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Health Resources and Services Administration

Advisory Commission on Childhood Vaccines

Thursday, March 06, 2014

Andrea Herzog



The National Vaccine Injury Compensation Program (VICP)

Division of Vaccine Injury Compensation Update

Advisory Commission on Childhood Vaccines
March 6, 2014
Vito Caserta, M.D., M.P.H.

Department of Health and Human Services
Health Resources and Services Administration

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Attendees

1. Allison Durham
2. Andrea Herzog
3. Captioner
4. Carole
5. Jonathan Salaveria
6. Katherine Perry
7. MARCO MELO
8. Mark Ditmar
9. Theresa Wrangham

Chat History

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Polls

N/A

Q&A

Q/A Done Over the Phone

Transcript

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Thank you for standing by. Your conference will start momentarily.

Welcome and thank you for standing by. At this time all is in her's are in a listen only mode until the question-and-answer session. [Operator Instructions] We would like to welcome you to the 91st quarterly meeting of the Advisory Commission on Childhood Vaccines . I will now turn the call over to the ACC fee -- ACCV chairman, Mr. David King We are happy for everyone to join us. It will be a while before we get to the [Indiscernible] we will do well call. I ask that whenever we speak during the session, there are a number of people on the phone lines, we identify who we are first so that it will be easy for people to record. Having said that, the chair of the ACCV and parent of an injured child.

[Indiscernible - low volume]

Charlene Douglas.

[Indiscernible][Indiscernible - low volume]

Ed Crouse, attorney for [Muffled Audio]

[Muffled Audio] [Indiscernible]

Barbara [Indiscernible]

Jason [Indiscernible] I am an attorney for Pfizer.

[Inaudible - static] [Indiscernible]

[Inaudible - static] [Indiscernible]

Dr. Vito Caserta , Acting Director, DVIC I believe there is a Commissioner signing in as well.

[Indiscernible] pediatrician. Hello David.

It is great to hear your voice again.

Two of the commissioners were unable to make the meeting today but we still have seven commissioners here so there is a quorum. We have an official meeting. We will continue. The chair will give its report. A couple of things that the chair would like to talk about their number one, we will --. Number one, we will have this posted to the website later but we received a missive from Kathleen Sedelias [Indiscernible] recommendations and the ideas -- idea is that they will [Indiscernible] very carefully in the department but to outline what the conditions are, we have not heard yet. One is extending the statute of limitations for injury and death [Indiscernible] injury compensation program. Increase the benefit for pain, suffering and death. Compensation for [Indiscernible] mother received the vaccine while the infant was in utero. Include vaccines that are recommended for routine administration to pregnant women and are not specifically recommended for routine administration and children. And finally, considering a health professional with expertise in obstetrics to serve on the ACCV. The other recommendations that have been sent , we have not heard a formal reply on. When that comes, we will get that posted to the website as well.

Let me continue. First of all, I think it would be remiss of me if I didn't make a comment on the fact that we are in a face-to-face, live, person-to-person meeting that has been long overdue from the chairs perspective and I do believe a number of the commissioners. We are delighted to be able to engage in full robust communication both verbal and nonverbal as we begin to do the work of the ACCV. We hope that we will be able to continue to do this.

We do understand that there are different characterizations within the department -- prioritization's within the department. Whether or not we can meet on a face-to-face basis more than twice a year. I would place the arguments and case that what could be more important and have a harder priority -- higher priority than dealing with those who are injured and ensuring that they are compensated in a timely manner for their contribution to some degree, to the science, in terms of what happened to them. That is the chairs comments from that particular area.

I did already mentioned, I just reiterated that we all mention our name prior to are speaking so that we are recognized by those were on the phone and who are not available. I would like to remind us all we might, if we have time today, on the agenda, we have a robust agenda. It is indeed possible that some of this might get done earlier than anticipated. If that be the case, I would ask that some of the items that we might end up bringing up under new business tomorrow, rather than give them short [Indiscernible] if we are pressed for time at the end of the meeting tomorrow, we move some of those items for the commissioners to consider while we are here today. With your permission I'm going to ask that if we have time to do that, we can do that.

Some of those items that we might end up talking about our, we received and it wasn't through to the commissioners process workgroup, that we have not had a official dialogue or discussion on it, suggested reports, to report information that is available already.

I am just bringing it up at something that we may want to consider. We may actually bring that up with the process workgroup, for all I know. That is an item we may want to talk about. The other item that we think -- I think we need to consider is, at some point, some of us will no longer be here based on expiration of terms and new members being appointed. I have been honored to be serving in this position for two years but I don't know if you guys is honored as I.

You might in fact they, time for new blood. Should that be the case, and even if it is not the case, I daresay that we ought to begin to consider what the condition plan would be for both the chair and the vice chair, particularly looking at the fact that new members will be coming on board as well as the fact that there are some members who have one year and there are some members who have two years left on their term. It is probably a good idea for us to be thinking of identifying who might want to pursue those positions.

At any point, if anyone wants to volunteer and say, I am interested in doing that, if you would alert and let the other commissioners know that, please do that. I expect we won't do this at this meeting, but I do think this is something we should put on our June meeting agenda.

Having said all of that, the only other comment that I have to make before I move the meeting to the next phase is that I want to remind us all that the purpose of the vaccine injury compensation program is to compensate those who are injured. And those who are injured, not only do they suffer that those who take care of them, those who go to the pain-and-suffering, particularly as far as children. I can speak from my experience, with my child. More and more of the compensations are not related to children and is really for the adults. The minors are not as big as it used to be. I would ask that as we make the decision, from the filter that we come from, that we temper that filter with an understanding that if we have to air and make a mistake, we ought to make those mistakes -- and make those errors as it relates toward those who are in need and in suffering versus those who are not. Having said that, I conclude the chairs report at this time. We now move to the next item of the agenda which is to open the -- for public comments for items that are currently listed on the agenda.

Lisa, if you would open the lines for people who are going to get the comment? A rule is one, it be an item that is on the agenda now. To, that you will stay to you are and what it is you are going to speak to, that you identify the agenda item that you're going to speak to, and if you have no agenda item to speak to, we would ask that we will have another public comment tomorrow at the end of the morning session for someone to be able to take any additional comments if it is not on the agenda.

Having said that, Lisa, do we have anyone wants to speak?

All lines are open for comment.

Hello Plex --?

This is Teresa, I am the executive directly for the national vaccine information Center. [Muffled Audio] I wanted to report for the position of [Muffled Audio] compensation and

I am sorry. We need volume up here. We are having trouble[Indiscernible - low volume]

Hello Plex

--?'s

Teresa, please continue.

Did you hear what I said okay?

We seek to agenda items that you're speaking to pick

The agenda items that I am seeking to are the reporting of action of injury compensation and the report from the process group. Previously, the SDF has requested that more meaningful information the publicist to the website with regard to injuries that are -- awards that are made for injuries. Much of that information is disclosed to the ACCV but the information is not put out meaningfully on to the website. Concerns that I have heard voiced here during these committee calls, centers around protecting the privacy of individuals. I am reviewing the law. The only thing that is [Indiscernible] name cause Street and telephone number. The person who received the vaccine. None of which, we have asked for. We have only asked for information for each faxing to be put out more meaningfully. For example, and alleged injury under the DT could include any commonly seen injury like seizure disorders or autoimmune disorders. And rake down in that respect. I know that is difficult to follow over the phone but I did forward to the committee a sample of what that might look like based on information that is sent to the Gentoo and based on what is on the website and the way it reports.

I am hoping that the process workgroup will entertain reviewing the sample and improving upon it. It is just a sample for discussion purposes. I really don't see anything in the law that prevents us from having more meaningful information that is given to the ACCV and is public, also being put on the website to the general public and have a better understanding of awards made. That is the extent of my comment. Thank you for giving me the opportunity to comment.

Thank you. Are there any other public comments?

Lisa, there being no other public comments, if you could mute the lines. That will enable anyone who is supposed to be speaking to speak their --.

The next item on the agenda is the approval of December 2013 minutes. I am assuming that everyone has had a chance to review. Is anyone have any changes or modifications, corrections, omissions, anything that they would like to add to it?

We will entertain a motion to approve these minutes.

[Indiscernible - low volume]

Any second to that motion?

[Indiscernible - low volume]

Is there any dissension to this? I see none. All in favor of administering approval not say I. -- aye. Those opposed say they. -- neah.

Next we have our Acting Director, DVIC, Dr. Vito Caserta they're

--.

Good afternoon everyone. We will get started. [Muffled Audio] [Inaudible - static] I would like to ask [Inaudible - static] In the meeting today we are going to hear from Mr. Vince Matanoski from the [Indiscernible] who is the Deputy Director, Torts Branch, DOJ. There are action information statements to be reviewed [Indiscernible - low volume] [Inaudible - static] Presentation on one of the adult vaccines that is not recommended for children pick --. Namely sumo, no -- pneumococcal polysaccharide axing. [Inaudible - static] Next slide.

