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Health Resources and Services Administration

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Health Resources and Services Administration

Advisory Commission on Childhood Vaccines

9/3/2015

Herzog, Andrea (HRSA)

Submitted by: ***Chris Williams, Adobe Connect Team***

September 3, 2015

ADVISORY COMMISSION ON CHILDHOOD VACCINES (ACCV)
Parklawn Building, 5600 Fishers Lane, Conference Room 10-65
Rockville, Maryland 20857
Teleconference and Adobe Connect
September 3, 2015
(9:00 am – 2:30 pm Eastern Daylight Time)
Dial in: 1-877-917-4913
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Time	Agenda Item	Presenter
9:00 AM	Welcome and Chair Report	Mr. Jason Smith, Vice-Chair
9:10 AM	Public Comment on Agenda Items	Mr. Jason Smith, Vice-Chair
9:15 AM	Approval of June 2015 Minutes	Mr. Jason Smith, Vice-Chair
9:20 AM	Report from the Division of Injury Compensation Programs	Dr. A. Melissa Houston Director, DICP
9:50 AM	Report from the Department of Justice	Mr. Vince Matanoski Assistant Director Torts Branch, DOJ
10:20 AM	Report from the Adult Immunization Workgroup	Dr. Sylvia Villarreal, ACCV Member
10:40 AM	Break	
11:00 AM	Discussion of Follow-up Items from June 2015 ACCV Meeting -VICP Administrative Funding -Prevention of SIRVA	Mr. Jason Smith, Vice-Chair
12:00 PM	**Lunch**	
1:00 PM	Update on the Immunization Safety Office (ISO), Centers for Disease Control and Prevention (CDC) Vaccine Activities	Dr. Tom Shimabukuro CDC

Event: Advisory Commission on Childhood Vaccines

Date: 9/3/2015

Event Coordinator: Herzog, Andrea (HRSA)

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Title:	**Advisory Commission on Childhood Vaccines_11**
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Recording Date:	**09/03/2015 8:29 AM**

Attendees

ACCV

Allison Durham

Amy Walker

Andrea Herzog

Annie

Caption Colorado

CaptionCO

Captioner

Cheryl Lee

Christopher Williams

Emily

Joe Anderson

Karin Bok

Marco Melo

Mary Rubin

Qaiser Sharaz

Sylvia F Villarreal,MD

Theresa Wrangham

Chat History

N/A

Polls

N/A

Q&A

Q/A Done Over the Phone

Transcript

Event ID: 2706437

Event Started: 9/3/2015 1:00:00 PM

Please stand by for realtime captions.

>> Thank you for standing by. Welcome to the 97th quarterly meeting of the advisory commission on childhood vaccines. This call is being recorded. If you have any objections you may disconnect at this time. I now would like to turn the meeting over to the ACCV vice chair Mr. Jason Smith. Thank you so you may begin.'s eMac good morning everyone and welcome to the 97th quarterly meeting on the advisory commission of childhood vaccines. If we could I'd like to take a roll call of all the commissioners and the room and also on the phone to the extent of the commissioners styling and this is Jason Smith and I'm vice chair and I'm the in-house counsel advisor.

>> [Indiscernible]

>> And I'm a disability advocate.

>> I'm: Beth Lucy a nurse practitioner from Utah

>> [Roll Call]

>> Sylvia can you introduce yourself first and will continue with other members.

>> Sylvia via hell out of -- Sylvia out of Taos New Mexico.

>> [Roll Call]

>> So again welcoming good morning. For the chairs report a couple of quick items as you can see Kristen our current chair of ACCV could not attend today's meeting so I will be filling in as chair for this meeting. I will do my best to fill her shoes in her absence. I want to take a moment and extend a warm welcome to all of our new members on the commission and on behalf of -- behalf of all the commissioners will accord to working with each of you and thank you for your service. I also want to thank outgoing members of the commission including David Kane, Michelle Williams and thank them for their service and their advocacy as well. This is the exciting day and it's been a while since we met as a commission in person and we know getting some opinions expressed over the last couple of meetings and live meetings provide an additional opportunity to enhance the effectiveness of this group and we think everyone and Melissa for allowing this opportunity to happen even though we are facing budget and fiscal constraints. Were appreciative of this opportunity. When speaking on the record its best practice that for those participant on the front it would be helpful to introduce yourself first and offer your comment on the item that's been discussed.

>> At this time, one other point I'd like to mention and I had a conversation with Charlie before the meeting started ends when were engaging in any discussion when we started a couple years ago is commissioners that came in there were a number of questions about so many of the different groups that help support the program. And if there are questions about an individual role or an agency's role please we welcome those questions and conversations and are an important

part of today's meeting as well. Please take that opportunity. At this time I would like to invite public comment on the agenda for today's meeting and please note that this portion of the public comment section relates to the agenda items only and to the extent that someone has a comment generally speaking we are going to reserve those for the end of the meeting. If there is anyone in the room or operator if there is anyone that has a public comment on today's agenda item could you please open up the call for those comments.

>> Crystal are you there?

>> Yes sir to ask a question or make a comment please press*one and that will put you into the question-and-answer cube. Again just record your name and its star one to make a comment.

>> [Silence]

>> Crystal has anyone entered a queue for pump -- public comment?

>> There are no comments in queue at this time.

>> Thank you very much.

>> At this time I would like to move to the review of the agenda from the prior meeting in June 2015. Do any of the commissioners have any comment of the meeting minutes from the June 2015 meeting?

>> [Indiscernible - Low Volume]

>> The last meeting in June was by telephone conference -- conference and WebEx.

>> Do I have a motion for many of the commissioners?

>> All in favor of the motion?

>> I

>> Thank you the minutes from the June 2015 meeting has been passed.

>> Can we have a reference here that this was a telephone conference? Because sometimes that makes difference. If we could just say how we are meeting in the minutes thank you.

>> Thank you. Before getting started today with the next item on the agenda I understand we have a guest this morning that new chief special master nor back Dorsey. And would you mind coming up and introduce yourself and I understand you're going to give us an update.

>> Thank you for asking me to introduce myself and I met some of you yesterday. I'd only been on the job for three days. [Laughter] anyway I am honored to be here today and it is wonderful to put some faces with names that I have seen and I just told Dr. near that and Dr. Houston I seen your name and it's lovely to see everyone this morning. We have at Digital conference coming up September Digital conference coming up September 23 and 24th part of it will be before the afternoon and part of it will be the express club [Indiscernible - Low Volume]. We've got a great panel lineup from trends and programs and we invite all of you to come and possibly see the [Indiscernible] during that time. [Laughter] if I can be of any service to you at any point in the future please contact me. Thank you so much.

>> Thank you. We will now move on to the next item on the agenda of the report from the division of injury compensation program. Dr. Melissa Houston.

>> Good morning everyone it is such a pleasure to see all of you here and new faces and faces that I haven't seen in a while. I'm very happy to see everyone this morning. I will begin my presentation and give you up to eight on activities from the division of injury compensation program some of the meeting highlights of today are receiving updates from our other members and they will update you on their vaccine related activities and we also have an update from the Department of Justice vaccine litigation office and we will have a report from this commission from the adult immunization worker.

>> This is showing you the number of petitions that have been filed with our program as of August 1, 2015. As you can see it's a busier. And FY 2014 we've had the highest number of claims filed with our program and based on 11 months of data it's been suggested we are past that high.

>> The next slide shows the number of adjudicated cases for the past 4 1/2 because it includes some of this fiscal year's data and to date we have had 455 cases adjudicated but based on 11 months of data we estimate that approximately 496 cases will be adjudicated this year.

>> This slide provides the breakdown for the adjudication category of claims for the past 3 to 4 years. If you notice the slide is updated as of August 10 where the previous two slides were of as of August 1. That's 10 Dade -- days greater and six more cases had been adjudicated.

>> As you can see from the slide it's just a snapshot of the amount of awards that have been given to petitioners and the amount of awards that have been given to cover attorneys fees and costs over the past system -- fiscal year. Based on 11 months of data it's estimated that

by the end of fiscal year 2015 approximately $205 million would be awarded to petitioners and $17.3 million to provided to attorneys to cover fees and costs.

>> As of June 30 this is the last day on the balance of the compensation injury trust funds and it stated that we have a little bit more than 2.5 $2.5 billion in the trust fund. The bold points beneath show the activity of the trust fund from October 1, 2014 to June $2.5 billion in the trust fund. The bold points beneath show the activity of the trust fund from October 1, 2014 to June 30 of 2015. As you can see an interest as a percentage of the net income is approximately 25%.

>> In addition to receiving -- in addition to us anticipating a record year of petitions that have been other significant activities occurring and the program. I am pleased to announce that the notice of proposed rulemaking for the vaccine injury table was published in the Federal Register notice on July 29, 2015. The public comment period has begun and is 180 days of public comment and the public comment period ends on January 25, 2016. Anyone is welcome to submit a public comment in the ways to do so are listed in the noblest -- notice in the Federal Register notice. If any commission members need a link to that please let us know and we will provide that to you. It was sent out in the meeting book but if you need it again please let us know and we'll be sure to provide it for you. There will also be a public hearing to hear any public comments that one would want to be provided orally. The date of that public hearing will be announced in the federal register.

>> This is Ed do you have any estimate of when this public hearing would be?

>> Not at this time but as soon as we have it in that data available and it's published in the Federal Register notice will be sure to send the link out to the ACCV members.

>> On a different subject I had a question about the award amount, I see that we have petitioners awards and attorney fees and I don't see anywhere, I'm an accountant's I might be reading this on. I don't see anywhere how much cash or money that goes out each year to people for example awarding for 2008 or 2009. Do we keep track of that?

>> Know the date we keep track of his won the award is made so that would be the year it was awarded. Even if someone filed a claim in a different your data we captured is the year the word is paid. -- Award is paid.

>> We can't and don't know we don't know how much cash was awarded in 2007? We aren't adding it altogether then?

>> [Indiscernible - Multiple Speakers]

>> This is Ed I think Martha is asking about people who received care plans and have payouts,

>> The lump sum and the annuity differentiation?

>> My understanding is in your case if it settled in 2009 with a life care plan that was purchased and annuity was purchased to cover the life care plan for the life of your child it's the purchase amount of the annuity that would be reflected correct?

>> Correct.

>> Those monies are almost like we aren't responsible for that anymore in these numbers.

>> This is Ed and their other people who can explain it.

>> How work for me is the government bought the one-time lump payment and then the company [Indiscernible]

>> So that is not reflected here in what time we bought it but it's done [Indiscernible - Multiple Speakers]

>> Yes that extends that once the government has made the award and once the government has purchased or paid the award that is what is meant by fiscal year so we don't keep her porting -- keep reporting that award past that fiscal year.

>> Flight eight now. -- Slide eight now. In addition to publishing we've been involved in several outreach activities and that's of interest to the ACCV and I wanted to provide a summary. We have partnered with the office of women's health in the FDA and they have whenever they attend meetings they distribute our material and the last media they attended was on July 7 through the ninth which was the national Association of County and city health officials. 1300 local health department leaders and public health partners participated. So information about our program is being made available through different avenues to the public. I also wanted to mention that we worked with the Indian health service and they contribute information regarding this program to 385 of its providers through their July newsletter. In addition the Bureau of primary health care and services administration distributed information about our program to over 5000 members of its mouth -- health Center program

in its July newsletter. I also wanted to make you aware of some upcoming advisory committee meetings. For the national vaccine advisory committee which will be held here in Washington DC on September 9 through the 10th and if you want the link it can be found on the web and if you want it emailed to you we can provide that information. And I also wanted to make you aware of the advisory committee on immunization practices which will be held on October 21 through the 22nd. Again we can provide you with a direct link to that advisory committee if you would like information.

>> Information on ACCV meetings, presentations and minutes can be found on the link below for those who are on the phone which is www.hrsa.gov/vaccinecompesation/commissonchildvaccine

>> And in order to submit a public comment or participate in our commission meeting please contact Annie Herzog at the park lawn building in room 11 C -- 26 this the 600 -- 5600 the 600 -- 5600 Fishers Lane. the 600 -- 5600 Fishers Lane, Rockville the 600 -- 5600 Fishers Lane, Rockville, MD the 600 -- 5600 Fishers Lane, Rockville, MD 20857 or by email at aherzog@hrsa.gov and that concludes my presentation and I'm available for any questions you may have.

>> Dr. Houston could you go back to slide three for a moment. For fiscal year 2015 with 597 decisions filed -- petitions filed as of August 1 what is the anticipated number that you project or can you project a number through the end of this fiscal year?

>> We found 11 months of data and we project there will be 651 cases filed however there have been a bolus of cases filed in August so I'm anticipating that will be a bit higher.

>> Thank you.

>> This is Ed and I have the same question, and not fabulous with numbers. There something I'm not understanding about that calculation. Were at 609 months into the air. Are our fiscal year ends on September 30.

>> [Laughter]

>> Does anyone else have any questions for Dr. Houston?

>> Thank you Dr. Houston for your presentation.

>> Thank you. We move onto the next item on our agenda from a report from the Department of Justice from Vincent Matanoski thank you Vince.

>> Thank you Jason.

>> And now I've been told not to touch the laptop. [Laughter] clearly they know my technical skills. Thank you. As I said this is Vince and I'm really happy to be here obviously we all prefer to be here in person and we understand budget constraints are such that you can do that but we like to take advantage of these opportunities when we can. As a speaker and seeing people in person gives you a special advantage because you get to see when the eyes start glazing over or the stifled yawns and you know [Laughter] that it's time to move on. And I'm going to move on now to slide to echo slide to is where we look at the number of cases that are filed and we look at three-month step -- snapshots because we take you from one meeting to the next. Last time we reported was in June and we looked at the pre-months -- three months preceding in the three months preceding this meeting

we had 211 claims filed in the court's. Or petitions filed. We tried to break it out for you as adults versus children. There were 175 adults and dirty sex were children. Percentagewise -- 36 were children and percentagewise most were from adults. I know that is running about the same that we've seen in the recent past and we were about $.80 -- 80% adults enter -- and 20% children driven by the flu vaccine which is delivered not only to children but to adults.

>> Rejecting this out -- projecting this out we looked at the number of cases in August and projecting it through the fiscal year we are going to run a little higher than if we are looking at this at the beginning of August. Projecting it out now to the end of September given that there is seasonality now in the number of claims filed and if it follows the pattern of our vaccination practices in the US and sense most of the flu vaccines are delivered seasonally we see a seasonal variation in the claims being filed. Going into the fall we see a ramp up in the number of claims filed. In light of that I project that we will be at over 700 cases and be nearing 750 for this fiscal year. So comparing them to fiscal year 2014 we had a little over 630 cases. Each successive year we are seeing fairly significant jumps in the number of cases that are being filed. We will probably see that again the next fiscal year. Driving this is flu vaccine and it's not my view it's not a signal that there is no difference in the vaccine but it's a greater awareness on the part of those who receive vaccines and of the availability of this program. And also recognition of conditions rate -- related to potential complications from vaccinations that have declined the numbers increasing -- defined the numbers increasing. Next slide.

>> This is Ed, I have a question. When you are determining whether a case is a minor or adult, I am thinking about the teenagers in the

Midshipman meningococcal kind of injuries and when the child is 18 when the vaccination occurred at 15 or 16. Had you categorize that you mark

>> We are going off the case caption. So it's at the time its file. I appreciate the background to that question so folks understand. I think Ed what you are getting at is this could be a vaccine that is delivered to someone when they are a minor but by the time they filed their claim they have three years to file their claim from the onset of the symptom, they may be adult at that time. What we are capturing is at the time of filing if it's filed by someone on behalf of a minor or is it filed by an adult?

>> Yesterday I asked a question and how do we define minor or adult? Is that 18 years old or 20 or 21? Everybody defines minor differently.

>> Basically you could say it's 18. I know there are a couple of states that define a minor at a little bit higher of an age. Maybe they think perhaps rightly we are not mature enough. I know I wasn't mature at 18. Spam --

>> But for this case would look at it it 18?

>> Yes. The next slide are adjudications during this reporting period. Again a three-month snapshot and 156 of these cases, 115 of those 100, 115 of those 156 adjudications were compensated. That's about 74% of the cases that were adjudicated during this period and the individuals received some sort of compensation. The vast majority have received compensation receive it by way of settlement. There were 29 of the hundred 15 cases that were conceded by the Department of Health and Human Services as being entitled to

vaccine compensation. Again that's about 74% of the cases compensated. This is tracking what we have seen in the last couple of reporting periods as well. There are a far greater number of cases compensated now.

>> This is Alexandra Stewart and I can see you mean these are injuries?

>> They either fit the table or show causation. Right now children injuries related to vaccine administered -- administration is pending being approved to be on the table. There is some evidence and what's driving that being added to the table is there is evidence that children injury related to vaccination under certain circumstances as defined by the proposed regulation is related to the vaccine administration. In those instances, while this regulation is pending and becoming final those cases may be considered to be conceded or may be conceded by HHS because there is actual causation. It's either table presumption or actual causation.

>> Thank you.

