

U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES

INTERAGENCY AUTISM COORDINATING COMMITTEE

FULL COMMITTEE MEETING

WEDNESDAY, JANUARY 14, 2009

The meeting was held in Conference Room A, 6001 Executive Boulevard, Rockville, Maryland, at 9:00 a.m., Dr. Thomas Insel, Chair, presiding.

PRESENT:

THOMAS R. INSEL, M.D., IACC Chair, National Institute of Mental Health

DELLA HANN, Ph.D., IACC Executive Secretary, Office of Autism Research Coordination, National Institute of Mental Health

JAMES F. BATTEY, M.D., Ph.D., National Institute of Deafness and Other Communication Disorders

ELLEN W. BLACKWELL, M.S.W., Centers for Medicare and Medicaid Services

DAVID DeVOURSNEY, Substance Abuse and Mental Health Services Administration (For Larke N. Huang, Ph.D.)

LEE GROSSMAN, Autism Society of America

JIM HANSON, M.D., *Eunice Kennedy Shriver* National Institute of Child Health and Human Development (For Duane F. Alexander, M.D.)

SUSAN HILL, Centers for Medicare and Medicaid Services (For Ellen W. Blackwell, M.S.W.)

PRESENT (continued):

GAIL R. HOULE, Ph.D., Department of
Education

YVETTE M. JANVIER, M.D., Children's
Specialized Hospital

JENNIFER JOHNSON, Ed.D., Administration for
Children and Families

STORY C. LANDIS, Ph.D., National Institute
of Neurological Disorders and Stroke

CINDY LAWLER, Ph.D., National Institute of
Environmental Health Sciences

MICHAEL MARGE, Ed.D., Office on Disability,
U.S. Department of Health and Human
Services (For Margaret Giannini, M.D.)

CHRISTINE M. McKEE, J.D.

LYN REDWOOD, R.N., M.S.N., Coalition for
SafeMinds

STEPHEN M. SHORE, Ed.D., Autism Spectrum
Consulting (via telephone)

ALISON TEPPER SINGER M.B.A., Autism Science
Foundation

EDWIN TREVATHAN, M.D., M.P.H., Centers for
Disease Control and Prevention

PETER VAN DYCK, M.D., M.P.H., Health
Resources and Services Administration

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P R O C E E D I N G S

(9:04 a.m.)

DR. INSEL: Good morning and happy New Year to everyone. This is a meeting that we hadn't originally scheduled when we developed the IACC schedule for the first year, but here we are trying to complete the strategic plan to music.

I'm just waiting to make sure that the phone lines are live.

(Pause in proceedings.)

DR. INSEL: Okay. Good morning, everyone, and welcome. This is the first meeting for 2009 for the IACC. We've got a relatively short day planned, but a lot to do to try to get the strategic plan completed with the budgetary requirements approved, and hopefully we'll have some discussion about next steps towards the end of the day.

Della has a couple of procedural issues to bring up, and then we want to do a round of introductions, because there are

several new people involved today.

DR. HANN: Good morning. This is Della Hann, for those of you who are on the phone.

I just wanted to bring to your attention at the bottom of the agenda that you received you'll see the upcoming meeting dates, and one of them is a little bit different than the last time you looked at this. Our next meeting is on February 4th, and the meeting following that has been now moved to May 4th in light of there was an important conference that a number of you were going to be attending, and therefore we changed the date for that one.

And then we'll meet again on July 29th, and then again October the 23rd.

The other procedural thing is for those of you who travel to the meetings who have to come a far distance, we are now going to be asking that you coordinate your travel through the Logistics Omega in order to

facilitate your travel, as well as your lodging when you come here.

So we can provide you further details, but I just wanted to sort of get that out there and get you alerted to that fact. Okay?

Yes, Alison.

MS. SINGER: The sheet says May 2nd. You just said May 4th.

DR. HANN: Yes, it should say May 4th. The brand new one says May 4th. That's why I said it was a change. It's a very recent change.

MS. SINGER: Okay.

DR. INSEL: Now, as often happens at the end of a presidential administration, there's a large turnover of staff, and partly for that reason, there are several people who sit on the IACC who are going to be leaving this week or have already left. There are also people who are on detail to one place or another, and there are people who can't attend

for other reasons.

So I wanted to go around and make sure we know everybody who's at the table, some who are here as substitutes, and some who will be here more permanently. But I should mention that Peg Giannini is officially stepping down this week. She's a presidential appointee. So she will be replaced by Michael Marge at least on a temporary basis.

Pat Morrissey retired after the last meeting, and Jennifer Johnson will be replacing Pat.

Ellen Blackwell is unable to attend today, and Susan Hill is representing CMS on the phone.

And Larke Huang from SAMHSA is on detail to the CDC for some period of time, and David DeVoursney has agreed to step in in her place. This may feel like in some ways bringing in people off the bench at the end of the fourth quarter, but in fact, many of these people have been quite involved, and they've

had a chance to be briefed by others within their agencies. So it's understood that they have some deeper insights into this process than somebody just walking in for the first time.

Let's do a quick round of introductions so the new people know who is here. I'm Tom Insel, the Chair of the Committee, and we'll start here on my left with Yvette.

DR. JANVIER: Yvette Janvier, a developmental pediatrician from New Jersey.

DR. TREVATHAN: Ed Trevathan. I'm a pediatric neurologist and direct the National Center on Birth Defects and Developmental Disabilities at CDC and represent CDC.

MS. SINGER: I'm Alison Singer. I am the mother of a beautiful 11 year old daughter with autism spectrum disorder, and I also have a 44 year old brother diagnosed with autism who, when I visited him yesterday for

the first time, pointed to the pack with my picture on it. So for anyone who says you can't learn to communicate in your 40s, not the case.

DR. VAN DYCK: Good morning.

Peter Van Dyck, pediatrician, Director of the Maternal and Child Health Bureau in the Health Resources and Services Administration.

DR. JOHNSON: Hello. I'm Jennifer Johnson. I'm with the Administration on Developmental Disabilities, Administration for Children and Families in HHS.

MR. DEVOURSNEY: I'm David DeVoursney with the Immediate Office of the Administrator of the Substance Abuse and Mental Health Services Administration.

DR. BATTEY: I'm Jim Battey. My background is in pediatrics and molecular biology, and I'm a Director of the National Institute on Deafness and Other Communication Disorders.

MR. GROSSMAN: I'm Lee Grossman,

President and CEO of the Autism Society of America, and a dad of a young 20 year old gentleman with autism.

DR. LANDIS: Story Landis, developmental neurobiologist and Director of the National Institutes of Neurological Disorders and Stroke.

MS. REDWOOD: Lyn Redwood, the Coalition for Safe Minds.

DR. HANN: I'm Della Hann. I'm currently the Acting Director for the Office of Autism Research Coordination, and serve as the Executive Secretary for this Committee.

DR. INSEL: And for those on the phone?

MS. HILL: This is Susan Hill, Senior Policy Advisor in the Disabled and Elderly Health Programs Group in the Centers for Medicare and Medicaid Services.

DR. MARGE: This is Michael Marge with the Office on Disability.

DR. INSEL: Anyone else with us on

the phone?

(No response.)

DR. INSEL: Okay. Well, we hope the two of you will actively speak up and participate, and we will, when it comes to votes, make sure that we include you in the voting process.

Della?

Okay. So there will be a couple of people who will be late arrivals.

Just to get us all on the same page, we are today trying to complete what will be version 1.0 of the strategic plan. The goal was to have a document that would be, in the current vernacular, shovel ready for the new Secretary when he takes over next week. The expectation is that Senator Daschle will become Secretary of HHS, and the strategic plan is meant to be advisory to the Secretary, to Congress, and to the Director of NIH. We do not yet have a Director of NIH, but the expectation is that that will also

follow in short order.

The plan that we have today is really just that. It's a 1.0. The understanding is that we will need to, once we get a document, work a little further to think about the implementation strategy, and the accountability to this, and then we will begin thinking about the revisions based on the science that's coming in to figure out what the next annual plan should look like. This is something that, by the Combating Autism Act, is required to be done once a year, and it's required in each year to have budgetary numbers or budgetary requirements that will be in the plan, and that's some of what we'll have to be talking about today, because that's the one piece of the plan we have yet to really visit in any detail.

Before we launch into this, I want to remind everybody that, as part of the process, we agreed to what we've at one point called shared values, the values of urgency,

scientific excellence, spirit of collaboration, staying very much consumer focused, both in the language and in the intent, to come up with aims that had real partnerships built in between the public and private effort, and to also have a sense of accountability with this plan so that we would be able to monitor what we're doing, and to make sure that we were able to know when we had succeeded, and know when we needed to do more.

With that as an intro, we're ready to launch, but let me, before we do that, see if there are any other general comments or any other questions, especially for those of you who are new to the process. Anything else that we can do to get you oriented?

I'm assuming that you've heard a lot about this from your predecessors. David, Jennifer, Susan, Michael, everybody okay with going ahead?

MS. HILL: This is Susan Hill from

CMS.

I'm very happy to be here representing Ellen Blackwell today, and yes, she has prepared me, I hope.

I'm wondering if there are procedures around speaking. I assume you all have buttons on your table. Do I need to follow any particular protocol?

DR. INSEL: Susan, you just need to speak up, and we can hear you just fine. So we do have buttons, but you have a phone, which is just as powerful.

MS. HILL: Well forgive me if I interrupt anyone. And forgive me in advance, okay? I'll do my best.

DR. INSEL: Right. The only thing that we would ask, and we'll try to do this as well, is that because you can't see us and we can't see you, each time when anyone speaks at the meeting if people can introduce themselves, and I'll remind you as well as I can remember to do this so that we have both

a public record of who's speaking, and also those on the phone can know who they're responding to if there's a question that comes up. Okay?

MS. HILL: Thank you very much.

DR. INSEL: Right. So we are ready to move back to where we left off. As I said, we're sort of in the fourth quarter of this. The part of the plan that is still not completed in terms of your concurrence is the part that begins, cross-cutting themes, and if you go to the chapter that you have in your folders that says introduction, it begins at the very bottom of page seven.

What you have in addition to the language that is shown in that chapter, on the left column, just to remind you, was the original language that we came out of previous meetings with. On the right column, or you could say the middle column, are the comments that were inserted as proposals only for your consideration from what we received from the

public, that is, from the RFI that went out where we asked the general public to make comments on the draft, and there are, both in blue, the comments that were inserted by the staff here, and footnotes that document where they came from.

So that is one set of recommendations that we'll need to look at. There's a second set of recommendations that came from Ellen Blackwell, and that is this page. It has a green bar at the top. These are mostly single word changes, such as changing the word individuals to people, and various things like that. You should have that in your packet.

And there's a third set of suggestions that come from Lyn Redwood, which the most recent version of that just arrived last night. So we've provided you the new version of that. It looks something like this. These are in green.

Everybody got the whole -- those

three sets?

MS. HILL: Excuse me. This is Susan Hill from CMS.

A little bit unclear. Is the webinar going to be keeping track and showing the current version that you're discussing?

DR. INSEL: That's right. So what you'll see on the webinar in front of you will be the -- and you can see right at the bottom of that page it says, crosscutting themes. That's the main document. That's the document with the plan as we now have it, and the comments, which will be in blue, that come from the public comment that we received.

The other two documents represent recommendations from members of the Committee.

MS. HILL: Great. I have them in print, also.

Thank you.

DR. INSEL: Okay. Any questions? All set to go, everybody?

Okay, and I should just mention

that Christine McKee and Cindy Lawler have arrived since we started. So welcome to both of you.

Before you arrived, we pointed out that there are several new people sitting on the Committee, either substitutes or as new members representing their agencies.

Okay. What I would like to do then is to move forward through this document. I'm not sure how you want to deal with this, because Lyn has a number of very, very substantial recommendations, including completely new crosscutting themes to add.

What I would like to do, with your permission, is to deal with those after we look at specific comments that came from the public, and those that came from -- there are some small wording changes from Ellen Blackwell, and then in terms of whether to insert new themes altogether. We can look at that independently. I'm afraid if we get hung up in that, we won't get to the document

in front of us until much later. So I think we can get through this very quickly, and then we can circle back, if that's okay with you, Lyn, and look at the specific themes themselves.

So the first one is around heterogeneity, and it takes us to page 8, where there's a comment that came from the public. Those who use augmentative communication systems and live somewhat independently would be added in to the sentence about who would be on the spectrum. Is it useful to add that again?

And as I said last time, many of the comments that we got from the public were inserted to reflect that we have heard them. Often those comments - I'm not saying it's true about this particular one - but often those comments were really meant to advertise someone's particular need. They have sometimes a different agenda than the entire document.

I put this in front of you not because we're recommending that this be inserted, but that you know that this was something that we heard, and it's up to the Committee to decide whether to include it or not. Does it improve the plan? Does it not improve the plan?

So quickly, is this something that we should include, or is this too granular to be inserted here? Is there a sense?

DR. BATTEY: I really don't think it adds very much to be quite honest, and for the most part, I think the document is getting very long and has a lot of words in it, and at a certain point in time adding more words simply dilutes out the core message that we want to deliver.

DR. INSEL: So let's just, further discussion. Those who want to include this, can I see a show of hands for including?

(Show of hands.)

DR. INSEL: We have two here. And

those on the phone, who would like to include it?

(No response.)

DR. INSEL: I don't see hands on the phone, but --

MS. HILL: No, you don't.

DR. MARGE: No.

DR. INSEL: Okay, and then in the room, those who would vote to just leave it the original version, show of hands?

DR. MARGE: I'm showing my hand.

MS. HILL: And I am.

DR. HANN: One, two, three, four, five, six, seven, eight, nine. Nine.

DR. INSEL: And then on the phone we have -- ?

DR. MARGE: I agree with not showing it.

DR. INSEL: And Susan?

MS. HILL: This is Susan Hill from CMS.

I think that the notion of

augmentative communication is unnecessary and could be struck, and in general I don't think the sentence needs to be included.

DR. SHORE: And this is Stephen Shore, and I also think it doesn't need to be included.

DR. INSEL: Okay. Welcome Stephen. It's good to have you here. Or maybe not here, but good to have you as part of the meeting.

Okay, and Della points out that there are comments from Ellen, as well. So maybe we need to go back, just backtrack. So it would be helpful I think to give the results of the vote so people know where --

DR. HANN: Certainly. The result of that vote was two to include the new language, and I have 12 to not include.

You will see that Ellen's comments, just for a point of clarification, if you look at Ellen's comments, the line numbers that she's referring to no longer

match the document you have before you, because this document has been augmented on your previous decisions and so forth like that. So the line numbers aren't matching up.

So the first comment that Ellen had here had to do with heterogeneity. She wants to change individuals to people in the first sentence, and then secondly, she had suggested that the whole sentence that we were just working on, the idea that people could not live independently was something that she didn't like, and also the issue of ungainful or gainful employment she felt needed to be changed.

Those changes are before you.

DR. LANDIS: Have we had a policy about substituting people for individuals? It seems to me it might be useful to make a decision about either its individuals or its people, and to try to have it consistent throughout the document.

DR. HANN: Preference?

DR. LANDIS: I personally don't have a preference, which suggests that I don't -- am not sensitive to what she's picking up, but there may be other people here who are who have --

DR. INSEL: Other individuals.

DR. LANDIS: Other individuals, right, who have a sense of the importance of this. I apologize for not recognizing that, and I think we should just make a decision and follow it throughout the document, so we're not sometimes people, and sometimes individuals.

DR. MARGE: This is Michael Marge from the Office of Disability.

We've agreed in all of our documentation to refer to persons with disabilities. We went through this argument before, this debate about whether it's an individual or people, but if you're going to use a phrase with something, it's better to -

- well, we feel that it's been more consistent with our area of activity to refer to persons, but it's debatable.

MS. HILL: And this is Susan Hill at CMS.

Here we use people. Granted, it's a little less formal than persons, but the point is to have person centered language to reflect the dignity of the individual, and so we use people.

I think I do agree with the comment that it should be consistent regardless of which term we choose.

DR. INSEL: Other insights about this?

DR. LANDIS: I mean, those of you with children or young adults, do you have a sense of which you prefer?

I don't mean to target you. I'm just --

MS. McKEE: Yes, this is Christine McKee.

I really don't. I mean, I'm an attorney, and it's the Individuals with Disabilities, you know, the IDEA, and individuals in the ADA. So all of the legal language in most of the documents that you see actually use the word individuals. So, but I'm sensitive to what Ellen is saying here. But it doesn't make a personal difference for me in how I --

DR. INSEL: Other insights? Does this matter to anyone?

DR. MARGE: No.

DR. INSEL: Okay.

DR. LANDIS: I hear three persons, individuals and people, and why don't we just vote on which of those, and then someone could edit, do a search and change throughout the document, except where it creates awkwardness.

