DEPARTMENT OF HEALTH AND HUMAN SERVICES

ADVISORY COMMISSION ON CHILDHOOD VACCINES (ACCV)

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Table of Contents

P R O C E E D I N G S

Agenda Item: Welcome and Chair Report, Magdalena Castro-Lewis, Chair

MS. CASTRO-LEWIS: I'd like to bring the meeting to order. Good morning – no it is afternoon, actually. Good afternoon, I am Magdalena Castro-Lewis. I am the Director for the Center for Community Services of the National Alliance of Spanish Health. I am the chair of the ACCV.

I would like to start by asking the commissioners and the ex-officio members to introduce themselves. I am going to start with Geoff.

DR. EVANS: Geoff Evans, I am the Executive Secretary of the Advisory Commission on Childhood Vaccines.

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

DR. HERR: Tom Herr, pediatrician, commissioner.

MS. HOIBERG: Sarah Hoiberg, parent advocate.

MS. GALLAGHER: Charlene Gallagher, I am a representative of industry.

DR. FISHER: Meg Fisher, pediatric infectious disease and a commissioner.

MS. TEMPFER: Tammy Temfer, pediatric nurse practitioner and a commissioner.

MR. SCONYERS: Jeff Sconyers, I am on the commission.

MS. DREW: Sherry Drew, co-chair of the ACCV and an attorney representing petitioners.

MS. CASTRO-LEWIS: Thank you. Any ex-officio members?

Tawny, will you please introduce yourself?

MS. BUCK: Yes, I am Tawny Buck and I am a parent rep to the Commission.

MS. CASTRO-LEWIS: Thank you. Thank you all and welcome to the 75th meeting. First I would like to thank Dr. Fisher and Dr. Herr for all your thoughts and your input into preparing the agenda for today. Also I would like to thank the staff for handing us the materials and the continuous support for the preparation of the meeting. Especially I would like to thank the advance receipt of some of the materials. I thought they were really, really good. I found them interesting and I learned tremendously by reading this document. So thank you so much for sending those.

In terms of the Chair Report, I attended the NVAC meeting as usual, with Dr. Evans, and I reported on the ACCV activities, including the workgroups that we have done in the previous period. I discussed the two workgroups that

we had and how and why we did not come to a conclusion or an agreement to submit any recommendations to the Secretary because I really think that those issues are still very important and maybe later we need to find another way of addressing them and perhaps, get to a point that we can do some kind of recommendations.

The Outreach Subcommittee met, as well as the nominating committee. They presented and it is in the books if you would like to look ahead of time, the process that they outline for election of the new chair. On that that will be tomorrow.

With that, I guess there is not much else to report so I would like to move onto the approval of the minutes.

Agenda Item: Approval of September 2009 Minutes, Magdalena Castro-Lewis, Chair

MS. CASTRO-LEWIS: Does anybody have comments. Somebody gave me some typos here that I have. Anybody else have any comments?

MR. SCONYER: I have a number of typos and I will just give those to you. I have one substantive item and that is on day two, which in our packet was page 10. This was in the discussion of the outreach workgroup report. The sentence says, "Mr. Sconyers noted that members of the

Commission had requested a copy of the Banyan contract after Dr. Evans explained that the contract had been submitted." I think there was significant frustration expressed by members of the Commission that the contract had not been provided either proactively ahead of time or in a timely response after that FOIA request went in. I would like to have the minutes reflect that – that frustration that was expressed at the time at the meeting.

MS. CASTRO-LEWIS: Thank you, Jeff.

DR. HERR: Where specifically was that? What page?

MR. SCONYERS: Page 10, the section dealing with the Banyan contract – second sentence.

MS. CASTRO-LEWIS: Any other comments? Do I have a motion to approve the minutes with the addition and the comments?

MR. SCONYERS: I so move.

DR. FISHER: Second.

(Minutes approved.)

MS. CASTRO-LEWIS: Minutes are approved. Thank you. I would like to pass the baton to Geoff with the report from the program.

Agenda Item: Report from the Division of Vaccine Injury Compensation, Geoff Evans, M.D., Director, DVIC

DR. EVANS: Thank you Magda, the baton is so passed. Welcome to the 75th quarterly meeting. To begin with, just going over your folders that you have in front of you, on the right side you will have PowerPoint presentations from my update, as well as the update from the Department of Justice and the CDC presentation. On the left side you will have a screen shots of the U.S. Court of Federal Claims website, for discussion when we get to the website discussion later, and two handouts relating to the Banyan contract. One is the HRSA's request for proposal, the RFP that you have been given previously, and the Freedom of Information Act response to Sherry Drew's request for the proposal submitted by Banyan in response to the RFP. Both of those are on the left side.

Moving on, in terms of the agenda for today we will have following my presentation, the update from the Department of Justice by Mark Rogers. Then Sherry Drew will discuss issues relating to transparency of the Vaccine Injury Compensation Program, and the website will follow that. The ACCV website discussion, as well as the court discussion screen shots of the webpage of the NCCVR(?) in tab six of your meeting books.

Following that we will have Dr. Ray Strikas give us another update on the National Vaccine Plan, and there

is an Institute of Medicine report summary of the plan and VICP excerpts of that plan are located under tab seven and eight, respectively in your workbooks. Following that, the day will end with updates from ex-officio members from CDC, NIH, and FDA.

Tomorrow morning we will start out with Sarah giving us an update on the Outreach Workgroup. Then Dr. Dan Salmon will discuss the H1N1 Vaccine Safety Working Group that Tawny has been part of – actually the overall NVAC Working Group has been following this along.

Then following that there will be the nomination election of the new chair and co-chair.

Turning to the statistics for the program, we will start out with claims filed and this is as of February 17th – which is about four and a half months into the fiscal year. As we have noticed recently, there have been two trends. In terms of the non-autism claims, there has been an increase significantly over the past year. If the rate continues at present, it will result in over 400 claims filed this year. The only time we exceeded 400 claims in the recent past, was in 1999, fiscal year 1999, when the deadline for the filing of hepatitis B claims, two-year filing deadline for retroactive claims going back

eight years expired, and we received 300 and some odd hepatitis B claims.

The other trend is that autism filings have decreased significantly over the past year. There have only been eight this year, which is a considerable difference from this time last year – 108 altogether, versus 8 so far.

I want to put this into a little bit of context starting with a 10 year overview – this is having to do more with the autism filings – you will see that there was a peak in filings in 2003 – several years into the autism proceeding process. Then that began to trail-down and then had a little bit of a up-surge we attribute to the publicity surrounding the 2007-2008 hearings, and now has recently gone down this past year after the - there were decisions in Theory One that were released in February of ’09.

If you take a look at non-autism claims, which is better viewed this way, with a five-year look back, you will see if you look at the red line, that influenza vaccine – I think that is clearly driving a lot of this. Influenza vaccine was added in ’05, and the two year deadline for the filing of older – meaning going back eight years – older influenza claims expired in 2007, where

several hundred claims were received at that point. Actually less than what we received of hepatitis B. Then it went down somewhat in 2008 versus that peak, and now and I think this is a trend that is going to continue for the sometime, we are seeing more and more claims coming in and that is mostly because of influenza.

According to data that I have for this fiscal year, 44 percent of claims are for influenza vaccines. And after influenza, everything else is less than 10 percent. HPV is nine percent, ETAP seven percent, DTaP is six percent, and everything else is less than five percent. So clearly influenza is driving this process now. With the increase in influenza claims since the addition in 2007, the majority of claims filed are now on behalf of adults – 57 percent so far this fiscal year. So we have transitioned to an adult program.

Just to give you an idea, a year or so ago, the top three vaccines that were being filed were – and I think in this order – DtaP, MMR and then HPV. Actually HPV may have been reversed – may have been the most at that point. So it really has changed with the inclusion of influenza.

Yes, Tom.

DR. HERR: On the influenza claims, whether they are children or whether they are adults, there is certainly

obviously a difference, but what kind of injuries are we talking about? Do we know?

DR. EVANS: Yes, we do. This is something we will be discussing more in the future, as I will talk about as we try to bring to the Commissions attention some of the kinds of information we are getting from our clinical reviews. But the predominant category clinically, are what are known as demylenating conditions. That is not too surprising because of the history with swine flu influenza vaccine in the seventies, and Guillain-Barre Syndrome is probably the most frequent of the demylenating conditions that we are seeing filed.

And there are other demylenating conditions; transverse myelitis is one, CIDP is another, and so on. Those are the more frequent ones. I think that you will see that in some of the data that Mark Rogers will have in terms of the stipulations. You will see that Guillain-Barre is the most frequent condition that you are seeing in the stipulations.

DR. HERR: Are we seeing that in injuries in children as well?

DR. EVANS: These are mostly adult claims and you are not seeing a disproportion number versus the very high numbers of influenza vaccines that were given. After all,

influenza is given in doses exceeding 100 million annually. This is just our skewed sample of the population. This is just the more frequent of the diagnoses that we see, but there are many other diagnoses also that can come in.

DR. HERR: I know we got into this a little bit at the last meeting on the question of number of doses and things like that. Do you know whether there are more doses being given to people under 18 or over 18?

DR. EVANS: I don't – my sense is that still the adult population is the predominant recipient of influenza vaccine. With the H1N1 program, children receive it in much higher numbers. Maybe Meg can expand on that?

DR. FISHER: I actually don't have numbers but I think that it is a moving target. So even if we had numbers for one year it is going to change. Just a few weeks ago the Commission on Immunization Practices – The Advisory Commission on Immunization Practices recommended now for everybody. So if it is recommended for a yearly dose for everyone, there is no question your numbers are going to go up. The temporal associations are going to be even more difficult to figure out.

I think there was a Lancet article and another article published somewhere about the background rates of things like Guillain-Barre, heart attacks, and a variety of

other things which are very likely to now happen in association with the entire adult population being immunized.

DR. EVANS: That is a good point because when I am asked this kind of a question and I give an answer that says demylenating conditions, GBS, bingo. Those can be cases that begin one day after, seven days after, three weeks or even a month or two after. So there is a whole variety of onsets. Some are more likely to be or could be, related to vaccine than others.

MS. BUCK: Geoff, have you received any filings on H1N1 cases that were jointly filed in NVITO'S(?) program as well. Because I understand that was sort of the recommendation that people obviously DICP had (?) statue of limitations so people are encouraged to file there first. There was such expectation that they would be dual filed in both programs while you sort of tried to figure out whether it was the H1N1 or the regular seasonal flu.

Tell me what you have seen with that?

DR. EVANS: The question was whether we were receiving claims for simultaneous administration or near simultaneous for both H1N1 and the seasonal flu. I am not aware of any double filings. Just to give you a quick update, the program that Dr. Caserta talked about, the

Countermeasure Injury Compensation Program, is still in the process of having a regulation published and becoming an active program receiving claims or receiving what are called "requests". But right now they are receiving what are called "notices to file", which certainly have the same power in terms of creating an opportunity for someone to pursue their injury. I am not aware of any double filings at this point.

MR. SCONYERS: Geoff, as the program really transitions to become one that has a preponderance of adults, I was wondering if you could comment – and maybe this is for Mr. Rogers – I am not sure who would know and you may not know – whether there is any appreciable difference either in the injuries that are claimed for the amounts that are awarded as between claims for children versus claims for adults under the program?

DR. EVANS: First of all, let me point out that the program has been receiving claims on the basis of adult injury since the beginning because we have been covering rubella vaccine, which is given to both health care workers and post-partum mothers. So we have been receiving the muskeleton condition, arthritis, and so on for a number of years. With hepatitis B that was also predominantly an adult vaccine injury situation.

MR. SCONYERS: My question really grows out of you and Mr. Rogers both, having noted that the program is largely becoming a program for adult claims and that is why I am asking the question.

DR. EVANS: I assumed that. We do have some experience with that and those are clearly some of the more serious claims having to do with adults are clearly different than a child who has a severe reaction to a vaccine and has say, encephalopathy and seizures and has a profound care needs versus adults that have different kinds of conditions. So we do see that kind of different pattern as we look at these cases. But some of the adult cases can be very severe, too.

DR. HERR: One, I hope, last question for the moment. Digressing again back to the Countermeasures Injuries Protection Program, do we have any idea how long that program will be running? You are saying that they are just sort of getting organized now and this vaccine period is going over soon. Hopefully we will be prepared enough so that we don't get stuck with another unexplained or unanticipated vaccine in the near future.

How long is this program going to be available for people for things that are happening maybe at this time?

DR. EVANS: The Countermeasures Injury Compensation Program covers the H1N1 vaccine. It also covers the antivirals that have been declared by the Secretary relating to the H1N1 virus. It also covers the anthrax vaccine, small pox vaccine, and several other countermeasures that could be possible for a bio-terrorism kind of situation.

The program is here, it is permanently authorized and it will be available for the next hopefully, not for many, many years to come, next pandemic that might be at issue.

DR. HERR: That is going to be really sort of a potential problem. Right now we are not seeing any active activity or current activity on those other issues other than the H1N1?

DR. EVANS: We don't know. There have been no requests received – if I understand your question correctly – there have been no requests received for some of the others. The upcoming flu season vaccine is going to have the H1N1 as part of it and it is to be a trivalent vaccine so that will be covered by our program.

DR. HERR: Right, but there are currently no major anthrax threats that people are receiving treatment

for at this time, et cetera, et cetera? The only one that is being currently worked on is the H1N1.

DR. EVANS: Right, but the anthrax vaccine is given to military personnel so there is still –

DR. HERR: So I am corrected.

DR. EVANS: Any other questions? Okay, moving on. In terms of adjudications, this is in your workbooks, the only trend is we are a little bit less than last year at this time. I don't know if I can contribute that to the government closings and the weather and everything in this area, but at least at this point we seem a little bit less than the rate for last year.

First of all, the awards. We have the breakdown that we talked about previously. Again, relatively small numbers, but you see settlements is still the dominant way that compensable claims are paid through that mechanism. Concessions are up a little bit and court decisions are up a little bit, but what meaning this has I don't know. But this is where things stand four months into this particular fiscal year.

In terms of awards, despite the fact that we are a little bit slower on adjudications, we are actually on pace in terms of awards. If my math is correct, we may exceed $100 million in outlays annually. I had 106, based

on the figure of nearly $40 million to this date. This is something again, we will see how that ends up.

MS. HOIBERG: Geoff, is that $37 million total amount – the total amount of money per the 52 claims that were –

DR. EVANS: You mean the adjudicated claims?

MS. HOIBERG: Yes.

DR. EVANS: No, historically there is always a difference between what is adjudication and the aware. There is always a difference in time so they never correlate that way.

One of my favorite slides is of course, is the Compensation Trust Fund and it stands at $3.225 billion right now. For those that follow this, for these four months it seems like that it is not quite at the pace that it has been in the past but I don't know that this reflects the revenues that come in from influenza vaccine or not. We will see what it looks like in the next report.