>> Sure. I've mentioned this before and we like to see, ideally, that the number of cases adjudicated in a given period matches or is greater than the number of cases that are coming in. As you can see from comparing flight number two and flight number three that is not the case. And it has not been the case for a couple reporting periods now. Because we've had so many cases come in. What that means is there is a growing number of pending cases. What is happening is we're actually moving through cases much quicker than we have at any time in the past. We are adjudicating far more than we have in the past. We are moving faster. The time period is also quicker for

each case. It's like we're on a treadmill and were running faster and we're getting closer and closer to the back edge of the transfer because more cases are from coming in. We are moving to cases faster and moving through more of them in a period but we are having a growing number of pending cases.

>> Next slide please.

>> This is Ed, could you go back. Part of this question is I think this is a good opportunity for the new members to maybe learn some of this yesterday, I'm not sure. But the cases that were conceded, the 29 of those. Are you able to identify of those 29 how many of them were filed originally or identified as special processing cases and before you answer that could you explain what the special processing unit is for the people new to the program?

>> We got a nice lecture yesterday.

>> Just to handle the second question first. Special processing unit is a section within the office of special masters or a process set up by the office of special masters by which certain cases are identified by the office of special masters as one's that one may be more likely to be compensated than others. They are more likely to represent a table injury or more likely to represent based on past experience cases that are going to be found compensable either by -- concession or through settlement. Within the office of special masters a group of staff attorneys has been working those cases, they are moving through more rapidly and they are identified as cases that lend themselves to more rapid and efficient processing. The chief special master provided to the new members a glance of that yesterday and how well it seems to be working in terms of moving cases through rapidly.

Unfortunately I cannot tell you how many of those 29 cases had received a special processing unit. At the Department of Health and Human Services and the Department of Justice we don't have a role in determining what goes into the special processing unit. That's the court determination.

>> Then without holding you accountable in any way if you had to estimate of those 29 do say half of them are those cases or do you have any idea?

>> I'd really don't know if I did I'd let you know. Sorry. The next slide number four we track the number of cases that are voluntarily withdrawn in a particular period in that's when the petitioner decide to leave the program without receiving a judgment on their case. It's at 11. That's typically what we have seen in the last couple of reporting periods as I recall. We just look at this and if this were to spike it would cause us to look back and see why our focus -- folks are leaving without eating answers from the program.

>> This is Martha why do people leave?

>> I don't know.

>> They don't have an exit interview?

>> It's completely their decision whether they leave the program, obviously if they thought they were going to get compensation in the program they would probably stay. But I don't know. They are not required to explain why they want to leave.

>> This is Ed. In my experience I think there are different reasons why people withdraw. One, they reach a point in the case where they are

not able to get an expert opinion to support their case and the courts have made it clear they either need to withdraw or it will be dismissed. There are cases that get withdrawn because the statute of limitations become apparent that the case wasn't filed within the 36 months. Error some cases that are withdrawn for other reasons as well I'm sure. But those, in my experience, are the main ones.

>> Thank you. Moving on to slide five. This is where we look at the appeals that have been filed recently. There has been a lot of appellate activity in our casework. I will give you the snapshot and Cliff notes about what we are saying. All of the cases that were filed here were filed by petitioner and most of these cases involve factual disputes rather than legal questions. And almost every instance when the court is decided a case they have affirmed the underlying decision of the special master. Turning to the specific cases on slide five there are three. From the throttle -- federal circuit that we've had in the past three months. The first is, the computer has turned off and I'm not touching it [Laughter].

>> The first one is Stillwell and was a case involving a flu vaccine and acute disseminated acetylated myelitis or A.D. a.m. ago and it was a battle of the experts case. And the factfinder found that the experts for the respondent of HHS were more perspective -- persuasive and that was affirmed widely Federal Circuit. Just for the benefit of our newer members there are two appellate tears. The first tier from the special master is the Court of Federal claims. They are a judges sitting alone and reviews the decision of the special master and issues a finding. About whether to affirm it or to find it was proper or to reverse it finding that there were some error, or to remand it and finding that there was some question that needs to go back to the

special master to be resolved. The next tier is the Federal Circuit and that is a court that has oversight over the Court of Federal claims and they are a panel of three judges who will review the decision of the judge of the Court of Federal claims and ultimately looking to the initial decision from the special master and decide whether or not the three options affirm, reverse, or remand is appropriate. Turning now to Cruthcfield that was a case involving MMR vaccine and type I diabetes. Again at spurt -- expert case involving expert persuasiveness and the special master found that the expert for the respondent was more persuasive and more convincing and that was affirmed both at the court of Federal claims and then again at the federal circuit.

>> Greenburg or the last one listed there is an interesting procedural case. It was a pro se case and that means it was filed by the petitioner themselves rather than the petitioner through legal counsel. This pro se petitioner has filed cases in the petition has been found to be not eligible for compensation because it was time-barred and in addition the special master went forward and said that you can't prove causation even if I were to consider this case timely. You have 30 days after a decision is issued to seek review at the Court of Federal claims. That's your time cared for doing. The petitioner here did not seek review in the Court of Federal claims within the 30 days. However within 26 days asked for reconsideration of the decision by the special master. There is a right to ask for reconsideration by the special master part of the time period for doing that is 21 days but here at the 26th day they filed a motion for reconsideration. Mork than 30 days past -- more than 30 days past did not seek review for the federal claims but then later went to the Federal Circuit without the intermediate step at the court of Federal times. Circuit took a look at

this and said it may be well be driven by the fact that was a pro se petitioner but you skip this step and we will interpret your motion for reconsideration as an attempt to get to the Court of Federal claims so we are going to send it back to the Court of Federal claims to look at. That's now pending at the Court of Federal claims.

>> Moving to the next slide three new cases, on slide six, --

>> This is Alexandria do you recall the underlying claims for this case?

>> Yes this was a case of a claim of artistic spectrum disorder caused by MMR vaccine I believe. Again the special master said it was time-barred because they didn't bring the case within the three years and special master to go on to say that regardless even if I were to consider this timely the evidence is not convincing that the vaccine cause the condition.

>> This is Martha again and I might correct that the parents brothers on behalf of their child. And they did themselves?

>> Yes they did it themselves. It's not clear whether they wanted to or not but they did. They brought it on their own.

>> Moving on to the next slide. I wanted to indicate there are three new cases filed. Most of those cases that you see filed and the three new ones I will discuss because of the decision at the Court of Federal claims are being appealed in the background on them.

>> Slide seven. These are the recently decided cases at the Court of Federal claims there are 10 of them. They've been very busy these past three months. D'Angiolini Involved a hep B vaccine and that claimed chronic fatigue syndrome was caused by the vaccine. The

underlying mechanism that was claimed as responsible was known as or called ASIA. And it stands for autoimmune syndrome and induced by adjuvants. Vaccines or many vaccines and clued adjuvants to end kris -- to increase the potency or effectiveness in the claim is that the components of the vaccine itself or the immunizing agents but the adjuvant causing autoimmune problem in this individual leading to chronic fatigue syndrome. The special master rejected that after a hearing from a number of experts and this went to the Court of Federal claims review and federal claims agreed with these federal master after reviewing the evidence. The significance there is we had seen ASIA in the condition being alleged in several cases and this may have impact on a number of these cases where this has been alleged as a potential mechanism for causing injury.

>> The next case Godfrey is a case where it was remanded, is that there were three possible results, this was remanded back to special master asking him to can -- reconsider the significance of the petitioner's expert. The expert had petition -- testified in other cases and they had noted the Federal Circuit in another case considering the testimony of this expert while it affirmed these special master's rejection of that testimony said that the Federal Circuit counseled that more attention should be given to what that expert had said. The claim in that case was juvenile rheumatoid arthritis caused by HPV vaccine or meningococcal vaccine. Interestingly, when the Federal Circuit in the other case had affirmed they said we think the special master should have given more attention to what the expert had said on prongs one and two. But because they had not met any of the three causation prongs and the presiding read -- legal guidance on how we prove actual causation and vaccine cases they affirmed the

decision anyway. The interesting thing about this decision and remanding it to the special masters is the special master in this case had also found that failed to meet all three prongs and it's not clear to me how the remand is necessarily going to affect the ultimate decision in the case because even if special masters were to review whether prongs one or two were met they would still have the prong three problem in the case. That has been remanded back to special masters for more research and additional findings.

>> The next case: is -- Rowan involves HPV with headaches, migraines, and it abdominal pain and this was another plate -- case ASIA claiming as the causal mechanism and was dismissed by the special master and affirmed when reviewed by the Court of Federal claims. Santini Is a case involving the Vaccine and significant aggravation of surveys syndrome -- surveys syndrome in several past meetings and there are number of cases that consider whether that syndrome is a genetically induced neurological condition in children is related to vaccine administration. There have been five decisions prior to Santini what was considered by the special master and reviewed by subsequent appellate, and found to be not persuasive or convincing and that there was a link there. That was subsequently reviewed and affirmed by appellate court. Yet it was considered again and found not to be a persuasive theory of causation. And that was affirmed by the court of federal claims. Barclay Is another as CS one -- SCS1 case with the same syndrome and was found not to merit causation on federal claims ground. The next case Padmanabhan --

>> This is at. And the previous case --

>> In Santini it was the And it was also the -- dtap in Barclay. And following up on Ed's question there is recognition that the underlying condition preexisted the vaccination and the claim their is that the vaccination made the condition worse. What you have to do in assessing that is not only find whether there could be a causal link between the two but you also to save the condition actually looks worse than what you would project in the first place. There's always testimony in the significant aggravation cases about what would be the perfect a course of that underlying condition and is it worse than what we did expect and if it is can you show that the vaccine is the reason why it is worse than what we would expect.

>> Padmanabhan Involved a claim and it is a per se clays as well -- case as well that involved MMR vaccine, the influent -- influenza vaccine, dtap causing autistic disorder. And there was also underlying claim that the child suffered from a mitochondrial disorder in this case.

>> Pre-existing mitochondrial?

>> Yes and the thought in the case is that left the child more susceptible to injury from vaccination. Ultimately the special master found there was not sufficient, and he questioned whether there was enough evidence to find whether there was an underlying mitochondrial condition.

>> What was the fourth?

>> And Vara Cella.

>> Just out of curiosity do we know if they were given it during a well baby visit? In one week or do we know the timing?

>> I don't know whether that was given at the same time. There were a number of orders issued by these best or -- special master to provide additional medical information including outstanding medical records and those orders over the course of several years were ignored by the petitioner and ultimately the special master dismissed the case for failure to prosecute in legal terms that means they have not moved their case forward even though the burden is on them to do so. And that was what was pending in front of the Court of Federal claims and was it an abuse of the discretion of the special master to dismiss that Craig -- dismiss the case in the court found it was not.

>> The computer is telling me that I'm talking too long. It is going to sleep. [Laughter]

>> It wanted to touch it everyone thought. [Laughter]

>> I am slowly grinding to an end here. And the computer will be happy. The next case, Mora involved flu vaccine and transverse myelitis. It is a case where there is a settlement offer the petitioner rejected the settlement offer and chose to dismiss their case in favor of filing civil action against the manufacturer. Once they had dismissed and rejected the judgment in the case and want to file be civil action they found out they did not have a liability claim against the special master. -- Against the manufacturer. They were legally precluded by the Supreme Court case from doing not. They came back to the program to ask for the judgment to be set aside. And there are certain grounds and limited grounds to set aside a judgment whether it's a mistake for example by the clerk in entering judgment and they did not meet these very strict grounds for having judgment overturned and that was the finding by the special master and was

affirmed at the Court of Federal claims. Is one of the cases you saw listed as now at the Federal Circuit for review.

>> And that was not per se?

>> Know that was with help of counsel. McLeod-Hunt Was achieved app -- I'm sorry partly on -- [Laughter]

>> Nutall Is an MMR case and there was the question in the case on whether or not there were normal MRIs, magnetic resonance imaging. The claim by the petitioner was that the MRI was abnormal and their case rested on the special master finding that it was. In fact one radiologist had said it's abnormal another radiologist had said it's normal. The petitioner expert found that it was abnormal and respond expert said it was normal and produced a number of medical treatises that describe normal MRI and showed it was consistent with what was described their. It turned out the one radiologist who had said the MRI was abnormal had been engaged after the filing of the claim at the court to review. So was not a treating doctor but another expert in the case. So special masters drew that distinction as well. In finding that in fact the MRI was normal and there was not any proof that the condition manifested itself at any time near the administration of the vaccine. The case was dismissed and affirmed by the Court of Federal claims. McLeod-Hunt

>> Was a Tdap meningococcal Vara Cella vaccine claim with multiple sclerosis. But the multiple sclerosis preexisted the vaccine and the question was did the vaccine significantly aggravate the underlying condition. The first symptom that was claimed that the significant aggravation occurred with in the same day the vaccine was administered. So that presented to problems for the petitioner and

that it was too soon for the exacerbation of the demyelinating condition and the projected course of the underlying multiple sclerosis was not any different than what would be expected in the normal course of the disease. So that was affirmed by the court of Federal claims. And last is Whitney which was remanded back to the special master for additional findings. Whitney involved a claim with dtap vaccine causing transverse myelitis and there are number of treating doctors that looked at the individual as an adult and several them said there's possibly a vaccine connection. One had very emphatically said no the vaccine is in no way responsible and in fact I believe there was a positive herpesvirus culture and the doctor said they thought I was responsible. The special monster -- master found it was more persuasive than the treating physicians who said it was possible vaccine. At the review of the Court of Federal claims the judge said I would like you to go back and relook at the evidence and re-way the evidence of these treating doctors who said it was possible. It back to special master for further finding.

>> Turning to the next slide. We had five new cases filed. I just wanted to point out that two of those five involve attorneys fees and costs in the other three are going to be factual disputes about findings in other cases other than Greenberg which I talked about and came back because of the pro se petitioner filing at the Court of Federal claims and is going -- the Federal Circuit has gone back to federal claims. I will move on to slide nine.

>> We have two scheduled oral arguments and one is today. And that is in Hodge.

>> And for us newbies.

>> Hodge Is, I just got done with this case, it is a claim that was filed too late. It was filed a month after the onset of the condition and was filed by an individual who is an adult but the claim is that the individual had a mental incapacity during the period of time where the statute was running. And that is equitable tolling should apply to allow his claim later.

>> This is Ed. I think he misspoke use it was a month after the aspect -- onset. I think you meant 36 months.

>> Yes I'm sorry. The month after the statute of limitations had run.

>> This is Martha again. Today's argument will be to allow him to continue or is this it for him?

>> The argument today will beat the petitioner sang there should be equitable tolling to allow him to continue his claim and you'll reach the underlying merits of the claim.

>> This is@. May be the concept of equitable tolling for those who aren't familiar?

>> In legal cases there are statute of limitations on cases. Used to bring them in a special -- certain time here. And it's because memories change in evidence disappears and is harder to know what happens the further away from event you're looking at it. Statute of limitations are there to try and force cases into litigation if there is going to be litigation at a time that is relatively recent to the events claims. With the vaccine program it's a three-year statute of limitation. That may be extended if you show grounds for equitable tolling. That means for equitable reasons and generally they are very strict as to what those reasons are, you could not get your claim filed within the three-year

period. Typically equitable tolling is some action by the defendant themselves misled you into believing that you didn't have a claim or that you didn't file your claim because of some action by the defendant. That is the classic case for application of equitable tolling. It has been allowed in certain instances for other reasons including mental incapacity. I don't believe that's ever been addressed here in the vaccine program as to whether that would permit equitable tolling under the vaccine program.

>> This is Alexandra. Is this notion of equitable tolling and this individual is only 30 days past is that consistent with the re-ICP about re-access and that type of thing?

>> To put it in context, it being one month after his taking the best case scenario for the petitioner. Taking their claims at face value. There's probably going to be if this case is heard and there might move some of the onset back several months earlier. I know a little bit about the background of this case because it's going to oral argument today. I'm putting it in the best light. The reason for having a time limit is to set a cutoff period and if you end up having that be, and this is my own views, if you end up having that period be soft, is it three years or is it three years in a month or a day then you create a lot of uncertainty. What we end up doing as we engender a lot of litigation about is the case timely filed or not as opposed to looking at the merits of the case. Often when we have this question before about is this a strong cut off. The court of Federal Circuit has come in and said you have three years from the time that you have the onset. And it does not matter that you didn't know there was a vaccine connection. They established a bright line and what that tends to do is it gives certainty and clarity to everyone involved about what the operative

periods are. We are actually not seeing this issue come up in a lot of cases. I don't see the petitioners come through the door so I don't know how many people come in and say that what we did have before we had a lot of litigation about whether or not you met three years and with the federal circuit very specifically saying this is a hard and fast time period you need to get your case in we don't have the collateral litigation as much and we are focusing more on the claims themselves. What had happened in the past is people brought the claim and it would be found to be untimely so they weren't having or getting compensation anyway but we were spending a lot of effort to get it to that point.

