U.S. Department of Health and Human Services
HRSA
Health Resources and Services Administration

HSB (Health Care Systems Bureau)

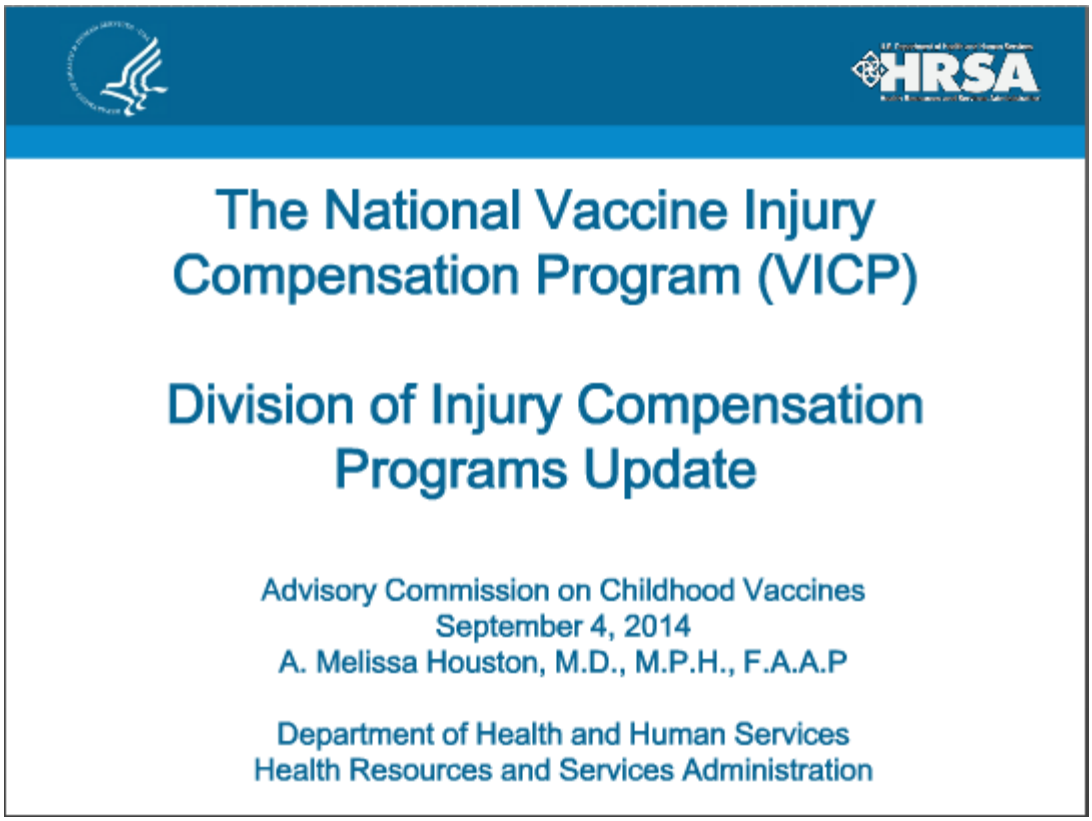
Health Resources and Services Administration

Advisory Commission on Childhood Vaccines - Day 1

9/4/2014

Herzog, Andrea (HRSA)

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



Event: Advisory Commission on Childhood Vaccines - Day 1

Date: 9/4/2014

Event Coordinator: Herzog, Andrea (HRSA)

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Problems Encountered with Adobe Connect Pro

No Problems Encountered

Recording

Title: Advisory Commission on Childhood Vaccines-Day 1

Type: Recording

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Recording Date: 09/04/2014 12:42 PM

Attendees

1. Allison Durham
2. Allyson
3. Andrea Herzog
4. Caption Colorado
5. Captioner
6. Dack Dalrymple
7. Dawn Beraud
8. Emily
9. garve
10. guest
11. Jonathan Salaveria
12. Katherine Perry
13. Kim Yamane
14. Stacy Sims
15. stephanie mok
16. Susan Daniels
17. Theresa Wrangham
18. Wayne Rohde

Chat History

N/A

Polls

N/A

Q&A

Q/A Done Over the Phone

Transcript

Event ID: 2429145
Event Started: 9/4/2014 12:53:19 PM ET

Please stand by for realtime captions.

Yes ACC be yes --

This is the conference operator. Please continue to hold. Your call will begin momentarily.

This is the conference operator. Please continue to stamp I. Your call will begin momentarily. -- Please continue to standby. Your call will begin momentarily.

Welcome to the 90's or quarterly meeting of the advisory commission on childhood vaccines. Throughout today's conference all participants will remain in listen only mode. During the portion for public comment you may ProStar 100 touchtone phone if you would like to make a comment. Today's calls being recorded if you have any objections you may disconnect at this time. Never to turn the meeting over to the ACCV chair Mr. David King. Thank you maybe dim.

Thank you this is David King. The chair of the ACCV. Before begin I would like to do a roll call of who falls -- of who's on the phone, who are commissioners and members of those who are physically present in the room. I'm going to start with the room members I will start with you.

Anne [Indiscernible - low volume]. Charlene, [Indiscernible - low volume]. [Indiscernible - low volume]. Anne Krause, [Indiscernible - low volume]. [Indiscernible - low volume]. [Indiscernible - low volume]. [Indiscernible - low volume]. Sally [Indiscernible - low volume]. Andrea [Indiscernible - low volume]. Melissa Houston, director the division of [Indiscernible - low volume]. [Indiscernible].

Anybody on the phone please identify. Smack Kristen, pediatric infectious diseases physician healthcare provider.

Jason Smith I know will be absent for day one and Michele is late today one. I think there was an extenuating circumstance agile that she is working with right other probably took a little bit longer than anticipated. When she joins the call we will be informed on that.

Thank you again we are delighted to be meeting mostly in person and a face-to-face format which the chair continuously argues is the most appropriate and effective way for us to be able to engage in the work that we have been commissioned to do. I would also like to do at this time congratulate Dr. Alyssa Houston on her position of being appointed and no longer being the active director so the chair would like to welcome you, thank you and we look forward to serving with you.

For those in person and in the room and on the phone, before you speak of in the interest of those who may also have filed then, if we can identify ourselves before we speak so we mention our name before we speak that would be helpful for the record and for the individuals to know who is speaking.

And item that we want to cover which we will do tomorrow but which I am making sure that all the commissioners are aware of at this time is that some of us to our terms are nearing the and and we know there are nominations that are not met nominated but candidates that have been submitted for being appointed as commissioners. As such, I note that Michele Williams and I have served as chair and vice chair for well past actually our terms normally would allow and it is imperative in our opinions that we elect a new chair and vice chair. We mention this now so that commissioners can give it some thought to the evening and as the day progresses tomorrow so that at the end of the day we can at least take some steps before the meeting ends to find a new chair and a new place chair.

Excuse me Michele Williams has joined.

Locum Michele.

Thank you, sorry I am late.

That is okay. Thank you. I have two other quick things to say when I will hold off on because we are going to do an introduction first and a welcome before and I do not want to take a way from that. I also ask as I do it every meeting that we have, I ask that we remember as commissioners at the vaccine injury compensation program was put in place because people get injured. I ask about decisions that we make into our deliberations that we consider and keep foremost in mind those who are injured so if we need to make an error or if an error occurs let that error be on the side of those who have been injured.

Having said that, will actually moved to the next item on the agenda which is Ms. Cheryl Dems, associated Mr. Nader, HRSA. -- Administrative chair, HRSA.

Please introduce yourself and speak.

Thank you very much, as were nice to meet you in person and I am [Indiscernible] M.D. administers administrative assistant for the peer within the agency nudges the girl with the vaccine compensation program resides prodigious want to thank you very much for allowing me to take a few minutes to speak with you today and I also wanted to personally thank you for all of the work that you all do. I really personally appreciate in and on behalf of the agency we all appreciate the work that you do as members of this commission notice very important work and I want to thank you. I do recognize it takes you away from your regular work at home and possibly your family so thank you very much for your dedication. As you have already mentioned and alluded to we have a new division a man yes, Dr. Houston, unless as a caller in the office, Dr. Houston has agreed to take ownership of that position and that is the position of injury compensation program that replaces did the division of [Indiscernible] and it doesn't because we have added two more programs to that particular division. It is also vaccine injury compensation paired with power measure injury compensation and medical claims [Indiscernible - low volume]. Dr. Houston 19 thank you very much for supporting us as we move forward to put our programs together in one division in our bureau.

Adjustment also let you know that Dr. Houston on a regular basis is talking to me about the accomplishments that your team is making all your commission is making on a regular basis. Just wanted to highlight a couple of things. When I just

wanted to acknowledge that the secretary's office does receive your recommendations and I want to thank you for all of your recommendations. We know the intent of those recommendations are to help improve the program. Those recommendations have been received and they are under review currently. I also want to specifically thank you for the work that you continue to do about the vaccine injury statement. Until recently you have provided some great updates on hepatitis A, hepatitis B, tetanus and this.. As a part of the work that you do with [Indiscernible - low volume] so thank you very much for your work there.

I will stop here, thinking you again for your service and see if there is a small window of time for any questions that you may have, I'd be happy to take them.

Do any commissioners have any questions?

Yes it, where does the medical review Board live prior to this?

It lived in a part of the agency that does not exist anymore so it is the office of special health affairs I believe was the title of that office. The agency itself to the reorganization and that program [Indiscernible - low volume] about a year ago and actually has been under the leadership of [Indiscernible - low volume] we just formalized it went to one division with all of our claims expertise in one place within the bureau.

[Indiscernible - low volume] can you give a sense of what is going on with the countermeasures compensation program how many claims are processed under that and if that, to what extent this change the fact the [Indiscernible - low volume] program.

It will not affect the program at all it is a separate team that is responsible for leadership and oversight for that program. Yes the person will report to Dr. Houston but in terms of the operations of vaccine injury compensation, none whatsoever.

What about the first part, just curious if that information [Indiscernible - low volume].

I'm sorry but perhaps we can provided later, I do not have that information.

I guess is the ACCV were not necessarily charged with having any responsible your concern. I was just curious how many claims were kicking to the program.

Sylvia?

Could you just give us an chart because my brain does not work with word so I have to [Indiscernible] so what happened?

[Laughter]

There is a were chart on the HRSA website and we can get one for you. [Indiscernible] girl there is one of five bureaus in the agency and within that bureau there are 11 programs and we have housed three of those 11 programs they are all claims related into one division and that the vision is within the healthcare system bureau and is led by [Indiscernible - low volume].