In terms of significant activities, as Magda stated, we both, she and I, went to the National Vaccine Advisory Committee Meeting in early February. I gave an update on the program, as did Magda and her role as liaison.

Just last week, I attended in Atlanta, the Advisory Committee on Immunization Practices Meeting at CDC. I should tell you that there was a familiar face around the liaison table. If you have ever been to ACIP, there are several dozen liaisons, Tammy Tempfer, our Commission member, was last minute stand-in for NAPNP, which is the National Association of Pediatric Nurse Practitioners. I don't know if you want to say anything about the meeting Tammy?

MS. TEMPFER: Just that I found it really interesting. I have always wanted to see that level of expertise in one room. It was just impressive to see the way that they look at every vaccine, the amount of time that goes into it to really look at a cost/benefit in everything. It was really a great experience.

DR. EVANS: As Meg mentioned, the big news that came out of that meeting was that at long last, the AICP has recommended to CDC – again, it is not official yet – that this upcoming flu season, that everyone six months and older, it is now recommended that they receive an influenza vaccine.

DR. FISHER: And the other thing was the new pneumococcal polysaccharide.

DR. EVANS: There was a new license Pneumococcal 13-valent polysaccharide vaccine. Actually, I think Marion Gruber is probably going to mention that. That is already part of the recommendation for ACIP. It is already part of the recommendation and covered in our program as a routine use in children.

DR. FISHER: Right, although there will be catch-up vaccines so there actually will be an extra dose recommended to enhance protection amongst certain groups. So although you are right, it is not a different vaccine, it will have a little different schedule – at least for the first year.

DR. HERR: This may go along with the other release from NVAC on vaccine financing, but do we know whether there was any discussion at that meeting about insurance and government financing of the new vaccine because it will be more expensive than the current Prevnar? Do we know whether there has been work with the insurance companies, as well as the VFC and the government, to provide that vaccine when it becomes available?

DR. FISHER: In the sense that this is a different new licensure of a vaccine and all of that happens, but it is in different people's interest to have it go through move quickly or more slowly. But, yes, every

effort is made to have the coverage be effective as soon as the recommendation is effective.

DR. HERR: That is one of the frustrations we always face is something comes out, it is very dramatic and it is very important for the kids and their coverage, but somebody doesn't cover it, VFC doesn't have it yet.

DR. FISHER: Well, VFC may not have it, but it is automatically covered by VFC as soon as the recommendation goes through. That actually has been a big advance.

MS. BUCK: I need to jump in and remind you all that you have folks participating on this phone and they don't know who is talking. You need to identify yourself. It is better for them to know who is making the comment.

DR. HERR: I am sorry Tawny, that was Tom making all those crazy things. But also thanking you guys at NVAC, for that work on that finance piece.

MS. BUCK: The good news is I can hear most of you. Dr. Evans is a little hard to hear – the rest of you are coming through well.

DR. EVANS: Okay, just finishing up my portion – this is for the telephone audience. In terms of points of contact, you can write the program at 5600 Fishers Lane, Parklawn Building, Room 11C-26, Rockville, Maryland 20857. The telephone for information about the program is 1-800-

338-2382, and the internet address is http://www.hrsa.gov/vaccinecompensation.

Those interested in providing public comment or to participate in Commission Meetings are asked to write Andrea Herzog, c/o of the address I just gave to you – Parklawn Building, Room 11C-26, 5600 Fishers Lane, Rockville, Maryland 20857. Her phone number is (301)443-6636. She may also be reached by e mail at aherzog@hrsa.gov.

With that, that ends my presentation. Thank you.

MS. DREW: Excuse me, Geoff, the number you just spoke as Andrea's number is different than the one listed. I think you gave a wrong phone number.

DR. EVANS: 6634. Thank you for point that out. Anything else? Yes, Jeff.

MR. SCONYERS: This is Jeff Sconyers. Geoff, I was looking at – I obviously had too much time on the plane – I was looking at 5.2 in our book, which is your list of claims filed or compensated or dismissed by vaccine. I was struck by several of the vaccines and what seemed to me to be a relatively low rate of resolution for those claims based on what I would have expected. I tried to in my head, account for fairly recently filed claims that would not necessarily worked their way through the system, but as

I went down the list just comparing the percentage of claims I sort of see as dealt with or relatively mature vaccines, compared to some of these. The DTaP, the DTaP, Hep B, IPV, I know that is not a very big one. The TD, the TDAP, the Hep A and Hep B, the H flu, pneumococcal – although maybe that is too recent, MMR varicella, another one that is too recent.

Those all seem to have a relatively low rate of resolution compared to the other ones that have been covered for some time. I wonder if there is any insight you can offer on that?

DR. EVANS: Some of the ones you mentioned towards the end are more recent vaccines. I know with hepatitis B, the bolus of claims that were received at '99 when that two year period expired, those were put on hold for a number of years. In fact, the court really did not begin adjudicating them in any active fashion until '05 or '06, is my understanding. So, clearly for that. That is one of the more significant vaccines.

MR. SCONYERS: Yes, that is the chunk in there.

DR. EVANS: Absolutely, there was a very long period of delay.

MR. SCONYERS: I had forgotten about that. I have one other question on this table. The last category

on here is unspecified and there are two compensated unspecified claims. Can you explain how this program can compensate two claims for an unspecified vaccine?

DR. EVANS: That is a good question. I will get back to you on that in terms of – certainly when the court - when it decided this or whenever the process went through, there was a vaccine name that we will tell you. We will find out why it is not specifically named.

MR. SCONYERS: Thank you.

DR. EVANS: Any other questions?

MS. CASTRO-LEWIS: Thank you so much, Geoff. Now we move to the report from the Department of Justice. Mr. Rogers.

Agenda Item: Report from the Department of Justice, Mark Rogers, J.D., Deputy Director

MR. ROGERS: Good afternoon. I am Mark Rogers, to speak for you from the Department of Justice.

On personnel, I think I mentioned to you the last two meetings that we were hiring two attorneys. We finally made those selections and they are in the pipeline. We hope to have them by the next meeting. We have one Assistant Director who is on extended duty in the Congo, Vince Matonoski. We have, one of our attorney's on a

detail to another section at Justice, who should be back within the next couple of months.

On the statistics, I wanted to reemphasize that we have a different timeframe from HHS. Our goal here is to give you a picture of what we have seen in the litigation process. Our timeframe is roughly from one ACCV meeting to the next, so if you are looking at the macro statistics, I would rely on HHS. If you want a quick snapshot of what has happened recently, you will look at ours. We are seeing the same things. We are looking at the same data so there are no real surprises here.

We have tracked 91 petitions filed, and this is from the last ACCV meeting. So we don't have a month of time that HHS was reporting. We counted 4 autism cases and 87 non-autism cases. We are also seeing more adult petitions than for children.

With Dr. Sconyer's question –

MR. SCONYERS: Don't promote me, please. I am just a dumb lawyer.

MR. ROGERS: Good for you. You have a Juris Doctor, don't you?

Your question about the difference and damages between a child petition and a petition for an adult, it is a good question. Of course it is the same Act, so we have

the same standard for a large part of the damages. For future costs, medical costs, all things being equal, the award will be less because we are predicting out over a reduced life expectancy. That would be most notable in a case where residential facility care was appropriate. That annuity to fund that award would be much less expensive than for a child. Ordinarily, in that kind of case, the most expensive by far, component of the awards. That would weigh in favor of a less expensive compensation award under the Act.

On wage loss however, it can go either way. For a child who files a petition under the age of 18, there is a formula. That formula is pretty predictable. I won't tell you what it averages because I don't know exactly. It is around half a million dollars - $450,000, to purchase an annuity to fund a wage loss award where the Special Master finds there has been a total loss of wage earning capacity for a child under the age of 18. It is based on a formula that is generic.

For an adult however, we have to do an actual wage loss calculation. So the award for a physician who is injured, is going to be much higher than for an autoworker – for lack of a better example. And for an adult who is in a high income – a job of that nature, that award could be

enormous and some of them are. So there will be variability there. Of course for a death claim, they would be identical. I hope that addresses that.

MR. SCONYERS: Thanks, Mark. It was really thinking about wages that made me think about the potential difference between child and adult claims.

MR. ROGERS: The short answer would be it would vary a great deal with an adult claim and fall into a very predictable – great deal of predictability on a child's claim.

Total petitions filed – the adjudications. We saw 33. Sixteen were compensable. We counted four concessions – which is more than we saw in our last snapshot. Twelve were not conceded and were resolved, as you see there, with nine settlements. Two decisions by the Special Master, and one proffer. The proffer being where both sides submitted evidence that the Special Master then accepted as dispositive of the level of damages. That is the kind of case where you would see that.

We saw 17 cases determined to be non-compensable; 8 were autism, most of those would be withdrawals or dismissals for jurisdictional reasons – untimely petitions.

If you compare the compensable with the non-autism compensable cases, you have about the same ratio that you saw in HHS's numbers.

You have the glossary of terms that you all have appreciated. I would just note that conceded by HHS, there have been a few more of those than the last time we met.

So on our chart, we had a few more cases move down the right side of that chart. With a conceded case in virtually all of them, you then move onto a settlement of damages where HHS concedes that the injury is vaccine related; we then move into the damages phase of the proceedings. The option down the middle is by far the most common and that is the parties either settle the damages or submit a proffer, on the right side there, where they agree to what the evidence demonstrates.

On autism, for Theory One, the movement in the case has been the development of the briefing before the Court of Appeals for the Federal Circuit. We had the decisions before the Court of Federal Claims the last time we met, since then we have had the two appeals filed in Cedillo and Hazelhurst, and it is still in the briefing process.

For Theory Two, nothing has changed since we met. The cases are still pending before the Special Masters and

we are waiting for their decision, which could come any time.

DR. HERR: Is this a typical lag?

MR. ROGERS: No, it is much longer than usual because of the voluminous records involved. If the decisions on Theory One are an indication, I am speculating here, but the Special Master's are working towards a single release of the decisions on the same day. So they would, I would speculate, wait until all three cases are ready to be published and then they will issue them. That takes time and the slowest case kind of – the others are on that schedule.

Appeals, we have the two new ones, Riggins and Masias, both involve attorney's fees and cost. We have had three decisions by the Court of Appeals for the Federal Circuit – Hocraffer was the a case where the Special Master had awarded $5,000 in damages and the appeal related to whether it should have been more. It was affirmed by the Court of Federal Claims, and here it is affirmed by the Federal Circuit.

Wilkerson was a statue of limitation's case. The Circuit published a decision in that case, affirming the decisions below that the case was untimely.

Moberly was an entitlement decision that was affirmed by the Circuit in favor of respondent. Moberly is an interesting case – I would recommend it to your reading – because it addressed an issue that – you had a presentation on here two meetings ago, I believe. If you recall you had a law professor come – Professor Gray, and one of the issues she talked about was there was some uncertainty in the Federal Circuits decisions over whether traditional standards applicable to tort litigation apply to a cause in fact case. Moberly addresses that issue and finds that they do.

Moberly has a big asterisk next to it and that is that on Monday we received a petition for rehearing. That case is now on appeal, if you will, to the Full Circuit. When one panel of the Circuit hears and decides a case, that is normally the end of the matter. The losing party can petition to have it reheard by the Full Circuit sitting en banc. Those are very rarely granted, but it is asked for here and we will hopefully have more news on that the next time we meet.

MS. CASTRO-LEWIS: What is the proportion of percentage of appeals on a daily basis and how many of those are reheard?

MR. ROGERS: The question is give us some sense of the numbers on cases that are either affirmed or reversed, and more specifically here, the number that are reheard by the Full Circuit? As far as how many cases are affirmed or reversed, my sense is – I don't have the numbers, but most are affirmed. It is unusual for a case to be reversed, but it may be a fourth or a third. It is not unheard of – cases are reversed.

However on rehearing, that is very, very unusual. It is very unusual for the Full Circuit to decide to rehear a single panel – a three judge panel's decision. So that would be unusual.

MS. CASTRO-LEWIS: Kind of discouraging, then. Not for you but the petitioner.

MR. ROGERS: It will depend on how good the issue is, I think. It has happened – it is just very unusual. If I had to give a number, I think that it is less than – maybe one or two a year. We have never had one reheard by the Circuit Enbank in this program.

MS. HOIBERG: What does embank mean?

MR. ROGERS: Embank means the full Circuit – all of the judges sitting.

MS. HOIBERG: Magistrate or the actual federal?

MR. ROGERS: This is the Federal Circuit. When a case goes to the Federal Circuit it is normally assign to a panel of three judges and there are a bunch of them. When it goes before the Full Circuit, the Full Circuit has the authority to reverse a panel's decision. They also have the authority to look at all the different panel decisions on this issue and decide which one is right, which one is wrong, or reconcile them however they see fit. That is what petitioner's are seeking here.

MS. DREW: Could you just explain what the levels of appeals are?

MR. ROGERS: The Special Master initially decides the case. Then there is the right within 30 days to seek review by the Court of Federal Claims. The Court of Federal Claims decides the case, then there are within 60 days, a notice of Intent to Appeal to the Circuit. Take that decision up a notch.

If the party appeals to the Circuit, it is assigned to a three judge panel. There are more than 12 judges. They have some senior status, some active – they have a panel of judges from which they choose that three judge panel. The three judge panel decides the case and it is normally over at the Circuit.

From that decision, you can petition for certiorari before the Supreme Court. As an intermediate step, you can ask that the Full Circuit look at the case. You don't have to, but you can, and that is what these petitioners have done. If you are going with the odds, it is even more unusual for the Supreme Court to grant certiorari. That has happened once in this program with the Whitecotton case. Incidentally, with Whitecotton, there was a request for rehearing that was denied by the Full Circuit. Hence, we don't have any cases where the Full Circuit has decided, yes, we would like to take a look at this panel's decision and decide whether we are going to reverse that or affirm it. Does that help?

DR. HERR: Certiorari?

MR. ROGERS: Certiorari – yes, that is vehicle by which most cases go to the Supreme Court. It is a request that the Supreme Court hear the case.

MR. SCONYER: It is so pleasing to me to hear this discussion compared to how confused I usually am when talking about immunogenecity and vaccines.

DR. HERR: It is one of those "gotchas".

MR. SCONYERS: I actually knew part of what we were talking about here.

MR. ROGERS: The easiest way to look at it is like a stairway that you can take the case up and the losing party has the opportunity to try and take it up another step. In this case they are petitioning to take it up to an unusual step, and that is the Full Circuit hearing the case.

MS. CASTRO-LEWIS: So now the Cedillo case is in an appeal or it has been submitted for appeal. Correct?

MR. ROGERS: The Cedillo case, yes.

MS. CASTRO-LEWIS: What step of the ladder is it now?