>> This is at -- Ed. Rebuttal. I think what Vince says is accurate but it's a perspective you would expect from the attorneys that are representing the government in cases. I think your question is an excellent one and the short answer is that it is not consistent with the purpose of the B IC program to keep people from filing their claims when they have legitimate claims to file. Vince is legal response is accurate that the courts have made the determination in interpreting the statute of limitations in this program with the exceptions being very limited. The judgment and the consequence of the court's decision is that there are a lot of people who have some pretty compelling reasons for why they didn't get their case filed in 36 months will not be able to pursue cases as a result. I think the courts have become an impediment in terms of resolving situations. I, and we as a commission have made a recommendation like the ACCV before us to extend the statute of limitations because there are, in my experience, there are many people who are unable to file claims because they are past the 36 month statute of limitations. Vince is I'm

sure correct, he doesn't see these cases because they don't get filed not because their art people out there who would like to pursue them I am fine -- fond of telling my new law students each semester that I get one call a week from somebody who again they may or may not be able to prove causation but they will never get in opportunity to file their claim because it's been 3 1/2 years or four years or six years. Having said all that, I think in terms of understanding what equitable tolling is and where these cases are heading as an attorney these are very interesting. But as a commission, I think one of the single most important things we can accomplish is to get the secretary to understand the importance of extending the statute of limitations in these cases.

>> Anecdotes are cute and statistics can be skewed. I don't know what situation as but I'm an advocate and I had someone who was injured when he is five months old and we went through our insurance and I can get access to anything because doctors kept saying he's got something and he can't say. On the other say with pro-vaccine and healthy children and let's be proactive. So for three years all the doctors within our insurance company were saying Johnny can play basketball with Apple's -- epilepsy. And he'll must have a heart attack and died and everyone said were finding them to get through this but no one would say he was dying and I kept saying could it have been 24 hours after the vaccination. And I kept asking an adult people said we don't discuss vaccine injury because vaccines are lovely and wonderful. It's the whole story of war vaccines are terrific but 24 hours after my son got the dtap he was dying and I kept asking and I asked Children's Hospital, I asked Rush University, ask John Hopkins. I asked famous people why my kid is dying. And they kept saying we

don't know why has it couldn't have been a vaccine. So finally we go to Georgetown. And we made this lovely guy who said has anybody told you your kid is a classic vaccine case? And I said no Dr. severe everyone Saying it doesn't matter where he got injured or why he's disabled or none of this matters and words were thrown out. She might die he may not. Then child protective services are called in because obviously am a not right. I kept asking and I kept saying the doctors were wrong and Dr. severe looked at my case five seconds later and said vaccine injury. It's almost 36 months when Renée, and how I got them as I was in Virginia and looked them up and it was too long ago. I got Cliff because he was the closest lawyer. They filed minutes before and I hadn't -- had I not met Dr. severe and died in my Kaiser Permanente unit and not gone to Georgetown my kid with died and I would never been here today that an child protective circus services I was on an active list and every month they come and check and this is the reality of the statute of limitations because people are not aggressive Irish moms like I am. Most people are like the doctor said the social worker said. And I am a mother advocate because I advocate for families and if I had a dollar for every time a mother or father said I can't be the vaccine. And how old is he now 18 ago I know six people in wheelchairs who have kids who can only use their eyes because there between 20 and three years old and they were vaccine injuries and mother told me what happened. So the reality is it's not like a murder where the cop can't get witnesses. The reality is the witnesses, I'm a witness to my son. I can remember yesterday putting day ACTH up his arm and being prescribed it to save his life and going to the pharmacy to get it and being told you can't have it. We don't keep it your. I had to go to New York City to get my son

ACTH and did you think any doctor told me was necessary? So were talking about mothers and fathers, you know we are in the trenches and were not thinking about statute of limitations. Were kind of safety -- our child life and learning how do shots and not give them a shoulder injury. I'm doing things outside my comfort zone. His teeth all fellow. So no I wasn't thinking about and until Dr. severe said and he's been a government Dr. and he's been a government Dr. And he's been the expert witness the government card. When I hired him. And I don't know what your experience was --

>> And they don't know but [Indiscernible - Low Volume]. So they start testing for a whole lot of other stuff and I asked the doctors why are you not looking at live viruses actually put in her system. Why are you not thinking it is possible?

>> There is no change then but you don't know what it was like before the vaccine was there so how can we -- [Indiscernible - Heavy Accent] I saw the poster knows looking at my daughter and I needed money to support her. And this is the only source I have. With her in the ICU at least once a year [Indiscernible - Heavy Accent]

>> We all make ourselves sick.

>> This is Ed. Personally I really appreciate those of you sharing your situations and help us function as a commission. No one is dumping on Vince personally here [Laughter] at least I don't interpret that.

>> No. It's hard.

>> The statute of limitation and you are talking about one case that involves equitable tolling and if we could laser beam focus as one thing it would be, and all I have to do is talk to these parents who are

fortunate enough to get it in within the 36 months. The point is that the statute of limitations issue is a really big issue and to refresh what we in our prior meetings have concluded is we are not going to get relief from the courts globally for the problem that is caused by the 36 month statute of limitation. If just one individual is able to establish that his particular circumstances fall within this very narrow equitable tolling situation than the court is going to say give him a break and that's because he was mentally incapacitated for 36 months etc. ergo he might get relief but in terms of Vince's report on the cases I think bringing up again how important the statute of limitations issue is and it might be something that if we could bring it up under new business to get a report again and request another of the secretaries some update on the status of our prior recommendations to increase the statute of limitations from 36 months to something like eight years because we thought that would capture the majority, not all, but the majority of cases not getting the opportunity.

>> This is Martha again. We also have good knowledge the elephant in the room that the increasing lack of trust in the vaccine schedules and vaccines in general, the increasing Bobby Kennedy amounts in the amazing amount of power the Canary party is beginning to have an policy. We don't discuss policy in this room but out there in the world there are people that are losing faith in vaccines. And when you say to them that the one place you can go to and purchase being as a good citizen and I have a whole family of doctors and my grandfather was a famous pediatrician and I understand that my job as a citizen is to participate in public health. I did what I supposed to do. My child was am is killed. I'm a soldier in the public health world. We are citizens of the public health world ago I did was supposed to do. Instead of

calling child protective services, why didn't anybody turn to me, hold my hand and say I am sorry let's get through this together? Instead I was treated like an insane woman and I was treated by the system and I'm not saying anything about anybody here, Ed knows in my lawyers know that took more than 11 years from the day we filed for us to get the check. In that time, he was did not -- denied physical therapy and speech and had brain part -- surgery and a stroke. Think about all the desperate people out there that if they had you and knew that you would step up to the plate and not attack them, you don't have to hold my hand during the proceedings ergo it got to be me versus them. The government them. And it has to be set up so I don't feel towards the special master or the lawyer who is representing the DOJ, it's all set up so I cried and you let me know what you need but I literally disassociate myself from the entire back is see -- vaccine preceding. I would look at the memos because it made me cry because it was so ugly when they asked about my daughter. I don't have a daughter. They kept asking things that we were willing to settle and from Judge Hastings we just wanted it over with and four days for settlement and they pulled the rug out from under us and made us go whole way through. Maybe my situation was a little more extreme than other peoples but I hate to think, it was a pretty uncomfortable spirits and I don't think it should be. I think we should be the place where moms or dads, or adult women or the place that people come and we don't have to give them cookies, but it shouldn't have been so miserable for me. The woman who is the opposing lawyer was doing the orientation yesterday. That was her. And I went outside and cried and Julie came out and helped me and it was really uncomfortable. That's why my husband and son are

here. None of you are at fault. It's not a person. It's not the lawyer was at fault it's just the system is so adversarial and it can be anymore because were getting more and more, we don't know why because we aren't doctors, we don't know why people are getting autism and we don't know what autism is and is a yesterday autism is not caused by vaccines. It could be the preserves is in our food, could be the tilapia from China, we don't know but something is going on. All I know is that we are here and we persevered and we know hundreds of people who aren't persevering and it's sad.

>> This is Alexandra. Maybe these cases that are time-barred go into an alternate system. We heard a little bit about mediation or something like that as opposed to going through the full vaccine court because they are time-barred. Those cases, it should be many of them really a can go somewhere else.

>> How many are there in the air?

>> I don't see that many and --

>> This is at. They don't get filed because if you contacted me and my child was horribly injured by a vaccine and I have a treating pediatric neurologist who will swear it was the vaccine and it was 37 months ago and I'd love to help you but you need to contact your congressperson that you need to support amending the vaccine act so it increases the statute of limitations.

>> I'm sorry to interrupt. I think it might be beneficial if it this is a dialogue we've had in prior meetings if we could defer to new business or future agenda items to make sure and be respectful of the time of other presenters. Let's table it and we do have time to tween

11 and 12 and we can probably utilize some of that time as well to look at statute of limitation discussion.

>> Think you.

>> To follow up and bring you. Goal is I'd like to think the parent members for sharing their experiences and showing the importance of why you are here on this commission because by necessity we need to deal with the global picture and the larger need for everybody in hearing your own experiences humanize his those numbers for us. That's very important and I thank you for sharing that. To the point of what the statute of limitations is I heard a comment that you are not going to get really from the court. They can't and I know that chief special Masters is not here to talk about this that the court doesn't have discretion. This is a statutory mandate. The statute says 36 months or three years. So the court has no discretion to change that. To the question of what do you do about these cases that fall outside that? Understand that what I'm saying is you need to have a clear breaking point. You need to clearly set out what the period is. Otherwise there is confusion and that's not going to help petitioners. If they don't know if that's 36 months and a day or 48 months or eight years it's what ever that period is and I understand the discussions here to be more about what should that period be. My plea to you is that it be a clear period part girl dashed. Because it's the collateral litigation about what is on which side of the line that detracts and draws attention away from getting answers to people about the merits of their claim. Whatever that period is and I guess that will be what you are discussing, what the breakpoint is needs to be clear. That's what the petitioners need to know. Turning to slide 10.

>> I will wrap up talking about settlements. For the settlements there were 86 during this period. And that is a lot a settlements. Again going back to the comments about an adversarial program but if you look at the numbers there were many more cases compensated than not compensated. A lot of these were settled where the petitioners to get some compensation out of the program. Breaking down this to give you a snapshot, 77 of those involved adult claimants and nine involved children. 52% of the settlements were reached in a year or less after the date of the claim was filed. That's really good. That's really good and we'd obviously like quicker but to get people answers quickly as desired by everybody. Going out two years you add another 31%. 83% of our cases that were settled reached the endpoint within two years or less. I know that someone yesterday, when we had the new commission members ask about how many settlements were flu cases, that was you Martha? 66 of those 86 cases involved the flu vaccine. Quite a few of those. And that is to be expected since by far in terms of the vaccines that are administered in this country in a given year the flu vaccine dwarfs the other axioms and in terms of administrations. That is my presentation. I draw the new members attention that we have an appendix to the presentation that has additional information with a glossary of terms and some flowcharts about how petitions are handled. If there any questions I'd be happy to entertain them at this time but I know --

>> This is Jason. Can I ask really quick for the three-month period we are looking out for most of the statistics you have shared with us you mentioned the number of pending cases and talking about adjudication's or settlements. What is the number roughly if you could estimate that?

>> I believe it's over 1000 right now.

>> [Indiscernible - Low Volume]

>> I'm sorry this is Sylvia and I can't hear nor know who is speaking.

>> I will repeat the question in the question from Jason is how many cases were pending and chief special Masters having the statistics right at her fingertips had responded that if 1100 had responded that if 1189. About 1100 1189 or 1200 cases pending and she further made the comment which I was remiss in not drawing the attention of the commission to this, if there is a move to extend the statue of limitations that will mean more claims will be filed at least certainly in that initial period that extends it and people whose claims had previously been outside the statute of limitations will come in. That is going to require statutory change. That it also is statutory limitation not only on the maturity time but also in the numbers special Masters that can hear claims. It statutorily set at eight. And without a statutory change to that the office of special Masters will not expand to meet the incoming cases. It's the position they have been put in now with our current influx of cases, they can't even if they were to have a budget increase, they don't have the statutory authority to hire more. Using imagination and ingenuity they managed to put together the SPU to extends the capabilities and what the chief special master's was commenting on a statutory change that might extends the statute that one needs to look at second-order effects of that an increased number affects the need to be processed it needs to be more ability to do that. I wanted to get it sent Vince and chief special master is that roughly the number and fiscal year to 2015 or

where we are today how would that look in relation to last year? Are the numbers flat?

>> [Indiscernible - Low Volume]

>> Our numbers are a little different there calculated on calendar year not fiscal year. [Indiscernible - Low Volume]

>> And just to make sure that the folks who are listening and heard that. That was the chief special master and she responded to the vice chairs question. Said that there is a 13% increase in pending cases this year over last.

>> Is that at the OSM level to clarify?

>> Yes.

>> This is Martha. Because I knew I don't know the procedure, has this commission ever tried to get more statutory, I do lobbying and I don't know what we do here as a commission but have we ever gone to Congress and ask for a few more special Masters, a better budget? Who lobbies for the special Masters is what I'm trying to ask who's responsible the is that?

>> I wanted to be clear that this commission is an advising commission and we advise that lobbying activities is not permitted.

>> I don't mean that literary but who speaks up for her to get more special Masters?

>> On the agenda today we will have an hour onto topics which will be administrative funding which is a narrow agenda and it will touch on those issues and part of the reason for some of my questions

whether to Melissa or bends to get an estimate on what the burden is on the program today administratively versus a year ago and where's the funding and what do our resources look like and is there something we can look at as a commission whether by committee or otherwise make a recommendation to the secretary and what our perspective would be an hour device to help with the administration of the program.

>> I didn't have any further questions ravens did anyone else?

>> Thank you Vince and as always we appreciate a.

>> Maybe take a 10 minute break and we will reconvene in about 10 minutes. [Laughter] recess for 10 minutes.

>>

>> [Silence]

>> [Captioners Transitioning]Hi everyone this is Jason Smith were going to get started in a minute. I wanted to check, cilia are you on the phone.

>> And looks like Silvius disconnected

>> Maybe we will give her another minute or two. Will have to skip that agenda item. And double back.

>> Operator, can you please let me know when Sylvia dials in?

>> Tran10's line is open.

>> A while ago she had me unmute.

>> So welcome back everyone. It is almost 11:00. We are going to move to the next item on our agenda which is the report from the adult in musician worker. Dr. Sylvia Villarreal. Sylvia, I will turn it over to you.

>> Baker Jason.

>> For folks that have a history because we have a lot of new members. Welcome to, I am a working pediatrician, meaning you will hear babies cry as I'm talking. We are in a clinic. [laughter]

>> On the only pediatrics for north-central, especially current members of the committee and commission. I have been on this committee to represent parents and children.

>> One of the things that been said which was very critical, as far as the Department of Justice is 80% of the injuries are currently ascribed to an adult person over the age of 18. I am a pediatrician, I am not an adult position. I have been on the national vaccine advisory commission in the 90s, as a pediatric representative especially for underrepresented minorities. Two years ago, with us as the ACCV we were presented some data . Looking at two vaccines that are not currently covered by the injury table. So for the newbies, you can only discuss injuries that happened to vaccines that are on the vaccine table. The vaccines that, and thank you to the committee members which is Jason Smith, Dr. Tom Shimabukuro, Jennifer represents the Department of Justice, Jason who else was on a commission? Our subcommittee?

>> The adult advisory commission for adult vaccines?

>> Putting aside our HRSA colleagues, I think you are on a couple of early cause from the Department of Justice, but I think that was it.

>> Again, I'm expecting you guys to pipe in and talk about what we discussed in the advisory subcommittee or adult immunization workgroup as it is called. This is all legal, this is not political. We are really looking at two vaccines and one is the pneumococcal 23. Tom cause it the PP SB 23. I think that's the correct terminology as far as its biologic name. And the other is the shingles sets. For the new members if you will please look at the CDC website on vaccine information sheet, and statement. These have to be updated by your pediatrician every time they come out. And given to families for informed consent. The shingles I do not provide to my patients because it is for adults. Tom 65 and older were 60?

>> I'm not sure about the recommendations, I believe it is approved for 50 and older. Shingles, but I have to get back to you on the specifics recordation.

>> I have the CDC website up.. These are two vaccines that have been advised for adults. The pneumococcal 23 and the shingles shot I will call it that. The zoster shot. One of the issues as a pediatrician that I was concerned about is the pneumococcal 23 is also advised for children who have chronic lung condition or immunological conditions that will, if they would get pneumonia with, it has been advised to give them that vaccine. That's the pneumococcal 23. We have met, usually the second Thursday of the month, at a 45 minute phone conference to discuss how to advise the Secretary. to include these two vaccines. Jason has been very helpful in looking at, and arranging

the pharmaceutical companies to look at advising the secretary to put those two vaccines on the injury table. Jason is out of synopsis?

