Health Resources and Services Administration

86th Meeting of the Advisory Commission on Childhood Vaccines

Teleconference

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Proceedings by:

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P R O C E E D I N G S

OPERATOR: Welcome to the 86th quarterly meeting of the Advisory Commission on Childhood Vaccines. Today's conference is being recorded. If you have any objections please disconnect at this time. I will now turn the meeting over to the ACCV chair, Mr. David King.

Agenda Item: Welcome and Chair Report

MR. KING: Thank you and welcome to all who are on the line with us today. We will begin by doing an around the virtual room to identify everyone who is at the meeting. I will start. Dave King, chair, parent of a vaccine-injured child.

DR. DOUGLAS: Charlene Douglas, representing the public.

MS. PRON: Ann Linguiti Pron, pediatric nurse practitioner.

MR. SMITH: Jason Smith, in-house counsel for Pfizer Vaccines.

MR. KRAUS: Ed Kraus, attorney for vaccine-injured people.

DR. FEEMSTER: Kristen Feemster, pediatric infectious diseases physician and a health services researcher.

DR. READ: Jennifer Read from the National vaccine Program Office.

DR. SHIMABUKURO: Tom Shimabukuro from the Immunization Safety Office at CDC.

LT. MARSHALL: Valerie Marshall, Office of Vaccines, FDA ex officio.

DR. MULACH: Barbara Mulach from the National Institute of Allergy and Infectious Diseases.

DR. CASERTA: Vito Caserta from the Vaccine Injury Compensation Program.

MS. HERZOG: Annie Herzog, staff liaison.

DR. VILLAREAL: Sylvia Villareal, pediatrician, dealing currently with a cold, non-vaccine-related.

MS. SAINDON: Elizabeth Saindon with the Office of the General Counsel.

MR. MATANOSKI: Vince Matanoski from the U.S. Department of Justice.

MS. DAVIE: I am Andrea Davie from the Office of General Counsel.

MR. KING: Jocelyn is here as well, right?

MS. MCINTOSH: Yes, I am Jocelyn McIntosh with the Office of the Special Masters and I have Chief Special Master Patricia Campbell Smith joining as well.

MR. KING: Is there anyone else on the line who has not identified themselves? Then we will proceed. Because we are doing this in a virtual environment I think it is important that we do a couple of things. One, as

usual we need to state our names before speaking so that everyone on the call will understand who is the speaker. Additionally, if we are going through presentations, whether they be slides, whether they be on paper, whatever, if the individual who is giving that presentation, as they move from one slide to another, that they state clearly that they are, in fact, doing that so that it is much easier for those of us to follow along who are working virtually. So we are good with that.

As you know we are doing this in a virtual environment. The chair's report is that we think this might be more effective in a face-to-café environment as opposed to a virtual environment, however, knowing there are constraints from a budget point of view we understand the need for, at times, being in a virtual environment. The Commission is also looking into – or HRSA is looking into – how, when we do virtual meetings, to more effectively do these utilizing different types of technology. I think on a go forward basis, if we begin to move more and more into this format, which I am not in favor of, but if that begins to happen we can hopefully be able to take advantage of those technologies so that we will be more closely able to simulate face-to-face interaction.

Agenda Item: Public Comment on Agenda Topics

MR. KING: Having said that I would like to open this up to the public comment that we have initially scheduled at 1:10 p.m. This public comment is solely on agenda items that are currently listed, and any new business is not to be brought forth at this time but will be brought forth in a second public comment section at the end of the day. Is there anyone who wishes to make a public comment on the agenda, on any specific agenda item?

MR. CONTI: Good afternoon, Lewis Conti. Thank you all of you-

MR. KING: Lewis, before you speak, if you could identify the agenda item that you are going to speak to and then you can proceed.

MR. CONTI: The report that Mr. Matanoski submits regarding statistics for the program, I have a question about one of the statistics.

MR. KING: State that question please.

MR. CONTI: I note that on the statistics form, in 2012, that a case from the omnibus autism proceedings was compensated. Is that correct?

MR. KING: It's just a public comment session. It's not really a question and answer session, so if you have a specific public comment please make the comment.

MR. CONTI: I guess I'm just curious-- it really is a question. I don't want to be disingenuous with you. My question is whether indeed the case was compensated for autism-like symptoms or autism encephalopathy or any of those issues?

MR. KING: Thank you very much. Are there any other public comments?

MS. WRANGHAM: I'd like to speak to the report by the Department of Justice with regard to adjudicated settlements. I appreciate the information on how long it takes to get a claim through, however, we previously requested some sort of report on the whole-- how many vaccine claims are being paid for which vaccine and for what condition. I'm just hoping that perhaps could be addressed or looked at in future presentations and preventing this particular report.

MR. KING: Thank you, Theresa. Are there any other public comments specific to an agenda item?

OPERATOR: At this time, there are no further comments.

Agenda Item: Approval of the Minutes of the September meeting.

MR. KING: Then the public comment session is closed, and we will now talk about the approval of the September 2012 minutes. Are there any corrections,

modifications, clarifications to the minutes that have been submitted to the Commissioners?

DR. READ: This is Jennifer Read. There's just a typo with one reference to 2011; it's written as 201.

MR. KING: Can you tell us where that is?

DR. READ: It's page seven, and it's the third bullet under NVPO. It just is a typo. It says "201" instead of "2011".

MR. KING: Thank you. Are there any other comments, corrections, modifications? I will make one then. On page five, the first paragraph-- or it's a continuing paragraph from page four-- seven lines down, it says "vaccine-elated injury". Most people aren't "elated". I think it's supposed to be "related". It's just a typo.

MS. WILLIAMS: Hello?

MR. KING: Michelle, welcome. The meeting is well underway, thank you. Let us continue on. Michelle just to bring you up to speed, we are in the process of reviewing the minutes of September 2012, corrections, clarifications, modifications.

MS. WILLIAMS: Was there any public comment?

MR. KING: There were two public comments that were given, and they both were related to the Department of Justice. They were really more questions than they were actual comments, and that was it.

MS. WILLIAMS: Thank you for bringing me up to speed.

MR. KING: If there is no more discussion about the minutes, then the chair will entertain a motion to accept them.

MS. PRON: This is Ann Pron. I move that we approve the minutes of September 6, 2012.

MR. SMITH: This is Jason Smith, I second.

MR. KING: All in favor? Opposed? Abstained? The ayes have it. The minutes carry.

(Whereupon, on motion duly made and seconded, the minutes of the September 6, 2012 meeting were unanimously approved.)

Agenda Item: Report from the Division of VaccineInjury Compensation, Dr. Vito Caserta, Acting Director, DVIC

The next item on the agenda is the report from the Division of Vaccine Injury Compensation, Dr. Vita Caserta. Proceed; I believe you have a presentation, correct? You'll have to guide us through on that. Why don't we give the title of the presentation just because so many came, and we want to make sure that everybody's using the one that you're supposed to give.

DR. CASERTA: Thank you, David. The first slide is the National Vaccine Injury Compensation Program, VICP, Division of Vaccine Injury Compensation Update. On the

second slide, it just kind of gives an overview of what we'll be doing this afternoon. We're going to hear from Ms. McIntosh, from the Office of the Special Masters. She's going to fill us in on the judicial conference that occurred recently. We'll hear from the work groups who have been hard at work with their agenda items. We'll get updates from the rest of the Department, from the ex officio members from FDA, CDC, NIH, and NVPO.

Next slide, the third slide — and in the future we will number these slides, sorry about that. The next of the slides goes over the workload that we've been processing and what's been happening with that workload. The first slide is the number of petitions filed by fiscal year. Our fiscal year goes from October 1 to September 30. It's very striking when one looks at this as to the increase in the number of filings. If one goes down to the present, it's clear that the rate of filing has significantly increased. I'm looking at the first column, the non-omnibus autism proceedings.

MR. KING: That would be the first quarter of 2013, the 55?

DR. CASERTA: That's as of November 13.

MR. KING: As of November 13, so I'm just trying to figure out if you're saying that they're increasing. Can it be extrapolated by multiplying that by a number that

would then tell us if it's 55 — I'm doing ballpark numbers thinking it comes to 330 or so if we were just to take that number if it maintained that kind of pace.

DR. CASERTA: I'm doing the math on the back of a napkin, and it looks to me like it comes to about 470.

MR. KING: I just figured this from October to November—oh, because it's one month.

DR. CASERTA: Well, it's actually about six weeks. The math that I did was I divided six into 52, and then I multiplied that by 55 and got 476.

MR. KING: Thank you.

DR. CASERTA: You're welcome. The bottom slide on that page shows the number of adjudications as of November 13 by fiscal year. The first line, number of petitions filed, that's the beginning of the process, but this slide is the end of the process where they're adjudicated. Again, we see the same sort of trend where over time, many more cases are going through the system and getting adjudicated than was true earlier. There was actually an increased workload for the courts and the Department of Justice for us here in DVIC.

The next slide is the categories of adjudications. The compensable cases can either be concession or court decision or settlement. A concession is where the DVIC staff reviews the case and it either clearly

ON the table or causation in fact is evident to us and we'll agree that the preponderance standard has been met. In those cases, we will concede. A court decisions is where we disagree with compensating here in DVIC, and it goes before the court. The case gets argued and the court disagrees with us and goes ahead and concedes the case. A settlement is where the parties get together and talk about the strengths and weaknesses of their case and decide on a plan to remove the case from the docket and settle the case and take care of the petitioners needs.

The non-compensable of course are cases that go through the court and the court decides that they're not compensable. They don't meet the program's preponderance standard or the table. The non-autism adjudication total is the next line. The bottom slide on that page tells us the amounts paid per fiscal year in awards as broken down by attorney's fees and the amount that goes to the petitioner. Again, we're seeing the same sort of trend where over time, because more cases are being filed, we're seeing more awards in terms of dollar amounts being paid out. Some of the attorney's fees, the increase, of course, stems from the autism proceeding. There's a definite trend with the attorney's fees also to be increasing, which again reflects workload to both the Department of Justice and the court

and us. Their fees are increasing presumably. There's more work being done that the other parties need to respond to.

The next slide is a summary of current status of the trust funds. As of September 30, because we get these numbers quarterly, the trust fund had just shy of $3.5 billion. In the last fiscal year the revenue from the taxes on vaccine was approximately $254 million. The interest on the total amount was $66 million, approximately, for a net income of almost $321 million. 21 percent of the net increase was from interest.

The significant activities, I attended the advisory committee on immunization practices meeting in Atlanta. They made two interim recommendations. One, they updated the recommendations for MMR, and the other interim recommendation -- and these haven't been published in the MMWR as far as I know, I don't think they have it — the other one was the recommendations to give DTAP to pregnant women at each pregnancy. The previous one was not for each pregnancy, but pregnant women get DTAP. Now they're recommending that it be given with each pregnancy.

MR. KING: Was there any controversy on that, or were people okay with that?

DR. CASERTA: There was a bit of discussion around the fact of hyper-immunizing people. If someone has 12 pregnancies, giving them 12 DTAPs may be a bit excessive,

especially with the tetanus component. When you get a tetanus shot and your arm gets sore, if you get a lot of tetanus shots, your arm will get sorer. There was a discussion about that, but they felt that the need to immunize folks with each pregnancy superseded that. That's why they decided to make that recommendation. Did I answer your question David?

MR. KING: You did, thank you.

DR. CASERTA: The next slide is the public points of contact with our telephone number, which is our telephone number and Internet site for information. Annie is the staff liaison for the Commission so the public can get in touch with her should they want to make public comments and participate in Commission meetings.

MR. KING: So in case people are not — we generally read out this information to people in case they don't have the slide in front of them for whatever reason. That would be so helpful.

DR. CASERTA: The telephone number is 1-800-338-2382. The website is: www.hrsa.gov/vaccinecompensation. The spelling of Annie's name is Andrea Herzog, and it's Parklawn Building, Room 11C-26, 5600 Fishers Lane, Rockville, MD 20857. Her direct phone line is 301-443-6634 and her email is aherzog@hrsa.gov. That concludes my update. Any questions?

MR. KING: There being no questions, let us move on to reports from the Department of Justice, Mr. Matanoski. I think everybody knows which one is your slide presentation, but why don't you give everyone the title of it so that they access it correctly?

Agenda Item: Report from the Department of Justice, Mr. Vince Matanoski, Acting Deputy Director, Torts Branch, DOJ

MR. MATANOSKI: Certainly. Again, this is Vince Matanoski from the Department of Justice. We apparently aren't as imaginative as the folks at HRSA are, DVIC, because we actually don't have a title on our slide presentation. We do have a very becoming or fetching logo showing the Department of Justice logo on there. The first page has the date of the conference here, the meeting of December 6, 2012.

Turning to the second page, these are some of our statistics. Just to clarify a little bit, where Dr. Caserta's talking about some statistics about cases being filed, he is clear about what timeframes he's looking at. We actually look at a little different slice in time than DVIC does. The first slide that you look at, and that's on page two, talks about the total number of petitions filed during the reporting period. It's a three-month slice here, beginning on August 16 and going onto November 15. In that period, we saw 149 cases filed. By far and away they were

all non-autism cases — by far and away the majority of those cases were adult cases, 124 of the 149. That's roughly 80 percent, I would say, of the cases being filed.