She got a lot more -- the budget [Indiscernible - low volume] for her domain?

I did not bring those numbers with me either. I would have to look.

Thank you, I appreciate it.

Dave King here. I will ask the question, on the in person meetings and whether or not you have any influence on making that a consistent component of the ACCV [Indiscernible - low volume] we talked about this about six months ago. This is something that we had shared back with the leadership and the agency and because we are doing everything we can to make sure that we have got funding to cover all of the requirements that we have, this is one area were not just ACCV but other advisory committees as well are having to do [Indiscernible - low volume]. We are monitoring the financial situation and if there's an opportunity to make some changes or shift in what we are currently doing we will absolutely do that.

Okay. What you're saying is if funds are available you will do it? Is that the bottom line?

[Indiscernible - low volume]

Our estimated, think that we have changed budget numbers as it is in the charter. The charter has a new date of July and has a lower budget allocated to travel than in the years past.

That is going to cause the entire agency not just the advisory commission or cancel it even affects movement around the country [Indiscernible - low volume] superslim doing more presentations virtually or [Indiscernible - low volume] recording messages to be played at meetings and so forth, is not just where we are right now. I have worked in the government for a while so I have watched these cycles of less travel, little bit more travel, let's travel, we are in a less travel.

It is the pendulum swings is what you try to tell us.

[Indiscernible - low volume]

I have no other questions. Does anybody else have any other questions of Cheryl Dammons? No wax thank you so much. We appreciate you coming in. Dave King speaking again. Before I moved to the next item which is the public comment on the agenda wanted to bring up the component because I didn't know we were going to have questions from the commissions on this but it has to do with the ethic standards and the ethic letter that all of us have received NSX letter some have received something of little bit more specifically related to their own personal component, it would not be a universal necessarily for all the commissioners but did anybody has any general questions as it relates to the ethics requirement and the ethics review, Laura Ritter is here in our audience in would be able to direct an answer any general questions is that correct? As long as they are not specific. Does anybody have any?

Lower your off the hook. [Laughter]. Thank you very much for being here to be able to answer any of those questions. We will move to the next item on the agenda. The next item on the agenda is public comment on agenda items. We would ask that when you identify yourself from the public that you specifically speak to the specific agenda items to please identify the agenda item that you are

going to speak to and we will commence this component at the meeting now. Does anyone have public comment?

Phone lines?

As a reminder if you would like to make a, impressed are one on your touchtone phone, record your first and last name at the prompt.

No parties Thank youat this time.

Excellent, thank you very much. There is a public comment section for the beginning of this meeting is now closed and will move on to the next item on the agenda. The next item is the approval of the June 2014 minutes. Is anybody have any corrections, amendments, clarifications on the June 2014, [Indiscernible] 2014 meeting? Are about that everybody. This is why you need a new chair. [Laughter].

This is and in it is under the review of the vaccine information statement [Indiscernible - low volume] and [Indiscernible - low volume] --

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Webpage are you on?

Is actually our mission there is nothing there right now, [Indiscernible - background noise] and 10. My comment was, at the meeting we discussed whether we're going to use the terminology healthcare provider as opposed to Dr., physician particularly since other types of providers, pharmacist, nurse practitioners may cancel patients and their parents. We always discuss that at the meeting but it never makes it to the minutes. The last meeting, I'm not sure which of those two but one of them made a statement that yes, that is something that we're going to have to consider in the future. Changing the language to be more inclusive. I'm not sure which part of the [Indiscernible] minutes that we're under the vaccine information statement. And no one of them is on page 10, the second to the last paragraph, [Indiscernible - low volume] if there's a to competition sometimes the doctor may not be available or the provider might not be a doctor it may be a nurse practitioner or maybe the pharmacy ready to get a vaccine bodegas I just question whether never makes it to the minutes.

Dave King here. I cannot answer that. I have no idea because I don't actually compile the minutes but I would say that I do recall that conversation occurring in the meeting and therefore should be inserted into the minutes. How do we make that happen and he?

We can amend them. Okay.

So, are there any other additions, omissions, changes, clarifications, corrections to the minutes did anybody else has seen? I will assume no, Dave King speaking again. Then to any to get a point of clarification here. I do not know whether, do we approve these minutes prior to this being inserted or is it approval subject to the insertion and does anybody know?

That is up to you guys. We can do it either way. Whatever your preferences. If you want to see them again, I can -- I will have to look into the recording so it might not be available tomorrow but at a later time C can either approve the minutes with the edit or you can wait and approve them at the next meeting.

I would like to get some guidance from the commissioners in a sense of the commission on how do they feel about the way to go forward with the minutes and the correction.

It does not matter to me, I am fine with approving it with the edits myself [Indiscernible - low volume], this is Ann.

Everybody else in agreement on that? So then we would take a motion to approve the minutes with the edits to be inserted and I wait for a potion to come.

I moved that we approve the minutes pending the amendment, approved the minute pending the amendment.

Second.

[Laughter]

All in favor say [Indiscernible].

[Indiscernible]. GO say they. And extensions? The minutes are approved. We move onto the next component.

The next item and agendas the report from the -- our director, Dr. Melissa Houston. We have copies of all of these in files correct?

Some of them came in a notebook if they were ready when I'm not those which the once missing from the book are now in your blue folder.

Would you identify as we go along so -- or will we overlook [Indiscernible].

I can certainly identify pretty first one is in the blue folder.

Audit, thank you.

Good afternoon have are one, thank you for attending our 93rd quarterly meeting. Before I begin my presentation I would like to take the opportunity to introduce some members, some people who are just bidding in the meeting today. As you are where the national vaccine injury compensation program is co-headed by two federal agencies pretty Department of Health and Human Services, the Department of Justice and [Indiscernible] Court of Federal claims. You'll be hearing from [Indiscernible] from the Department of Justice shortly on the agenda I wanted to take the opportunity to introduce chief master [Indiscernible] from the office of net cash Court of Federal claims. Thank you.

I also had to take the opportunity, we have gone through a reorganization in our division and essentially have had new personnel and I would like to take the opportunity to introduce our new chief medical officer Dr. Narayan Nair. During this meeting we will have several recitations. One of the presentations will be to discuss or propose some language to the vaccine injury table, to review the changes that were proposed and approved in March of 2012 in June of 2014 as mentioned will also receive an update from the Department of Justice acting division office. One thing that our program is working on that we are very pleased to share with you is our outreach and communication activity. You also your reports from the ACCV workgroup. Without a discussion on the form 2.0, [Indiscernible] and zoster vaccine is was updates from the ACCV ex officio members.

This slide represents a number of interactive and apply to the program as of August 1, 2014, as of August 1 451 petitions have been filed with the program. A stunt these 10 months of data it is projected that the numbers of petitioners that will be filed in FY14 will be 541 which is an increase from previous years.

This slide reflects the number of adjudicated cases as of August 1, 2014. [Indiscernible] 235 cases have been adjudicated. Ground make anticipated there is there would be total of 750 cases that be adjudicated in 22 2014 which is slightly lower than the previous year. When you look at the number of [Indiscernible - background noise] we see that in FY14 349 cases have been adjudicated as a August 11. It is projected at 418 cases which would be adjudicated in FY14 which is around the number of adjudications we look at the trend from FY 12 to FY14.

When we review the amount of awards that have been paid as of August 1 that have been paid as of August 1, 2014, we see that for petitioner, wondered and $77 million have been paid in awards to them and $17.4 million have been paid in attorneys fees and costs. It is projected that for FY 14, $212.4 million will be awarded to petitioner and almost $21 million will be awarded to attorneys to cover their fees and costs.

As of June 30 of this year the balance of the check fund was $2.4 billion. -- $3.4 billion. As you can see from the bullets on this slide it is that we have made a net income of approximately $117 million and the interest of the net income of 26%. Some significant activities that have occurred regarding that the since we last met come the national vaccine advisory committee held their meeting on June 10 and 11th and will receive an update regarding that meeting. Also the advisory committee on a meditation practices met on June 25 and June 26.

As mentioned during the last meeting, the it all back request from the GAL. And other members from the ACCV have participated in an interview conversation with the GAL. Have had questions but the vaccine injury compensation test fund, outreach efforts, assess is for making changes to vaccine injury table and claims processing data. It is anticipated or the GAO plans to submit a draft report to the program in mid-September. Not on the site but also significant activities that I would like to mention is that the nomination packets for the new ACCV members

has been submitted to the Department of the department has submitted that nomination package to the White House. It is under review at the White House so we are waiting their recommendation before any members can be nominated. Of like to take this time to especially thank the members whose terms have expired but have agreed to participate on the ACCV to continue to work with the ACCV until new members are appointed. Thank youvery much for your service.

One will see new members be appointed? This is Charlene.

When the White House has completed.

[Laughter]

Sorry.

.A problem. -- Not a problem. Are there any questions or comments? Thank you very much.

Usually on the last leg we like to let people know, for those of you are on the phone am I not be looking on the web we usually provide the information of the address [Indiscernible].

Out more than happy to do that. If you have any questions or comments, the contact information is for Annie Herzog, Parkland building, room 11 C-26, 5600, 5600 Fishers Ln. in Rockville Maryland. Zip code 20857. The phone number is 301-443-6634. She can also be contacted via e-mail at aherzog@hrsa.gov.

Thank you. I will be ready to move here. The next section on the agenda, the floor is still being held by Dr. Houston pretty clever additional proposed changes to the vaccine injury table. However before we begin, we probably should talk about that not every single Commissioner can ask questions on this. I think --

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This is Annie any to excuse Mr. for making commentary or voting on this next section although I am permitted to [Indiscernible - background noise] to verify information.

If we were to have a motion or do anything like that, be advised that at this time, a waiver is needed. Just to get some clarification on this, I think that we should share some information. There was at some point a review of the ethics policies and processes in the way they were being carried out in it was determined that some of the things in the way that we have been conducting or facilitating ourselves and not just us but across the board for commissions, that there was a potential conflict of interest depending upon what people may have had in their financial disclosure statements and while in the past it was looked on and said, not an issue, not an issue, at some point eyes and minds began to say to my maybe this does in fact have a direct consequence or has the potential for having a direct consequence uncertain public companies and the like if we were to, if people were to vote or comment or direct and influence others in a public format to try to do something in terms of swing their opinion as it relates to pieces of information. I know I'm talking rather vague because it is a fake. [Laughter]. To be honest with you. The issue has come down to that when the new interpretation because nothing has changed on the part of any commissioners a think it is important for us to understand. What has only changed is how that information that has been continuously submitted on an annual basis is now being interpretative. It is through that interpretation that now requires that some individuals or in this particular case with this particular area, one individual needs to have a waiver. That waiver is likely to occur in time for the next meeting. The problem was is that this issue came to a boil and there wasn't enough time to run through the process and my understanding is even in an expedited matter it wouldn't have been able, based upon the way these things work and I am not privy to every single object step along the way on how this works, suffice it to say that typically when dealing with multiple layers of approval and eyes looking at something takes time. Because of that, we don't have a waiver for in this particular case Ann. I wanted to bring this up so that the other commissioners are aware of what the issue is and what it is but also want you to be aware that we could choose, should we decide to make a comment or vote to say that we would hold off on that until the waiver is granted which we have been pretty much assured would be likely in time for the December meeting.

