it a comment made by Teresa Rangham I think she is correctly emitted from the minutes I can't remember I guess you must've been the last meeting we had or March but there was absolutely a discussion about the fact that for the vaccine information statements input from the public would be sought out and the national vaccine information Center and was an organization given his history and community these issues it made sense for NVAC to be contacted so they could provide any input to fulfill the statutory requirement of the public input in the VIS statement I think we need to him somehow acknowledge that discussion took place and figure out if we need to add it back into the minutes or more importantly we need to make sure it is in fact happening that the VIS statements, the input on VIS statements is being sought from the public and certainly there are other places in the public you can seek input but that seems to me that the national vaccine information Center would be an excellent place to start.

Okay. So, what do we do to do that? Is there anything we can do on that do you know?

Does anyone recall when -- that was absolutely a discussion that was had by the commission about input from the public and I just don't remember --

That would be on the closed captioning could be gone back and looked at?

We didn't do Adobe connect for the March meeting of that discussion took place during the June meeting we could.

This is Ed let's be more efficient with this I would like to request that whoever makes sense Vito, Annie, whatever, report to us about the efforts made to include public input on the drafting of the VIS statements and in particular, whether the national vaccine information Center has been consulted and asked to review and provide input on VIS's that we have been considering and we will be considering

Right. What I will do is I will contact CDC, because the vaccine information statements is there a maybe and get a response from them and we will report that back to you at the next meeting or sooner if you like.

Thank you Vito I appreciate that if you wouldn't mind commuting it sooner or soon as you have the information you can communicate it to Dave and Dave can share with the rest of us.

Communicate to all commissioners I see no reason why all commissioners couldn't get that.

We will share with everyone.

Yes.

Okay, that's fine, thank you

Okay. Is there any other new business? That we want to bring up at this time?

This is Ann Pron, I would rather defer to the next meeting. But I think in the agenda item needs to be about the adult -- at least we need to address it whether we want to even consider it is another issue but the adult vaccine routine adult vaccines being added to the ACCV -- I understand there is a number of steps that would take but I think we need to at least have a beginning discussion.

Do we in fact have jurisdiction as was brought up for us to be able to do it?Is that what you are talking about?

That will be one of the issues (multiple speakers) advisable first of all and what would be the steps involved and what are the possible?

Okay. Vito, Annie and Amber we can get that on to the agenda item somehow?

[indiscernible] report.

It did it also came up from comments from the public as well

This is Ed can I suggest that we ask the office of General Counsel and whoever else might be appropriate to provide us with some kind of assessment maybe not OGC as I'm thinking of it but sort of pros and cons of having -- of covering -- could somebody provide us with a background presentation about what vaccines are currently being not routinely administered to build -- the children that administers to adults what kind of information there is about injuries that occur or alleged injuries that occur from those vaccines and some opinion or view of the program as to whether or not it is a good idea to include adult vaccines in the program.

I think all of that would be very helpful in guiding our discussion, the decision-making about the effects that essentially would -- the working group did related to maternal immunization I mean that probably would be quite an undertaking unless someone who could pull back together -- I do think that decisions from NVAC did come in light of the suggestions we made for their a recommendations to the secretary if a statutory limit would be pursued we would then consider including adults in general so I think there is some recognition this would require quite a bit of significant change would probably require statutory amendment but it does sound like something that would acquire -- require a lot of input one regarding a little more background about the vaccines that this would potentially cover and [indiscernible] implications it sounds like that might be hard for one person to do unless I am wrong

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Dave King here so I think that we need to find out whether or not it is even a topic that we can truly address. Because I keep thinking if it is a vaccine that is not administered to children it doesn't fall under our commission.

No, it doesn't

For them to just say let's start a task force or doing a whole bunch of work on it we need to find out whether or not it -- are we outside of scope because if we are outside of scope, the juice might not be worth the squeeze for us.

The bottom line is the legislation doesn't allow us the coverage -- to cover it currently so if they want to make a recommendation to the Secretary to change the legislation because they want adult vaccines covered you can and the other thing about presenting data on adult immunization CDC has a metal immunization section four -- or office and we can request one of them present on the adult vaccines covered, potential injuries to the received the vaccine that type of background information.

Great.

So why don't we start with that and then we will know so it sounds like yes we can if we want to because we can always make a recommendation to the secretary and it sounds like there is a way for us to at least get information so we can then begin to think about how do we get to tackle this problem

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Dave I think already so many adults are being covered because of the flu vaccine -- Ann -- there are of course MMR all the others on the list there's really only two that Vito pointed out that aren't covered.

Okay so then I think we have an agenda item where Tamara, Vito, Amber, Annie what do people get this easy to get us that information and present to us on that topic is that correct?

Yes.

This is Tom. Is an 18 -year-old considered a child or where it is again? In the law?

I think -- does it and --

It doesn't define it just as routine administration the children.

So something like the recomment a vaccine which which is only licensed for a think 18-40 -- whatever that is covered right because of the flu vaccine?

Yes.

Even though it is not licensed were approved in that age group? Know what I mean?

We cover the flu vaccine that -- the stronger flu vaccine that is clearly not recommended for children.

Like a generic category so this applies to something like [indiscernible] trying to think of what others might -- what are the vaccines are there?

Pneumococcal polysaccharide.

Yes pneumococcal somebody contacted by people injured by vaccines it is a bit odd when the person contacts you with GBS and you have to tell them you don't have a claim under the national vaccine compensation program because it was the Dimona cockle vaccine that you received and of all the vaccines that can harm you that is the one for which there is no regress under the program so I think what we are all pointing out is the origins of the program obviously were childhood vaccines for the history has been that it includes vaccines either return the given to adults or in some cases -- some cases exclusively given to adult but not consistent very ripe for us to look at making a recommendation to the secretary to amend the statute to include to the extent we think we have a program that works for all the reasons that Congress passed it in the first place for childhood vaccines certainly makes sense for a couple of adult vaccines that of not -- have not through some quirk or another have been included I think we should move forward with the consideration.

Just to hopefully tighten or narrow the scope little bit doing a review of all vaccines routinely given to adults is a pretty daunting task but doing a review of those vaccines that are routinely administered to adults but not covered under the program is probably not that -- you would not be suggesting that we look at the vaccines currently covered but then focus on adult? Just ones that are covered?

Write the ones that aren't covered, Tom.

That is my thing too.

Okay --

That's manageable.

Much more manageable

Will we certainly want to do that.

This is Ann it makes more sense when you look at and say these are all the ones on the childhood schedule but it doesn't matter what your age is and there is only two vaccines in the country we don't cover that are given to adults and a certain age group so why not include them. Adults are not as good with upticks of these vaccines either maybe this is kind of make them feel more attention is being given to them.

Okay. I think we have some agenda items I think we have some to do's in the last one more time any new items we want to bring before the commission at this moment? Does not sound like we have any I think that we have had a highly productive meeting today I want to thank everyone for their input and everybody including all commissioners that everybody who participated on the call today I think it turned out to be a fruitful meeting, a lot of good discussion I think that are steps being taken to move us forward. So, having said that, I will entertain a motion to adjourn?

I second.

We adjourn this meeting of the ACCV.

It has been seconded, we are out of here. Meeting is adjourned. Everybody, enjoy. Thank you very much

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Thank you everyone.

Thank you, take care, all.

Thank you for participating in today's conference. Please disconnect your lines at this time. [event concluded]