There are a number of petitions filed as of February 3. You see where the trends are. For fiscal year 2014 [Muffled Audio] October 1 October 1, 2013, fiscal year 2014 as of February 1, we have had 134 petitions filed to the program. [Inaudible - static] And of the fiscal year, projected out to 100 117 filed for this fiscal year. [Inaudible - static] 2009. Moving onto slide 4. This is the number of the medication as of February 3 your is clear 2014 [Indiscernible] [Inaudible - static] A total of [Muffled Audio] [Inaudible - static] For the past two years that would project out to [Inaudible - static] A little less than previous years. [Inaudible - static] Project out to third teen and nine would project out to 19. And 100 would project out to [Indiscernible] [Inaudible - static] 404 which would project out to 474 which would be the same as last year. Seemingly less so far this year, 107 [Inaudible - static]

I am not sure I know why [Inaudible - static] This fiscal year as opposed to the past two years. That is what they are showing. Moving onto slide 6.

For fiscal year 2014, bus far commissioners have been awarded in [Indiscernible] -- petitioners have been awarded a proximately [Indiscernible] attorneys fees [Inaudible - static] [Background Noise] it would project out to \$168 million for the entire year, approximately, with approximately [Indiscernible - low volume] [Inaudible - static] Which is a little bit less but not

very much less than [Inaudible - static] Last year. What in line with that back -- [Inaudible - static] Let's move onto slide 7. [Indiscernible - papers rustling] [Inaudible - static]

This is the slide on trust funds. The balance as of December 31, 2013, last calendar year, is 3,000,485 3 million 485 million night 500 -- by hundred \$91,623.37. The trust fund had an income in the last quarter of October 1 December -- through December 31 of approximately \$63 million if we go back to slide 6, we can see that from October to February [Inaudible - static] Trust fund about \$73 million. From October to December we had about \$3 million. We are in line in terms of funding the first -- trust fund with adequate amounts to prepare for the payouts through the [Inaudible - static]

Slide 8. We had a public hearing on January January 13, 2014, [Inaudible - static] Proposed rulemaking. We recognize that we did not give people enough advance notice. We are scheduling another public hearing for the rotavirus. After that meeting we will report all of the comments received and ultimately publish the final results. [Inaudible - static] We are working on it.

The large vaccine injury [Indiscernible] and PRM -- NPRM, we are still working on. [Inaudible - static] The next few weeks [Inaudible - static] Part of that stems from the fact that I will be retiring and my last act before I retire is to get this injury paperwork moving. It is a high priority. It's just that with all of the work that we have needed to do, we haven't been able to give it the attention that it deserves. When they do retire -- I do retire, [Indiscernible] [Inaudible - static] Will take over as the direct -- Deputy Director. [Inaudible - static] [Inaudible - static]

Moving on to slide 9. I will leave it to Dr. [Inaudible - static] On February 11 and February 12. And [Indiscernible] will fill us in [Inaudible - static] February 26 and 27th. For public comment, if anyone has any comments that they would wish to send to the program, please send it to Annie Herzog, Parklawn building, room 11C -- 26, 5600 Fishers Lane. 5600 Fishers Lane. Rockville, Maryland Rockville, MD 20857. Phone number is 301-443-6634. E-mail is aherzog@hrsa.gov. Any questions?

This is add. -- Ed. [Inaudible - static] Do you know what the balance was at the end of 2012 and the end of 2011 compared to -- [Muffled Audio] -- [Indiscernible - multiple speakers]

The first time I noticed the Cayman was at the last [Inaudible - static] All times before that [Inaudible - static] If that is what you were getting at, the numbers are slowly going static act in terms of the trust fund. [Inaudible - static]

Any other questions that anyone might have as it relates to this?

One other question. About the proposed rulemaking, you said the goal is to get it out of the agency and next few weeks? There yes.

Could you remind us of the process and the timeframe that you anticipate for the rulemaking?

The rulemaking will go to the department once it leaves the agency. The department includes, CDC, FDA, NIH. They will look at the rule and provided comments. Of course, there is also the lawyers involved with [Inaudible] we would then respond to those comments.

There is frequently a back-and-forth that occurs. We would send it out for comments and incorporate the comments and then send it out again. That poster multiple cycles. -- Until it finally clears the department. Once that happens, then it [Inaudible - static] [Background Noise] the White House. When it gets to going the -- OMB, they share it with other departments such as the [Inaudible - static] Other interested parties that would then provide their comments. Then we go to the same cycle where we respond and finally it will get published. Once it is published in the Federal Register, there will be a six-month comment period where will -- we will entertain comments on the public. Once we are past the comment period, we will have a public hearing as well like what we are proposing for the rotavirus. Once those comments get Incorporated, the final rules get published and that is [Inaudible - static]

Any other questions?

This is Sylvia. I am so I hear that you will be leaving. Since I work with ADHD kids a lot do you have a timeframe for it so I can prepare?

[Laughter] I like to tell people that my first day of retirement is April Fools' Day. I am here for the rest of this month.

Welcome to Dr. Jason.

I have a question. We have talked about, at our last meeting, in terms of the improvements, what we can do and the medication with the secretary to find out what her priorities were and how we relate to that. The idea is that we can begin to do this possibly at the beginning of the year. I think we are all little bit behind on that. How do we implement and make that happen. Is that something that Melissa, you will end up picking up for us? How do we make this happen? [Inaudible - multiple speakers]

I think it is going to be a long process where we need to sort out how to approach it. One way of looking at this, the national vaccine program office may be of great help, the vaccines within HHS is delegated to the secretary of health who is the person in charge of the national program office and in charge of [Inaudible - static]

One of the key points in my talk last month was for the commission to understand and know what the priorities are in terms of vaccines. And to see how the commissions fit into those priorities and to assist with issues that are important for compensating any of the children and adults and doing the work of the commission and also [Inaudible - static]

I think, working with the ASH maybe an excellent way to start that process. -- Where we would -- I think the ASH informs us of what the priorities are. We could become part of that and work in that way. Our recent work with the federal immunization [Indiscernible] does that mean our findings to their committee went very well. I think that is a model to be [Inaudible - static] Helpful.

As I think about this I think that would be the most productive way of sorting out what the agenda items we should be [Indiscernible] working on. And to decide to resolve and develop.

Thank you for that. How do we take that -- how do we go from knowing -- how we make that happen?'s

--?

[Inaudible - static] Think of ways -- there is a national vaccine plan. We would need to become familiar with that, I think. We would need to know what the other [Indiscernible] are doing, predominately [Indiscernible] and Courtney with them some degree. And I think that would [Inaudible - static] What we are trying to do. The secretary is hearing, not only from us, from the ASH and from the ENVAC. And that would be a stronger voice. I guess what I am asking is [Indiscernible], how do we -- we have an idea? We know how to do it. But had a we sure -- make sure that we do do it. Instead of just thinking it was just a great idea and letting it go and we don't have it -- we don't act on it.

What is the process for us to be able to do that? Is there someone assigned that gets to do this work and begins this process for us? Is that how this works?

No. There isn't any one person who is assigned. The report that I summarized last time, one of the things that that report commended [Indiscernible] [Inaudible - static] Was to increase the staffing level for the support for the committee or the commission. That was one of the recommendations.

We are able -- what we are able to do currently, is heavy then you where we discussed issues but in terms of doing research and other things of that nature, our resources were weak

So, -- all sorts of thoughts run through my head. Some of those thoughts are, if we are not meeting in person, then there is budget that is not being allocated for that purpose when it was allocated for that purpose. How do we reallocated and take that money to possibly increase staff levels or assign additional staff hours, if you will to that --, to that? Order for us to effectively do what we have to do, there are ideas that come up in things that would allow us to be more effective than when we give advice to the secretary. In order to do that, we as commissioners, we need support from the staff level to do that.

It is dedicated for us to do that but what we do not have -- when we are saving money but not doing it one way, we allocate those monies elsewhere. What happens? Why can't we utilize some of that? And someone make the case to us why that cannot happen if it is not happening?

I think at current staffing levels, we could do what the commission needs as long as this is not extensive. In terms of doing basic research in terms of, for example the presentation I gave last time. With that sort of thing, we can do it. I was thinking more in terms of [Inaudible - static] Assessable report work there is a lot of --. There is a lot of work to be done with that. That would be difficult for us to do.

I don't know that we need to go there now because it is less likely that that will be successful. I think where the commission should focus is trying to get at what the priorities are with relation to vaccines and how you can dovetail with those priorities.

How do we do that?

[Inaudible - static] Does the ASH provide that to the ENVAC on a regular basis?