MR. ROGERS: The question is where is Cedillo – the autism case. That is a case that has been decided by the Court of Federal Claims against petitioners and they have appealed it to the Federal Circuit. They filed their brief and we are filing – I believe we have filed our response. We are right on the cusp of filing it, as a matter of fact, this week.

Once all the briefs are in, this case are in this case will be assigned to a panel of the Federal Circuit – a three judge panel. We won't know who those judges are until the morning of the argument. Then that panel will have all the briefs, they will decide the case, they will

hear argument, and then they will spend a couple of months cogitating and then they will write a decision.

Once that decision is issued, it starts a time period for seeking a rehearing before that full panel of the Circuit or a request that the Supreme Court hear the case.

MR. SCONYERS: As I read this Cedillo amicus that we got circulated a head of time, it sounds like Snyder is not going forward on appeal?

MR. ROGERS: That is correct.

MR. SCONYERS: I see from your notes that the joint appendix has been filed on Hazelhurst. What is the briefing schedule there?

MR. ROGERS: You know I don't know. I happen to know that our brief – once the appendix is filed that is the last step because the appendix contains all the documents anybody is going to refer to in the argument. So, yes, we have an argument scheduled in Hazelhurst, Cedillo. We are filing the last brief. So it is a little behind in the pipeline.

MR. SCONYERS: Hazelhurst is fully brief and Cedillo is about to be fully briefed?

MR. ROGERS: Yes. Okay, we have cases at the Court of Federal Claims that have been recently decided.

The take away here is that about half our appellate activity pertains to fees and cost now. A big part of that is settling out the meets and bounds of interim fees; when are they appropriate, how much is appropriate, that currently is a significant item of litigation. The Hazelhurst case is scheduled.

This is in response to a request that you made about settlements. What this is is information that is drawn from the stipulation. What the stipulation is is another word for an agreement between petitioners and the Secretary, as to what the award should be in this case. It is an agreement to settle the case. Those stipulations all began with a statement of petitioner's position, that is they received this vaccine, they suffered this injury, and they seek compensation.

Then there is this statement of the Secretary's position which is, we have looked at this case and do not believe that compensation is appropriate. Then it says, nevertheless, we are settling our differences and settling the case.

What this information is we had a paralegal take each stipulation as it came through as it was filed, and drew the information out of petitioner's section, with the allocation – the initial allocation and the alleged injury.

A couple of caveats – warnings, if you will, that I have mentioned before. First of all, the Secretary may not agree in these cases that the vaccine was even given – that is an extreme case. More commonly, the Secretary may not agree that this injury occurred. It is even possible, not unusual, that the petitioner, through the course of the litigation, that the alleged injury morphed into something else – the allegation.

You have to take this information with a grain of salt. This is how the case began – the initial allegation. It is also possible that the Secretary did not believe that the case was timely filed. However, the common denominator is that the Secretary saw enough litigative risk in the case to decide to settle it. With all those caveats, the information is provided with the hope that you can view it and see trends, or for whatever purpose you would like to put it to.

Another thing I would like to emphasize is that this information is on the Court of Federal Claims website. That is the stipulations are put on the website so you can go look at those stipulations if you want more information or greater detail.

MS. HOIBERG: This is Sarah Hoiberg. The stipulations – these are ones that – these are the vaccines

that were blamed. These were the alleged injuries and thee have all been compensated or settled?

MR. ROGERS: Yes.

MS. HOIBERG: Okay. And this was just from the time of the last meeting till now?

MR. ROGERS: Yes. These are stipulations as they came through our office. Now some of them towards the end, probably are not posted on the website yet. So it is a snapshot in time. We will do this for as long as you would like to look at these. If you think this is helpful, we will continue to provide it.

MS. DREW: Thank you very much. This is exactly what we have been asking for.

DR. HERR: These or these?

MR. ROGERS: They come from different time periods. I just couldn't guarantee that. Overtime, yes.

DR. HERR: This is your last time period, 33. Maybe I counted wrong – it is 32 or 33, if you look at both of these pages.

MR. ROGERS: They are roughly going to be the same. The reason I am a little reluctant is I have different doing this. The paralegal who did the stipulations – these were just on the cusp of being filed.

Whereas, I believe the other statistics – those would depend –

MS. HOIBERG: I have another question. Is there anyway of finding out how long – like when they were filed till when they were compensated? Like what time period – like it was filed in ’05. Do you understand what I am saying?

MR. ROGERS: Yes. Yes, we can do that.

MS. HOIBERG: I would like that.

DR. SALMON: Can I ask a question? Are these columns connected? In other words, can I read across a row. So is the influenza associated with the muscle pain, soreness, paralysis and Transverse Myelitis or are they not? Can they be read as a row?

MS. HOIBERG: Yes, influenza causes muscle pain, soreness, paralysis –

DR. SALMON: So they do correspondence. It is not just a list of vaccines?

MR. ROGERS: They do correspond, yes.

DR. GIDUDU: Did you see any cases of multiple injuries beyond these few linked to a particular vaccine?

MR. ROGERS: The question was did we see multiple injuries? I assume you are reading that here? With any other vaccine? What that would have come from is a

petition that was filed where we could not gleam a specific injury from the petition. That is what goes into the stipulation as what is in the initial petition.

Normally in a case like that, through the litigation and investigation of the case, the parties would have honed in on – would have some greater detail than that, but it just wasn't apparent on the petition. What we are trying to avoid here is making a project out of each and everyone of these of investigating them beyond what is in the paperwork because from a time management standpoint, greater particularity would mean going back to the attorney and making a project out of it.

I guess to answer your question, I don't recall any other cases like that.

MS. HOIBERG: I was just looking at some of the stipulations and under influenza on the second slide, it says ADEM. What is that?

MR. ROGERS: That is Acute demylenating encephalomyelitis --

DR. FISHER: Acute disseminated encephalomyelitis.

MR. ROGERS: Okay, there you go.

MR. SCONYERS: I just want to thank you for providing this information. Especially, for providing your

slides ahead of time. It was helpful to be able to read through. You provided a wealth of detail and I know it is a lot of work. You have been extremely responsive to our many unreasonable requests and I really appreciate you doing that. So, thanks. I would love to see our other presenters providing their slides ahead of time like you do.

MR. ROGERS: You are very welcome.

MS. BUCK: Mark, I would like to second what Jeff just said. I know that this stipulation information is something that is a direct response to requests we have made and just want you to know how much I appreciate the time spent to pull this together. Thank you.

MR. ROGERS: You are very welcome.

MS. CASTRO-LEWIS: Okay, thank you so much. Tawny said what I was going to say, thank you so much. We will see you again.

Okay, so Sherry is going to talk on the transparency of the National Vaccine Injury Compensation Program.

Agenda Item: Transparency of the National Vaccine Injury Compensation Program (VICP)/ACCV Webpage, Sherry Drew, J.D., ACCV Co-Chair

MS. DREW: Good afternoon, this is Sherry Drew. As Magda just said, what I would like to do more than anything else is to start a discussion. I am not going to make a presentation, but I want to start a discussion. I have two sections, you will note, in the agenda. The first one is on transparency and the second one is on our web page. I think the two things that we have there are sort of interconnected by improving maybe web accessibility we can conquer some of the transparency issues efficiently.

Maybe some of you have some insight than I do and somebody else that I have been speaking to, about what can be done on the internet. If you do, that would really be something that I think we should talk about. This may be something that we ultimately want to have a work group work on. I would just like to have some input from the rest of the Commission.

Basically we have here HHS, which communicates to us, and really by communicating to us at a public forum, I believe they are communicating to the public. We also have HHS, who runs a program in which they are – or a court program, where they are defendants. So there is sort of an inherent – I would not call it a conflict of interest, but there is probably a need for them to be more open, more transparent, than some other party that is not in a

position where they are running a program and they are defendant in that program.

I would like to think what we might do and perhaps you disagree, but I think they kind of have a greater burden to the people that they are here to serve. Which isn't us – it is the public – because they are in that position. They are sort of mandated to do a certain amount of public outreach, assistance to the public.

My concern has been many things, including as recently as this week the article in Pediatrics that was put in your blue books, I saw that in my local newspaper with headlines saying that one in four parents believe unproven vaccine autism link, but most do what the doctor say is best. So in the headlines we are seeing that one in four people are saying that they believe there is a link to autism.

I don't want to encourage that kind of thought if it is not correct. I think that openness here may be a means to dispel what may or may not be correct.

So, get into transparency – things that have bothered Commissioners have been things like our outreach program, the IOM contract, things that haven't been presented to us in advance. I would like to see if there is some way of getting better advance notice for us as

Commissioners, and also to get better notice to the public. This may be as simple as a website or a blog – that is not really the word – I don't know what the correct word is. Something where we have all the material that is provided to us at every meeting, available at the click of the mouse for anybody who may be wanting to either listen into the meeting or just read the things that are presented to us.

I don't know how to do that but I bet somebody here either knows how to do it or has available someone who knows how to do it. Mark Rogers mentioned to day that all of the information that he provided to us – and a little more – there would be the dates that Sarah asked for, are available at the Court of Federal Claims website. I understand that Geoff Evans wasn't even aware of that until he was informed fairly recently that you can go to the Court of Federal Claims website and actually ready all of the decisions – both published and unpublished. I am sorry if I am mischaracterizing that but I thought that that was what Geoff informed me.

DR. EVANS: I did not know about the stipulations but I certainly know the decisions have been on the website for many years now.

MS. DREW: Okay. I would like to talk to all of you about what we can do to make our own website, the

ACCV's website, more interactive, more accurate, more all encompassing. Whether it should include links to other websites. I would also like to see everything available to us, available to the public. I would like to see all our future meetings included as soon as they are scheduled. Our agendas up timely. If we can do it better than timely – as quick as possible. Maybe we should have deadlines for when things are suppose to up and kind of promise the public that we will have the minutes from the last meeting up three months later, two months later, whatever is possible and available to us.

With that said, I know that Sarah had some comments to me earlier and I don't know if she wants to jump in now or somebody else would want to do that?

MS. BUCK: Actually I have a quick comment. Speaking of all of this, the call in number on the website is incorrect. I am hoping that maybe somebody can fix it at least for tomorrow's meeting. I have been getting e mails all morning from people wanting to know what the number is. The number on the link on the agenda is right, but if you just go to the website page for the upcoming meeting, that phone number is not correct.

DR. EVANS: Thank you, Tawny. We will look into that. We were not aware of it that there was a difference.

MS. HOIBERG: This is Sarah Hoiberg. I just wanted to kind of reiterate what was said by Sherry. I guess that when I came on the Commission I felt that maybe I was going to have more – be privy to information more about like what was going to happen. We are here to advise the Secretary of Health and Human Services on the VICP. I feel that I don't have any more information than that of the general public. Programs are started in our name, without our knowledge. The IOM was a huge kerfuffle and I felt – I was very upset by that. And even then with the outreach – that was started and it wasn't even really what we wanted. But the way it went about was the way you planned it.

I am not asking for you to ask permission because I know that is not what you have to do, but I feel that if we are suppose to advise we at least need the information ahead of time.

I was also very appreciative of all of the information that was given ahead of this meeting because it did gives us time to read it and at least have some idea of what was going to be presented. But I would like the information, like Sherry said, to be on the website so that people who are on the phone can follow because it is very difficult to follow conversations on the phone and not have

the same slides that everybody else has. I found that to be true when I was on the phone last meeting and I did not have my blue folder so I did not have a lot of the information that was needed. I feel that needs to be provided to us.

MS. BUCK: Is it a realistic request – I know I think with NVAC, many of the PowerPoints are posted on website at least the day of the meeting or real soon once they have been presented. Is that something that is at all possible for us to do? Like I got PowerPoints early for Mark's presentation and I got the ISO one – some of them came out early. I think it would be really helpful that in addition to the link to the agenda in the call in information, that those are available. Is that an option with the tech people that you have in your department?

DR. EVANS: I don't know the answer and a lot of these are very good suggestions and we will look into it and get back to you. I don't see why it would not be but if we have the PowerPoints generated in enough time – I know for NVAC, it is a lot of the agency representatives get their PowerPoints probably – and Dan would probably know better than I do – how much earlier they get them to your office.

DR. SALMON: It is something that we have really been trying to work on. It is really challenging because you have the issue of people getting their presentations far enough in advance, which sometimes is an issue of how busy are but often it is also an issue of them having the data or waiting for the data and the information so it is up to date. There is also issues of what can be posted and it has to be compliant and there are some regulations that others in this room probably know better than I, but basically tables and figures are really tough because they have to be understandable to somebody who can't see so they have to be described.

Then there are the issues of posting on a government website, which isn't the same thing as someone updating their own website. It is something that we have been working on. It takes a lot of effort, not just on our part, but a lot of cooperation from the presenters because ultimately we are dependent on the people making the presentations to get into us in enough advance notice.

It is not as easy as it might seem I think is the simple answer.

MS. CASTRO-LEWIS: What about a webcast?

DR. EVANS: Again, all good questions. I will have to get back to you. I am just going to sit here today

and listen and defend less and have open ears, - I mean every agency has a certain IT quality configuration level of excellence or performance that they have. Tammy and I were just in Atlanta at the ACIP, where we are in this communications building that is set up for huge meetings and webcast and so on. That is a level of performance that has actually just been achieved over the past couple of years. I don't know what FDA is doing in terms of its meetings, but something we will talk with HRSA and see if we can at least get PowerPoint presentations in a timely basis, for example, for the meetings. Webcasting is something that I think –

MS. HOIBERG: there is also Skype. I a lot of people do meetings – especially Commission members could call in and you would have our little faces there. I guess my question is at the end of all of your presentations, Geoff, you give a contact for Annie – public questions/public comments. I don't know how many people actually – if anything is sent in ever. But if there is a place on the website where the public – and again, it is probably not going to be able to happen on the government website. There is probably going to have to be something that is open on the side, that we would be able to have people write in and get their public comments because a lot

of times we have had issues with people on the phones that have been in que to ask a question – not a question but a comment – and they haven't been able to because they get cut off or there was just technical difficulties.

A lot of times the public also has questions but because they are not allowed to ask questions because it is just comment on the phone, if they had a question they could write in and maybe we could possibly address that in the meeting, if it was appropriate. Or if not we could then send them a response to their question personally.

I really – you know my heart is outreach, you know that that is something has been just very near and dear to me. I am hoping that with all the information that Banyan is gathering, that they are going to be able to create a program that is going to make our program more user-friendly.

DR. FISHER: Meg Fisher. I think that opens a very interesting possibility if we could – first of all, forgive my ignorance, do we have a website?

MS. DREW: The ACCV has a website that is under HRSA's – it is a subsight of HRSA.