>> I think we looked at various stakeholders we wanted to reach out and get their perspectives about what we were specifically looking at, and I tried to facilitate through our industry organization called bio, not related to the break we just took but the biotechnology industry organization and we doesn't be back there. With other stakeholders as well. But absolutely Sylvia So the current issues that we have very similar to what Ed brought up when we advise the Secretary. as to issues that we as the ACCV see as problematic. Problematic is those two vaccines, are not in the injury table. I think that the CDC and other agencies are looking to see how many, and excuse this word, but noise, meaning how much data is coming in from those two vaccines. We don't have that information. We don't have, and again as Mr. Mattson Askey brought up, 80% of entries are adult claimants. Again, with the shingles shot and the pneumococcal, and we don't have enough historical perspective and data to say to the secretary that injury, that vaccine should be on the injury table. Now with the pneumococcal 23 that is a different issue. About, and he did we ever get that information whether it was two or three years ago that was presented as far as the pneumococcal vaccine injury problem?

>> Sylvia, and he just walked out. [Indiscernible] [laughter]

>> It was brought up as a discussion in one of the ACCV meetings, and one of the adult immunization workshops, and you had asked us, can you repeat your question?

>> The question was, with the pneumococcal 23 vaccine, we had presented to the ACCV , and again this is probably 2014 in September.

A presentation about the pneumococcal vaccine and alleged, perhaps injuries from the vaccine. I recollect, children with sickle cell that were given the vaccine. For the new members, if you look at the CDC site which gives you the vaccine information sheet, the PP SB 23 which is the pneumococcal vaccine is advised from anyone to two to 2 to 64 years old with certain long-term health conditions. Or two years old to 64 years old. With weakened immunity. And adults 19 through 64 years old who smoke cigarettes or have asthma.

>> Have that data as far as any other alleged injuries or adverse affects to that vaccine, and I really don't have the information on adult shingles shot or the post chickenpox vaccine. So the working group is, presenting our notes to and are minutes to any and in December I will present an accumulation of our work over the years. Looking at the two vaccines currently that are not covered by the injury table. Pneumococcal 23, that is advised for both children and adults, and the softer shot or the post very cello or chickenpox for adults, and I believe and Tom will figure that out if it's 50 or 65 years of age or older. We will present our findings and our advisement and recommendations to the Secretary. of potentially adding those onto the injury table work

>> So Sylvia you are actually incorrect

>> Correct [Indiscernible low volume] you had asked if we had data regarding the PPS 23 vaccine however this is not one of the [Indiscernible low volume] we do not have any data regarding potential injuries associated with that. Potential alleged because we just don't keep that data and it's not a covered vaccine work

>> This is at, I wanted to ask a question. At somebody tried to report to their, a noncovered, injury caused by a noncovered vaccine

>> I would let Tom answer that question for all vaccines

>> I recall that Eileen Miller who is a nurse at [Indiscernible low volume] an overview of PBS [Indiscernible low volume] safety [Indiscernible low volume] just to give the permission back on the information they were debating this issue of suggesting that [Indiscernible low volume] vaccines be covered by the program, I will just say in general, we are in the process of writing those, that data upper publication, I would say in general for both of those vaccines, softer backs [Indiscernible low volume] from the Bears data. The post-licensure safety [Indiscernible low volume] consistence with that and other post-licensure studies that have been conducted.

>> Let me summarize, this is Dr. Sylvia Villarreal again. We were asked as a working group to look at two adult vaccines and one that is also advised for children that is currently not on the injury table. The PP SB or pneumococcal 23 and the softer backs or the shingles shot or the Harpers shot. Time when I look at the CDC is that's also advised for adults, 60 and older. 60 years of age.

>> I will open this up for the rest of the ACCV committee to see whether as a working group I should push, and the committee members should investigate further whether we send a recommendation to the secretary to look at putting those two vaccines on the injury table. And again, some of the information I receive from the pharmacy, or Jason help me with that word. The bio pharmacy is that in opening the injury table, we would open all

vaccines to potential scrutiny. Jason help me with that one because this is more of a political thing and I'm not good with that.

>> [laughter]

>> Julia said that the vaccine table, when I talk about the taxing table what we are talking about is whether or not the vaccine would be covered under the program here and as trend 10 said Saussure vaccine, because is not routinely recommended in pediatrics, it's not covered. Flu is, it's getting to adults because it is recommended [Indiscernible low volume]. So I think the feedback we received, this is indicative or reflective of the discussion we had with the statute of limitations will carry that over. If were going to bring the discussion to this group in order to make a recommendation to the secretary, in effect, will say, open up the legislation, and amended, and change it. You need a pretty compelling reason and justification in order to do that. I think we started making progress in our back to the statute of limitations, we kept that in the back of our mind. I remember Melissa and Vito, discussing [Indiscernible low volume] what are the ramifications [Indiscernible low volume] what is the burden of the Department of Justice or the office of special master? For where we are in the adult immunization workgroup, were not entirely clear. We don't have transparency in data to help us articulate what the problem is that a recommendation to the secretary will try to sell. That's not to say that there isn't one, we are trying to figure out, is there one, what's its scope no audio Mac in order to make that determination before we come here and potentially [class is being polled]. I think there is work still being done to try to gather that information but some of the feedback received from various stakeholders including the I/O organization, they're going to do that

try to articulate what the problem is, and what the recommendation, or what the change to the legislation will try to fix.

>> In addition to the vaccines not being recommended [Indiscernible low volume] by the CDC, I also wanted to point out that of all Mac Congress has not enacted [Indiscernible low volume]

>> This is Sylvia again could you repeat that I didn't hear it. I think he came from Melissa.

>> The mic is not front of me but I will come to the Mike. So what I will say is, in addition to the vaccines not being covered, not being recommended for routine use, [Indiscernible] not enacted an excise tax on those two vaccines, so that's another reason why they would not eat a covered vaccine under this program.

>> Did you want to say something?

>> Yes, and I intended to be a part of that working group and I'm sorry that I didn't participate. [laughter]

>> I think, there are two questions. Did anybody look to see if there has been any civil lawsuits filed and everything to bio farm group would be aware of them. The manufactures for singles or PBS?

>> [Indiscernible]

>> [laughter]

>> It's okay Ed.

>> Did anybody look to see if there were any lawsuits that were filed?

>> I don't know the answer.

>> This is Sylvia. Ed we had , as a working group, tried to and will continue to, trying is not a word but we will try to look at any, I get this word noise, coming in from theirs on those two vaccines your that's why I am interested in, the legal side. Have you heard anecdotally how people approaching a legal perspective of saying, I was injured by these vaccines. We are looking for that data right now. And we haven't got it.

>> Again, it's very anecdotal but I've spoken with adults who have contacted me and other vaccine injury lawyers about pursuing claims involving both of those vaccines, and of course the response by a lawyer who practices focused on federal claims, on the vaccine program is, you don't have a claim that you can pursue under the vaccine act, if you believe you were injured by the vaccine, you would have to write a claim directly against the manufacturer. You think it was the vaccine itself that harmed you or if you think it was a vaccine administration error then you might have a claim against a medical malpractice time or administrator of the vaccine. I think, and I'm extrapolating from my own experience that it would be very difficult to pursue those cases and Jason can confirm this, that if you're going to bring a lawsuit against a pharmaceutical company, you better come with a check bull of money, because it's very expensive. Vaccine manufacturers typically will defend their products. They will hire big law firms that are very, filled with skilled lawyers and lots of resources. If you are one individual who is pursuing a claim against vaccine manufacturers, if, economically it's unrealistic to pursue it unless your damages are really significant. So if somebody dies, or if somebody has a severe disabling condition as a result of those vaccines, you might see litigation around that. But what I'm thinking,

again, I'm just, my own conclusion, assumptions are, most people who have, a lot of people who might have injuries from these vaccines, it might be more [Indiscernible] types of injuries. They might have claims against medical malpractice, in order to see if those claims are getting filed, you would have to look at the 50 states, and you would have to see if you could find cases where people are suing Walgreens or the pharmacy, or the medical divider they gave them the vaccine. I think the general point is, that I want to make, I don't know if you're going to pick up a lot of noise I understand that, I don't know what else to do. I don't have any constructive suggestions here. I think the problem is, the vaccine injuries are very rare. These are two vaccines that are administered to adults, and as Melissa points out, in order to get these vaccines added to the program, which I think personally would be a very good thing, for all of the reasons that the other childhood vaccines are part of the program I believe that the program is an efficient way to compensate people were injured by the vaccine. But you would have to open up this, you would have to change the name of the statute, or you would have to live with the and consulates of that you have adults who are suing for compensation under the childhood vaccine compensation program. The political ramifications of a proposal like this are probably pretty significant. On the other hand, if we are in the business of recommending, making other recommendations to HHS, that require amending the statute, maybe, what the heck if you're going to open up the statute and make some changes, we might then be justified in saying, that adding these two adult vaccines and changing, making the statute actually conform with reality, which is, this is a program to

provide compensation for people injured by vaccines whether the our children or adults.

>> This is Jason. I agree. It makes a lot of sense here. The one thing we talked about this as a group. I think there are other areas whether it is statute of limitations were others that we made recommendations that would require changes to the program. I think that if you add one, and we are not done with that calculus on this particular issue that we are looking at. If you're going to open the program, and it's going to be amended if in fact the secretary acted on the recommendation, you just have to be mindful of the potential risk that when it is opened up, there may be changes to the program as it exists separate and apart from the change that the secretary would be advocating in front of Congress, so to be sure that if you're going to make that recommendation to the secretary, that the benefits of that recommendation outweigh the potential risks that the program could look different at the end of the day because it is. Now open for changes. I think we just, as our responsibility to oversee the implementation and efficient administration of the program, we just want to be cognizant as a guiding principle at that point. As Sylvia said, there is still some work to be done, we will see if we can get some more data that we intend to bring back to the commission. At this point it's just as we talked about. It's a challenge to get some of that information, unlike the statute of limitations really articulate some of the problems that the recommendation could ultimately solve or help solve.

>> Right, and this is Sylvia. Just to finish up the comments , the hybrid pneumococcal 23 vaccine is recommended for children ages two or older. It is not solely an adult vaccine, though it is now predominantly

used in the adult field with eldercare. I am elder since I am 65. It has been offered to us for two pneumococcal vaccines for folks over the age of 60 or 65. It is being recommended for high risk children ages two are older. We will be looking at that hybrid, again the question is, open up Pandora's box. This department of justice, evidence and his group [Indiscernible] and we will as a working group look at that again. I don't like politics, I'm a working pediatrician. The reason I am on this advisory commission is, I was advised to be on here to present issues that affect children and their parents. Our next meeting will be October 8, Thursday. Any of the commission members who would like to join, and he can get you the information on how to dial and for that. Jason, that is the end of my comment.

>> Peggy Sylvia. Will move to the next item on our agenda which is a discussion of some follow-up items on the June 2015 ACCV meeting, specifically on VICP Minnesota funding and position of SIRVA, this is going to be a commission discussion. We reserve an hour to go over these two topics. Let me introduce it quickly. During the last meeting there was discussion, and I can't recall what started, or whether it was a combination of things that we discussed, but it may have hollowed Melissa's presentation from the division of injury conversation programs. Betz's report from the deferment of justice, but David King, our prior chair asked some questions around the burden, I mean the burden in terms of the workload of the program specifically on HRSA and the Department of Justice and we put a little bit from the office of special [Indiscernible]. The resources that are committed to those three important groups and other groups that may be are not, or as particular close to sufficient to efficiently handle the workload of cases that are increasingly coming in over the course of the past

couple of years. We talk about stretches and budgets and financial constraints. And we want to take a closer look at some of the data that we are seeing, and see if the person things that we can do as a commission to investigate further to potentially go back to a secretary and make a recommendation, regarding what we are worth observing in terms of numbers and workloads which, we don't want to have happen. Bench touched on it a little bit today. That could impact the timely and efficient adjudication of the cases that come into the program. Whether it be from HRSA to our colleagues at DOJ. We can talk about that for a minute. The other topic we had a great presentation from Kelly [Indiscernible].

>> Sorry.

>> I understand the commissioners received a similar, if not the same presentation. It is included on the information prevention of SIRVA. We've had a discussion on SIRVA in meetings pass and this was one not just looking at the condition itself, by virtue of vaccines administration and the injuries to the shoulder, but what are ways that various stakeholders that are connected to vaccines administration in the shoulder, how do we help prevent it through education and otherwise. It was discussed at the last meeting, we got into the beginnings of a conversation around what can we do as a commission to help push out this kind of information, and again potentially look at recommendations for the secretary and this particular area. We didn't have enough time to do that, and the thought was, were going to have a number of new members in September, so perhaps we can table that discussion for the September timeframe, and so we have, and now we are committed today on these two topics. We can also in the conversation on statute

of limitations if there is time for meeting and this section, we can accommodate that as well, if not we can do for that to create our own in the meeting. May be I will spare the confirmation. Some of the suggestions again now, I think would should be mindful of that, but one or more, [Indiscernible] if we have active, the adult immunization workgroup chaired by Sylvia, and perhaps these are two areas or maybe there are others that would merit either inclusion in a process workgroup or [Indiscernible] not sure what's there and I don't want to volunteer you prematurely but it doesn't necessarily have to be. We can form a new workgroup and I think certainly the funding issue is an important one. Especially in light of some of the work that we've done around statute of limitations and we've heard from the office of special Masters today just about what that would mean if the Secretary. Moose forward on that , to the already very significant burden on that group. With that, no particular order, maybe we can start with funding and we can talk a little bit about SIRVA but I open up either of those two, to the commission and I welcome any comments.

>> I think that it would be helpful, and I recognize the irony in this, but it would be helpful if somebody from the office of special Masters level Mac that's a body could give us a brief presentation bike at our next meeting, by which time you guys will be, fiscal year will be at least in times of it will be complete and maybe give us some of the conclusion about the impact this is having on the workload. This, comments were very helpful and the analogy with the treadmill. Clearly, OSM has taken the special processing unit has facilitated deciding cases more quickly and when you look at this average time for adjudicating a case from file to payment, we are doing, as a

program, it is doing better than it has in the past, which could be a little bit misleading. I think it would be helpful for us to understand as a commission how it is really, our concern is, getting people who have vaccine injuries compensated quickly. We don't want to have to rely on former stories how long it has taken cases to get compensated in order to have the evidence to make a recommendation to the secretary that there should be more than a special master group. I think that we could probably hear from OSM about average caseloads for example. With my crazy good math skills,, 150 cases for special Masters, so roughly 1200

>> Per year?

>> Their current caseload of any special master if it is distributed evenly is about 150 cases.

>> I don't think we know in a vacuum if that is unheard-of amount, is that too many? I think of, we could really benefit from hearing what effect that has on people who were filing claims. Anecdotally, as effective as the special processing unit has been, I think that a lot of the vaccine injury attorneys are finding that the nonspecial processing unit cases are taking longer. Not because the DOJ lawyers are working hard enough and not because the special Masters are working hard enough work it's just, the resource issue. If you are going to look at it as a whole program, then the does a good job of spitting out cases that you can resolve fairly quickly. There is good pressure from all of the stakeholders, from DOJ and the office of special Masters about let's resolve these cases if we can resolve them. The problem is, the ones that are hard that won't get resolved through mediation because you're going to end up having a hearing with experts. Like for

example, the two, those cases are getting pushed further and further. Anecdotally again. It's not through a lack of diligence by special Masters or DOJ, at least I don't have that sense. Others might. I just think that is where the volume increase volume is being felt. That is a bad thing, it in and of itself a basis for us to strongly consider to the extent it makes sense that we recommend additional resources for handling the additional caseload.

>> This is Martha. It would also be interesting to put the legal community, is not segregated on some island somewhere. It's interesting to find out what a Family Court judge here in the course of a year. What does, what if a County Court, let's compare their colleagues. Their colleagues are other judges. In different parts of the law. What does an appellate judge, how many cases do they have? Sitting on their desk. Just because interesting to put it in perspective and a lot of people on the Hill are lawyers and would some of them are judges, retired judges. They might be curious to find out when they were judges, it was 80 cases that were on their docket, and 150, I don't know. That sounds like a lot to me. It sounds like an overwhelming burden. I don't know about anybody else, but I would take the easiest task and put it on top, and I would keep going and keep going to get some level of success and then I'm tired. I would be very curious to find out what other peer groups are dealing with. I think that would be interesting if for going to be discussing it and to not segregate special Masters over there. What are the judges doing?

>> A couple of things. Is it possible to use some of this $3 billion that is in the on for administrative purposes? [Indiscernible multiple speakers]

>> If I can adjust that

>> The money in the fund is used to compensate [Indiscernible low volume] when compensation is awarded by the court, but it also funds the administrative budget of all portions that run the program. However, Congress appropriates a portion of those funds on an annual basis to provide the administrator funding stream for all three ranches of the federal, all three parts of the federal government administrative program.

>> So you do have to go every year, I guess and ask Congress to give us X number of dollars. So my second point,

>> Can I just say one other thing? Each of the separate parts of the federal government, and this is to Mayor, each of the parts of the federal government are getting appropriations from Congress separately. So the Department of Health and Human Services gets an appropriation, the Department of Justice it's a separate appropriation, and the Court of Federal claims gets an appropriation. When you are talking about the administrative hunting for the entire program, then you have to consider the three separate components because we are not all submitting our budgets together and getting an appropriation from Congress as the vaccine commons vision program. It's a various component of the executive branch and judicial branch are getting their separate appropriations. That also has been considered when you are looking at overall funding or the national vaccine injury compensation program.