[Indiscernible - low volume][Inaudible - static][Indiscernible - low volume] [Inaudible - static] [Indiscernible][Inaudible - static] [Indiscernible][Inaudible - static] [Indiscernible] [Indiscernible]

Knowing those things and working that into and communicating to them [Indiscernible] our interest [Indiscernible] so that they can consider if they want to do it. That is the synergies that we are looking at.

This is Erin. I have a question [Muffled Audio] [Inaudible - static] We don't know what comes out of static back pay for the [Inaudible - static]

The trust fund pays for [Indiscernible] cases. It pays for legal fees, for petitioners. It pays for the administrator budget for the department of judges -- justice [Inaudible - static] And that is that. It doesn't paper anything else. There have been multiple attempts by previous commissions to see if it could be used towards vaccine research but they have not been successful. That is what the trust fund covers.

[Indiscernible] I would assume that while on paper these things are funded that way, reality is, the budget is controlled elsewhere, because otherwise, we would have the travel budget for [Indiscernible] which has only been reopened a little bit. We would have the travel budget for us to have face-to-face meetings. It is not really what we think. We say it is this, on paper it is this, but that is not really but it is.

All of these things are paid for out of the trust fund that there are people that look at the budget and create budget that the programs have to fit into. The office of management of

budget for the executive branch does this. They are the ones that say not this is how much each department will get and how that money is distributed within the department.

Even though the money is in the trust fund and gaining interest and growing, we have to work within our budget.

Let's talk about that for a minute. We know that ENVAC gets to meet regularly face-to-face. That comes also from an executive that what we really have is we have a leadership component of who is prioritizing what and what is prioritized in terms of whether we have the same priority as they do. And it would appear that based upon the leadership of the group that we reported to, ages to think that what we have is not -- does not require the same level of interaction on a face-to-face level. In other words, it does not have a similar priority as the other group leaders have as it relates to this particular area. [Indiscernible - multiple speakers]

I would not say it that way. The priorities are [Indiscernible] for the ASH and the ENVAC are very different. The stresses on each budget are very different than different parts of the [Inaudible - static] Both the ASH and the administrative person may God you the -- value [Inaudible - static] It is just that one agency may have other priorities that supersedes and may not be present in the other departments. It is not that one is being valued last. It is all relative to what tasks need to be accomplished by the perspective components.

Dave King again. I appreciate that. I understand the nuance that is there. From my perspective, I would think that it would be helpful for us to know what those priorities are because those priorities may in fact, -- those priorities that reduce our ability to effectively function. We may argue they should not be a priority but we do not know what those specifically are. [Inaudible - static] We are not able to fully do what it is that we are supposed to do in a manner that is, as we go back to the effective component, [Indiscernible] unable to actually travel and do things that might have helped alleviate other situations and reduce expenses for others that are involved. What are those other priorities and how can we find out what they are, so that we can possibly let the secretary now that we believe that -- know that we believe that the priorities need to be adjusted?

That is an area that the information staff -- [Inaudible - static] Is not shared within our department and our work area. That is not the kind of information that people [Inaudible - static]

If you attempt to get that, that would likely be a difficult task. I am only saying that because with that sort of information, it is generally not shared.

Dave King again. In the words of John F. Kennedy, we do things because they are hard. It is a difficult task, let us rise to that challenge, so that we can do what we need to do.

This is Ed Crouse. I appreciate where you are going with this David and how you are trying to [Inaudible - static] A way that will perhaps be a legacy. Maybe the better of pros -- approaches

for us to say what we can do [Inaudible - static] And then forcefully assert/man that in order to be effective as a commission. We may identify meetings in person with some regularity is important. I think number two, I think it would be really helpful if at a [Inaudible - static] Level, we could get something or regularly [Indiscernible] by e-mail that would function as a report that would help us digest stuff that is going on outside of the agency but that relates to what we are doing. For example, summaries [Indiscernible] [Inaudible - static] A summary from ENVAC that is written for us, directed to help us to do [Inaudible - static] Are supposed to do.

I think that is an excellent suggestion. That would more likely affect what we want to affect as to -- as opposed to trying to second yes the department budget which [Inaudible - static] Frustrated by trying to do that.

Dave King speaking. I am comfortable with moving down that direction, only to the extent that some of that we have done and it has resulted in nothing, at times. My only concern is, if we continue to do what we have done and don't get any different results, we just keep getting the same results, it begins to tell us that perhaps we want to reconsider and think about doing something different.

What I heard Ed say that I thought was very [Inaudible - static] Getting a summary of important events such as anything important that happens at ACCV or ENVAC or other committees that are dealing with vaccines [Inaudible - static] So that you can as a commission see if this is something worthwhile and worth your efforts to investigate. [Inaudible - static] That would be something new. I think that will be a good thing.

This is an -- Ann. This is really what this amounts to, communication. [Inaudible - static] Programs of the commissioners. We get the minutes very late and so by the time we [Inaudible - static] Next meeting minutes. I think it would be also helpful if we see them sooner than that because there is a long time And I can't recall [Indiscernible] I know it needs approval.

[Inaudible - static] [Indiscernible]

[Inaudible - static] [Inaudible - static] We are tied to their -- [Inaudible - static] Try to give them reviews. You send them out to all of the presenters to review their portions and [Inaudible - static] We can try to [Inaudible - static] It would help us --

This is Ann. It would help us to do something [Inaudible - static] Whether it is timely are not.

You raise a good point here. Dave King speaking

If we are not adding them for six weeks, we need to make sure that is correct. I can understand where there will be a lag on that. Perhaps, some of the items where we commit to certain actions, do things like that, perhaps we can do a quick summary on a bullet point. This action was taken. This was done. We may be able to get that out any faster format to the commissioners of that we can then say, we ought to get moving on that. Let's not wake -- wait

for six weeks out. Even if something like that could happen, I think, that would be helpful. Does that makes it -- cents from your perspective or not, omission errors?

[Inaudible - static] -- Commissioners?

[Inaudible - static]

That would probably get us doing things anymore timely manner. That is what I am thinking. [Indiscernible - multiple speakers]

I think that is a good idea. [Indiscernible - multiple speakers]

Obviously, [Inaudible - static] Doesn't have to take six weeks. It depends on what you are willing to pay to do it more quickly. If we think it is a real issue to wait six weeks to have it transcribed, we could possibly shorten the timeframe. Maybe it could be hundred dollars and not \$1000. [Inaudible - static] To the -- \$100 and not \$1000. [Inaudible - static] To the extent that [Inaudible - static]

Any other questions?

Thank you. [Inaudible - static] [Inaudible - static] That is helpful. [Inaudible - static] [Indiscernible] more projective -- productive dialogue [Inaudible - static] [Inaudible - static] [Indiscernible]

So we get the connectivity between priorities plus the different government [Indiscernible] [Inaudible - static] Have a more productive dialogue [Inaudible - static] Pinpoint on behalf of the various [Inaudible - static] Would be helpful. If we get a really good snapshot of the trust fund [Inaudible - static] [Indiscernible] [Inaudible - static] We can go beyond that in the next chunk. [Inaudible - static] [Indiscernible] really nice job [Inaudible - static] [Indiscernible]

Any other comments?

One more. [Laughter] [Indiscernible - multiple speakers] I don't want you to leave and you are leaving us. How can you do this? [Laughter]

On the award amounts as of February 3, 2014, on our fiscal year 2014 which we understand has only begun in October, right?

The attorneys fees and costs you extrapolated out roughly \$18 million which is about a \$3 million difference in 2013 and 2014 on the attorneys fees. What was the number again, on the petitioners awards?

Approximately \$168,770,000. That is almost \$100 million. That is more significant.

It is less than the previous three or four years. Realize Scott the previous three or four years were a huge leap from the decade before.

The only other thing is a relates to that is, if we are -- since we at one point took in -- we are in the soft-money. We are taking in as much is we are spending instead of a going out. But in some years we took in less than what went out. I know you can't identify a trend with that limited amount of data. Might it not suggest that [Inaudible - static] Not to consider or not to think through or not to say, let's take the monies that are in the trust fund and use it for research rather than use it for compensation purposes.

If that were to be something that the commission were to recommend, in the amount that would be [Inaudible - static] Envisioning would be a drop in the bucket because [Inaudible - static]

I think CDC would be very happy if their budget was increased by \$3 million or \$4 million for research or if part of that money went to in the PO -- NVPO for research. But that would be a relatively small amount of money. [Inaudible - static]

We need to have another public session might this. We want to say thank you very much for the role that you took over at and the awards that you have [Indiscernible] [Inaudible - static] We have not had a chance to meet face-to-face, it has been a very [Inaudible - static] [Indiscernible - multiple speakers]

The next item on the agenda is the report to the Department of Justice. Mr. Vince Matanoski , come on down.