DR. EVANS: Well, no, it is actually the ACCV is -- the Division of Vaccine Injury Compensation has a website as being a program within HRSA – the National

Vaccine Injury Compensation Program. On that web page, there are pages that are a part of it – if you go down the left side you click on various links that will get you to statistics, vaccine injury table, ACCV. The web shots you see are for the link that will produce the page that has the Advisory Commission on Childhood Vaccines, which has the minutes and transcripts and the agenda and so on.

So there are a better part of a dozen different links on our web page, which is part of the HRSA website.

DR. FISHER: Can you bring it up? Do you have internet access on there?

DR. EVANS: No, we do not. We have web shots – it is in our meeting books.

DR. FISHER: That is the Federal Claims Court.

DR. EVANS: It is in our book that we show the section of our website, VICP, Vaccine Injury Compensation, having to do with the ACCV.

DR. FISHER: Got it. I'm sorry after that relatively interruption, so going back to Sarah's point, it would be – I think it would be an excellent outreach technique to have a contact us application where you actually could field questions. It would probably take a little – we would have to look at the questions and go through them and decide which ones, but even the people who

are making the agenda might be charged with part of that. I have no idea what kind of response we would get.

MS. HOIBERG: The outreach, because I am not doing anything right now – I don't really have anything to do as the chair of the Outreach Committee since Banyan has taken that over, I volunteered to at least read the questions and then be like, Geoff, Elizabeth, whoever can answer the question. I would be absolutely willing to even have a Facebook page or a blog of some sort, that would allow us to be more in contact with parents. I have so many parents of vaccine injured children and autistic children and all that kind of stuff, that have questions and genuine concern. I know that Tawny, that is her as well, with lots of the people she deals with. I am glad you are in favor of that.

DR. FISHER: I think it is a good idea. Just on Sherry's point, our minutes are in here. There is a little bit of problem with posting minutes before they are approved just because of some of the changes that might be typos and who cares, but might be substantial changes which you would not really want several different sets of unapproved minutes posted. That might be a slight cliché.

I think it would be nice if we had meeting materials. It seems like it would not be that hard to

incorporate onto this very nice website that I just for a second, forgot existed.

(Laughter)

DR. SALMON: This is Dan. I think could provide a little bit on insight into the webcasting issue because our office has been struggling with this recently. We have never webcasted a NVAC meeting but we have webcasted a couple of the NVAC Safety Working Group meetings. We did so because of a desire to be transparent and also because the largest room we had in our building, the Humphrey Building, we had more people signing up to pre-register for the meeting than the largest room that we had available. So we had a desire to try and accommodate that. So we webcasted a couple of these meetings.

The challenge is for it to be of any use you need multiple cameras because if you have one camera, either you are pointing at the screen, which makes very little sense because you might as well just look at the slides. Or it is back here looking at everyone, in which case you can't even see the screen or see who is talking. So you end up needing several cameras. It is really expensive. I mean it is really expensive.

We did it twice and then we looked at how many people actually watched it and the cost. That is probably

not the best measure because transparency isn't just for those number of people – it was really expensive. We discussed it with the Safety Working Group and they felt that having the slides available and an audio feed, gave you so close to as much access as having three cameras and a web cam. The cost was so much less that we felt that that was a better use of our resources and taxpayer dollars.

So that is our experience for what it is worth.

MS. GALLAGHER: Hello, this is Charlene Gallagher. I just wanted to add that I have attended meetings by WebEx, where basically you only hear audio but the slides that are being discussed are up on your computer screen or if you are in the room, in the room. That is a lot cheaper than hiring camera men, et cetera, I think that is a doable goal under the present system and our budget, et cetera. I would urge us to try the first step first. Sort of start with the Volkswagon, work our way up, maybe we will get a Cadillac someday – who knows.

MS. BUCK: This is Tawny. I had a couple of thoughts that came to mind listening to your discussion from the phone. I think that clearly the most difficult way to be fully contributing at these meetings is lack of access to the PowerPoints during the meeting time. I think

that would be huge improvement if we can at least get the PowerPoints early enough to have those up so that people can follow along.

I am really sensitive to you know, kind of hammering on the issue of transparency. It is an easy thing to complain about and I think in order to fix it we have to have some very specific asks for what it is that we need. A lot of the things that I am hearing people ask for – a lot of it is actually there. I think that one of the things that would be very helpful is a more user-friendly website and maybe a little bit more time spent with the Commission in these public meetings, addressing where to find information, where you go on the Court page to get this kind of information – the stipulations that Mark showed us. If you live and breathe this world you figure that out, but most people – don't. I think it would be very helpful.

Additionally, on the roster for the ACCV, it has our contact information on there. I am not sure – I think that maybe just a link or a better page on the website, for points of contact information would be helpful. In terms of questions from the people that we represent, I think it would be good to identify members, for who they represent, and their contact information, and that tool is there if

people have questions. If the people that we are representing have questions for this Commission, then that is your role. They contact you, they talk to you, you bring their questions before the Commission, you deal with them. To me it seems like perhaps a lot of this is there, but it is hard to find because people don't know where to look. The websites are not terribly user-friendly, not only just as education for the Commissioners on where to find that information, but also a good evaluation on how to improve the tools that you do have to use right now at your disposal.

Then just some real common sense stuff like making sure that anything that is suppose to be sent early and correctly, would eliminate a lot of the issues in terms of that. That is just kind of my thoughts.

DR. EVANS: We will certainly take that into consideration. I want to remind folks that the Policy Branch that runs this Commission, also is responsible for responding every week to e mails that are from the public, as well as inquiries from the 800 line. They do a fair number on an annual basis, so that is ongoing. There is a link to the e mail on our website. This is there to begin with.

MS. HOIBERG: Geoff, is there any way that we could be privy to those questions and the input that the public is giving?

DR. EVANS: I don't know the answer to that and that is something that we will also get back to you about.

MS. BUCK: Quick point of clarification, once we have a meeting and PowerPoints have been presented, those are public – is that correct? And if we are contacted as Commissioners, for those, we can forward those along?

DR. EVANS: Absolutely. Everything that is distributed to the Commission members is public. What we are talking about – a lot of what we are talking about now is just facilitating it so that it is transparent, more accessible to the public, and with the technology that is available, even in the somewhat limited formula that we have here versus some of the other larger agencies, I think that is something that we could probably arrange. We will certainly look into it and hopefully have some more put together by the next meeting.

DR. FISHER: Meg Fisher. Can I suggest for an agenda item for our next meeting that you collect the feedback that you get from public comment or public questions? That may be an outreach that we are already doing that we are actually not even aware of.

MS. HOIBERG: While we are on the subject of transparency, the FOIA request that we filed. When we got the information – the stuff that came to us was all of the things that we already knew. I did not see anything different. Maybe I did not read it all correctly or what not, but I did not see any difference. There was a lot of stuff taken out – or what is that word – retracted.

MS. DREW: Redacted.

MS. HOIBERG: Redacted. So I did not really see the whole point of us having to file a FOIA if all we were going to get was the same information that we already had.

I guess in the future, I just want to know why as Commissioners we are not privy to a lot of the information. Why are we still treated as the public in that way? Do you see what I am saying? So for me when things are taken out it throws up all these red flags like what are they hiding, what is it that they don't want us to see? What is it that they are really asking?

I guess in the future – I don't want social security numbers and I don't want account numbers and all that, but I think that if – I wanted to see the full charge. I wanted to see their answer to it. I just felt like all the stuff we got was just so generic and it wasn't anything different, and we went through all of that crazy

steps to file the FOIA and the time we waited for it, and then it just ended up being nothing. I would just like for you to answer that.

DR. EVANS: Sarah, I don't know that it is fair to characterize as being nothing. What was redacted, which is a relatively small part – very small part of it, had to do with commercially sensitive information that was explained in the Freedom of Information Act letter that accompanied the correspondence back to Sherry Drew.

In terms of you – this is a trust response, but in terms of what you were seeking, the information you were seeking was still available in those documents. It was not part of what was redacted. So if you wanted to find out the charge and the methodology and all of that, that was there and it remains there and that was not affected whatsoever, by the FOIA Act.

Now you can either believe that or not believe that, but that is the case.

MS. CASTRO-LEWIS: There are two things, one I believe is the contract and the other one is the response from the Banyan Communication in terms of what exactly they were going to do. I think you are referring mostly to the contract side of it because I read the whole response, which in my terminology is a response to a proposal. I

realize that there is everything that they are going to do except for information that is private to the organization of the company trademarks that are submitting the proposal.

In a way I understand that because I do other proposals and when somebody calls me from Georgia and says, I would like to see your proposal and such and such that you got a grant. I said, I am sorry, I cannot provide you with that information because that belongs to us. It has a lot of information that is private to my organization that is our living.

On the other hand, I totally understand why these were not sent to us way before. I could see here what information was taken out that to me was not relevant, but the point is in terms of the transparency, to make it available to us in a more timely manner so we are not trying to discuss the outreach without really having this document telling us what they were going to do.

MS. HOIBERG: My whole thing was I did not understand why we had to fill out a FOIA as Commissioners. Maybe that is me being just a simple mom and all that, but I just did not understand why it was such a big deal and why it could not have just been handed to us. This is what they are doing, this is how they responded – why it had to be this whole charade of filling out a FOIA.

DR. EVANS: I do want to clarify one thing, you are members of the public. You are not a government employee in the sense that –

MS. HOIBERG: We are, we are special government employees.

DR. EVANS: You are special government employees but according to the FOIA rules – maybe Elizabeth may want to clarify, but my understanding is you are still treated as members of the public.

MS. HOIBERG: But we are held to very strict ethics and all that. You have all of our financial information.

DR. EVANS: As are we, Sarah. And I would also say that – I want to say once again, as I did last meeting, we have definitely heard the message that sooner than later is the way you would like to see things. We will do everything we can – certainly for any contracts in the future, to make sure that this is provided to you as soon as we can.

MS. HOIBERG: Okay, thank you.

DR. HERR: This is Tom Herr. I am not sure whether this would satisfy some people's questions or not, but I am just wondering, maybe it was mentioned but it went over my head, either it was before I was here and my head

wasn't here or I was still trying to catch up. But if when this contract was being developed or the concept for the contract was being developed, if the Commission had been discussed of what goals they would like to see with this kind of a contract, along with what HRSA's goals are, that may have been – some of the input into that planning may have been all that was necessary.

DR. EVANS: I know there were several workgroup meetings prior to this RFP being put out. We certainly had a very strong sense of some of the areas and issues that you wanted to see the program go forward with in terms of a communications plan. So that was certainly taken into account when we did this.

DR. HERR: But something a little bit more formal of just something saying, this is what we are looking at. We have taken into account things that you talked about and these are those issues that we think that you think are important. We are going to be working with Banyan on this or we are working with a couple of companies, we will let you know as the contract develops and what comes up of it. But this is just where we are going in response to things that you wanted, the Commissioners wanted to do. They may have been enough.

MS. CASTRO-LEWIS: Geoff, you indicated that you are going to look at all these comments and all these suggestions and you are going to respond to us. But I would like to suggest here is that perhaps you have a group of people, a working group or a subcommittee, whatever is the technical thing, to help you out with these and get together and see what is in reality that the Commissioners want – some kind of a modified dialogue, which is actually something that Sherry suggested at the beginning, to maybe have a working group respond to all of these.

DR. EVANS: We have one.

MS. HOIBERG: Yes, but you did not involve us.

MS. CASTRO-LEWIS: But this is not just the outreach.

DR. EVANS: I understand that. Outreach is communications. Whether it is outreach outside with our program, or whether it is vis-à-vis the Commission. So what I would suggest, maybe while Banyan is in the middle of its contract doing a lot of things right now, to see that go forward, is that one of the tasks that you could take on as the work group is to do this too, with us.

MS. CASTRO-LEWIS: I think what we are talking about and has been presented, is a little larger than the outreach, is transparency. It is like more open – it is

not just the outreach - the communication. You just used the word communication – it could go there – but outreach, not in the way we are seeing in communicating just to the parents about the program, which has been the focus of the outreach working group. I think what I am hearing is something a little bigger, more inclusive.

MS. HOIBERG: Yes, it is deeper than that and it is the communication to us as far as what projects are being worked on, what is our name being put on, what is the program doing, so that it is not just here at this meeting that we hear. A lot of the stuff that is presented to us is huge. The IOM – I know that is like beating a dead horse, but that at least smacked me across the face. I was like, what? What is this? What is going on? It just boils down to transparency.

Tell us what is going on. I mean I want to know personally. I would like to have some input. I know there are some things that I really have no business having input into, but at least if we are going to be involved in it at some point that we hear it before.

MR. SCONYER: I would like to make one point that I don't think has been made so far. That is I think the responsibility of each of us as individual members of the Commission. We are here primarily because we have been

appointed as essentially, representatives of certain constituents. I think when we come here it is incumbent on us to have done the work to know what our constituency's, or whatever portion of it we have access to, have in mind about the issues that are before the Commission.

I think we all need to come prepared ourselves, having thought about, considered and consulted with whoever we need to consult with, in order to make a contribution here rather than necessarily on being given the information somehow from somebody else.

There is a lot of information that does come to us. I appreciate that. I think you have already heard a couple of times today, as suggested that perhaps some of the things that come to us at this meeting could come ahead of time. I know that that is a struggle in getting presenters to produce things in time to be distributed. I have run many a meeting where that is a frustrating thing. It would be great to get it ahead of time, but we all have to do the work of reading and knowing what is going on when we come here so that we can participate in the meeting.

MS. BUCK: When we talk about transparency, I was thinking of it more in terms of the VICP operating transparently to the public. I think that when we have come forward with specific suggestions on information that

the public has been telling us they want to see – again, I go back to Mark Roger's presentation today where he includes the stipulations – it was a specific kind of request where there are issues regarding public trust in vaccines and there is a spotlight on the program in terms of that as well, and to address that in terms of having your process in the information that you do and can make available, easy to access and available, it is where I was coming from when I looked at the agenda and saw conversation about transparency.

I think there have been points made today that we have already raised in the past meetings, about specific issues that have come up that the Commission has felt that they needed to be more involved in. But I don't want to lose the bigger picture on transparency in terms of the program and what it does and how it operates, and the information that the public is asking for and needing to have and to process so that they can make their own educated decisions about what they think is going on.

MS. CASTRO-LEWIS: Any other thoughts? Any additional suggestions?

MS. DREW: No, other than hopefully the Outreach Work Group can get together with Geoff and discuss the web

page in greater detail after you have consulted with the people who know to do those things.

DR. EVANS: Yes.

MS. GALLAGHER: This is Charlene Gallagher. Can I just make one comment? I started working for a rather small organization 25 years ago. By the time I left the organization last week, it was rather large – that was about the seventh merger transaction that there have been – acquisition, what have you. I found that the larger an organization got, the harder communication is. I dare say that the Federal Government is larger than any organization that I have worked for.

