

HEALTH RESOURCES AND SERVICES ADMINISTRATION

ADVISORY COMMISSION  
ON CHILDHOOD VACCINES

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P R O C E E D I N G S

(9:07 a.m.)

MR. SCONYERS: Good morning, everybody. Thanks for joining us. We had a busy day yesterday, and I think we are going to have a busy morning today, so I want to go ahead and get started.

I know that we have Tawny on the line with us from Alaska. I want to take a moment to thank her for joining us.

It is quite early in Alaska, about five a.m., is that right, Tawny?

MS. BUCK: That's right.

**Agenda Item: Unfinished Business from Day 1**

MR. SCONYERS: So not only is she with us, but she was working after we were all done yesterday to produce the draft statement that is at your places. That is the first item of business I want to take up this morning.

This is a follow-on to our discussion yesterday with Dr. Dan Salmon about the National Vaccine Plan development and the public engagement strategy that his office has been working with. As we discussed yesterday, there is a suggestion that ACCV make a statement in support of that public engagement process. You see a draft statement there. Very simply, that is what it says. So I would be interested in hearing any comments about it.

MS. GALLAGHER: It is beautifully written. I think it says exactly what we want it to say, and I would move that

we approve it.

DR. FISHER: I second it.

MR. SCONYERS: There is a second. Is there any discussion about that?

MS. CASTRO LEWIS: I think it really reflects what we discussed yesterday. I would like to add a sentence, if it is appropriate for this kind of a statement, something that says, I would like to see that this process or model be implemented to include stakeholders in other populations. The process was really helpful in finding out values and other issues that went to immunization and safety, et cetera. I think it would be worth it to include other populations.

MR. SCONYERS: So how about a sentence that says, we encourage the use of this process to include all affected populations?

DR. FISHER: Maybe not all, but others.

PARTICIPANT: How about, more representative group?

DR. FISHER: I think the idea is to get to the underrepresented, to engage people in different thoughts. But the problem with all, all, all, --

MR. SCONYERS: I got it.

DR. FISHER: The way you said it seems right to me.

MR. SCONYERS: Yes, if you have it.

MS. CASTRO LEWIS: I would like to see this process or model implemented to include the stakeholders in other

populations.

MR. SCONYERS: We encourage the use of this process to include stakeholders in other populations? Tawny?

MS. BUCK: Yes, that works.

MR. SCONYERS: Since we had a motion to approve this, does somebody want to amend it?

DR. EVANS: The people reading this may not know that we are talking about the immunization safety office of CDC.

MS. BUCK: Yes, that is a good idea. I thought about that later.

DR. SALMON: Can I just make another suggestion? Is it possible to think about including the NVAC in there? Because this was really a joint activity between the National Vaccine Program Office and the National Vaccine Advisory Committee, so it was really done at the request of the National Vaccine Advisory Committee. Maybe after National Vaccine Program Office, comma, National Vaccine Advisory Committee, comma.

DR. FISHER: Move to include those amendments as stated.

MR. SCONYERS: So we are adding NVAC, and we will spell it out, after National Vaccine Program Office. We are adding CDC before Immunization Safety Office, and we are adding a sentence to encourage the use of this process to

include stakeholders in other populations.

DR. FISHER: Exactly.

MR. SCONYERS: And there is an amendment, and I would like to hear a second.

MS. GALLAGHER: Second.

MR. SCONYERS: I hear a second. Is there further discussion? If we are ready for the question, all those in favor say aye.

(Chorus of Ayes.)

MR. SCONYERS: Any opposed? We will consider it passed. So having amended the original motion now, now on the motion to approve the statement. Any further discussion on that? So I will call for the question. All those in favor say aye.

(Chorus of Ayes.)

MR. SCONYERS: Any opposed? Tawny, I didn't hear your vote.

MS. BUCK: Aye.

**Agenda Item: Review of the Vaccine Information Statements**

MR. SCONYERS: Okay, good. So we will work with Michelle to get a nice clean copy put together. Excellent.

Is there any other business from yesterday that any member thinks that we need to take up at this time? Hearing none, we will move to a consideration of the Vaccine

Information Statements that are in your materials.

We have Skip Wolfe from the CDC on the line. We have received all of the Vaccine Information Statements. I did ask Drs. Fisher and Tempfer to take the lead in reviewing them from a clinical point of view, since they are the clinical experts, but all of the members are not only welcome but encouraged to offer any comments. It is important that these be scientifically and factually correct, but also they communicate effectively to the populations that are going to be receiving them. So that is a role for all of us to play.

So who would like to start out? We have them in order in our book. Skip, would you like to see any introductory words before we start lobbing comments at you?

MR. WOLFE: No, that's fine. Did you all get the influenza one that was sent separately?

MR. SCONYERS: We did get the influenza one.

MR. WOLFE: I guess we can take these in any order that you want to. You can just tell me what your comments are, rather than going through them item by item.

For influenza, I just wanted to mention a couple of things. That is the one that may cause the most discussion, since it has changed the most since the last edition. I just wanted to explain what we were trying to do with that one.

First of all, you will notice that there is only one VIS this year, instead of separate VIS's for TIV and

LAIIV. One of the reasons for doing that was to try to de-emphasize the differences between the two vaccines, which having two VIS's seems to do. So we combined them into one document to try to emphasize that they are both vaccines that prevent flu, rather than emphasizing the differences.

One of the problems with that always was that with LAIV, you wind up talking about who can't get it than who can get it, so this should make MetaImmune happier, for one thing.

Another thing we were trying to do with this year's is to simplify the language a little bit. I think we are going to be using some stimulus money to do some focus groups, to find out exactly what factors make the VIS's more readable. So this influenza VIS was partly an attempt to simplify the language mainly by eliminating details. So I would like to get your impressions about how you think that works.

MR. SCONYERS: Okay. LAIV is the live attenuated influenza vaccine, the nasal spray.

MS. GALLAGHER: I have a comment, sort of an overarching comment, about all of them. It may be that we discussed this before; I apologize because my memory is not perfect.

At the very top, it says, many Vaccine Information Statements are available in Spanish and other languages. I

just wondered if we had explored whether somehow in Spanish up there it could say, available in Spanish if you wish. If you don't read English, I'm not sure that would --

MR. SCONYERS: I think we had exactly that conversation, in fact. Skip, could you hear that comment?

MR. WOLFE: I'm not sure what the point was.

MR. SCONYERS: The point is, at the top of each of the statements we have in English that this Vaccine Information Statement is available in Spanish, which doesn't seem that helpful to native Spanish speakers. If we want to be clear that it is available in Spanish, perhaps we could put that in in Spanish.

MR. WOLFE: Oh, I see. Instead of English or in addition to English? It refers to other languages too, and obviously we can't put it in all 26.

MS. CASTRO LEWIS: I think it should be in both English and Spanish. That way, for those who do not speak English or Spanish, at least English would be an alternative. But I think it is necessary to include it also in Spanish.

MR. WOLFE: Okay.

MS. CASTRO LEWIS: And the font.

MR. SCONYERS: Yes, the font is small for that.

MR. WOLFE: It is, but we are always struggling with space issues in these VIS's.

MS. GALLAGHER: If it has to be so small, could it

be bolded? It wouldn't take up more room, but it would perhaps call your attention to it.

MR. WOLFE: Okay. We can try that, yes.

MR. SCONYERS: Think about that. Do you have an order that we would like to take these in? They are in my book in order, and I have them with influenza as the last. Is that okay as a way of taking it?

So the first one in our book, Skip, is rotavirus.

MR. WOLFE: Okay, we'll start with rotavirus.

MR. SCONYERS: Let's hear comments.

DR. FISHER: My concern was, in the What Is Rotavirus, the very last sentence there, your baby can become infected by being around other children who have rotavirus diarrhea. We know that there is asymptomatic shedding like crazy, and those people are contagious. So I don't think we should limit it to people who are sick. And I think this is a theme that we have to have elsewhere.

I would have said other children who have rotavirus diarrhea, and children who do not have diarrhea but who have the virus in their stools, or something to that effect, to make it clear that you don't know who you are getting it from.

My point is you can't protect yourself by staying away from children with diarrhea, because it is very likely you will still be exposed.

MR. WOLFE: Maybe we can simplify it even more just by saying, in children with the virus who are asymptomatic, you are not going to know who has got it, anyway.

DR. FISHER: That would be fine.

DR. HERR: And it doesn't have to be children.

DR. FISHER: Yes, good point.

MR. WOLFE: Maybe we should just eliminate the whole thing.

DR. FISHER: No, I think it is an important concept. By people who have rotavirus in their stools, would probably do it.

My only other comment on this is, on the second sheet, number six, number six is kind of the same for all of them, but since you have changed the wording here to baby, I think you should say, call a doctor and get the baby to a doctor right away. It is only the babies who are going to get the vaccine.

MR. WOLFE: Okay. This is an interesting point that may apply to other VIS's, too. We got some comments from FDA that suggested we add a couple of signs to look for the rotavirus. I don't have that sheet in front of me right now, but I think it includes vomiting, diarrhea.

We want to get your opinion on this. Right now this is the boilerplate paragraph that we use for every vaccine. Maybe we ought to customize it for each one, if

there are particular things to look for that are keyed to certain vaccines.

DR. FISHER: I don't have a major concern there because of number five; you do list those things. So I think to list them again in number six, I'm not sure that is really necessary.

MR. SCONYERS: Other comments on rotavirus?

MS. CASTRO LEWIS: Number seven, with the information about the National Vaccine Injury Compensation Program, I think this is also for all the Vaccine Information Statements comment. Some of them read better than others, and I think it should be consistent throughout the Vaccine Information Statements.

I would also like to suggest something like this, that a federal compensation program has been created to help pay for the care of people who might have been harmed by a vaccine, rather than to help people. It sounds a little like --

DR. HERR: Is it redundant by having compensation and pay?

MS. GALLAGHER: If you look at the next one, the next sheet is hepatitis. Look at the words in hepatitis under seven.

DR. HERR: Compensation is not in there, but doesn't compensation imply payment?

MS. CASTRO LEWIS: If it is redundant we can take it out.

MR. WOLFE: Are you talking about the word care? The reason for the inconsistency, by the way, it just depends on how long ago it was written. We changed the wording, and rather than go back and change all the existing ones, as we update them we just put the new wording into each one.

MR. SCONYERS: So which do you consider the most current words?

MR. WOLFE: These are the most current. It is simpler. Plus, the older one was syntactically a little weird.

MR. SCONYERS: But I think our point was that this isn't a program that helps people. It helps pay for what happens as a result of the vaccine injury. It is not a social service program.

DR. FISHER: And it is an injury, not a reaction. So in fact, many people we would consider serious reactions are not covered under the program.

MR. WOLFE: Right now, the first sentence reads, the federal program has been created to help people who may have been harmed by a vaccine. If we just change that to add, has been created to pay for the care of people, would that -- ?

MS. CASTRO LEWIS: Yes.

DR. HERR: Take the one from the hepatitis.

(Simultaneous discussion.)

MR. SCONYERS: One at a time, please. Skip is having a hard time hearing the comments.