Sure. [Indiscernible - papers rustling] [Background Noise] [Indiscernible - papers rustling] It is a pleasure again to be in front of you [Indiscernible - papers rustling] .Mac -- [Background Noise] I have a tendency to forget to say what [Indiscernible] I am on. I will be careful about that [Background Noise] I appreciate that. [Background Noise] turning to slide to -- two.

[Background Noise] [Inaudible - static] As you heard from Dr. Caserta , the Department of Justice will look at these chunks of information, different time frames [Inaudible - static] We try to move from reporting periods can siding -- coinciding with [Inaudible - static] [Inaudible - static] [Indiscernible] we look at the first number that we have their, 128 claims filed. That actually represents started? -- [Inaudible - static] The number of cases[Indiscernible - low volume] [Inaudible - static] If we turn to tran10's slide 3, you will notice that the PIC -- DVIC [Indiscernible] reported in the last year, runs about [Indiscernible] [Inaudible - static] This year we are projecting out about 500, a little over 500 for the fiscal year. What we have witnessed, as we have reported, in the last couple of years,[Inaudible - static] Last summer, we witness a large percentage of cases filed. [Inaudible - static] All-time high, watershed [Inaudible - static] We were monitoring it closely to see whether or not that was an aberration. We are seeing now that it is running about [Inaudible - static] Projected out to the full year, runs out to about [Inaudible - static] That could present some challenges. [Inaudible - static]

While the case is [Inaudible - static] The resources [Inaudible - static] [Indiscernible] it is something that we are very aware of [Inaudible - static] I don't want to see it [Indiscernible] they are aware of it as well. This is going to be a challenge [Inaudible - static] Looking at slide 3 from the presentation, [Indiscernible] essentially a four-month period [Indiscernible] [Inaudible - static] Particularly if there are no [Inaudible - static] I project that out [Inaudible - static] For the full year. My projection was 128. Run that out four times and you would have 500 [Indiscernible] for the whole year. The same with slide 2. [Inaudible - static] The number of cases that we had come in, by whether they [Inaudible - static] About 80%, adults, about 20% minors. [Inaudible - static] Last period it was [Inaudible - static] 50% for minors. The period of for that was 75% adults, 25% minors. We are averaging about 1/5 of [Indiscernible - low volume] Children about 4/5 [Inaudible - static]

I just wanted to ask, how do we define minors? [Inaudible - static]

Thank you. What we have done is anyone under 18 [Indiscernible - multiple speakers]

That is correct. [Inaudible - static] The court will eventually essentially -- essentially recognize anyone who is [Inaudible - static] Um as they have some other disability [Indiscernible]

[Inaudible - static]

That is right.

[Inaudible - static] [Indiscernible] [Inaudible - static]

Turning the slight three, the first statistic you see is [Inaudible - static]

Reminds me that I might be sure talking about -- talking about slight three but I am not showing you slide 3.

[Inaudible - static] The number of adjudicated cases is slightly down during the period. That becomes important [Inaudible - static] Compare that number to the [Inaudible - static] Period with the number I gave you on site to -- slide 2. [Inaudible - static] More are being adjudicated [Inaudible - static]

I am not sure if this trend will continue [Inaudible - static] [Indiscernible]

[Inaudible - static] [Indiscernible]

I do note that they were not in [Inaudible - static] Which could have an impact as well [Inaudible - static] After a long period of time [Inaudible - static]

The other statistics here are, one that jumped out at me that was different than previous reporting periods is, the number of settlements that were reached during the period was sharply down. I think that is an aberration as far as I can tell. [Inaudible - static] Change the pattern of [Inaudible - static] [Inaudible - static] [Indiscernible]

Thing onto slide 4. We monitored this, total petitions voluntarily withdrawn because we wanted to [Inaudible - static] Might be an indication of satisfaction with [Inaudible - static] What we have seen in terms of the cases that it been voluntarily withdrawn, from my experience is that [Inaudible - static] [Inaudible - static] [Inaudible - static]

Are there any questions? [Inaudible - static]

[Inaudible - static] Comments about [Inaudible - static] I realize how that multiplies the number of [Inaudible - static] The forward projections I gave with the data [Inaudible - static] Multiplied in number that is [Inaudible - static] That will take you where the production will be -- projection will be. [Inaudible - static] I have the wrong multiplier.

Dave King again. What slight are you referring to?

[Inaudible - static] As of February 3 in order to correct this, just multiply that number by three [Inaudible - static] Slide number three, slide number four, slide number six, [Inaudible - static]

I was sitting there and [Indiscernible] [Indiscernible] slide 6 multiply out what the [Inaudible - static] Would be and project that out for the amount of the award that was paid out [Inaudible - static] It would come out to about 119,000 -- \$198 million and project out to [Inaudible - static] The awards were attorneys fees would project out to about \$82 million -- \$22 million.

Turning to slide 5, we had one case that went up in court [Inaudible - static] [Background Noise] it is before the Supreme Court. It does not necessarily mean that the court will [Inaudible - static] That means one of the parties [Inaudible - static] [Inaudible - static] Whether or not they will [Inaudible - static] The case that went before [Inaudible - static] Tembenis v. Sebelius Was about [Inaudible - static] Award for past suffering or death benefits but also a you know -- an award for future lost wages [Inaudible - static] Had the sufferer -- child survived. [Inaudible - static]

Court of Federal [Indiscernible] agreed with [Inaudible - static] Federal Circuit filed [Inaudible - static] [Inaudible - static]

Reimbursed expenses we are talking about, we have seen subsequent [Inaudible - static] Wage earner, lost wages [Inaudible - static] At that time. Not for injury damages would they have [Inaudible - static] This is now [Inaudible - static] Someone is asked [Inaudible - static] We may not have [Inaudible - static]

[Inaudible - static] [Indiscernible] [Inaudible - static] Turning to slide 6.

Question please. [Indiscernible] on this one, what was the age of the child and the vaccine?

If you give me a moment, I will take a look at that and see if I have that information.

Thank you.

I have it in front of me but I have to find my glasses. [Laughter] Age has certainly caught up with me.

Project your lost wages without your glasses [Laughter]

I don't have the age of the child but it was a

-- [Inaudible - static]

The age is the question of how do project future income at what age, whether it is an incident or an older teen.

The statute provides a basis for projecting out lost wages. In the statute there are certain calculations for age [Inaudible - static] Predictable life of the average person [Inaudible - static]

That is actuarial data. Thank you.

[Inaudible - static] Turning to slide 6 so we had to decisions that the Federal Circuit. The first was Carson. That was a case where the petitioner [Indiscernible] [Inaudible - static] For a long parade of time while the other case was decided on [Inaudible - static] Carson as well, the petitioner sought [Inaudible - static] [Inaudible - static] And the Federal Circuit denied [Inaudible - static]

[Inaudible - static] To anticipate [Inaudible - static] Snyder/Harris v. HHS [Inaudible - static] Those cases involved [Indiscernible] reversed cases [Inaudible - static] As reported to this medical [Inaudible - static] Previously [Inaudible - static] [Inaudible - static] [Indiscernible] [Inaudible - static]

[Inaudible - static] Reversed [Inaudible - static] Federal Circuit [Inaudible - static] The attorney for [Inaudible - static] More likely to [Inaudible - static]

We have two new cases that are then filed for the Federal Circuit. One is, slide 7. Koehn v. HHS. That involves human papilloma virus [Background Noise] [Indiscernible - papers rustling] Conditional [Indiscernible] caused by that was systemic, the juvenile was impacted [Inaudible - static] There was extensive evidence, medical evidence [Inaudible - static] Concerning the virus itself. Concerning the underlying condition. [Inaudible - static]

That was affirmed by the or the federal [Inaudible - static] Price v. HHS There also was the case, -- there also was a case, Price v. HHS. After the decision [Inaudible - static] The Council for the petitioner moved for a [Inaudible - static] [Inaudible - static] [Inaudible - static]

Simanski v. HHS Was a very lengthy re--- lengthily procedural [Inaudible - static] [Inaudible - static] Further questions being answered [Inaudible - static]

Dillon v. HHS Was a case [Inaudible - static] [Inaudible - static] [Indiscernible] requires a hearing from a special [Inaudible - static] Surgery to prevent that back -- [Inaudible - static]

Turning to slide 9, I will briefly talk about two cases, that are on this slide because the others Contreras v. HHS was another case that was going -- [Inaudible - static] The case of [Indiscernible] and the other [Indiscernible] the individual suffered transfer silane is one day after oxidation your weekly -- key collection -- the key question was [Inaudible - static] Several expert's [Inaudible - static] Period time for [Inaudible - static] Trigger [Inaudible - static] Period time later than [Inaudible - static] That went up to [Inaudible - static] The judge there had questions [Inaudible - static]

[Inaudible - static] [Indiscernible] [Inaudible - static]

Now it is back to the federal Claims Court. I apologize [Inaudible - static] I don't know how to pronounce that Chuisano v. HHS, Chuisano? Chuisano v. HHS was a maternity case. [Inaudible - static] The original case was filed that to medical records. Counsel involved, had trouble finding experts [Inaudible - static]

It helped to file [Indiscernible] [Inaudible - static]

Other any questions before I turn to [Inaudible - static]

[Captioners Transitioning]

We have cases brought to court by attorneys. Visit, we will likely come this, and so they did. Another group came in and they look at it and they did the same thing. They said, we are going to back away. Then, when it was done, the second group said, we probably should get compensated. We thought there would've been something here, but then there was it. -- Wasn't.