DR. INSEL: If you would make a motion for what you -

DR. LANDIS: I move we use people.

DR. INSEL: In favor?

DR. HANN: The vote is one, two, three, four, five, six, seven, eight, nine, ten, 11, 12, 13 at the table.

MS. HILL: Aye on the phone from CMS.

DR. MARGE: Michael Marge says, yes.

DR. SHORE: And I say, yes, Stephen Shore.

DR. HANN: So that's 16. It's unanimous for people.

DR. INSEL: All right, and then that's the first thing I think that's true, maybe the first that we've agreed about, and then in terms of her other comment about, is there ungainful employment.

If I can be so bold, there actually is, and there are many people who get employed in jobs where they don't receive compensation of any sort, and I thought that the intent of the language was to find truly

gainful employment, and to allow people to live independently, but again, if other people have read that differently, it might be useful to revisit this.

DR. BATTEY: I agree with you, Tom.

DR. INSEL: Can I get a show of hands of who would like to make this change? She wants to just delete the word gainful.

I'm hoping we won't spend the whole day on specific wording like this, but I do want to move through this quickly.

Interest in taking out the word gainful, show of hands.

(Show of hands.)

DR. INSEL: Okay, and then staying with the -- anyone on the phone? There's no one raising their hand here. Does anyone on the phone want to make the change?

DR. MARGE: No.

DR. SHORE: Not really.

DR. INSEL: Okay. We're moving on

then to Ellen's next comment. It actually doesn't go until page eight. So we're ready to move into -- go back to your original document, and it takes us now in the original document down to Line 18 on page nine, where the insertion is also single subject experiments may be useful to test and gain preliminary data on possible treatments.

Is this helpful or not?

DR. BATTEY: I actually think most single subject studies are fraught with peril and misinterpretation. So I would not be in favor of including this line.

MS. REDWOOD: Tom, I think the intent was - and this is Lyn Redwood - to look at more case studies, and that those might actually bear some information with regard to etiology and treatments. I think that was the intent if this addition. Maybe I'm wrong.

DR. INSEL: Any other comments or thoughts?

Ed?

DR. TREVATHAN: Yes, I would suggest it shouldn't be included, and the reason is we've identified in the work groups, and the scientists have pointed out that we really need more clinical trials. I mean, that's been a big emphasis of this group, and we need to try to as much as possible move into strong science and away from single case anecdotes and small series. Those obviously have their role, but there's obviously a major emphasis coming out of the scientists for more rigorous science. So I would agree with Jim that it would not be appropriate to include it.

DR. INSEL: Other comments?

Those in favor of including the additional language, can I see a show of hands?

DR. HANN: There are two at the table.

DR. INSEL: On the phone, anybody

want to include this?

DR. MARGE: No.

MS. HILL: Susan Hill, no hand.

DR. SHORE: Stephen Shore, no hand.

DR. INSEL: And then I'm assuming those who want to keep it out and go back to the original, show of hands?

DR. HANN: Okay. One, two, three, four, five, six, seven, eight, nine, ten. It carries.

DR. INSEL: We'll retain the original language, and we move on to the top of page 10. Here again we have language both from Ellen and from the public comment. Let's start with the public comment. It's listed as discussion point intro eight. Additionally, if one views ASD as a biological disorder triggered in genetically susceptible individuals by environmental factors, then prevention can include prevention of new cases of ASD through the

identification and elimination of environmental causes.

And then it goes on, what is essential for ASD research is to develop a state of knowledge, and then onwards.

Comments?

DR. BATTEY: I'm going to sound like a broken record, but I think it's unnecessary. I think it's obvious.

DR. INSEL: That's from Jim Battey. Are there other comments in looking at this? Does it help or not? Is it useful to include this in the plan?

MS. REDWOOD: Well, I like it. I think it does add some additional focus on the potential that autism could be prevented, and I don't think there's enough of that in the plan the way it's written right now.

DR. JANVIER: I agree. I like it, actually. I think it does help focus on something that we could use significantly to prevent autism. I would vote to keep it.

DR. INSEL: Lee?

MR. GROSSMAN: I was at a policy strategy meeting yesterday with other disability organizations around environmental issues, and there's a lot going on now in terms of trying to bring the awareness of environmental factors to a greater level so that we can do more prevention. So I would definitely leave this.

DR. INSEL: Comments from others? Anyone on the phone want to add to this discussion?

DR. MARGE: I approve it.

MS. HILL: Susan Hill, CMS.
Approve.

DR. INSEL: Let's take this to a vote. Those who want to add the additional language, can I see a show of hands?

DR. HANN: The vote is one, two, three, four, five, six, seven, eight, nine, ten at the table, and I believe there were two of you on the phone who also agreed to

accept the new language.

DR. MARGE: Michael Marge.

MS. HILL: Susan Hill.

DR. INSEL: And those opposed to wanting to just retain the original?

DR. HANN: The vote is one, two, three at the table.

DR. SHORE: And four on the phone.

DR. HANN: Okay.

DR. INSEL: Okay. Thank you.

So we will add this additional language on page 10.

There are some comments here from Ellen Blackwell, and Della, I'm going to need your help in tracking where these are, because they don't match with the line numbers.

DR. HANN: It's at line 12 and 13, to preempt the more serious consequences.

DR. INSEL: Okay. So Ellen wants to strike the language that would say that early interventions are applied upon the

detection of risk factors so as to preempt these more serious consequences, and her comment is the language should be struck. There are no studies that track early interventions across the life span.

So I'm not sure that there's complete understanding. These, I think, were referring to what we know from cardiovascular medicine, where we actually do know that early interventions do preempt more serious consequences later in the life span. I think we can move on. Is that fair?

Okay. So that takes us to the bottom of this section, having sound, well funded research on the risk factors and the environmental and experiential triggers for ASD ultimately may allow us to achieve the goal of prevention, preventing the development of the disorder in some people at risk for -- or I assume it means preempting the most serious disabilities in those affected.

Comments.

MS. HILL: May I interject? This is Susan Hill, CMS.

May I interject a comment on page 10, Line 19? I'm a little unclear where you are right at this time.

DR. INSEL: We're right there.

MS. HILL: The term, the most serious disability is disabilities in those affected, might be better said as, preventing the development of the disorder in some people at risk or preempt the degree of ASD severity in those affected.

DR. INSEL: Right. So we had that language from Ellen. So that's quite helpful, Susan, to include this here.

MS. HILL: It's already reflect in the text?

DR. INSEL: It's in Ellen's recommendations. She says that this should be written in a manner that discusses maximizing potential.

So that would change the sentence accordingly. I guess the question first is whether we want to add this in at all, because it's somewhat different. The terms well funded research, and experiential as opposed to environmental triggers, are those really useful?

Most of the heads are shaking around the table. Is there anybody who wants to make that change?

DR. LANDIS: Are we talking about experiential now?

DR. INSEL: Let's start with well funded. Does anybody want to include the term, well funded research?

MS. REDWOOD: I do.

DR. HANN: Okay. We have a vote of one. Are we voting?

DR. INSEL: Okay. I'm sorry. We're on Line 14.

DR. HANN: Oh. Vote on well funded, and then experiential.

DR. INSEL: So I hate to do this because it's going to take a long time, but let's go through quickly. Well funded research, do we want to add the term, well funded, which came from the public?

We have one person who wants to add.

DR. HANN: Two.

DR. INSEL: Two. Anyone on the phone want to add this?

MS. HILL: No.

DR. INSEL: Then the term experiential in addition to environmental, is that useful to add?

MS. SINGER: Can I -- what is an experiential trigger? Can someone give an example of one?

DR. LANDIS: I think we're back to refrigerator moms with experiential. I think it implies bad -- it raises specters of things that you'd rather have dealt with in a scientific, more understandable fashion as

environmental. I mean, experience is part of environment, and full out experiential, I think you end up -- but I --

DR. INSEL: So who would like to include this change which came from the public? Experiential?

I don't see any enthusiasm. Anyone on the phone want to include this?

Okay. Moving to the last part of this then, this is now triggers for ASD ultimately may allow us to -- the additional phrase is, achieve the goal of prevention, as opposed to just saying, may allow us to prevent the development of the disorder.

Actually, if we go back to the original language, let me just read it. It was, may allow us to prevent the development of the disorder in some children at risk, or preempt the most serious disabilities in those affected. And the new language is, may allow us to achieve the goal of prevention: preventing the development of the disorder in

some people at risk. Or I assume it was supposed to be preempting the most serious disabilities in those affected.

And as you just heard from Susan, the recommended language could also be preventing the development of the disorder in some people at risk, or preempting the most serious -- I'm sorry -- right, preempting the degree of severity.

So we've got two ideas here. What's your pleasure? What do you want to do with this section? We can go back to the original. We can make the -- do the changes help?

DR. LANDIS: This is Story.

I would go back to the original change for people, which I thought was good, and I liked the degree of severity. That's kind of a hybrid. Preempt the degree, or reduce the degree of severity in those affected.

DR. INSEL: We've got that as a

motion. All in favor of that additional language? So that this retains the structure of this, but says, instead of the most serious disabilities, it's the degree of severity.

DR. LANDIS: Reduce the degree of severity.

DR. INSEL: Reduce. So I guess it would be reducing, since it's preventing and reducing --

DR. LANDIS: Reducing, right.

DR. INSEL: -- the degree of severity in those affected.

In favor?

DR. HANN: Okay. The vote is one, two, three, four, five, six, seven, eight, nine -- it's unanimous at the table.

DR. INSEL: Are people on the phone okay with those changes?

MS. HILL: Agreement on the phone.

DR. MARGE: Yes. Okay. Michael Marge.

DR. SHORE: Yes.

DR. INSEL: Okay. Thank you.

We're moving on to page 11, and we're in the middle of the page where we're looking at an addition from the public that says, it is critical that the field enhance methods for detecting ASD earlier in life, and then the addition is, and across diverse populations. In addition, more programs for training service providers are needed to recognize behavioral symptoms in order to have the capacity to support earlier intervention.

It sounds a little bit like a plug there, but that's one of the comments that we received from the public, and this is in the category of earlier detection.

Comments?

DR. LANDIS: I see the training is not research related, so I would go back to the original language.

DR. INSEL: How about the language

on across diverse populations? What did you
-- was that useful?

DR. MARGE: You can try, like, and
across diverse populations.

DR. BATTEY: I'm fine with across
diverse populations, but I agree with Story.
This is a research document. It's a research
strategic plan, and that is not a research
goal.

DR. INSEL: So Jim, do you want to
make a motion about how to handle this?

DR. BATTEY: Yes, this is Jim
Battey.

Leave in the language about
diverse populations, and don't add the
sentence that follows.

DR. INSEL: In favor?

DR. HANN: Okay. It's unanimous
at the table.

DR. INSEL: On the phone?

MS. HILL: Yes, on the phone.

DR. MARGE: Yes.

DR. INSEL: And anyone else on the phone? Is there anyone opposed to that vote, and want to retain the language? It might be useful to note that now.

Christine, you want to include the language on training. Okay. All right.

Anyone on the phone want to vote for retaining the training language?

(No response.)

DR. INSEL: Okay. We're moving to the bottom of page 11, which is listed as discussion point intro nine. At the same time, parents and ASD self-advocates have urged that efforts to promote earlier detection be guided by sound bioethical principles in order to prevent very young children from exposure to interventions that pose more than minimal risks."

Comments?

DR. JANVIER: This is Yvette.

I would hope that that type of statement would not be necessary, that it's

obvious. I don't think it adds anything.

DR. LANDIS: Story.

It raises the specter of unethical scientists messing, or researchers messing with your children. I just -- I mean, I would hope that IRBs would be --

DR. BATTEY: Yes, that's the purpose of the IRB.

DR. INSEL: Does anyone see this as being helpful to the document, helpful to the plan?

On the phone?

MS. HILL: Susan Hill from CMS.

I had one comment. If we were to keep it, I would change very young children to people with ASD. Are we on line 23?

DR. INSEL: Right, right, on line 23.

MS. HILL: If we were to keep it.

DR. MARGE: Yes, I like that change if we were to keep it.

DR. INSEL: Well, let's put this

to a vote. Those who would like to include this new language with that single change, because we said we were moving to the term, people, in favor of this addition to the plan, can I see a show of hands?

This is to include the new language.

DR. HANN: There's a vote of one.

DR. INSEL: And on the phone, those who want to include this addition?

(No response.)

DR. INSEL: I'm assuming we'll go back to the original then, and we'll move on to the life span perspective, which is page 12, discussion point intro 10.

Some suggest that greater priority be given to research on treatment and services rather than the causes and prevention. That's in the middle of that paragraph on life span perspective.

Comments?

(No response.)

DR. INSEL: Ellen has some language there, too.

Any changes that people want to make in this, or anyone on the phone have -- this doesn't seem to ring a lot of bells for people, but let me ask -- or let's just put this to a vote.

Who would like to include this additional language? Hands? We have one in the room.

DR. HANN: One.

DR. INSEL: Anyone on the phone want to include this?

DR. MARGE: No.

DR. INSEL: Okay. Then we will move on.

Ellen Blackwell had some additional changes. Now we're onto page -- I guess it's the same line here. So we're on page 12. At the top of that section on life span perspective, she says, has ASD been characterized as a childhood disorder?

Since there is no cure, and most people with ASD have it throughout their lives, we may wish to strike this language. The sentence says, historically, ASD has been characterized as a disorder of childhood. And I think that when we originally crafted this, that is, we being all of us, we wanted to make that as a historical comment.

So I understand Ellen's sensibility to this, but does anybody think we need to change that?

I don't see any interest or -- interest in discussing? Okay. Let's move on.

We're now moving to page 13, the bottom half of the page, intro 11 discussion point. We have a long insertion that talks about partnerships between school and intervention research programs.

For example, donations of post mortem biospecimens from individuals who have the disorder are limited. This limitation

impacts both the scale and quantity of medical research possible. A comprehensive and robust outreach campaign focusing on tissue donation is essential. Donor registration and listening to cooperation of medical examiners and coroners is critical to building this resource.

Do we need to add this?

DR. LANDIS: I think that those are two separate comments. The first adding that as well as partnerships has one reference, and then the issue about the brain donations is a separate reference, and they're not really linked. So you probably want to get input on those two separately.

DR. INSEL: So let's take the first one, which is partnerships between school and intervention research programs. Is this helpful?

MS. HILL: This is Susan Hill at CMS.

I want to reiterate a prior

comment of Ellen's, and that is her challenge that the only -- that schools, partnerships with schools are not the only kind of partnership, and in her mind, we're not focusing on the plan, only on children, and so I recommend that we delete the word school, and have the sentence read, partnerships between intervention research programs and a wide array of service providers.

We could say, including schools, employers, agency providers, et cetera, but that we not focus just on schools.

DR. INSEL: Other comments about that? Ed?

DR. TREVATHAN: I don't have any concerns really about the content so much as that this is so specific in an introduction about a specific area, and you know, I think the concern I would have about including this is it's too specific. If we include this, does this send a message that somehow this is

more important than all of these other things that are not included in this section?

So I would suggest excluding it or not including this for just that particular reason.

DR. INSEL: Other comments?

DR. BATTEY: This is Jim Battey.

I agree with Ed.

DR. INSEL: So Susan has a recommendation for changing this to take out school and make it service providers. So if we were to do that, I'd like to see a show of hands for those who would just eliminate this altogether and go back to the original language, and the alternative would be to make it a little more general by saying, partnerships between service providers and intervention research programs.

So the first vote would be for just retaining the original language and not putting in this addition. Can I see a show of hands?

DR. HANN: Okay. The vote is one, two, three, four, five, six, seven, eight, nine, ten, 11, 12, 13, 14 at the table.

MS. HILL: Yes on the phone.

DR. MARGE: Yes on the phone.

DR. SHORE: Yes on the phone.

DR. INSEL: Okay. So we will not worry so much about the specific language. We'll just go back to the original. That takes us to the second part of this, which is the specific issues around donations of post mortem specimens. Do you want this in this part of the plan?

I see a lot of head shaking. Let's just quickly put this to a vote. Those who feel this should be added, the whole section on donations of post mortem specimens. Who would like to put this into the plan?

MS. REDWOOD: Tom, I'm not certain I agree with that, that it's probably not appropriate here, but I do think it's an

important comment to make, and I'm wondering, if it's not reflected anywhere else in the document in the appropriate category, if we might go back and look at possibly inserting it into one of the questions.

DR. INSEL: I believe it actually sits in --

MS. REDWOOD: It's already in there?

DR. INSEL: -- Chapter 2 under the "what we need" section. There is a call for an increase in a very robust campaign to try to bring in more postmortem specimens. So it's really redundant in that sense.

DR. LANDIS: I also think it's ghoulish in the --

DR. INSEL: And that is coming from the head of NINDS.

(Laughter.)

DR. INSEL: All right.