>> Okay. I have another question. About the vaccine. Is it true that if a special master holds onto a case and fails to move it forward, after a

certain amount of time he has to release that case? Or lose that case or something?

>> Is that case?

>> This is Ed, there is a 240 day notice by the court when no decision has been made within 240 days, [Indiscernible low volume] it's almost every case that this order gets issued. But it's basically telling the petitioner, if you want to walk away from the program right now because 240 days has gone by, you are able to walk away from the program. The problem is, where are you going?

>> You were our generative is not, it's basically to file a claim in civil court which we know is very problematic for a lot of different reasons.

>> I have a third question them. Isn't there a smallpox vaccine, vision program?

>> [Indiscernible low volume]

>> The smallpox vaccine is covered by a separate program? It's not part of the program, the VICP and ACCV [Indiscernible low volume]

>> Is exclusively for smallpox. You could not been at the other adult vaccines that you are talking about. The pneumococcal and the softer to the smallpox program. It's not exclusively a small packs program.

>> It's a medical countermeasure compensation program. It is a totally different program than the VICP and the mechanism by which it works is different. Secretary has to make specific declarations so what medications would become her under the program. A medical countermeasure is a specific definition for the purposes of this

program, but it's like a threat or an anticipation of a threat against a larger public [Indiscernible low volume].

>> I also wanted to talk, make one comment about something that Ed had made about the 240 days. The accountability office needs to report about the program last year. I wonder if they are finding regarding the length of time is that, there is a lapse movie program, a lot of time the link the time has increased due to the petition of the request. Asking for additional time to do certain things or meet certain requirements. That also plays a factor in how long it takes for a case to be adjudicated and whether something would be finally adjudicated in 240 days.

>> Going back to extending the time. When that eight years was presented, was it presented in any evidence aced support or just, we wanted to go from three years to eight years. Was there some kind of other lines of support for cases shown or something?

>> The system era again. I've been with the program a while now. [Indiscernible] I can state that for the most part when those recommendations about [Indiscernible low volume] they are [Indiscernible low volume] there was an data to support the recommendation. It was basically the timeframe suggested [Indiscernible] not necessarily that there was data to support it. [Indiscernible low volume]

>> I just think, as it goes through so many hands in so many offices, [Indiscernible low volume]

>> I agree, and that is what has started to happen as you can tell from the adult immunization working group. Seeking support for recommendations.

>> This is Ed, we absolutely agree and recognize that the process working group when we were working, this recommendation, we were trying very hard to figure out how we could get support and you might, just by way of review, we had, I wish Dave King were still here. [laughter]

>> Will be talked about, how can we get the data? And as a person on the commission who has relationship with the other vaccine injured attorneys, I, on many occasions, anecdotal because we don't all it and make a list of the clients who call us who are past the statute of limitations, probably a majority of them never even call because they realize that it's beyond the statute of limitations. It's very frustrating to not have some easy way to provide that data, and one of the things we talked about was, what if we had an opportunity for [Indiscernible] to tell their story to somebody who is in a position to make, to understand the importance of this recommendation and this is where we hit up against, Melissa is already, I can see it in her eyes, she is about to say, all we can really do is make these recommendations. We don't have political clout. It's not our role to lobby. It's frustrating, and I don't know, I wish we could understand why there is no action on extending the statute of limitations. There is no constituency that should be opposed to it, with the exception of the special masters, wanting to, and Asterix that it should come with some additional funding. Even the Department of Justice in its policy, threw been has explained that their general interest is just a definitive statute of limitation, whether it is three years or eight years make it

definitive because we don't want to litigate the statute of limitations. It's not efficient or effective. I guess I'm feeling defensive as somebody who worked on the process workgroup, but we didn't know we could do to generate the data, this is when Dave asked if we could fund, get some funding to do a survey. Just so you knew members know, and old members remember, we really try to figure out how we as a working group could get data, but I don't think we were successful. I welcome anybody's ideas, new members who think of some other way to get data.

>> This is Alexandra. Just that quick easy. Survey monkey is free.

>> Can I respond to that? This is Martha. Part of the problem, and I deal with this every day. Were getting more and more polarized every day on this topic. There are people who won't go to government vaccine sites to get the information because they don't trust them. Then there are people who only get their information, the Canary party or they only get their information from the interestingly named vaccine information, I forget the title, but the anti-, then there are people who get their information from Bobby Kennedy. I'm in the middle of this because I am a moderate, and I hear everybody's side every day. I'd actually lost friends because I'm on this commission, because, oh my God. We have to understand that we are discussing a really polarizing issue in the community. There are people moving from one state to another to get away from the California mandate for vaccinations. There are people moving. We've got, 85% of the [Indiscernible] they don't vaccinate her child and have moved their, this is becoming sort of the big issue that you guys are trying to be academic and trying to think. Are not going to go on survey monkey and get anyone's response on a government commission trying to get

[Indiscernible] they do not going to get. Bobbies trying to do a survey on his [Indiscernible] people were moderate a pro-vaccine are not going to respond to Bobby Kennedy. Or you get the information when there are so many different, then there is the religious exemption, political exemption. I go back to the disability community. We say that as a community. Everybody is a disability community. On the disability so are you. This perlite disability advocates, there is, we are trying to get information from people who don't really exist. In a way that it doesn't exist, in a way nobody will respond. We got the survey out there. Child find. At the survey out there. The child is doing a half, you're doing [Indiscernible] I don't know, it's going to complicate it. That's why the practice of this committee to try it all. [Indiscernible] sort of brave. I have actually no suggestions except to say, that if we did do a survey we have to ignore knowledge one of the public comments in here. I hear it every day. Who are you to tell me what to do. It is a big issue. We got a presidential candidate with that issue. I just think that if going to do any kind of public outreach we have to ignore knowledge people that have Internet, people who don't have computers, don't have Wi-Fi, a don't speak English, think, they are blind, they are deaf. They are computer illiterate. We have to think of all of the commendations so their backs County school system has 1500 languages that they have to accommodate. We have to figure out when you are dealing with CDC you have to figure out who we are talking to. We are talking to every single person. [laughter] [Indiscernible] I just find it almost, I would think that sometimes the assumption is eight years. That's the essential.

>> I was think it, because one person story [Indiscernible] the injury. The injuries that are on the table. [Indiscernible low volume] as you look at all of the injuries, what would have the longest leadtime?

>> This is Ed. I think it's a good suggestion but I don't think most interest, if you're going to be able to prove, and if it's some autoimmune problem, it's going to be within a couple of months that the first symptoms start to emerge. And the way the court has interpreted it, the statute of limitations provision, UBS is, symptoms that emerge, even if nobody understands the significance of them at the time, when you go to file your case. If it's in the medical records or if it is apparent that those exceptions existed, which you are going to argue that they did because in order to prove causation you need to say, the symptoms started back here. That is the current [Indiscernible multiple speakers]

>> I think just hearing what Mark has said about her own story. It's a lot of intangible, hard to understand, factors like survival mode with a disabled child with two or three years, or doctors insisting that this couldn't be a vaccine injury, not getting [Indiscernible] at there are many factors.

>> [Indiscernible low volume]

>> I see all of these things coming together and hopefully they were with recommendation and I guess we want to go from three years to eight, but the reason we want to go to eight years is because of [Indiscernible multiple speakers]

>> There was some language around that being supported. I did not see the final case, but what you are saying, the survival mode. The

unknown, the lack of in the establishment community. Given those factors together, support advocates this new position versus, we want to go from 3 to 8. I have knowledge that aid will take care of all of this stuff that happens around it.

>> Keep in mind, this is Martha. Keep in mind, there is an excellent well-funded, overfunded community effort to tell you that vaccines are perfect. They are wonderful. There is nothing wrong with them. So we are working against, and it's great that we are vaccinating more and more kids against malaria and all of these things, but we are working against a situation where the pediatrician that we had, and this is no insult to her, we also had a study that she was being paid to do [Indiscernible static] so the cynicism and I don't know if you guys are cynical or not. Cynicism is that she is never going to help me because she is on the table of the pharmaceutical company. A lot of research hassles are, teaching hassles are, so cynicism begins to roll the day. Cynicism also makes you not while a claim because you don't think, you begin to see, the drug trials and you which are hands up. I want to go back to a different subject and want to clarify. We say Congress as if it is the White House. Congress does not exist as Congress. We have Congress subcommittees that put together budgets with the secretary of, put together DOJ

>> There is a lot of people up on the hill to do this. Doorstep do this got us up. Is it really, data thing that starts with [Indiscernible] going to the subcommittee subcommittee ghost limit committee Mittie goes to the floor. It can take a long time. Congressional practice takes a while brick sophisticated, who is allowed to be there, who's not allowed to be there. I just have another stupid question because I have yet to see this.

>> Up on the hill, who do we have as an elected official to go to bat when are people in the department, when Secretary. [Indiscernible] department of justice and air colder would go up. Who would go to bat for our program, do we have a representative, is there a subcommittee that is particular couple for us [Indiscernible] or go to it. I'm just kind of curious if we have friends on the Hill?

>> If I'm asking the right question work

>> What I would say from where I sit is that we follow the process and we as,, I do not go out and lobby. We do not lobby. We present, just like you said, a budget is presented by the head and decisions are made [Indiscernible] congressional subcommittee. Then the appropriation is made and we are informed of the appropriation.

>> So the cards are stacked against us because there are trillion dollar lobbyists working against us and they go up there every day and have lunch up there and they do stuff up there. It's kind of stacked it we can't even have you go up and explain your budget request, but the other side is paying somebody, [Indiscernible] they are all over, I call them nice you guys. All wear expensive shoes and they are lobbying every day. We are stymied I guess. We don't have anybody up there that can go explain why we are asking for the money.

>> This is Alexander I think there is another point that we should all not Lucite up. In terms of, you just because you have adjudication or a case, doesn't mean that it's going to be resolved [Indiscernible]

>> Exactly

>> You may have, expand the statute of limitations to eight years and you'll get more cases in, but they will probably all lose anyway.

>> [Indiscernible multiple speakers]

>> The percentage of loser [Indiscernible multiple speakers]

>> Statistically there is more and again.

>> I think that [Indiscernible multiple speakers]

>> I don't know the basis for thinking that the new cases will have less merit than the old cases, there might be something to that, what I don't think we are assuming that the cases are filed, that would not have been extending the statute of limitations would be a different kind of case I think it would be more of the same some of which you would be able to establish causation and review compensation, some of which you won't. That would be my response to that one.

>> [Indiscernible low volume]

>> The Iowa address the common about lobbying. So while the federal government doesn't lobby, the secretary does put forward justification, and past justifications are available once appropriated. It's not that the federal government doesn't have an opportunity to [Indiscernible multiple speakers]

>> State its case or explain why they would support this budget or not. They do have that opportunity. And justifications are provided when we, and anyone can seep past justifications once the money has been appropriated or a budget is made public [Indiscernible low volume] are available.

>> To follow up on Melissa's point Mrs. Jason Smith. I think one of the things that we can do as a commission, and Martha the points that you raised were all valid just between the executive branch and

congressional one, especially on budgetary matters but when you look at, for us I think that would be hopeful as far as if it were the secretary putting forth a justification for the money to help administer the program, for this body to say we have looked at data, at workloads, at numbers of cases and in order to ensure the continuing efficient resolution of these cases, they come into the system. It's our view that in order to keep up with the increase in demand, that the resources and financial commitments should parallel that. It's our view that the secretary should take a look at that and asking for budgets whether it's next year or otherwise. I don't know if that's going to sway [Indiscernible multiple speakers]

>> It's a nice way of saying it too, but it's so easy to get a crying mom to go and testify in front of Congress and you are the Mac you get may be on the today show. I've been on the today show crying. They love to have a crying mom. [Indiscernible] 24 hour news cycle. Once I've done crying, everybody moves on and they are doing something else, I'm not saying anything against the way the system is run, but then a lobbyist, or congressman their donation prettier, my crying on TV. I got lunch out of it. But I didn't get [Indiscernible] out of it. It's a very coveted program. It's all we can do, advise and say what our expert opinion is. What we think our expert opinion would mean something. I don't know, for us newbies, with all of the energy, we will be tired and a year. [Indiscernible multiple speakers]

>> UB slumped over the table. [Indiscernible multiple speakers]

>> It's disconcerting because people who are new want to do change everything and [Indiscernible] everything we thought about before. Had said, acknowledge what we can do and accept the limitations and

work with [Indiscernible] very frustrating for people who. A friend of mine said, and less you are changing a 25-year-old diaper, don't talk to me. [laughter]

>> Talking about people dying from vaccines.

>> This is add. To [Indiscernible multiple speakers] at first, she raised good point. We did raise a nice justification for why, I don't remember him a digital ride it to merit? I can't remember who, but we looked at it [Indiscernible multiple speakers]

>> [Indiscernible low volume]

>> It was concise and I'm sure we could do more in Seymore and obviously we could support it. It would be more effective if we could support it from data and not just anecdotal commentary. I would, it might make sense. New energy, to kick back to the process workgroup. And to also drag and some of the new people to the process workgroup.

>> [Indiscernible low volume] [laughter]

>> The issue of, what can we do to make more effective the recommendations that we made in the prior three years, which we keep talking about statute of limitations I think that's most important, but we've made a recommendation to increase the pain and sufferingthe issue partially, I feel it's a separate issue and our focus on the process workgroup should continue to advance the cause that directly affect the vaccine injured folks and not necessarily the functioning of the program as a whole. May be my recommendation would be that we, I don't know where Lewis is, we are the same [Indiscernible] we are both cycling off next year. It might make sense

to reconvene the process workgroup and have a meeting to talk about those recommendations and perhaps a point some new chairs. Of the process workgroup.

>> This is Jason. I agree, I think that makes a lot of sense. I think it's a good idea for a couple of different reasons. One, to look at the prior recommendations with a fresh eye, and some of the discussion that we had today may not be data, but I think there is an important narrative for the reason to help justify whether it's eight years, the timeframe is not as important as the concept to look beyond three years potentially. The stories we heard today, the inability despite clock is ticking, to be able to find someone to provide the medical expertise to help on the causation termination is an important one. May be [Indiscernible] and add recruit and we would very much enjoy it was participating on the process workgroup because there will be continuing transition of commission members and I do think that, as Martha properly said, the brand-new and go get them spirit. That's usually helpful on that initiative. On the VICP administrative funding, I also agree, I think with Ed's suggestion that perhaps that may be looked at by a different group, and maybe I can ask Melissa, you and Tamara and Eddie. We can talk about it as we create the agenda for the December meeting where the end of the year, I don't know when your budget timeframe he is, but I don't think it's a problem that will go away in December or necessarily be fixed. In 2016, if they're in fact there is a problem. It may be coupled to take some additional time on the agenda if we had it, to try to get, great statistics and data about numbers of cases, how many do we settle, how many are pending, but I think some insights behind those numbers, how many people are committed to looking at the cases that come in. Committee

medical reviewers, how many did we used to have, what their caseload is like. And the Department of Justice, how many attorneys do we currently have supporting the cases that are there. Just a little bit more flavor. We always look at just the numbers. How long does it take to resolve the case from beginning to end or reach a conclusion. But a little bit more on, what's the, I guess to expand on penses analogy, that Ed touched on about the treadmill, how far back are we on the mill before we fall off? And that's not just by the numbers, because it seems aggregating through cases maybe quicker than we've ever been, I say we, I mean the department of justice. With the influx of those cases, there is a real strain, and we don't want to fall off the treadmill, because that's usually important.

>> Mrs. Alexander. Another important question might be, how many hours a week [Indiscernible] is working in the department of justice. If they're working 75 hours a week.

>> [Indiscernible low volume]

>> And may be, before the formation of a workgroup, if we can have a little bit more time, it doesn't have to be. I was on the agenda but for the presentations we already get, a little bit more detail, more geared towards that issue to help us get subordination rather to make, a polar discussion on that issue.

>> I agree with how you, with what you've proposed and I don't want to be too negative work maybe before we even do that, we should request, we should ask the question. Is it going to make a bit of difference if the ACCV makes a recommendation to the secretary to get more money , I mean the secretary is already fairly motivated and self-interested in terms of getting the funding to do the job that you

guys want to do. Similarly, with DOJ,, so my question is, if this is something that, I think we probably would end up with some good statement about why we think additional funding is important, but would it add anything to the efforts that are ongoing from DHS and DOJ, to the extent that it is a separate communication channel. And please be honest.

>> I'm always pride myself on honesty. What I would say is, it's just another case, piece of data.

>> That will do it work

>> The system era, I want to address your question about the, and Charlie about the recommendation [Indiscernible low volume] regarding the statute of limitations actually hear from 3 to 8 years for injury, and could justification that we [Indiscernible low volume] or we'd did include the letter is that is our current statute of limitation [Indiscernible low volume] which runs [Indiscernible low volume] that was the extent of the communication that we use.