So, I could see that the reasoning behind that is, but what I'm also afraid of, and tell me if this sets precedents, that might it then, before, well, I am certain must have cost some level of investment for an attorney to even have a conversation with somebody about a specific case. And, to say, but we see what homework I can do. Are probably is some time, effort, and expenditure that occurs without. When they come back to say, you don't have a case, we should not do this, --, that is a risk where they will lose money. But, is it something that sends a

signal that, because, some attorneys are wealthier than others, and some firms have more money than others, does it potential we conclude people from having a conversation with people the by be enter just because, you know what, I'm not point to get involved because of you don't have a case, any investment I make will not happen. But, it seems like they actually may have done the right thing here by saying, we will not pursue something that is foolhardy. We are going to not do this. You don't have a case. I think there is something out there. Perhaps we should explore a little bit. Individuals don't know if there case or not. We don't know if we have a case, we suspect we do, people tell us we ought to get the investigation. We were fortunate enough to have the means to be able to do that, but many do not. So, I'm afraid we are frightening people off. Doesn't sound to me that these attorneys are trying to rip anybody off. That doesn't seem like anything what happened to you Arco

I will preference any comments I have with full disclosure that I do not have funds. So, I don't think I can speak to and whatever same district -- speak -- and would presume to speak to the economics of the practice. I could speak to some objective ways as to whether this is a problem. The statute requires that the case be filed. So, there is the notion that, before a petition comes through the door, there is going to be some investigation of it. So, it seems that, there would be Council I would essentially be willing to take the risk.

They will do some background investigation --

[Indiscernible - low volume]

The statute also says, attorneys fees were available provided that it is brought in good faith. That is subjective. You might believe in good faith that --, but, when the evidence comes out, some others might not be -- believe objectively Arco way this is played out over the course of the program has been in a reasonable basis. So that, if you just filed it, there are lowers -- lower standards.

From that point, it is reasonable for you to apply and file for the case. As time moves on, the standard makes it a little harder so that, if some counsel is involved in the case and yet they've continued to pursue it, the court may look at it. If you're the second Council, it may even be part to show it is reasonable. We can bring these things forward. And, it could be that the claim was potentially \$45,000. It is not an insignificant amount.. Now, there are other ways of looking at this.

Notice that we can look at other factors here Arco one of the ones I looked at, what is the universal assurance for counsel willing to claim? The court maintains a list of counsel who indicated -- and brain vexing claims. The indicated to the clerk of the court. I don't recall the number now, but, it is --. Pretty much, it is been the United States, Alaska, and why. I can speak to this. I've been very pleased that, in addition to this counsel, there are a lot of new things we are bringing. So, from that, I haven't seen it a problem. But again, my comment, just from my standpoint and I don't have the ability to talk to the economics, how much of this can I do?

That actually helps a lot. Any other opinions? Add, you are on that side of the table. Doesn't that sound reasonable?

I think that is a fair explanation. Are concerned has to be whether injured people have access to an attorney. It would appear as if there was an opportunity for most people who have a potential claim to be able to secure attorneys. The issue of reasonable basis and good faith is important for us to monitor and to figure out. It will be interesting to see what happens on appeal. This is a problem with drawing conclusions from a particular case. There are facts that are probably unique that prompted the master to deny that these. But, I would say, in general, it's not. It is very rare forecourts to sign no reasonable -- basis. I don't know, there are a handful of decisions that the court has said, you are cut -- entitled to know attorney fees because there is no reasonable basis for ever filing this case, so, --

That is been my experience also. It's rare that you'll see a decision like that.

But it is very much true that there is a lot of --. If you are representing people, you don't know what category they are in. Until you've spoken to them, that's the first best, and then review medical records, and the paper medical records and then sometimes, you need to have an expert look at it before you can file the case. There are --. As been pointed out, there's a lot of time and money that event put in. It is challenging. It is a balancing act. We should keep an eye on it. The question is well taken, but we will see what happens on the appeal.

Thank you.

During to slide 10 Arco we have one case is scheduled. That is court of federal funding.

On slide 11 through 14, we have summaries of cases. I digested some of the information for you for those slides. The total number of cases that were settled during this time, where 40 of those 33 that involved adults and seven involved minors. Those that involve the flu vaccine alone for a conjunction with other vaccines was 28. I know group reported on this on the bat -- in the past.. This is not surprising given the number of -- for each. As we see in this stipulation again. The average length of time from petition filing to the case stipulation be filed, is two years and four months. That is up a bit from what I've seen in the past. It is a little concerning. I did break down as I usually do how they fell out the percentages stayed up the same. I look at the percentages in the year category. In other words, I may have more one year and 11 month cases than one year and one month cases. But when I broke it down by how long it was by year from the time of filing the time of it being filed, it is what I reported to you earlier. This period we had 20 -- I cannot read my own writing. 28% of the cases where files by stipulation of year. In other words, 28% of those that went to settlement or would be done within the year Arco that tracks well with what we had seen in the past couple of times where, last time I reported he was 28.7 Arco now, you push that out to two years, you get an additional four cases -- 14 cases within a year or less. Two years or less, you add another 14, that captures 35%, an additional 35%. Put it out to three years, you get another seven for 70%. The total then within three years of cases that went to settlement was 80%. We had a high watermark of 90% of the

cases. I was pleased about that and wondered if that was a trend to be repeated in the future. These numbers, tracks well with what we have seen when I recorded it in September. When I reported to you in June, 83% within three years. Interestingly, even though the average amount of time has gone up the outlier cases between the time of filing went down. Usually, as seen the longest case be seven or eight years. Now, the longest case was four years.

What is the reason for the delay?

It is not one particular factor we can see. Getting records maybe at problem.

I understand that they have difficulty getting experts on the case..All cases would have same petitioners getting an expert. So, it may not always be the case. It may not always be the situation., Some of those cases have gotten an expert. That may have been what have pushed it. Usually, that particular problem --

[Indiscernible - low volume]

I do understanding -- I do have some understanding that there is difficulty tracking down an expert in a crime of passion.

This is at. It's not necessarily binding, but it is also the experts that we have to rely on. It tends to be specialized. They tend to have to take your credentials and they are busy. You might wait months for an expert to have the time to review the records on the report.

Right.

There are other factors also. I want to chime in on the medical records because I'm sure that DOJ knows this, but, you can spend all day, everyday, following up with medical providers on medical records. I'm sure, from the response perspective, it must be like, why does it take so long to get these medical records? I would make a plea for, from the petitioners, that it's really something that is beyond your control. It will take to the three or four or five months to get records saying that it sounds ridiculous. But, I don't know how to improve that. Think it's probably a significant source of delay. Other source, which you are probably going to mention is, the special Masters were not at their special complement. There were six during the time period. There were some delays and I think this would not be disputed. It's just the court is overwhelmed by the number of cases they're having to adjudicate and deal with.

Right. I would agree. My caveat would be that, special Masters, that would have more of an impact. Now, certainly, special Masters can play a role. But, settlements are largely in control of the party. Certainly, the kissers are having difficulty getting, and I'm sure there are number of frustrations getting records. But, if they're having trouble getting records, or other evidence, the default is always going to be to allow the time they need to develop the case. We wouldn't want this -- to disadvantage them. Obviously, we want to move the case along for their benefit. But there will be the balance that you have to do in determining how you perceive.

This is interesting because, I think it highlights that there are many areas in this process that have delays creeping. I suspect it will only get longer because, when he started out, you talk about how we are averaging 500 which is a 25% increase. It's only likely that this to get into a position that is even worse. So, the question that I throw out your, we can answer this question today, but I do think it's something that, we need to be cognizant of it. If that slows things down, then what are we doing if we are anticipating that we can see the process is going to have some issues based upon what we perceive to be significant trends. And, the automatic component where medical records are sometimes getting late. I will tell you, sometimes the file right at the end of the deadline because, they want to file in good faith. That means they have to have some records, but sometimes they might file without any just to meet the deadline that we had. The areas that are under their control, what can be done in that particular area if anything? I don't know. Maybe that's an area, to me it is a process. It is all different components. Which areas other and had we managed to to create the best, this particular case, we are looking for efficiencies.