I don't think that there is an intentional lack of transparency. Just the way Sherry, you noted that some things actually are available publicly on a web site if you know where to look, is I think, twisted into this whole conundrum. I don't think there is one simple answer but I believe that we can work towards clarifying where things are. But I have to say that I think that Geoff and his staff have provided me over the years, with a lot of information when I requested it and I have not been disappointed. Some timing issue – hey, I have those myself. The Freedom of Information Act is another federal

statute and whether Geoff likes it or not, has to deal with it.

So some of the issues that we have, he might well share our frustration but he doesn't get to make the call. Elizabeth has to tell us what the law says – whether she likes it or not and whether she thinks it can be clarified. Sometimes our issues are with congressmen who should be changing other laws that are getting in our way and not really the operation of a program.

I just wanted to say that I don't feel as though there has been any intentional lack of transparency in the program while I have been here. Although, perhaps communication has not always been ideal, as often happens in real life.

MS. DREW: I think you are perfectly right but I think that there are other things we can do and not necessarily terribly difficult things. We can include Andrea's e mail address on our web page. Those are the kind of things that I would like to see done. I would be happy to tell people include a link to the court's website- which can be not as user-friendly as other websites. It is a little strange to try to find some cases, but I would be happy to write up a little thing – go here and click on this and then you scroll here.

MS. GALLAGHER: Would you suggest that we have a group of people to make the list of the things that we think are immediately doable without getting the blessing of congress on changing laws? I know that there are certain things that you can't just post on websites and certain things that you can. I personally don't have any idea what they all are. If we could make the individual lists of what we would like to see and you sound like you have a really good list to start with, then we could have maybe Elizabeth or someone else, assess doability given present circumstances.

MS. DREW: That is really what we have kind of been gleaning out of the discussion that we have been having. Geoff and the work group will get together, but in the meantime during the next half hour when we are talking about this – if that the discussion goes on that long – or when you get home and you think of something, if you would share it with the work group and with Geoff, then I think we can all make some small doable improvements.

MS. GALLAGHER: Okay, I just did not know if you anticipated the work group getting back together to actually glean over the list and add to the list, et cetera. So you do and I fully endorse that and agree with that.

MS. DREW: Okay, thank you.

MS. TEMPFER: This is Tammy Tempfer. I just want to say that I think that a lot of great ideas that came up today – a really good brainstorming. I think Jeff Sconyers brought up a good point that we really could be more specific with our information – that there would need to be deadlines. Like we could get the minutes earlier if they were transcribed and went to the Commissioners and you said you would have to have any corrections back by a set date. We could actually get those minutes on the website much earlier, but we would have to do our work, get the corrections done and get them back, circulated among ourselves, and to get them on there.

I think the same with the agenda. The Agenda Committee, when it meets, there has to be a deadline. Like the agenda is going to be up a month before the meeting or something like that. Presenters the same thing – give them that deadline. I think you may lose some current data if you give presenters deadlines too far out. So I think you have to kind of weigh what extent you want the latest and get it on last minute or do you want an early deadline where you may not get as much current information that you would like.

I think we need to be more cognizant of deadlines within ourselves to really get that information out there.

MS. CASTRO-LEWIS: So it looks like just to kind of summarize, it looks like the Outreach Working Group will be in addition to what is already on the table. The outreach plan and the research will be discussing this whole issue of transparency and all the ideas that were here today. That is great.

The other thing is, Sherry, your next agenda item is the website discussion. Did you have something else or do you think that everything that needed to be – because we have the whole hour for the discussion of the website – so I am just trying to see how the agenda is going to be here now.

MS. DREW: I think that I have covered what I wanted to cover and I don't think there are anymore comments. If we come back after a break, maybe we could have a few more minutes in case anybody has thought of anything, but I don't know that we want to get too far ahead of the agenda because I think we still need public comment when we are scheduled to have public comment.

MS. CASTRO-LEWIS: Exactly, that is the point that we are an hour ahead. Okay, let us take a 15 minute

break – somebody suggested 30 minutes so let's take a 30 minute break and we will meet again at 3:20 p.m.

(Break)

MS. CASTRO-LEWIS: Now we have a report from Dr. Strikas on the National Vaccine Plan. I hope you had a chance to review the 300 pages that were sent to us and have your questions ready. That was great, 300 pages. So Dr. Strikas can you summarize the 300 pages? Thanks you.

Agenda Item: National Vaccine Plan Update, Dr. Ray Strikas, NVPO.

DR. STRIKAS: Thank you very much. I am Ray Strikas. I am from the National Vaccine Program Office and I have addressed this committee several times before about our work on the National Vaccine Plan, which dates back, god forbid, almost three years and will continue for a while longer. You have just the paper version of the slides and if you want an electronic version for some reason, let me know.

You also have received what is called the second image on the right here on the screen, and they are talking about what we should do to update the first National Vaccine Plan which was issued in 1994. It had not been updated until we began work on it in '07 and we are actually getting near the end and we hope to incorporate what comments we have received prior to now. We have done

that. I will show you the timeline, how we are going to proceed from here on out.

We are also supposed to incorporate the work that our department is doing on the Healthy People objectives for 2020 which will be released the latter part of this year.

So I will go over the current status of the plan, the timeline for completion, what the Institute of Medicine expert committee that our office contracted with to offer independent advice said about priorities. I think Dr. Evans has sent you some of that information, and the National Vaccine Advisory Committee, which advises the Secretary for Health and works with our office on vaccine policy issues, what they have been thinking about regarding priorities for the plan as well.

So this is a simplified schematic that I think I have shown many of you before of the vaccine system, or the vaccine immunization enterprise, as we talk about it. Things begin sort of on the left-hand side with disease surveillance, getting information developed on vaccines, vaccine research, manufacture vaccines, sell them, get them out, vaccinate people, which is sort of in the middle right. You may have adverse events. This is what you deal with, and then there comes the issue of vaccine injury compensation, and actually that arrow should go both ways – you get information about adverse events and you feed the information from the compensation program back to the

various programs that do safety monitoring as well as vaccination programs. SO we need to add a second arrow there.

Ultimately we would like to ends =up on the right side with high vaccination rates and protecting population health against disease, as well as avoiding adverse events and reducing morbidity and mortality.

The plan as constituted at present, and again many of you have seen the five goals in the current draft plan which is on our web site. The first four goals stem from the 1994 plane – develop new and improved vaccines; enhance the safety of vaccines and vaccination practices. That is the sole emphasis on safety and that goal int eh '94 plan it was safety and effectiveness of vaccines. Effectiveness now has been migrated to goal four.

Goal three is about communication, education and informed decision making. Goal four has a dual purpose, talking about stable supply of recommended vaccines and then improving programs to better use them to prevent disease disability and death.

And the last one was added to emphasize the US role in working with others on global prevention of death and disease through vaccination.

This is a timeline that I will walk through with you and that actually should extend backwards about a year before October of 2009, where we published in November of 2008 the draft plan that s still on our web site. We are

moving towards a second draft. We have addressed or looked at 466 public comments. We hosted three public engagement meetings. Also the National Vaccine Advisory Committee, February of 2009, held an open public meeting to discuss the plan as it stood then. SO all of that has been worked on and we were waiting until December when the ION issued its expert committee report, which you then have a brief of and I will talk about a little bit.

Taking all that information, what we are last waiting for is the National Vaccine Advisory Committee, with the double diamonds in the middle, having meetings early February in a conference call last week, to talk about what they view based on the IOM input and on their own input. And I will talk about their criteria for that input, what the priorities of the plan should be. The plan presently has five goals, 36 objectives, 140-odd strategies. We would like to do all those things but they are not all equally important.

SO what are the most important things that should be accomplished in the ten-year window for this plan? That is the challenge. The IOM has told us about that. I willmention those to you shortly. The NVAC is going to tell us about it.

Once that occurs we are going to take those priorities and measurements, what we call indicators – our contractor, Rand, indicated at the bottom – we will talk to some stakeholders further about their roles and about how

we should measure their roles. We will have another round of public comment once we issue the second draft. WE hope to issue that by early April.

With that input we will complete a final strategic plan by some time in the summer, and it is only a strategic plan. It says you should establish better mechanisms for vaccinating people, remove disparities from vaccination rates in adults, improve public health infrastructure for adult vaccination – these are examples of some things in there. But it doesn't say how we are going to do that and who is going to do what.

The who is going to do what by when and so on is the implementation plan action steps and that will begin this summer and we hope to complete it this year or shortly thereafter.

I have mentioned the Institute of Medicine several times. They met over a period of a year and a half from the middle of 2008 through the end of last year, issued their final report, which I have mentioned. And they issued a number of recommendations. This is pulled from their briefing document, which you have, some of the more salient or important recommendations, though we have taken them all into account.

Remember goal one in vaccine development, they agreed with us that prioritizing targets or vaccines for certain diseases is an important activity that should be done in a comprehensive way, which was not done in this

country. Vaccines have developed sort of ad hoc as what the industry thought was a good idea or if NIH funded something people went down that road. But it has not been done altogether and we have begun a process of discussion within the government how to do that and we will fold in private sector partners soon. So that process is actually already started.

The IOM said in subsequent plans, not in this one, address noninfectious diseases vaccines. There are vaccines in development or licensed for treating various cancers, in development for treating nicotine addiction, to try to prevent Alzheimer's disease, all very important steps in medical progress. How do we deal with those in the context of a national vaccine strategy? Well, our charter for our office talks about prevention of infectious diseases. It does not permit us to move afield, but it doesn't mean that the government and other shouldn't think about prevention of other things besides infectious diseases and how to incorporate those in some government policy is something we need to address, though this plan will not do that.

Vaccine safety – there was a strong feeling among the IOM committee members that a national research agenda – we've transformed the word to scientific agenda – for all federal agencies and stakeholders is important. SO we have embraced that and that will show up in the next draft of the plan.

The IOM felt we had a lot of useful information, the communications information, goal three, but we did not have an overarching strategy. SO can we articulate a strategy for communications?

In goal four they concurred that a stable vaccine supply, going beyond just stockpiling vaccines, is important. We have concurred and we will talk about other mechanisms for assuring supply. They use the words "eliminate financial barriers to vaccination." Some of us are not so sure you can eliminate them. We would like to reduce them and we talked about a 90 percent level – that is something worthy of further discussion.

We certainly concur that assuming an active role in the National Health Information Initiative, which the Recovery Act has issued a lot of funding for to state governments and health departments, is important in how we weave in immunization information systems in that process and that is something that we should embrace in the plan. It is not presently there but we will say more about it.

The fate of national health reform I don't pretend to know or be able to tell you about, but should there be national health reform, whatever it looks like, we need to be aware of what is in the legislation as it comes out and articulate that role in prevention and immunization, in particular, in this plan. SO how does that play a role in eliminating financial barriers, for

example, which is one of the main ideas behind health care reform?

Lastly, the IOM talked about global vaccine issues in goal five to support low and middle income countries' capacity to implement new vaccines, certainly something that is said but not as clearly as this statement in the plan, as well as providing expertise and resources to incorporate new vaccines at the national level for again low and middle income countries.

The last – actually they made it the first, but they called it goal six in the first set of recommendations that the IOM made was a very strong statement that the Secretary of our Department should actually demonstrate support for this plan by clarifying its prime role as "the" strategic planning tool applicable to all federal agencies with roles in the national vaccine program, including HRSA, CDC, FDA, NIH and others, and allocate resources necessary to insure robust planning and implementation with coordination by our office. We are still trying to get a read on this as to what we can expect from the Department The Secretary has been briefed about the plan and we are still discussing how to implement this language and what we can actually say about the role of our office. SO stay tuned.

I mentioned the National Vaccine Advisory Committee that looks at vaccine policy. It has reviewed the IOM recommendations, they have looked at the existing

draft of the plan, and they are trying to come up with what they think are the priority areas. They have used the following listed criteria to do that. HHS did the same thing in a process that dates back several months.

The criteria that NVAC used and HHS to some extent were feasibility, both financial and technical, potential impact of the activity on morbidity and mortality, strategic opportunity defined as likely to acquire and motivate multiple stakeholder involvement, something you could not do without a lot of partnership, and public salience, which is derived from our public engagement meetings. These were primarily five areas to do with vaccine safety, promoting childhood vaccination, better communication and education – those wew the types of things the public was interested in so they took that into account as well.

I mentioned one priority. Geoff may have listed others, but this is one that HHS came up with and we have discussed at length and we think is important. There is at least one other one, but this is one we think deserves attention and we will talk about it some more. By 2015 90 percent of both the public and providers should be aware, knowledgeable about the Vaccine Injury Compensation Program. I don't have baseline data for this. Some of you may have it, Geoff may have it, but we couldn't find any. We think this is something important to achieve and I would

like to hear your thoughts about that as a priority activity.

So that is the extent of my very brief review of a lot of documents but I didn't want to take up a lot of time talking at you. You have received a lot of material. Many of you have read it. And I talked about the plan before to this group, so I am happy to take questions or have discussion with you.

MS. GALLAGHER: I just wanted to start off by saying I have read the plan and I have to congratulate you and everybody who worked so hard to put that together because it is incredibly comprehensive and it is clear that a lot of time and a lot of effort has gone into it. SO first of all I just want to say thank you for all that work.

DR. STIKAS: Thank you very much on behalf of many, many people, Dr. Evans included.

MS. HOIBERG: The portion that you have on the actual program is very good. I found that it was very straightforward and reiterated again what the goal of the National Vaccine Program was. I would also like to congratulate you on that.

DR. STRIKAS: Thank you.

Certainly somebody found something they would like fixed.

MS. CASRO-LEWIS: I was very pleased also.

DR. HERR: It is way too early in the discussion of that because it is going to be planned later, but on vaccines and vaccine distributions and trying to increase the penetration, so to speak, if the government is going to get involved ni providing or thinking about providing the vast majority of vaccines I think we have to look at the experience of this past winter and year with the H1N1 vaccine. It was horrendous in the sense of who got the vaccine, when they got the vaccine, what the supply was.

Even if we look at the Vaccines for CHildern Program, the private practitioners, there were a lot of times when we just can't get it. Certain vaccines, a percentage of our kids have gone unimmunized for a long time because we just can't get it. Trying to get these people to go to the health department to get it, getting it form a different provider, is also very difficult. I think there has to be a better thought out program of how you are going to get vaccines reliably and steadily to all different levels of practitioners, whether they be at the health departments, whether they be other publicly funded clinics as well as private practitioners.

DR. STRIKAS: Thank you. I think you said or I infer from your comments a number of things that have direct relevance to the plan. H1N1 is an example of the first thing that, quote0, went wrong was it is a flu virus and flu virus notoriously don't grow well sometimes. So the very optimistic projections of vaccine production

didn't turn out to be what we wanted. So the vaccine was late. One might argue that was the biggest problem. If the stuff had shown up at 100 million doses in October as opposed to 35 million, or whatever it was, I think we would be talking a little bit differently, although I know there were problems, given tha government had not done a wide scale distribution of vaccine, not just to people used to vaccinating children, which is the Vaccines for Children Program where there are 45,000 or so providers – they enrolled 120,000 providers ready to participate in the H1N1 program and some people signed up and there wasn't anything to distribute for a while. SO it was challenged by that.