>> Could you just give yourself [Indiscernible]

>> Sure we can. We can just send it to you over email or [Indiscernible multiple speakers]

>> That's interesting.

>> You could add a lot more [Indiscernible multiple speakers]

>> I don't remember what we ended up documenting but that is a helpful, that is helpful because what seems like we had so much more [Indiscernible multiple speakers]

>> I would just say with these recommendations how it initially started is that workgroup has several recommendations and so the intent was to provide the recommendation and be sustained, but [Indiscernible] recommendation to, then at that point [Indiscernible] initially started with several and with the intent of trying to make a sustained [Indiscernible]

>> This is Alexander. Something else about the vaccine and the special masters. I have a feeling that a couple of them might be retiring soon. I don't know.

>> One of them just did.

>> That's why special master is now chief, but cause former chief special master just retired

>> See you going to have new people coming in and they can't manage this caseload. May be one additional attorney would be really helpful to them. To pick up maybe 80 cases [Indiscernible multiple speakers]

>> Common sense [Indiscernible multiple speakers]

>> Who was the lovely woman that was introduced us yesterday [Indiscernible multiple speakers]

>> This is Ed, the point is, by statute there can only be eight special masters and certainly they start out, that you don't expect a brand-new special master to be able to handle as quickly as or efficiently the same number of cases and there has been a lot of turnover in the last three years. For the special masters, actually more than that. The last five or seven years, there has been a lot of turnover. Turnover issues

aside, the point is that eight special masters simply, wasn't enough in the 19 Turnover issues aside, the point is that eight special masters simply, wasn't enough in the 1990s and maybe in the early to thousands, but now either you weren't asking the special masters to, either they had half a caseload 10 years ago or they have a double caseload now. Based on the numbers.

>> [Indiscernible low volume]

>> That's a great point.

>> [Indiscernible low volume]

>> This is Sylvia can you repeat that, I didn't hear.

>> I think that the theme of what you said is with the addition of the flu vaccines, the amount of vaccine that is administered through wise puts a burden on the number of cases coming in that ultimately closed down to the OS M. I think we have, it sounds that we had a pathway to look at the statute of limitations we will refer that to the operations workgroup. We will see if we can [Indiscernible] process. The process workgroup on the administrative VICP bonding and the various stakeholders , with branch we can talk on another agenda Melissa, for the December meeting. I want to be mindful of the type of this particular session we haven't spoken much about SIRVA. A very important topic and some things that we can look at not just to understand what that is, I think we have a good idea from prior meetings, but there was a [Indiscernible] set coming out of the last meeting about what we can start to think about as a commission on how to help educate and spread the word on SIRVA which is fairly novel event associated with vaccine administration. I wish we had

Kristen here along with Sylvia to help think about ways. There were some good ideas coming out of the presentation, but I want to get the commission's perspective on, how do we help facilitate that dialogue to at least start to think about what can be done, on the creation of another workgroup to take a look at that. What does everyone think?

>> This is Sylvia. The server I just, for the new folks, that's the shoulder injury is that correct?

>> That's correct. Shoulder injury resulted from vaccine administration I think.

>> And surprisingly, if you look at the literature and I think Tom and I have talked about this briefly. It's not described in pediatrics. For one thing, for children, most of the time for infants, it's in their legs, and for the teenagers, of course it is in their arms. The vaccine for children and CDC are very adamant about training nurses, MAs and I don't know what the retail markets do, like Walgreens or CBS to train their personnel. That's all whole training component, and I don't know whether the recommendation is that we push the agencies who do the training to address that in a driven mode. I'm not sure we've got, we have the focus to push training and more operational and policy for administration. That's my, because as a pediatrician, I give all my hemophiliac was their vaccines. The nurses are petrified, because of course those boys are bleeders. I am very, in giving immunization but most pediatricians and docs don't get their shots. So you're really looking at a different kind of modality to train people and that's probably a different agency,, I don't know if you're still there you can comment a little bit on that.

>> Yes, [Indiscernible low volume]

>> So Jason, I don't know what your focus was with the prevention of SIRVA or the recommendation to the agencies who do , and I don't know the correct words, the administration. Of these vaccinations in order to prevent injury so you're sort of saying the axis of interest.

>> I think that's right, but I think the edge and item that we want to have a discussion on, or I think we had a 15 or 20 minute timeframe to discuss, I know Dave had made a couple of suggestions, and were just running out of time. Let's table it, if there is a continue to follow a discussion on SIRVA and some things, and Tom shared super perspective at the last meeting, I want to make sure that we, have ample time on the agenda that were additional thoughts that we capture them, and we don't think that there is any further actions we can take as a commission at this time, or we don't need another review. That's okay as well but I wanted to at least have that discussion.

>> There is a commission, develop some language for the VIS [Indiscernible] sheet. [Indiscernible low volume]

>> This is Ed. We did actually talked about it. That is one of the things raised the cause that's right about the point that we said, wait a minute. We probably need to take that back and have some time to really discuss. Is that what you remember as well?

>> Yes that was in the minutes [Indiscernible multiple speakers]

>> I think I remember there were three response, brief response that, who's really getting the VIS statements and would that be an effective vehicle for promoting, and that's where we realize there were a lot of

moving parts within the federal government and at the state public health level that are involved, vaccine administration

>> Everyone is supposed to get a VIS statement.

>> That is correct, but I guess the question is, is that the target audience that you're trying to [Indiscernible multiple speakers] because the VIS is for people receiving the vaccines. Actually, I would suggest if you want to target a person [Indiscernible low volume]

>> How but posters or something like that?

>> This is Sylvia. If you guys look at the CDC site, again I'm posting the CDC but there is a whole section of guidelines for administration, and it's very well written and it's for all of the different levels of administrators. For the vaccine for children fund, New Mexico is one of those two states on the universal vaccine purchaser, but everybody has to be trained. Every state has its own training modality but if you look at the CDC right now, I'm going to turn my head away from the bone, it's CDC.gov\vaccine and its administration. It is very well written and everyone has to go through this training who administers vaccine. So Jason, I'm not sure we can state the local levels, have to be trained in administering this to prevent the problem.

>> This is Alexandra. I wonder where the hundred and 36 cases came from.

>> Are they clustered in certain parts of the country or all over the place?

>> That's a good question. We don't have that data available because the data we have is just the total number [Indiscernible] we don't

capture when, where it is coming from. We just received them all and [Indiscernible low volume]

>> I would love to know with the provider is.

>> Who administer the vaccination,

>> It would be so helpful.

>> Aren't we, I'm just going to play devil's advocate here. Aren't we trying in the big picture, to retrain people already got tremendous school already been trained as an think it to myself, for some people, I guess we are properly educated or trained, and this is such a huge picture. [Indiscernible] she's a nurse, and she teaches and art we now a little over our ability. We are asking people to be trained. They are going to be trained, and now we're looking for people who might have made mistakes. I'm going to train drivers all over again, and I'm going to look for the bad drivers causing the accident. [Indiscernible] I don't know, I'm not sure this is really our place because supposed to be trained to do this.

>> This is bad. I kind of look at it from a, so much retraining, [Indiscernible] I'm in clinical practice. I didn't know that this was an issue until I came here. So as Tom was saying, with a professional organization, I think people have already done it, and are out practicing, just bring attention to the fact that [Indiscernible low volume] CDC site that is is so well written. On the other and, you have your people coming through school. Those programs. And I'm not entirely sure the pharmacist and everything. I know ours is accredited. I don't know if you can work something into an accreditation, I don't know. Food..

>> This is Jason. The topic on the agenda was a necessarily for the ACCV to do something, we were starting to have a dialogue we wanted to make sure that we continued that during this meeting. I think the point of the June 2015 meeting has been, something that is reasonably new in terms of some of the data coming out there it seems to be that the various stakeholders involved in vaccine administration from the CDC to the AJ, they're doing education and outreach on SIRVA and being particular on administration guidelines and such and maybe it's just , this is an important document we will continue to hear from Tom in meetings in the future and Beth, you can help as well. Maybe down the road that are important for us to hear. [Indiscernible static] the point was not necessarily let's come up with something and make a recommendation, it just to make sure that we tied up some loose ends from the last means. It's been a very good discussion and it's an important topic, and I think we can continue to monitor that.

>> Any other comments on any of the three?

>> Just one brief one. Is is Ed. How feasible would it be to look back at certain cases in the last three years and determine who administer the vaccines?

>> It would require somebody, I'm sorry. [Indiscernible multiple speakers]

>> I mean cases that were filed in the program.

>> [Indiscernible low volume]

>> It's in the early stages but it's ongoing. Which I think that captures the national [Indiscernible] I think that we get that information, we

are happy to provide it. [Indiscernible low volume] although we, we are a little bit limited [Indiscernible low volume] we tend to dig a little deeper. So you have some ability to say, was this in a provider's office, was this at an occupational clinic, was it at a pharmacy? Sometimes we can get that information. That information may be available [Indiscernible low volume].

>> Thank you Tom.

>> That reviews, focused on [Indiscernible low volume] I think that would be represented in what's going on and generalized with other [Indiscernible low volume]

>> Thanks Tom. So, we've concluded the items on the morning agenda, why don't we break for one hour for lunch and return at 1:30 PM Eastern time. Sylvia, why don't you hang up and redial in about an hour's time, is that okay?

>> Would be perfect, as long as she links me in, because she had me waiting and you kept asking me.

>> We will make sure that that happens.

>> We need not discuss this on a national level. [laughter]

>> Data Sylvia we will take a recess for one hour for lunch.

>> Have a good lunch.

>> Were going to disconnect.

>> [The meeting is on a recess. The session will reconvene at 1:30 PM Eastern Time. Captioner is on standby.]Welcome back everyone from lunch. Let's get started with our first agenda item on the afternoon

session. The update from the immunization safety office, disease control and prevention, Dr Tom Shimabukuro.

>> Thank you Jason. I would like to welcome all the new commission members and the existing ones, great to see you again and meet you in person. You should have gotten a lot of attachments, I guess Andy sent them out, they are PDF fails. They are -- PDF files. There is one file in there that is a presentation that I gave at the IP meeting which is end of season summary car on vaccine safety plus a summary of the preliminary results of a vaccine safety data link study car and I would encourage you to look at that PDF of the AC IP visitation which is also available online, you can just go on to the website and look at it. I'm going to present that in one slide in about 30 seconds. It is really about a 20 minute presentation. So it might be worth your while if you have time to look at that slide.

>> I'm going to start off with updates on the selected sessions from the June AC IP meeting and then covers some selected vaccine safety precautions so at a ACIP meeting there was a boat for Sarah group B, meningococcal vaccine and that was for the series to be given 16 to 24 years of age to provide short term protection against most strains of meningococcal disease. There are two recently licensed meningococcal B vaccines, one of them was used under an expanded IND and a couple of outbreaks of at college campuses, and this was a follow-up to that, the initial recommendation, the preferred age for the men B vaccination is 16 years to 18 years. This is a category B recommendation which means made for individual clinical decision-making so that is really a decision between the position and the patient or parents. It is not an a recommendation which is more of a hard ACIP recommendation, recommended for children that age

group. This used to be called a permissive recommendation now it is called a grade B recommendation. So in the influenza session there was a vote on algorithm for determining which children aged six months to 10 years need to doses of the vaccine, and also new products incorporated into the recommendations. Some of the new Quadra valent and inactivated intradermal vaccine. Trivalent recombinant influenza vaccine for ages 18 and older. That is an expansion of the initial approval ages. And then AFLURIA was recommended with the jet injector for ages 18 years to 64 years. AFLURIA is the only FDA approved vaccine that can be administrated with a jet injector.

>>, What was the age for the card drill valent?

>> I did -- I believe it was 18 and older. They used to be an actor -- older cut off. It was on the backend not the front-end.

>> I have a question about the AFLURIA? If the jet injector considered preferable to an ejection or something?

>> No it is just a different delivery device.

>> Okay thanks.

>> And there is no ACIP recommendation it's just that as a vaccine can be administered by a jet injector if the product is available and you choose to administer it.

>> And can I ask a question about the mentor cockle vaccine? How does that impact inclusion as a vaccine?

>> It covered.

>> Thank you.

>> It covered because of the excise tax language. Second there was about the vaccine to recover that is more of a procedural vote.

>> So at the session there is also a vote to enforce -- endorse strain selection for the 2015, 2016 session made previously by phone and FDA. And you can see the 28 strains and the H1 and California H1 and one like virus has been the same strain that has been in the vaccine since the year after the pandemic. And then for Quadra valent vaccines you have the bottom will it there that is the peace train that is included in Quadra valent vaccines. So there is also an vaccine safety vaccination, the PDF is available at one of those web links below. I'm going to come back to this but let me just run through the end of my presentation and then I will move back to the slides. So if the pneumococcal vaccines session there was a boat to change between PCV 13 and pneumococcal polysaccharide vaccine 23 until age 65. The change to adults in the PSP 23 should be given at least one year following a dose of PCV 13. If a dose of PPS the 23 is given earlier than the recommended interval the dose need not be repeated. Previously the integral in adults from P CB 13 to PPD 23 was six CB 13 to PPD 23 was 6 to 12 months.

>> So there was also a vote on small packs -- smallpox vaccine. To update the smallpox recommendations which were last updated in 2001 and since then a camp 2000 has come on to replace drive X. And I'm not going to dwell on this at the top really relevant. It's just for your information. So let me move back -- I'm going to spend a little bit of time talking about the end of season update and the update on the vaccine safety data link study. I can't really do it justice it was a longer

presentation. So for the end of season update, there are no new safety concerns detect it in our surveillance which we do on an annual basis for informed vaccines. This year we detected and elevated relative risk in the rapid cycle analysis that we do in our vaccine safety data link for seizures and following I I be three, that is the trivalent IID and the Quadra valent I I three for children 6 to 3 months, so for the new members I have made several new presentations going over the data for seizures after inactivated influenza -- but -- vaccine anti-As well. Although the BSD rapid cycle analysis is an ICD-9 coder to surveillance, we know from previous surveillance that the positive predicted value is for seizures is about 85% or so so what we are doing is monitoring for febrile seizures in children. We saw originally saw this risk in 2010 and 2011 or increase risk for seizures and when we looked at this further the risk was highest in children 12 months to 23 months peeking around 15 months of age. The attributable risk was about 45 additional seizures per 100,000s of children vaccinated with inactivated influenza vaccine and PCV 13 at the same time. This data was presented to CDC and ACIP and there were no changes to the recommendations. The following year we also saw this increased risk after I I be again highest in children age 12 months to 23 months, highest when PCV 13 was given along with IID, and I also want at a previous meeting to present data on epidemiology study which confirm some of this information but also included all commendations of vaccine and the take-home from that was that when I ID3 and PCV either seven or 13 because the spam the years when I was a transition from 7 to 13, and D From vaccines were administered at the same visit there was an increased risk for febrile seizures and it was strongest in those three were given together. In the following two seasons after

2011 and 2012 in our surveillance we did not see this increased risk that this past season we saw this increased risk again. The magnitude and the shape of the curve were remarkably similar to previous seasons, so this is not a new safety problem this is something that has been observed in the past, and the magnitude was about what we had seen before. We presented this at the June a CIP meeting. And we will follow this again next year. But this was not completely unexpected given that we had seen this increased risk in the past.

>> So the vaccine safety data link study, this was look at spontaneous risk of abortion after a seasonal influenza vaccine with a specific focus on H1 H1N H1N1 vaccines. There has been a lot of work on spontaneous abortion and interacted -- enacted -- inactive influenza vaccine. When we conducted this good -- let me say this is to permanently data there is still work going on on this and we're also doing a follow-up study. But the net result of this weather preliminary results for the 2010, 2011 and 2011, 2012 seasons the data showed an increase risk of spontaneous abortion following inactivated influenza vaccine among pregnant women in the 1 to 28 day risk window. That is 28 days from the time of vaccination. Until the event or the interval expires. For individuals who had received an H1N who had received an H1N1 containing vaccines the previous Sims season. So if you contained -- received the vaccine the previous season and then you got a vaccine in this season there was an increased risk during that 28 day season. So these findings are inconsistent with a lot of prior studies looking at seasonal influenza vaccines and we presented this to ACIP there was some concern about bias and confounding in the study and for that reason and the fact that this is inconsistent with what we've seen before we are going to undertake another study

looking at more recent years which also includes the H1 and one containing vaccine to see if that finding persists.

>> Moving on. To give you a summary of some recent publications. The sukkah Moran demographic characteristics of members of the VSD comparison of the United States publication -- population. The take-home is that it is representative of general US population at several key telegraphic and social economic variables. Despite a few specific groupings being underrepresented in the VSD compared to the US, the absolute number of members is large enough to ensure significant representation of these groups in vaccine safety studies that use VSD data.