Right.

Wanted to add a comment. I would hope, now that most practices are using electronic records, that there is not a situation where you have a copy page after page after page of notes. Is it better?

It so much better.

There are still delays.

Could it be that some of the delays are that, oftentimes it's different medical institutions that are going to be involved and affect cross strait -- state borders as people begin to realize, were not sure what it is, but you to go over here. So, there's a whole bunch of delays like that to try to get all the records and contact each one of those places. I don't think there is a universal place where they are all stored except maybe at the NSA.

One other component. They feel the same strain that we are feeling in the Department of Justice. One good news story that came out of this process the petitioners counsel helped address the issue Arco or we cut down in the area of settlement, we cut down some of the other final processes. That cuts a little bit of time off of the back end of the process which is a good thing. And then on the front end of the process, getting to so -- settlements. Again, we came up with fast track. Therefore, the court doesn't have to be involved. It might not be agreed upon by the party. Cutting some of the procedural requirements my ticket out of the process as well. There might be an efficient way to do the filing.

So, I think that is really helping Arco efficiencies like that will be more critical as we face increased numbers of cases with a fixed number of resources.

Other questions?

If you notice, I moved a lot of the information that used to be in are slide section 2 and appendix. There were reference materials I thought were helpful, but we didn't necessarily have to go through each slide. 15 to 19 by the final reference materials. Other any other questions?

When I started this, I said 40 min.

I originally started with 20 min. and now it is up to 40 min. No matter how much time you give me, I eat it all and more. I apologize for that.

Did not apologize for taking the time to help us understand and the public understand. We are grateful that you do. Thank you.

We are past the break time. We should have a break. The break is scheduled for 15 min. I will add 2 min. to it according to my watch and call it a 3:15 PM start after the break. We are on break until 3:15 PM start after the break. We are on break until 3:15 PM.

[The event is on a 15 minute recess. Captioner on stand by.]

We are getting started again.

I wish you were here.

I would like to be. With the weather, it was unpredictable.

Fair enough.

Okay. Next item on the agenda is the report for the process group. -- Is the chair of the process work group. Proceed.

Hello everybody. I gave you a copy of our report.

We only had one opportunity to meet. We had a brainstorming session. We are looking for ideas on what things can the commission due to support the recommendations that we are ready to produce to the secretary?

The recommendations have completed the Irish of for each permission. This is recommending vaccination of adults. The medical number I added was the one coming from the maternal workgroup process. The attorney member, is the lawyer who has experienced with the vaccine injury program. The other two were lengthening the statute of limitations and reducing pain and suffering.

After discussion the commission can bring to the secretary's attention the members searching for new members. The workgroup has three separate letters of recommendation on each category of membership that were already submitted to the secretary.

The workgroup proposes of the commission seeks feedback from the secretary on the other two recommendations because they are critical to help the vaccine individuals and the family. This can be done through a letter formally requesting the secretary senior position on these matters. And, request for feedback. If we can get any response, it should help guide us on the next steps taken. The workgroup suggests further discussion of this recommendation take place --. The input, writing be met vaccine manufacturers is essential because they would be in recommendation for the, legislation. The workgroup also suggests percentages of vaccine interested individuals and other members be invited for discussion. David King suggest inviting parents to participate informally during the public commentary section of the meeting. This strategy can also help bring recommendations to public awareness. Andrea pointed out that this particular strategy is to get better support for future recommendations. And, I addressed this also. The issue on the tabular presentation of the data. So far, we had discussions providing data efficiencies on workgroups on data mining.

That was the future science workgroup that began to do some data mining. A recommendation came out of that and that was sent to the secretary at one point.

It also is regarding this presentation of adjudicated cases. These are publicly available already, right?

They are on the website.

There is little bit more detail than what is presented.

Yes. So, we've forwarded that, but not to the process workgroup. I'm thinking, what we should do is, forwarded that to you and then, that can be disseminated to all of the commissioners and then, because I think if we don't do that, the process workgroup although, I don't think we have the expertise at our level to do this, or do we?

Really looking into all these cases to find out what she is asking for. Looking for more specific terminology for it

So, here is my question. I can forward the spreadsheet to disseminate to the commissioners. There some commentary we have around them as well. Are you willing we sure that as well so we could schedule it for the commissioners to take up and have a conversation? We can have announces a don't have information from them. Doesn't make sense? This way, you'll get the thought process. And, I get the thought process, you'll have some understanding what it is and what some of the thinking of -- and against might be. It will help you draw conclusions and we should discuss it as a commission. Less you think I am overreaching you guys.

I'm not sure what it is for

Exactly.

In the public comment today, there was an issue around the reporting. The reporting is there, the information is there, but there must be another way to share that. It will give us an example of an idea. Not send this is what you had to do, rather idea, this is something you might want to consider. We can consider it unless we make it official, so, process workgroup, look at it, we don't know what to do. So, I'm thinking that maybe the best course of action is, have it disseminated to everybody and then we will have a conversation. As a group, we can either say, this explore this further or, we don't know whether the Jews is good to squeeze.

We need everybody's input on it. That is my recommendation on it.

Is nothing also.

This is at. I would suggest that we put on the agenda, consideration of the suggestions regarding dissemination of information, program information statistics. And, I think the commission as a whole is comfortable with it. We could talk at the next process workgroup. We do have that on our agenda as well just to help shape and be prepared to give our opinions on the value and the merits of the proposal.

So, as the chair of the process workgroup, which you be willing to have your take that on?

What?

Just a discussion? What Ed is proposing, but go on the agenda for June so the commission -- to the commission as a whole, but prior to that, we have a meeting of process workgroup to give it another look at and give other ideas to everybody Arco

Okay. That is our April agenda then Arco

Great.

I think we should also invite and reach out to -- to see if she might be able to participate in our process workgroup and provide us with information.

Yes.

Help us understand how this will be helpful information and why. I would appreciate hearing it.

I think that is a great idea. Is fine. As a parent and public person, looking into the website for example, what I am interested in would be how do I go about putting my case report on? I know I read it. It said the table, but what do I do? I won't worry about how to cases have been

adjudicated. I will be too busy taking care of my kids. That's why so, who will be the people that are benefit of the this change?

As a parent, it's not my interest at all. I don't know. That is my point of view to begin with, like you said, I don't know who's going to be benefited by us giving that particular change in the presentation of the data. It was already available to begin with. The second question I have is, does the commission have the manpower to provide us with that information? Do the work because, actually, I will volunteer. Is a lot of information to document. Those are a lot of years that we have to look into. I'm definitely not going to volunteer to do it.

Some things may be easy and some may not be. We just have to look at it.

Dave King. I do think that the first question you ask is, how does this benefit? I think that is a great starting point for us to think of. I think that is a terrific place to start.

And only one our discussion in April.

Left Mac

So, I to follow-up question. I can't remember ever receiving copies of the actual recommendations that we made. I thought it was the last process workgroup, but, I apologize if was and I missed it, but we could -- could we have the actual recommendation?

Of the I e-mailed them. My apology. He won the actual letter.

[Indiscernible - multiple speakers]

Would you resend them?

I well.

That reminds me, I was was give this to you on the break. Thank you.

Okay. Further discussion.

We have a proposal.

[Laughter]

That we think of what I think the idea of the proposal is. We were thinking that, there are some issues that, in the brainstorming session of the process workgroup thought of and came up with that, at times, we feel that it really should be something that the entire commission really hears

and is part of and is also part of the public record. We found that some of what we are talking about what we are thinking about, and who the different, I don't want to call them, I'm sorry, the where the pops into my head is stakeholders, but I'm not sure that is really what we mean. Really, those who have an impact on or who have to deal with, maybe those are stakeholders, the vaccine injury compensation program. Ranging from parents, attorneys, special masters, apartment of justice, ranging from we as the commissioners, ranging from those who are actually injured about those who are caretaking for them, all of those people. So, the idea was, there are things that we probably, while we think we know and understand, there probably are some that, maybe we haven't quite understand..That, in my view asked for the commissioners, two, at times, where we would invite a speaker, if you will, to come in who is familiar with that particular area and educate the commissioners as a whole so that we could then choose to say, that is something we probably ought to spend a little more time on and work on or, you know what, I got a now and I think we got that whatever and I think -- so, it would provide a level of education. And my capturing this correctly?

That is the second part. The first part is, we meet as commission for feedback.

The feedback we got was not what we wanted. RA? So, the feedback that we were looking for is that, we want to know the secretaries opinion or position on our recommendation. We are thinking that, once they receive the recommendation and acknowledge they have it, that we could then ask for the position. Does it have merit in your eyes are not? The secretary is on an advisory commission. They can just to respond to that are not. That is the way it is.