I didn't participate directly in – though I am not avoiding responsibility in part for the program, since many of my colleagues at CDC worked on it and they worked long and hard hours but it was very challenging. SO we accept that. There is a lot of after action planning going on about what went right and what went wrong. And one of the right things is at least you got 120,000 clinicians or clinical sites interested enough to participate. You now have a roster of people erady to participate we hope again when we could do things better, or in a national emergency of some other sort, be it vaccination or something else. SO it is one of the things that I think went right.

Certainly vaccine supply has been a challenge when you say certain – even within the Vaccines for Children Program you can't get certain vaccines. I would

be curious to know if there are particular vaccines that you want to pick out as examples. But certainly there have been challenges in Hib vaccine, years ago pneumococcal conjugate, TDAP early on – take your pick. There have been challenges in supply across the board.

We would like to think – again I welcome your comments – VFC offers a floor that for certain kids, kids uninsured and kids who are underinsured, can receive vaccines, even very expensive ones like Prevnar and Menactra and HPV, that sometimes the health departments can't afford to finance for other kids who are not VFC eligible but are, quote, the working poor or have limited insurance or whatever it is. So we have talked for years about a two-tier system where VFC kids actually in some cases are better off than kids in other circumstance, in lower middle class or whatever their situation is in that they don't have the best insurance coverage or other limitations.

So again I would appreciate your comments and I am just sort of re-interpreting to say these are some of the things we certainly have thought about and I agree with you, they need to be addressed.

DR. FISHER: Actually looking at recommendation 4.6 it really is nicely outlined there and the whole vaccine delivery and system. You relay hit the points. You also hit some of the problems, for instance, eliminating barriers to full use of all appropriate

personnel. Even that becomes a political fight in different states where pharmacists can – for instance in New Jersey a pharmacist can immunize an adult but not a child. So there are all kinds of things – the devil is n the details for sure.

I think that is the same – the whole VCF program is a fabulous program that on paper is beautiful, but it seems to break down when we get to the distribution part and at least in our state getting it from wherever the centralized place is out to the actual physicians' offices.

I think that was a major problem with the whole H1N1 thing. I think the government did what they thought was appropriate – leave it up to the states. Unfortunately some states did a great job and some states did a terrible job. It shows that we need this infrastructure which is relay outlined here I think beautifully.

DR. STRIKAS: Yes, in a resource-challenged time it is great to argue for infrastructure, but one has to be savvy. I don't pretend to have a solution for that and say if you hire people one argument could be they can't be solely for purposes of vaccination or something – what else do they do? And how can you get more value for your personnel.

This is something we have argued for years about, more people who can foster, promote, facilitate vaccination of adults, which we don't do as well as we do for children in this country, although we have done somewhat better over

the last ten years. But we realize you cannot simply willy nilly add people. There just simply aren't the resources and states can't readily hire them and so on. So I appreciate your input.

MR. SCONYERS: Thanks for coming in to talk to us. It is a huge piece of work. I have two comments for you. One is your suggested priority for the program. In less than five years 90 percent of the public and 90 percent of providers will be aware of the program. I am not sure – is there any federal program of which 90 percent of the public is aware? Other than the Internal Revenue Service? It does not seem like a realistic goal to me. It doesn't seem achievable. It certainly doesn't seem achievable to me within five years.

DR. STRIKAS: I guess the best question I would have is, is it useful? Is that a worthy goal? Then we can talk about the target and the time. I preseume, and Geoff may wish to comment, but we developed this with his and other people's input and it is still a straw man. SO we are happy to take informal input. We haven't put the second draft to bed yet. If you have suggestions that is fine. We could easilyl make it 2020 and that is easier. The problem is there is no baseline that we could identify, so it makes it a little tougher.

I don't know of anything off the top of my head except that I am old enough to remember when people got drafted and I think most of us men knew about the draft 40

years ago or 35 years ago. Other than that I don't think there are too many out there.

MR. SCONYERS: My questions about that goal would be what does it achieve? If it were to be met, what would the value of meeting it be? How would that help to promote the aim of assuring compensation for people who have been injured as a result of vaccines? I am not sure that awareness of the program, by itself, is a measure of effectiveness of the program.

DR. STRIKAS: Necessary but not sufficient. I think the inference is, but you all are the experts on the program, not me, is that underlying that was, at least in my mind – I am happy to ake input and be corrected – is people need to know about it and also they need to know where they can get more information about it if they know it exists, and this is a bit of a leap, but perhaps say well, the government stands behind vaccines, it offers this program that if you were injured or you think you were injured we will take care of you as best we can, whatever the limitations may be in the programs, but that is the sort of next step.

It is a meaningful protection and that is one of the messages we hope they take away. That is not stated in the awareness piece, but that is I think part of the understanding we would like people to have about the program.

MS. HOIBERG: I think your goal is high, which you have, and so you are going to at least try, work hard to make it 90 percent. SO I think that is wonderful, right up my alley.

DR. SCONYERS: The other thing I wanted to mention in passing, the notion of a prioritized research agenda I think is very important, because I think there has been a lot of friction, heart without much light, within the program, within the claims, centering on the point about the relationship between vaccines and injuries, and developing an objective research agenda that is driven in the same way that fundamental biological research is done at the NIH, to understand functioning. I think that would help to eliminate some of the dueling experts situations that I think we hear a lot about, involving many claims that are brought within the program. I would love to see there be not only an agenda but an agenda that is then accomplished within the same kind of structure that the NIH currently has. SO there could be a source of objective data to drive decision making in the program.

DR. STRIKAS: You are specifically referring to the4 idea for a vaccine safety research agenda, right? Since I used the word research agenda during the priorities issue for picking new vaccine targets, yes, and I think again people working within the safety working group on the federal side all concurred that a Department-wide, frankly government-wide research agenda -- and I think one of the

successes of H1N1, happily one that no one had to be more aware of than maybe you are is to multiply by a significant factor, and I won't estimate what it is, the resources and the number of systems that measure vaccine safety to see if we have a national vaccination program with H1N1, even though perhaps only something under 90 million doses got used, the intent was to use 200 or 300 million doses or more – if we are going to do that we better be able to pick up signals and study safety issues. Multiple systems are put in place. The question now is which of those are still valuable? Which can be maintained? So we have stretched out but can we maintain some of those accomplishments on the safety monitoring side? And that is to be determined.

MR. SCONYERS: I was specifically talking about your summary of the goal two vaccine safety research agenda.

MS. BUCK: Ray, This is Tanya. I know we have talked about this before in other settings, but just specific comments related to your recommendations with the program I think one of the communications challenges you are going to face is also tied up in the dialog about the recommendation 2.1 also, which is in the public arena of vaccines and vaccine safety we are an interesting entity in that we have some policy factors that play into decisions on compensation.

So I think that it is going to be interesting when you try to achieve your communications goal and you

face your challenges with the public – is to try to explain better how decisions are made and what they mean and what they don't mean. I talked about this a lot in just vaccine safety overall. We should really always try to be very honest about what you know and what you don't know and I think that a lot of that comes with the program in terms of what d=decisions actually mean and what they don't mean and how they are viewed and what they accomplish in terms of the safety net with vaccine safety.

I appreciate that you have addressed that in here although I still think that identifying it is one thing but rising to meet that challenge will be far different.

DR. STRIKAS: Yes, writing action steps and acknowledging how we communicate better and do research better is going to be a challenge.

MS. HOIBERG: I was just going to say that in order for the program to be effective, in order for you to get the data, VAERS really needs to be more put to the forefront because I think again a lot of people are not – I mean we have received a lot of reports on the flu vaccines, but I don't know how many have come in on H1N1. Again, doctors being aware of adverse events and recording adverse events is so crucial to even the program functioning correctly.

Like you said, it is a peered program and VAERS and CISA and all that needs to be more at the forefront and more available, just kind of really out there in front, as

well as the VICP being 90 percent known and seen – VAERS needs to be almost a hundred percent.

DR. STRIKAS: I think so. I think that points up, for example, by legislation FDA is supposed to have a hundred million people under surveillance for stuff by 20120. The stuff is to be determined. I mean, adverse events of some sort or other and how that parses out with vaccines versus drugs versus devices is still being figured out. We have some discussions on can we use that target of a hundred million and we actually proposed it as a target to have a hundred million peple under active surveillance. We are trying to figure out if we can actually say that and whether it will happen by 2012 is another story.

So that is a piece of what we are talking about and also in the H1N1 work thre was at least one aggressive post-marketing surveillance system put in place. I forget how many million people it covered, but it was on the order of the size of VSV. SO there are things being done, but the major point you make that I don't have an answer for is does the public know about this, do providers know about it so they can either report to the system or say, gee, there should be information about this somewhere. That is something that we need to do a better job of communicating that information.

DR. EVANS: I want to mirror what others have said, Ray. You have done a very good job being the face of the National Vaccine Plan Update, which is dated November

2008 is the current draft copy. But you have done a tremendous job shepherding this through what has been many, many hours. I just appreciate what you have done and we all appreciate your coming here and keeping us up to date on what is going on.

It is important, picking up on Jeff's point, to distinguish between flashpoints about what is vaccine-related and what is not vaccine-related, and the fact that VICP does have a valuable database of claims and information on clinical conditions. And from the earliest days of the Act and vaccine safety going forward under the Act I know our program has worked with people from the Vaccine Safety Datalink, for example, in the early nineties when they were constructing the list of adverse events that they were going to be tracking. They asked us what we were seeing and we reported back to them.

And we have worked with VAERS quite frequently over the years, and we have worked with the Clinical Immunization Safety Assessment project, the CISA project. So there has been interaction, there has been sharing of case information, claims. Whether it is vaccine caused or not vaccine caused is not the issue. The issue is that this is valuable information that can perhaps help the research agenda for various components of HHS.

SO that has been going on and I wanted to let you know that. And I think that is reflected in the paragraph in the IOM report which says creating such a mechanism for

sharing or expanding what is currently going on in the program is important, and that is exactly what we will be looking to do in the future. And some of the other narrative had some very good suggestions in terms of how that can be done.

DR. GIDUDU: I also wanted to thank you, Ray, for the National Vaccine Program. We will have a draft agenda that we are struggling with completion that we are going to reference a lot of national vaccine plan knowing that some of the things we want to enable would not be in one agency.

DR. STRIKAS: Thank you. We appreciate CDC's and others' participation in the work. Everyone has some skin in this game and that is what makes it a valuable process.

Geoff says I should repeat what he said – so the second draft will be out I hope the first week in April or thereabouts. We will let you all know through Geoff in some fashion. Please feel free to make comments on it. It will be presented in such a way that will have both the track changes version so you can see what changes were made from the last one, and that is what is most important. It won't be, at this point I would say something on the order of a quarter of it will change or have things added to it. It won't be a wholesale rewrite.

The most striking change will be some listing of priorities up front in a box saying these are the top X number of things we should do in the next ten years. If we do nothing else we should do these things. That is

probably the major change besides important things such as mentioning a safety research agenda or scientific agenda that we have talked about, that IOM said.

I am trying to think what else. Obviously making a little more prominent some of the things about the Vaccine Injury Compensation Program, which was less prominent in the first draft. Those types of things. SO again we will elt you know when time is up for comment. It will eb at elast 30 days, probably 45 or 60.

MS. HOIBERG: Is there a place that we can go online to look at this? Or would you be sending a link?

DR. STRIKAS: Yes, we will send a note out to everybody and his cousin and it will get to you one way or the other. It will be on our web site. We will leave the first draft up and say here is the second draft. The public comments are open. They will go in the Federal Register as well as just letting people now in whatever way we can, the formal way and the informal way, and clearly say comments are requested by such and such a date, and then we will go through our review process to write the final version of the thing.

MS. CASTRO-LEWIS: Any other comments? I would also thank the entire team and everybody because it is clearly the most comprehensive plan that I have seen in many issues that include service. SO it is there and the coordinated research. When I first started in this Commission, there was the situation of using some of the

funds of the program to fund research. Of course there was a position frm the Commission, but then the next qeusiton was, well, who is doing that research? What is going on? And we have different positions of FDA, NIH, everybody – this is what we are doing, the pharmaceuticals also had a presentation and we remember all that. But at the end I was like, wow, it is a lot of that there and there but they are not connected. What I like about looking at this is that there is that call for coordinating all that research. So it is not just isolated pieces.

So again, thank you so much for your coming to our meeting today and for your presentation.

DR. STRIKAS: Thank you.

MS. CASTRO-LEWIS: We need the update from the Immunization Safety Office. We are going to hear from you, and thank you so much for coming.

Agenda Item: Update on the Immunization Safety Office (ISO), Jane Gidudu, M.D., M.P.H., CDC

DR. GIDUDU: Good afternoon everybody. I am Jane Gidudu from the Immunization Safety Office. I hope you can hear me. I am going to be talking about three things – monitoring the safety of the H1N1, and then I will be giving you an update as well as the few recent publications from and updates from the recent ACIP meetings that took place last week.

So the updates I have for you on monitoring the H1N1 vaccine, again I will say these objectives which I

have already mentioned to you – to identify clinically significant events following the vaccine in a timely manner; rapidly evaluate the serious adverse events following the vaccine and determine the public health importance of some of them; evaluate if there is a risk of GBS associated with the vaccine; and communicate vaccine safety information in a clear and transparent to health care providers, public, health officials and the entire public.

So I have shared this diagram before. I am going to list our routine systems – we have VAERS, we have CISA, we have VSD. And on the right we have the enhanced systems that we have. We have enhanced our systems like VAERS, and then we have the real time immunization monitoring system, and other systems which I will be mentioning later. Maybe I will note the ones at the bottom where we have involvement with American Academy of Neurology for monitoring GBS and we have been involved a lot with international groups – we have been on conference calls weekly – with our colleagues all over the world in discussion issues around safety, even if using a slightly different vaccine.

So I will walk you through some of the systems that we have here and I am sure that Dan Salmon may go through some of them tomorrow. SO we have the Vaccine Adverse Events Reporting System, VAERS, which you all know is a spontaneous reporting system run jointly by CDC and

FDA. It is generally for signal detection and it is intended to coevr the entire US population, which is 305 million people. And we habe so far 150 million doses that have been shipped. We don't know those which have been administered and we have about 100 million doses that are inactivated vaccine, and the live vaccine is about 20 million. SO far we have not gotten any signals in our system.

The Vaccine Safety Datalink, which is a national active surveillance system monitoring eight managed care organization covers about 9.5 million people om the US and so far we have a total of 1.2 million doses given to their population, largely the inactivated vaccine, close to a million doses, and the live vaccine is about 4oo,000 doses. No signals so far.