>> So vaccine safety resources for nurses Carmella at all. Explains how nurses and others can assess the CDC's inquiry channels and other resources and gives examples of recent inquiries and their resolution. So for the nurses on the group this is actually a pretty good paper and it is a very easy read, written for a general audience. And you might find it interesting. Others would find it interesting as well.

>> These are the MM WR recommendations, those were covered at ACIP as well.

>> Dr Tom Shimabukuro et al. this is how we conduct vaccine safety in VAERS.

>> Baker at all advanced clinical decision support for vaccine adverse event detection and reporting. What this is is some software with some flags embedded into an electronic health record to basically notify clinicians if a certain ITD nine codes come up within a certain interval after vaccination and prompt them to think about whether

they want to report an adverse affect. And the conclusion was that an open source, electronic health record-based clinical decision support system can increase detection and reporting rates in VAERS.

>> Morrow and all debts reported to the vaccine adverse event reporting system United States 1997 to 2013. This is a large conference of review of all the death reports submitted to VAERS during that period and the conclusion was there was no concerning patent, the main causes of death were most consistent with a common causes of death in the US population.

>> Haber at all. Intussusception after monovalent rotavirus vaccine United States, report 2014. The authors reserve -- observed an increased risk of intussusception three 3 to 6 days after dose one of the monovalent rotavirus vaccine, the excess risk ranged from 1.2 to 2.8 per 100,000 in sensitivity analysis. So there has been quite a bit of work from the CDC and FDA on the risk of intussusception after the newer dose of rotavirus vaccines. And this is really consistent with what we know that there is a small increased risk of intussusception after rotavirus vaccines. To cover the estimated small number of intussusception cases after beautiful to our the one is outweighed by the benefits of rotavirus vaccination.

>> So our preparation for global introduction of a number rated poliovirus vaccine, safety evidence from the USsystem 2000 , to 2012. We did this with you in preparation to inform a lot of international programs that are switching over from an oral polio virus to a regular virus vaccine and the desire to have some safety information for this switch. The reason for the switch was safety in the first place so basically this is more to provide reassurance and data on IPV safety

since the US actually made that switch. And fairly few adverse events are reported for the more than 250 million IP the doses distributed between 2000 and 2012. Sudden deaths reports after IPV were consistent with reporting patents for other vaccines. No new or unexpended vaccine safety problems were identified for fatal, nonfatal serious, and nonserious reports in the assessment of adverse events after EPD -- IPV. Most vaccines given in the US these days are a combination vaccine? Which company -- obligates the picture a little bit but still the data on a TV -- IPV is reassuring. So that concludes my presentation on the half of the Centers for Disease Control and Prevention. Are there any questions?

>> I had one question about that paper article. I'm not understanding what that means. Generalizable clinical support decision system?

>> This was a pilot project, a research project to see if the software which could be incorporated into Martin electronic health record like the epic or other systems, could be incorporated into the electronic health record where basically you would link and exposure, a vaccination and an outcome in the ICD-9 code. And taking into consideration risk, and risk intervals. And if you did have an ICD-9 code appear after a vaccination within a certain risk interval, that would create a system platform want -- lack of a better word, and you could get back to the provider and say your patient was seen in your clinic or patient -- hospital with this condition after getting the vaccine. Would you consider submitting a VAERS report? I may be simplifying a little bit but essentially it is like a flag, the provider -- and I believe these are email or electronic message lacks, the provider could then go in and based on the clinical judgment make an assessment of whether they want to submit a VAERS report were not

so basically it is a decision support system to help identify and facilitate recording. A fully electronic measure.

>> Thank you. That sounds very interesting and promising. To the extent that there are sadly VAERS doesn't capture a lot of the situations that may be adverse reactions. So is there any federal health support for trying to expand the project?

>> We are certainly interested in pursuing more work on this. I think there is more IT issues to flush out like compatibility across systems, and ease of just incorporating this, I don't think it's as easy as when you download a patch from Microsoft, it is not that easy. It's a little more involved but I think that the ultimate goal would be to in a cost-effective way to have some type of open source software that could be incorporated to help providers make decisions about reporting adverse events. Does anyone else have any questions for Tom?

>>, This is Sylvia. The question with the rotavirus, was intussusception seem that the two dose or the three dose? I don't know the manufacturer name.

>> R1 is rotor X I think. And this was primarily seen after dose one.

>> After one? Okay. A lot of us to deal the young babies have gone to the two dose, it's a little bit easier so that's where the question came from.

>> RFE one is rotor Rex Sylvia.

>> Thank you I appreciate it. And the second issue is back on slide seven. PCB 13 is covered in the entry table and PPS the 23 is not?

>> That is correct.

>> Thank you.

>> Any other questions? Great thank you Tom.

>> And you have emailed copies of all the articles? Did it include the two that have not been published yet? Your article and the Baker article?

>> They are available by PDF.

>> The next item on the agenda for today is an update on the national Institute of allergy and infectious diseases, National Institutes of Health, vaccine activities, Ms. Claire Schuster.

>> Hello very nice to see everyone here and welcome to our new members. I'm going to talk a little bit about some of the activities with supporting related to vaccines but first I thought this might be of interest to the group in 2000 you may have heard that Congress approved a national children's study of children's health and development. In 2014 the advisory committee to the NIH director said that while the goals of the study were worthwhile and worthy of future support the study itself was not feasible as outlined and so our director Dr. Francis column decided to discontinue the national children's study. So after this decision was made, NIH leadership and staff were to identify alternatives and they came up with the proposed environmental influences on child health outcomes or ECHO program. And they recently invited the prop -- public to comment. The country is now closed but you can still view it online using this link at the bottom of the slide. And this proposed study was leveraged from existing studies to look at longitudinal influences on perinatal, prenatal and postnatal exposure on pediatric health incomes --

outcomes. In four focus areas. Obesity, birth defects and other outcomes, neurodevelopment disorders including autism, ADHD and depression, and airway diseases including asthma and allergies.

>> So moving on to some of our vaccine examples. The next two slides will discuss our support of various vaccine candidates. And these are all written up in press releases that are available on the NIAID website. I've also included the references for the relevant papers at the bottom of the slides. NIAID supports a variety of influenza research including development of vaccines such as a universal vaccine. A universal flu vaccine could protect against a wide variety of influenza strains and this is considered a public health goal is the impact of seasonal flu each year as well as the potentially devastating effects of a pandemic flu, and so instead of trying to predict which influenza strains will be a problem each year and match a vaccine to the strains, NIH scientists created a vaccine cocktail with four out of the 16 different subtypes of an influenza protein called hemagglutinin. Two of these were from human influenza virus strains into a form avian influenza strains that could affect people. The vaccine is made of virus like particles which help produce immunity that they cannot replicate or cause. And so far the vaccine has been tested in mice were it did show protective immunity and now scientists are evaluating it and if the results are similar to what the scene in mice than they hope to advance the candidate and implementation of testing.

>> And other vaccine currently in development is for Epstein-Barr virus. Which is one of the most common human viruses in the world and effects nine out of 10 people join their lifetime. It is best known as the major cause of mononucleosis and worldwide it is also

associated with 200,000 cases of cancer each year. Including Hodgkin's lymphoma, non-Hodgkin's lymphoma and other cancers. Currently there is no licensed vaccine to prevent Epstein-Barr virus or EPP. Researches and collaborators have developed experimental nano particle-based vaccine. Nanoparticles are microscopic particles that are being investigated as potential delivery mechanism for vaccine. They used a structure based design which means that the vaccine design was guided by an understanding of the structure of the virus. And it was found to elicit potent neutralizing antibodies in animals. Such as mice and nonhuman primates. The scientists believe that using this approach they could also develop a promising vaccine to prevent Epstein-Barr virus in humans. We also believe that the nano particle vaccine design could be used to design other vaccine designs against other pathogens especially once for what it has been difficult to induce.

>> Nightlight to switch gears a little bit and talk about middle east respiratory syndrome or Morris. A viral respiratory illness that was first reported in 2012. The virus that causes MERS happens deep in the lungs and the numbers have increased more than the slide, it affects over 1400 people over the world and caused over 500 deaths mostly in Asia and the Middle East. Currently there is no licensed vaccine against MERS. NIH recently issued several press releases on MERS vaccine candidates. Our colleagues recently reported that there was a MERS vaccine given six weeks and fully protected monkeys and camels. You may be wondering why camels? Because you don't normally feel -- here about testing on camels. Camels have been found to help transmit the virus to people. And so finding an

effective way to slow MERS could involve vaccinating towels -- camels to stop infecting people.

>> A lot of camels in Saudi Arabia, a lipid racing industry. -- Big racing industry.

>> So now researchers are looking at this and the findings from this study are written up in the August this and the findings from this study are written up in the August 19 issue of science. And another study of different MERS candidates they looked at is due -- to step regimen that prompted any responses in mice and monkeys. And this vaccine used a structure based design that researchers think old promises for creating a vaccine for humans. In this paper was also published recently it is in the July 28 issue of nature communication.

>> And now I would like to talk a little bit about antimicrobial resistance. Usually we think of this in the context of developing drugs to fight this issue but vaccines are now on the tables as an innovative approach to address this problem. Some bacteria is now sent to available and about its and this is caused an increased escalating health care costs. There was a report on and about six resistance in the US does a very costly problem and the world. We see about 2 million drug-resistant text infections in the year and 23,000 steps in the annual costs are in excess of $20 billion of healthcare costs and $35 billion in lost productivity. The White House has also recognized the importance of this issue. And beginning in 2014 the Obama administration released several federal interactions that are related to addressing this concern including several high-level reports and Executive Order and a national action plan to combat antibiotic resistance. To address this growing problem we are conducting

research in many areas including diagnostics, therapeutics and vaccines. In July Dr. Carole Harmon to the division that I work for the division of microbiology and infectious diseases published an editorial connect vaccines and the way to combat antimicrobial resistance. And she outlined several issues for consideration. She noted unique characteristics of the organisms of concern, many are associated with hospital environment infections remote resulting in small localized unanticipated outbreaks and these are bricks that need to be controlled quickly for many reasons including safety of the patients. There are many challenges to vaccine relevant, many of these pathogens are associated with healthy human floras of their role is not clear we don't know what that would mean vaccines eliminated the healthy human activity and how bodies. There are complex regulatory policy and implementation processes for vaccines so the potential solution Dr. Harmon proposed using these vaccines as prophylactic immune interventions, they would be very targeted to at his populations for example people undergoing elective surgeries and other at-risk groups. And used as a preventive approach for infectious disease control. This is all still very new, very early, and also just another way to tackle problem as we work on adding new antibiotics to save lives. Thank you.

>> Any questions?

>> This is Sylvia. First program you talked about, ECHO, are they looking for comments from the population on continuing this or reviving this, is that how they can about?

>> So ECHO is an alternative to the national children's study they were looking for comments on how to bring this forward. I think they

are committed. To seeing this happen and they are looking for an put. Unfortunately the window is now closed if I hear of other opportunities for in put I will let you know.

>> What is the PI for that Claire?

>> I don't think that far along yet.

>> Okay thank you.

>> Do have a question"

>> Yes I was going to ask about ECHO. What was the reason that the study was abandoned initially?

>> There was an IOM report that outlines some of the issues with the study it was very ambitious, very big, they were going to follow children a huge cohort for 21 years to gather data and I think they were looking at a more efficient ways to gather the same data along with other issues. It was an IOM report. Do you have anything to add?

>> I know the last part of the presentation was [Indiscernible - low volume]

>> It is preexposure. So to take one example as given is before people have surgery if they have a vaccine to prevent staph infections you would preemptively get that two people preparing for surgery and so hopefully they would not acquire infection but they were in the hospital. So it is a very different model to what we are used to.

>> One thing I just remembered. A thank you reported last time about people -- the development of the Ebola vaccine? Is there any update on that?

>> Yes there are several tests -- press releases on Ebola, check on our website check on it it's been going well, initially they had managed to do it -- planned to do a trial for 2000 people, and they finished that first phase that they were striving for. So things are moving along very well.

>> Thank you we appreciate it.

>> Thanks.

>> The next item on our agenda is an update on the center for Biologics research and food and drug administration vaccine activity, Lieutenant. Commander. Valerie Marshall, welcome memory.

>> Thank you I have a very quick overview to provide today. A brief update.

>> Will give you a quick update on current vaccine approvals. May 2015 the FDA approved the supplements for Prevnar 13 to update the package to insert data from the community acquired pneumonia immunization trial in adults which is a confirmatory efficacy study in adults. The study demonstrated that Prevnar 13 prevented the first episode of vaccine type community acquired pneumonia in adults Tuesday five years and older.

>> In June and July 2015 the FDA approved supplements for biological license application for the licensed seasonal influenza vaccine to improve the formulation and the strains that will be included that are included in the vaccine are listed here on the slide.

>> I will provide you on an update on our upcoming advisory committee meeting which is the vaccines and related biological

project -- committee. We'll meet in an open session on September 15 to discuss and make recommendations on the safety and Imogen's city of seasonal trivalent influenza vaccine, inactivated adjuvant MF 59 manufactured by Novartis. We seek update prior to licensing. This was my report.

>> Thank you. Any questions for Valerie? Thank you very much.

>> The next item on our agenda is an update from the national vaccine program office, after Karen Bach. Are you on the phone?

>> Yes I am. Great thank you alternate over to you.

>> I'm sorry I couldn't be there today. Before we begin I would like to clarify an issue that came up yesterday. Every few years we do a survey and a review of all the data published on vaccine safety. IRM has been one of the physicians that conducted a review but I would like to clarify that the last reviewed and was last year in 2014. And it was done by another agency, the agency of health care and promotion. And I think I've shared that document with ACCV but if new members want to see them happy to share it again.

>> So this is an upbeat from the national vaccine office. We have to new collaborations with CDC that we are co-funding, one of them is to evaluate the vaccine safety system to include a better surveillance for vaccines administered during pregnancy. And that is a very important part of our program right now. And we also have another pregnancy related study that we are collaborating and it is a clinical study of the safety of diphtheria toxoid and a cellular processes -- pertussis. The next slide I've been telling you about this agreement that we started last year, we have had one authority for a while but we never used it.

And we decided to invest in new safety research so we finally awarded the agreement to institutions. Anti-projects are going to start this year. One is the establishment of a new vaccine safety pregnancy database. And we're going to test the database with several queries and the second project is the prevention of the injection site and sync up a associate with preteen and teen vaccination. We are very proud to collaborate on his two new research program and looking forward to this program growing and awarding even more research projects. And I think that's all I have for now. Thank you. If you have any questions I be happy to answer them.

>> Thank you Karen. Does anyone have any questions?

>> This is Sylvia. Who is doing this site pain and syncope?

>> It is been doing a -- done at Kaiser, the one in Oregon.

>>.Oakland,?

>> No problem. Oregon.

>> Any other questions? Thank you for your presentation.

>> Thank you.

>> So that was the last item on the agenda for today's meeting, we will now turn to the public comment portion of the agenda. Operator can you please open the lines for public comments?

>> Absolutely. If you'd like to make a comment please press start one. You will be prompted to record your name. Again*one to make a comment.

>> Okay we have to comment into, one moment please. Our first comment comes from Janet Shakira. Is open.

>> Hello I'm glad to have the opportunity to talk with you today. I have a couple of? Comments to make. I like to say the ability to process claims should not prevent the expansion of the statute of limitations. And we should not wait to expand the statute of limitations while we figure out how to accommodate all of this. So every child in the United States to fit deserves a fair chance to file a claim and we need to take steps to make that happen. I also recommend that the advisory committee on childhood vaccines resubmit its letter on the statute limitations to Secretary. Burwell and question an official response within two months communicating either presence or lack of support. To enable the advisory committee members to proceed by contacting the Senate subcommittee on health, education and labor intention to draft legislation. Or proceed with a thorough review of the plan to further persuade the secretary. I also recommend that the advisory committee request that the health resources services administration post the notes from this with meeting in HTML form in 2015 printed and expanding notes into PDF form to be interpreted as an attempt to secure the discussion from public discovery. We would not want people to think that. I also want to report that I have been trying to file a claim for my son for four years and have encountered several obstacles. First in 2011 I was told by the health resources services administration to wait until the autism proceedings were complete. Then I called a second time a year later I said I wanted to file a claim and HRSA representatives told me I couldn't unless my child had died. I called again and I said I did not think that was right. I wanted to file a claim. They said they would add

me to the autism Omnibus. I called again this past spring and I said I wanted to file a claim. They told me I couldn't because the statute of limitations had ended. I said hello yes I can because the table was revised. I had some discussion with them about that. And then someone with health resources said let me take you with information. This person took my child's name age address and vaccines that he had been given and told me that I had claim number 003-5174. And told me to call back in 90 days to I called back in late summer and was told by HRSA representatives that there was no such claim and that was a number -- not a number that they used. I called back and left a message again asking to speak to someone because I couldn't figure out what was going on. And a representative of the health resources and services administration left a message on my phone saying that I couldn't file a claim unless my claim were dead or -- my child were dead or hospitalize pics so I recommend that the committee conduct a review of customer services messages by HRSA. And that the advisory committee directed the special Masters court to apply equitable tolling liberally in cases where HRSA provided people with misleading information. As most people know all of the statements made by HRSA were incorrect. I also recommend that the advisory committee on childhood vaccines recommend to Secretary. Boutwell to direct the health services administration to post on their webcast page the number of cases awarded and the number of cases the way related to autism. I recommend that the committee recommend to the health resources secretary Burwell to invite representatives from the Senate subcommittee on House labor and human services and the house of committee on energy cars and health to represent the political concerns of the committee. So that committee members are not a

second guessing the political ramifications of their recommendations. And finally for the new program where you are going to scan health records and potentially recommend that doctors ask doctors if they want to report an adverse event, that they also recommend to doctors to ask the mother's and fathers of the children if they want to report an address -- adverse seizure. In my case I told my doctor's there was something wrong with my son and they told me it wasn't possible because children are not injured by vaccines. I now know that that is not true. My child was injured by vaccines. However he may never see his day in court because of the problems with this program. Thank you.