MS. GALLAGHER: I think it should read, a federal program has been created to help pay for the care of people who may have been harmed by a vaccine. It is a blend of both of them. I think that is better.

MR. WOLFE: I'm sorry, could you say that again?

MS. GALLAGHER: A federal program has been created to help pay for the care of people who may have been harmed by a vaccine.

MR. WOLFE: Perfect.

MS. HOIBERG: I had a quick question. I just had a question about the worrying about when a child is moderately ill or has a mild illness, they can still possibly get the vaccine. I was always told that even if your kid has the sniffles, but especially a mild fever or whatnot, they shouldn't get the vaccine, because their systems are already compromised, they are already fighting off other illnesses.

MR. WOLFE: This is standard ACIP general recommendations language, or not the language, but the concept. A mild or moderate acute illness, you can usually get the -- that is why we say usually, because it is really a clinical decision -- can usually get the vaccine. If you

have got a severe acute illness, usually they say to wait.

MS. HOIBERG: I have a question about the last section that we worked on. We were told yesterday that there is not a lot of information or outreach out there about the program. So I think most people are relying on the VIS's to find out about it.

Is there some way with a very short sentence in that section to encourage people to contact the program immediately if they believe that their child has a reaction?

I know this isn't necessarily a tool kit to educate people about the program, but it is actually a tool that is being used. What is missing here is the piece that a lot of people are getting caught up in, and that is the shortened window of time, the three year statute of limitations for people to file a claim.

Although I don't want to go into all the legalese in this section, something in there to encourage people that they have to respond pretty immediately to the program if they think the child has suffered a vaccine injury, I think would get us somewhere in terms of bridging that gap between people who are dealing with possible vaccine injuries and that short window of time where they can file a claim.

DR. FISHER: I think that is a great idea.

MR. SCONYERS: A lot of support for that. So something like, you should contact the Vaccine Injury

Compensation Program immediately in case of a serious reaction to a vaccine.

MS. GALLAGHER: Should we maybe say right away?

MR. SCONYERS: We don't want to wordsmith too much. We are talking a whole new thing, asking to be included into it.

MR. WOLFE: We can work that concept into it.

MR. SCONYERS: Other comments on rotavirus?

MS. CASTRO LEWIS: Yes. Number eight, is this a more general information about vaccines or about the Vaccine Injury Compensation Program, or is just general?

MR. SCONYERS: Vaccines. Also on rotavirus, I had a couple of comments in section number four, babies who are moderately or severely ill at the time the vaccination is scheduled should probably wait until they recover. I don't find that gives much guidance to families. Is that usually? Usually sounds --

DR. FISHER: Here is the problem with this specific vaccine. If you don't get the first dose by 13 weeks, it is not licensed to be given after that time period. So the reason that this is written with a little bit more flexibility is to try to get the first dose in, because otherwise you are stuck. You can't immunize the child off label.

MR. WOLFE: That is going to be the provider's

decision, not the parents'. This is more to inform them, to give them a little bit about what their doctor or nurse might be telling them.

MR. SCONYERS: I understand. It is just the word probably to me that sounds like we are asking the parent to make a statistical determination about whether it is appropriate or not.

DR. HERR: But it says at the bottom, it says later on, as your doctor or nurse. So it is just something in conjunction with the child's physician. It opens discussion, which it should.

MR. WOLFE: Could we say something like, will usually be asked to wait, or something like that?

MS. HOIBERG: Yes, that sounds better.

MR. SCONYERS: That sounds better to me. That sounds more like guidance to me.

Then my other comment is, in paragraph number three, when you are talking about the design schedule, you say first dose, and then should be given by age 14 weeks, six days. I think what you mean by that is no later than that, right?

MR. WOLFE: Yes.

MR. SCONYERS: I found that wording a little bit confusing. To me it was more clear to add in, no later than. That doesn't mean it is clear to anybody else, but it wasn't

clear.

MR. WOLFE: If it is not clear to you especially, it is not going to be clear to anybody. So not later than?

MR. SCONYERS: Yes. I just thought that clarified it. Anything else on rotavirus? Let's move on. Skip, the next step in our package is hep-B.

MR. WOLFE: As I mentioned, the main change here was that we had gotten a lot of the routine schedule back in that had been missing from the last. People felt more intentionally about that than I ever imagined they would.

MR. SCONYERS: Comments on hep-B?

DR. FISHER: The biggest comment on hepatitis-B, at the end of the very first column, being stuck with a used needle on the job, just take out on the job.

MS. HOIBERG: Yes, because they are not going to be working as --

MR. WOLFE: Wait, I'm trying to find that.

DR. FISHER: The very last one.

MR. WOLFE: First column, yes, I see. Just take out on the job?

DR. FISHER: Yes, because any needle that happened to be contaminated would do it.

MR. WOLFE: Okay.

MR. SCONYERS: Other comments on hep-B?

DR. FISHER: Except for, we now want seven to read

the same.

MS. GALLAGHER: And we want Spanish at the top of it.

MR. WOLFE: That will change on all of them.

MS. HOIBERG: They added back the birthday. They changed the vaccine, took out all of the mercury, all the thimerosal that was in it that was causing all the problems. There had been a study come out that said they recommended you wait until six months to get the first dose.

MR. WOLFE: As I recall, that was an option. But the thimerosal is out now, so that shouldn't be an issue.

MR. SCONYERS: In the dosing schedule, paragraph three, some babies get four doses, usually when a combo vaccine is used. I was interested in the definitiveness of the statement, the extra dose is not harmful.

MR. WOLFE: Yes, I wondered about that, too. I don't know how equivocal you can be and still be understood.

If anybody has any suggestions, I would welcome them. In a way, you hate to say should not be harmful, because then that is going to raise questions too.

MS. HOIBERG: Can you just take it out? I think it just needs to be taken out.

MR. WOLFE: That is always a good solution. Okay.

MS. HOIBERG: You are saying that it is not harmful; what if you did? Then you can almost get sued for

lying.

MR. WOLFE: I suppose people will wonder, but the implication is that it is not harmful if you don't say anything about it.

MS. GALLAGHER: Or you could even have the implication that the other three doses are harmful. It is only that last one that is safe.

MR. SCONYERS: How about this, though? I think your point here is that this schedule is acceptable.

MR. WOLFE: Yes.

MR. SCONYERS: So something like that.

MR. WOLFE: Good, okay.

MR. SCONYERS: This schedule is acceptable. I guess there are too many syllables, but --

MR. WOLFE: Yes, we will figure out a simple way to say that.

MR. SCONYERS: -- I think that is your point.

MR. WOLFE: Yes, it is.

MS. GALLAGHER: Maybe you just want to say, both schedules are okay.

MR. SCONYERS: Anything else on hep-B? Skip, under paragraph five, the risks section, the generalized section that says we may not figure out some adverse effects until we have a jillion people immunized, I like the way it was worded here. I thought that this was accessible language, more so

than the one we just looked at in rotavirus. This is language that is common to all of them, and so I would encourage you to find your most communicative language and stick with that, instead of --

MR. WOLFE: That last paragraph in the first column, you're talking about?

MR. SCONYERS: A vaccine like any medicine could cause a serious reaction, but the risk of a vaccine causing serious harm or death is extremely small. You can't include the number for the other ones, but I just like the wording of this one.

MS. BUCK: But I don't really like the last sentence. The first thing that I thought of after I read the last sentence was, how many of those ten million people had an adverse event, you know what I mean? It almost threw you back to that. More than 100 million people have gotten it. Your next thought is, well, how many of them got hurt? So I'm not quite sure what the point of that --

MR. WOLFE: I guess the implication was supposed to be, of the 100 million people that got the vaccine and are still alive, there are a billion other -- maybe that is too subtle.

MR. SCONYERS: I think it probably is. I agree with Tawny's point here.

MR. WOLFE: Take it out?

MS. BUCK: I think you are trying too hard there.  
I think you should take it out.

MR. WOLFE: Okay.

MR. SCONYERS: Anything else on hep-B?

MS. GALLAGHER: Now, are we changing rotavirus? I just got confused.

MR. SCONYERS: I would encourage CDC to use standard language for all of the VIS's for the things that are common to all of them, whatever the most communicative language is.

MR. WOLFE: I guess that would mean -- yes, when we do change the wording, we do get around to changing them all.

But I guess a more time consuming but better way to do it was, once we decide on wording, to go back and change all the existing ones to match that.

MR. SCONYERS: I think what I am suggesting is that for these ones that we are considering today, --

MR. WOLFE: Yes, to make them more consistent.

MR. SCONYERS: We already made comments about seven, we have made comments about six. I would say the same thing about this paragraph in section five.

MS. GALLAGHER: Section five of rotavirus should read, a vaccine like any medicine could, yadda, yadda, yadda?

MR. SCONYERS: That is what I would encourage.

MR. WOLFE: Okay, if you like that wording. Yes,

we have experimented with different ways to word that. If we have got one that you all like, let's use it.

DR. HERR: If you want to add a last sentence to that section five, the longer vaccines are in use, the more obviously the side effects and deleterious reactions.

MR. WOLFE: I think we won't use the word deleterious.

DR. HERR: But something on that idea, that the more you use them, the more you are going to find out what the bad effects are.

MR. SCONYERS: The other possibility there, Tom, is to pick up the last sentence of section five of rotavirus which says, like all vaccines, rotavirus vaccine will continue to be monitored for unusual or severe problems.

MR. WOLFE: I think that one we ought to put in all of them.

MS. BUCK: One of the things that is a little troubling is that first statement in number four, because it seems like it is a statement about, if you have a life threatening allergy to yeast or any other component of the vaccine, tell your provider. I think that as a parent would be kind of troubling when you are recommending a first dose of a vaccine.

MR. WOLFE: I don't know if there is any way to get around that though, because that is a contraindication, so we

have to mention that. Even a two month old, I don't think parents are going to necessarily know about what kinds of allergies their children have.

MS. BUCK: That is kind of scary though, to think that you are providing vaccine that can have a problem with an allergy like that, without some way to screen for that first.

It is good that you are being up front about it on here, but in the concept I think that is a little troubling.

MR. WOLFE: I don't know how we could not say it. Then if the child did have an allergic, an anaphylactic reaction, they could say, nobody told us about it.

MS. BUCK: Right. I just think it is definitely a sign of a bigger issue, which is that if you are going to provide vaccines that early, at some point trying to screen for some of this stuff before you build the guides on whether or not they have these allergies is -- not certainly in your purview, but doing the VIS's, it definitely brings that issue up.

MS. GALLAGHER: But isn't it more complicated than that? You can become allergic.

MR. WOLFE: Usually, as I understand it, on the first dose it will probably not cause a reaction, but the second one might.

MS. GALLAGHER: But even as an adult you can

develop an allergy, so there is no way to screen in advance effectively.

MR. WOLFE: That is why we added that, tell your provider if you have any severe allergy. That seems like the only reasonable way to get at that without listing every ingredient and going into a lot of other detail.

MS. HOIBERG: But you actually say, any other component of the vaccine, so don't you need to list every single component?

MR. WOLFE: Not necessarily, first of all because we assume that probably parents are not going to know if their children have any allergies. So this tells them to tell their provider about any allergy that they do know about. Also, I think that should probably be the provider's responsibility, because they have got the package insert there with all of the ingredients listed. I don't think we can reasonably list every component of every vaccine on the VIS's.