Dr. Caserta mentioned a trend that he was seeing in increasing numbers of cases being filed. We seem to be observing the same trend. It's a little early for us to tell where we're going to end up at the end of this year. One thing that I've always been curious about is after the flu vaccine was added to coverage under the Act, would there be seasonal variation in the numbers of claims filed, or in the way we received claims? We have a seasonal variation in the administration of that vaccine. It's primarily administered at this time of year, knowing that there's a certain time limit of bringing your claim, that is you've got three years to bring it.

Would these claims follow the same pattern, the flu claims coming in, follow a pattern that we would see most of the claims coming in three years after they had been administered, or in the fall time period after they were predominantly administered. So far, it's been my experience that we have not seen this kind of seasonal variation in the filing of the flu vaccine claims. If this pattern that we're seeing right now of increased claims being filed — it might continue throughout the course of this year, in which case we would be, as Dr. Caserta was

projecting, at a higher number of total cases filed from this fiscal year than we saw in the past, in the previous fiscal year. I'll keep an eye on that, and certainly report again on that in the spring meeting of the ACCV.

MR. KING: Based on Dr. Caserta and your report here, it would indicate that the trend seems to be an increased number of cases being filed. Am I reading that correctly?

MR. MATANOSKI: Yes, that's the way I'd see it, too.

MR. KING: Are we also applying a similar increase in resources to address these claims or are we creating a backlog?

MR. MATANOSKI: I think it's a little early to tell whether we're going to have a backlog. To answer your first question, we don't have additional resources. Our resources are fixed. Until there's an increase in our budget, we don't have additional resources, at least not additional financial resources. Financial resources translate into being able to hire additional personnel. They're the fuel that you need to move the process along faster when you're constrained by personnel, for example. I think it's a little early to tell whether there will be any kind of backlog. In the past I have seen variations in the pattern of filing.

For example, during the summer months filings tended to dip. For this time of the year, when there are holidays, filings tended to dip and then pick up again after those periods of time. It's hard to say with a degree of certainty that we're going to end up at a higher level. We may see that dip come and the filings peel off a little bit. I can assure the ACCV that we will with the resources we have available do our utmost to continue to process cases as quickly as possible.

MR. KING: That answers the question. I don't know if it's the answer that people want to hear, but it answers the question.

MR. MATANOSKI: My sense is this bears watching, in terms of the filing pattern. If it continued, it would strain our abilities if there were not additional resources found.

MS. WILLIAMS: Your Department, and all the divisions of the Department do a budgeting request I assume each year. You would have an opportunity if you saw an increase to request additional funds through your normal budgeting process.

MR. MATANOSKI: Yes, that's correct. That would be what our step would be. Our budget doesn't come from the Department of Justice budget. Our money does not.

MS. WILLIAMS: There is a place to which you submit a budget?

MR. MATANOSKI: That's correct.

MR. KRAUS: Can you clarify where your budget does come from then?

MR. MATANOSKI: It comes from a trust fund. Our funding comes from a trust fund, as does the DVIC and the court funding. If there are no other questions on that, I'll move onto our next slide, which is page three. This again is a statistics slide. Here we look at the total number of petitions that have been adjudicated in this time period and breaks them out a couple of different ways. The first way we've broken them out is between the compensated cases and the non-compensated cases. The total number of cases that were adjudicated during this period, the three-month slice, is 361. Out of those, 88 were compensated. The remaining 273 were not compensated. Dealing with that latter category, the non-compensated cases or dismissed cases, 50 of those were cases that did not involve claims of autism. 223 were cases that did involve claims of autism. What we're seeing there is some more of the efforts to move through the cases that have been filed in the OAP. I know we've talked about this in the past. The number would probably, if I were to project that number, get smaller and smaller as we go forward because we've moved

through a large number of cases that would have been fairly quickly resolved at the end of the OAP. We're getting to the cases that are going to take a little bit more time to resolve one way or the other.

As far as the cases that were compensated in this period, there are 88 of those. We've broken those down further by cases that were conceded by HHS and those cases that were not conceded by HHS. Four of the 88 were conceded by HHS. The remaining 84 were not. Of the remaining 84, three of those were compensated by proffer. What that means is explained in our glossary of terms. Basically, that is when there has been an agreement as to what the evidence shows regarding damages. There's a decision by the court, setting out what the damages are in the case after the parties have done a lot of fact finding, usually with experts, to determine the amount of damages and the parties potentially say to the court we agree this is the amount of damages in the case.

The remaining 81 of those cases were resolved by settlement. We've broken out those settlements in our last presentation today, which gives a list of the vaccine-involved, the injury claimed, and the time it took from filing to final resolution of the case.

There was some question in past meetings about comparison between the average time it took to process a

case that was conceded by HHS versus the average time it took to process a case that was compensated but not conceded by HHS. What we did at that meeting is we wrote that our slice of cases that we're reporting on for that particular period -- we did that again. We looked at the slice of cases we're looking at now and ran the same question. How long does it take a case that's conceded by HHS to get finally adjudicated and compensated, versus how long does it take to get a case that's not conceded, but is compensated, how long does that take to get to final resolution?

Just as we found the last time we looked at this, there really is not an appreciable difference in the amount of time it's taken to get these two classes of case to get through to compensation. They both run about two years, on average. We're only looking at a really small sample when we're talking about cases conceded by HHS. We normally have four in this period. I'm getting a little bit more comfortable by reporting this to the committee, because now we've looked at it twice, and both times there wasn't an appreciable difference. Both times, if I recall correctly, it was about two years.

We did something a little different this time. We broke out, within the cases that were not conceded, we looked at the average time for processing those that went

to damages or went to compensation via proffer, versus those that went to compensation by way of settlement. Not surprising to me, the cases that went by proffer took longer. In fact, they took on average about five years to get to compensation.

MR. KRAUS: Did you say that correctly? You said the cases that were compensated by proffer took longer than the ones not--

MR. MATANOSKI: That were compensated by settlement. I'm sorry if I wasn't clear.

MR. KING: You're saying that based upon the sample that you looked at, the time frame was significantly longer under proffer versus settlement. Is that correct?

MR. MATANOSKI: Exactly. I say it was not surprising to me, and I'll explain why. When we have a case that's going to proffer, there's usually a process that's involved in that case before it gets to that point. That case is not being conceded, so there is still a question of whether they're going to get compensation at all. It may even have gone to a trial before it got to that point. There may have been a finding by the special master--generally that is how it will get there. It will be a finding by the special master that the case is entitled to compensation.

You have this entitlement hearing and processing of the case, that proceeds even getting where you're working up -- whether the damage is involved in the case. Those cases are very resource intensive, very time intensive, and have a much more involved, intricate, and complicated procedural history before they get to the compensation part. It is a small sample size. It does tell us that, and again I felt this was pretty predictable, that those sorts of cases do take longer.

If there are no other questions on that, turning to the next slide, which is page four, we had six cases that were withdrawn during this period, voluntarily withdrawn. Four of those were non-autism, and two were autism cases. Again, as we've seen in the past, voluntary withdrawals from the program are not a very often used method of resolving the case, and not enough of the courses reside solely with the discretion of the petitioner who brought the case.

The next three pages, pages five, six, and seven, are a glossary of terms. They've appeared in past presentations. I won't go through those again, but I would entertain any questions if someone has questions about those. Similarly, pages eight and nine and ten are various wire diagrams, the one on page eight about processing and on page nine and ten, they're about the appellate process.

I won't go through those either. We've kept them-- but of course would entertain any questions-- we've kept these in because we were actually going to take them out and we had some calls for keeping them in, so we've kept them in and are happy to answer any questions about that, but I won't belabor these since we've covered these in past sessions with the Commission.

Now I want to cover some of the appellate activity. We have a case now pending before the Supreme Court, a case which we've talked about in past meetings. The respondent, or Health and Human Services, sought certiorari law that is have the Supreme Court take a look at one aspect of the court case that had to do with the awarding of attorney's fees. The Supreme Court agreed, they granted certiorari. A briefing is now underway. It looks like the case will actually be heard by the court perhaps as early as March of 2013, and then we would be getting a decision from the Supreme Court thereafter. This would mark the third time the Supreme Court has taken a look at the Vaccine Act. The first time they looked at it being Whitecotton case; the second time the Brusewitz case, and now in core with respect to attorney's fees in time-barred cases.

We had two new appeals decided at the Court of Appeals for the Federal Circuit. I can't pretend that I

know how to pronounce the first case there. I'm just going to spell that one. I'm now on page 13 of our slides. The first case is spelled Hriethe. That case was part of the OAP. It was proceeding pro se, that means that it was proceeding by the petitioner alone without assistance of counsel. The case was dismissed on May 31, 2012. There's a certain time period for seeking review of that case at the Court of Federal Claims, and the petitioner did not seek review before that tribunal.

When judgment was entered, then the petitioner sought appeal at the Federal Circuit. We've moved to dismiss the appeal because it's not proper. They have not sought a timely appeal at the Court of Federal Claims, which is required before seeking a review at the Federal Circuit. The other case, Shapiro, is a case where the special master had found that the petitioner had not offered sufficient evidence to back up their causation theory, and the case was dismissed. The petitioner there appealed to the Court of Federal Claims from the special master, essentially characterizing the appeal as one where they were attempting to re-argue their case. Now that appeal has been sought at the Federal Circuit.

We saw during this period, turning to page 15, six new appeals filed at the Court of Federal Claims. Five of those appeals are really about factual matters, expert

testimony, and matters involving the evidence in the case, and whether that was sufficient to establish entitlement to compensation. All of those appeals, all six, were brought by the petitioner. One of the six -- I've talked about the five there that are really fact based -- one of the six involves a mixed question, if you will, of fact and law. I would say it's more about law than fact, and that one is the Wax case.

That case is a statute of limitations case. There was a finding that the case was time barred. It was brought in the program five years too late. The petitioner sought relief through equitable tolling. We've talked a little bit about equitable tolling in past meetings. Equitable toll is now available through the court case, the court en banc decision. The claim for equitable tolling in the Wax case was essentially that the petitioner believed that by Marisol in vaccines, which they were claiming was responsible for the injury in that case, was an adulterate. Therefore they could not bring a case under the Vaccine Act, because the Vaccine Act does not permit cases that involve claims of adulterated vaccines.

They did file a civil action. The civil action was dismissed because it was found to be properly brought, that their claim that Primarisol was an adulterant was not found to be legally sound. The court said that that in fact

they would have had to have gone to the vaccine program to file that claim because this was a claim that probably should have been before the vaccine program.

The special master found that the petitioner was not entitled to equitable tolling relief as a matter of law that claims of confusion or mistake regarding court jurisdiction are not matters that are amenable to remedy through equitable tolling. Again, the other five cases basically are turning on evidence, where special masters have found that the evidence has not been sufficient to make a finding in favor of petitioners, and that decision is now under review.

Finally, turning to page 17, this is going to cover essentially pages 17-25, this is our list of cases of adjudicated settlements against the same three-month slice of time. There are 81, as I reported earlier, 81 cases that were resolved via settlement. Here I've taken the opportunity to drill down a little bit. You have a lot of information on those pages, I guess about eight pages of material there. I'll just summarize a little bit, or give you a snapshot of what this translates into in certain categories, which I think are probably of interest to the Commission.

I took a look at how long it's been taking to process these cases. You can see there that we lift the

time of petition following to settlement following and broken them out into five different categories: settlements that were achieved in less than a year, settlements achieved in less than two years, settlements achieved in less than three, in less than four, and then in greater than four years. There were 16 settlements that were achieved in less than a year, but an additional 30 in less than two years, an additional 25 in less than three years, then we see kind of a tailing off quite a bit.

After that, less than four years, seven more cases, and then the greater than four years settlement were only three cases. That total brings us to 81. What that means, let me try to give you some percentages. About 20 percent of those cases that were settled were done in less than a year. 57 percent of cases that were settled in this period were done in less than two years. By the time we get to less than three years, 88 percent of the cases that settled have settled. What we're seeing by far and away, if cases are going to settle, they're going to do so. We're going to get them done within three years. After that, you've actually captured most of the cases you're going to settle.

I also wanted to take a look at what kind of vaccines are involved in these kinds of cases, and the predominant vaccine has been influenza. 62 percent of the

cases that were settled were flu vaccine alone cases. The predominant injury that's been involved in those cases has been Guillaume Barré syndrome. This is holding-- looking back at what we've reported in the past meetings before the Commission, this has been the same pattern that we've seen, that most of the cases that are coming in now, or at least that are settling, are flu cases. If there were one particular injury that were involved in those cases, it's been Guillaume Barré syndrome.

I know we had during the public comment period two questions that came in for the Department of Justice. Really, I guess this should have been at the end of the period as the chair pointed out during the question period, but I will entertain them now if it's all right with the chair, and attempt to answer them.

MR. KING: The chair is fine with that.

MR. MATANOSKI: The first question asked about a slide that reported on a case that involves autism uncompensated. That actually was not reported by the Department of Justice. I can't really speak to that first question. I guess I just said I'm going to answer questions, but I can't answer one of them. The second question was about the adjudicated settlements. That is within the slides that I'm presenting on. The question as I

recall was can we see the amount that is involved in these settlements.

Taking a step back from the question, when we put together this information for the Commission, there's a tension that we have. When we look at case-specific information, there's a statutory protection for information submitted within a case, but it can't be divulged without the permission of the individual involved. When we deal with aggregate information, that's fairly easy. There isn't much tension there with that statutory provision protecting information. The more we drill down into case-specific information, the greater the tension that we run up against with that statutory provision.