However, just are not necessarily recommending a course of action because I really don't know which with this conversation is going to go because we have a presentation and it may become obvious on what actions we should take or not take as a relates to that. I'm just saying that we have options in front of us and to

that degree, we may not even have to make a comment at all because things can be done in an administrative matter. Is that correct? Is that part of what we're doing here?

There will be a point where I will ask [Indiscernible - low volume].

Fair enough. I said all I'm going to say on this matter at this time. The drawn a might have something else to add or say to it but at this moment, I will now turn the floor over to Dr. Houston.

Thank you. In recognition that it has been some time since the proposed changes that were approved in March 2012, having been brought to your attention and in seeing the process to the ACCV [Indiscernible - background noise] approved changes I will do so in this presentation. There were also some additional proposed revisions that were discussed and approved by the commission in June of 2014. Since then the program has modified some of -- is proposing to modify some of the approved language in the qualification and interpretation. Does the chapter's of this presentation are to review the proposed revisions that were approved by the ACCV in March of 2012 . They were designed to improve the presentation and readability of the vaccine table and to make the table more consistent and easier to understand and interpret.

Number two, to review the proposed revisions that were approved by the commission in June of 2014. And finally, to present the additional proposed revisions to the QA I. Prior to these proposed changes the vaccine injury table was made in 1997. Since then nine vaccines have been added to the table although no related injuries are specified in the table for those vaccines with those vaccines were hepatitis B, [Indiscernible] [Indiscernible - low volume] rotavirus, [Indiscernible - low volume] hepatitis A, [Indiscernible] and human couple of the vaccine. These were contracted with the [Indiscernible] expert committee to review the available scientific literature on vaccines. Then a task force was convened to review the items of recommendation. The task force research the guiding principles that were developed by a prior ACCV and adopted I this current ACCV during the review process. One of the principles is that the vaccine injury table should be scientifically and medically credible and that changes whenever possible should be made to benefit the petitioner. Based on the [Indiscernible -

low volume] report it was opposed unapproved that several injuries be added to the extreme injury table which I will now review.

[Indiscernible] there is convincing evidence to support an association between the fellow vaccine of vaccines by its activation which is the parent of a rash, [Indiscernible - low volume]. I'm going to be talking about vaccines -- there is convincing evidence to report a [Indiscernible], measles, mumps and rubella vaccine and [Indiscernible] encephalitis but the condition that was on the table with the vaccine strain infection and was on the table for immunodeficient recipients are however cents [Indiscernible] is one type of measles is a disease the proposal involves the decision of the current injury including MIB. MIB is a rare and fully developing several is caused by chronic infection. The disease does the disease is confined to [Indiscernible] patients. This the change in the table was to change the vaccine strain infection, the vaccine [Indiscernible] Antinita [Indiscernible - low volume] to include them IPE. [Indiscernible - low volume] fortes nine months after inoculation but that is the proposed changes to the time interval were as follows, that a broad interval of up to 12 months [Indiscernible - low volume] or laboratory testing. However, if laboratory test identified the vaccine [Indiscernible - low volume] no timeframe was applicable.

The [Indiscernible] also affirm that there is convincing evidence to support a positive association between the federal vaccines and disseminated vaccine bile disease on the skin and in other organs. Proposal was to add the disseminated for cell vaccine strain viral disease without any [Indiscernible] if the virus was identified by conclusive laboratory testing or within a timeframe of 7 to 42 days with laboratory testing not performed or was inconclusive. It should be noted that the justification for the latter provision [Indiscernible - low volume] and keep in this program policy when the vaccine might have caused injury when proof was not available.

[Indiscernible] also from that there was conclusive evidence to support an association between Verizon vaccine and vaccine strain activation which is the apparent of the rash months or years after vaccination with or without some cognitive infection and other organs. It should be noted that the [Indiscernible] specified that the [Indiscernible - low volume] also be involved in vaccine regulation usually in an immune compromised individual brick the proposal did not limit the involvement to those two organs because in keeping of your spirit of

the guidance principles the task force did not recommend [Indiscernible - low volume] individuals [Indiscernible - low volume].

I will now review some general proposals that remain improved in 2012 purchasable by the table that trait that is listed on the right-hand side, any cute complication or sequela would be moved or deleted from the individual vaccine line and placed in a new paragraph entitled subparagraph B. [Indiscernible] concluded that there was evidence that reported a positive relationship between any vaccine injected with a needle and identified [Indiscernible]. This entry was cop I the injection itself and not a specific vaccine that was ejected for the express of the program supported this injury could produce [Indiscernible - low volume] such as tendinitis, [Indiscernible] syndrome, [Indiscernible - low volume] or aggravation of a be existing symptomatic cough entry. The program propose that the injury, shoulder injury related to vaccine administration or [Indiscernible] he added to the table. Applying the guidance as well as the task force agreed to broaden the definition to ensure that all of the injuries more than are just [Indiscernible] recovered if they occurred within the 48 hour time period. In addition, the Iowa found evidence that supported a positive relationship between effective vaccine and the [Indiscernible]. The [Indiscernible] [Indiscernible - low volume] occurred within 15 min. of vaccine injection, however, in keeping with the guiding principle, the program propose to add [Indiscernible] to the table as the person fainted within one hour after vaccination. During the following to slide it shows the covered conditions shoulder [Indiscernible] were added to the following vaccine.

The [Indiscernible] also found evidence that convincingly supported a positive relationship between [Indiscernible] vaccine, Marisela and papillomas Pechstein. [Indiscernible - low volume] reviewed by the Institute of medicine found that all had an [Indiscernible] shortly after vaccine administration with most occurring in less than one hour. In accordance with the guiding principle it was proposed to add Anna Flach six to the table for these for vaccine with an interval of less than or equal to four hours.

In addition to adding new injury to the table, the [Indiscernible] were expanded from 9 to 13 in order to accommodate the new effort events that were added to the table. [Indiscernible - low volume] on the slide to Adobe connect I will not read the entire definition that was approved in approved in March I want to let

you know this is the language that has been approved for SIRVA on the slide and the next. It also should be noted that the paragraph on [Indiscernible] has changed to make it harmonize in the new coverage for to 19, if conditions were similar and the changes are [Indiscernible - low volume].

The proposed [Indiscernible - low volume] disease by the requirement regarding repertory testing and applicable time period, [Indiscernible - low volume] ennobles that involves the skin [Indiscernible - low volume] it also stated that clear evidence of disease must be covered so there must be shown to be disease in the organ and not just mildly elevated [Indiscernible - low volume]. This chart shows the language that was opposed proposed and reviewed regarding the disease. The [Indiscernible] stated that this disease is a present of the herpes rash with or without concurrent disease [Indiscernible - low volume] skin. The vaccine [Indiscernible - low volume] must be specifically identified in the skin or organ involved and there is no timeframe associated with the entry since the vaccine strain virus [Indiscernible - low volume] link this [Indiscernible - low volume].

This slide shows the language for [Indiscernible - low volume] about -- proposed and approved in 2012. It states that the loss of consciousness or other causes would not be considered an infection related [Indiscernible - low volume] in the context of the injury table. Regarding the QAI changes to anaphylaxis, [Indiscernible - low volume] wording. The [Indiscernible - low volume] since there are no findings that would concern a diagnosis anaphylaxis. In regards to vaccine strain [Indiscernible - low volume] significant [Indiscernible - low volume] proposed and approved in order to provide more detail as to the definition to show that it was involving the skin and/or other organs, [Indiscernible - low volume] and exclusion such as identification of [Indiscernible - low volume] or other non-vaccine [Indiscernible - low volume].

In regards to the proposed and approved changes regarding the [Indiscernible - low volume] it was important to note that the [Indiscernible] concluded that the evidence was [Indiscernible - low volume] a positive relationship [Indiscernible - low volume] and encephalopathy -- or between the MMR vaccine and [Indiscernible] encephalitis. However, in keeping with the spirit of the guiding principle, it was decided that these vaccines and the adverse effects remain on the table. The current [Indiscernible] were injured in the definition for

encephalitis was added. Although the main substantive definition has not change the following revisions were proposed and approved. Similar sections were designed and working with [Indiscernible - low volume] sentences will be moved and [Indiscernible - low volume] exclusion of [Indiscernible] were added as the previous definition included many illnesses that were pediatric in nature.

River opposed -- proposed and approved language for [Indiscernible - low volume] on the following slides period lease is up for a few moments to let you be able to read it. Into proposed and approved [Indiscernible] the phrase intracranial pressure may be a clinical feature of acute as the philosophy in any age group and has no impact on the diagnosis of encephalopathy.

Encephalitis is always been together with and subplots to be in the table but does not have a definition. In a definition for encephalitis was proposed and approved in March of 2012. The definition can be found on the slide in the following few slides which I will leave up on the screen for a few moments to let you be able to read.

For clarity, [Indiscernible] was added. Although [Indiscernible - low volume] on the table was proposed. Although there was no proposed change, the vaccine injury table regarding specific [Indiscernible - low volume] the definition was expended to make it compatible with medical diagnostic [Indiscernible - low volume] instead of just a test result definition.

In order to accommodate term that was used more than once, a glossary was added in subparagraph B which now includes definitions for chronic encephalopathy which was moved from the SF office of -- encephalopathy section. The term injected was further defined. The definition of an immunodeficient recipients is mentioned in the MMR and polio vaccine table was also added to the glossary. Entries from the in outback is also to the glossary section. The definitions to sit -- significantly to his level of consciousness, is indicated by the presence of one or more of the following clinicals the -- clinical signs. The definition of seizure was also moved to the glossary section. At cemetery for the definition of chronic in [Indiscernible - poor audio] -- [Indiscernible] with moved to the glossary section. Finally the term sequela was moved from this section to the encephalopathy section [Indiscernible - low

volume]. That concludes the review of all the changes that were proposed and approved during the March 2014 [Indiscernible - low volume].