MS. HOIBERG: No, but because of the wording here, they are going to do, well, what is in it. You are saying this person should not get the hepatitis-B vaccine if, anyone with an allergy to yeast or to any other component of the vaccine. They don't know what the components of the vaccine are, unless the doctor takes time to say these are what is in it. But I have never had a physician go, oh, and by the way,

these are the components of the vaccine.

MR. SCONYERS: But the next sentence says, tell your provider if you have any allergies. That I think is how it is intended to be --

MS. BUCK: I think the major problem is the birth dose. I think there is a lot of concern and discussion about the birth dose that have B, anyway. So I think it is just definitely going to open up that conversation with a lot of providers and their patients with the birth dose.

MR. WOLFE: Is there anything you think we should change to deal with that?

MS. BUCK: Actually I don't. I think it is just making more of a statement about the birth dose that has B and that whole concept. I think for the purpose that you are doing with the VIS, it is good that you have got something in there like that. But I think it certainly does bring that issue up with that particular vaccine and the birth dose. I don't think there is anything you can do there that you haven't already done.

MR. WOLFE: Incidentally, and this may apply to this. Something we are starting to work on here is one page quickly cheat sheets for providers that we want for each vaccine, that will contain the essential information on the route, the site. It will include a list of all the ingredients that are in the vaccine, contraindications and so

on, that could be provided to doctors and nurses and people who give shots, to save them from having to page through the ACIP statements or the Red Book or whatever when they are giving a shot. They can get the essential information they need on a one page sheet.

So we are starting to work on those. That could help give providers some of the information that they might need to deal with the things that we are talking about here.

MS. BUCK: That is a really good idea. I'm glad to hear you are doing that. The Department of Defense has got some materials that are similar like that, that even follow for providers a cheat sheet.

MR. WOLFE: Oh, good. Are they on the website somewhere?

MS. BUCK: Yes. I think you might be able to talk to Renate Ingler. But they have even got some steps on, once there is an adverse event, real quick steps on what you want to do immediately, or how to use that with following doses. So I think that is great.

DR. SALMON: Maybe a partial remedy on these concerns, it might be helpful to say, if you are aware that your child has an allergy. It recognizes that some people might be aware.

MR. SCONYERS: Dan's comment is to tell your provider if you are aware that your child has any allergies.

MS. BUCK: Yes, that is good.

MS. HOIBERG: Also, it says here to tell your provider if you have any particular allergies. If you yourself are allergic to latex, you probably should not give your child the vaccine because they could possibly also have that allergy.

MR. SCONYERS: We are consuming our time on this. This is a good conversation. I am just worried about running out of time for it.

MR. WOLFE: We will think about those issues at least.

MR. SCONYERS: But these are good comments. I'm not trying to cut it off at all. I'm just watching our time. What else on hep-B? Next up, Skip, in our package is the multi vaccine infant VIS.

MR. WOLFE: In there, as I mentioned, the only real change from the previous one was adding information about rotorex.

MR. SCONYERS: Comments?

DR. FISHER: I had a lot of comments on this one. In the first page I had no comments, but on the second page, about the diseases, there is just a lot of information that isn't quite totally right.

In tetanus, you can get it from a cut or wound. You can't get it from a cut or a wound. We do surgery all

the time, no one gets tetanus from that. It has to be a contaminated or a dirty -- it has to be something else in there. That doesn't imply that people are going to get tetanus from the usual cut that they get. So I think that was my one on tetanus.

Then on hemophilus, you can get it from contact with an infected person or a person who is carrying the bacteria in their nose. So again, we have to make the point that it is not just infected sick people who can transmit these diseases.

Then in polio, you had, there may be no signs or symptoms at all. In fact, that is probably true for most of them. So to say it for polio implies that it is not true for the other ones. So I think you need to decide if you are going to say it or not say it, but include it in the other ones where it may be true as well.

MR. SCONYERS: And your point, Meg, about rotavirus, it is just contact with an infected person?

DR. FISHER: Right. I changed that from, you can get it from contact with other children who are infected, to other children who have it. I think that would be understandable. Again, it could be other people who have it, as opposed to other children.

Then signs and symptoms include severe diarrhea, I would leave out the severe there, because most people don't

get severe diarrhea, they just get regular diarrhea.

MR. WOLFE: Okay.

DR. FISHER: So those were my main things. Pneumococcus, you can get it from contact with a person who has it, I thought would be an easier way to say that. It would leave out the fact that you had to be infected.

Then I'm sorry, I'm jumping around a little bit. In hepatitis-B, it says babies can get it at birth if the mother is infected or through a cut or wound. Again, I would leave out the, or through a cut or wound. Every baby has the umbilical cord cut.

MR. WOLFE: I think the reason for putting that in there is we keep having to justify where we give it to babies. So the more reasons we can think of that a baby could become infected, but I agree, that is probably not useful.

DR. FISHER: Yes, but then you can say, children can get it from exposure to blood that is infected. I think that would be fine. That actually would be better.

MS. BUCK: To say a cut or wound, it sounds like if your baby is cut they are going to get hepatitis-B. That is not accurate.

DR. FISHER: Then in how vaccines work, immunity from disease, it is not true that when a child gets sick with one of these diseases, their immune system produces immunity.

It is not true for all the diseases. We know from hemophilus influenza type B, if you got it and you are under two years of age, you didn't make an immune response.

For tetanus, we know that even if you get full-blown tetanus, you don't make an immune response. So it is just not quite accurate. I think it would be better to, all you have to do is put in the word usually, an immune system that is usually or often.

Then the immunity from vaccines, vaccines are made with the same bacteria or viruses, for instance, tetanus toxoid has nothing to do with the bacteria. It is a product of the bacteria.

MR. WOLFE: True. The reason I simplified it is because I think those nuances are not going to mean anything to most people. This is one of the things I want to test when I do those focus groups, is to see if something that is not quite factually true can still communicate what we need to communicate.

DR. FISHER: Yes, I hear that, but I also don't like the idea that we are giving people stuff that is not factually true.

MS. BUCK: Yes, and you need to be careful not to imply that just because you have gotten the vaccine, you are immune.

DR. FISHER: That is true, too. So I was going to

say, or from products of the germs that cause a disease, but they have been changed, weakened or killed, to make them safe.

DR. SALMON: I think you can make a similar point with the next sentence.

MS. BUCK: And your statement, able to develop immunity without having to get sick first, that is a little strong.

MR. WOLFE: Maybe we can make this a little more theoretical.

MS. BUCK: Yes.

MR. WOLFE: To say that this is how they work, not necessarily that it will happen every time.

MS. BUCK: Yes, more of a concept, the concept behind vaccines, or something like that. That is what you are doing, you are describing the concept, but you are not making a statement that --

MR. WOLFE: That it always happens.

DR. SALMON: I would say that line of thinking is true for the next sentence that says, a child --

MR. WOLFE: Dan, I can't hear you, sorry.

DR. SALMON: I'm sorry, Skip. The next sentence that says, a child's immune system responds to a vaccine the same way, I think it is similar. It is not exactly the same way. There are differences between immunity from disease.

DR. FISHER: Yes, in fact hemophilus responds better.

DR. SALMON: I would say similarly, which is the general concept.

MR. SCONYERS: You can say similarly instead of the same.

MR. WOLFE: Okay. Again, the readers may perceive those two statements the same way. I think the point we were trying to make there is, we were trying to respond to the accusation that vaccine immunity is not natural. When an immune system responds to a vaccine, it is doing basically the same thing as it would if it were responding to a disease, was the point I was trying to make there.

DR. FISHER: I think similar would do it though.

MR. SCONYERS: I think we have to find a way to be both communicative and accurate. So I think you are hearing from us that we want you to do both. Don't sacrifice accuracy for ease of communication.

DR. FISHER: And that was the ones I had on those.

MR. SCONYERS: Other comments on the multi vaccine for infants?

DR. HERR: The only thing I was going to say is on the question of immunity. There is one thing with being simple. I think to most people, saying immunity implies perfection. When you recover from an illness you have

developed immunity. It may be transient.

So the difference between vaccines and response to certain illnesses is, in those situations you develop a protective immunity, which is different than getting cold after cold after cold after cold with the same rhinovirus. You do develop immunity. But that is probably for the vast majority of people standard, we don't have to worry about it.

MS. CASTRO LEWIS: On the first page, it sounds a little weird to me, but English is my strength. When it says, your baby will get vaccine today that will prevent diseases, I don't know if that is in the right place, and is not essential for the content of the --

MR. SCONYERS: I think the idea is that this is delivered at the time of vaccination.

DR. FISHER: You are talking about a misplaced modifier.

MR. WOLFE: If we put it at the end of that sentence that would be worse, because then it would sound like it will only prevent the diseases for that day.

MS. CASTRO LEWIS: At the beginning, today your baby can get vaccines that prevent diseases.

MR. WOLFE: Okay, good.

MR. SCONYERS: That seems fine.

MS. CASTRO LEWIS: Then on the third page, under the DTAP, can get vaccine for DP which does not contain the

pertussis. Is it worth it to say why?

MR. WOLFE: The sentence before that says that some children should not get pertussis vaccine, which is an explanation of why that --

MS. CASTRO LEWIS: It doesn't say why.

MR. SCONYERS: Didn't we refer before that to its own vaccine information sheet?

MR. WOLFE: Yes, and again, it is a question of how much detail we should put on VIS's and how much it would be the responsibility to explain.

DR. HERR: If they are going to be getting another VIS for DTAP, it is going to include that information, in addition to getting these handouts.

MR. SCONYERS: I had a question about that, Skip. Is it your idea that they will get this multi vaccine as well as the individual?

MR. WOLFE: No, it should be instead of, or it could be either, but the reason was getting one document to give people instead of five.

MR. SCONYERS: Right, so I think what Magda is saying is that there needs to be a flag here to talk about this with your provider. We don't provide them with any information about why a kid might not get pertussis vaccine. As a parent, you go, is my id getting it or not.

MS. GALLAGHER: I don't know if it is the place of

this Commission to give this advice, but I am not comfortable with this summary sheet replacing the individual sheets. I think that the information on the individual sheets is necessary.

MR. WOLFE: The mandate for VIS's is that it is to provide information on vaccine risk and vaccine benefit, and tell people about the compensation program. That is all legally they really have to do.

MS. CASTRO LEWIS: What is the purpose of the summary, and how is it going to be formatted? If this is the way that it is going to be formatted, nobody is going to read it. I am telling you, in all the focus groups that we have done with parents that receive information about vaccine or any medication for their children, this is not very friendly.

I think it is important, but it is also important for the parents to read it.

The font is very small. Everything is difficult to read, three pages, and I find it not very easy to read. I don't know if it is going to be more of a colorful brochure or something that invites the parents to read it.

DR. TEMPFER: We have been using at my clinic, and we really found that the parents really like them a lot. I think the important point is, it gives you the information that you need to have a discussion with the parent. That is why I think providers like them also. That is what they are

about. More concise, start the discussion, and then from there you can really expand on it. We really like them.