We are comfortable with reporting publicly the information that you see in pages 17-25. It's some information that's case-specific, but it's generic enough that it would be hard to tie it to a specific petitioner that's come in. The more information that we provide and the more specific information, the greater the tension that-- we're actually now reporting a little too much on case specifics that a petitioner involved might actually prefer not to have reported, if you will. We've stayed away from getting anymore specific than we have presented to you so far. We believe that this information that we do present to you is helpful to you to see some of your areas of

concern, which are what kind of vaccines are involved, what kind of injuries are involved, and how quickly these cases are processed. That's perhaps a long-winded answer, but I thought it important to give you some background into what you see there and our thoughts process behind how we put this together and what we report to you.

MS. WILLIAMS: Just to-- you may not be able to answer this question because a lot of times attorney's don't know right off the bat, but you said a statutory protection you happen to know off the top of your head, the citations, because somebody's going to ask for it I suspect.

MR. MATANOSKI: Certainly, I do. It's 42, United States Code Section 300AA-12(D)(4). The site would be 42 USC Section 300AA-12(D)(4).

MS. WILLIAMS: Thank you.

MS. PRON: I apologize if you mentioned this already, but the case of the Guillain-Barré syndrome and the flu for adults?

MR. MATANOSKI: We don't report on whether they're adults or children, but I can give you my general sense. It is by far and away predominantly adult cases we're talking about.

MS. PRON: Thank you.

DR. VILLAREAL: On page 18, you're lifting DTAP and Prevnar, and what I try to tell folks is not to use the proprietary name. Should it be pneumococcal or truly Prevnar?

MR. MATANOSKI: I don't know. What we do is we take our abstract or abstract the material from the petition, and so that would have been what was alleged in the petition. What we'll do though, I understand your concern, and what we'll do is we'll try to, when we see a trade name, we'll try to figure out the vaccine that's involved and not use a trade name.

DR. VILLAREAL: Like on page 20, you have Pentasol, hepatitis B, and Prednar, with the last injury of gastroenteritis.

MR. MATANOSKI: What we'll do-- again, we're taking that from what was in the petition, but what we'll do is we'll try to go through that before the next time we do this and make sure we give you a generic name.

DR. VILLAREAL: Thank you.

MR. MATANOSKI: Certainly. Are there any other questions?

MR. KING: I'm looking at slide 11 where you have the core going in front of the Supreme Court. I understand that the question is whether a person is petitioned under the National Vaccine Injury Compensation program is

dismissed as untimely, if they can recover and award of attorney's fees and cost. There's one philosophical question involved in that, which is do they know it was untimely when they first started or was there a question about whether or not that was the case? It looks to me like the Federal Circuit said the attorney's fees should have been awarded, is that correct?

MR. MATANOSKI: Yes, it was the 7-6 en banc decision.

MR. KING: That's what I thought. So when they said that it should be awarded-- so from our perspective, we're wondering if the concern is that would a decision going against the award of attorney's fees and costs frighten attorneys from taking on cases where there is some ambiguity or grayness to it, which may in fact harm those in the sense that the cases wouldn't be brought or compensation wouldn't be requested because attorneys would do even more of a filtering process out of fear that we could spend years on this baby and not get paid. What are your thoughts on it? Since the case was lost and then was appealed, what was the thinking there? Was it more strictly of law or was it the spirit of what we're trying to do here?

MR. MATANOSKI: It was the decisional process, or the way we were looking at this was from a legal

standpoint. Section 16 says no petition may be filed for a case where the time period is greater than 36 months between the time of the injury and the time the claim is filed. That language "you can't file a petition" means that the case essentially shouldn't be in the Vaccine Act at all. There's no authority. The doors to the vaccine program are closed, if you will. You can't even file a claim. Therefore, all the other things that follow, which require that a petition be filed, can't happen. You can't get compensation for your injury because you haven't filed a petition. You can't get compensation for attorney's fees because a petition hasn't been filed.

Congress used specific words and phrased it a certain way which meant that access to the program is foreclosed. That may make an individual think twice or an attorney think twice about bringing a case unless they feel pretty strongly that the case is timely. The attorneys, of course, have-- they can review those cases before they bring them. They can enter into whatever kind of agreements they want. I won't pretend to speak much to that practice, because I practice with the government and not with clients.

I can see where if you believe that you may have trouble getting paid, you may screen cases very carefully before you decide to take it. I think that would be not

unrealistic to think is going to happen. Our review of it or analysis is on the statute itself and the words that Congress used. The words that Congress used in our view were pretty plain and pretty clear. I believe that at least six of the 13 judges at the Federal Circuit felt the same way. We'll see what the Supreme Court thinks about it.

MR. KING: The only concern we have is that if the spirit of what we're trying to do doesn't get jeopardized when we pursue-- I think that there are times when there are probably gray areas and that people there thought things were timely but then other decisions that occurred made it appear that it was no longer timely. I guess looking at-- in the spirit of the law, there was always the idea that we're trying to better things for human beings I would think. Who really loses here?

MR. MATANOSKI: Just to follow up on that comment, and I certainly understand the thought behind it, we've encountered places or parts of the law in the past where we would wish it would read something a little different, I suppose. For example, on guardianship fees, guardianship costs we-- and the Commissioner has taken the position we've looked at trying to see a way to get guardianship costs paid. Looking at the statute as written, there's a view that they're not permissible.

The fix, it seems to me, when the statute reads one way and we want a different result is to go back and try to get the statute changed. I know that there has been support for changing the time limit for the statute from three years to extending it a little bit. Whenever you draw any kind of line, whether it's three years, four years, or five years, there are some folks who sit on one side of it and some folks who don't. You're going to include some, and you're not going to include everybody. Where do you draw that line?

The important thing that we've found at least in processing cases is that that line needs to be clear. The gray area can be resource-intensive to try those kinds of cases out to the end. There are those sorts of considerations that come into play as well. This is more of a philosophical discussion that we've been having. We went back, and in the court case our focus has been on the statute itself because we don't feel that we're free to-- we know we're not free to operate outside the four corners of the law that are given to us and only Congress has the authority to change how that comes out.

MR. KING: Thanks, Vince, I appreciate that. That begs the question, which is not related specifically to this, but rather the process workgroup I know is working on a number of different types of issues and recommending

changes and in the past there have been changes that have been recommended. If your Department were to agree that those changes-- would you be willing to co-recommend or put letters of recommendation in on some of those changes as well that are recommended from the Commission?

MR. MATANOSKI: The process of determining what the Department recommends-- as the old saying goes: it's beyond my pay grade. There's a process that involves taking recommendations and figuring out what the Department's position would be on that. My own sort of take is that whatever we have it needs to be clear. If you create gray areas, if you're working in the gray areas, then it tends to drag down the resources so that you're spending a lot of resources on a couple of cases to the detriment of the vast majority of the other cases. Resources are limited. Certainly the court, the respondents, HHS, even petitioner's counsel, I'm sure, feel this. I've talked about tension previously in another context; there's tension there as well.

MR. KRAUS: The petitioner's counsel who represent Cloer-- I'm not necessarily speaking on behalf of them, but I can say that in general the position of attorneys who are representing vaccine-injured individuals is exactly what you articulated, Dave. It's really difficult to get involved in a case where there is a question about whether

or not the case has been brought within the statutory time period of 36 months. In many cases, the only way you can determine if a case is timely is if you get involved, spend a lot of time requesting medical records, sometimes even involving experts, going back through the medical records, and only then might you discover a comment in the medical records, which the Department of Justice will then argue is the trigger for the statute of limitations.

If they're successful in that argument after you've briefed it and perhaps employed an expert to try to argue that the documentation doesn't reflect the onset of the beginning of a manifestation of a vaccine injury, if you lose, you've spent a lot of time and money as a petitioner or petitioner's counsel that you then have no ability to get compensated for if the Cloer decision is overturned by the Supreme Court. I would respectfully point out that the decision to appeal the Cloer decision to the Supreme Court is a decision that-- I don't know exactly who is vested with that decision, but I think it's unfortunate.

I think the case, for the reasons that you've just pointed out, Dave, that what we want the program to do is to be able to attract attorneys to take even the cases that are kind of tough on timeliness. If Cloer is overturned, you will absolutely create a situation where there's a strong disincentive for any attorney who needs to

be paid for his work and also reimbursed for the costs that are involved in representing these clients, assuming that your clients don't have any money and you're fronting costs. I understand, certainly, and am not in any way pointing a finger at Vince, but I think the consequences of the Cloer decision being overturned by the Supreme Court would be a real negative for the program.

One other thing, if the attorney brings a case that's untimely and that's obviously untimely, even if the Cloer decision wasn't overturned, the Department of Justice could very capably argue that attorney's fees shouldn't be awarded because there wasn't a reasonable basis to bring that case. It's not as though attorneys who are trying to get compensated for cases-- trying to get attorney's fees for cases that they've spent a lot of time, effort, and money that subsequently turn out to be untimely -- these are not cases that are obviously untimely and attorneys should have known better. That's all I have to say, thanks.

MR. MATANOSKI: I guess this is still open for anymore questions to me, but if I may, I'd just follow up a little bit. Thinking about this a little bit more, I want to make sure that there wasn't confusion. Cloer, the 7-6 decision in Cloer, permitting attorney's fees in time barred cases represented a departure from the existing case law. Up to that point, the accepted understanding of the

Vaccine Act was that if a case was untimely, then the attorneys were not eligible for Vaccine Act compensation. Cloer does not represent the continuation of existing case law. It represented a change in the way case law was interpreted or the Act was interpreted. The decision to seek certiorari from the Supreme Court is essentially to -- it's posited a statute. But if the Supreme Court were to overturn the majority opinion in Cloer, it would be a return to the Vaccine Act as it had previously been interpreted as opposed to a departure from a pervious interpretation of the Act. I invite any other questions.

DR. SHIMABUKURO: Returning to that adjudicated settlements line listing and how you described the vaccines, would it be a pretty easy thing to do to split out the influenza into either live or inactivated? I think inactivated you can lump as a category even though there's multiple vaccines.

MR. MATANOSKI: We can take a look and see. It may be a little difficult to do based on the way we are getting our information for these. If it's possible, we will, but I think it might be a little difficult to do. I can understand why you'd be interested in seeing whether there's more associated with a live vaccine versus the injected vaccine. I can give you a sense that of the cases I see, most of the ones that have come in are with older

adults-- they would have been beyond age 50, so they're likely receiving the inactivated vaccine.

DR. SHIMABUKURO: I would suspect they're almost all TIV. It's not really critical. It would just be interesting to see how many are live because I would suspect almost all of these are TIV. Thanks.

MR. KING: Any other questions for Vince? That being said, Vince, thank you very much. The next on the agenda, the report on the 2012 judicial conference, Ms. Jocelyn McIntosh, and I believe you have the chief special master with you as well.

Agenda Item: Report from the 2012 Judicial Conference, Ms. Jocelyn McIntosh, Office of the Chief Special Master

MS. MCINTOSH: I do, and the chief special master will be addressing the Commission.

MR. KING: Wonderful.

MS. CAMPBELL-SMITH: Good afternoon. This is Patricia Campbell-Smith. I'm pleased to address the ACCV on a highly successful 25th Judicial Conference, which took place on November 15 at the National Courts Building. Three vaccine sessions were held. The first session involved a discussion of the proposed vaccine table amendments that grew out of the recent IOM report on vaccines. Ms. Andrea Davies from the HHS Office of General Counsel spoke. The

session included an abbreviated version of what had been presented to the ACCV at the March 2012 meeting and gave a projected course for what it takes to get to an actual table amendment.

The second session involved an update from the Office of Special Masters, a number of practice points of interest to practitioners and the announcement that we are anticipating the appointment of two new Special Masters this month. Of further note and of interest perhaps to the broader community is a reorganization of the court's website, and in particular, a re-delineation of the categories of decision to reflect-- right now, we have a distinction of published, unpublished, but we anticipate being able to more descriptively segregated those opinions so that we would have summary dismissal decisions, which would probably bear the weight of a number of the dismissed autism decisions.

Decisions on stipulations and proffers, which is of value to practitioners and pro se petitioners as well who are trying to get some sense of what cases might have settled for in the past. Then in a category that speaks to substantive decisions and orders, which often reflect those matters that were contested, went to hearing, and resulted in the issuance of decisions.

Finally, we held a session discussing the Office of Special Masters proposed revisions to the guidelines to vaccine program practice, which is intended to be a tool to flesh out expectations of what actual practice in the vaccine program is like and what the range of expectations would be in terms of moving a case forward through the program. The proposed revisions can be found on the court's website. The Office is currently accepting comments and edits from the parties until the end of the year with the expectation that the guidelines would be finalized in January and published in February.

As a concluding note, I point out that all three of these vaccine sessions were digitally recorded, and the audio can now be accessed on the court's website. I'm happy to provide that website address, which is: www.uscsc.uscourts.gov. There is a link provided at that address under the announcement session on the homepage that would connect an interested person right into the digital recording. Thank you kindly.

MR. KING: Thank you. Does anyone have any questions? Dave King has a question, and that is, and I don't know if you have this information, but at our last meeting we had talked about the fact that there were departing Special Masters and we were looking to get an

understanding on what the process and timeline was for the replacement of those departing special masters.

MS. CAMPBELL-SMITH: Well, my words reference to we're expecting the appointment which would mean that the process has taken place and the judges will vote, which is how special masters come to be, it's by a vote of the sitting judges at the Court of Federal Claims. We are expecting that appointment process to take place this month.

MR. KING: So then they'll be replaced by the beginning of the year with a little luck.