DR. BATTEY: Story certainly knows ghoulish when she sees it.

DR. INSEL: Okay. So does anybody want to include this? Quick show of hands? No.

Anybody on the phone want to include it?

MS. HILL: No.

DR. SHORE: No.

DR. INSEL: Okay, all right.

MS. HILL: May I have a point of clarification, please, on the prior question about as well as partnerships between school and research programs? What did we vote on? I'm a little confused.

DR. INSEL: The decision there was not to put in -- this was felt to be too specific, and it was understood that there was a need for partnerships. So the decision was simply to go back to the original language, which here talks about resources, and there's a whole other section coming up which deals with public-private partnerships.

MS. HILL: Thank you.

DR. INSEL: That takes us to the top of page 14, where the term "collection of biospecimens of individuals," and would now be "of people," "who do not have the disorder as a basis of comparison," and this is simply adding that comment to the term "that assessment of people who do not have the disorder will be important as a comparison."

So I think this was intended to be a little clearer that having assessment needed to include the biospecimens.

Comments on that?

DR. LANDIS: I'm fine with that.

DR. INSEL: Yes. Anybody else have a comment?

So all in favor of including this clarification, a show of hands.

Anyone opposed and wanting to retain the original language?

Those on the phone, are you?

It's unanimous to include. Are you okay with that?

MS. HILL: Yes.

DR. SHORE: Yes.

DR. MARGE: Yes.

DR. INSEL: Okay. Thank you.

Now, we're now to the final part of this section of resources, and it says an additional sentence that's been added:

"attracting a cadre of rigorously trained researchers, including those outside of ASD research field, will foster innovative ideas and interdisciplinary approaches and should be viewed as a priority. This cannot be overstated."

Comments?

We had already a comment that training shouldn't be part of this plan, but this actually is not about training. It's about attracting a different group of investigators.

Is this an insult to people who are currently in the field?

MS. SINGER: I don't think it's an

insult. The line I would take out is the sentence at the end, "this need cannot be overstated," because I think it applies a priority to this paragraph that is missing elsewhere. So I would strike that last sentence and then move forward with it.

DR. INSEL: That was Alison.

Other comments?

MS. SINGER: I'm sorry.

DR. BATTEY: Jim Battey.

I agree with Al.

DR. INSEL: Anything else?

So the motion we have would be to include this language up to the word -- we have the footnote for 21 and then take out "this cannot be overstated." In favor -- Peter, did you have a comment?

DR. HANN: Peter, can you use your microphone?

DR. VAN DYCK: Can we eliminate the last few words of the first sentence then? "It should be viewed as a priority"

and just stop with "approaches?"

So it would read, "Attracting a cadre of rigorously trained researchers will foster innovative ideas and interdisciplinary approaches," and take "they should be viewed as a priority."

DR. INSEL: Okay. Again, heads are shaking. So the sentence will end with the word "approaches," and we'll delete the last ten words or so.

In favor?

Again, I think it's unanimous in the room.

MS. HILL: Aye on the phone.

DR. SHORE: Same on the phone.

DR. MARGE: Same.

DR. INSEL: Okay. All right.

Thank you.

And that takes us to the last section, public-private -- I'm sorry. Not the last section -- public-private partnerships. There's nothing, but it takes

us to page 15. Oh, I'm sorry. Ellen has a comment on the very first part of -- sorry to backtrack here, but on page 14, Ellen says -- did we?

DR. LANDIS: That is in community engagement, right?

DR. INSEL: No, this is with the public-private partnerships, and she's asking why are we just identifying these groups, and the reason for that, just to explain -- Susan, maybe you can transmit this to her -- is that it's the advocacy groups have made very significant financial commitments to research, and so the intent of this sentence was to talk about the need for a partnership between all of those who are funding and sometimes at a very high level, funding research in this area.

The question was why not putting in service providers, employers, friends, and medical professionals, but those are not currently funding research. So --

MS. HILL: I'm sure that clarification will be helpful. I'll pass it along.

DR. INSEL: Okay.

MS. HILL: Thank you.

DR. INSEL: So we're back to page 15, and we're looking at the section on community engagement, and here there are a number of comments that talk about, in the initial sentence, adding advocacy organizations.

We may just go do them one by one. So is that useful to put that in there?

MR. GROSSMAN: I would say that it is.

MS. HILL: This is Susan Hill on the phone.

I would say that I think the organization is perfectly fine. I would mention that I think care providers may want to be expanded to caregivers so as to include physicians, friends, employers, and reflect a

broader array of support, broader than just providers.

DR. INSEL: Other comments?

So the language that we have in the motion would say individuals with ASD, their families, their educators, their caregivers and advocacy organizations have vital roles to play, and it goes on from there.

In favor?

DR. HANN: I see one, two, three, four, five, six, seven, eight.

DR. INSEL: I think it's unanimous.

DR. HANN: I think it's unanimous, yes.

DR. INSEL: In the room all the hands are up. On the phone?

MS. HILL: Yes.

DR. SHORE: On the phone as well.

DR. MARGE: Yes.

DR. INSEL: Okay. We're moving on

to discussion point Intro 12. "Finding ways to capture and balance the diverse viewpoints of stakeholders some suggest is fundamental to the purposes and success of the strategic plan."

Comments?

DR. JANVIER: I don't see that as necessary. I think that's been creating the plan.

DR. BATTEY: This is Jim Battey.

I agree with that. I think it's redundant and not necessary.

DR. INSEL: Other comments, issues, items?

This sort of goes back to Jim's original comment that sometimes less is more or shorter is better, if it's not adding and it's understood.

In favor of including this additional language, a show of hands. There are no hands up in the room.

Anyone on the phone want to

include it?

MS. HILL: No.

DR. MARGE: No.

DR. INSEL: Okay. thank you.

We're moving down to the last discussion point, Intro 13. "Strategies are needed to gain and use the first-hand experience of individuals with ASD, their parents and caregivers, as well as strategies whereby people can request specific research and share first-hand experience relevant to research. Community engagement that" -- we'll stop with that one, and then there's an additional comment as well.

Comment?

DR. JANVIER: And I don't feel that that should be added at all.

DR. BATTEY: Jim Battey.

I agree.

DR. INSEL: Does this provide something though that was missing before?

No? Ed.

MS. REDWOOD: I'm going to put in a plug for it. This is Lyn.

Just that I think that there are a lot of success stories from parents that have been overlooked and haven't been investigated. So I think that this does add something to the plan, that we need to embrace a little bit more the families of these children and what they're saying about them and what therapies have been helpful and which ones have not.

MS. HILL: CMS agrees.

DR. SHORE: And Stephen Shore on the phone also agrees. This is important information here.

DR. MARGE: Michael Marge agrees.

DR. INSEL: Ed.

DR. TREVATHAN: This is Ed.

I agree with Yvette. I'm not sure that it really adds anything, and again, just getting back to Jim's point of trying to keep things simple, my concern, I'm not sure if

we're talking about the whole addition or just the first part, but --

DR. INSEL: Just the first.

DR. TREVATHAN: All right. Then I'll reserve my comment for the second.

DR. LANDIS: So I guess the question, we dealt with this earlier by asking if this was elsewhere in the plan. Is this reflected elsewhere in the plan?

It isn't. So even if we wanted it in the plan, and it's not clear we do, is this the right place for it?

MS. REDWOOD: It's in community engagement.

DR. INSEL: Yes. So community engagement would probably be the place to bring in first-hand experience of individuals with ASD.

Della, can you refresh our memories about whether this shows up anywhere else?

DR. HANN: I don't believe it

does, based off of my going through the chapters a number of times. I don't believe it's in there anyplace else.

DR. LANDIS: Well, I guess one question is do we want to include it or not. If it ends up that the Board supports including it, I would take out "requests specific research." That strikes me as committing the plan and the resources to something which I don't even know how you do that.

MS. HILL: This is Susan Hill from CMS with another comment.

From a service org. perspective, we absolutely want to insure that people themselves, their families and individuals with disabilities can offer, can participate in the public policy making process and can offer information, and a first-hand experience is critical to making sure that services, in this case research, is focused on the true needs of people.

I do agree though with the comment that "requests specific research" is odd in this context. I think it would be very difficult to operationalize that concept, and I think the real main point is share first-hand experience.

So I would recommend that we or I move that we accept the sentence but delete "requests specific research."

MS. REDWOOD: Could "requests" be changed to "suggests?"

MS. HILL: I would say through what means would individuals themselves request specific research, individuals, not an advocacy group.

DR. BATTEY: This is Jim Battey.

Tom, why don't we vote on whether or not we want to include the sentence in any form?

DR. INSEL: Okay. Jim, why don't you make a motion. There are two pieces here, but let's take the first piece, which

has to do with the language as it now sits and whether we would want to include this as it has been proposed, which does say "requests specific research" and "share first-hand experience relevant to research."

DR. BATTEY: I move that Item No. 24 not be included.

DR. INSEL: And those in favor then of not including this additional sentence, can we see a show of hands?

DR. HANN: Okay. The vote is one, two, three, four, five, six, seven, eight, nine, ten, 11.

DR. INSEL: And those who would like to include this as it's currently worded?

MS. HILL: Susan Hill on the phone.

Yea, although I have a procedural question about voting for a sentence and then later --

DR. INSEL: Yes. So Susan we will

come back to this in a moment. Let's start with the wording that we now have, and then based on your recommendation we may be able to take a fresh look at this by modifying the sentence.

So with the current language, that's the first question, and we have two who would like to include it in the room. Is there anybody who wants to include this on the phone?

DR. SHORE: Me, too, on the phone.
Stephen Shore.

DR. INSEL: Okay, and two on the phone; is that right?

DR. SHORE: Yes.

DR. HANN: And you want to include it in some form, right?

DR. SHORE: Yes.

DR. HANN: Susan?

MS. HILL: Yes.

DR. JOHNSON: Okay, okay, and then at this point the recommendation is not to

include the sentence. If we were to modify the sentence to take out "requests specific research" and to shorten it, does that make this more attractive to those who voted against it or is it still dead on arrival?

DR. LANDIS: We could use "strategies are needed to gain the use of first-hand experience of individuals of with ASD, their parents and caregivers and share first-hand" -- well, actually you could just stop right there. So maybe you could have a vote on that.

DR. INSEL: Okay. Story has a proposal that we revisit this sentence stopping at the word "caregivers," and Gail.

DR. HOULE: Yes, I have a comment. Just to be consistent I would change "parents" to "families" because we talked about families in the first part of that.

DR. INSEL: Right. Thank you.

So it would say "individuals with ASD, their families and caregivers" -- I'm

sorry -- "people with ASD." Thank you.

Okay. So we have a motion with that slight wording change that this be included. In favor?

DR. HANN: Okay. One, two, three, four, five, six, seven, eight, nine, ten, 11, 12. Excuse me.

DR. INSEL: On the phone?

DR. MARGE: Yes. Michael Marge.

MS. HILL: Yes. Thank you.

DR. INSEL: All right. So this motion passes, and I believe it does, Della; is that right?

DR. HANN: Yes.

DR. INSEL: Okay. And we will move to the final sentence here, which says, "Community engagement also should include greater participation in discussing the relevance of research during the grant making process."

Comments.

MS. HILL: Susan Hill from CMS.

I'm a little puzzled by the notion of "grant making," and I'm wondering if a better term is "funding."

DR. TREVATHAN: This is Ed Trevathan.

I have, well, two separate concerns. One is I don't really think it adds anything. I don't know that this really needs to be in the introduction, but the concern I have is that this sort of, I think, has the flavor or could raise concerns about sentences like this somehow circumventing or being parallel to or conflicting with the scientific peer review process.

And so if we included this, we would then need to have other discussion and the introduction about preservation of the sound scientific peer review process, which it gets back to Jim's point. Why do we need to go into all of this in an introduction?

So for that reason I think it should just be not included.

MS. REDWOOD: This is Lyn Redwood.

As a parent, I think there's a lot of criticism that I hear from other parents with regard to the focus of research and that it's not really focusing on the need to know science with regard to the way the parents view it. It's more focused on the nice to know science.

So I think this does add something here, and I do think it's important to increase public participation, and you can do that without jeopardizing the peer review process.

I think I mentioned before the Department of Defense model where a third of the advocacy community are stakeholders, are actually involved in the decision making process. It doesn't bypass peer review. All of the grants go through peer review first, and then it comes back to a panel, an integration panel, that votes on the relevance of that research to really answer

the mission and goals of the program.

So I don't personally view this as in any way trying to bypass the peer review process.

DR. TREVATHAN: Lyn, just for clarification, I want to make sure we know what you're talking about. You're referring to the Department of Defense congressionally mandated research or the earmark related research that goes through the Department of Defense, correct?

MS. REDWOOD: The congressionally mandated program.

DR. INSEL: Can I ask for clarification here? When it says "greater public participation," greater than what? What does that mean? What's the comparison for this?

MS. REDWOOD: What we have now.

DR. INSEL: Do people know what we have now? For instance, how clear is it about public participation in peer review or

in councils or in any part of the -- at least for NIH, are people aware of the current status of this?

MS. REDWOOD: Maybe not.

DR. BATTEY: This is Jim Battey.

There is no activity which I am involved with at NIH where there's more public participation than in this area already. So I really don't think this sentence is necessary.

MS. SINGER: This may be a discussion we want to move forward to the second year because I do think that if we talk about putting something like this -- if we include this, we should include some sort of statement about peer review. So this may be like some of the topics that came up at the last meeting, one that we want to push forward to 2.0.

DR. INSEL: Other comments?

DR. LAWLER: This is Cindy Lawler.

I just want to reiterate what Jim

said. I think the process by which this strategic plan is being developed has reflected, you know, at multiple points community engagement. So the very priorities that we will now have before us I think will take care of some of the concerns that have been raised, you know, in prior years about funding priorities. So I think it's somewhat redundant.

DR. INSEL: So just as a process comment, I think what this is about is a sense that many of us who are inside these funding agencies have that there is a tremendous amount of public participation in the sense that many people in the public have that it's totally obscure and news to them.

I would have concerns about our voting on something where we don't know the facts, that is, where there hasn't been a full explication of what does exist, how it's done, who's involved. I can understand the perception that there needs to be more, but

without having the data, I don't know that it's useful for us to make a comment about whether it should be greater, the same as, or less than what we currently do.

So let's just put this to a vote though. I mean, those who would like to include this, the choices are to include the language or not to include it. If we don't include it, it doesn't mean we can't deal with it, as Alison says, a couple of months from now when we come back to start working on the next version.

Those who would like to include this language, can I see a show of hands?

Okay. We've got one hand here in the room. Those on the phone, to include?

DR. MARGE: No.

MS. HILL: No.

DR. SHORE: No.

DR. INSEL: Okay. All right. We are now finished with the comments from the public, and with those from Ellen. I want to

now take your attention to the document that Lyn has shared with us, with a whole series of things that would be additions to the crosscutting themes section.

And let me ask the group how you want to address this. There's an awful lot here. Lyn has helped us by rather than getting too bogged down in individual words, she's actually just provided whole sections that she'd like to add, and I think one possibility would be simply to talk about those initially. We can worry about individual wording within each section, but the real question first is do we want to add these to the crosscutting theme section.

And I guess, Lyn, what do we have here? Three or four of them? Maybe it would be good to just start off by giving us some orientation to where this comes from and why you think we need to make these changes.

DR. TREVATHAN: Excuse me, Tom.
Just before, I'm sorry to interrupt but some

of us have two handouts that look similar, but I know they're not identical. So if we could have some direction on which document we're working from.

DR. HANN: The document that you should be working from begins with crosscutting themes, the first one saying and then in green, "Autism is a national health emergency."

Now, the one that was in your packet this morning is the most recent of those.

DR. SHORE: This is Stephen on the phone.

MS. SINGER: The first visual difference is on page 2 where on page 2 in one version there are three boxes and on page 2 in another version there are four boxes. Can we just determine whether we want the three?

DR. HANN: The four box.

MS. SINGER: The four box.

DR. HANN: Page 2 with four boxes.

DR. TREVATHAN: So you want the thinner of the two.

DR. HANN: I don't have the other version so I can't compare.

MS. REDWOOD: One of the things is the section that was, I think, called "recovery," is now labeled "treatment." So that would be an easy way to tell the difference.

DR. INSEL: Do those on the phone -- are you three clear about what we're talking about here? So if you go to page 2, this is the edition that has a lot of green type, and it has "autism is a national health emergency" as the title. On the second page it will say -- the first line is, "Finally, the ability of basic and clinical research," and there are actually four boxes underneath that, and on the third page the word "treatment" is used instead of recovery in the third box.

So you have two versions. We want to make sure we're all using the same version for this discussion. Everybody clear?

DR. JANVIER: I guess I'm just a little perplexed as to why we're actually looking at this because we worked so hard over many months as a committee, and you know, as the one person in the field constantly seeing more and more children with autism, this sense of urgency seems to be sabotaged by this constant barrage of another opportunity for one person of this Committee to try to rewrite the plan.