MR. WOLFE: Thank you. That is the idea. The VIS's aren't intended to give parents all the information they need

MS. BUCK: I do think that the reality is, a lot of providers -- all due respect to Tammy, because my guess is that she is probably a little atypical because of your interest in this and your knowledge of this, but a lot of providers are just handing the VIS to patients, and that is about it.

So if that is what is happening, then I have to agree with Magda. I don't think it is very user friendly. I think it is too long and too wordy, and I don't see a parent who has maybe been handed this by the nurse who is waiting for the doctor to come in, however long they are sitting in the waiting room, to go through this as much as they would the original VIS's, which were pretty simplified and kind of sweet.

MR. WOLFE: But they might have to go through six of those, as opposed to one of this one.

MS. BUCK: But they are not always getting all six.

MR. WOLFE: No, that is why it is an option. Providers can do whatever they want. If they want to give the individuals, they can. If they prefer to give this one,

they can give this one. We were just giving them another option.

MS. BUCK: I was under the impression that this would be given along with the others. Then I thought, this would be helpful for people who want to wade through the information and do a lot of reading. But if it was the only one given, I think it would be as effective, is my only comment.

MS. CASTRO LEWIS: Many years ago, this is like 13 years, 14 years, I don't know, CDC had a nice brochure like a small booklet, a nice size. It was for parents, everything parents need to know about vaccines. I can't remember the name.

MR. WOLFE: We still have that, I think. We have a book called The Parents' Guide to Childhood Immunization.

MS. CASTRO LEWIS: Right. But that was a much more friendly to read booklet. It had information that was necessary, and it had pictures that explained things. Let's face it, sometimes young parents need more pictures and more color and something that makes them feel -- they are in a stage with a baby, and it is an emotional thing. So I think it could be better presented.

MR. SCONYERS: I want to move us along. We have got a lot of comments on this, and we have some others to cover. I don't want to cut it off, but --

MS. BUCK: This one is a little bit more involved, on the last page where you are talking about precautions. Although this may not be very popular, I would argue that you need to say something in here that they aren't evaluated for their safety if given to sick kids. You understand that they are safe or relatively safe when giving them to healthy kids, but you don't know, and they are not tested on sick kids.

MR. SCONYERS: Is that the first paragraph there, Tawny?

MS. BUCK: In that section, it seems to be a little bit more involved of a piece. So I think you would have room to put something like that in there. If you are talking about communicating that it is a risk, I think you need to be pretty clear about that.

DR. HERR: I'm sorry, could you say that again, Tawny, please?

MS. BUCK: They are not testing vaccines on whether or not they are safe when they are given to kids who are sick. It is like what Sarah brought up before, when you say --

DR. HERR: You mean in the preclinical trials?

MS. BUCK: Yes.

MS. GALLAGHER: Well, actually there are some, and it varies from vaccine to vaccine, but there are trials in sick children in different populations. If you wade through

all the package inserts, you will see that. When they are doing clinical trials, generally the protocol is the same as what comes out in the package insert, that if you have a mild illness you can still get the vaccine.

So they are testing it in children that have a mild illness, and that is how the package insert is created. Sometimes they test them in sick as well children, sometimes they test them in immunocompromised children. I can't tell for all vaccines across all populations, but there are studies in vulnerable populations, and they are published, and they are available.

MS. BUCK: I still think that when you are dealing with this, you need to be a little clearer about that. If your child is sick and you go into your provider, you are not nearly as confident in the safety or in the potential for an adverse event for the vaccine than if they were completely healthy.

MR. WOLFE: That is something we can include in the focus groups that we do. That is something that parents are really going to be interested in.

MS. BUCK: And I'm not very eloquent in my wording. I'm glad you will consider it for just the concept of it.

MR. GARRETT: I just didn't want to put something false down, that they have never been tested in sick children. That would be false.

DR. HERR: I can't speak for it, but I have been looking into this. The recommendations for many years has been minor illnesses and not a reason not to infect. There has been a push over the past 20 years to try to increase the use of vaccines during minor illnesses, increase the immunization rate. I would have expected that there have been some studies that have looked into, has anything more happened during those periods, but I can't answer that.

MS. BUCK: That's the thing. You guys are providers, and you are not quite clear. So I think that clarifying that a little bit better would be helpful for parents and providers than when asked directly on the questions. So if that is something you can float to a focus group to get --

MR. WOLFE: Okay.

MR. SCONYERS: I have got a couple of comments on this one. One is, I was overwhelmed by the schedule. The schedule is accurate. I just am commenting that keeping straight what doses have to happen in two months, six months, 15 months, two years, it is just --

MR. WOLFE: Again, that is just something that we put in that is not really necessary. It is something that, a parent gets this because their children are getting that. So it is something that the provider is going to tell them, anyway.

MR. SCONYERS: No, that is not my point. My point is that the actual adopted schedule of vaccination is very confusing for parents and difficult to follow. It is not anything for us, but I don't know whether that is an ACIP issue or what.

MR. WOLFE: You are talking about the top of the third page?

MR. SCONYERS: Yes, the actual schedule. I'm not saying that there is anything inaccurate here. I am saying that that schedule as recommended is hard for parents to comply with.

MS. GALLAGHER: On the CDC website there is a nice little chart. That might be better than saying it in words.

MR. SCONYERS: But the problem is not that there is a good chart. The problem is that the schedule is a hard one.

MR. WOLFE: Well, there is nothing we can do about that, I guess.

MR. SCONYERS: Nothing today, but it is a comment for folks who have some access to ACIP.

MS. BUCK: I do agree with that comment, which is that the chart is easier to read than the text.

MR. SCONYERS: Yes, that may be a good idea. A couple of other comments. In the adolescent multi vaccine statement, you have a little box that includes definitions

for mild, moderate and serious. I liked that. I wonder if you can pull in that little box to this one, so that people have a handy reference to what mild, moderate and serious means.

MR. WOLFE: As a matter of fact, I would sort of like to incorporate that in all the VIS's.

MR. SCONYERS: I think that is a great idea. A couple of comments on the risk section. Under other reactions --

MR. WOLFE: Are we back on the pediatric one now?

MR. SCONYERS: Yes, sorry. Other reactions, you have a sentence that says, an association doesn't prove that a vaccine caused a reaction, but does mean it is probable.

My grammar teachers taught me that the referent for it is a little bit unclear. What does the it refer to?

MR. WOLFE: Okay.

MR. SCONYERS: So what is it that is probable, that a vaccine caused a reaction? I wrote out some comments, that something like that does mean that the reaction happens more often in vaccinated children than in children who aren't vaccinated. I don't know if that is right or not. I just found that when I stopped to think about what it meant, I wasn't clear about what it meant.

Under polio, hep-B, HIB, you say, these vaccines have not been associated with mild problems other than local

reactions or with moderate or serious problems. I thought that it would be better to put the word any or with any moderate or serious problems. I just thought the referent was a little bit confusing.

MR. WOLFE: Okay.

MR. SCONYERS: And under both pneumococcal and rotavirus you only list mild, and you don't say whether there are any moderate or serious reactions that are known. Just for completeness, since you had addressed mild, moderate and serious in each of the other vaccines, it seems like you ought to say whether there are any identified moderate or serious reactions for pneumococcal or rotavirus, and if there are none, just say there are no identified moderate or serious problems with these vaccines.

MR. WOLFE: Okay.

MS. BUCK: In that section on vaccine risk, I totally understand what you are trying to get at there about the communication of benefit over risk. But I just don't like how it reads. It just seems to me like you are protesting too much. I wish there is some different way that the CDC can consider doing that communication piece, because it just sounds like you talked to your attorneys here, and you are just trying to hard to talk about how adverse events almost don't happen, or they can't be associated or all that.

I understand what you are doing, but it doesn't

read very well. I think you could do a better job of explaining the benefits and the risk and the difference, and the rareness of risks, but understanding that they do occur occasionally and all that.

But just a general comment, I understand what you are trying to do, but I really think you are trying too hard.

It is going to give you more grief, the way it is written.

MS. HOIBERG: I agree with Tawny. I think where it says various problems under DTAP, and it talks about long term seizures, coma, lowered consciousness and permanent brain damage have been reported very rarely after DTAP vaccine. Then you add, they are so rare, we can't be sure that they are caused by the vaccine. You are contradicting yourself.

MR. WOLFE: Maybe it is not necessary to even say that. I guess it is a difficult concept to get across without getting into a discussion of statistics, so maybe it is not even worth saying.

MS. BUCK: I think people are going to understand that there are adverse events and you need to talk about them, and you need to talk about their rarity. But unlike any other sections where you talk about the efficacy of your bad things, and that they will prevent disease, and that you will be immune, you are being pretty affirmative on those sections, and then in here you are spending a lot of time

highlighting words, associated, and using italics and bold, and it feels like you are trying too hard to play down the risks, to the point that you may be creating more problems for yourself.

I don't know if I am being clear about that, but I think you could re-look at that section.

MR. WOLFE: Okay.

MR. SCONYERS: A lot of comment. Are we ready to move on to the adolescent multi vaccine?

DR. HERR: On the adolescent, just to jump ahead, because you already opened the door on the vaccine groups and reactions. I actually think that whole section is terrible.

It is incredibly vague, and it is incredibly difficult to understand.

When you have a DTAP reaction and it is showing serious swelling, severe pain, redness under the arm where the shot was given, you had swelling in the beginning in the mild. It doesn't say severe pain. Pain is relative. A child who gets a shot will yell and scream. How do you know how severe things are? It is relative pain? Redness on the site of a shot is common.

I think this is incredibly confusing. It is confusing for me to read it, no less somebody who doesn't have any medical training. I think, try to improve many of the things that are on this paper. I don't think we need to

go line by line on it. I think the whole idea needs to be rethought.

MS. BUCK: Is there syncope or a fainting event with HPV?

MR. SCONYERS: I noted that, too. It is on the precautions page, Tawny.

DR. HERR: Little kids will cry when they get a shot.

MS. BUCK: Yes, but fainting is something that is being looked at as happening more than normal with HPV. Am I wrong, Dan? I thought that was something that was being looked at.

MR. WOLFE: I'm trying to remember. When that was presented at ACIP, was syncope more common after HPV than other vaccines? I thought they said that it wasn't, but I can't remember for sure.

MR. SCONYERS: I think there is a perception that it is.

MR. WOLFE: Yes, but I'm not sure that it really is.

MR. SCONYERS: But it is unclear whether you are treating it as a risk. The difference between the risk on page three and the caution on page four is unclear.

MR. WOLFE: I think the point is that we want to tell parents that we do encourage them to be aware of it and

wait, which is why it is more of a precaution than a risk, I think, because we are asking the parents to do something. We are asking them to sit there for 15 minutes afterwards, where they are sitting down so they don't fall.

MS. HOIBERG: On the HPV, the vaccine risk, the National Vaccine Information Center was overwhelmed with reports of paralysis and severe adverse effects on the HPV after having gotten the HPV vaccine. Is there a reason why that is not on here?

MR. WOLFE: With paralysis?

MS. HOIBERG: Yes.

MR. WOLFE: The risks here come from the ACIP statement, so if ACIP doesn't mention it, we don't mention it. I don't know if that is something that was just reported a lot, that there was never shown to be a causal relationship. I'm not sure.