>> Thank you. Operator is or other public comment?

>> Absolutely. Our next comment comes from Teresa roaring home your line is open.

>> My name is Teresa Wrangham and Executive Director for the national vaccine information Center. The mission of which is to reduce vaccine injury and death to public in education and to -- I appreciate the opportunity to comment today. I would like to express both my personal and professional banks to members of the commission today demonized what it means to be a victim of vaccine injury and the very real challenges facing those who are injured and who die as a result of vaccine adverse events. Your stories and stories we have heard since our inception in 1982. NCIC's cofounders worked with Congress to pass the law that created the ICP. Part of the intent of this law is to acknowledge that vaccine injuries are both real and deserving of compensation, the need for ongoing vaccine safety research to prevent future injuries and death, and to provide compensation in a

no-fault environment. The low also provided that those receiving vaccines also receive information on both the risk and benefit of vaccines and information on disease the vaccine was designed to prevent. The law has changed over the years and the VIP program more specifically has become more increasingly adversarial for practitioners. Today vaccine injury Tim's who vaccinated in good faith and those who delayed or declined more vaccines are treated as traitors to public health for even suggesting that a vaccine is responsible for health condition. They are demonized in the media and minimized by government and public health officials. An BIC received consistent complaints from parents like the one you just heard and adults who are literally crying on the phone as they tell us that vaccine injury story. Stories of horrible financial and emotional burdens associated with even finding a doctor who will treat their concerns with respect and consider the possibility that a vaccine is responsible for the health condition of concern. Stories of parents fears the child protective services will be called if they do not continue to vaccinate their already injured child. Shock that through no fault of their own they have found out about the ICP too late and are not eligible for compensation. Anger because parents cannot get a non-medical exemption for the injured child which is now becoming increasingly narrowed in definition. Fear that the travel be excluded from day care in school. That fear is now a reality. In California. We hear stories of anger because non-medical exemptions are under aggressive attack and human parental and informed consent rights are being eroded. These families have become truly aware that vaccines like all pharmaceutical products carry with them the risk for injury and death. Many were never told that vaccines are not risk

free. However vaccines are not exempt from informed consent and precautionary principles. This attack on non-medical inventions is being encouraged by the federal government and the national vaccine advisory committee and tramples upon basic human and informed consent rights of voluntarily accept what to delay or declined one or more vaccines without sanction. This trampling of rights and the wholesale promotion of mass vaccination or not giving equal effort to prevent vaccine injuries and death creates the very challenges commissioners and an BIC poised today. It is the vaccine injured who are paying the price politically charged high-stakes game of compliance with the one side -- one size fix all vaccine for the greater good at the expense of human informed consent) vaccine risks are not being equally shared in the loss of non-medical extensions make the vaccine injured accessible collateral damage. The sacrifice of human life and the demonization of those injured and who have vaccinated in good faith is morally and ethically bankrupt as a value that created our country. Because people do not always respond to vaccines the same way. There will be those that are injured and to die as a result of vaccination. We encourage the AC CV to encourage nonmedical conformed and human right of every human baby who need voluntary medical risk-taking decisions without governmental coercion and inferior interference. We note the characterizing reoccurrence of vaccine injury is rare that it is no comfort to those who the risk is 100% when they are risk it. It is likely to be an*in condition -- voted by the Institute of medicine and the fact that vaccine injuries are grossly underreported. Not only are parents continually challenge to find doctors to investigate vaccine injury and appropriate medical treatment for their loved ones, they are

challenged in finding there is in that the ICP all against a backdrop of a government that lacks the political will to find a quality research that caused vaccine safety research deaths. As a result if we confine this within the statutory timeframe they are likely to have trouble finding medical experts for a claim which comprise the majority of claims today and the claim will be dismissed. These challenges put into question the need for statute of limitations. Would any amount correct this vicious cycle? Shouldn't vaccine injury cases be judged on the merits of the case. While petitioner's suffering the consequences of inadequate plans and gaps in plants that may prevent them from maintaining conversation. The minimizing and lack of interest in vaccine injury by government and public health officials is likely to evolve in many families being left uncompensated and to become victims to being bullied and demonized publicly as bad citizens. An BIC supports increasing statute limitations however it can't be at the expense of civil action. The intent of the law is twofold to provide a mechanism for compensation while preserving the ability of the petitioner to pursue. The Supreme Court ruling has essentially closed the door on liability law and it does not follow that the AC PV should trade the ethical intent and spirit of the Lord to achieve an extension on the statute limitations. Outreach activity of the V ICP while incentives missed the mark. Efforts are needed to raise awareness and the general populace. Whether VIS is concerned we received many complaints that they're not being given out what they are being given out after vaccinations and there was no discussion of the VIS making the awareness of the VIP challenging. Soon there will be no lack of ad campaigns to take a flu vaccination. Where are the same campaign informing vaccine risk, vaccine reaction reporting and

vaccine injury compensation? Citizens have a right to know about these programs and to know about the known and unknown risks posed by vaccines, outreach efforts that include commercials are at campaigns about vaccine injury in these programs and actually doing some direct consumer marketing similar to what vaccine marketers use to market their vaccines. These outreach efforts include stories that would humanize vaccine injury and create a less hostile environment that would empower parents and health service professionals to explore the possibility of vaccine injury and timely investigation. We encourage the AC CV to recommend aggressive outreach efforts directed at the general populace. We would also encourage the AC CV to actively pursue a line of reasoning from the secretary on my previous recommendations are not -- including increasing the statute limitations and outside acknowledgment of proceeds of those recommendations there has been no recount posted on the website that informs why this recommendation like so many others is not being pursued by HSS. We support the need of the AC CV to meet face-to-face and asked those meetings be posted well in advance for the public to physically attend face-to-face meetings. In closing, we appreciate the opportunity to provide you with public comment today and welcome all the new commissioners. Thank you.

>> Thank you. Operate other any other callers who wish to make public comment?

>> No so there are no other callers at this time.

>> Thank you. We will now move to the next end up on our agenda and I will ask commissioners to discuss any new business or future agenda items.

>>'s back before we do that can I ask a question when Dr. Houston was giving her presentation earlier? Proposed table changes? Will there be a look back. For those including SIRVA? And does that happen automatically?

>> No.

>> Okay so, and the look back could you explain what the look back. Operates?

>> Once the table becomes effective [Indiscernible - low volume] two years from the effective date [Indiscernible - low volume] eight years from [Indiscernible - low volume] up to eight years prior.

>> Thank you. Back

>> [Indiscernible - low volume] this is Sylvia I'm having trouble hearing background.

>> Can you come to the microphone if you don't mind?

>> I appreciate it.

>>

>> I'm sorry I'm don't have to take up other people's time but for example if HPV -- if there's a new vaccine that is added to the table can you give me an example of a vaccine not on the table, come think of any from our prior [Indiscernible - multiple speakers]

>> Rotavirus gets added there will be a look back.

>> A new category of vaccine, so seasonal flu will be added in 2013. Before trivalent. And approve vaccine [Indiscernible - low volume] is added in November 2013 [Indiscernible - low volume] seasonal flu vaccine for eight years prior to 2005.

>> Thank you.

>> Are we -- to the next meeting, the two items that we discussed about the funding and shoulder injury will that be on the next agenda?

>> They could be. If we going to have SIRVA we are going to have the discussion on --

>> Are be done with SIRVA?

>> We could do whatever we would like to do. We were going to continue to monitor that generally and hear reports about the adverse effects and the continue outreach to the shareholders. Unless there is any -- okay.

>>, Going to continue to pursue the funding challenges and the statutory --?

>> I will follow up with Christine and talk to Melissa and the rest of the group at herself -- HRSA and see what we can put together for the next meeting on that topic.

>> The first caller from public comments raised pretty significant problems that she experienced. Is there any way for us to have some -- can we request that there be some thing done to determine and I don't know that it has to be specific to this individual who called, but

can we have some explanation or report about what happens if somebody calls HRSA about a vaccine about a potential claim?

>> Claims not filed with HRSA [Indiscernible] so if anyone were to call [Indiscernible - low volume] claims are not filed with HRSA --

>> So there would be no giving of advice about whether someone has a claim? Whether they have a statute of limitations issue? Whether it is a particular injury?

>> Note that is outside of our -- [Indiscernible].

>> Thank you.

>> If I had a call to HRSA with these kinds of issues with Michael B then sent to the court?

>> Not to my knowledge.

>> So they could've been talking to someone else within another organization?

>> [Indiscernible - low volume] the one 800-number comes directly to our division. So how you get that is standard [Indiscernible - low volume].

>> We actually provided the precedent for an information center so basically of people called [Indiscernible - low volume] to contact the court information to file a claim [Indiscernible - low volume] so they couldn't find a claim [Indiscernible - low volume].

>> That's my experience. [Indiscernible - low volume] but actually I got a letter saying that the court and I also got a copy of [Indiscernible - low volume] after they get that booklet. At the same time.

>> Is in the letter we will provide a fact sheet or brochure with information about how to file a claim. But if you call we will refer them to the website if we don't have access to the website we will send out information on hard copy.

>> Is very clear in the letter [Indiscernible - low volume] the numbers, [Indiscernible - low volume].

>> Would anyone to think about establishing a [Indiscernible] on this person?

>> I've been thinking that. I've been thinking why don't we have one? I don't understand why we don't have one.

>> I missed the term?

>> Of vaccine history on this person. To help because their court in a maze like this.

>> I will get their information. They consider themselves [Indiscernible]

>> They are not government funded or affiliated organization.

>> But the office could be a government office. The CDC or here, the IRS has an office in the department of education. So this might be something to think about for all these people level these concerns.

>> And the IRS started that office in response to the civil rights was passed finally in the early 1980s and they had an awful lot of PR and administer to issues and that office was started in response to the Bill of Rights. Because that was a huge problem.

>> Is there anything specifically for the agenda for December that Kristin and I can discuss in the next --?

>> Do we know if that meeting is in person?

>> Something that you usually would discuss as you know [Indiscernible - low volume] FY 15 [Indiscernible - low volume] if that were to continue in FY 16 then [Indiscernible - low volume].

>> Just so we are clear that fiscal year -- what is the fiscal year [Indiscernible]

>> The 30th is the last day of the fiscal year.

>> So the first meeting of the new fiscal year.

>> And you explained that we like to have meetings that can also piggyback on the orientation for new members and we don't know when the next new members to come on board because -- so just in the past we have reserved [Indiscernible] for the new members coming on board. But not sorry [Indiscernible - multiple speakers]

>> For obvious reasons you've got to have an in person meeting when you have new members, you don't have to but it's very compelling basis for having one. When we first joined all the meetings were, and up until this sequestered, all the meetings were presumptively in person and that for budgetary reasons they were telephonic, originally I understand they were every other meeting, but the way the schedule went down we have one in person meeting last year. So we have talked about this issue a lot and it's obviously budget driven and I know enough to know we have to wait and see, there's nothing

people around this table can tell us for certain about the budgeting for meetings.

>> Edges want to make sure because I've always belonged to things that have rules. Even on telephone if we miss how many meetings you get kicked off? Do we have this attendance rule?

>> Not that I have ever been aware of. We've never been -- [Indiscernible - multiple speakers]

>> It's never been a problem. People here because they want to be and if they don't then they decline. It is their choice [Indiscernible - multiple speakers]

>> I've been on meetings in big boards but they don't come, you send them a note that says I hope you are not sick, and the second mode is is there a problem? [Laughter] and the third note [Laughter]

>> In Virginia is a little different from this commission.

>> I think everyone who is a commissioner takes the responsibility seriously because we are representing constituents and as you know you have to be nominated so

>> It to me 80 is to get here so I'm not going to miss one meeting. [Laughter]

>> That is a nice segue for my question about other replacement commissioners and you have nominations that you can tell us about and where are we in the process for the next round of new commissioners who would be actually knew to take --

>> As you know the last meeting we did not see nominations in all the categories. We did not receive nominations for all of the categories of members that would be --

>> And what categories are they?

>> This time we plan to replace all of the [Indiscernible - low volume]. So the notice would be sent out that six members -- we also indicated a domination for an OB and as Melissa said it did go out or we didn't get recommendations in all Agree so we reposted

>>

>> Which pedigrees did not get responded to.

>> We do not receive a parent. [Indiscernible - multiple speakers]

>> A petitioner attorney?

>> I never got a resume. We don't usually hold onto them.

>> We are aware of individuals who are willing to be nominated. We should tell them to --

>> Send them our resume.

>> And if they send resumes in the past that have been acted on for other reasons not because they were deemed not a good candidate that we don't keep them around. And just so we continue to review all the categories just so we're clear. For the six.

>> Healthcare professional -- professional.

>> And the public one is the OB. A parent, could be the other category and [Indiscernible - low volume]. The manufacturer.

>> What we can do to is --

>> So for categories parent attorney manufacturer and healthcare professional.

>> To health care professionals and to attorneys.

>> But there are four categories. Two are in one category --

>> It categorizes three categories. Healthcare professional is the third category and the public category. So in a healthcare professional category it's whether looking for the two pediatricians, and the attorney category is really looking for the physician the attorney the representative for the [Indiscernible]. And the general public category we are looking to fill one of the parents slots and a number of general public which at this point could also be an OB low false -- [Indiscernible - low volume].

>> Or it could be a general member of the public healthcare profession or it could be anyone [Indiscernible - low volume]

>> And what a deadline? We haven't gotten a day back at courage to going to the parents but as soon as we have that we will forward that to everyone. The Federal Register notice for nomination.

>> And I can't remember where we ended up a discussion about the parent, I'm in the statute does specifically say parent so we couldn't use a vaccine -- [Indiscernible - multiple speakers] with the statutory change.

>> So thank you you will definitely email us. So we can -- let's put you [Indiscernible - low volume] are you in a position to know of people in the industry?

>> It sounded like you received, this is Jason Smith, nominations for the vaccine -- no --

>> [Laughter]

>> Will have to follow up on this.

>> You could just use a lot of people writing us and pushing it out there that we need to fill the spots.

>> And so I did have an attorney in my family and I have an OB.

>> [Laughter] [Indiscernible - multiple speakers]

>> I.e. going to hold up putting forth the nominations so you have one person for every category? I'm a little concerned that it might be difficult to find an OB and I think -- etiquette was a recommendation that it would be good to get a note to OB but I don't think our intention was to hold up the nomination process until he found one.

>> We don't intend to hold up the nomination process to find an OB. We saying that OB resumes are welcome. Because the general category is the general public.

>> This Alexandra can you advertise for more from the Federal Register?

>> We actually have sent it out and we are in the context that we are aware that [Indiscernible] if a person has a list of partners and a medical society it is part of the HRSA partners. We focus on

Facebook, twitter, we have it on our website, so we would like you to help us improve.

>> Because of being a parent do you have the DOE on your list? So that it would go to every professional advisory committee? I forget how many there are that each state is mandated to have --

>> What about the DOD Council? Each state is mandated to have a DOE Council. And the Virgin Islands DD Council cut and Maryland has a very notion [Indiscernible - multiple speakers]

>> It has to be somebody who's been to the program.

>> Owner you need a lot of people to go to the program that the Virginia Board of disabilities we had three people on the board who were parents somebody new or Dr., you're also going to reach people who are the members, every single state-based Department of Health and Human Services to Board of Education corridor going to hit anyone who has anything to do with DD and get the emails and that's a good way to do it statewide.

>> Could you send that information to Andy?

>> Rehab relies [Indiscernible - low volume] the advisory committee members to help us get the word out and I'm curious how we've gotten referrals in the past.

>> Because that's her attitude because they know that each of the directors [Indiscernible - low volume] that would be very helpful.

>> Every County school system, every school system, every school district has a special advisory committee. And they can indicate with parents and her teachers and the personal weekly basis. So you

already got -- you just need to get to the person [Indiscernible - low volume].

>> Okay. Anything else? So with no other business doing of emotion?

>> A motion to adjourn? All in favor? Any opposed?

>> Past, the meeting is concluded I look forward to hearing or seeing everyone in December.

>> Thank you operator.

>> Thank you. That concludes today is called thank you for your participation. Commit disconnect at this time. [Event concluded]