It just doesn't seem to be the correct process to me.

DR. INSEL: There are heads shaking here. I mean, why don't we take a moment and have Lyn talk about what the intent was, and then given this sentiment, if others agree with this, maybe we should have a more general discussion about whether we even want to dive into this or whether this

is sort of too much too late in the game.

But Lyn, go ahead and take us through.

MS. REDWOOD: And Yvette, just to answer that, there was an email that came out from Della several months ago when we had input from the public comments where we were asked for additional language, additional wording, additional sections. So you know, I'm sorry if this is perceived as, you know, me responding by rewriting the plan, but I guess I just responded to the request, my opinion.

Since we do have throughout the plan a sense of urgency is necessary because of the dramatic increase, and there was research that just came out this last week from Dr. Irva Hertz-Picciotto that documented in California that this dramatic increase really isn't from substitution. It's not from immigration, and that it's real, and that we need to focus on environmental

factors.

So that's where this first section. I felt as though it was important to lay that out, that we are facing a national health emergency. That's where that first section came from.

Also this next section that's in here talks about autism affecting more than just a brain, because I think that's been a focus, and I think that's something that is throughout the plan that is a theme, that autism is defined behaviorally, but it's driven by other biological mechanisms that we need to understand better, and that the effects are pervasive within the brain and throughout the body, and that we need to consider the wide range of the function in multiple organ systems as potential targets for research and treatment.

I think that summarized what's throughout the plan, and that making rapid progress and elaborating these mechanisms for

these pervasive problems require collaborative efforts across disciplines. That's also in the plan already, but it's just -- I felt as though it was critical enough to be added as a theme.

The next section was balancing gene-environment causation research, and again, I think that's what we're seeing within the current emerging research, and that needs to be specifically addressed in the plan.

The last part that I felt was really important that we didn't have in the plan at all as a crosscutting theme was the need for treatment of people with autism, and that we embraced the uniqueness of people with autism spectrum disorders, and that our goals for children/adults with ASD are that they lead independent lives, otherwise expand their capacity to learn, grow and develop, and play a productive role in society, enjoy mutually satisfying and loving relationships

as they desire, and that individuals diagnosed with autism have biologically based differences that can lead to both disability and superior abilities and that they cannot be purely viewed as behavioral or psychiatric in nature.

Substantial gains in function, quality of life, and health are possible across the life span through targeted approaches developed through careful assessments of the person. Thus, personalized treatment across a variety of domains, including medical, educational, and behavioral must be made a high priority.

There really wasn't anything in here that spoke to treatment. So that's why I felt like that was important to include, and that it also embraces some of the comments that were in what we received from the public.

I'll stop there.

DR. INSEL: So what is the sense

of the group? Do you want to dive into this? Is this something you want to put off to the next version? Is it worth having additional crosscutting themes? What's your sense?

DR. BATTEY: I don't think this language should be added at this time.

DR. INSEL: Others? Alison.

MS. SINGER: I'm comfortable with the existing crosscutting themes. I think there's a lot of information in these new suggestions that are ideas that may or may not be grounded in fact.

DR. INSEL: Christine?

MS. HILL: This is Susan Hill from CMS.

Specifically, I would be concerned about the sentence that talks about the fact that adults with ASD are receiving none of the supports necessary, and in general I conclude that maybe much of this has already been said or is included in other areas and it might be redundant.

DR. INSEL: Christine.

MS. McKEE: I think some of this, the national health emergency portion of it, can go into the introduction. I don't know if anybody went back and read the first paragraph of our introduction, but it is about the poorest written.

I mean, we're trying to do this by Committee, and it's really hard and it's oral and then we go back, and we plopped the whole definition of what an ASD is in the very first paragraph of this and as our kickoff to a year's worth of work, the very first paragraph of our entire plan starts out by talking about the rate, the prevalence rate. It hits on cost, and then goes into a very mundane definition of what autism is, then goes back and picks up, oh, the cost issue because we have a real need for research.

And I think that with what's come out recently that if we just go back, some of this can be plugged into the very first

paragraph in a very concise way to make it read better.

DR. INSEL: That's an interesting idea, which we have tried not to backtrack, but it's a compelling case for providing a better introduction at least for the first paragraph.

Ed.

DR. TREVATHAN: Well, I think the Committee spent a very long time over the last several meetings. In fact, we are having extra meetings as a result of spending a lot of time on some of these late entries and new items, and I mean, I certainly agree with Christine that the effort to be as democratic as possible at the Committee has had a negative effect on some of the readability perhaps, as with most of these reports. And I think that that just happens any time a group engages in this type of activity.

However, I really do have -- there

are a number of individuals' specific concerns, I think that several of us have with this long, new list of introductions here. To go through all of this would take a long time, and I would say, as I think someone said, this is too much and it's too late, and that we consider these concepts in the next version.

To go over all of these things now I think would cut into valuable time, and we need to really get down to the budget. So I would suggest that there be an up-down vote on whether to deal with any of these at all now, and then if it's voted to deal with them, then we would need to go into a lot of these details.

DR. INSEL: Other comments?

Well, let's take that under advisement. Let me see a show of hands for anybody who wants to include this, we will afterwards dive into it, but before we go there, does the group want to --

DR. LANDIS: Lyn has a comment.

MS. REDWOOD: I was wanting to say in response to deliberations that we've gone over in the past, much of this document early on was written by the autism team, and in my opinion, this has really been our first opportunity to go through it in detail and for the Committee to make comments on the plan.

So you know, I guess I sort of disagree that we've worked really hard on this. We've reviewed it, but this has really been our first opportunity to make comment. And I'm sorry if it's late in the game, but this is just where we ended up.

DR. INSEL: Okay. Lee.

MR. GROSSMAN: Yes, I agree with Lyn. I mean, this is the first time we're really dealing with the intro. We backtracked ourselves into it. So it's not as though this has been hijacked by any number of people to reconsider this. This is

really our first real in-depth approach to dealing with the intro.

And I agree with Christine. The intro doesn't express to me the sense of urgency that we keep discussing here, and somehow I would like to see that changed, and some of the wording that Lyn has proposed here incorporated.

DR. INSEL: So there are sort of two things in this discussion, one coming from Christine's suggestion that we look more carefully at the beginning of the document, the very first paragraph, to figure out whether we can give that a lot more oomph than what it has now.

But separate from that, and we can come back to that and we can sort of direct the office to provide language because we won't be able to do that here I don't think.

I need a show of hands for those who want to incorporate the comments that we have here in some form at this point. So can

I see who wants to begin this process? Hands up.

Okay. We've got three hands up in the room. What about on the phone?

DR. SHORE: You have one hand up on the phone.

DR. INSEL: Okay, all right. Given that, and I'm assuming then we're talking about there's also a whole section on implementation that we didn't talk about, those who would at this point want to move on, we could still come back to talk about this in 2.0, but we will not include this language in any form currently in this version of the plan. That's the vote.

Who would not include it? Could I see a show of hands?

DR. HANN: The vote is one, two, three, four, five, six, seven, eight, nine, ten, 11 in the room.

DR. INSEL: And on the phone?

MS. HILL: Yes, on the phone.

DR. MARGE: Yes. Michael Marge.

DR. INSEL: Okay. So we will move on. There will be a chance to come back to some of this, but the recommendation as I hear it is that some of you are asking that the language that introduces this whole thing be given a facelift. It needs to be a little more exciting and compelling, and to incorporate some of what Lyn has suggested around the importance of autism as a national health emergency, which doesn't really get reflected in the current language.

Okay. So the introduction, we have now a version that you've all approved with that one exception. We'll have to go back to it. As I looked through the plan, there were some items in Chapter 3 that the office had flagged as needing us to go back, and Lyn, you had asked us to go back to something in Chapter 3 as well.

There was some language. As you remember, we looked at this in December 12th,

and we decided not to revisit it then because we wanted to get finished, but we should look at it now.

MS. REDWOOD: And I wasn't prepared to re-address it, but basically it was the section that -- Della, what page is it on?

DR. HANN: If I recall correctly -

-

DR. INSEL: Page 7 on Chapter --

DR. HANN: It was actually page 4. There was a section in page 4 where I believe you had asked us to go back to. It's now on page 4. It's the section that's highlighted in red because it reflects the changes that were made.

DR. INSEL: Oh, you're right.

So okay. Let me get us all caught up. This goes back to the meeting before the last meeting, and we at the very end of the meeting made some decisions on language related to vaccines and autism.

There are two pieces to this. One is on -- they're both in Chapter 3. On page 4, we have a section about what do we know, which is shown in red, which the Committee voted on at that time, and Lyn, I believe you wanted to revisit this for the next meeting. We didn't get to it because we decided to do the rest of the plan and then circle back to it.

And then there is language on page 7 which as I understand it, Della, the Office of Autism Research Coordination has asked us to look at because you're not clear what it is the Committee wants.

DR. HANN: That's correct. Based on our discussions from the last meeting when we took this up, there was a lot of -- and we looked back over our combined notes, and there was a lot of discussion, which was excellent, but it was less specific than some of your other suggestions were in terms of changes.

And so we wanted to make certain that what was here was accurate in terms of reflecting your opinion.

DR. INSEL: So Lyn, we do not have to revisit page 4 unless you want to. It's up to you. This was something you had brought up. We're trying to make sure the Committee has a chance to get this document in the right shape.

MS. REDWOOD: I know at the time there was a lot of wordsmithing that was taking place, you know, on the run, and that Lee had also expressed some concerns about the way it was worded, especially the part that some do not agree or it may concern ASDs led through vaccination through exposure to measles, mumps and rubella and posing challenges to a weakened immune system or possibly due to a mitochondrial disorder.

I tend to agree with Lee that that does need to be reworded a little bit better. So could this potentially be something that

the staff could work on and come back or no?

DR. HANN: No. I would really strongly endorse the idea that if you want changes to this section that we handle it out here and that you not put it on the staff to do interpretations because this is very difficult in terms of the topics that are being discussed and a variety of opinions.

DR. INSEL: So we don't need to revisit it. I'm just trying to be responsive to your request on the 12th of December.

MS. REDWOOD: I guess what I'm saying, Tom, is that I was prepared at the next meeting to discuss it at the time, but I wasn't aware that we were going to circle back around to this today. I have drafted an actual sentence that reflected, and I can get that, but I can't get it right now.

DR. HANN: We can get it. We'll retrieve it if you want to go on with the rest of the discussion.

DR. INSEL: Okay. Was this

submitted?

DR. HANN: Yes.

DR. INSEL: Okay.

DR. HANN: She did.

DR. INSEL: All right. So we'll
pull that up.

On page 7 then we have language
that the office is asking us to help with,
and again, it's on the same topic, and this
is under what do we need, and I'll quickly --
it's the next page for those -- okay. It's
on the Webinar.

Those who are convinced by current
data that vaccines do not play a causal role
in autism argue against, and so there's a
whole paragraph here that was based on the
public comments and the IACC discussion on
the 12th of December, and frankly, the
feedback we're getting from the staff is
they're just not sure if this is what you
want or not.

MS. REDWOOD: Tom, could you

refresh us? Has this been something that was voted on and approved at a previous meeting, this language?

DR. INSEL: Right. So this was language that the staff thought that we had approved, but they weren't clear, and Della, you may be able to help me because you're the one that's asked for us to revisit this.

What's the question here for the group?

DR. HANN: The discussion last time, if you will recall, we took parts of one section and suggested moving it to another place and then moving another remnant essentially to another place. So we wanted to make sure that in our movement, as we understood what you asked us to do, that we did it, that we actually tore it apart the way that you were envisioning it.

I believe Alison and a number of the suggestions had come from you, but in light of other discussions we had throughout

that day, this section was much less specific in terms of what you really wanted us to do. We just wanted to make sure it was reflecting accurately what the Committee wanted.

MS. SINGER: I think the point that was raised -- this is Alison -- at the last meeting was that when we're talking about what was expressed in the public comment and the diversity of view, that belonged in the what do we know as opposed to the what do we need, and I still see it here under what do we need, and I would -- I think what we suggested was that that type of information be included in what do we know in that we know that there is a diversity of view as reflected in the public comment.

DR. HANN: Right, and I think the reason that we thought a little confused was it was very difficult for us to figure out how to say then what do we need without sort of reiterating a little bit the what do you know because it sat there kind of like a sore

-- in my opinion -- like a little bit of a sore thumb. It needed a context in order to be able to make it flow.

DR. INSEL: Is this useful to include at all? Is there information here that's helpful or is this something that's just redundant with what has already been stated on page 4?

DR. LANDIS: So one scenario is to move the blue to replace the three sentences that start with "some contend that cumulative research on this topic." I mean that's essentially the same.

So on page 4, if you go to Line 15 under -- it's Line 15, I guess, "Public comment reflected opposing views on vaccines as a potential environmental cause," period, and then "some contend others contend a third view." This --

DR. INSEL: Says the same thing.

DR. LANDIS: Says the same thing.

DR. INSEL: I thought we had done

that on the 12th of December. I thought that's what we had agreed to.

DR. LANDIS: And I actually think the blue --

DR. INSEL: Says it better?

DR. LANDIS: -- says it better. So I would suggest moving the blue in place of those three red sentences, "some others, a third."

DR. INSEL: Right. I guess my memory may not be perfect on this, but I thought that was what we had voted on at a previous meeting because we had said then that this seemed to be redundant.

Other thoughts about this? Other comments?

DR. BATTEY: I think it's definitely redundant, and I think it only needs to be stated clearly one time, and it should be moved in the manner that Story suggests.

DR. INSEL: That sounded like a

motion in favor of making that change. So we'll take what's in blue on page 7 and insert it in place of the final three sentences in the paragraph on page 4.

In favor?

DR. HANN: Okay. The vote is one, two -- is unanimous here in the room.

DR. SHORE: Same on the phone.

MS. HILL: Yes.

DR. MARGE: Yes. Marge.

DR. HANN: Great. Thank you very much.

DR. INSEL: Now, there's one other issue that's come up from this chapter, and that has to do with the two new initiatives around vaccines that have been raised, and there have been several issues that have been brought up around those, but one of them has to do with the process, and I just want to get a sense from the group about this because we followed a fairly clear process on many of the other things that ended up as

initiatives. These came from the work groups, and that's why we had budgetary requirements.

There was as you remember a whole series of meetings through January of last year, beginning then and then bringing in the program officers to give us the budgetary requirements.

We did something quite different here, which is we added in these initiatives as a Committee without having the input from those work groups or from the program staff around what the budget should be.

So we're in a bit of a quandary about how to handle these. These are under I think they're short-term objectives that we voted on last time.

Study the effect of vaccines, vaccine components, and multiple vaccine administrations. So this is Chapter 3, the bottom of page 12, and then there's an additional one that was added. Actually --

yes, there's an additional one added at the top of page 13 on the feasibility.

And so I with your permission want to make sure that we're okay with that. Now, even though this is a bit of a different process, we may not be able to provide budgetary numbers here that we know and we have any confidence about, but is this something that the group wants to revisit or should we just move on?

DR. LANDIS: So Tom, where are you?

DR. INSEL: Page 7.

DR. LANDIS: Page 7?

DR. INSEL: I'm sorry. Page 12.

DR. BATTEY: The bottom of page 12.

DR. INSEL: Chapter 3. So we're on Chapter 3, bottom of page 12 and top of page 13.

DR. LANDIS: So it's what's in red in this document.

DR. INSEL: What's in red. These were comments added at the last meeting and discussed at some length. There was a very close vote on both of these items, and there was some confusion about them because there was a third option which Alison had recommended, which actually didn't make it to the table, although I didn't realize that until later.

So I'm asking whether since we don't have budget estimates this is something that, again, we want to revisit later or whether we want to accept this as is and move on. We've already voted on it, but we want this document to be something that reflects what the Committee most wants, and if this is what you most want, we will do this.

But let me hear if there's any interest in that.

DR. TREVATHAN: One of the concerns that came up later, and I would agree that I think one concern I have with

these two is it didn't come up through the scientists. I mean, this bypassed our experts in the work groups, and that we don't have vaccine research experts here.

One of the things that came up when we were looking at this and thinking about budget is that -- and everyone should have a handout on this that sort of begins with this National Vaccine Advisory Committee, the NVAC, which is an HHS committee, and I apologize to those on the phone. I guess they don't have that, but it's actually --

DR. HANN: Yes, they don't have it.

DR. TREVATHAN: But it's actually -- if you go to the HHS Website, it's under the National Vaccine Program Office there, but there actually is a committee, you know, the National Vaccine Advisory Committee Safety Working Group, that their charge is actually to draft a research agenda on

vaccine safety. They have a large number of experts, community representation, and have a fairly, I think, impressive plan for nationwide community input.