MS. CAMPBELL-SMITH: That all turns on — they would be appointed, which means that they have actually effectively—they have the appointment. The lag time for when they show up is a function of the candidates winding down their current obligations and presenting themselves to the court to come serve. I certainly think that as an expectation we could actually see some show up after the beginning of the year would be reasonable.

MR. KING: Thank you.

MS. CAMPBELL-SMITH: Certainly. Are there any further questions? Thank you kindly.

MR. KING: Thank you so very much. We appreciate that you took the time to come. The next on the agenda is

the report from the maternal immunization workgroup, Dr. Kristen Feemster.

Agenda Item: Report from the Maternal Immunization Workgroup, Dr. Kristen Feemster, ACCV Member

DR. FEEMSTER: Thank you for this opportunity to provide an update regarding the activities of the Maternal Immunization Working Group. Just to quickly summarize, the workgroup convened to consider both current recommendations to immunize pregnant women against influenza, pertussis, and tetanus, as well as potential future recommendations for vaccines that are currently under development, an RSV vaccine and a Group B streptococcus vaccine, for example. In light of these recommendations, our goal is to review the current safety assessment and monitoring infrastructure to make sure that the vaccine injury compensation program is able to offer appropriate support among vaccines that are administered during pregnancy.

At the time of our last meeting, we presented our newly adopted charge and since that time have really been working to fulfill that charge, of which for review, our charge is as follows. The first point is to provide information to the ACCV regarding the eligibility for compensation by the program with respect to vaccines that are currently not covered by the program, so that refers to vaccines currently under development that may be

recommended exclusively for pregnant women and to identify the pros and cons of covering these vaccines and then to draft a recommendation based upon this discussion.

The second point is to consider compensability of injuries related to covered vaccines. This would be injuries sustained by a live-born infant from covered vaccines received by the mother while the infant was in utero. The third point is to provide information to the ACCV regarding current safety monitoring infrastructure of vaccines administered to pregnant women. A fourth topic that we also discuss was to review the ACCV charter membership guidelines and to potentially make recommendations to reflect changes in the VICP related to coverage of vaccines administered during pregnancy.

Since that time our work has primarily focused upon the fulfillment of our charge. As such, we have had two teleconferences in which we spent time discussing the pros and cons for the compensability for injuries from vaccines that are not currently covered and also that are currently covered by the program. We've also continued to gather information to further inform our discussions. This has included a presentation regarding a rotavirus vaccine that would be recommended exclusively for pregnant women, as well as the review of safety data regarding inactivated vaccines administered during pregnancy that was put

together by medical officers from the CDC. This presentation took place this morning. Later this month or in January, we'll have a presentation regarding Group B streptococcus vaccines that's also currently under development.

We've also reviewed the current safety-monitoring infrastructure and learned about efforts from the NVAC maternal immunization working group to ensure that our work complements other efforts that are currently underway. Lastly, since our last report we also welcomed a new member, Richard Beigi, who is an obstetrician gynecologist at the University of Pittsburgh and also co-chairs the NVAC maternal immunization working group, so he will provide important perspective and insight to our discussion.

Moving forward after our group B strep presentation, we will synthesize information from our multiple discussions as well as the safety information compiled by working group members and through presentations so we can develop recommendations to hopefully present at the March meeting. I really would like to thank everyone on the workgroup for sharing time, insight, and expertise, and I'm happy to answer any questions, or happy to have anyone from the workgroup throw in anything that I left out.

MR. KING: Actually, I don't know if we were doing that.

DR. FEEMSTER: I just meant from the other working group members who are here as part of the meeting.

MR. KING: As it appears that there are no questions and no one wants to add any comments to what you said, well done, thank you. The next work group report is from the process workgroup, Luisita dela Rosa.

MS. DELAROSA: Hi, can you hear me?

MR. KING: We can hear you, but you might be coming in with some distortion though. Does anyone else hear that distortion? Luisita?

MS. WILLIAMS: Are you on a landline or telephone?

MS. DELAROSA: I am on Skype.

MS. WILLIAMS: All right, I think we're all just going to have to bear with it, thank you.

MS. DELAROSA: I couldn't be heard on the landline earlier. That's why I went on Skype. I could hear you guys, but you couldn't hear me.

MR. KRAUS: Can I suggest that we take our break now and that Luisita tries to call in because I'm having a hard time hearing her?

MR. KING: I think that's a reasonable thing for us to do, to take the 15 minute break, we'll make it 17 minutes, and everybody comes back at ten minutes of three, and Luisita by then hopefully we'll have a better

connection going for you. Everyone is okay with that. We'll reconvene at ten minutes of three, Eastern Standard Time.

(Break)

MR. KING: Do we have everybody back on the line? Let's go around the room again just so that we know we have everyone. We have everyone but Sylvia it appears.

Agenda Item: Report from the Process Workgroup, Ms. Luisita dela Rosa, ACCV Member

MS. DELAROSA: This is the report from the process workgroup. We've had six meetings since its formation in June 2012, the last one this morning. The group decided to take a historical approach and did all our deliberations using the two documents, the ACCV summary of recommendations to the Secretary from May 2009 and the ACCV summary of 1998 legislative proposal. Links to both of these documents and the Secretary's responses are on the program website.

At the September 6 meeting, we had DHA representatives and OGC. The discussion helped to classify this recommendation and to the following group. The first group are the recommendations which would definitely require statutory changes in order to be useful. The recommendations in this group are one, the extension of the statute of limitations for injury and death claims, and the recommendation to increase benefit caps for death, pain,

and suffering. These recommendations are logged(?) by repetition or compensation. We changed the ACCV quarterly meeting requirements to three times per year.

The second group is recommendations that may be resolved by decision of law, and I group them into two, the second group being the litigations that were issues that were generated during the autism cases. These recommendations are first qualified that a petitioner who establishes a vaccine-related injury and death is entitled to both death and injury benefits. The second one is allowing the compensation for family counseling expenses, and expenses for establishing and maintaining guardianships, conservatorships, or trusts.

The third in this group is allowing payment of interim fees and costs to petitioner's attorneys. The next one is modification of procedures for paying fees and costs solely to petitioner's attorneys.

The recommendations that came out of the autism cases is all the qualifications for the definition of manufacturer, verify definition of vaccine-related injury or death, and to add the definition of "vaccine".

Into this classification we also added to allow the petitioners to pursue the design defect claims against the vaccine companies based on VICP adjudications of the Brusewitz decision.

The third classification would be recommendations that can be acted on through internal action of the Secretary. Under this there is only one, the appointment of a person who had received a vaccine injury as an adult or representative of the Commissioner to the ACCV.

After much deliberations and lengthy discussions, the group has made so far the following conclusions where we have all agreed already. First, the issue of modifying procedures for paying fees and costs to petitioners' attorneys may be resolved by some form of release or agreement between attorney and petitioner at the outset of the relationship. Apparently some attorneys already do this in practice, and it may be good information to disseminate to other petitioners' attorneys. That particular issue may be resolved without having to go through any kind of recommendation or any statute change.

The second that was agreed upon by the group was to remove from the discussion the recommendation to reduce the frequency of the ACCV meetings because this particular recommendation does not have any significant impact on process.

The other conclusion that we had all agreed upon is that the recommendation to consider a person who's an adult when he or she received a vaccine injury — we will send a recommendation for the Secretary to consider. This

person has the third general public membership, and this particular appointment will meet the requirements without prejudicing a balance of viewpoints for the Commission. The group this morning has decided to formulate this particular recommendation, which will then be presented later in the meeting. If there are any questions, I will try to answer as best I can.

MR. KING: Luisita, I don't know if there are any questions for you at this time or comments, so you may want to proceed with the process workgroup's recommendation.

MS. DELAROSA: Okay, I would like to present to the Commission for consideration or voting the following recommendation of the process workgroup. It reads as drafted by Ed Kraus and Elizabeth Saindon.

The statement is as follows: The ACCV recommends that the Secretary consider the appointment of a person who was vaccine-injured as an adult or his representative or family member, or a representative or family member of such a vaccine-injured adult as the ACCV member representing the general public.

I would like to ask the Commission to consider this statement.

MR. KRAUS: I'll speak to it. I'm on the process workgroup and we talked about the fact that we've been hearing repeatedly that the program has shifted quite a bit

since its inception in 1986, towards a program that involved adults who were injured by vaccines. We discussed the fact that it would make sense to have direct input from a vaccine-injured adult or the representative of a vaccine-injured adult, on the ACCV and that since this was something that could be accomplished without legislative change, we talked about — and I'll agree that it would make sense for us just to make this recommendation now, separate and apart from other recommendations that we anticipate making in the future, because the timeline for soliciting ACCV members for the next term is to begin sometime in January.

We thought it would be appropriate or necessary to bring it to the ACCV today, and we recognize — we want discussion. We want everybody on the ACCV to have an opportunity to discuss and weigh in on it, but it is something that the reason that we brought it today was for it to be timely for next year. I guess by way of process, I would move that we accept the recommendation from the process workgroup concerning the appointment of an adult who was vaccine-injured.

MR. KING: So then we would be looking for a second on that motion.

MS. PRON: I'll second that.

MR. KING: Now it is open for discussion with everyone on the Commission.

MS. WILLIAMS: I guess Luisita is going to answer questions. Would this recommendation mean that they Commission would be increased by one or would one category be dropped off?

DR. DOUGLAS: I currently represent the general public.

MS. DELAROSA: And your term is not up until 2014, isn't it?

DR. DOUGLAS: Yes.

MS. DELAROSA: Yes, actually, this particular membership then will have to be for that year, but then I believe according to Ann this morning, usually the search begins at least six months prior to the change happening.

MR. KING: The answer to your question Michelle, it is not going to add an additional Commission member. It would only —

MS. DELAROSA: We cannot change the number of Commissioners because that is decreed by law to be just nine. The general public membership is made up of three persons, two being parents or legal representatives of children who had vaccine injuries as children, and there is a third membership of the general public. This is not

defined clearly in the statute. For this particular Commission, Charlene is that representative.

MS. WILLIAMS: So it's usually been a healthcare worker?

MS. PRON: It's been a public health representative, I believe, the last few times. I'm not sure if it was always, but it seems like it has been recently.

MS. DELAROSA: Since there are already there public health professionals on the Commission and there is this particular recommendation that is asking for the inclusion of a person who was vaccine-injured as an adult, that it would be easiest without requiring any statutory change to include this person to suggest to the Secretary to consider such a person as a possible candidate for the general public slot.

MS. HERZOG: Prior to Charlene being selected, our last member of the general public, Magdalena Castro-Lewis, she wasn't a health professional. She was the director for the National Hispanic Alliance for Healthcare, but she was not a healthcare professional. That seat hasn't always been filled by a health professional.

MR. KING: So the non-members on the Commission, if you break it down to three categories, three in category A, must be health professionals. You'll always have health professionals on the Commission.

MS. DELAROSA: Two of them being physicians. And then the general public, two of them have to be parents or legal representatives of vaccine-injured children when they were still children, and the third being open to general public membership. Because of the recommendation that a person who was vaccine-injured as an adult be included in the Commission, this is one way of getting that person included because the original recommendation actually is suggesting that one of the parents be replaced by this particular person, but this requires a statutory change. This may be a way of getting that kind of representation by suggesting that the Secretary consider a person who was vaccine-injured as an adult.

MS. WILLIAMS: If I understand correctly, then would all three of the public be parents or related to vaccine injury?

MS. DELAROSA: Yes. Again, this is still a suggestion for the Secretary to consider that person that's an adult as a possible member. Finding a particular membership, again, I think is quite a bit of work, finding the right people. The process workgroup is asking for or suggesting a particular category to be considered.

MR. KING: There's no binding on the Secretary. It's more that we recommend that you consider this appointment, but there may be other reasons why the

Secretary would choose to do something else. We're saying, hey, here's a thought, consider this.

DR. FEEMSTER: I agree that it's important to consider potentially making some recommendations regarding ACCV membership and to reflect the evolution of the program, but I think we also would need to consider the importance of having one of the general public representatives be somebody who hasn't been related to vaccine injury, a representative of the general public who-- I know it doesn't say that specifically in the statute, but it seems that that's also an important perspective to have. I understand that it seems like there are limitations on the number of people. I guess that's the question that we really need to think about.

MR. KING: That's a good one to put on the table. The statute, it is a function of how one interprets it, that at least two shall be legal representatives of children, which means that it could be three, meaning at least two could be three, so you could actually have three representatives of children who were injured by vaccine. That hasn't seemed to be the way it's traditionally done, but the recommendation here is to have that other person be a person who is a representative or who was actually injured by the vaccine as an adult to be on it for that specific perspective.

DR. FEEMSTER: Replacing a representative of the general public who would not be impacted by vaccine injury, either the parents or legal representative of the child, or having been injured themselves as an adult.

MR. KING: That is correct. Of course, being there is the requirement that you couldn't have three people injured from vaccines already.

DR. FEEMSTER: I see what you're saying. It would just take away the possibility of having a representative from the general public who is not-- someone who's been vaccine-injured or a representative of someone who's been injured.

MS. PRON: One thing is that you're always going to have – members on the Commission are always going to have some perspective and some bias based on whatever they do in their professional or personal lives. It's very hard to find the common, general public person.

DR. FEEMSTER: That's a good point as well. That's why I said think about the role that that position plays on the Commission. That's a good point.