The next section will be --

Does anybody have any questions, comments? It would appear not. Wait, actually we do.

[Indiscernible - low volume] CDC. For the glossary for rejected there is an intradermal rejection now, I do not remember [Indiscernible - low volume] those are available in 2012. Sumac maybe it wasn't available in 2012 but we can definitely --

---

I know a recent device was approved.

Using the definition may be that he did not fit the definition for the purpose of the table.

I wouldn't go back and look.

I would think shoulder injury would be [Indiscernible] at night. This -- there is any device that just got approved so that's not a needle, that is intramuscular subcutaneous injection but now with a needle so that wasn't available [Indiscernible - low volume].

Thank you.

Dave King here purchased we all understand, what we have done is we have reviewed what we did in March of 2012.

Correct.

Thank you.

Now would like to review the proposed changes that were proposed and approved during the June meeting of this year. [Indiscernible - low volume] gently for team meeting all seasonal trivalent influenza vaccines have been

covered under the program since July 1, 2005. At that time, all seasonal influenza vaccines for trivalent, [Indiscernible - low volume] influenza became available for general use during the 2014 [Indiscernible - low volume]. In June 26, 2014 public law 15 was enacted which extended to applicable excise tax on trivalent influenza vaccine to includes any type of vaccine against seasonal flu. It was proposed that wasn't does appear that the category trivalent influenza vaccine a change to seasonal influenza vaccines.

Also, multiple assembling the type be [Indiscernible - low volume] and have been recommended by the CDC [Indiscernible - low volume] since 1991. The secretary proposed to modify the category knowing of the table in [Indiscernible - poor audio] type be vaccine to in [Indiscernible - poor audio] type be vaccine in order to be conclusive with the language [Indiscernible - low volume] statue. This concludes my presentation of changes that were proposed and approved during the June 20 during the June 2013.

Are there any questions? Before go to the next section.

Does anybody have any questions? Let's keep rolling. Thank you.

Going to move on to the program [Indiscernible - low volume] of our to been approved in March 2012.

Dave King speaking, we are going to cover what you're about to do is to propose modifications to things that we approved in March of 2012 is that correct? Just to make sure that we all understand. These are proposed changes to something that we've already approved. Does that require us to approve those changes?

It requires 10 want to make a recommendation on whether to concur or do not concur with the proposed modification.

Okay. This is a an area where Ann must be excused is that correct?

That is correct .

Okay, proceed.

The change just the proposed change it to be make the definition less restrictive in regard to encephalopathy. Sitting back that one could show that the king -- exclusion were related to the vaccine, the to backward still apply. Does anyone have any questions? The change languages and bolts of that would be the only difference. It would be an underlying condition or systemic disease shown to be unrelated to vaccine and that risk -- [Indiscernible - low volume].

Dave King, RN looking at what was approved so the first paragraph I see word such as, if, after evaluating the entire medical record the preponderance of evidence shows that it was caused by -- when I look at the proposed come I don't see that.

I think that language was probably removed because it the statute of the entire record is to be reviewed and that is not stated for any of the other [Indiscernible - low volume] and the standard that is used is the preponderance of the evidence that language is not stated for each of the other definitions because that is the standard by which things are elevated.

[Indiscernible - low volume]

Exactly.

Is it a given that, this is Dave King speaking Cheryl so that is a given in all cases. Is is a given in the sense that it is documented that it is in writing or is it one that people just assume wax

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The entire medical record has to be reviewed in order for a case to be decided and [Indiscernible - low volume] the standard is that it is the preponderance of the standard.

Sylvia?

I think Dr. Houston the point being made is one is approved in 12th and then the proposed modification therefore we should have [Indiscernible - low volume].

That is correct.

[Indiscernible - multiple speakers]

[Laughter]

I put them both up to be compared but I could be more explicit in stating with the changes are, thank you for making that point.

I don't think the question of medical record --

That is not my issue, right. What I'm saying is what we have and what we have it has --

---

I will be more explicit but again on this screen, I copied the language directly but owed more explicit in pointing out the changes.

So just so we understand, the proposed modified language deletes that component.

Correct.

Which component?

The [Indiscernible] the evidence shows it was caused by, is in both.

That is fine. Going to make sure everyone is clear and make sure that they understand what is being proposed.

Go ahead, Ed.

One of the reasons I think we have come back to this is because almost all of us as commissioners in March of 2012 were [Indiscernible - low volume] our first, second or third I think [Indiscernible - low volume] and we were confronted with a lot of changes and proposals which would ultimately approved. We can go back and look through the minutes, personally recall that my head was spinning. My very first meeting as a ACCV member . I also recall feeling a sense of urgency to prove recommendations that at least from my perspective were designed and intended to add to the table injuries that would ultimately make it easier for

petitioners to get compensation, the vaccine addition her attorney perspective I think. I remember that we did get some very good and thorough presentations on the underlying medical support for each one of the changes. We made those back in March of 2012. We didn't really talk or think about those changes again for at least a year or two at which point we were brought the additional proposed change to the vaccine table to add [Indiscernible] following the flu vaccine which I remember that with significant and we discussed that, which meeting was that? Two meetings ago?

December 2013.

Said -- so, three meetings ago. Now we approved that. Now were being brought to changes in 2012, I'm sorry, then in June 2014 we were brought some changes to the additional changes to the March to the additional changes to the March 2012 changes which to me were pretty much no-brainers. They were language clarifiers, it wasn't anything real substantive, lease that was my interpretation. However it does cause me to go back and look again at those recommendations that we had considered back in March of 2012 and look at them again and think about them again. In doing that, certain issues have, I have got a bunch of questions and issues. I would want to bring them up and raise them but I think procedurally want to make sure that it is appropriate. It seems to me by bringing this back to us to propose additional changes to the March 2012 recommendations, it reopens those recommendations and you're not asking us about some of these things that I'm not noticing and thinking about but I feel that it is important to raise those issues now and I wish I could have understood enough in March of 2012 my very first meeting to ask some of these questions but I didn't. I'm guess I'm asking the chair if it is appropriate to get into the substance of some of those March 2012 recommendations, given that we will be addressing them again for other purposes.

Dave King speaking. The chair thinks that we are going to be addressing anything about them, that it is in fact discussing them but I am not sure if I understand what you're asking here add because what I'm trying to find out is if you are asking that we reconsider some of those comments that were you're going with this or is it that because it comes to doing are your concerns the other commissioners might say, we haven't thought about that, and we have had different experiences. We bring a different us to the table at this stage in our lives

as commissioners then back then. We are different. Would that then cause us to say, we wish we had done something different then, is that what is potentially at stake here? I'm going to get a clarification, putting it out here. Is that we are talking about?

Yes. This is Ed speaking again. I do not want to railroad the discussion , not an ambush but I can't as I am looking through some of these changes now I'm thinking about them, I have some concerns. I guess I would like to be able to raise them. I do not know if I'm the only one who has these concerns or not, whether that prompts, guess what we are called upon to vote, whether to approve the recommendation, we can each do what we are going to do.

Dave King speaking. Is going to take me a moment to speak, know that is hard to believe, but I have to think here, because they're so made different issues that are on the table. On what is being -- we are being asked to change the language on proposals that we voted on in March of 2012 at actually sure of our to been done and submitted and processed through already it shouldn't even be at the stage where we are doing it. However, we do not blame you.

[Laughter]

Thank you, this is [Indiscernible - low volume]. What I am bringing to the ACCV for consideration today , our minor modifications of language that the program believes are less restrictive than what you had approved back in March 2012 but because they are changes in the statute states that we want to be transparent that we consult with you we wanted to bring these clarifying language to what started been approved. That is what I was proposing.

Dave King speaking. Only the word minor is what we in sales call a green word meaning that it could mean different things to different people.

It could be.

Not sure what that exactly is but we understand that somebody could view it, one man's treasure is another man's trash.

Absolutely.

It could have different meanings to different people. What I'm hearing Ed say zip we're going to be having a conversation around some of these and continue to correct me if I am wrong here, you're saying I want to talk about something other than the proposed modified language potentially, I would like to in some cases question what we voted on, is that accurate?

Yes, that is correct.

This is Charlene. I guess in terms of process, I would like to see those things listed out so we don't ramble through the entire recitation but also I'm not seeing this as a form to question the underlying science. We can discuss [Indiscernible] but that is the only area that I can see that could be problematic if we get into a discussion that challenges the underlying science. That is the only area that I see that could be problematic.

Dave King, I am inclined to think that is probably true whether the Western in the underlying science is not where we should be at. I am inclined to agree. I actually have an additional concern that I am going to voice which is not directly related to the proposed modified language or what Ed is talking about but throughout the course of the past several years I have found that Ann input has often times been insightful and we are denied that right at this moment. I have an issue around the fact that we have a commissioner who has voiced an opinion on things and right now is being told that they're not able to do that until the December meeting most likely. That is a potential issue here from my perspective on whether or not we even -- where we go with this. I suspect [Indiscernible] has are you but I do not know because she cannot talk. Smacked of a specific list of issues?

I have got a couple.

I am more than willing to entertain them but at the same time, are you going through, Melissa we be going through point by point on these or all at once so in other words, do we want Ed to do point counterpoint?

Can I do that?

Were we talking that issue now is on the table. My concern is, do not know where this conversation is going to take this and I do not we have allocated the time your that I daresay that if we begin to talk about modifying language on items that we voted on last March, in all fairness what we are saying is to some degree we are reconsidering what we said. I think that is a logical extension of that at least in my mind it is. I do want to hear what Ed has to say on these and any other commissioner who might have a thought or two on it as well so I am trying to figure out the best way to proceed on this without causing -- so that we have a logical format so it is not a free-for-all because I think Charlene's point is we have a list otherwise we will be scattered all over here and Sylvia, you know -- otherwise would our has will be spinning, does that make sense? Does everybody get it? I guess the starting point is, do you have a specific comment on something that has already been stated?

Yes.

Let's hear it.

I have questions and concerns about the changes to encephalopathy.

Would you take us to the page on the slide where we are with this so that we all look at it. Smacked have a question about the proposed clarifying language or about what you approved in March 2012?

What we approved in March 2012.

Again I apologize the [Indiscernible - low volume].

But if we're going to change wording.

That is a good point Sylvia. Are we going to be discussing about what we proposed or are we discussing the proposed language?

What was approved in March 2012 which is the slide that says, QA I changes, and sub philosophy, current language on the last approved March 2012 on the right.

[Indiscernible - low volume]

It was the one that we deleted. It was a slight that there was a deletion. No, that's not the slide you're talking about?