And as an aside, when I was shown this and was looking to I think this is so good; this might be something that could advise us, advise our efforts in that regard going forward.

But this is a committee that actually is charged with looking at this type of research. I think that issues such as feasibility of a large study that was brought up is an issue that's been brought before this Committee already, and I think they're in the process of considering and deliberating these issues.

And my impression from talking with some of our experts at CDC, we don't have enough detail in this to even have any understanding what the testable hypotheses are, and when that's the case, we can't

really devise a budget.

And we're also working in parallel with this Safety Committee here and not being necessarily informed by what they're doing. So I wonder one approach would be to roll these two issues to 2.0, but I would suggest if we do that, it would be helpful for this group in some form or fashion to be advised as to what the activities are of this group that obviously is very active in this area, that's a separate HHS Advisory Committee and look at ways that the IACC can interface with, collaborate with, inform that group and vice versa, how that group can inform us as to what we're doing.

I'm concerned we're following a parallel course here and have sort of dueling or competing government committees, and it's clearly in their charter or their charge, and I have questions as to whether this is in ours.

DR. INSEL: Other comments or

thoughts about this?

So there are really two or this gets to a central issue that we talked about last time, which is how does the Committee want to deal with the issue of vaccines in autism.

MS. REDWOOD: Tom, I guess I'm somewhat disappointed we're going back to this because we spent a significant amount of time at the last meeting deliberating these two additions to the plan, and they were voted on and they were approved, and I think coming back to these the way we are now, we discussed at the time that this was a specific autism issue, and it should be in the autism strategic plan.

So I'm just strongly objecting to coming back to this again after it was already voted on.

DR. LANDIS: I mean, I wasn't here for all of that discussion. It seems to me that a recurring question has been vaccine

safety is not restricted to autism. There's a lot of concern about vaccine safety, and that we would want to be informed as we, I think, are better informed now about what else is going on at HHS.

So I mean, if you think about scarce dollars investing, duplicating something that this well-informed group might do, using our dollars for that, I mean, my question, Ed, would be whether or not there is appropriate consideration of autism as a vaccine safety issue on this Committee.

And I note that there's someone here who has a child, somebody Buck, whose child is -- parent of a child injured by a vaccine, and I'm wondering the extent to which -- I mean, I don't know what the nature of that injury was, but it seems to me that this would be an important strategy for -- it's like capturing a whole bunch of extra dollars for this question that isn't coming through the NIH.

DR. INSEL: Let me introduce another issue, and I'm sensitive to Lyn's concern about reopening things we voted on. I think one thing that didn't get discussed when we voted on this is a problem that didn't occur to me until after the meeting, which is that this is perhaps the only issue that we've dealt with that is now part of litigation that involves the department; that it's a HRSA issue, and I'm concerned about the optics.

So the optics of having HRSA vote on issues related to autism and vaccines, when they have a large court case, the optics of having people who could be perceived to have or to represent those who have a financial investment in this issue.

It takes it out of the realm of a scientific question, a research question, and it raises the possibility that some could see whatever comments we make as being biased by non-scientific issues.

And I understand that's a risk in lots of things that we do. This one really feels since this is a court case that is soon going to become public, and I think it's fairly close to a large omnibus effort; I think this one really does represent some jeopardy for this process, for this Committee almost any way in which it comes out.

If we say, yes, we think it's important to look at this and to provide additional information, it implies that we believe that there's a relationship between autism and vaccines, and it suggests that in some way this runs opposite to what HHS may define through the HRSA process.

If we say we don't think that this needs to be pursued, it opens us up to the possibility, at least the optics, that we were trying to keep HRSA from having to go down this road legally.

But I don't know that there's anything else that we're dealing with that

has quite that set of complications, and to not talk about that or to not have that as part of our deliberation when we make a decision, which seems to be a purely research question, should we encourage research in this direction or not, I think is a little naive. I think there's something else here that will be part of the way that this strategic plan would be interpreted, particularly because it's advisory to the HHS Secretary.

MS. REDWOOD: Tom, I don't think considering litigation with regard to research is really appropriate. I think this is an area that's deserving of research efforts, and I don't think you would do the same if it were something with breast cancer and hormone replacement therapy, saying we're not going to investigate hormone replacement therapy because there's litigation. I just don't see that. This is a scientific question. This is not a liability question.

DR. LANDIS: But I think Ed made the point that these did not come up through the scientific teams, was added by this Committee, which further complicates it.

DR. INSEL: That does complicate it, and so it has the appearance as if this Committee has chosen in spite of the fact that the scientists through the workshops did not generate any initiatives in this area and, in fact, as we say, that the science -- I think we say the bulk of the science does not support any connection. We as a Committee are saying actually we think we need to demonstrate this connection. We need to really study this in a much greater point.

And there's a \$10 million number down here for doing that, which means that we put it at a pretty high priority, and it may be that the Committee really wants to send that message. I just want to make sure that before we put this thing to bed, all of you have taken a close look at that and you've

considered what this means because this is a real expression of a position we're taking on an issue that is both scientific and legal.

DR. TREVATHAN: Just to make a clarification, I think that the concern that I see -- and I agree with what Tom and Story have said -- I think the concern that I have with going forward is that we are not informed as we should be by the scientists that are experts in the area because this did not come up through the work group, but also because the scientists who are experts in the area are actually, in terms of vaccine safety research, are actually in this other work group or actually in this other advisory committee.

So it seems if we're going to do our very best, and I agree it's under difficult circumstances, to sort of do what's right scientifically, in spite of political and ideological agendas, that the right thing to do is for us to engage in some way and be

informed by the National Vaccine Advisory Committee's safety working group. I mean, that would be the usual way I would think that the science that cuts across two different committees would be explored.

DR. LANDIS: So one scenario is actually to put a note in the "what do we know" section, recognizing the existence of this committee, encouraging this committee to pay attention to autism as a potential vaccine thing, and that we will, if the questions remain, address this at a future time.

I mean, that might be a way of acknowledging that there are differences of opinion, but that that's being dealt with, potentially dealt with by this other group

DR. LAWLER: This is Cindy Lawler.

I think a stronger statement may be to include a short-term objective that reflects activities that attempt to coordinate with this standing committee, and

that we can do in a short turnaround time in terms of thinking about feasibility of conducting studies.

You know, I am a little bit concerned because this is very late in the game, and it's not as though we have not heard that vaccines are just a key issue for, you know, many parents of children affected with autism. So this isn't the first time we've heard it.

We've had opportunities to sort of seek advice from other committees and so on. So I would, I think, be more comfortable if we at least had as a short-term objective that we would go forward and try to build those partnerships and, you know, assess whether studies were feasible as opposed to just put it more in the opportunities as Story suggested.

DR. INSEL: Lyn.

MS. REDWOOD: I'd like to point out one of the initiatives approved states

that we would study the effects of vaccines, vaccine components and multiple vaccine administration and autism causation and severity through a variety of approaches, including cell and animals studies, and understand whether and how certain subpopulations of humans may be more susceptible to adverse effects of vaccines.

That was given \$6 million, and we have what, a \$900 million or so budget? So I don't see that this is really taking away a lot of resources from our budget, and I think it's a very important question that needs to be asked, and it's not this group that needs to be answering those types of questions.

So I think it's important that this be in the NIH research agenda.

Now, the other one in terms of determining the feasibility, if you're saying that that's being done somewhere else, but I think that it's important that these stay in. We've already voted on them. The Committee

has already approved them.

DR. HANSON: Jim Hanson.

DR. INSEL: Jim is here
representing Duane Alexander from NICHD.

DR. HANSON: I spoke with Duane
both yesterday and again this morning in case
he wasn't able to be here when this topic
came up. I think our position is that this
topic is important to remain in the plan, but
we would certainly not assert that the
exclusive responsibility for the conduct of
such research would be directed through this
Committee.

I think as Ed points out, there is
a whole committee and a whole structure
looking at vaccine safety and its
relationship to usabilities of a variety of
types, and likewise it's not just
epidemiologic research but basic science
research and clinical research as well.

And so we think the topic should
remain in the report, but certainly we should

be informed by the activities of a major ongoing effort directed through the National Vaccine Program Office and the National Vaccine Advisory Committee. So we should certainly coordinate with and understand what they're doing.

There was a time in which I was involved with the National Vaccine Program Office, and I can assure the members of this Committee that they take this issue very seriously, but on the other hand, I think it's also fair to say that they are vaccine safety experts that are not exclusively focused on disability issues and that this Committee has perspectives that would be valuable to share with them as well.

So I think we would want to see it remain in. We're not sure that the \$10 million for a feasibility is appropriate. We think it's probably substantially less than that for feasibility studies, but at least keeping in the budget some significant amount

of funds for research involving vaccine safety of all these types is appropriate.

DR. HOULE: Tom.

DR. INSEL: Yes, Gail.

DR. HOULE: Gail Houle.

Is there anything in the way that this is worded now that would prevent coordination and collaboration with the national vaccine work that's going on?

DR. TREVATHAN: Well, I'll just say I think that part of the problem we have with keeping up with a budget is that we're sort of running in parallel to another group that I would suggest is loaded with vaccine research experts, and we're not.

And so until we do engage with them, I mean, given that I hope we're going to spend a lot of time on budget today, I don't know how we do the budget for this when we have not engaged with their scientists or with their overall committee that does budgets for these sorts of issues.

DR. HOULE: Yes, that's not a solution to determining the budget problem, and from another agency I'm going to sit back and let you people who do this type of research hash out the budget. I mean, I know what it would cost us in the types of research that we do, but it's very different.

So is anything that you're proposing in a budget more than something that's in a range of estimates. You're estimating what it would cost for any of these studies or any of these items within a range, within the balancing of what's going to come out when you actually try to implement it.

It is a very difficult task.

DR. LANDIS: So can I just paint what I perceive to be a really unattractive scenario? The vaccine safety group, National Vaccine Advisory Committee, goes ahead, comes up with a set of studies, runs them, is poorly informed about issues related to

autism, ends up with a set of results which provide no evidence for a role of vaccines in causing issues.

This group, which is informed about autism, designs a set of studies and for whatever sets of reasons, the studies are different and that appear to provide evidence for a role of vaccines. You then have two parts of the department supporting research efforts, which in fact come up with conflicting results.

I mean, it just strikes me that that would be really -- we'd be no further ahead. We'd probably be further behind, and that until we know what they're planning and we are convinced that they have adequate information about issues related to autism, I would think that this is important to table.

DR. INSEL: So what if we were to change the language here to simply say to work with the NVAC or, Cindy, I'm not sure I remember exactly how you had it worded, but

coordinate with the NVAC.

Whatever it is, essentially I'm not even sure how much they're doing it, we're late in the game here to work with them, but we could make sure that we -- because they have been tasked to do precisely this. It doesn't make a lot of sense for us to task somebody else to do what they're doing.

Is there some language that we --

DR. LANDIS: How about insure that the National Vaccine Advisory Committee consider autism in their studies, in any studies that are proposed to test vaccine safety.

DR. INSEL: Is there a budget that would have to go with that or is that something that's really kind of a need but not an initiative?

DR. TREVATHAN: I would suggest that -- I mean, I don't know that it needs any money other than I know that we all spend

money when we come to meetings, but it seems to me we need to get together, get some people together. As I look through the list and I wanted to make sure everybody saw the list of people on this Vaccine Safety Working Group, as I look through here, I mean, I realize that there are actually some people here that I know their names, and they actually do know about autism. For example, --

DR. LANDIS: Ben Schaywitz.

DR. TREVATHAN: -- Ben Schaywitz, who's Chief of Pediatric Neurology at Yale and works for the Yale Child Study Center and has been working in this field for a long time, so he's on that committee.

But I think it -- and I would say we don't have a vaccine safety researcher of Ben's stature on our Committee. So I wonder if the first step may not need to cost very much money, but it's critically important, is that we do engage and get together with them.

DR. INSEL: Is this an initiative or is it just something that we put in in the plan as one of the needs is to coordinate closely with the NVAC?

DR. BATTEY: Jim Battey.

I think it's a need and not an initiative.

DR. INSEL: Other sense of the group? Anything else? Is this something that we need to discuss?

Why don't we vote on this because it does mean revisiting something we voted on before? And it may be that in spite of your sense that others really want to see this still remain in the place where it is.

So the motion, if you could maybe make a motion about what you want to do with this, let's see what the sense of the group is in terms of how to handle the initiative on determining the feasibility and design of an epidemiological study.

DR. TREVATHAN: So you want to

separate these two out, is that what you're suggesting?

DR. INSEL: Yes, I think they are two different issues.

DR. TREVATHAN: Yes, right.

DR. INSEL: That second issue which we can visit is based really on what we want to do with the epidemiology.

DR. TREVATHAN: Okay. So with the determine the feasibility and design of the epidemiologic study, I would suggest that, you know, whether or not the correct way to do it is either table that and then insert something else that has either no funding or some amount of funding that perhaps Della's staff and people can determine what it costs to have a meeting.

I want to be sensitive to the fact that we're all under travel restrictions and we're traveling and going to more meetings, and for the public members there's funds, but that we actually have a statement that we

will in this next 2.0 or this next year of strategic plan engage with the National Vaccine Advisory Committee, be informed of our activities, have them be informed of ours, and together look at feasibility and advisability of further studies.

DR. INSEL: So we could actually use the same language, but it would be in the sense of a need, not an initiative, this adding and coordinating with NVAC.

DR. TREVATHAN: Right. Yes, I want to be sensitive to the fact if any of us were sitting in the seat of vaccine safety researchers, I mean, you know, we have a Committee that really does not have expertise in that area, and we basically can be viewed as telling that group what to do without being informed of what they're doing already.

So I guess my first sense is that we need to engage them, sit down with them, and hear and us share our interest and concerns and hear what they're doing in terms

of determining feasibility of these sorts of studies.

DR. HANN: Just for point of clarification, just to make sure I'm follow you, this is Della. What I'm hearing you say is that in the section under, what do we need, which would be on page --

DR. INSEL: Pages 5 through 8.

DR. HANN: Right. So probably what is currently the big blue paragraph, which is going to be moved, it won't be in there any longer.

DR. TREVATHAN: Right, right.

DR. HANN: to have in its place a couple of sentences to talk about that this Committee exists, the NVAC Committee exists.

DR. TREVATHAN: Right.

DR. HANN: It's charged with X, Y, and Z. You know, we can get that off of a webpage, and that there is a need for the IACC and the NVAC to engage in conversation about these issues with regard to that.

DR. TREVATHAN: About issues of joint interest.

DR. HANN: Right.

DR. INSEL: And specifically on the feasibility on the feasibility question, which was the one that came up.

DR. TREVATHAN: I think, yes. So if we did that and inserted that where now the blue paragraph is --

DR. HANN: Right.

DR. TREVATHAN: -- on page 7 in our draft, and then struck the determine the feasibility and design, under the short-term objectives, and we could even say something. I would suggest put some clear language in here about timeline that we expect we need to do this with --

DR. INSEL: This year.

DR. TREVATHAN: At the first part of this next year, yes.

DR. INSEL: Okay. So that's a motion. I think that's a motion, yes?

DR. TREVATHAN: Yes.

MS. REDWOOD: Tom, I'm unclear.

Are you saying the entire language here that says that they would look at the feasibility of designing an epidemiological study to determine health outcomes, including ASD among various populations of vaccinated, unvaccinated, and alternatively vaccinated groups, would then go into a need?

DR. INSEL: What it would say in the need section is that we need to coordinate with the NVAC, which has been given this charge, to make sure that they're attending to the specific interests of autism in terms of vaccine safety, and it would have this language because they are charged with determining the feasibility of an epidemiological study to determine if the health outcomes, including ASD among various populations with vaccinated and unvaccinated and alternatively vaccinated groups could be done.

MS. REDWOOD: So all of this wording.

DR. INSEL: Could go into the needs section.

MS. SINGER: Can I? Why would coordinate with the NVAC be limited to the epidemiological study? Doesn't the NVAC also look at vaccines, vaccine components, and administration? Shouldn't it apply there as well?

DR. HANSON: Yes, it should and does.

DR. TREVATHAN: Yes. So the NVAC is an HHS level committee. So it actually interacts with NIH, CDC and I guess really any HHS agency, is that correct?

DR. HANSON: Yes.

DR. INSEL: So, Alison, if I understand what you're saying, you would put in both of these initiatives and say why don't we remand those to this other group which has the expertise and the

responsibility and work with them? Is that -

-

DR. LANDIS: Actually that's what I thought we were doing. I had not recognized that the principal focus was the epidemiology study, and with the understanding that as a consequence of that coordination in a year or two it might turn out that some of that gets handed back to us under their supervision, but to undertake those studies in the absence of knowing what they're doing and how they're doing it to me just doesn't make scientific sense.