MR. KING: I think, Kristen, you raise a good point, because you're trying to keep us with some perspective. I would think something for us to think about is that we have the non-Commission members, as Ann has said, that everybody comes from a different perspective

already, but the Secretary's not going to be bound by the recommendation. All the recommendation is saying is that, Secretary you should consider the appointment of a person who was vaccine-injured as an adult or a representative family member of such a vaccine-injured adult. I am certain that it is hard to find people to get on the Commission, or maybe it's not hard. Actually, we'd probably have to defer that to Vito and Annie in that area.

It might not be easy to find an individual who was actually injured as an adult who wants to serve, who was willing to serve, who is able to serve, and we don't know that the representative of family member would be either. It's just that since the dominant number of cases that are currently in process seem to be about adult vaccinations rather than the children vaccinations, it may still make sense to make a recommendation from a statutory point of view, but in the meantime, in order to do something rather than just let this lay fallow is to actually make a recommendation and bring it to the Secretary that says this is something you could do to get input from that segment.

MS. WILLIAMS: Could I offer a minor change to the amendment, or do we have to vote on this wording before we go?

MR. KING: Technically, we should vote on this wording first, but I think we're going to use chairman's prerogative here and allow you to chat regarding what it is you want to do.

MS. WILLIAMS: I guess it doesn't have to be in the wording of the recommendation. It could be in a supplemental explanation of a recommendation like we did for our last recommendation where there was a recommendation and background, but perhaps some background to go with the recommendation as to the shift from children to adult would certainly be helpful. I'm sure the Secretary is aware of that, but it certainly would be helpful to explain why we want to make such a recommendation.

MR. KING: Does anyone want to speak to Michele's comment?

MR. KRAUS: I think that that's exactly the spirit with which we would want to make the recommendation. We were just proposing -- that's the substance of the recommendation we just read, but I would agree that in communicating the recommendation to the Secretary we should provide some justification or background along the lines that you suggest, that Michele suggests. That's just what we talked about on the workgroup.

DR. CASERTA: That would be the standard approach to provide the rationale behind the recommendation and make that rationale as convincing as possible for the Secretary.

MS. DELAROSA: May I suggest that Ed write those explanations that you just mentioned when you gave the support for the recommendation because you gave it earlier.

MR. KING: May I respond before you, Ed? I think that in the workgroup the idea was that this is the essence of what we wanted to do, but that we thought that Vito, Elizabeth, and people like that would, knowing what the typical process is for putting the justification in first, would actually have the verbiage and the data readily available to be able to do that. Vito, am I overstepping when I say that?

DR. CASERTA: No, sir, you're not.

MR. KRAUS: I agree with your proposal, not to get out of work. I'd be happy to look at it, but I would defer and trust Vito et al to know the best way to package it.

DR. CASERTA: Considering this is the Commission's advice to the Secretary, it probably would be best if the program did not write the justification. It really should come from you. We can certainly help you with data and statistics and answering questions you may have as you're putting it together, but it really should come from you. That's the way it's been done in the past.

MS. DELAROSA: Ed, you just gave a very good justification earlier.

MR. KRAUS: I'm happy to draft up what we talked about and what I said. I guess I misunderstood you, Vito. I thought you were saying that you would help. I can shoot you an email or give a paragraph with the justification that we discussed as a working group as to why this makes sense, and I would appreciate feedback from your office as to whether you think it's consistent with the sort of support, rationale for previous recommendations.

DR. CASERTA: Absolutely.

DR. VILLAREAL: If I look at the charter, and it's an advisory commission on childhood vaccines, and again, pediatricians are really concrete, and the elephant is it's childhood vaccines, so do we have to split it so that-- I'm not saying let's do more bureaucracy, but the focus should be on childhood vaccines and injuries to children, however you define that, age 18, age 21. Then we'd have to look at what defines an adult vaccine injury, and again age, pregnancy, whatever. Are we outstepping the boundary of the Advisory Commission by then saying also 80 percent of the DOJ's case load are adult-related? Does that make sense?

DR. CASERTA: I don't think the Commission would be.

MR. KING: You don't think the Commission would be what?

DR. CASERTA: Outstepping its bounds to speak to adult usage of childhood vaccines.

DR. VILLAREAL: Are you defining influenza as a childhood vaccine, or are you defining vaccines that are given in childhood and adulthood?

DR. CASERTA: In order for a vaccine to be covered by the program, it needs to be recommended for routine use in children by CDC, regardless of whether or not the vaccine is given to adults. A vaccine that's recommended for routine use in children when it's given to adults is covered. That's how we've interpreted from day one the statute in the program. So if that is how it gets defined because that's how it gets on the table, and that's how it gets covered.

MS. PRON: We did have a little bit of a discussion in our workgroup about how the Act really allows for life changes, which means that there are many more adults getting immunizations than used to, and many of them are ones that are often given to children, and therefore they are covered by the program.

DR. VILLAREAL: Thanks for the clarification.

MS. DELAROSA: Is the voting going to take place now, Dave?

MR. KING: Voting could, but I want to make sure that everyone who has thought about this has given their thought on this. Is there anyone that wants to speak to this recommendation? Okay, well, if not, then I could call the question to a vote. In order to call the question for a vote, we're actually going to go around the table and vote yay or nay, because I see no other way of doing this. We can't do "ayes" or "nays" because we don't have that in this set-up.

PARTICIPANT: You could read the names, and they could reply.

MR. KING: That's what we could do. If you'd like, as the chair, I could just read everybody's name off and you can just say "yea" or "nay". Does that make sense? Why don't we go through that process, and I will start with Ann Pron.

MS. PRON: Yes.

MR. KING: Thank you. Jason Smith?

MR. SMITH: Yes.

MR. KING: Sylvia Fernandez [Villareal]?

DR. VILLAREAL: Yes.

MR. KING: Luisita dela Rosa?

MS. DELAROSA: Yes.

MR. KING: Michelle Williams?

MS. WILLIAMS: Yes.

MR. KING: Kristen Feemster?

DR. FEEMSTER: Yes.

MR. KING: Charlene Douglas?

DR. DOUGLAS: Yes.

MR. KING: Edward Kraus?

MR. KRAUS: Yes.

MR. KING: And I would vote yes, too. It's unanimous.

PARTICIPANT: I don't think you have to.

MR. KING: I don't think I technically have to vote. I just said I would have voted yes, rather than say I did vote yes. All right, then it has it. We'll get the process rolling to get this recommendation sent to the Secretary. I know that it might take us a little bit of time to get the wording right and the documentation, but that's where we're at right now. Luisita, do you have any other information or report from the process workgroup before we move on?

MS. DELAROSA: That's it for now.

MR. KING: Thank you very much. The next item on the agenda would be the update on the Immunization Safety Office, Centers for Disease Control and Prevention on vaccine activities, and that would be Dr. Tom Shimabukuro. Do you have a presentation you want us to see or are you just giving an oral report?

Agenda Item: Update on the Immunization Safety Office Vaccine Activities, Dr. Tom Shimabukuro, ISO, CDC

DR. SHIMABUKURO: I have a presentation. It's the one that is titled immunization safety updates, Centers for Disease Control and Prevention.

MR. KING: Does everybody have that? Very good.

DR. SHIMABUKURO: Moving onto slide two, I'm going to cover several topics. The first is recent Immunization Safety Office contract awards, then some October 2012 ACIP meeting highlights. I'm going to discuss a CDC clinical immunization safety assessment project working group response to an article that came on a death following quadrivalent HPV vaccination, and then just review a few select publications.

The last time we met I believe was in September. We had two of our main contracts, or two of our safety systems that were actually ending in September, the last year, the fiscal year, and we awarded contracts for these systems in the end of September 2012. One was the vaccine safety data link contract, which was one of our main surveillance systems. The other is the clinical immunization safety assessment project contract, and just to remind you about CISA, this is a group of medical research centers, mostly academic medical centers, that CDC

works with to look at individual risk factors, clinical reviews, and that also do clinical research.

In addition, we also awarded a contract to conduct an enhanced evaluation of the risk of narcolepsy associated with Pandemrix and aviary Panrix vaccines, which was awarded to the Brighton Collaboration, again in September 2012. The context for that contract is probably many of you are aware that there was an association of narcolepsy following Pandemrix, which is a monovalent H1N1 vaccine given during the 2009 pandemic. This association with narcolepsy was seen in Europe and really limited to Finland and Sweden, not observed in other European countries or other countries that administered adjuvanted vaccines. I just want to say that the United States did not use either of these vaccines. In fact, adjuvanted vaccines are not licensed or used in the US. This is looking at adjuvanted flu vaccines that were used outside of the US.

Moving onto slide four, just to recap some October 2012 ACIP highlights, and Dr. Caserta touched on this first one, but I'll just repeat it. ACIP recommends that providers of pre-natal care implement a Tdap immunization program for all pregnant women. Healthcare personnel should administer a dose of Tdap during each pregnancy irrespective of the patient's prior history of

receiving Tdap. If not administered during pregnancy, Tdap should be administered immediately post-partum.

This is a change from the previous recommendation that a pregnant woman receiving a dose of Tdap either during the pregnancy or immediately thereafter. This is essentially saying that a pregnant woman should receive a Tdap at each pregnancy. The guidance for use says optimal timing for Tdap administration is between 27 and 37 weeks of gestation to maximize maternal antibody response and passive antibody transfer to the infant. However, the recommendation is to provide the vaccine in pregnancy. The guidance is just really to touch on the optimal timing of the vaccination.

ISO and FDA will monitor the safety of this recommendation as it's implemented. As Dr. Caserta said, there isn't really a whole lot of data on this repeat immunization of Tdap, although there is some data in this particular group of individuals -- although there is data on repeat immunization of Tdap and other pertussis containing vaccines, but they ACIP felt that the benefits outweighed the risks and voted to recommend this change. This is interim. It doesn't become official until it's published in the MMWR.

Moving onto slide five, this next slide was about a vote on MMR and persons with HIV. The language for the

recommendation was persons with perinatal HIV infection who are vaccinated with MMR before effective antiretroviral therapy should be considered unvaccinated, should receive two appropriately spaced MMR vaccines, once effective antiretroviral therapy has been established. Two doses of MMR are recommended for all persons greater than 12 months or older with HIV infection who do not have evidence of current severe immunosuppression. I think to the medical folks on the call, this is self-explanatory, but I'll stop here to answer questions if anyone wants me to clarify what this recommendation is about.

MR. KING: When do these things typically get published in the MMWR?

DR. SHIMABUKURO: I'm not sure about the exact timeline, but what happens is there are some slight adjustments or maybe some edits in the wording that need to be incorporated into the recommendation. In order to get published in the MMWR, there is a review period. It's probably-- I don't know this for sure, but probably several months, maybe a little bit longer before they officially get published in the MMWR. These also have to pass through CDC review, because ultimately CDC decides what gets published in the MMWR. It will be a little while, but in the meantime, these come out as interim recommendations.

MR. KING: Thank you.

DR. SHIMABUKURO: Moving onto slide six, there are votes on the childhood immunization schedule and the adult immunization schedule. Those are routine votes. There was a vote on the VFC program. The resolution passed to change the term from trivalent inactivated influenza vaccine to inactivated influenza vaccine in the VFC language to incorporate quadrivalent inactivated influenza vaccine when licensed and available. My next slide will explain, and I'll get into more detail on that. Medimmune has a licensed quadrivalent live attenuated influenza vaccine, and both their trivalent and their quadrivalent-- the term is LAIV, so you're sort of generically covered because we're talking about a live attenuated influenza vaccine that doesn't get into specifics about trivalent or quadrivalent.

There are a number of quadrivalent inactivated vaccines that are in the process of being submitted for licensure. Currently, the terminology is TIV. In order to move forward from TIV as these vaccines are approved and come into use, the decision was made to move towards using the term IIV, inactivated influenza vaccine, which would cover pretty much any inactivated influenza vaccine. That name IIV would apply to a TIV or a QIV, which solves the problem of that nomenclature. In order for these vaccines to be covered by the Vaccines For Children program, we had to update the language. Actually moving towards using the

term formally is a multi-step process. There are additional steps that go in before IIV replaces the term TIV or QIV. The vote for the VFC program took place in October.

Moving onto slide seven--

MR. KRAUS: Just a quick question, did either of the schedules for adult or childhood change from 2012 to 2013?

DR. SHIMABUKURO: I can't answer that question specifically, but I will say generally for the routine recommendations I do not believe there was a change. There may have been some change for special populations, but basically the recommended vaccines for healthy children I don't believe changed. I will get back to you on that.

MR. KRAUS: Okay, thanks.

DR. SHIMABUKURO: I'm on slide seven now. We had three manufacturers that presented on quadrivalent influenza vaccines. Medimmune's quadrivalent LAIV is already licensed. We expect to have that vaccine available in the fall, but they reported on the study of both efficacy and safety, and as far as safety, QLAIV had a similar safety profile except a higher rate of fever in children age 2-8 years after the first dose looking at QLAIV versus TLAIV. GSK's Fluarix QIV, the biologic license application has been submitted, and the data shows similar safety profiles to their TIV and no differences in rates of

fever. Sanofi Pasteur has Fluzone QIV that they submitted the BLA for, and they also have a comparable safety profile for QIV versus TIV and no increase in fever.

Moving onto slide eight, I just want to make you aware of a response that CDC posted to an article on death following quadrivalent HPV vaccines. An article came out recently from a group up in Canada that described two case reports of death in young females following quadrivalent HPV 4 vaccines. The authors reexamined these cases which were originally the medical examiners gave an undetermined or in the case of another one as a hypoxic injury.