The other one. It is where -- it is basically the intervention to be under laid [Indiscernible - low volume] complicated migraine use with a [Indiscernible - low volume].

Could you please hold for one second per, to make sure we are all on the same page with the slide. Which page? Which slide the upper?

It is right above the one that says intracranial -- interesting -- intracranial pressure. The pages are not number two.

Why do we number them what we have Democrats of us. -- Why don't we number them what we have Democrats of us. -- While we have them in front of us.

[Indiscernible - multiple speakers]

Slide 23.

[Indiscernible - multiple speakers]

Let's number the slides pretty the slides have numbers?

Slide 24.

I am numbering in my thing, the slides. Which would be slide 23.

This is hurling, what is the issue? The change that we approved back in March 2012 can you help me understand what this language was intended to do?

This language was intended to further define what is that a lot of the [Indiscernible - low volume].

Is I'm looking at this and I am thinking these are table injury and the benefit to the practitioner in the table entries that you get the presumption of car patient.

Correct.

Now is I'm looking at this, it seems to me that a change like this, whatever the intent might be can be used to shift the burden to the petitioners to have to rule out other causes in order to move forward with a table. Is seems to undercut unnecessarily the purpose/benefit of presumption that comes from being a table injury. Obviously if the evidence shows that the S' was caused by something else, stroke, some other condition, it is a rebuttable presumption but the burden should be not on the petitioner in order to stay on the table, tuple that out. The burden should be on the respondent. That is the purpose of the table when I know historically when the definition of Encephalopathy was change back in 1996, or 95, whatever, was defined in such a way as to -- it was narrowed considerably and it was a lot of [Indiscernible] previously trafficking cases were no longer Encephalopathy cases. My understanding is that it was because the change was designed -- it was based on science and medical presentations, that the definition of Encephalopathy was too broad, I do not know, I was not a part of that. As I'm a jazz I'm looking at this come I am concerned that this is another situation where we might be narrowing what the table injury so that is my concern. I was also, that is my number one concern. My other question is, why, and this is under anaphylaxis, a couple pages earlier Toma why language was added that said, when from an acute severe potentially lethal systemic reaction to [Indiscernible] involves two or more organ system. To Charlene's point may be that is purely medical.

[Indiscernible - low volume]

The has to be more than one system involved for it to be considered anaphylaxis?

That is correct.

Okay. That was more of a clarification. That is my biggest concern I do not understand, for example, [Indiscernible] was not on before, stroke is now one of these things that you have to prove, basically have a table case and prove that --

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[Indiscernible - low volume] slide 24?

Yes, I'm sorry, slide 24. Now my concern would be that you've taken with this language what would the a table injury case for Encephalopathy if there was a stroke that was involved following the vaccination would you then have to prove that the stroke was unrelated to Encephalopathy in which you then , it is about burdens of proof on petitioners in an area as the Federal Circuit has said that is rest of direct evidence of starvation in this is supposed to be the beneficial probe petitioner approach to getting compensation, moving forward with the table [Indiscernible - low volume]. I do not know if anybody else -- maybe I'm the only one who has that concern. That would be my concern.

This is Michele, I share your concern.

Dave King, I to have some concern here but also, when I look at the slides and I look at what we approved [Indiscernible - low volume] propose. How do we voice that concern I guess is the question I asked to the group wax first of all our only three commissioners concerned except maybe commissioners that are concerned I cannot talk so my concern is, it is hard to have this conversation without full input from all commissioners. What are we doing here? Is one thing if you cannot be here because of your schedule, does another if you want to be here but you cannot speak to kiss we have been muted because of a change in thinking.

[Indiscernible - low volume] as a layperson that understanding outside medical or legal, [Indiscernible - low volume] the law itself is that if you are able to find a [Indiscernible - low volume] within the table, it is always been the burden of the other sides to prove that it is or is not a table injury. It is in all black version to approve it. If it is off the table -- if it is off table then is the petitioners burden to show that this injury is good for

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May or may not be compensated depending on how you're able to do it.

[Indiscernible - low volume], this is Charlene. Now we're getting to another area. If it is a table injury, I didn't realize the burden is on [Indiscernible - low volume].

[Indiscernible - multiple speakers]

I disagree.

[Indiscernible - low volume] reading the law it is -- I [Indiscernible - low volume] because injury happened within that and I believe I as a parent [Indiscernible - low volume] and then the medical records then would be provided as you provide all the medical records you then go to review it, tell me whether additional [Indiscernible - low volume] and maybe a fight between medical people. My side of it, your side of it and then the lawyers of course.

It would be -- this is Andrea appeared to be petitioner burden to prove that their case met the table and if it meets the table [Indiscernible - low volume] assumption so under that situation a petitioner would [Indiscernible - low volume]. It is the petitioners burden, not respondent.

It is the petitioner's job to provide a medical person to say the injury happened so that would be -- the medical records will be provided and both of you then would lookup the medical records to see whether, which medical records then support this or do she would always come up with some reason to say [Indiscernible] so used to promote the reason why you did.

Dave King speaking. I think we can go back and forth on this and we could go round and round at the same time as well. I think that what we approved in March of 2012, what we are looking at on the slides is a snippet of that information and not the entirely what we have and we may -- we have the summary of what it is, do we have the actual?

The actual tables were provided to.

Is that in the --

It is in the folder.

Okay. Then we have what we need to have this conversation. Okay. Which tab is it under?

In the blue folder.

This is Ed. I think a way to clarify this, [Indiscernible - low volume] may be comfortable --

They are color-coded. Audit. Thank you. Ed proceed.

I was just going to say that maybe one way to clarify this is that it is always the petitioners burden to prove causation the difference is if you have a case in which you can claim that it is a table injury so if you meet the table requirements then there is a very good chance you're going to prevail because it creates a presumption of causation which then means it is the burden, then and only then that the respondent has the burden to show that it was some other cause. I don't mean to be getting into the legal weeds here but to the extent that this is on one person with a very obvious perspective of probe petitioner I would be, we have some other legal folks Vince, Julia, [Indiscernible] could also be able to answer questions, Charlene or that any of else might have about the significance of a burden on petitioners when it is table versus not table. I am saying I don't want to, I'm not the authority.

Okay, thank you. Are you just raising a concern?

I would move that we do not approve a recommendation or I would move that we reconsider the recommendation that we approved in March 2012 related to the change in the language of Encephalopathy. That we consider it.

Is there any second to that motion?

Which you repeat that?

I move that we reconsider the question of the recommendation rather of the change in the language to Encephalopathy in the Q&A, QAI. I guess I would say at our next meeting. If that helps because will have hopefully the participation of all commissioners.

Is 32nd that motion orderly to understand the competitions of that notion are before we get a second? What are the implications? Is it that we are out Julie

holing this recommendation back from what we approved in March with Debbie with that is? That's what it sounds to me, that is what it would be.

[Indiscernible - low volume] is the vaccine injury table, where is -- Charlene speaking. Where is the Encephalopathy? Webpages that? -- What pages that?

It is on page --

[Indiscernible - multiple speakers]

The color-coded is on page 5.

I see.

It is on page 5. It is in to a -- 2A.

Somebody tell me the green and blue.

[Indiscernible - low volume] different colors, they have been moved.

What I would like to point out, in the current language even before they were proposed changes to March 2012 had exclusion so does want to point that out. If you look at the current language, if you look at the slide, the current language, there is a specific exclusion if you look at evidence of the Encephalopathy was caused by [Indiscernible] and going Denny can see the list of exclusions that already exist in that are currently in the table that is used, the table it stands right now.

Still have a motion the needs to be seconded but additional point of information based upon what Melissa just said and that is on the current language, was that language that ACCV approve or was it that --

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That was the approved and that is the table that is in existence.

That is not something that was interpreted, changed?

No.

Thank you. So there was a motion on the table and is indeed waiting for a second. The chair does not know and I point this out whether country would be checking the function or not.

Not every motion is seconded.

Technically we could pull that.

[Laughter]

Know the motion dies if it is not.

That is correct but we also have, in all fairness what we have here is a Commissioner that cannot speak and we do not know whether they would be seconding it or not which means that --

I would suggest that we operate under the -- the reality that Ann is not able to participate to cast a vote so there is the second there is no second.

So there is no second the motion dies.

Yes.

There is no second, as far as I know so that motion has no life. The chair cannot second and he? -- Can he? You on top of it.

[Indiscernible - low volume]

I do not think the chair supposed to second. We will move on back to where we were.

If you would just give me a moment. Would any of you like me to repeat the information that I proposed? Is everybody clear?

Just update us as to where we are.

We are on QAI changes we're going to be moving to the second Encephalopathy side which is the current Encephalopathy. [Indiscernible - low volume].

We should number.

Certainly, we could definitely number.

Is a future component all slides should be numbered. Thank you.

Certainly.

I'm not sure that I met the right slide. Was like you think it is roughly?

Slide 41.

Ed come the approved language in 2012 stated that occurs when a change in mental status or neurologic status persist for at least six months from the date of vaccination. This proposed change wanted to provide greater clarity to ensure consistency between parts one and two of the definition of chronic come to consider is proposed that really six months from the first symptom more manifestation of onset or significant aggravation of an acute Encephalopathy or encephalitis. Additionally had said six months from vaccination and out of six months from the symptom if you turn to the next slide, new look at the language that was approved in March 2012 commit states from within six months of the acute 213 or encephalitis Otis try to get consistency between both parts of the definition of chronic [Indiscernible]. Expended show that it was the first symptom of the initial onset or first Onset of significant aggravation.

[Indiscernible - low volume] language as well?

Yes. The other modification to the language concerns [Indiscernible]. Again in keeping with the good of the guidance FSBOs the proposed modification would make the definition [Indiscernible - background noise] because there were exclusions that were approved in March of 2012 we wanted to explicitly state that if culture [Indiscernible] testing was performed of the viral illness which should be the vaccine strained [Indiscernible] and the [Indiscernible] would remain in effect.

Finally, the last modification was regarding the [Indiscernible] definition. Wanted to make sure that when and it was clear that we mention infection it was mentioned for [Indiscernible] in the upper arm because the needle used in an intramuscular [Indiscernible] is longer than it is used in [Indiscernible]. An intramuscular infection has just if the vaccine is incorrect whereas the same would not be true for to back. We wanted to clarify that, that was what the intent was.

My last but, once to make sure there were no questions or anything. I am asking ACCV concur with the modified language to [Indiscernible] work to do not concur with the recommended modified language?