DR. FISHER: I have a bunch of comments on this as well. I am happy since we are low on time to just give them to you. But I did have just a couple of them.

I personally don't like the picture on the first page. The adolescents don't have faces. I actually found that truly offensive, to not have a face for the adolescents. Maybe that is just me, maybe I am just strange.

MS. CASTRO LEWIS: No, I agree with you on that.

MR. SCONYERS: That is how they will perceive it,

as offensive.

DR. FISHER: Then in the, what do I do if I have a moderate or severe reaction, to me this is written for the adolescent to be reading it. It says, call a doctor or get to a doctor right away. We don't want them driving if they are having anaphylaxis. I would say, call a doctor and have someone get you to a doctor right away.

The other way we say it for the other ones is, get the person to a doctor. I don't want adolescents who think they are having a problem doing something nuts.

MR. SCONYERS: You heard that they had significant concerns about the risk section.

MR. WOLFE: Yes. I appreciate what you are talking about in the TB section. What we were trying to do there is include all the risks that the ACIP mentions. We were trying to differentiate between extensive limb swelling and R-2s with the moderate and severe without actually using those terms.

MR. SCONYERS: I think Tom's point is, it doesn't provide a lot of guidance to consumers. To the extent that that is what we are intending to do, it doesn't really achieve that.

Other comments on this one? Skip, on page two under meningococcal, this is what I have always heard, but let me just ask, why is it that it is college freshmen living

indoors?

MR. WOLFE: Because I think that is just what the data showed. I don't know if anybody actually explained why, but it was only freshmen living in dorms that were at higher risk in the studies.

DR. HERR: More upperclassmen don't live in dormitories.

MR. WOLFE: That may be part of the reason. I don't know.

DR. HERR: They live in apartments and things like that. They are not all grouped together. You are all talking more about people who live together, whether they are in homes or institutions. But certainly a college dormitory is a representative group here. It is no different than children who are handicapped who live in group homes.

DR. FISHER: And it may also be that it is the first time they are getting together. We know for recruits, the risk was --

MR. SCONYERS: It made the epidemiological assumption, and so I wondered if in terms of communicating risk, college students -- if you live at home during your first year, --

MR. WOLFE: But that wouldn't be consistent with the data, because sophomores living in dorms apparently were not at higher risk.

DR. SCANLON: I understand what you are saying. I wonder if they studied college sophomores who are living for the first time in a dorm.

MR. WOLFE: I don't know whether they did or not.

MR. SCONYERS: If that is the data, that is the data. I'm trying to plow through. Influenza, which you started out saying was the most extensively revised, so I am sure we will have zero comments about it. That was the last one that was at your places, and e-mailed out to us ahead of time. So comments on influenza? You got the same comments in the comments section.

MS. CASTRO LEWIS: I am just saying the same comments, the Spanish section and the number seven.

MR. SCONYERS: Anything else on influenza? I will comment that under section three you are talking about who should get flu vaccine. It is recommended for children six months through 18 years. Then at the top of the second column under the third bullet there, anyone at risk of complications from flu, you go down and say, anyone from six months through 18 years. So it seemed like a repetition.

MR. WOLFE: You are talking about on aspirin therapy?

MR. SCONYERS: Yes. You are recommending it for everybody from six months through 18 years, so it doesn't really matter if they are on aspirin therapy or not.

MR. WOLFE: Good point. I will mention that to ACIP, because I think they were putting that as a separate indication also.

MR. SCONYERS: They need a good editor. I am available. Then the only other comment that I had was on page two, over on the right-hand column under nasal spray, you have that box about syncope. It is small font.

MR. WOLFE: It is.

MR. SCONYERS: So to the extent you are trying to call attention to it, you are making it hard to call attention to it from a legibility point of view.

MR. WOLFE: Again, we were struggling with how to fit everything onto two pages.

MR. SCONYERS: I get it, real estate.

MS. GALLAGHER: Try bold, maybe.

MR. SCONYERS: It is just a comment. That doesn't mean that there is anything you can do about it.

MR. WOLFE: We'll try.

MR. SCONYERS: Anything else on influenza? Hearing none, --

MR. WOLFE: Does everyone agree that trying to combine both vaccines under one form is okay, or do you think it is better?

MR. SCONYERS: I think you got no pushback about it.

DR. FISHER: I'll just leave all my comments for you to throw out or do whatever you want with them. I'll give them to Michelle.

MR. WOLFE: Yes, if there are written comments, if there are things that you wanted to say that you didn't get a chance to say today, Michelle knows how to get it through e-mail.

DR. FISHER: Thanks.

MR. WOLFE: Thank you.

**Agenda Item: National Vaccine Plan**

MR. SCONYERS: Are we ready to move on? We are running a little bit late, but we are going to make up good time, not however on the next presentation. We are very pleased to have Dr. Ray Strikas here again to talk with us and give us an update on the National Vaccine Plan. Thank you very much, Ray, for taking this on.

DR. STRIKAS: Thank you very much for inviting me back. That means either I was a big hit the last time I was here in September or I was totally mysterious and I have to re-explain it all to you. Whichever it is, I am happy to do it.

I am going to give you an update on where we are with the National Vaccine Plan. Actually there is some good news. The outline is, I will talk some about what the plan actually looks like. Before when I spoke here, it was a

concept, now it is a reality, at least as a draft. Talk about a Federal Register notice that solicited non-federal input January 14, and a subsequent one extending the comment period. The status of several stakeholder activities, including the Institute of Medicine that I mentioned the last time. The public engagement meetings which will begin a week from tomorrow, and NVAC's role and some roles that ACCV may wish to consider.

The plan is at this website which you can see on the slide up there. More importantly, it is on your handout.

It was posted November 26.

Its contents, briefly. There is a preface, a letter from the then-Assistant Secretary for Health, Dr. Garcia, some acronyms, abbreviations and executive summary and introduction with the pieces that you see down there.

The most important part is the middle of the plan which are five goals. The first four are similar to the original four in the 1994 plan I talked about the last time, developing new and improved vaccines or research, in short. Number two, enhance the safety of vaccines and vaccination practices, which is all about safety. In '94 it said safety and effectiveness. There is a brief mention of a compensation program in goal two, but a more extensive in when I jump to goal four, where we talk about the current program, which deals with both supply and achieving better

use of existing vaccines. There was an executive decision made that programmatic issues, and one can argue that the Vaccine Injury Compensation Program is an integral part of the vaccine program in the U.S. perhaps fit better there. It has a separate objective under goal four.

Jumping back, number three is about communication and education to inform decision making by the public, providers and policy makers. The new goal, which was one or two objectives in the old plan, now is a separate goal unto itself, global prevention of death and disease through safe and effective vaccination.

There are some appendices. The old plan had 14 anticipated outcomes. We make some commentary to the reader in which we think those have been accomplished. We comment on the Institute of Medicine's initial report on what they thought the new plan should contain based on the '94 plan. We list key stakeholder groups in the U.S. who should have a role in this plan. They are also listed throughout the plan under each objective. We have roles and responsibilities for HHS, agencies, offices and some other federal departments. Lastly, we list websites for strategic plans that we looked at in developing this one.

We asked for written comments in the January 14 Federal Register. We asked for them in a very short time window, by January 30. We received comments from over 40

persons and organizations. That was the fuel of the February 6 meeting of the NVAC. We asked for comments on priorities.

The plan is for a ten year period, comments on its existing goals, objectives and strategies, with parentheses saying, should it be an aspirational plan, achievable, or some mixture of both.

We have in the plan what are called indicators, which are broad measurable things, and asked people, are these indicators reasonable things to measure, although ultimately this strategic plan should lead to an action plan with action steps and people who will do those things, and should each have measurable actions, to give ourselves an idea of where we might be going.

We developed some broad indicators which preface each of the goals, and you can look at those on the website where the plan is. Then comments by the stakeholders, particularly about their own organizational or individual role in the plan, to the extent they wished to comment. We just issued a Federal Register notice on February 17 extending the comment period, because we didn't want to limit it to two weeks, but we wanted something for the meeting. We had to issue another notice saying we will take comments through March 31. The e-mail address I will show you shortly.

This is a simple slide. It is probably much better

than the next one, though the next one has more detail, saying the plan and its input. We already had input from the feds who wrote the thing. We need it from non-federal stakeholders including committees such as yourselves. There will be public engagement I will talk about shortly, and the Institute of Medicine committee, all feeding information in.

To make it complicated, but this is a time line of how this is going to work. Along the left-hand side in the blue box is, the first box is just listing processes and who are these people. The second box on the left is the HHS, the feds. The third box is the National Vaccine Advisory Committee and HHS agencies and so on. Public engagement meetings are down there, and then the Institute of Medicine process which I will talk about. So this is an attempt to show this in a time line.

The most important part is that we want to finish the strategic plan by the end of the year, early next year. Our challenge is, the Institute of Medicine doesn't give us a final report until November, so we will do a lot of work before then, but we can't dot the I's and cross the T's until we have the IOM report. Then we will work next year on an implementation or action plan to flesh out what is going to be done and who is going to do it.

To go back to the IOM's work, I will remind you, their job is to hold workshops, national expert stakeholders,

review the draft update. The specific thing they have to do is give us recommendations about priorities for this plan.

They have had meetings July 24 last year on what is now goal four, December 1 on research and development or goal one, February 2 on communication and education, goal three. April 14 upcoming they will do vaccine safety in Washington, and they will talk about global health June 4. As I said, they will give us a report in November.

These are the highlights of what they talked about in December about research, talking about scientific innovation, financing, addressing public needs and priorities and regulatory issues. They had four panels with brief presentations or comments from a series of people within industry, within government and academia. It was a well done process, frankly much better done, we thought, than having a litany of speakers, which is what they did in July. This worked better, to have more exchange of ideas.

They used the same format. Several of you were there. Mr. Moody was there February 2, as were others, about communication and informed decision making. I would say the vast majority of what was discussed was how to better inform people about the risks and benefits of vaccines. There was very little discussed about things such as supply disruptions or that sort of thing; that is part of what we need to inform people about. So we talked about who and what informs

personal decision making, the science of communication, ethical, legal and policy issues, and communicating to encourage innovation. It was a well attended and vigorously discussed meeting.

Posted on the IOM website which is listed on the bottom of this slide is the agenda, the panels and the questions. I only list the panels that they will have. They have a series of questions under each panel they will discuss April 14 in Washington. Hopefully some of you could perhaps attend that. They will webcast this. If you cannot attend, you can attend by webcast. They webcast the last one, as well.

Panel one is, how does one identify vaccine safety concerns. Panel two is studying safety. Panel three is basic science, in vivo, in vitro, in human and clinical models. Panel four, related to this Commission in particular, is policy issues related to vaccine safety and compensation. Although they heard from Dr. Evans about compensation in their very first meeting, March 3 is an overview of the plan. They have carte blanche to discuss what changes or what issues might be modified for the compensation program.

Regarding public engagement, we set up three meetings, hopefully as many as 100 individuals to come and talk in large groups and small groups about the plan. I'll

show you in a second, we have subdivided those five goals into 12 topic areas to try to make it more digestible for people. Five goals is too broad, 36 objectives is too many.