The Emerging Infections Program, which is a population-based program monitoring GBS in about ten states covering about 45 million people. There is ongoing collection of data but so far preliminary data doesn't show any signals here.

And we have the Real-Time Immunization Monitoring System, which is a collaboration between CDC and the Johns Hopkins School of Public Health, is a web-based system for active monitoring of ehalht events of vaccination. The focus here is school children, health care workers and pregnant women. It is intended to cover the entire US population but it began as a pilot. SO far there are over

7,000 doses of vaccine and most of it is inactivated vaccine, and less of the live vaccine. They are looking at the similar population with two vaccines, the H1N1 vaccine and the seasonal vaccine for comparison. So far there have been no signals that we have received so far from this system. Youi may be hearing more about this system.

The Defense Meidcal Surveillance System that I mentioned earlier in my presentation teo mweetigns ago covers about 1.4 nillion active people in the military. The have given over a million doses, the inactivated vaccines morethan the live vaccines, as you have see. That will be consistent across most of the po[pulations. It is the one that has given most. And no signals have been identified.

Then there is the Veterans Affairs Database, which is an active surveillance of the population again using pre-specified outcomes. The population is about 1.2 million and the total doses distributed are over half a million. There is a mix here as I speak. Some are the doses that have been received, but some are distributed, so we don't know actually the total proportion of those who have gotten the vaccine in some of these systems. SO it is a mix. Again here the inactivated vaccine is what was likely distributed, and no signals so far.

There is the centers for Medicare and Medicaid Services, CMS, which covers a total of about 38 million

people. A total of 1.7 doses have been distributed and no signals have been identified.

And the Indian Health Services is v=covering about 1.4 million people, a total of over 200,000 doses given, largely inactivated vaccine. No signals have been identified in this system.

Then we do have the Post-licensure Rapid Immunization Monitoring System, which is a joint collaboration between NVPO, FDA and CDC, to increase the capacity to monitor vaccine safety and link exposure data in vaccines and registries for outcomes. It is also looking at 30 million people with 10 million people in registries. I don't have data here, but we haven't heard any signals reported back to us. I think you will be hearing more about these systems, but I wanted to share some of these systems with you.

We all know VAERS, again, is a voluntary reporting system, as you all know, jointlyu managed by CDC and FDA, largely for signal detection. It is national in scope and the reporting is from a variety of people including health care providers and reports from vacinees and others. We have had a lot of system enhancement. We have increased our staffing to process VAERS reports within CDC, and I think FDA and the contractor, SRA, have been able to really, really work on reports in a more timely manner. This is seen by the visibility of increased use of

both the VAERS web site and the CDC web site monitoring H1N1.

This graph here is an effort for me to show you the weekly number of VAERS reports and doses of H1N1 vaccine distributed. At the bottom you have weeks from October to February 12th, and on the left side we have the number of reports, and on the right we have doses distributed by millions. SO the blue bars are the VAERS reports and the red line is the doses distributed. As you can see the activity is slowing down. There were issues of administration of the vaccine, as you already heard. But we had a spike in November and then it came down and right now we continue to receive reports but the activity is slowing down.

This table is an effort for me to share with you data as of Friday last week. These are the VAERS reports following the seasonal vaccine and H1N1 vaccine – we try to use these to compare so that we can see any issues that we see in the H1N1 vaccine and the reverse. We don't want to forget the seasonal vaccine. SO if we see anything there it would show up here.

SO on the left we have the vaccine type, live attenuated vaccine is in the pinkish, inactivated in the blue, and we have a category of unknown. We receive reports where there is no indication of the type of vaccine that has been given.

So as of last week we have had a total of over 10,000 reports, as of last Friday. Then going across the table we have serious reports, we have total reports in the first two columns. The seasonal vaccine is in what would be a yellowish color, right next to the H1N1. WE have a total, as I said, of over 10,000 reports in H1N1 compared to over 6,000 reports in the seasonal. Then across the chart we have fatal cases, and I will go over the totals. We have 51 deaths in the H1N1 compared to 36 in the seasonal. Then we have the non-fatal serious reports. The definition of serious is right below there. It is any life-threatening illness, hospitalization, permanent disability and death. GBS cases were also counted as well. This leaves out some of what we thought was serious -- like anaphylaxis didn't meet this definition, but I will talk about that later.

So the non-fatal; serious cases for H1N1 were 636 as of last Friday compared to seasonal, which was under 500. The non-serious reports here are the majority as usual. Most of our reports are non-serious. In the GBS we have a total of 103 GBS reports for H1N1 compared to 121 in seasonal. All these are below the expected numbers. As you may know, GBS in the US, it is expected that we get about 80 to 150 cases of GBS regardless of any vaccination. So these are all below the expected so there is no signal here.

DR. GRUBER: I am sorry but I think this may be important to know. When you look at these tables I may have missed you saying this, but I think it would be important to state the number of vaccines distributed to sort of understand the VAERS reports received, because just looking at the number for the total erports of H1N1 that you have received more – can you tell us, you had about 120 million doses distributed for H1N1. For the seasonal how did this compare so we can get a little bit of a denominator?

DR. GIDUDU: I don't have the numbers right here, but it is about 80 million. It is less than what we have for H1N1. I can confirm the number with you. And there has been more cumulative reporting for H1N1.

So walking you through a comparison of the seasonal and H1N1 live vaccine, we have a total of 2,000 reports in the first column, and this is by age group. Walking you through this the numbers of reports received must have been in the 5 to 128 year age group, and we have also many reports in the 25 to 49 year age group, and going across the board these are the numbers we have had. WE have a total of seven fatalities in the H1N1 vaccine compared to one for the live vaccine. I will move on to the next table for you unless –

DR. FISHER: For the live attenuated, the ages, it is not licensed for over 50. So there is a lot of

reports there for a group that shouldn't have gotten it, right?

DR. GIDUDU: Which one?

DR. FISHER: Live attenuated influenza vaccine. You have numbers for age 50 to 64 and greater or equal to 65, and the vaccine is not licensed for that age group.

DR. GIDUDU: That is correct.

DR. FISHER: And the same for under two.

DR. GIDUDU: Yes. That is correct. We received these vaccines and this was what was described. I think it was either errors in administration, but this is what was the information we got.

DR. FISHER: SO they both got it in error and had an adverse reaction? Or was it just reported if they got it that that was an adverse reaction?

DR. GIDUDU: I would have to clarify that, but the data we have here – I believe they received the vaccine and reported the adverse event even if they are outside the age group. We occasionally get those numbers outside the recommended age groups.

DR. FISHER: I wouldn't be surprised at a few, but these are a lot higher numbers than I would expect. I wouldn't think there would be that much off label use.

DR. GIDUDU: I can get back and verify that. This is automated data. By the way, you can run this analysis and the data show what is out there. I will later let you know some of the issues with some of this data. On

the inactivated vaccine - by the way, we have some in pregnancy so we have some numbers which were worrisome but unfortunately there are very minor adverse events.

DR. FISHER: That is a little more understandable though if they are in the age group they might not realize they were pregnant.

DR. GIDUDU: SO for the inactivated vaccine this is the group. We had more reports with this vaccine, over 7,000 reports in total compared to over 5,000 reports in the seasonal vaccine. In the age groups here it is a slightly different age group. We have more reports from the 25 to 49 year age group. And then we have also many reports in the 50 to 64 year age group and the 5 to 18 year age group.

This table is a table of chart reviews. We have been talking about automated data. This is data that has been – this is reviews from medical officers between CDC and FDA and we have used various methods to get these reports. Like for anaphylaxis, if you did a search on our data you may get about 80, so we have used many more to try to get to some of these conditions.

SO for the deaths so far we have 51 deaths. There has been a lot of collaboration between CDC, FDA at times, and the states in trying to get follow-up information and in some cases the states have taken the lead in helping us get more information and some have had autopsy and as you can imagine it takes a while to get a

conclusion. But so far most of them have not been associated with the vaccine.

For GBS we have a total of 123, again they are above the number of the automated data that I mentioned earlier in VAERS. The pending column shows that we don't have additional records yet to make a determination on these cases. So the whole pending shows you the number where we ar still pending to get additional records to make the determination. In anaphylaxis it is still below the expected numbers, but it has been high and we have looked at all these cases. Many of them were not admitted but nonetheless they made it to this category and there are 58 pending cases that are yet to be completed. FDA took the lead in looking at these anaphylaxis cases. There was a lot of joint collaboration between CDC and FDA. At some point we were getting daily calls to consult.

There is a special group that is looking at adverse events in pregnancy and special adverse events of spontaneous abortion and stillbirths, and these are the numbers we have so far. All of them are below expected.

DR. FISHER: If I am reading this correctly about half of the Gullain Barré syndrome and about half of the anaphylaxis was ruled out, meaning on record review you could not document those?

DR. GIDUDU: Those that were ruled out were not consistent with our diagnosis. And we used the Brighton

criteria for GBS, anaphylaxis and for where the definitions were to make the determination.

MS. BUCK: I am sorry to interrupt. I am having a little trouble hearing. Can you qualify the zeros on the deaths in pending and ruled out? I didn't hear what those meant.

DR. GIDUDU: This was for sure. It was certainly not anything else.

MS. BUCK: I can't hear you.

DR. GIDUDU: So for this the zeros are for sure. We identified the person died.

MS. BUCK: You are not saying that you are ruling out whether or not the cause. You are just confirming that those bodies aer dead.

DR. GIDUDU: Yes. We do verify the diagnosis on autopsy.

MS. BUCK: And what is the status of those 51 deaths? Were there autopsies and information on determining whether or not those were caused by the vaccine.

DR. GIDUDU: No, most of those that have been reviewed have been other causes of death and it has varied from stroke, to lots of diversified causes of death that have been put at autopsy. It has not raised any flags thaty vaccines have caused these deaths.

MS. BUCK: SO you are saying that most of those autopsies have now been completed?

DR. GIDUDU: Not most. I don't have what proportion off my head. Not all of them requested autopsy. Some of them did not. SO for those that had autopsy, they have been tricling in at a small rate, probably 30 percent.

MS. BUCK: Just a couple comments before you move off of your H1N1 presnetation. Were you finishing that up and getting ready to move on?

DR. GIDUDU: Yes.

MS. BUCK: I wanted to just comment that administration errors with the vaccine have been a problem with H1N1 and those do cause adverse events. Some of that in this campaign with H1N1 – some of them have been compounded by the point of delivery issue, and I know none of this is new to the people who have studied the response to H1N1 but it is certainly a concern as we look at how we handled it and how we prepare for the next pandemic that comes along.

Also to clarify that, you are comparing H1N1 to seasonal flu when you are looking for a signal.

DR. GIDUDU: There are various ways for signal detection and working with FDA they have been using various methodologies. There has been data mining, we meet every two weeks to discuss those results. That is one of the ways that we dicuss the signals. This is one way that CDC detects signals.

MS. BUCK: You are comparing H1N1 to seasonal flu and you are using those numbers to determine whether or not you are seeing a signal?

DR. GIDUDU: That is one way. The other way is data mining where they use a different methodology.

MS. BUCK: Just a reminder to folks, though, that no signal at the population level doesn't mean that these vaccines haven't casued problems at the individual level. It has been very reassuring for everybody to know that there wans't a signal detected with H1N1, but it eos not mean that there weren't injuries related or adverse events related to the distribution of that vaccine. Hopefully not every time we come into this kind of situation injury reports have to be channeled into a countermeasure program because, you know, very reassuring that you didn't find a population level signal, it does not mean that there were no injuries.

DR. GIDUDU: That is correct. I guess having gone into so much detail we have had a lot of very complex discussion, sometimes involving the providers, and this data is being compiled. This is largely an overview of what we have seen, and not the details.

DR. HERR: Would you define then again a population signal and what identifies and what defines a population signal?

DR. GIDUDU: We use proportions of previous historical numbers that have been used in VAERS. SO a

population signal – that is a good question – we do have boundaries for what is expected and that is what is the guidance to see whether we are stepping over to gauge an unusual number of adverse events. I think VAERS we use our proportional reporting – we use only numerator data. We used those comparisons to come up with tables(?) of interest. Sometimes we have a table for one or two and then we look further and do reviews to confirm some of that information.

MS. HOIBER: So a signal is if you have more adverse reactions?

DR. GIDUDU: Above the expected, yes, then we would have to confirm and then sometimes it is a false signal and then we really go into these things to see where that happened.

For the recent publication that I put together for you are these three – the MMWR, which maybe some of you saw came out in November. This was earlier on. At that time we mentioned when the vaccine was licensed. It has been licensed since September 16th and there were two types of vaccines, a monovalent vaccine, a live attenuated, and the inactivated that I have been talking about. Then the licensure and manufacturing processes for the pandemic vaccine were similar to the seasonal vaccine. I think you heard this. CDC monitored the safety using VAERS as well as the VSD, and as you have heard the various other sources of data that have been used for this pandemic. There are

no substantial differences between the seasonal and H1 vaccine. So there were no signals.

Many agencies have been using multiple systems to monitor H1N1 that you will be hearing probably beyond my overview today.

SO that was the first application and we are continuing. We are now in the next stage and we will be publishing more information and we will be sharing whatever we have published with you. SO right now this was the first one, but there are many papers down the road that we are working on with our group, jointly the FDA and various groups, and as the influenza season winds down we are going to be wrapping up some of these and wrapping up more publications.

This paper that was published recently as well by our VSD group had an objective of mimicking the prospective surveillance system using pre-specified adverse events of the seasonal influenza using binomial-based methods. It is really methodological. We looked at case histories and different methodologies. They are in the Federal Register, but mainly it was one of the ways to look at its use in the pandemic. Quite frankly it has been less than useful(?).

There were pre-specified neurologic and allergic adverse events among eight managed care organizations in the VSD that were evaluated and the conclusion here is that near real-time surveillance for selected adverse events following seasonal or pandemic influenza vaccine is

possible in the VSD. For fairly common events they are using binomial methods and using the Pasqual regressions and some of this data you will be seeing in the future.

DR. FISHER: Before you switch to non-influenza, I am sure you have also communicated with the World Health Organization and other groups. Outside of the United States they are using different vaccines, adjuvanted vaccines – are there any signals from Europe where primarily adjuvanted vaccines were used or from other areas of the world where different vaccines were used? Are there any safety signals with any of them?

DR. GIDUDU: The answer is no. I represent my group on those international calls. There have been some conditions of interest. There was a lot of anaphylaxis in Canada. We discussed that but they did constitute signals. The bottom line does not agree with what I have been saying, but there have been various conditions of interest. There have been flaring up of other conditions and there were neurological events in Taiwan, but they couldn't be discussed don the phone as well due to the issues with China. There are many issues, but none of them contributed(?).

DR. FISHER: And was there a difference between live versus inactivated?