The authors reexamined these cases and concluded that the patients died of autoimmune cerebral vasculitis related to the HPV 4 vaccination. CDC staff and our clinical immunization safety assessment project partners identified key deficits in the data provided to support the conclusions of these authors. The CISA working group working in consultation with CDC staff to include our laboratory staff here drafted a response in the form of a technical report to the CDC website.

If you go to page nine, you have a screenshot of the report and the link there. I don't want to get into the specifics of the response, because that's probably an hour presentation in and of itself. If you're interested in reading the response of CDC and CISA you can go to this

link and read the report. It's pretty short. It's probably only about two pages long.

MR. KING: So the response is the response to the first bullet point that described two case reports of death in young females, or is the response to the authors reexamining the cases and concluding that the patients died of autoimmune cerebral vasculitis.

DR. SHIMABUKURO: It's a response to the conclusions in their paper, which is really addressing the issue of autoimmune cerebral vasculitis and the methodology that they used to come to that conclusion and what we believe are substantial deficits in the methodology and in the data that they presented to support that conclusion.

MR. KING: Thank you.

DR. SHIMABUKURO: Moving onto slide ten, I'm going to report out on three publications. The first one is Abadi et al, and this is adverse events following a third dose of MMR vaccine in a mumps outbreak. This describes an outbreak where-- there was a mumps outbreaks and a decision was made to give a third dose of MMR vaccine to manage this outbreak. The recommendation is two doses of MMR, one at 12-15 months and then another one roughly a month later. That second dose is usually given when kids enter school. This was a mumps outbreak and the decision was made to give a third dose in this outbreak setting. The results were

that the injection site reactions were reported more frequently than systemic reactions. Generally, there were no safety problems, however to assess the risk for rare or serious adverse events following a third dose, long-term studies would be required.

The next paper, O'Leary et al, febrile seizures and MMRV vaccine, what do primary care physicians think? This was really a survey that looked at knowledge, attitudes, and practices of physicians and focused on MMR vaccines. Measles containing vaccines are associated with an increased risk in febrile seizures in young children around the 7-10 day period. It's established that MMR vaccine, there's also an increased risk above the risk that you see in MMR vaccine. Given this information and what data has come out in the published literature after receiving data regarding febrile seizure risk after MMRV, few physicians report they would recommend MMRV to a healthy 12-15 month old child. Given that we have a separate MMR vaccine and a varicella vaccine, clearly the risk of febrile seizure is lower if you give an MMR vaccine as opposed to MMRV vaccine.

Moving onto slide 11, this is a publication by Moro et al, safety of the seasonal influenza, and H1N1 monovalent vaccines in pregnancy. This was a review of data from both domestic and international surveillance systems

and a review of the literature. The bottom line on this was that the safety profile of seasonal influenza vaccines and H1N1 vaccines in pregnancy was reassuring. That is my last slide, and if there are any other questions, I'd be happy to answer them.

DR. VILLAREAL: When I look at slide ten with O'Leary, and then I go back up to the vote on the immunization schedule, are they being recommended now to do the combo MMRV at the 12 month? By rumor, I heard that was a recommendation, to do a combination MMRV.

DR. SHIMABUKURO: There's not a preferential recommendation for MMRV. I believe that there used to be a preferential recommendation for MMRV because it was basically one shot instead of two. CDC removed that preferential recommendation. There still is a recommendation for MMRV, but it's not a preferential recommendation of both MMR and varicella vaccine separately.

DR. VILLAREAL: Correct, we can give the MMRV usually at age four to five years, and for the kindergarteners that often works easier, again for parents, the child, and the pediatrician from the practice. What we had heard was at the one year, that was going to be the recommendation.

DR. SHIMABUKURO: To give MMRV? Preferentially? To my knowledge that's not a preferential recommendation to give MMRV. You do bring up a good point that the risk for febrile seizures is limited to the younger children that would be getting it at 12-15 months. I think risk peaks around 18 months. There really isn't a risk increase for febrile seizures in older children, at least for MMR. Like I said, I'll check on that, too, but my understanding is that MMRV is a recommended vaccine, but there's not a preferential recommendation for MMRV.

DR. VILLAREAL: Thank you.

MR. KING: Any other questions for Tom?

MR. KRAUS: Can you tell us anymore Tom about the new contract that was awarded for the VSD and CISA? What is that?

DR. SHIMABUKURO: VSD and CISA were existing programs in ISO. They had just reached the end of their performance period. They expired this past fiscal year. We basically competed and awarded a new vaccine safety datalink contract and a new clinical immunization safety assessment project contract. The main difference is that previously there was a prime contractor who was sub-contracting out to individual sites within the VSD and CISA. Now CDC has direct contracts with the VSD sites and the CISA sites. Does that answer your question?

MR. KRAUS: Yes, I think so. So there are some changes-- generally just renewing the same contracts although with some slight changes in terms of how things are operating, but nothing significantly different about who's participating in the VSD?

DR. SHIMABUKURO: The VSD sites, I think one of the previous sites dropped out, so the VSD sites are essentially the same. There are a couple additional-- there are two new CISA sites. Duke and Cincinnati Children's were added, and then Stanford is not on this current contract. I will say for VSD and CISA, the basic concept of VSD and CISA are continuing on where VSD is on active surveillance systems. CISA does a lot of clinical case review and assessment of individual risk factors and clinical research. The Brighton contract is a separate issue to look at a particular subject.

MR. KRAUS: I understood that. The other question I had was about the CDC's response to the article by Shaw and Tomljenovic report about HPV and cerebral vasculitis. What was the motivation behind the CDC responding to that with a report?

DR. SHIMABUKURO: This report was published in the peer-reviewed literature. There are staff at CDC that had detected some significant deficits in the data and in the methodology, specifically about the theory that these two

individuals died of autoimmune cerebral vasculitis, which was related to HPV vaccination and basic disagreements about the Actual existence of cerebral vasculitis and about some really non-standard methods that were used to come to this conclusion. We thought it warranted a response, so we engaged our clinical partners and some of our partners in other parts of CDC to do this response, which is posted on the link, but anytime you're dealing and speculating about death, I think it's important.

MR. KRAUS: I guess my follow-up is did clinical folks that you engaged or CDC in-house, did you look at the medical documentation and do your own analysis or did you just critique the study that was done from a peer review kind of perspective? The reason I'm asking this is that you have two researchers or some researchers who propose, who look at the death of two people following vaccine, they write up a case study saying that in their view, these two individuals died following the HPV vaccination. I would understand if there's some flawed science behind their conclusions, that that would be an issue for concern for the CDC, but I would also expect that the CDC would want to get to the bottom of whether or not the HPV vaccine was related to the death of these two children or young adults. What do you know about that?

DR. SHIMABUKURO: We essentially did the latter. We reviewed the paper. We reviewed the images that they used in doing the histologic-- the images they used. It wasn't trivial. There were claims that viral particles were detected in the cerebral vasculature, yet there was no indication that electron microscopy, no description of that, and you can't detect viral particles with light microscopy. There was no mention of electron microscopy. That's a significant flaw in the data-released report, and from the histologic images that were used and also from the description of what was found in autopsy. There was actually no evidence of cerebral vasculitis. If you look at reviewing what was written in the paper, there was no evidence of that. CDC felt it was important that this was out there and our vaccine partners out there domestically and WHO were asking if CDC had a response to this. We felt it was important to at least address this paper.

MR. KRAUS: Thanks for your response, Tom.

MR. KING: Any other questions for Tom? Tom, thank you so very much. Let's move on on the agenda. The update on the National Institute of Allergy and Infections Diseases, the National Institutes of Health vaccine activities, Dr. Barbara Mulach.

Agenda Item: Update on the National Institute of Allergy and Infectious Diseases (NIAID) Vaccine Activities, Dr. Barbara Mulach, NIAID, NIH

DR. MULACH: Thank you for giving me an opportunity to update you on a few things that are going on with us. I do not have slides, so this is just a verbal presentation, but I'm happy to follow up if anybody needs me to send anything in advance, links or anything. I just wanted to let you guys know that I guess Dr. Collins, our institute director, has kind of gotten in the swing of things. He's got his own blog now. For those of you who like to blog, he's blogging about three times a week. Some of the topics that he's been blogging about recently are super storm Sandy and prescription drug abuse among teens, but stay tuned for some additional topics of interest. Certainly, if any topics of particular interest to this group become available, I'd be happy to share them with you at the time.

We also have an NIAID YouTube channel. For those who are interested in that, it's in www.youtube.com/user/NIAID. Some of the highlights of the types of things that you can find there, you can find information about how influenza pandemics occur; find information about understanding the bacteria, the good bacteria and the bad bacteria, the micro-bio type activities; information about allergies; and so a lot of good information for those

people who like the YouTube clips as an addition to some of the written information we have on our website.

I also wanted to let you know that NIAID awarded several contracts in September of 2012 to expand our pre-clinical services for researchers. These are vaccine pre-clinical services to allow for a lot of different activities. For those people who are researchers who are developing vaccines and they have a hurdle that they need to overcome, either in assay development, immunogenicity, safety, toxicity studies, clinical and non-clinical sample testing, and pilot blot manufacturing and things like that. It's a supplement. For those people who are developing new and improved vaccines and wanting to evaluate them, this is an opportunity offered to researchers to try to get them over those hurdles, to move those new vaccines forward.

The last thing I wanted to let you know is that NIAID recently put in the NIH guide a request for information on the availability of dry formulation technologies for vaccine formulations. The idea for this is to find out what the pharmaceutical and bio-pharmaceutical community is doing in terms of developing formulations that increase stability, eliminate cold chain, minimize the needs for preservatives, and other things like that.

As you can imagine, there would be a lot of uses for technologies like this in enhancing some of the

vaccines that we currently have for thinking about international use of some vaccines where transportation is an issue and certainly removing preservatives where you can is always a good thing. Again, that announcement is out through Friday, and the idea is to find out what the lay of the land is to think about how we might explore funding opportunities in the future. That concludes my report. I'm happy to answer questions.

MR. KING: Any questions for Barbara? Barbara, thank you very much.

DR. MULACH: Thank you.

MR. KING: Next on the list is the update on the Center for Biologics, Evaluation, and Research, Food and Drug Administration Vaccine activities, Lieutenant Valerie Marshall.

Agenda Item: Update from the Center for Biologics, Evaluation and Research (CBER), FDA, LT Valerie Marshall, CBER, FDA

LT. MARSHALL: Good afternoon. I'll be providing a brief regulatory update of activities within CBER. On November 14, 2012 the Vaccines and Related Biological Products Advisory Committee met in an open session to discuss and make recommendations on the safety and immunogenicity of the influenza A H5N1 virus monovalent vaccine manufactured by GlaxoSmithKline. The committee

voted that immunogenicity and safety data are sufficient to support use of this vaccine.

On November 15, 2012, the committee discussed and made recommendations on the safety and efficacy of the Hepatitis B vaccine, Heplisav, manufactured by Dynavax. The committee voted 8-5 with one abstention, that available data do not support the safety of the vaccine in those 18 to 70 years of age. The committee voted 13-1 that immunogenicity data submitted in a BLA for Heplisav report the product's efficacy.

On November 20, 2012, CBER approved Flucelvax, an influenza vaccine indicated for active immunization of persons 18 years of age and older against influenza disease caused by influenza virus sub-types A and B containing the vaccine. This vaccine is manufactured by large vaccines and diagnostics and is the first seasonal influenza vaccine licensed in the United States that has produced using numb(?) cells instead of fertilized chicken eggs. Cell culture technology is another manufacturing alternative to conventional egg based influenza vaccine production. The advantages of this type of technology include ability to maintain an adequate supply of readily available previously contested and characterized cells for use in vaccine production and the potential for faster start-up of the vaccine manufacturing process in the event of a pandemic.

On December 3 and 4, the Parenteral Drug Association and FDA held a joint conference which focused on the regulatory and technical challenges to effectively produce and supply vaccines to developing countries. While advances in science and technology are leading to the research and development of a wide array of new vaccines and other manufacturing approaches, ethical, logistical, and regulatory challenges continue to face the vaccine industry in developing countries. That concludes my report. Thank you.

MR. KING: Does anyone have any questions for Valerie? Valerie, thank you very much. We have the update from the National Vaccine Program Office, Dr. Jennifer Read.

Agenda Item: Update from the National Vaccine Program Office, Dr. Jennifer Read, NVPO

DR. READ: I have a short report. One is to again address the issue that we addressed last time, which was the status of the Institute of Medicine's committee on assessment of studies of health outcomes related to the recommended childhood immunization schedule. Previously, the timeline that had been reported to NVPO was that the report would be ready this fall. The latest update I have is that it will actually be available in early January. By

the time the committee meets again, there should be a report out.

The next NVAC meeting will be held in February, specifically February 5-6, 2013. The agenda is not yet fully developed, so I can't report on the agenda items at this time. As has been alluded to previously, and I don't believe this was reported to the committee specifically previously, but NVAC at its June 2012 meeting voted to create the Maternal Immunization Working Group of NVAC. That working group has begun work, and their draft report will be presented to NVAC in June 2013 with a final report in September of 2013. That's it. Any questions?

MR. KING: Does anybody have any questions for Jennifer? I have a question. The work that you're doing on the immunization, how does that work with our workgroup?

DR. READ: I'm on both working groups, and Dr. Beigi, who is an obstetrician, is on both working groups. Between the two of us, we communicate back and forth in terms of any issues. We'll be in close communication over the next several months.

MR. KING: Anyone else?