DR. INSEL: Okay. So that changes the motion a little bit. So this would be to take both of these items that have to do with vaccines, vaccine safety essentially, both cell biology studies and the epidemiological studies, and say we want to essentially remand that to another group that has been given this charge already, find out what they're doing, and then come back to this at

a later point when we have the scientific expertise to be able to inform what we should do.

DR. LANDIS: Which would enable us to assess the need for that to be in our plan and our resources used for that. But maybe we should do this one at a time, which is to take the epidemiology study and move that, and then, second, consider whether or not that second piece gets moved. Because I think we may end up with the same business of the group not being able to follow the goals and changes.

So why don't we go back to Ed's proposal, which you could reiterate, and then vote on that?

DR. INSEL: Story, I hear you, but I think we can simplify it. I really do think that if these are both really issues of vaccine safety, one has to do with the epidemiology and the other has to do with mechanisms, and what you're saying is there's

another group that's doing this. We can look to them to provide guidance to us about what needs to be done before we start manufacturing studies and budget numbers.

DR. TREVATHAN: My understanding of their charge is that it includes both. Both of these could fall under their charge. So I think we could subsume both under the same.

I certainly think the right thing to do scientifically I would suggest would be to discuss the issues in both of these with this group.

DR. INSEL: Okay. So is that a motion?

DR. TREVATHAN: Yes. So I would motion that we take both of the objectives listed, the first listed on the bottom of page 12, to study the effects of vaccine, vaccine components, et cetera, and the next one at the top of 13, determine the feasibility.

Take both of those objectives without budgetary assignment and move them under needs. Where is that now?

DR. HANN: Page 7.

DR. TREVATHAN: Page 7, and state that we need to -- there's a need for the IACC to be informed of the activities of the NVAC and to collaborate with them in the --

DR. LANDIS: And actually just before we vote, I'm looking at one of these pages. These are now open for public comment. Comments being sought include people's concerns about vaccine safety, their values.

DR. INSEL: Story, we're not sure what you're looking at.

DR. LANDIS: Okay. I am looking at the National Vaccine Advisory Committee opportunities. It's on page 1 of 3 in the second set of -- actually the third set that we were provided, and what it describes is the opportunity for public comment at the CDC

Immunization Safety Office to help draft a scientific agenda.

And I think that because we now know about this, it's an opportunity for the autism community to really inform this Vaccine Safety Committee in a way that perhaps wasn't obvious before.

MS. REDWOOD: Story, I think they have been doing that.

DR. LANDIS: hey have? Oh, great.

MS. REDWOOD: But I don't think it's really been very successful so far.

I would like to suggest an alternative motion that these be voted on separately. I think they're two different initiatives. I think both can conduct this type of science throughout the country. We have researchers focusing on the same issues, and yes, I agree, Story. Oftentimes they have conflicting research findings, and studies need to be replicated. So just by saying one group is doing this, we shouldn't

be doing this, I just don't see the logic in that. I think it's important for this Committee and for NIH to be doing this type of research.

DR. INSEL: Well, I think that's the issue that we'll have to put to a vote. That's part of what the debate has been about around this table for a while.

So one possibility is we could separate these out if people are more comfortable with that and take on the epi question first. I see heads shaking that they'd like to do that.

So what Ed is recommending as I understand it is that we move the epi initiative to the section on needs. It doesn't have a budgetary implication. We simply say that there's a need to coordinate with the NVAC, to look at the feasibility question.

In favor of that change? This is a change from what we voted on before.

DR. HANN: Okay. The vote is one, two, three, four, five, six, seven, eight, nine, ten, 11.

DR. INSEL: And on the phone?

MS. HILL: Aye. CMS.

DR. SHORE: Aye.

DR. INSEL: Anyone else on the phone?

Opposed?

DR. HANN: Opposed is one, two, three, four.

DR. INSEL: On the phone?

So the motion carries. We'll make that change. So the second piece of this has to do with the mechanistic studies, the studies that have to do with mechanisms. Well, we can read it.

And what's your interest here? Do you want to deal with this? Is this something that we want to revisit at all? To study the effects of vaccine, vaccine components, and multiple vaccine

administration in autism causation and severity through a variety of approaches, including cell and animal studies.

Is that premature? Is it something that we want to make an investment and a recommend, or do we want to handle it in the same way and simply say coordinate with the same group, find out what they're recommending in terms of scientific agenda and go with that?

DR. BATTEY: I would move that we handle it the same way we handled the first initiative, and that's that we coordinate our efforts with a committee that has considerably more expertise in vaccine safety, and that's the other HHS committee, the NVAC.

DR. INSEL: That sounds like a motion. Jim Hanson, last comment?

DR. HANSON: I'm a little unclear as to what we're actually recommending. I mean, obviously neither committee does any

research or directly sponsors research. It's through the participating agencies that the research is conducted and being conducted so that child health is involved in such research currently and has been for a long time and will continue to be, and we would like to insure that it is clear that this is an important to coordinate function.

I think that somehow or other we need to insure that we are addressing these ongoing concerns and that the document be clear about the fact that we think that this is a continuing need and that what we're trying to do is to make efficient use and effective use of research resources, and that we provide advice to them and that they provide advice to us that is fully informed.

It is full of vaccine experts, but it is thin on disability experts. It doesn't have a lot of geneticists. It doesn't have a lot of environmental health people. It has some, and they could profit from advice from

this Committee, just as this Committee could profit from advice and counsel from them.

And I think it is that notion that we need to insure. This is a priority. It is a continuing need, and that we are endorsing that, but that it would be foolish not to work together.

DR. INSEL: Thank you, Jim. I think what I'm hearing, and I don't want to speak for you, Ed, is the concern that you could imagine people on that Committee might have with a process going on in parallel with people who have almost none of the expertise that they need.

We would feel the same way, I think, if they make suggestions about what we should do in terms of autism therapy research, which they have no expertise in. So part of this is a wish to make sure that the scientific recommendations come from the place where you have the best science advice.

We started this conversation by

saying that these were initiatives that did not come through our scientific process, our work group process. They were ones that we added in at the last meeting.

DR. HANSON: I think there is an analogy that went on 15 years ago in which concern was not yet as much about autism as it is now, but there was a great interest and concern about sudden infant death syndrome. Subsequent research has supported to a substantial degree by us, has shown that it is a positional effect of how babies sleep accounts for most sudden infant death syndrome and it has little or nothing to do with vaccine safety.

There is that interaction that as we do more science, we learn things that change our priorities and our perspectives. We're learning more about the genetics and genetic components. May learn about more about environmental components, and this will change, and we need to have a dialogue that

insures appropriate participation and that is flexible and adaptable, but does address community concerns as well as scientific issues.

DR. INSEL: So, Jim, I think you made a motion, but maybe it's worth restating it because we do need to move on. If we could get a vote here and find out whether the group really wants to go this direction or not. So let me send it back to you.

DR. BATTEY: Well, I think what I moved is that we handle the second component of the language that we're considering to be a need to coordinate our efforts with that of the NVAC.

DR. INSEL: So this would move out of the initiative into the need pile, and it would be language, again, around vaccine safety, but be coordinated with the group that's charged to do this.

DR. BATTEY: Correct.

MS. REDWOOD: Tom, can I ask a

question? The way I understand this this would go out for an RFA or some type of announcement, and any type of researchers could apply to do this type of research, correct?

So we could still have experts in vaccine science conducting this particular research. I have concerns about this other national vaccine program office in that with CDC at the helm as an agency that's responsible for promoting vaccines and holds patents on vaccines heading up vaccine safety, I think that are some inherent conflicts of interest, and I think that the NIH does not have those types of conflicts of interest, and I think that the autism community would view this type of research being done under the auspices of NIH much more favorably.

DR. INSEL: I don't think there's an NIH institute though at the table that knows anything about vaccine safety. Maybe

I'm misspeaking. I'm sorry if I am for Story or Jim, but this is not what --

DR. LANDIS: No, no, I don't. I mean, so I think the issue is we have to do this every year, and the question, although I'd have to say I can't imagine doing this every year, the question is are we ready in January 2009 to commit to this or do we want to in a sense table it till April 2009 when we might have had a chance to be better informed.

So it's quite possible that the Vaccine Safety Advisory Committee has no interest nor plans in anything that's on this study the effects of, in which case we could take it back up, but right now since we don't know, it seems to me I would vote with -- I would endorse Jim's suggestion, we put it in a kind of need to know with the understanding that once we're informed it would reappear on our agenda of things for 2.0.

DR. INSEL: Yvette.

DR. JANVIER: Yes, I'm concerned, I think, with Lyn, kind of the opposite, but I can tell you every single day I'm seeing children with autism in my office, and every parent is concerned about vaccines, possibly rightly so, not rightly so.

I think that, you know, when you look at epidemiology of vaccine safety, you're looking at all the kids of the United States, possibly a subpopulation. If you look at kids with autism, they may have a different molecular issue. I don't know, but I think if we abandon this line of research, we're really letting down families of children across the country.

I am hearing this every day. I'm looking for a pediatrician who's breaking up the vaccines. I'm slowing down the vaccine recommended schedule. I mean this is something on the minds of families of all children constantly in this country, and I think it's not adequate for us to just say

there's another committee that will handle it because I don't think their priority is autism.

DR. INSEL: I don't want to revisit the whole discussion we've had before, but one of the questions that comes up is whether cell biology will answer that question and whether doing studies of vaccine components in cell lines, which we've been doing for a long time, whether that will really reassure people.

But Ed.

DR. TREVATHAN: Just by way of clarification, I mean, I don't know if you intended to suggest this, Lyn, but it is not true that the NVAC Safety Working Group is a CDC committee. It is not. It's an HHS committee. It's at the HHS level, and so it actually does, and I think, Jim, you might be able to correct me if I'm wrong, but it does actually involve NIH and other federal agencies.

So this is not turning this over to the CDC.

DR. INSEL: If there's interest, we could have Bruce Gellin, who leads the NVAC effort, come to the next meeting and ask him a lot of these questions about what we should be thinking about and when they will have answers for us and how far we want to take this.

I'm very mindful of the time, and I think that I'm not sure we're going to get this any clearer for the group. It is a central issue in front of us. So I want to move this to a vote.

Jim has given us a motion about shifting the issue around vaccine components and vaccine safety to a need, and again, integrating it with what's coming out of the NVAC. Let's go ahead and get a show of hands if you want to do this or not.

Those who want to make that change and actually take this out of the list of

initiatives and put it into the need section,
can I see a show of hands?

DR. HANN: Okay. The vote is one,
two, three, four, five, six, seven, eight,
nine.

DR. INSEL: On the phone?

MS. HILL: CMS, aye.

DR. INSEL: Yes, and then those
who are opposed and want to retain this in
its current form.

DR. MARGE: Aye.

DR. HANN: There's one on the
phone. One, two, three, four in the room.

DR. INSEL: So in this case I
think what we'll do I'll check with Bruce
Gellin and have him come to the next meeting.
This could be back on the agenda for Version
2.0. I believe they will have information at
least about the feasibility question in short
order, and we can push this into the next
discussions about what we want to do with the
revised plan.

DR. LANDIS: It also strikes me that if, as you say, Lyn, the autism community has had little success with this committee, that bringing someone here from the committee and impressing upon them concerns from the community about this issue and that they run the risk if it isn't dealt with, kids not getting vaccinated at all.

I think it's not as good as bringing them to a hearing, but it's maybe the next best thing.

MS. REDWOOD: Tom, can you also hold the vote in terms of like a roll call vote because it stands out to me that the public members on this Committee are the ones voting in favor of this research, and it's the federal members that are voting not in favor of this research, and I think that needs to be reflected in the minutes of the meeting.

DR. INSEL: I don't think that the numbers would reflect that. The vote,

there's six --

MS. REDWOOD: It does.

DR. HANSON: We abstained from either, voting either way because I think that the options were not entirely reflective of our point of view. So we voted to sustain and enhance research in this area, not to remove it. It's ongoing.

We do vaccine safety research at NICHD. We do it in coordination with CDC, and our research helps to inform the NVAC in terms of its federal advisory role.

Also there is a National Vaccine Program Office which coordinates the specific activities in an ongoing way between the various federal agencies and the private sector as well.

So it is not just the Advisory Committee that we should be concerned about, but the Program Office, which was at the Secretary's level until about 1997 or 1998 when it moved to CDC as an administrative

cost saving device.

But I think it's very important that we recognize who's coordinating the research and who's advising the federal government.

DR. INSEL: Right, but let me clarify that the NVAC is not in the CDC. This is out of the Office of the Secretary, and so if Bruce Gellin comes here, he comes representing the Secretary. Our report is advisory to the Secretary, not to the CDC or anyone else.

So it may be logical that the secretary himself or herself, but it looks like it's going to be himself, would prefer to have a single group that he's charged to do this actually do it in the way that he's asked for it. Possibility, just a possibility, but that may be what we'd hear from him.

Gail.

DR. HOULE: I just wanted to echo,

I guess, some of the same concerns about the lack of clarity. It's not or I wouldn't want to characterize that we're voting against this research. What I was voting for was coordination, coordinated research.

DR. LANDIS: Informed.

DR. HOULE: And coordinated with other entities that are working in parallel, and so I voted to move it because the language that was going to be substituted in the needs section included coordination. We didn't have any language to keep it here in the research section as a coordinated effort. That was not an option.

DR. LANDIS: So I guess the issue was informed and coordinated.

DR. INSEL: Informed and coordinated, but I think Story's point, to go back to what she said, was there's a little bit of a process issue here, that the rest of this document reflects comments that we got through a process that had to do with

scientific workshops and ideas that the scientific community gave us.

This was one that didn't come that way, and it may. So it may be that the NVAC will say this is precisely the kind of work that needs to be done. They're doing that process, and they're getting public input about that process. Why not wait and find out what they tell us from that process?

If we're not satisfied with that, we can always go back to this, have our own scientific workshops, have our own process that we put together.

DR. HOULE: Well, I agree, Tom, that that is a good description of how one would go about coordinating, and in hindsight, you know, we just found out, a lot of us just found out about this other line of research that's going on, and I'm, you know, not entirely sure how you handle it at HHS, but I mean, we do a lot of times co-funding. We contribute money to other agencies to over

sample populations that we want in their research study rather than just duplicating.

I think that might be what we're looking for as a solution.

The other thing that we deal with in our agency is the Office of Management and Budget, and if we submit this and it gets to the Office of Management and Budget and they way there's another agency that's already doing this, you know, we're not going to approve you to duplicate this. Is there another way you can do it? Can you contribute to their study? Can you over sample and whatnot?

So we have a checks and balances. It's not always what we want to do. We've got the OMB who's program specific, has staff who are looking to make sure that the federal government is not duplicating efforts and funding the same studies twice or funding it in a way that could be better done by combining.

DR. INSEL: Okay. Della wants to review where we're at, and then we can look at the time and make some decisions about where to go from here.

Della.

DR. HANN: Just for my clarity in terms of what we've just decided, that the two elements, the bullet that begins at the bottom of page 12 and the next bullet after that, so the first one being study the effects of vaccines and vaccine components, the second one on determining feasibility and designing an epidemiological study to examine vaccines, those will be removed from this section. They will be moved to page 7 in the needs section in a description of better coordination and being better informed by the NVAC committee.

DR. HANSON: It goes both ways. They listen to us and we listen to them.

DR. HANN: Right. That's coordination in terms of two-way.

DR. INSEL: And we'll start by bringing Bruce Gellin to the next meeting that he can attend. Hopefully, he'll remain in his position. I don't think he's a presidential appointee. So I assume he'll still be in the same role in the next administration.

DR. LANDIS: So to address Lyn's concern that that committee is not listening to the autism community, we might have an opportunity to write in a comment on behalf of this Committee to say that we would hope that they would be considering this as part of their scientific agenda.

DR. INSEL: Right. I think that's something that can be done even before the meeting.

DR. LANDIS: Right.

DR. INSEL: That's certainly feasible to do.

DR. LANDIS: No, they have a comment period open until January 26th.

DR. INSEL: So the IACC could certainly tee that up for them and then ask them to report to us. Jim.

DR. HANSON: As a brief comment, and that is an example of where we could work together would be the creation of research infrastructure that is commonly needed by both groups. The surveillance resources and infrastructure nationally needs to be enhanced both to answer the feasibility issues with regard to the questions in this document, but it also needs to be addressed for vaccine safety reasons as well, and it's an expensive and difficult and complex infrastructure that is critically needed by both groups.

DR. INSEL: The other piece I just want to highlight here, as Della was saying that there will be some shifts. What we don't want to see happen here is in any way to take away from the priority given to studies of environmental factors in this

report. This is a single environmental factor which got a lot of prominence and should have because it's of such, as Yvette says, such intense public interest, but one of the comments that we heard over and over again was that the other 999 potential environmental factors have not gotten sufficient recognition or significant study or at least sufficient study, and we want to make sure that that language still continues to be highlighted and that people read this report understanding that we need to look at G x E, as well as environmental studied.