This is a question for clarification. It is the next to last like talking about [Indiscernible - low volume], the modified language would include only intramuscular administration in the upper arm. That would not include the subcutaneous injection was given incorrectly.

Correct because the science support that intramuscular injection would cause the injury.

[Indiscernible - low volume]

Infants, [Indiscernible - low volume] injections in the five but this particular injury, shoulder injuries [Indiscernible - low volume].

[Indiscernible - low volume].

Dave King speaking. The course of action is to concur with the recommendations or to not concur with the recommendations. When we approved of these in March if I'm not mistaken we went through each one individually to give our approval. I would suggest that if we want to proceed in move forward here, that we go through each one individually again. This way it maps to what we did in March of 2012. I will say that March 2012 was an awfully long time ago and that we would certainly want that things move along in a much faster clip than what we have done here. I know you were not there so you are lucky.

[Laughter]

It would seem that somehow, someway, somewhere along the line something broke down in terms of this being processed and being done in a timely fashion. I think it goes without saying but it should be said also so the chair asks. Having said that, I guess we need to work our way back. I think before we do that, think it would be appropriate that the group took a break first before we came back because I do not know how long Warwick conversations will be around that that I think that a 15 min. break is a warranted for everybody. Does that make sense?

Certainly. Would you let me just which led me to leave this slide up?

Yes. We are on a 15 min. break. Thank you.

[The meeting is on a 15 minute break. We will reconvene at approximately 3:05 pm ET. Captioner standing by. Thank you.]

[Captioner's Transitioning] [The meeting is on a 15 minute break. The meeting will resume at approximately 3:05 ET.]

I have unmuted line. We are reconvening after the break. Where we have left things off was that the last slide up on the screen was -- we had some options in front of us. Those options were if I can get to my last slide because we keep switching them around -- to concur with the recommendations or not concur with the recommendations. I submit that while effectively it may not be concurring with the recommendations we could also choose to absolutely do nothing. We don't have to go on record as being in favor or against it would just let things be where they are. I ask a couple of questions first. Those questions would be what happens if the commission simply passes and does nothing right now?

I guess we'll have to evaluate that. It's not any review that the must be first provided to the commission a copy of the proposed regulation or revision requested recommendation and, by the commission and a fourth commission at least 90 days to make such recommendation are you essentially your commission would be that you are not making a recognition? P I'm saying it is an option for the commission to choose to do nothing but that it would fall within the purview of the 90 days to request being made and you have the timing so the secretary

could just move on and do it the secretary wants. Spec that this is Charlene. I would not want to be part of a do-nothing commission.

AQ Charlene.

I would be too embarrassed.

I was touring out the option.

And I'm throwing it back.

Slam. [Laughter]

[Inaudible - multiple speakers]

I have another clarification question. That has to do with if the commission does not approve, and the language be changed anyway? Or -- in other words whether we approve or not or do nothing even though Charlotte will not allow us to happen, could the wording be changed anyway?

If you decided to say we don't recommend you change it?

Yes

Yes

Wording could still be changed anyway. Spec back it could.

Historically do we have I know from the March 2012 do we have a record of that but we do not since never moved forward. But in the past has the wording of the ACCV been accepted or been changed or do we know?

I do not know the answer to that.

I would have to go back and look at the previous two meetings of the table.

[Inaudible - low volume]

I don't know if it's worth doing that. I don't of we should ask you to do that.

Clarification. The multi-pretty colored version of the final draft proposal for comparison for ACCV the competition of the table is not yet currently in the law?

No. This is what is the changes we are approved in March 2012.

Where is it? I itches and proposal because it hasn't been made into a final rule. The current stable -- the old table is what is the current table in use.

So the plan would be that this is to mirror. The plan is that all the changes proposed in March 2012 and back in December and potentially these changes are being proposed now be part of one comprehensive proposed rulemaking to make changes to the table? Is a plan?

Point of information. And I do think -- we may changes or proposed changes in 2012 -- the commission did. If we are proposing -- and that was related to wording as well if I'm not mistaken. He proposed to add things and the wording was given to us at the time as well. If we are adding or changing wording, are we in fact changing but we had originally proposed?

Is presented to you because there were some changes proposed to you to make sure you are okay with those proposals.

I'm not sure I understood what you just said. [Laughter]

This is Charlene. Most bodies tend to operate on a unanimous ascension. Not everyone has to do so can be an up-and-down vote.

We don't have to have concurrence across the board. Great. Do we have and got to the vote.

But that is the point. Let's not. And if it doesn't pass

We're so doing some clarification points. I just want to be sure from what Andrea just said that what we have proposed -- we have proposed changes to proposed changes. Is that all we really have?

For more clarification to the proposed changes. I guess it's not that the whole entire proposal is being dramatically changed. I think there is some clarifications of the program believes are actually beneficial. They want to have the ACCV blessing considering the statute requires

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That we make a comment on or least implies that we should make a comment on it. And we choose to ignore it but we've already determined based on Charlene's input that that is not going to happen. [Laughter]

Thank you.

If I understand what if a lot of part of the table is what is operating right now?

Correct

In 2012 changes was triggered by the fact that there were a number of the effects of the different added vaccines added were not clarified and so the 2012 put in several of those. The virus et cetera.

Could you repeat what you said

In March 2012 changes were triggered by the recommendations that came in -- were triggered by a whole number of defining what injuries would be for the newer vaccines.

I believe so yes

And now we are basically looking at right now for this new changes that 2000 2014 -- and the changes are basically an edit of the 2012?

Correct.

We are just editing the language subject in your predicate and all agree with

That is correct.

And this is come through the department. A look at it and said hey as you were writing or this was being put into its more final format to actually go out to proposal able said it probably could be worded better. Is that what happened?

Not at that level. Use of the program level and going to the final review we -- in that chronic encephalopathy definition that one way to find it in one way and another section said it differently so we're trying to harmonize the two to make sure that everything was consistent. It really was in the final year of the program that we found these editorial things that needed to be clarified. But statute said that any changes that were proposing to do and we would want to have reviewed by the commission and bring to you to have those present them to you and have you recommendations. Whether to concur or not to concur.

Perfect. Okay. I think the chair believes we're not ready to proceed. So in order to do that we decided we would go through the one by one.

We need to have assigned numbers again. Spec back slide number 40

This is the first QAI change. Here would be of like it. Proposed modifications to clarify language in the QAI. It's slide after that.

Is on the blue color coded as well in here? Spec back but we in the blue color coded in March to 12 that is that like which.

We can look at the section where we are making the change and work from there. Perfect. Thank you.

The motion that we need on the table I guess is to make a motion to modify the language in this specific -- we have a title to it?

Plug-in or find another power source. Are you plug-in? The power suppressor might have been hit. Does that work? Make sure the server suppressor do not get attached. Spec back everything is in there. The phone the projector. Everything would've gone down

Is there a specific area -- when we look at this we all look at this is there something

Look on page 5. It is the QAI for encephalopathy I I I. The one that says regardless? Spec no bonuses underlying condition.

Does everyone have that?

Is there a motion?

I move that the proposed changes be adopted.

For this specific language related to encephalopathy.

I second the motion

The motion seconded. Is there any discussion?

Comments?

Vote. All in favor -- let's do a roll call vote.

Ann we know you cannot vote. We will start with short -- Charlene.

Yes

It is an abstention.

Sylvia

Yes

Shall

Yes

Kristin

Yes

Dave King is yes

Let's go to the next one.

I make a motion that the proposed changes for chronic encephalopathy -- this is Charlene -- be adopted as presented.

I do so everyone knows that the where we are on the color-coded we're moving from one to the next if you can identify that for us please

Section page 8.

[Inaudible - multiple speakers]

Two separate slides. If you look under the middle of page 8 chronic encephalopathy small I small to the change Ms. for both.

We have a motion on the table. Do I have a second next

I second

The motion is seconded. Again we will do a roll call vote.

And do in the same order that we did last time. Charlene yes

Transcends abstain

Michelle? Spec back yes

Kristin spec yes spec back Dave King is yes

I make a motion of the pro-changes for double-sided Punic purpura be adopted as presented.

Is there a second to the the motion

Isn't that a songs?

[Inaudible - multiple speakers] [Laughter]

If you could highlight status the area

That is on page 7. Just so everyone knows

Near the top of the page and numeric number seven.

Let's do a -- is there any discussion?

No discussion. Let's move to a roll call vote.

Charlene yes

Ice B Ed's yes spec Sylvia yes

Michelle yes

Kristin

Yes

Dave King yes

Be advised that Ann was not allowed to vote .

Finally I make a motion that the QAI change is related to shoulders injury later to vaccine in ministration be adopted as presented.

Is there a second spec

Second. Spec back is there any discussion or conversation?

Is a to assume that is on page 7 as well ask

You are correct. Page 7 number 10.

Rollcall vote. Charlene?

Yes

Yes

Yes

Sylvia yes

Shall yes

Kristin's yes

Dave King yes

Thank you. That concludes. I like to thank you and the commission for allowing us [Inaudible - multiple speakers] [Laughter]

Thank you. The next item on the agenda is the report from the department of justice. From Vince Malinowski come on down.

Good afternoon everyone. I'm pleased to be here. Thank you welcome Mr. chair. This won't be nearly as exciting as what you just went through.

Give it a chance

[Laughter]

I will try to remember as I go through the slide to identify which like I am on.