I worked in the office of the secondary per year in the early 90s. All of our recommendations go to a number of the secretary. You got the letter so you know we received it. That the appropriate response. We will will get back to, but we need to go through the system. It is working through a system. It is working through a live system Arco the system of this agency and is there. It takes a while. Is never lost. That is the way it goes.

I think that is a good point. I think what we should do in light of that is follow up with a letter saying, we appreciate your response that you are reviewing our recommendation. We monitor it closely. We stay on that, so that they are understanding, as commission, we are not going to go away. We want a response. I agree. As an agency we have worked of the channels but we had to push them.

We are talking about likelihood statute of limitations. These are integral to our program. Would like you to take a look

What is a typical response time for it to flow through?

I cannot address that. There is a great. People are account for. Things don't get lost. That will make us feel better. It is not going to get lost. People are accountable. There is a grid when it came in. What is the date? What is the different -- disposition? Everybody knows. For me, this can cost me a minute next motion so I will not lose you. When you came in, who sought, and

what is the disposition. It will not be lost. But I think that makes commission feel better. We need you that. But, on a tight ship.

Okay. From my perspective, I think it makes it feel better because I sometimes think that the squeaky wheel gets more oil. I sometimes think that is annoying enough where it's like, okay already. So, sometimes, I don't see how it can hurt unless somebody at this table can tell us that it would hurt what we are doing. So, if it can't hurt, whether it may help not might be developed -- debatable. I will concur that that is possible. I think it is not a bad idea to do that. Particularly in light on how important some of those recommendations are to the beneficiaries and potential beneficiaries.

I guess I wonder what our responses were in the past. I thought this was the type of letter we got in the past. Thank you for your recommendations and we will take it under advisement Arco maybe I'm wrong, I don't know the

I thought it would be helpful to read the language from the other report. The title is, monitor the status on a regular basis. Beginning a copperheads of list is information on the status of recommendation will help impact the target, the follow-through, and dissemination efforts. Per instance, the recommendation is not been implemented, you think about how to better 20 how invocation are involved. The list of recommendations and their status should be updated on a manual basis. The input should include information on which recommendations are being pursued and what actions are being taken Arco

Dave King here. So, that strongly supports that we should send something out, but I think it adds an element to which is that we should actually be describing what the benefits are.

It doesn't work the first time, we should explain it better.

Get the opportunity do that. Like that. Thank you.

The question is, who will draft the initial statement? We will say it is very important and we would like to hear, at some point, the position of the secretary. And also, reiterate the reasons we think is are such crucial, important recommendations.

Dave King here. Does that come from the staff support that we have?

Sure.

[Laughter]

The secretary letter is dated February 25.

Dave King here says we will not have this in a week. We will understand that. That is one piece we have an action item on. That will be one of the bullet points. Does everybody agree you with that?

Yes.

The Spanish and then go back to this other component. It would be helpful to have a sense from the commission here and on the phone, what are your thoughts on this? What do you think of this? Is one thing for us to Tocco this, but what do you think was

This is Sylvia. What I found, for me and working with communities of need, we have Strict guidelines of who gets represented he doesn't get excluded. One of the issues brought up to me earlier is, do they speak English? What language do they speak? Do they understand the process? Maybe surely can help me with this this. I'm not sure it is under our mandate to look at that. I think it is important, but I'm not sure how we will address community input for a national committee.

Thank you. That is good input, actually.

Good thinking Arco

There is always public organizations whose regular speakers speak in public comments. In that, regular people show up to make public comments. They do that to their. And then you see difficulty recruiting participants. What is there? Is there a national community? I don't know. You know?

I do not. I do not know.

Is there a coalition base established for individuals with concerns about vaccines? Other than the big names people know? Is there some type of coalition out there? We don't have the money to do something like that. It has to exist. I am taken aback that reports say they need recommendation for people to serve on the commission. It doesn't make sense to me.

Some of the commissioners, from a more limited pool. In the sense that, whether it be a parent or guardian, there's not 1 million of them there. Maybe there are and we don't know. You're right. But, when we do have that, not all of them would have the luxury of the time investment because of the what they have to do care for the injured person. That can really be something. I don't know the answer to that.

That's sort of a separate issue. Maybe this is for tomorrow's agenda.. But, back to the more broad issue about, what would be helpful for the commission as a whole to hear? Something that we are not hearing. I guess. One of the people that brought it up, will, the examples I had were, would it be helpful to hear from other attorneys who, you know, spend the majority of their time doing vaccine injury representation, to hear their thoughts on how the program

could be improved? We could put some grounders a what we want to hear from these people. Another thought is, and I actually asked person three or four weeks ago, a compelling story that sounded like a vaccine injured child. It was 4.5 years since the onset of this is -- symptoms. I slide 100 times, you cannot proceed the claim now because of the statute of limitations. I can do the conversation. I know it isn't fair. I know your doctor didn't tell you. I know they told you it probably wasn't and I know you are only now think it doesn't matter. So, again, I'm like, you know, thinking out loud here. Because, we all as a commission are already committed, to try to convince the secretary that likening the statute of limitations is extremely important Arco so maybe it is just a reminder of that, you know, hot sequences of not being successful at what it is that we are already trying to do? I don't know. The other thought I had is, maybe, perhaps not listening to the chief special master, but for example, you know, former chief special master Gary. If we invited him to talk to us about his observations sort of running the program, being the chief special master for four years. I don't know if that gives us further advancing our goals, but I think that was part of what we were thinking about.

What kind of information to do want?

From the chief special master? I'm not sure. Don't know if that was a good example. I have a lot of information from representing vaccine injured people. I was at the covers less than two weeks ago were the chief special master gave a report. I seen all these statistics, but I don't know. Dave repeats that those are vaccine injured parents. Parents of vaccine injured children. Will have different perspectives. I think that is why Dave is saying, we are okay with it. I think, Silvius point is a good one about, you know, are we going into a minefield here in terms of trying to say that certain people represent certain constituents? I think that is a good point. I don't know. The only other comment that I would have, and I think it is a good question, that Charlene raised, there is no sort of national issuance group for vaccine injured people that I am aware of other than the national vaccine information Center which, I find the commentary and input that we get from Teresa on behalf of it is important. They are an organization and have an agenda, but I think it is an agenda that we should be speaking to understand. I think it directly feeds into what we are trying to do. That would be another example of somebody we might want to hear from. You know? That organization that has, for the last 20 some years, been focused on the issue of vaccine safety.

This is Jason Smith. I'm trying to see if I can collate some of the different thinking. Let's take for example, the statute of limitations. If we said, okay, I think we've done this in the past. Let's do a deep dive into this. Let's have inspectors, maybe medical professionals, to identify systems and injuries get that clinical practice. And then there's another stakeholder interest in the process. Those in the public who are interested can see. They could be into an installing all the discussion and now I have the opportunity to give a public comment on that issue. Then, maybe after that, you take all of that information back and follow up with a correspondence to the secretary. Do it a little more in-depth. Little more rationale and more perspective supporting the recommendation and in other touch point is a, how is it progressing? And you can do something similar. You talk about the different priorities and is there is synergy there. I think we said, was some of the important things are. Let's make our own priorities and see if we can

advance of a little bit maybe get a deeper understanding. But I don't want to suggest -- of this point. Just dig a little bit deeper.

Dave King here. Catastrophic thinking.

[Laughter]

I think the opposite together. I totally agree. Let the record reflect that all the commissioners are nodding their heads to those present.

[Laughter]

I think that is a tribute this deletion of what we were wanting to accomplish.

Dave King here. How do we make that a reality? What is the process for us and how do we do that because, each one of us doesn't go out and -- people that is not the process. With to formalize the agenda. We turn to our support staff to tell us what we need to do your make this a reality on the agenda. How much time do we need to allocate? We can figure that out, but who should be invited because I think, maybe this the statute is the one to start with Arco is that the right one to start with? And so, what is the process to do that so that we can have that as a distinct agenda item so that we can understand it better from other people's points of view, but that would be experts in the area to give us that point of view.

I would think a subgroup of the commission would need to figure out who the appropriate presenters should be that the commission wishes to understand and deeper depth so that they can rewrite letters that have a greater and better participation, as I mentioned before. Might want to hear from the Department of Justice. You might want to hear from --. You might want to hear from the manufacturers attorneys. And others. So, --

One of the issues that I ran into is, it is always something. I was lucky. Well, I don't know if it selected, but it is dramatic that they were forced to look at it. So, they have to start looking. They tested for all different viruses and nothing was coming up. The only question I asked is, the only buyers is introduced into the system is this. Why are you looking at the?

They were like, it can't be the vaccine. They looked at everything else. The thing is, the medical field should be consulted here. How do you distinguish the difference to be able to know how the vaccine is?