Okay. So we, I think have made it through the document, except for budgetary requirements. We're only about an hour off on our schedule. I'm mindful that people need a break. Shall we take a break now and come back, work on budgetary requirements through lunch? What's your pleasure?

Okay. So if we take a break now, there's a cafeteria down the hall. We can

grab something. It's 11:30. Bring your lunch back and let's say we reconvene in maybe 20 minutes, and we'll start on the budgetary requirements and get those completed in short order.

Those of you who are on the phone, we'll just plan to reconvene about 11:55. So we'll talk to you then.

(Whereupon, the above-entitled matter went off the record at 11:36 a.m., and resumed at 11:55 a.m.)

AFTERNOON SESSION

(11:58 a.m.)

DR. INSEL: We overstayed our lunch a bit. We've got to get back to work.

Are those of you on the phone back with us?

MS. HILL: CMS is here.

DR. INSEL: Good. Stephen are you here?

(No response.)

DR. INSEL: Nope, and Michael?

(No response.)

DR. INSEL: Well, hopefully you will join very shortly.

We have now a quorum at the table, and, Della, can I ask you to frame up what we need to do here with these budgetary objectives and how you want us to go through this?

DR. HANN: Okay. I'm going to go now to the document in your folder that looks like this. It is the excerpts essentially

from the main text. We thought it might be easier to walk through this. We literally just pulled it out. Okay? We didn't change the words. The words are the same.

And you will see first the description of the objective. So on the first page are the objectives, both short term and long term, for the first chapter.

And in the second column is the number of proposed years that came from the implementation work group this summer in terms of how long they thought it would take to do this type of work.

The first estimate that you have then is the implementation work group estimate. That was their suggestion as to what they thought the work would cost. In some cases there's also dollars that have been suggested by the public, and so that's where that public comments column comes into play. This first question doesn't have that, but it will come into play in subsequent

areas.

In addition, there were some items that were developed by the Committee or substantially changed by the Committee in terms of your prior deliberations in which my staff tried to talk with various program staff, et cetera, to develop a new estimate for your consideration.

And then the final one is an area labeled total budget, all years increased for inflation. When the work group met, it did not consider inflation, and sadly we do in some regards, and so we used the biomedical price index, cost inflation figure, and applied that then to the work group estimates.

Also, for those objectives that were worded such as to say at least two studies or at least four studies, the phrasing, at least, was included. We expanded on the work group estimate to essentially take half and add that onto it.

So if it said at least two, then we budgeted, we provided you a budget for three, okay, because essentially the way the objective was worded, it was the floor, and we wanted to give you something that was a little bit above the floor since it said, at least.

DR. INSEL: Is that clear?

Now, the other point to make is what do these numbers mean. So we're not making funding decisions here. We're making decisions on what government people call professional judgment, that is, if the funds were available to do this initiative, what would it cost, and this is, again, advisory. These are not commitments of dollars. We have a whole other process by which we do that, but these are judgments about the cost. So that's why they're called budgetary requirements. Okay?

Shall we just go through them and see whether these makes sense?

Really the question is as you look

at the objective and you look at the dollars involved, does that sound like it's realistic? And the numbers we have here are provided by program officials within the different agencies who do this for a living, who know the most about what it costs to do a certain kind of science.

DR. HANN: We also had Autism Speaks, also provided some of those figures as well, as part of that programmatic effort.

DR. INSEL: Right. So it was a combined effort.

And, Della, one last question about this. Will it be workable to vote on these en bloc so that we can take the whole first objective rather than getting -- well, let's see. Let's see what the conversation is.

So we can just walk through them. We're on an objective one. The first short-term objective is to have at least one efficient diagnostic instrument developed for

diverse populations, and the estimate was \$2.5 million over two years, and because it says, at least, am I understanding this right? The number goes up to something much higher than that, and the final number is 5.2 million.

Questions, comments?

The next is around validate and improve sensitivity and specificity of new or existing screening tools. That was a \$5 million effort, and the inflationary figure drives that up over three years.

Those are the short-term objectives. The long-term ones you can see are much larger in scope. The biomarkers at \$30 million over a five-year period. Five measures of behavioral or biological heterogeneity, \$40 million over five years. This is, I believe, the autism phenome effort.

And then finally, look at continuous dimensions of symptoms and

severity that can be used in practice or by parents to assess response to intervention, and that's over, again, a five-year period, a \$10 million effort.

There, there was a broad range in cost between 1.5 and ten million, but the group working on this decided that because it says at least three dimensions that they would take the high number and increase it accordingly.

Peter.

DR. VAN DYCK: It looks like there's a big difference in the second one, 40 to 71. Is that just in -- I mean, I suppose it's just inflation, but that seems like an awful lot for inflation.

DR. HANN: The reason is inflation, but then it's also because that was one of the ones that said at least five, and so we took the five and then we added three more studies on top of it.

So we broke it out, you know, a

rough estimate of cost per study out of that 40 thou., and that would have been for five, and then we added three more to that. So that's why the cost went from 40 to 71. It takes into account more studies and inflation.

DR. VAN DYCK: Okay. So that's doing eight studies then.

DR. INSEL: Right.

DR. VAN DYCK: But is anybody going to understand that's what that means or are they just going to question the difference in number?

DR. INSEL: the only number that we'll see is the final number.

DR. VAN DYCK: Okay.

DR. INSEL: And, again, these are professional judgment numbers. We did the increase based on the conversation that the Committee had about trying to make this plan more ambitious, and in many cases you remember we often had -- some people said

five is the right number, some said ten, some said 20, and we felt that if we were going to provide only a floor, we needed to give at least the budget to allow an expansion beyond that.

DR. VAN DYCK: Well, then will the objective be restated to say eight or will it still say --

DR. INSEL: No, all of the objectives remain. We're not changing the language in the objectives at all. We're just providing the professional judgment estimate of what it would cost to do something that says, at least five, and we're assuming that at least fives means that we hope to have the funds to do eight.

All right.

DR. TREVATHAN: So, again, I think that your point earlier that this is a professional judgment budget exercise is a good emphasis. I know that when I travel and speak and people ask me questions, people

misunderstand what we're doing and actually think that we are in the process of making decisions about where funds are allocated. So, I mean, I know that everyone on the Committee understands that, but with that being the case, are you allowed to put ranges into this document, given that incredibly large range between five and eight studies?

I know the concern, of course, would be that we're not obligated, saying we have the funds to do five studies and then you have eight great studies you want to fund. But I can't see how when you have that kind of a range, it is -- you know, \$30 million is starting to get to be pretty significant for some of us. So how to handle that in the report is my --

DR. INSEL: Yes, you know, I think this is up to all of you. I mean, it's our document. We can decide how we want to manage this. We don't have to have a single number. We could have a range. It gets a

little more complicated than to give the totals, but then you just do the range for the totals as well. So it's manageable.

If people would prefer to have the -- in this case, you know, you take the five measures. It would go from 40 million up to 71. Well, we can show that. What's the sense of the group? Should we include the range of values for each one?

We would probably for the five-year ones, we would include the inflation factor. So that would change a little bit.

Jim.

DR. BATTEY: This is Jim.

It's basically a guess anyway. So I don't know that putting a range in adds very much, and one suggestion I would make is that in the numbers I see on the far right hand that have been adjusted for inflation, going down to 978, for example, implies a level of precision that I think is ludicrous. So I would suggest a rounder figure be put in

that right-hand column.

DR. INSEL: Rounding to the nearest \$10 million?

DR. BATTEY: Something like that.

DR. INSEL: Okay, but it could be rounded to the nearest million anyway.

Can I get a sense of the group in terms of this issue about whether to provide a single number or a range? How do other people feel about it?

DR. LANDIS: Is there going to be a paragraph that makes the point that Ed did, that this is a professional judgment budget and that we've provided a single number, but in a number of cases there were ranges? I mean just some explanation, is that possible in this report?

DR. INSEL: It's your report. If you think we need something.

DR. LANDIS: I mean, I think we do. I get calls all the time from people who want to know if the present stem cell policy

changes, how much will NINDS increase its spending in stem cells, and that's not the way the system works.

So I think some explanation about professional judgment would make sense.

DR. INSEL: We can put some language into the early part of the report explaining what the budgetary numbers mean.

DR. HANN: Just to be very clear on that, in the introduction on page 3 we have a paragraph at the top of that page. I hate to break you up and go to another document again, but anyway, there's a paragraph there that talks about the Combating Autism Act and what it requires of this Committee and the fact of the yearly. You have to do the strategic plan, and that to develop an annually updated strategic plan for ASD research, including proposed budgetary requirements.

We could then put a sentence or two describing this idea about the

professional judgment with required to do those estimates. Is that satisfactory to everyone?

DR. LANDIS: Thank you.

DR. INSEL: I'm not hearing a lot of enthusiasm about the range even though it's actually shown on the left. So what --

DR. TREVATHAN: Yes, I'm not proposing a range. I'm just asking the question.

DR. INSEL: But we are hearing that you want to round these to the nearest million anyway so that they don't look more precise than they are.

DR. LANDIS: Or hundred thousand.

DR. INSEL: Well, hundred thousand is still pretty precise on numbers that are in the 70 million range, right? So it would certainly be feasible to give people a ballpark.

DR. LANDIS: So actually nearest million unless it's hundreds of thousands.

DR. HANN: Correct.

DR. INSEL: Okay. So show of hands then. In terms of the numbers as you see them, they would be rounded off to the nearest million. We would provide a single number, include these inflationary adjustments, and the at least would include the 50 percent add-on.

These would be the number for Objective 1. In favor?

DR. HANN: Okay. I see no dissenting votes at the table.

DR. INSEL: On the phone?

MS. HILL: No dissenting votes.

DR. INSEL: Okay. Anybody else on the phone at this point?

(No response.)

DR. INSEL: All right. We're moving on to the second objective, and again, I think rather than my reading through these you can read through them yourselves. You can see what the numbers look like. There is

one that has a zero dollar figure, and you can see again we've got short-term and long-term, and there's one that goes out to 12 years.

MS. SINGER: I sent an email in on this one.

DR. HANN: I didn't get it.

MS. SINGER: Okay. I mean, this is an area in which I have some professional expertise, and I also consulted with the Ad Council and with two ad agencies, DDB&O and McCann-Erickson, and for a national campaign their estimate was \$700,000 a year, and that they could do it in two years.

DR. INSEL: So it's essentially 1.4 million would be the total?

MS. SINGER: I think so.

DR. INSEL: Other comments on any of this? So we'll be rounding to the nearest million. We'll be including the inflationary factors. Anything else?

Do these numbers look realistic as

you look? Particularly, Story, you know, you know about biobanks or Jim Hanson. Do we need to do any adjustments as you gaze at this?

I think all of these numbers came from your program people. So this was their best sense of what the cost would be.

DR. LANDIS: Looks fine to me.

DR. INSEL: Okay. Good. In favor?

DR. HANN: Okay. I see no dissenting votes.

DR. INSEL: On the phone? Anyone on the phone dissent?

MS. HILL: No dissention.

DR. INSEL: Okay, good. thank you, Susan.

And we're moving on to Objective 3, the same issues. Just take a few moments here and look through this list. Look at the numbers. Let us know.

So that's right. So on Objective

3 there are two of them that have been shifted out, feasibility and effects.

DR. HANSON: With regard to the two that were shifted out, those will disappear from this table?

DR. HANN: Correct.

DR. HANSON: And will there be some dollar amount anywhere else in the document?

DR. HANN: No.

DR. HANSON: There will be --

DR. INSEL: The professional judgment budgets will be in these tables. That's it.

DR. HANSON: Maybe it can be considered next year.

DR. INSEL: Right.

DR. HANN: Also, just to be clear, this table is not going to -- I wasn't anticipating this table being part of the document. This is used today as an aid for you. Everything you approve will appear in

the text.

DR. INSEL: Actually it's all in the text now. If you go back and look, you'll see it's in blue because it hasn't been approved yet, but those are -- that's the way it will look. At the end of the day each of these will be appended to the particular initiative.

Okay. Further comments here? Yvette, anything? Nothing.

In favor?

DR. HANN: Okay. I see no dissenting -- Jim, are you voting?

DR. INSEL: Jim Hanson?

DR. HANN: Jim Hanson, are you voting? Okay. I see no dissenting votes.

DR. INSEL: On the phone, in favor or any dissention?

MS. HILL: Favor.

DR. INSEL: Okay. Thank you.

And we'll move on to Objective 4. We've got a whole series of things here that

are costed out in the way you've been seeing. There are only two long-term objectives. Is there anything, Della, that has been modified?

DR. HANN: Yes.

DR. INSEL: Or needs to be modified?

DR. HANN: Yes, I just wanted to explain that the one, two, three, four, the fifth one down the page, which is to standardize and validate at least 20 robust models, that was a significant increase in the number of models compared to what the work group had estimated for in the summertime. So that's why there's such a big differential there.

I think originally it had been like three or four, something like that, and it was expanded up to 20.

MS. SINGER: I'm still confused about that because I remember when we looked at this item at the last meeting, the

budgetary figure was significantly higher. It was closer to \$260,000 for the 20 model system studies, and I remember we had talked about that that was appropriate because the mechanism of action was how other diseases had been cured.

I think, Dr. Insel, you had brought that up.

DR. HANSON: I guess I would have just the safety and efficacy of at least five widely used interventions for \$15 million. I wonder if that's sufficient. You guys obviously have more direct experience than I do with behavioral things.

DR. INSEL: Well, it would be 27 million, is the final figure.

DR. HANSON: Well, okay. That's per year you're saying.

DR. INSEL: Not per year. That's in total. The figure that we got from Program was that clinical trials -- there was a sort of statistic that they gave us. I

think it was 2.5 million per trial, was the figure that they recommended, and we used that as an estimate all the way through.

DR. HANSON: Okay.

DR. INSEL: There's 60 clinical trials here, and I think 57 of them will be done by NICHD. Just kidding. Okay.

DR. HANSON: We will accept the 27 million.

DR. INSEL: So back to Alison's question around the budget for the 20 robust model systems.

MS. SINGER: I'm looking at the document from the last meeting now, and it said 268.2 million.

DR. HANN: Yes, you're right. It does. It's in the former document. This was in the former document, and there had been several estimates provided. So the first one was based off of three model systems, and it was a cost figure that was done by the implementation work group, the three.

Then someone wrote in and provided an alternative that said to do at least 20, and then they provided an estimate of 268 million, 292, et cetera, for that.

So there was a range essentially. There was a range to be considered to do the costing for that. So if we went with the implementation work group in terms of the number of years that it would take and the number per model system, I believe that's how we arrived at the figure that you have before you, the 49, the 50 million.

Don't know how the 268 was derived. It was submitted to us de novo from the submitter.

MS. SINGER: So how much was the professional judgment per study when they did the three?

DR. HANN: So it will be three into -- it would be about two million. It would be about two million per system roughly.

MS. SINGER: I think what we voted on though was this objective priced at the 268, and that we had talked about that that was a high number, but that this was such a significant area and this was an emerging area, and this go to mechanism of action, and that's why that number was higher.

DR. INSEL: But we didn't vote on the budgets last time. We voted on the numbers, and we can get a sense from people to a lot of this. It would be the difference between two -- it's about two to 2.5 million per project versus a \$10 million cost per project.

I can tell you that for a typical RO1 grant, which is this kind of work, you're usually talking about 250 to \$300,000 a year for five years. So let's say roughly 1.5 million would be the right figure, I would think, for doing a single project.

Story?

DR. LANDIS: Well, I'm thinking

with ability now to use and induced pluripotent stem cells and there is a pioneer award now of someone using induced pluripotent stem cells to study autism, that probably something between the 50 million and the 268 million is appropriate.

You know, a mouse model is different than an IPS cell model, and how you validate and how you look at. So I think that this number -- you're right -- is probably too small when you're talking about 30 with a 50 percent differential, but I think 268 is probably awfully high, and if you compare that with what's allocated for trials.

So I think scientifically the number, the 268 is too high, and I think just in terms of perception by the community creating animal models when some people don't believe in animal models of disease, 268 is too high.

So I would -- 75 million.

DR. INSEL: Story, are the IPS cell studies more expensive than doing a mouse model?

DR. LANDIS: Well, I think creating them is less expensive, but then how you actually analyze them in a meaningful fashion, and would you end up wanting to do animal studies to look at differentiated induced pluripotent stem cells in the context of a normal mouse or rat cortex? Then I think it becomes more complicated.

DR. INSEL: So it's like on the ALS project that you guys funded that was the breakthrough of the year last year for science? Was that an RO1?

DR. LANDIS: That's Manny Ottison. It's a Pioneer Award. So Pioneer Awards are 750 a pop, 750,000 a year a pop. So 3.5 million; so somewhere between 1.5 and 3.5, and if you average those, it's 2.5 times 30, is 75 -- what do you know? -- million.