We created 12 topic areas; I'll show you those. Then we will try them out next week, Saturday, in St. Louis, two weeks later in Columbus, and a week later in Syracuse, New York. I think it is unlikely we will add a site. We wanted a site on the West Coast to add some geographic balance, but the edicts of budget dictate we probably won't do that.

The 12, I call them sub-goals here, we are going to re-call them topic areas, I think that is a better term. Improve tools for making vaccines is a research area. Increase vaccination of adults, increase vaccination of adolescents. Makes vaccines affordable or available to everyone. Maintain high rate of vaccination of children. Develop new vaccines, which goes along with the research one of improving tools. Assuring vaccine supply, there was enough vaccine. Improving safety. Assuring compensation. Helping other countries. Improve systems to monitor diseases and vaccination. Finally, improve communications.

We think these capture the five goals, but also capture the essence of what is in the 36 objectives in the plan. We will use these as a focal point to asking the public, how would you prioritize these after we ask them to first develop a series of values around what is important to

you in health care and in vaccines. Things we heard from focus groups are, children are important, communication is important, safety is important, access and affordability is important. These stood out in preliminary work. We will see what happens when we do it on a larger scale.

The NVAC met February 6 -- Ms. Castro Lewis was at that meeting -- to review and discuss the plan. We had a brief plenary session and extended breakout sessions to talk about the five goals, and then four sessions, because the other group didn't have enough people in it, of vaccine industry and researchers, professional organizations, health care payors and plans and public health groups.

The summaries from this meeting will be posted shortly on our website with a list of participants. We have detailed notes. We thought the summaries that were presented that day would be more useful, and if folks want to know more about what was said in detail, we have that available. But we will post the summaries.

Just to remind you that this is the website for the plan. Comments can be sent to this website, NVP comments at HHS.gov. We received about 70 comments since the meeting happened; 57 of those at last count were focused on safety issues, by individuals and organizations. If you wish to send comments as a Commission or individually, we would like to get them by March 31 so we can summarize them.

The NVAC role at this point is as they have done, to orchestrate comments and input, review the IOM report and comment on it. We are going to provide them summaries when we receive all the comments through March 31 to the NVAC and to the IOM for their consideration and deliberation, and any recommendations they have for inclusion or not in the strategic plan.

We think, as I said the last time, this iterative process with the NVAC and to some extent the IOM should insure a quality strategic plan, and we hope it incorporates stakeholder input, although the real horse trading and the difficult parts when we get down to action steps and implementation plan, which we will start thinking about but not write until next year.

The roles for this Commission, for you to decide. I think this is similar to what I talked to you about last September. Obviously we would like you to review the draft plan. You don't need to read the front matter or the back matter unless you want to, but read the goals and objectives.

There are about 35 pages there, and there is a lot of white space, so I hope it is not too difficult to read. It is detailed but it is manageable in the course of a plane ride.

Provide comments to us. You can send them to me. You can send them to e-comments. Participate in the IOM meetings if possible. I would certainly hope that many of

you could participate by webcast if not in person in the meeting on April 14 on safety, which is the issue that you spend most of your time on. You obviously can comment on the IOM committee's final report when it comes out, which we will be happy to share with you.

I think that is the end of my comments. I am happy to take questions.

MR. SCONYERS: Questions for Dr. Strikas?

DR. EVANS: In addition to the panel for discussion on the compensation program, there were a series of questions that were attached to each panel. Those should be shared with the Commission. If you look at those questions, as I recall it had to do with financing vaccine safety, I guess the trust fund and so on. It didn't specifically talk about the program process. But it is something I wanted them to be aware, at least the questions that were in that panel.

DR. STRIKAS: Perhaps one of your staff could -- it would be one page. I didn't bring it with me. You could print that and hand it out to the people. It is right there on the website. I gave you the IOM website, but if Michelle or someone could get it for the folks before they leave to add to your pile of paper.

DR. EVANS: That would be great.

DR. STRIKAS: This one will take five minutes to read. Then you can tell the IOM, feel free to tell them, you

are missing the boat. You need to talk about A, B or C.

They can still modify this. They have not yet listed who is speaking. They are actively looking for speakers, I think. Dan Salmon has talked to them at length, and Dr. Wharton at CDC. Jeff, I don't know if they have talked to you. They should, I hope they will. They ask for speaker suggestions. Obviously you all can participate in framing that discussion, which is an essential one to this whole process.

MR. SCONYERS: Do you know, is this an all-day event?

DR. STRIKAS: It is all day. You will see on their website this question I get asked often, and they do. The public meeting is April 14. The committee then meets the next day to digest what they have heard. So it is April 14-15, but for our purposes it is just April 14.

It is all day. I think they have the time of 8:30 as a start. It is in the Keck Auditorium on Fifth Street, in the new NAS building, which is easy to get to by Metro and all that sort of thing if you are in the area. 8:30 to 5:30 is a rough time frame.

MS. HOIBERG: And it is here?

DR. STRIKAS: In Washington, D.C. at the National Academies' main building, 500 Fifth Street, Northwest. That should be on the website.

MS. BUCK: Did you indicate that the questions that Dr. Evans is referring to can be found in the National Vaccine Plan on the VBPO website? Is that what I heard?

DR. STRIKAS: No, I'm sorry, they are on the Institute of Medicine website. I don't know if, Ms. Buck, you received the slides. If you simply go to the IOM.edu website and then type in National Vaccine Plan in the search engine, it will take you to their website, and the first thing you will see there is for the fourth meeting, the stakeholder meeting. You will click on that, and you will see the agenda and you will see the questions.

MS. BUCK: Oh, great. Thank you very much.

DR. STRIKAS: So it is easy enough to find, but for the folks here we will try to get the printout of the questions.

MR. SCONYERS: Unfortunately Tawny does not have your slides.

MS. BUCK: I do now.

MR. SCONYERS: Oh, do you? Good.

MS. BUCK: I didn't have them, but I have them now.

MR. SCONYERS: Other questions or comments? We really appreciate you coming and providing this update. It sounds like you have been busy, and things going on. You can get the 12 sub-goals answered, it should be pretty easy.

DR. STRIKAS: Well, we will see what the citizens

say. I have been a participant though not an organizer of several public engagement sessions, and they are always stimulating.

MR. SCONYERS: We have been invited to participate by personal presence or by web presence. I would like to suggest, I don't know that this requires any action, but my hope is that our incoming chair will assure that at least one ACCV representative is physically present at the meeting on April 14. So I would really like for us to have at least one representative there to participate.

DR. EVANS: You just asked if we have the budget to support that. We certainly would be happy to send one representative.

MR. SCONYERS: We can and will send one, and if others are able to come on their own recognizance, or participate via the web. Thank you very much. We appreciate the update.

DR. STRIKAS: Thank you.

**Agenda Item: ACCV Recommendations Work Group**

**Report**

MR. SCONYERS: Is everybody okay to plow ahead? We made up a little time, not that that wasn't a meaty presentation, but we made up a little bit of our time.

I would like to -- while we have some momentum, if you are ready to turn to the draft recommendation letter that

the work group prepared, that is at your places, along with the summaries of the work group conference calls that we had.

We met by conference call a couple of times, once in January and once in February, as I recall. Then the work group met in person yesterday morning just prior to our regular scheduled meeting of the full Commission.

I want to acknowledge and express appreciation for the work group members who did work hard on this, Tammy, Sarah, Charlene, Magdalena and Tom, all of whom went through draft after draft, very carefully considered everything that is in here, and engaged in a substantive discussion about the recommendations this Commission ought to be making to the Secretary to improve the functioning of the program.

As I think you all know, we were building on work that had been done in prior Commissions, and trying to reflect a consensus set of recommendations to the Secretary on ways that the program in its function could be improved. I hope that you find that we have done that.

I want to express thanks to Geoff, to Michelle especially for their support of the work group process. I also want to recognize Julia and Elizabeth, who with their great familiarity with the program were able to make sure that we didn't make errors of fact in describing how things work. That was very helpful, to make sure that we stayed accurate in all of our activities.

So you have a draft letter that reflects a unanimous consensus and recommendation of the work group. The letter would be sent from this Commission to the Secretary of Health and Human Services. I am hopeful that by the time this letter can be produced and signed that there will be a name to insert in the name section on page one. I think that we are well on our way to that, based on events of this week.

There was a little question yesterday. The first two pages are introductory, and there will be a signature at the bottom of page two. Then the recommendations are attached as not so much a stand-alone document, but a document that can be torn off and handed to someone in the Justice Department that will draft legislation, assuming that the Secretary supports this.

I want to run briefly through what the recommendations are.

DR. FISHER: Can I ask a question, having not been on the work group? Do all of these recommendations require legislation?

MR. SCONYERS: I believe they do. Yes, they do. That is why they are captured this way.

DR. FISHER: That is why it is done that way, okay.

MR. SCONYERS: There is some advice that is contained in here, but there are legislative changes in each

one of the paragraphs that are being proposed.

Let me just briefly run through them for you. Recommendation number one is to adjust the benefit caps for death and for pain and suffering to account for inflation since 1988 when they were established. They haven't been adjusted since the legislation was adopted in 1988. This would not apply to cases already decided, but would apply to cases to be decided following the adoption of the legislation.

So first of all, inflate that number from 1988 to the current time, and then adjust it, index it for inflation, as virtually everything else is adjusted these days.

We had a long set of discussions about recommendation number two, extending the statute of limitations. It is primarily because the statute of limitations is complex and hard to understand, not only for non-lawyers, but for lawyers who are outside this system.

The bottom line recommendation is to move essentially to an eight-year statute of limitations for both deaths and injuries, but to the extent that this change would bring new petitioners into the system, to make the program the exclusive remedy for those people who would be getting a remedy that they don't current have. So we are not expanding the availability of tort remedies in state courts, but we are expanding the applicability of the system.

There was some question about why is that chosen, that period of time. I think the rationale of earlier work groups was that it corresponds to the eight years of retroactive coverage that is provided under the act when a new vaccine is added. So it just brings the limits in line with each other, and you don't have to go through a complicated analysis about what limits apply.

Recommendation number three is to provide for compensation under the program for family counseling expenses and also for expenses of establishing and maintaining guardianships, conservatorships or in trust. As I think most of you know, in most cases awards that are made to a minor have to be administered through a process of a trust or a guardian, and it costs money to set those up. You have to go through a state court proceeding to establish that. So those expenses would be covered.

Currently the act -- moving on to number four -- would permit the appointment of an adult who has been injured by a vaccine to the Commission, rather than to require that the representatives be the parents of children who have been injured by a vaccine. The idea here is that the Secretary could appoint a member to the Commission who either was themselves an adult injured by a vaccine or was perhaps the spouse. Currently it has to be the parent, but it could be the spouse or maybe a sibling of the person who was injured

by the vaccine.

Number five is to put into legislation what is currently the law under the established circuit court case for the federal circuit, which is that benefits are available both for injuries and for deaths. So it is not an either-or proposition, if a person qualifies for benefits both for a vaccine related injuries and for a death that arises as a result of the vaccine.