DR. VILLAREAL: Do you know, have we heard anything from the IOM question of, and let me word this correctly, of families who do not want immunizations and looking at those families and their kids as far as

outcomes. The question is, were they working on-- maybe Tom you can help me with this, or Ed -- proactive refusal of immunizations and outcomes.

DR. READ: That's the committee I referred to previously where the draft report -- the knowledge that I had with the last meeting was that they said they would have it in late fall. The updated timeline was that they will not have a report that will be put out by them until early January.

DR. VILLAREAL: That originates from IOM or NVAC?

DR. READ: It's an IOM committee that's been formed to address the question. IOM will issue the report. It's completely separate from NVAC.

DR. VILLAREAL: Thank you.

MR. KRAUS: I have a follow up question. Can you tell us anything about the conclusions in the report or those are not available?

DR. READ: Absolutely not, and they're not communicated to NVPO specifically. I don't have knowledge of what the final report will say.

MR. KING: Any other questions? Jennifer, thank you so much. At this stage in the agenda, it is time for us to go to a public comment section. This is an open public comment session. Operator, if you could give the

instructions on anyone who wants to make a public comment, please.

Agenda Item: Public Comment

OPERATOR: Thank you at this time, if you'd like to make a public comment, please press star one; to withdraw your request, press star two.

MS. WRANGHAM: I want to thank the committee for offering two public comment sessions today. My name is Theresa Wrangham and I'm the executive director for the National Vaccine Information Center. NVIC is entering its fourth decade of public service and is the largest continuing organization that monitors vaccine safety and advocates for informed consent in vaccination practices.

I would like to clarify my previous comment regarding the Department of Justice. Our previous request that the DOJ respect privacy concerns expressed today by Mr. Matanoski. What NVIC had previously requested is that additional information be added to the report title claims filed and compensated or dismissed by vaccine that appear on the ACCV website. Our request is to break out under each vaccine and with support the injury or condition for which compensation was awarded in total amounts by year.

The request doesn't require that privacy be violated and is information that would be useful in determining what research is needed as well as should be a

matter of public access. I would be happy to provide the DOJ and the ACCV of an example of this format, as it's very hard to explain verbally.

With regard to comments made on the possible chilling of the process of claims that were overturned by the Supreme Court made by Mr. King and Mr. Kraus in terms of attorneys taking on a case, we would add that the statute of limitations that helps to fix this measure of the law, 36 months, doesn't acknowledge that the state of the science is extremely lacking as demonstrated most recently by the IOM report.

We would point out that the law also requires that ongoing vaccine safety research be conducted. Given that 85 percent of the most commonly reported adverse events associated with vaccines didn't have enough quality science or that there is an absence of science to determine causality as noted by the IOM, that ongoing research is not happening in a manner that would allow professionals, parents, and individuals to realize that a condition or outcome that's sustained as a result of vaccination.

The Department of Justice's interpretation of the statute of limitations doesn't appear to acknowledge the intersection of the law with ongoing research and how it might impact the current statute of limitations. This lack and lag of science will effectively bar those injured or

who have died as a result of vaccination from the appropriately compensated when held to the strictest interpretation of the statute of limitations.

There is also an ongoing lack of awareness with regard to the existence of the VICP that contributes to this loophole. NVIC consistently hears from the public on the statute of limitations issue and has worked with Congress to create a program of vaccine injury and death that be compensated in a no-fault, non-adversarial manner, and awareness of the program must be kept to a higher standard.

Earlier this year, we were very pleased that the ACCV was supporting the expansion of the vaccine-injury table based on the 15 percent of the vaccine adverse events that the IOM reviewed and were able to make recommendations for. We would ask for a status from those efforts. I was under the impression that there would be some sort of public engagement, but we have seen no announcement in the Federal Register.

In closing, given that adults are increasingly becoming a majority of the compensated individuals of the VICP or the majority of claims that are submitted, it follows that they should have representation on the ACCV. Again, I'd like to thank you for the opportunity to offer comment today.

MR. KING: Thank you. Any additional comments from anyone?

MR. RODEY: Good afternoon. Mr. Chairman and members of the Commission, my name is Ray Rodi, father to a vaccine-injured child who later was diagnosed with severe regressive autism. I'm a member of several national organizations that promote vaccine safety, individual informed choice, healthy food, water, and oxygen advocacy. I want to bring to your attention the real need to examine your previous work on public outreach. I've reviewed previous years' transcripts of your quarterly meetings and read all the good work that was conducted by the Commission and its sub-committee chair, Sarah Hoiberg during 2009 and 2010.

I'm very disappointed in the lack of attention to consumer work progress since that time, hardly mentioned in 2011 and this year. As you're aware, there's a growing and public distrust of vaccine safety as evidenced by the greater number of vaccine exemptions by their parents, local schools, and day care facilities. People are becoming very aware of firms, neighbors, business colleagues that have suffered some form of vaccine injury. With the estimates that only one to five percent of all adverse events through vaccines are reported to the VAERS system,

many of us are concerned about vaccine safety and how many people actually know about NVIC.

I've extensively researched many of the petitioners and the families who have won petitions or have lost or are still pending, plus many who did not file. One of the biggest reasons for those who did not file was because they did not know of the program, or they did not know about until it was too late. Another concerned answer that I've heard from many parents, a lot of them who filed petitions in 2010 and 2011, were denied from their doctors that vaccines cause injury or reluctance for medical practitioners to help parents file the VAERS report.

Also, now with the large expansion of vaccine clinics and retail pharmacies and other big box stores where these individuals and parents know about the NVICP, the VAERS system, and more importantly what to do in case of vaccine injury. The Commission has spent a lot of money developing communications to develop targets for outreach a couple of years ago. What is the outcome of that effort? I encourage the Commission to reestablish as a priority a public awareness campaign directed at the general public. This can be in the form of public service announcements, TV, radio, plus the use of social media such as Facebook, Twitter, and others.

I also encourage the Commission to accept written comments from the public and insert them into the record by the public who cannot attend the quarterly meetings.

Lastly, I suggest that the next ACCV meeting with DOJ representatives answer those questions by Mr. Lewis Conti that were asked earlier this morning during their presentation for the next ACCV meeting. Thank you very much for your time.

MR. KING: Thank you. Are there any additional comments?

OPERATOR: At this time, there are no further questions.

Agenda Item: Future Agenda Items

MR. KING: Then we will close the public comment section. The next item on the agenda is for us to talk about future agenda items, new business, and I'm going to add if there's any old business. Does anyone have any thoughts here? Anybody?

DR. CASERTA: I do want to give an update as to the issue with in-person meetings as opposed to meetings done electronically. We in the agency are getting clear direction from the Department that the way that future meetings are to be held are to be more on the electronic and less on the in-person both because of efficiency reasons and because they're less expensive. In terms of

what it means to us here now with where the rubber meets the road, the amount of money that we have budgeted that could be used for the ACCV that could be used for future in-person meetings would allow us to potentially do one meeting for this fiscal year.

Again, the writing is on the wall, but this money, even the little bit that we were able to fight for-- it's hard when all the different Commissions and groups are being told the same thing. Everyone would prefer to meet in person. The competition is going to be strong for that money. The way it looks for the future is that we're going to be using this mechanism more.

We're not going to do it this way for this meeting, like we did it for this meeting, and we're looking into video monitoring technologies that would make the meetings more effective and easier for folks to see people as the meeting is progressing. I have a meeting next week on one of those issues. There are a couple of potential possibilities. I wanted to inform the Commission that the budgeting for our meetings would potentially allow for one in-person meeting this year. We would want to use that carefully and sparingly and not use it unless it was truly needed.

MR. KING: Does anybody have any comments?

MS. PRON: I'm not commenting to the method of meeting, but I'm just commenting to the logistics that it seems that if we were going to have an in-person meeting, it might be better to have it June than March when the weather could be compromised.

MR. KING: Of course, June 1 starts hurricane season.

MS. WILLIAMS: I know that doing the telephone meeting we're still ironing out the kinks, but I want to thank Annie for getting the start time up on the website. I know it wasn't there earlier, and I think there was some confusion about whether we were starting at 9:00 or 1:00. She was very quick to act on that and it's appeared. Maybe we can talk in the process workgroup about the website and what's posted, because I know that in my notebook, I have the written public comment, but it doesn't look when I look on the website, some of the things that I have in my notebook don't look like they're on the website. Maybe they go up afterwards. I just don't know which goes up in advance and which goes up after. As we're working through this electronic communication meeting process, maybe we can give some thought pertaining to that as well.

MR. KING: Okay, any other thoughts?

MR. KRAUS: I'm curious about the budget for the ACCV. I'm not at all questioning your conclusions about how

much the budget is and where and therefore how many meetings can be done in person, but I just had no real sense of what the ACCV's budget is used for. It didn't change, did it? Is it more expensive to travel than was expected or is there an actual cut to the ACCV's budget? I'm just not clear about that.

DR. CASERTA: There was a cut to travel budgets across the board in the Department. Many travels that aren't worthwhile are going to be difficult. For example, I normally go to the ACIP meetings in Atlanta, and I was told that the February meeting I'm not approved for. It's across the board, and they're deep cuts.

MR. KING: So, when Vince was speaking earlier, he had talked about how they were funded by the trust fund. He said that the court's funding and the DVIC was funded that way. Was that an accurate statement on his part?

DR. CASERTA: Yes.

MR. KING: Who controls that?

DR. CASERTA: Congress.

MR. KING: Is Congress telling you that your budget is cut then as it relates to us?

DR. CASERTA: Indirectly. It's the Department that's telling us now in anticipation of what Congress may do. We have this fiscal cliff facing everyone, one continuing resolution which by definition puts you at less

funding than you had last year. Travel was just under scrutiny in the Department. Someone at a pay scale much higher than mine has made that decision.

DR. SHIMABUKURO: I can confirm that the same thing is happening at CDC. As Vito said, it's agency-wide.

LT. MARSHALL: The same thing at FDA as well.

MR. KING: Vito, you had said that there was funding for one in-person meeting, you thought, per fiscal year you said?

DR. CASERTA: There is now funding that we could use for one meeting this year.

MR. KING: That would take us all the way until and including our September meeting, is that correct?

DR. CASERTA: Yes.

MR. KING: Let us ask what is the criteria that one would need to justify an in-person meeting instead of the virtual meeting.

DR. CASERTA: The primary criteria is the money would need to be available. If that criteria is not met, the in-person meeting can't happen.

MR. KING: Back up for a second then, we've already determined that the money is available for one meeting. Are you saying that even that is at risk?

DR. CASERTA: My boss is telling me no meetings, and I'm arguing with her that it's important that we at

least have the money available should issues come up where the Commission feels strongly that an in-person meeting would be much more useful than an electronic meeting. Recognize Annie may work magic with the electronic and we may be totally satisfied with that once we get a good system in place. I just wanted to be prepared in case something came up where an in-person meeting was necessary. There is no criteria. It really depends on our funding and what is before us and how to best tackle it.

MR. KING: Who makes that decision?

DR. CASERTA: Who makes the decision of whether or not we would have an in-person meeting? Assuming the money is there, the decision would be made by the folks who budget the money to us for one of these meetings. If they budget the money, we could do the meeting if you felt strongly you, as the chair of the committee, wanted to use this next meeting, the June meeting, or the September meeting.

MS. WILLIAMS: The only criteria I could think of would be when there's orientation of new members.

DR. CASERTA: That would be a strong justification.

MS. WILLIAMS: It would seem to me that we could have an in-person meeting there, because otherwise your

orientation of these people and then the next thing they do is get on the phone, it wouldn't be very--

MR. KING: Michelle, just so you know, that would not occur in this fiscal year, that type of meeting. It would be impossible to have that in this fiscal year unless there's a resignation.

MS. WILLIAMS: Vito, I thought you said we could have one in-person meeting.

DR. CASERTA: Yes, we can. I think what Dave is saying is no one's coming off the committee this year.

MR. KING: Correct. I'm saying if that's what the justification is for a non-virtual meeting, a face-to-face meeting, that won't happen in this fiscal year. There are only three meetings currently left in this fiscal year unless the chair were to call a meeting.

DR. CASERTA: I think a good course of action would be to see what magic Annie can put together and see how effectively we can do the Commission's business electronically and then based on that, if we have a strong justification for an in-person meeting, we would then do what would be necessary to make it happen?

MR. KING: Much like the Justice Department doesn't like to work in gray, what I'm trying to understand is, get me out of the gray. We're in a gray area here. It seems that no one is willing to create the non-gray and say

this is what justifies an in-person meeting, this does not. Do you understand?

MS. WILLIAMS: I think what's on the agenda would be dictating or help create parameters for what's an in-person meeting or not. For instance, if we were going to go through the IOM process again, that was a critical meeting. I think that would be something—

MR. KING: So this would not have been a critical meeting, what we just did today?

DR. CASERTA: No, and I agree with Michelle.

MR. KING: No, this is not a critical meeting or yes this—

DR. CASERTA: No, this is not a critical meeting in the sense of it needing to be in-person. All the meetings are critical, of course, but where the in-person interaction would be of most use, we need to save our money for that meeting. That's what I mean be critical meeting.

MR. KING: Where does that money come from?

DR. CASERTA: The money ultimately comes from the trust fund that's given to us by Congress—

MR. KING: And how much is in that trust fund?

DR. CASERTA: $3.5 billion at last count.

MS. WILLIAMS: I think if we have additional thoughts on this, on the mechanics of meetings, maybe we can send them on to Vito. We're not going to change the

congressional hold on travel that the Department is responding to regardless of how much is in the trust fund.