Moving from the first slide to the second, here we set out how many cases we received in the reporting period. There were 168 cases received. We are on track as I mentioned in the last couple of meetings where going to be over 500 cases for this year. Well in excess of 500 cases as it turns out. For this fiscal year. As I mentioned before I see this as continuing and not as an aberration. In fact I would say we're probably going to continue to move up and maybe pass 600 in the next fiscal year. From what we're going to see the driving factors for this seems to be the flu most of these cases are related to flu vaccine. A fair number are GBS cases but also now we're seeing a lot more SIRVA cases. I think we're going to continue to see this pattern . I also see a much more active petitioner's bar that are out there and so I think that maybe another driver for why our cases are up. One of the things we aren't seeing is I mention this right now because going talk about appeals cases you're going to hear me talk about a couple of time-barred cases. We're not seeing are many time bar cases. I think that is probably due to in part to the fact that there isn't much more active petitioner's bar. There are a lot more resources out there informing essential petitioners of the availability of the program. In addition to this method that were already out there before like information sheets. Spec that question

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Dave King speaking. When you last presented you talk to us about the fact that it appeared that were going up and we can see that things continue to go up and you truly believe that in the future it is only going to get -- certainly going to sustain being where it is. And the question has come up on resources and we need to allocate additional resources to be able to manage this workload? Until I'm trying to find out as any conversation has begun to take place occurred about what you may need to do to apply additional resources to this? Spec yes much care there has. We have been of course -- we have to make do with what we have by way of budget we also have to be imaginative and find new efficiencies and how we work through our cases. But resources there have been discussions and efforts are underway to try to secure additional resources. Spec back great

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Breaking down this cases just to do the rough math there are about 80% of our cases -- actually more like 75% -- that come in are from adult petitioners. That is petitioners who are over the age of 18. Or 18 and over I should say. Turning to my next slide slide number three, this is a breakdown of the adjudication that we had during this reporting period. I always like to see the adjudications at least match if not exceed the cases coming in because that means that we are working through

some of the cases that are pending and you see less backlog of cases if you will although we did 152 adjudications is really a very significant number. I will put that into context in a moment. You can see that that's actually a few less than we had come through the door. The trends that you don't want to see continue over the years. Because that will just increase the number of pending cases continues to expand. But to put this into context 152 cases would average out to over 600 in a year adjudications. Previously from 2009 until a year ago we were seeing on average 400 cases per year. So sad cases being adjudicated would actually mean that we are adjudicating more than we have coming in. But again the numbers coming in now have really moved up. I'm really pleased that we know through one of the two cases but it's something that needs to be monitored and watched to try to make sure that that difference does the delta between the two incoming and adjudicated doesn't go to grow. Within a breakdown of the cases there in terms of commentated and non-compensated, about two thirds of the cases received compensation. Of the ones that were adjudicated in this period. By far the majority of those received compensation through settlements.

Moving on to the next slide slide number four. Nine cases were voluntarily dismissed in this period. And if there are any questions at any point please don't hesitate to ask.

Slide five. Appeals. There was one appeal that was potentially pending at the Supreme Court was Tim Bennis. That was the case involving the damages issue. The issue in the case was whether or not the estate of a child who had died of the vaccine injury would be entitled to receive compensation from future lost wages finding of the Federal Circuit was that the estate would not be entitled. The petitioner in the state in that case moved for or filed a petition for to the supreme court decided not to take the case. Which is not uncommon. Most cases that go through the spring court are not granted.

I caveat when I talked about incoming cases that we really don't see that many that are time-barred. I thought that was important to caveat because I'm going through appeals going to talking about three cases that have the time bar issue on appeal. It's a little bit too we saw in the appellate in terms of what we decided was little bit of aberrational in terms of time cases that we have coming to the door. Those cases actually were from -- filed five or six years ago. So they are not really what we're seeing coming in.

The first two cases on slide six graves and praise or both cases that were deemed to be time-barred by the trial court. In fact when they were appealed the pills were filed late as well. So the cases were affirmed by the court. The Federal Circuit and the procedural reason that they were filed too late. I should think that was the primary reason that they were affirmed. It feels themselves or filed too late. The case do bread give found by respondent that was a face case that involved a decision by the trial court that the petitioner had not established actual causation. That was reversed on appeal to the Court of Federal claims. Respondent intern appealed that decision for federal claims decision to Federal Circuit. Arguing that the judge at the federal claims had not used the proper standard to violate the decision by the special master. That is the judge had in fact applied her own fact-finding without giving enough discretion or deference to the trial court fact-finding. There was a limitation as far as the appellate court whether they can fact-finding or not. The rule being that they can't end up doing their own fact-finding unless there is a legal error by the trial court judge that was the issue on appeal. The Federal Circuit agreed with respondent and reversed the decision of the Court of Federal claims.

Turning to slide seven. Those are pending cases. There were no new cases filed at the Federal Circuit during this period. At the Court of Federal claims we had two cases of recently decided. The first was best that was a case where essentially the trial judge found that the evidence of the experts presented by respondent were far more persuasive and reliable than the expert presented by the petitioner. Develop petitioner had not prevailed in establishing actual causation in the case. The Court of Federal claims agreed with the trial court judge. In Scanlan this was a case involving attorneys fees. Scanlan had -- that involved a case of vaccine that was not covered by the vaccine injury compensation program. Ultimately the underlying case was dismissed. However the petitioner's counsel sought attorneys fees for bringing the case. The trial judge found that there was no reasonable basis to bring a case for vaccine that was not covered on the vaccine table. That went up to the Court of Federal claims in the Court of Federal claims reversed essentially saying that they weren't clear enough that it wasn't covered because there was a pneumococcal vaccine that is covered and there is one that's not covered is not necessarily clear to the petitioner's counsel that it was not going to be covered. The adults not covered but the child vaccine was covered. Because of the decision -- one part of the decision focused on how much judicial

precedent was out there to establish the default vaccine wasn't covered. This probably won't be repeated because now there is reported or a case that the Court of Federal claims the decision saying not the vaccine is not covered so the search counsel that's not a covered vaccine and the silly [Inaudible - low volume]

Move on to slide nine there were four new cases filed at the Court of Federal claims. Install the was a case of time-barred case involving a claim that of an time-barred and that's why I'm again preface my comments before because it seems we had several that involve the time bar issue. Interestingly the special master not only found the case was time-barred but when into the underlying theory that a been presented and said that the theory would not have prevailed either. Three of causation without of sufficient. In some ways I guess it's a way of reassuring the supposed petitioner that it was a display coming to the program but it really wasn't a good basis at that point to bring the case. The mostly case involved tennis toxoid vaccine and an allegation that that caused transfer smiling us. Special master found that essentially what happened was transfer us my latest can appoint a after vaccination special said that is actually too soon to occur from that kind of injury. It takes time. The medical process for Tooker takes time. It has to been essentially caused by something else. The Godfrey case is hepatitis -- I'm sorry it is HPV vaccine human papilloma virus vaccine. And manager, vaccine -- meningococcal. These two vaccines caused juvenile rheumatoid arthritis. This was another instance like the AST were special master found that the experts responded though she was a battle of the experts in special master found that the experts at responded were more reliable evidence was more reliable than a petitioner's expert. Harris was a case involving HPV vaccine and lupus. The petitioner in that instance the trial court found that Mr. failed to establish that HPV axing can cause lupus. They've not made that initial showing that theoretically possible for it to cause -- for the vaccine to cause lupus. In addition the special master but on to find that there was evidence in the medical records that the petitioner had actually suffered or was beginning to show symptoms of lupus prior to vaccination. So there would be another grounds for no conversation in that case.

Moving on to slide 10. He said there is no -- when we prepared this a couple days ago there was no cases scheduled for oral audit at the time. Yesterday: -- AOE HN at the Federal Circuit was scheduled for argument on October 7. Moving on to slide 11. These are the adjudicated settlements which we primarily review at the

commission to determine how quickly our settlements moving through. There were 90 settlements in this. It's really a striking number of settlements for us in that three-month period. It is continuing on a trend where we see more cases and more cases being settled. The breakdown and we usually do a breakdown how quickly have removed through into categories of within a year or a year or less cut two years or less country years or less, and an greater than three years. The total number of cases that we had that were in a settlement achieved within one year of the date of being filed was 40 cases. That represents 44% of the cases that were settled in this period. Moving from one year to two years, so greater than one year but less than two years, there were 30 more cases that added to the total. From setting another 33% of the cases settled. So essentially 77% of the cases settled within two years. Going out three years another 10 cases which is another 11% bringing us to total of 80% within three years. Finally at more than three years we have another 10 cases again roughly another 11% of the total. Looking back I check back to see what is happened in the last several reporting periods to see if we were following the same trends or not. We have always seemed to be within 80 to 90% of our cases settled within three years or less from the date of filing this is a good total. Why have seen is that cases that are extending out past the three years sometimes we see cases that were nine or 10 years and we are not seen as right now at least in this period. Some say that there aren't some out there but most of these cases were four years and even the talent of the.. We're staying within that 80% to 90% range. Even though we've actually adjudicated or settled a large number of greater number of cases in this period than previously.

This is Charlene. What do you account for such a big difference. Historically it was a very protracted process. What account so she can't just be more people spat back is not more people. In fact we have the same number of people doing more work and that's true in not just for me justice but in other places as well. We've gotten more efficient for one. It's just my own thought and sharing the burden of my fault you. -- My thoughts with you. We've learned some efficiencies. Some of the cases are similar. It doesn't need to be as protracted when we see the same injuries. Each case can be a little different. There can be a little variation in each case but if it's a fluke GPS case or a SIRVA case for example there are going to be certain patterns and develop so it's easier to assess the overall exposure and how much is at stake in the case to the negotiations can move through towards settlement. They can move through more rapidly. I know the court has valued

living through these cases quickly. And has undertaken many efforts to make sure that the process moves through smoothly. There are sticking points. The court makes itself available for mediation. Parties sometimes engage in court mediation or the engage in mediation with private mediators. As if there are sticking points. But generally there are some fairly cooperative air that has pushed Harmon of justice with the petitioner's bar in trying to work through the early identification of potential settlement cases that's another big step that we've taken where we identify cases early on to determine whether or not they are likely to be candidates for selling. Talked about that fast track settlement process before. That takes out some of the procedural steps that could slow things down. And moves the case along to settlement much faster

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It is been -- though steps up and very help. Why did notice an imposter. Is that we had more cases move up to one year or less than we had as a percentage of cases that were settled. 44% of the cases settled in a year or less. We jump around with that number but that is the highest I've seen in terms of the number of cases within a year or less.

Part of it is I have trouble with her memory all the legal process but what is your sense of how many of the settlements are based on injuries that's the first part and the second part is the fact that there has been some recommendation from 2012 or a C there's a lot of SIRVA on here . Is that fast tracking some of those that have not been officially approved or

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Dealing with the first part of the question. Few of these -- I'm not certain exactly take a quick look but I don't think that many of these cases we would've been -- two of these cases would've been cases where to permit health and human services received title mid. Generally this because they make table is possible that it could be actual causation because there may be a case for example of SIRVA right now that I tooting on the table the department of health and human services they deem that is an established actual causation and can see the case even prior to being on the table. So to those 90 cases that the majority of the cases as you can see cases where there is not a defining 15 on the table. As we move these injuries on the table will probably see a couple more make their way into settlements as well. The second part of your question -- can you remind me next

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In 2012 we reviewed the island recommendations -- island recommended certain change to the table that we cannot haven't really officially taken place. Does not have any influence on your process?