We spent a fair amount of time on paragraph number six. I want to thank Sherry for clarifying a number of things in there for us. This paragraph would permit parents or legal guardians to seek their own damages for loss of companionship, loss of earnings, and for the medical expenses that they experience as the result of a vaccine related injury to a child.

Paragraphs seven, eight and nine are a set of definitional changes that clarify that those components that go into the vaccine when manufactured in accordance with the approval that is issued from the FDA constitute part of the vaccine and are not adulterants or contaminants. So that is to say that when an ingredient appears in the license application, it is part of the vaccine and not to be treated separately from that. The three sets of definitions work together. You need to affect all of them to make that change.

Paragraph number ten is to put in the statute what is currently the case under federal circuit law, which is that interim fees and costs are available. This is, Meg, to your point where we are providing advice as well as suggesting a statutory change. We don't feel like we know how to prescribe the exact schedule on which interim fees ought to be paid. We did talk about that as a possibility, but we don't think that we know enough to say that. But what we are prepared to say is that we encourage early payment, and that that be if possible within 12 to 18 months of the filing. The point was made several times that, especially in getting some of the early expert witness fees, it is expensive to move a case forward at that point.

Then finally, a situation that doesn't arise very often, paragraph 11 deals with making it possible to make payments directly to the petitioner's attorney rather than to the attorney and the petitioner. There are unusual cases where petitioners can't be found or for other reasons, that payments to their attorneys are awarded under the court, but can't be paid because of the requirement that payment be made jointly. So when that happens, when the petitioner can't be located, or in other exceptional circumstances, that would give the court some discretion. Those payments can be made directly. That seemed only fair to the attorneys, who after all have put in the time and effort to move the case forward.

That is a summary of what the recommendation letter contains. I would first invite anyone on the work group to correct any of my misstatements or to express any views that you might like to express for the benefit of those who were not on it.

Then I would like to invite any questions or comments.

DR. FISHER: Number five. Since the very first recommendation is to up the cap, I would not use the number 250,000. I would just say the death award. Number five, you have clarification when you can get both.

MS. HOIBERG: That makes sense.

DR. FISHER: The very first thing is to up that number, so don't block yourself into a number.

MR. SCONYERS: Tawny, did you get that?

MS. BUCK: I was on mute.

MR. SCONYERS: Meg's point, and a good one, is that the reference in paragraph number five to 250,000, if our first recommendation is adopted, that won't be accurate. So we will modify that language. That is a good catch.

DR. FISHER: Otherwise, first of all it was very easy to read through the minutes and understand what all the issues were and how you went about getting to these recommendations. I certainly would support them all.

MR. SCONYERS: Great. Sherry, did you have any

comments or concerns? You were not on the work group. Tawny, you were also not on the work group. Do you have any comments or concerns?

MS. BUCK: No. I was on the work group that developed the original document you are working off of, so I have a pretty good understanding of what you are working from. It doesn't look like you have made any significant changes to the original work.

MR. SCONYERS: What I would like to acknowledge is that in this current work group we had a unanimous recommendation of this set of recommendations to the Secretary, which for whatever reason we were unable to achieve in 2007 when Tawny and I both worked on that previous work group.

Well, hearing no further discussion, I would be interested in entertaining a motion to approve this letter to the Secretary as modified by Meg's comment.

DR. FISHER: So moved.

MS. HOIBERG: Second.

MR. SCONYERS: Is there any further discussion about that? All those in favor?

(Chorus of Ayes.)

MR. SCONYERS: Any opposed? I would like to make sure that the record reflects this was unanimously adopted.

I am going to seek the indulgence of the Commission

for a moment. The next order of business is going to be the election of the new chair. I would request the indulgence of the Commission in being permitted to be the signatory to this letter on behalf of the Commission. Would that be acceptable? It would be the only tangible evidence of my presence.

MS. BUCK: I would like to sign it as the co-chair then as well, before I am no longer the co-chair.

MR. SCONYERS: And I would welcome that opportunity.

**Agenda Item: Election of Chair and Co-Chair**

MS. BUCK: Thank you. The next item of business is the election of chair and co-chair, vice chair for the upcoming period. This is done annually, so we are a little bit late to do it.

I want to express my gratitude to the members of the Commission for participating in the nominating process, but I want to take a moment and say that Tawny has done an extraordinary amount of work on behalf of this Commission and on behalf of its mission. For so many months, she has been involved in so many different things, and really has worked very hard.

In this connection, she served as our nominating committee, and did a lot of work on that as well. So Tawny, if you are prepared, I would like to turn this over to you

for a report from the nominating committee.

MS. BUCK: I am. Thank you, Jeff. I appreciate your comments very much. I would like to also state that for the record, it is clear that Jeff and I have a good working relationship together. We have great respect for each other.

He has worked equally as hard for this Commission, and absolutely is due the same amount of gratitude and respect from the Commission for everything that he has done.

Jeff and I have been on here for awhile now, obviously you know that, and we are close to being done. We have seen the nominating process a lot of different ways, and tried to take a bit of a different approach this time, which was to come out a little organized today, instead of a little chaotic, which is how it has been done in the past.

That being said, I don't want anybody to feel like the groundwork that I have done up to this point is anything that anybody is locked into. What I have done is had a lot of conversations with people about their willingness to serve, their ability to serve, their comfort in serving, the time that they have available to do all of that.

In the past, a lot of these issues all come up all at the same time in the nominating process, and it is pretty chaotic, and maybe doesn't always make for the best choices. So I have done that groundwork for you. It doesn't mean you have to go with it, but I do want you to give it some

consideration and know that the folks we have spent a lot of time talking to are really prepared to take on these roles and understand the importance, understand time requirements, and have opted to do that. Also, Jeff and I feel strongly that the chair and the co-chair have a really good working relationship and a good dynamic, so that piece has played into it as well.

So for the purposes of the nominating committee, and it is not just me, a lot of this conversation has gone on with Jeff as well, so I'm not just a solo flyer here, we will put forth the recommendations for the name of chair and co-chair. Beyond that, my work is done. Then I want to leave it to the Commission to contemplate those suggestions, and then do what you think is best, because Jeff and I are rotating off and leaving it to you all, to your leadership and your direction beyond that. So please understand the spirit with which the nominations are coming from, and also understand that you all can then take this and go where you want.

The nominating committee through our discussions like I have said, has chosen to nominate Magda to be the chair, and we would like to nominate Sherry Drew to be the co-chair. The only point that I want to draw when you consider these names is that we were trying to pick somebody who has some experience and a newer member.

What happens this year is, you have got two of us rotating off at the same time, and we are trying to not have that happen. So Magda, who has been on the Commission for awhile and has a lot of experience and understanding of the position to be the chair, Sherry is the co-chair coming in new, will be here once Magda rotates off. I think that would be very helpful. I think probably the downsides of what is happening now is that both of us are rotating off at the same time.

That being said, if you want to ask me questions, you can, but honestly I think at this point the conversation should go out to the Commissioners to decide what they want to do from here on out. So if that works for you all, I think I will stop.

MR. SCONYERS: So you have heard from Tawny. I can see a couple of options at this point. We can have a discussion in open meeting if you would like to do that. We can take a brief break and wander down the hall if you would like to do that, or we can move forward to act if you are ready to do that.

MS. TEMPFER: Are you going to take floor nominations at all?

MR. SCONYERS: Absolutely. It is the pleasure of the Commission. This is a report. These names haven't been placed in nomination yet. This is a report from Tawny. So

to move forward we need to have that happen.

So what is your pleasure? Would you like to move to action at this point with nominations and action, or would you like to take a brief break to consider and reassemble in ten minutes?

MS. TEMPFER: I would suggest a break.

MR. SCONYERS: Ten minutes? Can we do that?

MS. GALLAGHER: Can I ask one question?

MR. SCONYERS: Yes, Charlene.

MS. GALLAGHER: Who was on the nominating committee?

MR. SCONYERS: Tawny. Ten minutes.

(Brief recess.)

MR. SCONYERS: Tawny, I don't know if you are still on the line.

MS. BUCK: I'm here.

MR. SCONYERS: We will go back on the record. At this point you have heard the report from our nominating committee. I would be prepared to accept a motion either to place those names in nomination or place other names in nomination or to abandon the process. No, I'm not prepared to accept that last motion. I think we have to do this, because I am not prepared to continue to serve.

So what is the pleasure?

MS. HOIBERG: I support the nominations.

MR. SCONYERS: Moving the adoption of the report of the nominating committee?

MS. HOIBERG: Yes, there we go.

MR. SCONYERS: We have got a motion. Do I have a second for that?

DR. HERR: The motion wasn't seconded.

MR. SCONYERS: Right, we're not acting yet. We have a motion and I am seeing if we have a second for it.

MS. TEMPFER: Second.

MR. SCONYERS: Thank you.

MS. TEMPFER: I would like to make a nomination because I think it is great that we have an election. I would like to nominate Charlene Gallagher for chair.

MR. SCONYERS: I think we need a second.

PARTICIPANT: Second.

DR. FISHER: Can I ask a process question?

MR. SCONYERS: Yes.

DR. FISHER: If we nominate a certain number of names, are we going to vote separately for the chair and the co-chair?

MR. SCONYERS: Yes, we will vote separately for chair and -- actually, in our charter the term is vice chair, but we act like it is a co-chair position. So we will vote separately for those offices. Charlene?

MS. GALLAGHER: Can I nominate Dr. Tom Herr for

vice chair?

MR. SCONYERS: Okay, sure. So Dr. Herr for vice chair. Do I hear a second for that?

MS. TEMPFER: Second.

MR. SCONYERS: Any further nominations?

DR. FISHER: No, but I don't want to close the nominations yet, because depending on who you get for chair, you might want to nominate that --

MR. SCONYERS: Let's keep them in order then of office. I understand the election of chair may guide the election of vice or co-chair.

MS. HOIBERG: I would just like to say that I feel that the public needs to be represented on the Commission.

MR. SCONYERS: What I was going to do at this point is, we have got two nominations for chair, and I was going to invite the nominated individuals to speak, and then I think Sarah has already made an appropriate comment; I was going to ask for any other comments. Then we will do some kind of a secret ballot. Tawny, you can text me, if people are willing to trust me on that.

So I would like to invite Magdalena to say something, and then Charlene to say something, and then anyone else who has comments, to offer them.

MS. CASTRO LEWIS: Well, I don't want to say anything at this point, but anyway, I had extensive

conversations with the nominating committee regarding my ability to serve in this position as chair of the Commission.

Like Jeff said, in looking at my time and many other things, I feel like I could fill this position.

The other thing that I think is important which is what Sarah just said, this is a very diverse group.

Yesterday, depending on the issue that we were discussing, who will jump to give an opinion, and definitely the lawyers at one point and the doctors, and then there was also the representatives from the community that came at a time when we needed that.

I thoroughly agree with the conversation that I also had with Tawny, regarding the need for the public to be represented in one of these positions.

MS. GALLAGHER: First of all, I want to say thank you for the nomination. I am really flattered and humbled that people think that I would do a good job in service. I also want to say that I think Magdalena is one of our very best Commissioners and would also do a fine job in the position of chair of this committee.