DR. CASERTA: That's really what's driving this.

MR. KING: I don't dispute that. Where I'm coming from is if we strongly feel things of that nature, it's way to vague in my opinion. I don't know what the other Commissioners, how they feel about it. They might actually think virtual is better than face to face. We haven't actually polled and asked people, what do you guys think?

MS. WILLIAMS: I do many virtual meetings, and I have to justify my travel for any of my clients. In fact, many of my clients will pay for travel when we need it. We're very accustomed to virtual meetings. Annie and I, my secretary and I, have been talking about some of them methodologies that we have at our disposal here in my company. Annie is checking to see if those resources may be available as well that make meetings a little bit more user friendly. I would rather have flexibility, the vagueness, in deciding what meeting we want to have in person than trying to put advance criteria around it, so that we can be reflexive.

MR. KING: Thank you. Any other thoughts on that from the group?

MS. PRON: I'm just thinking do we know if there are any big issues coming down the pipe this year, or are

we still in responsive mode? I guess that would go to both Dave and Vito.

DR. CASERTA: We're looking at each other around the table here. There may be vaccine information statements, I think. VAERS is updating the VAERS form, so there may be issues such as that that would come before the Commission. I don't know of anything else off hand that — I don't know if anyone else on the call can think of anything.

MR. KING: Anne, I think you raised a terrific point there in terms of big issues, and what are the big issues. If there are none that are coming forward, should we be generating them as we look at how we can make this operation run more effectively, and when I say "operation" I mean the Vaccine Injury Compensation Program runs more effectively, not so much that the ACCV runs more effectively. I would hope that we would continue to work that area.

Perhaps, maybe as some of the issues that are being worked on in the workgroups — at times it may be that they would be to the benefit of all particularly if there is going to be interviewing of attorneys, special masters, and things, those types of things might warrant everyone to be listening in and sitting in on it so that informed decisions can be made as opposed to just summaries of that

information coming. I don't know, but just some thoughts to consider. Does that help?

MS. PRON: Yes.

MR. KING: Any other thoughts on the virtual meetings versus the in-person meetings? Is it too late in the day to have this conversation?

DR. DOUGLAS: I think this worked well. I am getting more and more used to these kinds of meetings coming out of the university, but with the material in front of us, I really felt it was effective. Working through that, this meeting went on. It works for me, and I'm probably the closest one.

DR. VILLAREAL: I don't think any meeting is any good if we don't have a clear direction and clarity so that me coming from Taos, and I know Luisita comes from California, that is a long haul. I don't like these meetings that last so long, because I'm always moving and for me to stand this long is really difficult. The criticism is not directed to anybody, but when somebody's getting an update, if they'll have one slide saying what the organization does and in the website that would be helpful, again, just for visual learners that's important. I'm not sure we all want to Skype and blow our load with everybody with that kind of stuff. Instead if we can focus and say, is this meeting important? I know we have the

directive, but we need x amount of time, and I don't know who put that together that we meet quarterly or whatever —

MR. KING: That's statute.

DR. VILLAREAL: I know, but I'm asking the gorilla question. Why do we have that gorilla and which part of it am I looking at to define this as critical? I think the IOM paper when it is published is important for us to discuss. I think that the chair of the maternal immunization — Kristen can work with NVAC so we don't duplicate a lot of that meeting time with NVAC and with us as far as maternal immunization. We could have some say on that. It is unfortunate because we don't have camaraderie, and there's nothing so we can work together as a team. I don't know how to address that part, since the world's become quite impractical and not hands on.

As a pediatrician, I do telemedicine, and I know for some, unlike others, it is easier to talk to the specialists by computer and by visual and not for them to drive three hours to see the specialist. That really doesn't do anything. I'm very ambivalent. I would not be opposed to not flying to DC. That's fine with me. Again, it cuts into my clinical time of eight hours, and I'm sure everyone else is extremely busy. For us to focus and say okay, what are our directives and where do we go and do we get these meetings going?

MR. KING: Good, anyone else? We'll close out on that. I actually have one other issue that I think we should — and we only have to spend a moment on it actually — and that is we had talked about at our last meeting about putting the list of attorneys on the website and that that would be explored. Vito and Annie, do we have anything going on that area yet?

MS. HERZOG: That's on the website.

MR. KING: It is? How did I miss it?

MS. HERZOG: It is under "how to file a claim". I think if you go all the way to the bottom. I don't have a computer in front of me, but I believe that's where it is.

MR. KING: I was looking for it this morning -- how to file a claim. I have to scroll to the bottom of this thing?

MS. HERZOG: I believe it's towards the bottom, yes.

MR. KING: More about the — and it lists the attorneys?

MS. HERZOG: There should be a link there under the US Courts' website.

MR. KING: More about the Court of Federal Claims— click here for attorney submission. Does it list the attorneys, is what we wanted?

MS. WILLIAMS: I think what we had requested is that there be a link to the court, which lists the attorneys.

MR. KING: Right, and does that list the attorneys, the court?

MS. HERZOG: Yes.

MR. KING: All right, I'm on the court website now. Can someone walk me to it? Jason?

MR. SMITH: The last time that we met with Jocelyn and we looked through the court website — and Dave, I apologize if I'm going in the wrong direction here — there was a link to the bar where these attorneys practice because the court felt, and again I feel uncomfortable speaking on behalf of the Court, that using a list of names did not want to appear to be an endorsement by the court of those particular attorneys, but that a link to the bar of attorneys and the individuals who are members of that bar that practice in this particular area would be made available. You'd have to hit the link to go to the bar and then do a search for attorneys in your particular area.

MR. KING: Right, you had actually sent out a link in an email giving us an example of what we were talking about.

MS. MCINTOSH: If you go to the Court of Federal Claims' website, if you're on there, if you look down,

there's a tab. You'll see "vaccine info" if you reach the bottom. That opens up another drop-down and if you go to—

MR. KING: Great, I got it. So here's my question. Is there a way for us to be able to on the ACCV's website link directly to the list of potential attorneys there?

MS. WILLIAMS: I think when we talked about this last, we also didn't want to have the appearance of endorsing — I think what you're saying is can you go to the link straight away or go through the court.

MR. KING: I think that it doesn't mean that we're endorsing it. You can have a statement that says that this link will take you-- so it would open up and the link would be in it and before you get to the link would be the statement along the lines of this is not an endorsement but these are attorneys that are working in this particular area of expertise.

MS. HERZOG: If you're on the VICP website and you're under how to file a claim, if you go all the way down to the bottom, it says more about filing a claim, and then up at the top it says "obtaining a list of lawyers who file VICP claims"—

MR. KING: Where? I'm looking for that. At the top? Ah, it's not actually at the top, it's buried in the middle — obtaining a list of lawyers, and it just tells you it's 31 pages.

MS. HERZOG: Right, if you click on that pdf—

MR. KING: That will give you the lawyers. It's not really user friendly. One would have to really research it, but technically I guess we could say it exists to some degree. You just have to dig.

PARTICIPANT: Can you search the website or is that on it, and then could you type that in somewhere?

MR. KING: Type in?

PARTICIPANT: Lawyers?

MR. KING: Oh, into the ACCV website? I'll have to try that. There is a "search this site", and I'll put in attorneys.

MS. HERZOG: I think that searches the whole HRSA website, not just the VICP website. You can try it, but I'm pretty sure.

MR. KING: Yes, it's not going to quite bring you where I want here if I type in attorneys. When we hear public comments, one of the things that-- the public outreach component that was raised, perhaps is there something we should be doing in that area that we could do that might give that without it being where it looks like we're actually recommending those attorneys? I would think there would be a way to do this, and that makes life easier for people.

MR. KRAUS: I personally am less concerned about people being able to find an attorney. I think that when people know that they have a claim and that they need to pursue it in the vaccine compensation program, I think the access to attorneys who can handle those claims is not too difficult, or it's not severely lacking. In terms of this new business, I think we should talk about the larger issue of making the public aware of the existence of the program. Part of that is making sure that when they're aware of the existence of the program, they also are aware of how to access attorneys who take claims, who represent people in the program. I think the bigger issue is, just not knowing that the program exists. I don't mean to take us in a different direction Dave, but I think that you can get to that list of attorneys. We can make it a little bit more accessible.

MR. KING: I am of the opinion that we need to find a way to make it more accessible. That's where I'm at. Fellow Commissioners, you may or may not agree. I don't know that we have to decide it right now. I just bring it up again because I think that in initially hunting down an attorney, it was not nearly as easy as one would think. It required several flips to be able to find one who was familiar with the process.

MS. DELAROSA: This is a comment about vaccines being given by pharmacies and especially the influenza vaccine. I stopped by a pharmacy, a Walgreens or CVS, and I picked up the vaccine information sheet from them. They are being given out. I don't know if they—of course, they are expected to provide it and the VCIP information is right there.

MR. KING: That is true. The information about the program is on the statements. It's there.

MS. DELAROSA: It's a very, very long sheet, and the one for CVS that I saw, it's been duplicated and all the stuff, and they have to sign it that they've received it and know that stuff. At least I did see that information there. It's really very short, but it did say that if there is any issue or they feel that they are injured by the vaccine, they are given the phone number and the website. It is available.

MS. PRON: I agree that the information needs to be maybe more user friendly on the website only because the vaccine that Luisita said earlier about a child was affected, and just what the whole situation was, it's harder to think straight. We can sit now on the computer, and we can search, and we can look here and there and whatever, but if you're in a stressful situation, it's better if it pops out at you.

MR. KING: I would agree. I would say that in the minutes of our last meeting, we had actually — and I know Geoff's not with us anymore, not with us meaning that he retired, Dr. Evans, but he said that we don't want to advocate any particular list of lawyers, that the office would look at possible solutions to that particular constraint. We also talked about is there a way that we can put this on the ACCV or VCIP website where we would have a list of attorneys.

MS. DELAROSA: It is also on the Court of Federal Claims website to because I saw it earlier. It comes out as a pdf.

MR. KING: I guess I think it's just easier for people.

MS. WILLIAMS: I don't know of any government website or many websites that are very user friendly. Maybe when we're, if you will, converting to electronic meetings and we will have more things posted on the website, it would not hurt to talk about website issues globally. It's not just links and things like that. Frankly, if people are going to be looking for attorneys they're going to go to their state's bar websites probably more readily, and the information I would think would be more valuable on the state bar website than the ACCV website. When you get right

down to it, where do people go? They go to their state bar association or their city bar association.

MR. KING: That's if they know to do that. I'm of the view that many people don't know. We are thinking of educated folks that know what's going on. There are some out there that don't know what's going on. That's the real issue.

MR. WILLIAMS: I think those are two separate issues. I think we're talking about a list of attorneys versus information about the program.

MR. KING: Right, and I'm thinking in terms of a list of attorneys, where you're thinking that people will immediately go to the state bar and the city bar and things like that. I'll submit to you that I do not think that that is the thinking of the general folks in the public. I don't think that's their first reaction on what they first think of.

MS. PRON: I think they need both access to the program and access to then what's the next step, which would be to find an attorney.

MR. KING: I agree, I do not think we're going to resolve it right at this moment, so I guess the question then becomes is this something that another group takes up, a work group, or do we incorporate it into one, or do we

say we're too busy to address this issue at this time and move on? How do people feel?

MR. KRAUS: I don't feel strongly either way, except if you're concerned that it should be made easier I would support you in that and maybe say that we can ask again for Vito to re-look at that issue.

MR. KING: Vito and Annie, would you be willing to do that?

DR. CASERTA: Absolutely, if we can see how we can make it more easy to find and user friendly, we will institute that. I did want to add that there are other ways people can find the information. We not unusually get phone calls from people asking questions like that and then we direct them to the court's website. There are multiple ways to get there.

MR. KING: Okay.

MS. DELAROSA: A long time ago, I saw this as a poster in the neurology clinic after I saw it in the bathroom.

MR. KING: You saw what, Luisita?

MS. DELAROSA: A big poster about the Vaccine Injury Compensation Program, a big poster in the bathroom, the ladies room in the neurology Department of the university.

DR. CASERTA: We also have them in Spanish.

MS. DELAROSA: There are some Spanish ones, and at that time, I used to phone to get the information. I was sent the booklet. I was sent the news from the federal claims and I was sent the vaccine dispatch itself to start the whole process. It's just a poster, like I said, in such an odd place. I did not pay attention to it at first because I was too busy trying to deal with my daughter's issues, but it was only towards the second year that I was finally fully convinced it was a vaccine injury. That's when I started my research. It's hard because at that time it was very difficult to get doctors to agree, just like the public comment said, very hard to them to acknowledge or agree that it was, that it could possibly be a vaccine injury. It's a big hurdle for petitioners to even start. You need that medical support. That's already a big issue right there.

MR. KING: Thank you, Luisita. Are there any other issues that we want to bring forward? In summary, correct me if I'm wrong but just in the summary of things, Vito and Annie, you guys are going to look a little bit deeper into what might be able to be done in this particular area; two, getting a consensus from the group as to in-person versus virtual meetings. I think that people seem to be okay with the virtual meetings. I think I'm getting that. While we may prefer face-to-face that virtual seems to work and that

we’re well into being continued and move along in that, and Annie’s going to look at technologies that might foster a better or more effective way for us to be able to do that. If there’s nothing else before us, I certainly think we should entertain a motion to adjourn.

MS. PRON: I agree.

DR. VILLAREAL: Seconded.

MR. KING: All right. There being no objections, the meeting is over for the day. Thank you very much everybody.

(Whereupon, the teleconference was adjourned.)