That would be harder. Unless people over handling cases already, the health professionals the they always go to to review those types of records that are called upon. Another point that I want to point out from having worked on national conferences and arranging guest speakers is, also want to take into consideration people that might be more local. They wouldn't have to take about two days off account for a 30 min. meeting. I don't know. That is my perspective.

So, let's talk about the, well, doesn't make sense to have a workgroup identify who it should be and, if so, how quickly can that be done? Is a June meeting on the agenda timeframe really sick if we have the process? Is it? Can we move that quickly? For all intensive purposes, June is around the corner. It is here. Doesn't everybody have something scheduled in June already? I would think so. It is here.

The people we invite are likely to be very busy people.

Another practical point is, whether this is an in person meeting. Those are logistical, pragmatic decisions. I would recommend that we take it up as a subgroup of the whole.

I don't know if we need to call it something else. Know if we say we do it as part of the process workgroup because, for of us are on the process workgroup already rather than sort of reconstituting another subgroup. I think it is something we could just bang out and say we would like it outlined already. We would like to hear from the doctor, why there are so many people who are not understanding vaccine? I think it would be helpful to hear those that feel called on the regular basis about why people aren't aware of the program until it is too late. I think we can do it as part of the process workgroup meeting. But I think we also then need to figure out, are we talking about December because that is the next in person meeting?

I'm sorry. This is in addition to this. This is parallel. It looks like this will take six months now. That will be time for another reminder.

I think that is also a good point. On to point out the process workgroup set his agenda for the month of April a little while ago.

[Laughter]

The spreadsheet component.

So, the question I have is, can anybody think of any other potential groups that we might want to think about or talk to or listen to that would educate us on this than what has already been mentioned? Maybe we have a list and this is what we want to work with? How much thought does this require to invite who should be invited?

I think it will take some thought, were partly the reason that Sylvia brought out. We don't want to have people representing more than what they should be representing. I think it requires some, you know, it is not incredibly complicated and I like the idea of finding local people. But I think, again, it's not like they have dozens and dozens of possibilities. I think, I Like the Way, Jason pitched it. If they help us laserbeam focus on why it is so important, to extend the statute of limitations, because we heard from the doctor who said it is difficult to treat the condition. You not necessarily concerned whether it was triggered by a vaccine or a virus. You are treating

that patient. Whenever. We will get that medical perspective and then we will also give the perspective other from an organizational point or from a parent to can say, you know, the first year and a half I was in the hospital with my child. And then the second year, I was recovering and one actually, I came up for air 3.5 years later, or, three years, I tried to find an attorney, and before I found somebody, it was four years, or whatever. We can use that as a basis for a follow-up letter. We wanted to follow-up on our recommendation..

As I am listening to hear you -- as I am listening to, it seems like we can come up with a number of these ideas ourselves and look in the literature to see if there's anything to back that up. I'm not sure why we had to go through the effort to bring everybody here. Is a hear you talk about it, it's like all right, we got the letter.

This is Charlene. I would like to say, looking at this, that not be any juridical underpinning about vaccines. It would be called nursing to live. If we think about the experience, I people on this commission, by their experiences, it is the reason they are here. But, just think of whatever areas you want to do. Somebody who had a lived experience in that. This is not a discussion of theory yes are no.

Good point.

So, I think, to make the letter effective, we need to show the secretary that groups that you might think would be opposed are not so that, the secretary doesn't believe that there's going to be significant pushback. So, one would need to look at the issue. Clearly, the manufacturers would have a strong voice their. So, we would need to make clear that the manufacturers are not opposed to this if in fact they are not. That would go far to strengthen the point. Another group that may have an interest is the CDC. They are interested in vaccine safety and fostering it and getting people vaccinated. Lengthening the statute of limitations. It may appear that vaccines are not a safe. So, we need to think about who has a horse in this race, and show the secretary that each of these are in favor of doing this or least they are not opposed. That would help move it along. If we have say we didn't find any opposition?

Dave King here. He sold me. We need to do thinking about this. Does in the process workgroup would help. Yet to tell us whether or not if this can be taken out with that other right or do we have to try to create another subgroup? Maybe that is the appropriate answer. We create another subgroup.

The availability, as far as making the meeting, so far, we haven't been able to meet our goal of meeting every month. So, we are trying our best, but the past is difficult. Having a subgroup means, the timing is an issue. Especially, the people that have those meetings. It is subject to their schedule.

Yes. Is good point. That's why I think we should take it up on the process worker really it might others.

Or make it it to our meeting or something like that.

I don't know the other issue about the information that is something that will take that much time. We just need to understand what it is this information could be used for and then we will bring it to the commission. I think both of those issues could be dealt with either the process workgroup. It will be more difficult to create another subgroup and make a schedule for it.

Dave King here. I agree that, I personally think that one hour will not be enough. If two hours is too long, maybe we can Coppermine is a 1.5 hours. Need to allocate the right amount time for this. I think one hour is enough. I don't. In one hour, we cover a lot, but --

We don't cover it up -- we don't cover enough. As we explored the issue and think about it, there will be more things that come up. I'm confident about that. So, I ask, we can rent as part of the process workgroup. So that, we'll just figure out when to schedule it and how to Corneille it and do it on that so then, that's what we will do.

Other any other questions, comments?

On lengthening it, I've a question for Ed. Is there any way to gather data? Just even if it's anecdotal, survey of petitioner's attorneys, show that Sony people per week, on average, you know, multiplied by 15, are missing out on the program because of whatever.

Yes and no. Ultimately just going to be anecdotal. I could certainly reach out to the vaccine injured purchasers and say, can you, and there are only handful of firms getting called.

Are even perspective we, keeping track. If you get a call, I'm sorry. It written process name down and the contact information and then you have something that ultimately you can point to.

I was going to add, I think part of it is, if I understand correctly, some type of legislation at the end of the day. Getting a better be on it. Like living it won't solve the problem if there is a problem. It could be 10 years, but if it is the challenge of the injury and then making that Association to seek some type of legal advice, well then maybe that is something we can focus on.'s maybe getting a better understanding of what the issue maybe and then the recommendation flowing from that.

Good point.

I. I think we know what we have to do. We have a path set out and we need to execute on it. That is the hard part.

[Laughter]

So, I find that it is after four clock p.m. Arco we offered a public comment section. I was going to talk and bring in new business, but I guess we should move that until tomorrow where it belongs on the schedule since we are following this agenda and we are at this agenda. Having done that, --

Allowed to give public, now?

I will never forget the public. If I do, is definitely time to add.

So, I would like to on mute the lines. We have an open public topic or public comments from anybody that is member of the public who wishes to make a comment.

I'm sorry. The lines are open.

This is a normally the way we do it.

All lights are open. What you can do, you can talk at this time. You don't have to do less you want -- you don't have to do *1 is you want to.

We want to.

Okay.

If he would announce this speaking?

Okay.

Teresa ring him Arco

Teresa -- Teresa Ringham. Thank you for discussing the spreadsheet. I appreciate the consideration you given to them. Secondly, in terms of the recommendation, and what some of the reasons might be for extending the statute of limitations or getting an idea about how many individuals are being turned away because their claims exceed that. I don't normally share my own story, but I will share briefly today. I wasn't even aware of this program until 12 years later. I lived overseas for part of the time. There's no way that I could gather records because they are in Saudi Arabia. A lot of what we hear from our parents, who come to us after the children have been injured, they didn't know about the program. The second thing we hear is that they are discouraged from reporting. I also think there's a problem with the fact that, when you look at the Institute of medicine report and we look at gaps the research, I want to be fair to the doctors. There are a lot of risks we don't know about. Claims will fall through the cracks until that is close. People are being shut out for number of reasons. I'm not trying to discourage retroactive or proactive anecdotal data-gathering. I'm simply pointing out that, you still may be missing a large portion of people who are unaware of the program in general and

made aware far too late and never get to the standpoint of consulting an attorney. They know that they missed that boat.

From our viewpoint, we believe the statute of limitations should be extended. It can't be at the cost of an outside appeals process. In light of the Supreme Court's ruling, it makes it far more difficult to even do that. You know, that would be our standpoint. The statute of limitations, you know, should be extended but not at that cost. That was never the intent and Congress in trying to get this law into place, although I understand your role is to compensate as many parents as you can. That is the extent of my comments. Thank you much.

I am showing no further comments at this time.

Thank you. Being that there are no further comments, we adjourn or do we recess since the meeting continues tomorrow? I think it is a recess, right? So, we will recess until 9 AM tomorrow with the Commissioner take it up again. Thank you very much. That is it. Goodbye.

This concludes today's conference. You may disconnect at this time.

Good Mac. -- At this time.

Glued back -- at this time.

[Event Concluded]