I personally believe that as chairperson I would not be representing one interest over another, that it involves administrative duties that require you to be mindful of various different viewpoints, various different people, stakeholders who come at the issues in different ways. I

believe that I am fair to people in listening to their views, allowing them to speak, and respectfully putting forth my views when I feel it is time for me to do so. But I don't try to impose my views on anyone else.

I think that I have the skill set that is required to run meetings and to chair a committee, as I have done that before, and I think I have done a good job. I would be happy if I were elected to this position, and I would do my best to serve all members of this community, all members of the committee, and to do that in a fair and even-handed manner.

MR. SCONYERS: I am going to exercise the prerogative of the Chair and accept comments from nominators, which would be Sarah for Magdalena and Tammy for Charlene. Please feel free to pass if you want to pass, but rather than engage in extensive discussion, I think that is about all we are going to need. I don't want to go through a lot of process here. I am prepared to be overruled, but that is my thinking at this point.

Sarah, would you like to say anything in support of your nomination?

MS. HOIBERG: I feel that Magdalena has a lot of experience. Let's say it this way. Even if we had Charlene and Magdalena, they work phenomenally well together on the planning committee for the last meeting that we had when Barbara Lo Fisher came. That was a phenomenal meeting. So

if that is any indication of how the Commission would continue to run, I am in favor of that.

But like I said, I do feel that in chair or co-chair there does need to be a representative of the public. That's all.

MR. SCONYERS: Thanks. Tammy, would you like to say anything?

MS. TEMPFER: Just a few comments. I agree, I think both candidates are wonderfully qualified, and it is wonderful to have the choices. I think it is important to have an election, so people can vote for people and try to figure out which we think might do a little bit better job. I agree, they both work together very well.

I am impressed with Charlene, how articulate she is and how fair she is. She really seems to be a good listener, which I think is key to being a chair.

MR. SCONYERS: With the indulgence of the Commission, I would like to suggest that you take one of the security ballots that is at your place, indicate your vote on it, and Michelle will collect them. Tawny, I would like to invite you to send me a text and I will not open it except after Michelle is standing by to clarify what we sent her.

MS. BUCK: Okay, I'll see if I can figure out how to do that.

MR. SCONYERS: The results of the election are that

Magdalena will be serving as chair for next year. So congratulations.

On the theory that that may or may not affect nominations, we have previously placed in nomination the names of Sherry and Tom to serve as vice chair/co-chair. I would invite the individuals who nominated them to consider - well, I don't know what I am inviting you to do. Meg, I can see you have a comment to make. Help me out.

DR. FISHER: I was going to add another nomination. I would nominate Charlene.

MR. SCONYERS: We need to hear a second for that.

MS. HOIBERG: I'll second it.

MR. SCONYERS: So we have three candidates placed in nomination. Are there additional nominations? Hearing none, let me go in alphabetical order and invite Sherry to say a word, followed by Charlene, followed by Tom.

MS. DREW: Thanks, Tawny, for the nomination. I think I could work well with Magdalena. I am experienced, I will learn. I would try to dignify the knowledge of the vaccine program. Thank you.

MS. GALLAGHER: Thank you again for the nomination. I think I adopt most of my previous remarks. I can tell you that I know for sure that I can work well with Magdalena, because we have done it in the past. Thank you.

DR. HERR: I am honored that people think of me

that I should be some part of the leadership of this Commission. Just being here is an honor enough.

I think that as far as representing one side versus the other, I view myself as sitting more in the middle, because I do provide immunizations, but I also care for quite a number of children who are disadvantaged and been injured, whether it is by vaccines or other causes, so I have quite a good bit of advocacy for that.

I would be very happy to serve as co-chair. I think there is a lot I need to learn about this Commission. I certainly know some of the ropes. I think working as co-chair would certainly perhaps let us be better leaders for the time when the chair is elected. So I appreciate the nomination.

MR. SCONYERS: I have lost track of who nominated whom. I am assuming that the members remember. Is there a need for an additional comment?

Again taking your security ballot, if you will please indicate your choice, and Tawny, if you will follow the same procedure that you did last time, and Michelle will collect ballots from you.

The results of our balloting are to elect Sherry as next year's vice chair/co-chair. So congratulations to you.

Here is my editorial comment. This is such a much better process than what I have experienced in the past with

this Commission. I really congratulate all of you for your diligence and efforts. So thank you.

DR. HERR: Can I ask that next time we have a committee of the outgoing members be the formal nominating committee?

MR. SCONYERS: That is a good idea. Before we move to the public comment portion of our agenda, I believe Dr. Evans has a comment.

DR. EVANS: Well, no good deed goes unpunished, or actually in this sense it is not a punishment. As you have had the privilege over the past year or so, Michelle Herzog has been the liaison office contact for the Commission. You have gotten to know her. She has made sure you were paid, and the paper has flowed magnificently back and forth.

Last Friday, I learned that Michelle is going to go on to a new challenge, new responsibilities, assuming that the budget is passed, which we have assurances it will be. So I have gone through my Kubler Ross four things of accepting this. I thought that it would be appropriate for us to recognize Michelle for the tremendous job she has done in shepherding this Commission and making sure that everything gets done beautifully, the editing and the putting together the minutes and the phone calls and the contacts, and just the wonderful way that you could always depend upon her to make sure that things worked and worked well.

So I want to take this opportunity to thank Michelle for the wonderful service she has given us, and to also give her a card with some wonderful words, and a beautiful bouquet of flowers to accompany it.

MR. SCONYERS: Hear, hear. Thank you, Michelle.

MS. HERZOG: Thank you.

**Agenda Item: Public Comment**

MR. SCONYERS: Operator, we are ready to see if there are comments from the public. So I invite public comments from anyone who is here, and of course from our telephone audience.

OPERATOR: Thank you. If you would like to ask a question, please press star one at this time. To withdraw your question, you may press star two. If you have any questions, please press star one at this time.

At this time, there are no questions on the phone.

MR. SCONYERS: Thank you very much.

MR. MOODY: There was some discussion of the omnibus cases, and I apologize for missing that. I would like to offer a couple of observations. One is that the compensation program is as important a part of the vaccination program as the vaccines themselves, because without strong public confidence both in safety going to the program and the adequacy of a safety net, that will quickly shatter public confidence and risk a drop in uptake of

vaccines.

The present state of play with these three decisions is that these cases will be going on for years in their appeals, as the science of vaccine safety, particularly as it relates to autism, continues to develop.

But a couple of points. In all the three opinions, I think there were rather injudicious comments. One by Master Hastings at the end was that families were misled by doctors who were guilty of gross medical misjudgment -- that does not really bespeak of a family friendly non-adversarial process.

I think everyone recognizes on both sides of this debate the science of vaccine injury as it relates to autism is developing rapidly. There is an article coming out in Pediatrics next week, the fact that confirming the association between bowel disease and autism, which undermines a great deal of the premise of Master Hastings' decision. In particular it validates what Dr. Vasio did ten years ago in London, when he was the first to publish on a case series associating bowel disease and autism. So the science is going on.

These cases will continue on appeal. I think it would behoove the Commission if it could to take a very strong stance in one of the issues, which is the availability of the Vaccine Safety Data Link, CDC's taxpayer funded

database of vaccines and vaccine injury data. That is available only to the government at this point, and it should be available broadly to petitioners and their counsel and their experts to be able to do studies. That is one of the appealable issues. There is a pure question of law, and on that issue alone, the decision should be set by masters with instructions to make that data available. So that process would help you to move along if the Commission could take a stand on that.

The other thing is that without strong baseline data on the occurrence of chronic adverse events in vaccinated versus unvaccinated children, this issue is going to continue to arise, in part because vaccines are the victim of their own success. As vaccines prevent disease, all you are left with is acute and chronic adverse events, as you add more and more vaccines to the schedule, and as there are more answers to this baseline data on chronic disease in vaccinated and unvaccinated children, the public will continue to grow in concern over these. Without an adequate safety net to support them in a non-adversarial way, that is going to contribute to reducing public confidence in vaccines.

So I know other committees are looking at those issues right now, but I think I would challenge ACCV to take a strong stance on supporting an aggressive safety first

agenda, in particular developing an aggressive program of research focused on mechanisms, animal and human models, on the chronic question of vaccinated versus unvaccinated children.

Thanks.

**Agenda Item: Future Agenda Items**

MR. SCONYERS: Other comments? The last thing we do at every meeting is look at what might be on our agenda for the next meeting. Magdalena will appoint an agenda committee, I believe, for the next time around.

I know that we are going to be hearing a report on the survey results, the petitioner survey. We constituted a work group yesterday chaired by Sarah to develop suggestions and comments on the outreach plan. Sarah, you have got Sherry, Magdalena and Tom with you on that.

I would invite members to indicate topics that they know now that they would like to see addressed in June. We will certainly solicit a call for agenda topics, and we will have our agenda committee process, but if there are things that you know now.

MS. GALLAGHER: I know that we were going to have a subcommittee try to work on ideas for outreach. Should we just assume there will be some interim report at the very least for our next meeting?

MS. HOIBERG: Yes, there will be.

MR. SCONYERS: Anything else that people know now you would like to -- we will have some kind of report from the April 14 session.

DR. EVANS: Between now and the June meeting, I expect that the IOM will have had its first organizational meeting. This is the project that HRSA is funding for the study of four vaccines. That is going to tentatively take place April 20 in Washington. There may actually be a second scientific workshop in between that date and the June meeting. So I will keep members informed. In fact, I expect as early as next week that we will have a roster of committee members on our website and everything, so you will be informed about this before anyone, as soon as the public is informed.

MS. HOIBERG: My question would be for us to get together to do the outreach idea. Is there a way to set up a conference call?

MR. SCONYERS: We will consider doing that, yes. Tawny, anything from you that you know you will want to have on the agenda?

MS. BUCK: No. I would like to remind everybody that the NVAC vaccine safety working group is having a stakeholder meeting on comments for the ISO scientific agenda on vaccine safety concerns in March 16. If you go to the ABPO website you can find information for that. There is a

call-in number. I think it will be webcast, but if you are close to the D.C. area and have the opportunity to participate, you need to go online and make sure you are registered.

MR. SCONYERS: Well, Magdalena?

MS. CASTRO LEWIS: This didn't happen last time.

MR. SCONYERS: But what I will tell you is, you have to get a motion for an adjournment. I tried to adjourn without a motion for adjournment one time, and Geoff slapped my wrist.

MS. CASTRO LEWIS: I was just going to say thank you all, and I am going to really need the support of everybody, because I don't think this is a one person job. It takes the whole Commission to really do it.

I was going to ask Geoff what size shoes you have. I think they are going to be too big for me.

MR. SCONYERS: I don't want to lose sight of how much of a contribution Tawny has made for the success of this.

MS. CASTRO LEWIS: Right, exactly, that was my next thing. Tawny, she was involved in every aspect of the Commission, especially the vaccine safety issue. She has put a tremendous amount of time. I think that she is really well recognized in the immunization field. Also, she has represented the ACCV in a wonderful manner. So I think we

owe thank you very much to Tawny. It has been great.

DR. FISHER: Move to adjourn.

MR. SCONYERS: Second.

(Whereupon, the meeting was adjourned at 11:37

a.m.)