DR. GIDUDU: We did not see much of that but as you clearly see the rest of the world used a lot of adjuvanted vaccine and most of their issues were local

reactions, so a lot of the issues could have been the use of the adjuvanted vaccines. Then various countries produced their own vaccine, so the comparison is very interesting. We are going to have a publication out to allow comparison with limited by that(?). Some countries refused to give up signals.

DR. FISHER: SO is raw effect the live attenuated? Is that mainly a US product that is only used in the US?

DR. GIDUD: My understanding is yes. Most of the world has used the adjuvanted vaccine and other vaccines. I think so. I could check. Maybe FDA has that.

DR. GRUBER: Yes, I wanted to make this comment. I know for sure that Europe doesn't have the live attenuated vaccine. I am not sure about the other countries you mentioned. But I think the LAV is primarily a US vaccine. I don't think the other countries have live attenuated influenza vaccines.

DR. GIDUDU: The last paper within our group – this was assessment of recalled Haemophilus influenzae conjugate vaccine, It was recalled in December 2007 by Merck voluntarily -- 1.2 million doses had been distributed -- due to concerns regarding potential B. cereus contamination.

So the objective for our group was to conduct enhanced post-recall surveillance to detect vaccine associated B. cereus infections. So VAERS received 75

reports following this vaccine, but none described a B. cereus infection. CDC and FDA rapidly conducted the enhanced surveillance, as I said, through VAERS as well as through lab-based surveillance, which is very unique to this follow-up.

SO this assessment showed no incidence of vaccine contamination and the message here is conducting laboratory-based surveillance was feasible and may contribute to public health response capacities for future vaccine safety emergencies. But for H1N1, where there has been need to even discuss laboratory issues, it has been postponed. So that is ongoing and I don't have any data on that.

Lastly, recent updates from the ACIP meeting last week. I have these three bullets for you. The ACIP recommended universal annual influenza vaccine for adults in the 19 to 49 year age group. They previously covered I believe 83 percent of the US population.

When the pneumococcal 13-valent conjugate vaccine, which is Prevnar, was licensed on February 24 – and that was the same day the ACIP recommended it – I thought I would share that with you – and this is to replace the 7-valent vaccine. Those links can take you there.

When the rotavirus vaccine recommended for all infants can cause in babies with severe combined

immunodeficiency – called SCID – and this is now a contraindication to Rotavirus vaccine.

DR. FISHER: I just want to add one point. It sounded as if there was a big rush to get that Prevnar-13 recommendation. Just so people are aware, three has been a working group of the ACIP that has been looking at potential recommendations for that vaccine for several years. Just so people don't get the idea that you license it one day and make the recommendation the next or the same day. Just be aware that this is something that was very carefully thought out, probably for this one almost a year, at least a year if not more, in advance of the licensure. SO there is a lot of stuff that goes on before so that we don't have a problem of having a licensed vaccine but no recommendations from the Centers for Disease Control or the other groups that make the recommendations, which was something that happened in the past.

MS. CASTRO-LEWIS: Were there any reports from people that had the H1N1 and seasonal vaccines together?

DR. GIDUDU: This is where the vaccines have been given, same day, two days apart, two weeks apart. I can't remember the numbers offhand but that data is there. O just tried to get what I thought you needed today.

MR. SCONYERS: I would just like to express my thanks for you getting your slides to us ahead of time. It was very helpful to be able to read them before coming here. Thank you.

MS. CASTRO-LEWIS: Any other comments? Thank you so much. Dr. Mulach?

Agenda Item: Update n the National Institute of Allergy and Infectious Diseases (NIAID-NIH) Activities, Barbara Mulach, Ph.D.

DR. MULACH: I hope no one is too disappointed. I don't have any specific topics on my list for you from NIH today, but I did want to say, based on the conversation that we were having before the break and during the break, that I do work with some of the NIH entities on some of the aspects of our web site, and I know you guys have it covered but if there is anything I can do or people on my staff can do to help try to think of ways to implement things within the confines of what the federal government can do I would be more than glad to help – maybe just another viewpoint. So if there is anything I can do to help please just let me know.

MS. CASTRO-LEWIS: Thank you so much. Did that conclude your report?

DR. MULACH: That is all I have. If people have questions I am moer than glad to answer them.

MS. CASTRO-LEWIS: Thank you then. Dr. Gruber, would you like to discuss the activities at FDA?

Agenda Item: Update on the Center for Biologics, Evaluation and Research (CBER), FDA, Marion Gruber, Ph.D.

DR. GRUBER: I would be happy to, although I guess you have heard already about our major approval

activity. SO I can make my presentation relatively short, which is the reason I don't have slides today, Geoff.

In terms of vaccine approvals since our last update in December I can report that we actually had two major approvals since December. On February 19th we licensed an additional meningococcal conjugate vaccine named Menveo that is manufactured by Novartis Vaccines and Diagnostics. This vaccine is indicated for active immunization to prevent invasive meningococcal disease and it is indicated for individuals 11 through 55 years of age. With that approval we now have the third licensed meningococcal vaccine to prevent meningococcal disease in this country. The other two are made by Sanofi Pasteur. One is Menactra and the other one is MediImmune.

Then as you jest heard the CDC update on February 24th, the FDA did approve the pneumococcal 13-valent conjugate vaccine that is manufactured by Wyeth, now Pfizer. That is the successor to Prevnar-7, how we call it, because Prevnar-7 contained 13 serotypes of streptococcus pneumonia and this vaccine provides protection against an additional six serotypes that are also found as part of streptococcus pneumonia.

The vaccine is indicated to prevent invasive pneumococcal disease caused by streptococcus pneumonia and also prevention of otitis media, but only half of the serotype. So the seven serotypes that are shared with Prevnar are there to prevent otitis media. For the other

six serotypes contained in Prevnar-13 we don't have the data yet. Therefore we split the indication for otitis media. The last point, the vaccine can be administered to children six weeks through five years of age. It is usually a four-dose schedule, 2, 4, 6, and 12 to 15 months of age.

So these are the two approvals that we had. As an additional point of interest our Vaccines and Related Biological Products Advisory Committee met on February 22nd to discuss what influenza viruses should be contained in the seasonal vaccine for the upcoming 2010-2011 influenza season in the US and based on surveillance data and responses to current vaccines the Committee actually voted and recommended two strain changes as compared to the last seasonal vaccine.

As you may know our seasonal vaccine contains three influenza vaccine strains to A and one B strain. The current vaccine strain to prevent influenza B remains the same. For the influenza A types there are two changes. The previous H1N1 seasonal vaccine strain is now being replaced with the pandemic A-H1N1 vaccine virus strain. So the pandemic vaccine that you may have received, the monovalent vaccine, is going to be part of the new seasonal vaccine beginning next season. We also replaced the second influenza A vaccine strain, the H3N2, based on surveillance data.

The last point, these recommendations that have been made by our advisory committee regarding the composition of the seasonal influenza vaccine for the 2010-2011 season are identical to those recommended by the WHO. That committee met a week before.

So that actually concludes my very brief update today. Thank you.

MR. SCONYERS: Dr. Gruber, could I just ask on the second flu A strain that is included in the seasonal trivalent vaccine – do you know what the prevalence rate for that is? My impression has been that H1N1 has essentially driven out all other strains. DO you know what the prevalence for that strain is?

DR. GRUBER: That is true. It is very, very low. I think the update given of the surveillance data at the Vaccines Advisory Committee I think was about three percent or something – it is very low compared to H1N1. H1N1 is basically the prevalent influenza virus. But there is some disease of N3N2 and the cautious approach was taken and it is included.

DR. FISHER: Is it just a different H3N2 strain? The second one?

DR. GRUBER: Yes. It is actually a Southern hemisphere vaccine virus, A/Perth.

MS. CASTRO-LEWIS: Any other questions for Dr. Gruber? Then thank you so much again, Dr. Gruber for coming to our meeting and updating us.

WE have about 20 minutes before the public comment and I think we should wait until then just in case people are not ready to do their comments, unless anybody has objections. We don't want to hear that people came on the line at 5:15 and they didn't have the opportunity because the meeting was dismissed earlier. I don't know. SO anyway, I was just thinking that the outreach working group – who is on that committee?

MS. HOIBER: Outreach is me, Tom and Sherrie.

MS. CASRO-LEWIS: Since the scope of work for that committee has been kind of expanded, would you like to have more people working on that committee?

MS. HOIBER: Yes.

MS. CASTRO-LEWIS: Anybody would like to join?

DR. FISHER: Can I volunteer?

MS. CASTRO-LEWIS: Okay, and I will work on that committee, too.

MS. HOIBER: You want to work on it, too?

MS. CASTRO-LEWIS: Sure.

MS. GALLAGHER: Can I just propose that maybe you change that to the communication and outreach subgroup? We felt that they sort of extended their charter and so we will give them a fancier name.

MS. CASTRO-LEWIS: All right, outreach and communication.

MS. HOIBERG: That sounds fine.

MS. CASTRO-LEWIS: I don't think we need a vote for that. It sounds good. Okay, what shall we dio? Any suggestions? Wait?

MS. HOIBERG: I think we should take a break and we will wait.

DR. GIDUDU: I wanted to ask whether there were any issues you want to hear for the next time. I just put together what I think you would want to hear – the guess(?) on people receiving what vaccines for H1N1 – is there anything else that this group would like to hear>

DR. FISHER: I think the other thing that would be very interesting would be the follow-up on those severe adverse events. So the anaphylaxis and the Gullain Barré and is that going to be above background? I suspect anaphylaxis probably is, but we don't know about the other ones. Just more follow-up on the serious ones, and also kind of an indication of what the non-serious ones were, just to give us a kind of flavor? And then why there is so much off label use?

DR. HERR: The other question is, in breaking down different age groups, you certainly see with the live inactivated there seemed to be a blip around the 18 to 19 year olds as opposed to the others, which were adults 25 to 49. Was there any reason why? And the other question would be what was the frequency of that in the sense of do we know how many doses were given at that age?

DR: GIDUDU: That is a very tough one for VAERS to answer.

DR. HERR: I know it is hard.

DR. GIDUDU: We can try but I already can tell it will not be easy to get a breakdown in doses by each group.

DR. HERR: It is one of those nice to know questions.

DR. FISHER: I don't think anybody keeps that information, except that at least some of the states required you to enter each dose into your immunization group. So there might be more information coming out about that. But the other denominator that somebody should have is what percent of the population is represented in each of those age groups. SO at least you would then get a feel. The uptake of the vaccine may not be the same but at least you would know what the denominator is as far as the population that is that age.

MR. SCONYERS: It allows you to figure a rate.

MS. GALLAGHER: I have one more question. When we saw the adverse events in the age group that were not indicated to get the live attenuated, could some of those adverse events simply be reporting they accidentally gave the wrong one? That is what I wasn't clear on. Or was it that they got the wrong one and had an event, because sometimes a health care professional, when they realize they gave the wrong vaccine, will report that as an event, and I think that is within the ambit of what is collected.

DR. GIDUDU: I can' promise for sure we can get that.

MS. GALLAGEHR: I was just curious if that could just be a reason.

DR. GIDUDU: They are looking at that and I can get back to the group and see whether this can be looked at. It is a lot of effort so I don't know.

MS. BUCK: You can collect those VAERS reports and look at why they were field and see. I have looked at the VAERS reports quite a bit over the course of the season, but haven't looked recently, but my guess is those are numbers reported as errors in administration. But you can look it up. You can go into VAERS and pull up those age groups and I would think there would be some indication of why they are beign filed.

MS. GALLAGHER: I just asked because accidental overdose, even if there is no adverse event observed in the patient, is reported into VAERS.

DR. GIDUDU: Of those we have received - we have gotten some of those calls from providers themselves. We have received some of them. The numbers are not very many, but those were the issues.

DR. FISHER: So while we are waiting for the public comments, since we have the FDA and the NIH here, anything that we should be waiting for or holding our breath? Anything close to licensure that you can tell us?

DR. GRUBER: I cannot disclose that.

Agenda Item: Public Comment

MS. CASTRO-LEWIS: Operator, would you please let me know if there are people who would like to do comments?

OPERATOR: If anyone on the phone lines would like to make a comment, please press star 1 on your touchtone phone.

(Pause)

OPERATOR: There are no comments at this time.

MS. CASTRO-LEWIS: Should we wait? What would you like to do, Jeff?

MR. SCONYERS: In the future I would like to be more clear with the agenda. Either we should schedule public comment at a time that won't delay our adjourning, because we have already sat around for a considerable amount of time this afternoon not doing naything very useful. What we ned to do is have a definite time for public scomment and schedule it earlier in the day. My conception of what public comment is is to repond to what has been presented to the Commission and to comment on the things that have come before us. If that is what the purpose is then people who have been listening to the presentations have now heard what has come before the Commission today and are prepared to comment about it. So one or the other. I just would like to be clear in our agenda – this feels like a waste of time. I have a book. I am prepared to read my book. But this feels like we are

wasting time and rpeventing people who ought to be getting home from getting home.

DR. FISHER: I guess I disagree. I think we did post an agenda and we do have the public comment time. I agree with you, I think the public comment is meant to be a comment on what we have presented and they cannot do it in the middle of our day. SO I think it does make sense for it to be at the end of the day. The fact that we happen to get going early shouldn't punish people who may have listened to the morning but not the afternoon and have planned to come back on at 5:15. SO I think we need to at elast have the ten-minute courtesy if there is anybody there at 5:15 they get the opportunity to say whatever they might want to say.

MR. SCONEYRS: My comment, Meg, is really that for the future, and maybe I may just be wrong about this, but I would prefer that our agenda reflect that public comment comes at the end of the presentation rather than at a fixed time.

DR. EVANS: I want to mirror that. No one is right and no one is wrong, by the National Vaccine Advisory Committee practices that nothing is set in stone. There is a general time period when the public thing will happen, but if the meeting ends earlier or goes later it will be variable. And it is expected that people will be aware of that. WE have ahd the circumstance where there is a very big gap in time and people relay weren't aware of it, but I

think this is different and we are certainly close enough that you can go ahead and do it, and that is done all the time.

MS. BUCK: The last phone call I was on for NVAC, we ended like an hour early, and I think as I recall we called for public comment and then adjourned and it was very early. So I kind of agree with that. At this point in the game, a little bit after five back there, I think people who want to make a comment are either on the line to do it right now or they are gone.

MS. CASTRO-LEWIS: One last time. Anybody on the line?

OPERATOR: No one is on the line for comment.

MS. CASTRO-LEWIS: So we are here tomorrow. Anyway any motions to adjourn the meeting?

DR. EVANS: We are not adjourning the meeting.

(Whereupon, at 5:08, the meeting was adjourned to reconvene the following day at 9:00 a.m.)

(Whereupon, at 4:20 p.m., the meeting was concluded.)