It does. Thank you for reminding me. I think I mentioned last time in a discussion that the chair and I were having about what happens to disk is aware contemplate them being on the table. You are not going to see remarkable change when it makes on the table because if the change a number of cases that are, then. Not going to see a jump from two thirds were compensated of cases that came to the door. It not going to see that job to 100% of cases going through the door because there is already the parties already preparing for that eventuality. So cases end up receiving some compensation based on these recommendations that the table be changed. So you are seeing cases that are -- is affecting cases being comforted now of course everyone would like to see it move through to the regulation and then be put on the table. I imagine it could confirm that if you have, but there's a reality that's taking place when you see the regulation take effect.

Thank you

Question. You know it was coming.

We have these settlements but as you get more and more cases being addressed and filed, this tells us what is being settled the only cause what's open. What is the number that are out there open?

I think we're in excess -- iPod as I should have checked on that. I'm pretty confident we are in excess of 1000 cases pending. Which is why it would be nice to have worked for the cases coming in and 600 going out but it's not happening that way. Spec that you have the opposite thing occurring here.

That's why noticing. This is not going to guess -- this is a potential I know we're in this age 90% but those might be because of the reasons that will continue at that pace but we have a bigger problem where other things could drag

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Exactly. I haven't seen it happen yet. And it actually would expect that we are going to see it if the resource state as it is I would predict that would see creeping

into the process in times because you just can't -- wear to the point where we can't squeeze very much more out of in terms of efficiencies where we are running out of the efficiencies we can find at this point. What these numbers don't show -- there are a lot of people who are involved in this process. Several of the folks there several of the organizations involved are fixed -- fixed by budget. HHS, department of justice. When that happens more work comes in -- we find efficiencies and we do it we can but to get to 152 adjudications with the same number of individuals involved same amount of resources and yet more work because there are -- you don't see the file number doesn't tie you all the other things involved to get to the phone number. The of 600 cases coming in there is just a lot more work to do. But what you don't see is the amount of effort and work that's gone on. I have to say I take this opportunity publicly to acknowledge our recognize the court, HHS, there are many folks working very hard and certainly my folks at DOJ working very hard to get those cases to move them through even in light of the additional work. We don't have a column there for missed soccer games or dinners out of the microwave that's part of the reality of the time numbers.

That's it for my report. And having to take any questions.

Does anyone have questions?

Well done. Thank you very much.

[Applause]

The next item on the agenda is the VICP outreach program. I don't know if I said quickly Captain Narayan Nair. You can always come to me when I get it wrong. Spec back

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These sites are numbered.

Thank you.

We need that at the stage of the game.

Welcome. Congratulations.

Think of the opportunity to speak. I will say that my presentation actually is relatively brief. Just starting off what I was going to talk about is some historical background on VICP and outreach am going to talk a little bit about our outreach strategies and then finish up with recent activities as of the coming future activities that we have planned. As of the end is a replay of time for questions. I do want to preface my remarks I'm going to use the language of we and things have been encompassed. But for the most part I am new here. Today's my one month anniversary. So we doesn't actually physically mean myself. And other folks about work on this I want to college to numbers of the team committed Karen Williams and Shirley Jones have been working on the outreach with me.

Historically since the inception of the program outreach is been an important component in the national childhood vaccine injury act of 1986 is the secretary should undertake reasonable efforts to inform the public about the veil ability of the program. To that end we formed to groups one is the outreach worker which was quite active between 2009 and 2011. The number of recommendations that were implanted. The second or group is committee case and liaison and outreach group. As a staffed from within herself and her focus was really on correlating a presence at exhibits and presentations professional meetings.

[Inaudible - low volume]

Department of justice as well. Spec back

As an offshoot of these workgroups and based on their feedback a contract was issued to any medications is coming that specializes in medications and they developed a marketing and to medications plan for VICP and results of their research was presented to ACCV in 2010. A lot of what you're going to turn terms of our strategy really came from their recommendations.

I wanted to outline the purpose of our outreach efforts and its twofold really to increase awareness about the veil ability of VICP and increase knowledge about how the program works. And also want to develop partnerships with organizations that facilitate dissemination of our message.

How are we going to achieve these purposes? We have broken down into internal strategies where we think of organizations within herself and want to identify and engage HRS a euros and offices and levered partnerships while his practice in my presentation is an exploit partnerships in my way for me that sounded creepy. So I put in leveraged. [Laughter]

HRSA in the birth of the number of grants that it issues to different organizations and I listed a few here of potential grantees that we feel provide an opportunity for outreach. Committee also does there are 9000 committee health centers across the nation that serve 21 million patients. We think as transiting committed to those health centers we conclude messaging. The maternal infant early tablet home visit program is a program where Dammons invites grants for home visits for at-risk children and infants. And we think there's an opportunity that we could potentially explore with them. And healthy start program which is a program that provides grants to committees that have a high if mortality. These are all potential opportunities that we're looking at exploring in the future. In addition to our internal strategy where also looking at external strategies to sustain partnerships with other HHS government agencies professional organizations. Academic organizations and so forth. We want to search out topic specific meetings or meetings that may have an audience with a particular interest in vaccines and promote VICP at these types of meetings. Worked with our office of medications to develop relations with the media. And we want to develop and disseminate wet outreach material newsletters and social media post in those types of things.

I wanted to talk about what been doing recently. We have a toll-free number that the public can call us at any time and respond in a timely fashion to inquiries. We also respond to written inquiries whether they received by email or through the Postal Service. And then we do inquiries from the media who had a few in the past few months where we provide information to various media outlets. In addition when senior leaders from HRSA such as ours going on speaking to large groups we went appropriate would provide them talking points for the highlight VICP. A few months ago Wilson provided to John Hopkins University and that was some of their future health policy position makers the summer area particularly local academic institutions nursing schools schools for nurse practitioners pharmacist docents for Patricia we think we can reject students and have them early on before they are in practice understand VICP and the components of our program

I went to finish up with some of the things we have lined up for the future. And really outreach as described in 1986 is very turn the front outreach in 2014. The Internet is obviously a private component and its the face of the organization. We had a communication specialist from the office communications section X bite -- expert on the website look at our website objective in critique it. Based on their feedback we're going to upgrade the website and make navigation this is the Dammons a website and create a more user-friendly content. Back they gave us they said they found the website has a lot of useful information that there were some areas where for improvement. But the content was somewhat difficult understand. In some cases the language wasn't certified. We don't have a lot of supported graphics on there. It wasn't clear from the reviewer's perspective whether the program actually provides competition to adults. Your precipitate adults are mainly many of our petitioners.

Some of the future activities aside from the website are looking at are bogus and brochures and necessary were going to revise those again trying to hear to these plain language principles. Try to identify the media in terms of blogs freelance writer sites and other social media or perhaps we can do some outreach directed to them. Were continually looking at partners and asking them when appropriate to include our message in their medication vehicles and outreach activities. And then a key component really for the success it that we view is developing process measures to evaluate our effectiveness. For each activity we hope to have a bit of five metric something where we can quantify whether it was effective or something we should continue to do or whether something we should shift and devote resources to some other outreach effort.

That is all I had. I would be happy to answer any questions if you have any. Again takes again for providing me the opportunity to speak. Spec back under any questions

This is Michelle. I don't have a question but I know that one of our past commissioners was very interested in this. I spoken to her recently and she would be pleased to be a resource. She's a parent of an injured child. She went through the program and she would be happy to be a resource to you as you go through this. I think we on the commission have always found her comments to be useful.

Thank you. that Amos layer because I think -- that name is the layer because I think she led an effort and so I went through the minutes and yes Thank you. that.

Any other questions or comments?

I have one other comment. I have gone through a number of other injury compensation funds websites. For instance the Ground Zero one and there are some others. There really are some very good models out there for website information. I know ours is a good website but there are some graphics and charts that I think might be useful to be looked at and maybe you already have done that. I just googled injury compensation fund and you'll get 10 or 20 funds always websites. Spec back was there when a particular user Ground Zero you thought was particularly effective? Spec yes I thought that was a very good one.

Thank you. That is for helpful.

Anyone else?

Thank you.

The next item on the agenda is public comment. Spec back

Does anyone want to give public comment is there anyone on the phone line who would like to connect in and make a comment or two?

As a reminder on the phone lines if you would like to make a public comment press*one record your first and last name clearly at the prompt. Again*one please be sure your line is unmuted and him record your first and last name clearly at the prompt

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Is anyone in the queue?

One moment please. Teresa rank him.

Thank you. Good afternoon. I am three set rank him and say director for the national center. I'd like to offer a few public comments based on today's meeting. First I like to say it's a very nice that the ACCV could be in person I think it's a long

time coming. Certainly this committee should be meeting on a regular basis face-to-face as do many of the faxing policy committees like the ECA a national vaccine advisory committee. I hope that future budget allotments will acknowledge the importance of the commission and budget appropriately for travel and meeting face-to-face. With regard to outreach I would not that the Banyan report was issued in 2010. That specific report was on the heels of an altar and study. There were some deficits in both of those reports and recommendations in terms of outreach. I think it was really not mentioned today but certainly merits further investigation. In terms of public awareness the Banyan reports adjusted that television advertisement mailings public service announcements, should be considered given the low awareness the public has of the VICP. And so I was working with vaccine watchdog organizations such as ourselves what also note that the report of the permit specific recommendations with regard to satisfaction of petitioners of the VICP process . Because so much time had elapsed when petitioners were queried the response was very low. I would encourage that the satisfaction survey be done on a regular basis when there is our fresh cut when people can be easily gotten hold of. Certainly there can be a sharing of information amongst those involved to make that happen. So we have a better understanding of satisfaction of this program. With regard to the discussion the commission had today on encephalopathy, I'm cognizant that it was a very thoughtful discussion that the commission gave a great deal of thought that I would also point out that changes over the course of time have taken place within the vaccine injury table that happen outside of ILM recommendations need to be weighed very carefully. The ILM has specific protections in place for public engagement transparency. They wait the weight of the literature on whether or not its epidemiology against biologic mechanistic data. They do quality assessments. It is unclear at least from myself when I watched previous presentations there was science presented I'm not aware of that sort of approach when changes are undertaken outside of recommendations of the ILM. I would sit opposed to the change that's a place overtime with regard to set encephalopathy. Coming to know and shutting the door on too many that require compensation. And that will conclude by comments for today. Thank you.

Thank you. Are there any other comments?

There are no other parties in the queue at this time. Spec back anyone in the room

There being no other comments then we have come to the adjournment of day one which essentially we are in recess until tomorrow beginning of the meeting. It starts at 9 AM tomorrow so everyone is aware. Nine and start to the meeting tomorrow. And having said that I don't meeting I need to take emotion because we're not really ending the meeting we're just taking a long break. Everyone have a good evening. We will see you all in the morning. Thank you. Goodbye

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[Event Concluded]