DR. INSEL: Times 20.

DR. LANDIS: Times 20? No, but you've been doing plus 50 percent for each of these.

DR. INSEL: Okay.

DR. LANDIS: I think you're right that if you want to do the 50 percent mark, 50 million is not enough, but I think 268 is unreasonable.

DR. INSEL: So we've got a professional judgment of 75.

DR. LANDIS: Well, you've got a judgment. I don't know if I'd call it professional.

DR. INSEL: Okay. So that would be a modification we could make here.

DR. LANDIS: -- estimate.

DR. INSEL: It's rounded to the closest 25 million.

Are there any other recommendations or suggestions about this?

What about the other items on here? Again, we've tried to adhere to about

\$2.5 million per clinical trial, which is where those numbers at the bottom get generated.

Okay. In favor of this with that one modification of going to 75 million for the robust model systems. Hands up for those in favor.

Anyone opposed?

On the phone?

MS. HILL: No opposition.

DR. INSEL: Okay. Thank you.

We're moving to number five. And this has a briefer set of objectives. We've got only four of them. You can see the first two are actually fairly small in terms of budgets.

Comments, questions?

DR. LANDIS: I think that the second one down under short term is probably not reasonable. It doesn't seem like enough money to me for two studies. I mean, I don't do this kind of research. I don't know about

prices. It just seems you wouldn't get three of anything at three years. I mean that's \$100,000 a year per study.

DR. INSEL: Yes. These came from a program officer who does this kind of research in other areas and felt that it could be done for this, but it would support -- well, it says studies over three years.

DR. LANDIS: But if you're doing the 50 percent -- oh, it's at least. No, for this it's not.

DR. INSEL: And I guess it could go up to a million if we're rounding.

DR. HANN: Right, if we're rounding.

DR. INSEL: But I get your point. That does seem like a low number.

Alison.

MS. SINGER: I would just call attention to the last objective. I think there was so much focus by this Committee on the importance of doing these types of

studies, the evidence based services for people of all ages and community settings that I think this one might be low, not based on professional judgment, but based on the priority that the Committee has felt should be applied to this.

DR. INSEL: So would you change the budget? I'm not sure what you're suggesting. It's now set at, let's say, \$17 million over five years.

MS. SINGER: To me that just feels low based on how much time we spend talking about how critical that need is. But, again, it's not based on professional judgment of how much it costs. It's based on priorities that were expressed by the Committee.

DR. LANDIS: In fact, if you look at the order, you might want to test the efficacy and cost effectiveness before you looked at four methods to improve dissemination of effective interventions.

I mean if you don't have the

effective interventions, there's no point in testing dissemination. I mean, that's a pretty trivial change, but I think it puts the testing the efficacy and cost effectiveness first, which gives it a higher priority, and then to talk about dissemination.

DR. INSEL: Would that fix this for you if we flipped them and had the same budgets?

MS. SINGER: Yes, I'm just -- that's fine.

DR. HANSON: Has there been any contact with AHRQ as to what they think?

DR. INSEL: No, they have not been part of this process.

DR. HANSON: It would be useful to do that. There are several problems with databases and resources to do some of these things on persons with disabilities in general, and that would be worthwhile to talk to Denise Dougherty about.

DR. INSEL: It hasn't happened.

Now, I want to clarify. We don't really want to change the objective at this point. It's really only a question of the budget.

DR. HANSON: Yes, the budget.

DR. INSEL: So we could find out about their perspective on the budget as we take these forward, sure.

Okay. In favor of this, with that one switcheroo that we changed the order of the long-term objectives? Can I see hands for those in favor?

Any opposed?

On the phone?

MS. HILL: No opposed.

DR. INSEL: Okay. then we're down to the final objective, which you can see has seven different budgetary items.

DR. TREVATHAN: This is Ed Trevathan.

This may have been one of the things that we had so many people involved

that the email got dropped, but actually I thought that our group had communicated with someone in Della's office.

Under the launch at least two states, the second one down, our suggestion was to bump that up to five million from 2.3. That's what it looked like it would cost, adding some of the -- doing some follow-up studies with some of the already existing surveillance projects, to look to see how adults are functioning in communities that were ascertained in various surveillance systems in the '90s. And so children in the '90s that are now adults, that that could be done for another two to \$3 million so that if that total was five instead of two, we could do that.

That was discussed, but I think that somehow it got dropped in the email traffic.

DR. HANN: Could you clarify which one you're talking about again, Ed?

DR. TREVATHAN: Short-term objective number two.

DR. HANN: So have that be five million?

DR. TREVATHAN: Right, and I think that -- right.

DR. INSEL: Any other recommendations here or changed?

All in favor of these budgets for Objective 6, could I see hands for those in favor?

No opposition in the room. How about on the phone?

MS. HILL: CMS in favor.

DR. INSEL: Okay. That takes us to the bottom line, which is a mere 700 and roughly \$80 million with a little bit of change based on these recommendations. It will go down in some, up a little bit like with this last one. I think we're going to end up still above 750 million as an agreement.

Question?

DR. HANN: Actually, the staff just pointed out there's a little bit of a discrepancy here. On Question 6, the one we just looked at, the second long-term objective which is to develop and have available to the research community a means of dah-dah-dah-dah-dah, that one, actually there's an error. That has the same cost structure as to conduct the needs assessment by which to do that. So that number is too low.

DR. INSEL: Where's the needs assessment?

DR. HANN: So to conduct a needs assessment is the very last short-term objective, and that was estimated to be about 500 thou. Okay?

Then once you did the needs assessment, then you would want to actually do it, right? And the do it figure should be probably higher than the needs assessment.

No?

DR. TREVATHAN: What was that?

DR. LANDIS: By at least a figure of ten.

DR. INSEL: Did we have a number in the original document?

DR. HANN: The original document was also rather shaky on this point, but we can find it.

DR. INSEL: No, it was a mistake.

DR. HANN: See, this is -- it was a mistake there, too. So we'll need to up it.

DR. INSEL: Do we have anybody here who could give us some help on this?

DR. HANN: I think part of the reason is that the needs assessment would probably, therefore, indicate the costing of what the thing would look like at the end. I think that's what some of the confusion has been about.

DR. INSEL: So should we leave out

a budget altogether until we know what the budget should be? It doesn't sound like we have any information.

DR. HANN: And just have a TBD?

DR. INSEL: Right, to be determined or because this is something that doesn't happen until 2018, I don't know that we need to put in a dollar figure for something we're going to do in 2009 or ten. Okay?

So we can -- unless anybody is opposed to it, we'll leave out the budget because that actually will flow from the short-term objective.

All right. So we've got a document that you've approved. We've got budgetary requirements that you've approved. What's next?

There are a few suggestions you made about tweaking the words. We have the suggestion from Christine about the introduction and trying to come up with

language that is more compelling for the intro.

Story made the comment about putting in some language for the budgetary requirements and defining what that means. The staff can do that.

Our goal was to try to have a document to the Secretary next week when he begins his job, which will be probably some time next week.

Do you want to see this, again, before it goes forward? Do you want to -- how do you want us to handle the document from this point?

DR. LANDIS: It seems to me that that first paragraph is a really important paragraph in the introduction, and that it would be nice to distribute that to the members of the Committee with the understanding that the issue would not be massive rewriting, but just some level of comfort.

DR. INSEL: Well, Lyn has given us some pretty good language to start with. So we could potentially begin with language we've seen already. The office could draft an introductory paragraph. Hopefully we'll get your input about how to make it as exciting as possible, and we can get that around to you to get your approval before this document goes any further.

Jim.

DR. BATTEY: I think that's a good suggestion, but I just ask that whoever writes it be mindful that everything that's stated in there can be supported either by a publication or by some means, and that there's not too much in there that if we were asked or told, okay, prove that, that we would have trouble doing that.

DR. INSEL: Okay. We've got the instructions on that. The other issue we should address at this point is the thing that we haven't really dug into in the time

that we've been talking about the strategic plan, which is how we monitor the whole issue around accountability and how we follow this through to make sure that things are getting done and getting feedback about which things are not getting done.

So I want to put that in front of you as the next big thing we'll have to wrestle with. At one point we've had different conversations about this. One has been that we have a subcommittee or working group or something like that, but that is something that's not completely consistent with the FACA policy which requires that everything be transparent.

Della, do you want to?

DR. HANN: Well, I was going to say that we were actually going to have a longer discussion of this at our February 4th meeting because I think it's really, really important that you all develop a process that you're comfortable with in terms of how to go

forward with doing the updating, and so we've been mulling out various options for you to consider essentially and hopefully will have a fuller, richer discussion at the fourth meeting in terms of how you want this process to unfold over time.

DR. INSEL: So all I was going to do is to tee this up. I don't think we can get this resolved today, but it is an important issue that I want to make sure we have all of you thinking about and participating in.

And one of the things we'll have to recognize is that FACA comes with its constraints, and so we may end up having to do this as a committee of the whole and really looking at this in a way that could be tedious, but I think it is an important responsibility for all of us to make sure that things we're recommending are being implemented in some place, and that we're monitoring how they're being implemented.

Lyn.

MS. REDWOOD: We have a subcommittee on services, and I know we had discussed previously about creating a subcommittee to work on strategic planning, and I'm just not real clear with how that would violate FACA if it's something we're already doing with the subcommittee on services.

DR. INSEL: Right. So that's a great point. We could have such a subcommittee, and this will be something we can talk about at the next meeting.

When we started to ask who wanted to serve on such a subcommittee, I had the sense that we'd have an awful lot of hands going up, and once you get a subcommittee that's virtually everybody involved, we may not need to make it a subcommittee anymore, but let's make sure we talk about that, and if, in fact, the group is comfortable with having some subgroup really dig into this,

because I think this is going to take some heavy lifting on the implementation part of the plan, then we can have such a group do it.

But all I wanted to do today was to put this on your radar. The reason we're meeting -- and that will be February 4th, so it's just three weeks away -- is to be able to focus in on this and to make a final plan, a final decision about how to go forward with the implementation. That will be really key.

Story.

DR. LANDIS: So I guess I don't -- it sounds really stupid -- so we have a plan. The plan goes to the Secretary, to Congress, and whatever. Do they say yea, go ahead? Are they likely to say, take this out?

I mean, will this plan be modified by the people to whom the plan is going or is this -- I'm sorry. It never occurred to me that I didn't answer that.

DR. INSEL: I wouldn't expect them

to do anything except to say that this is the best judgment of the most experienced people and the advisors they've had about the highest priorities for autism research, and then I think the Secretary and others will look to the community to actually do what's in this plan, and if it doesn't get done, they'll ask why not.

So our task will be to figure out how it will get done, and in many cases that becomes a who question. Who's going to take this on? Who's going to do the clinical trials? Who's going to develop the biomarkers, all of those issues?

And so that's where the implementation comes in. We had a previous discussion about kind of getting this accountability piece together and making sure we had people who were going to take ownership for each of the objectives. So we have to revisit that again and figure out how it will happen in real time.

DR. HANN: Because I think that as a federal advisory committee, that's the role of this group, is to provide advice and to ask questions. So while the Committee in and of itself can't do any implementation, which I believe Jim Hanson mentioned earlier about another committee, the Committee in and of itself isn't responsible for being able to do that, but your ability to monitor and to ask questions and to sort of keep pressing the button as it were in terms of reminding people what these priorities are that have been set forth, and so forth, that's really very much within the role and the domain of this Committee.

DR. JANVIER: My question is sort of reminded me a little bit of a fantasy basketball team or something with the numbers, and you know, so we have a great plan and great ideas, I mean, and I've seen over the year that I've been working with the group that there are different organizations

coming up with dollars, but I mean, it just seems like an incredible number of dollars.

You know, where is that going to come from?

DR. INSEL: Taxpayers. No, again, I want to emphasize this is not a funding document. This is a document that is advisory to the Secretary and the Congress to say this is the most important research that this group feels should be done over the next few years, and this is what it would cost to get that done, but it will be up to the appropriations process to make sure that the dollars are made available for the items in this plan.

The good news is that a lot of this is either about to be implemented anyway because the same people who are advising us are the people who have been applying for grants or who are involved, and so even though it may not necessarily be new dollars, there will be dollars that will be dedicated

to a number of the things that are in this plan, but there are some things that are actually completely new that we'll need to start figuring out how they'll get funded.

Jim.

DR. BATTEY: Just to place this in context, could you give me a rough dollar figure for what the NIH investment annually in autism research is right now?

DR. INSEL: So I can give you the 2007 number. The 2008 numbers will become public tomorrow. So as of today we have the 2007 number, which was, I think, \$127 million. That's in the old system. We don't yet have the new RCDC numbers.

The total HHS obligation for autism is about 186, I think, somewhere in that range.

DR. BATTEY: So my point in raising that number, for your benefit, is to give you some context. You know, we've been dealing with numbers that are not completely

dissimilar to the number we're talking about here for autism research already. It's not like we're going to double our investment in autism over what we're currently spending right now. That's not what the document proposes.

DR. INSEL: Okay. Are you ready to start on document 2.0? Because that's the next --

DR. LANDIS: Tom, before we go, I raised the possibility of this Committee sending a letter to the vaccine NVAC, and I just wanted to make sure that we didn't lose track of that, and maybe staff could draft something that could get circulated quickly to this Committee and then could go as part of this public comment.

I was very sensitive to Lyn's comment that that committee was not attuned to the autism community.

DR. INSEL: Why don't we plan to draft something for you all to look at at the

same time that we're working on this introductory paragraph? And we can get this out quickly, and also plan to have Bruce Gellin come to the February 4th meeting if he's available to give us a better sense of what's going on.

I suspect we'll be back having this same conversation about the vaccine research commitment and what that should look like and who should do it and where it should be focused very soon as we start to put together the next iteration of the strategic plan, and hopefully at that point we can really bring in the scientists who can give us the most information about how it should be done and what the right investments would be.

Are there any other comments before we put this thing to bed? Those are the two issues we'll come back to you about, the introductory paragraph, this letter, and there's one other small piece within the

document on the budget.

Anything else?

We have done it. Congratulations.

Good job.

DR. LANDIS: If this were not a federal facility, I think we should have had a bottle of champagne.

(Laughter.)

DR. LANDIS: I could go to jail for that. So I'm definitely not buying.

DR. INSEL: So remarkably we're actually ahead of schedule here, and this allows us time for public comment. I don't know. We have two people who have signed up for public comment. Katherine Walker from SafeMinds, and Paula Durbin Westby from ASAN, and I'd like them to come forward and we can have them sit right here and share their views with us.

Thanks for joining us.

MS. WALKER: Good afternoon. I'm Katherine Walker, mother to a son with autism

and a Government Affairs Committee member of SafeMinds.

I thank the committee for the opportunity to speak today on behalf of SafeMinds and applaud the progressive objectives approved during the strategic planning process, particularly those related to the role of the environment.

However, the continued emphasis on funding genetic research which substantially outpaces environmental research remains a significant concern. The 2006 IACC report validated this concern when it concluded that research on environmental causes and treatments were under funded.

Current funding for environmental research is insufficient to achieve the congressional goals of identifying the causes and treatments for autism. This month the NIH funded research confirmed that autism's rise is real, and as a result, it creates great concern as to how this growing

population's immediate and future need for treatments, services, and support will be met.

The rise in autism and the role of age at diagnosis in this month's edition of *Epidemiology* found that of the estimated 600 to 700 percent increase in California's autism cases, less than one-tenth is due to the inclusion of milder cases, and less than one-quarter is due to earlier diagnosis.

Lead investigator David Hertz-Picciotto stated that this is a clarion call to researchers and policy makers who have focused attention and money on understanding the genetic components of autism. She added that these findings require that research funds and emphasis shift from genetics to environmental threats, including chemicals such as heavy metals, pesticides, and infectious agents.

These recommendations echo those from the 2007 IOM workshop, *Autism and the*

Environment, and require that emphasis be placed on environmental research to understand autism's etiology and identify effective treatment.

Considering the national economic turndown, NIH must now more than ever wisely invest the Combating Autism Act research funds. SafeMinds requests that the NIH autism research portfolio reflect a preference for funding environmental risk factor research over genetic research.

Environmental risk factor research must include vaccines and their components as specified in the Combating Autism Act colloquy statements of Senators Enzi, Santorum, Dodd, and Kennedy, and Congressman Barton and Smith.

SafeMinds also respectfully recommends that the research budget be significantly increased to achieve congressional goals and avoid interdisciplinary conflicts for resources.

This action would require a comprehensive disease cost analysis to be conducted, as well as a review of approved research opportunities not funded due to resource constraints.

Additionally, the inaccurate description of vaccine autism research in Question 3 of the, what we know, section must be corrected. Specifically, the limitations and recommendations as noted in the 2004 IOM report should be included as well as the findings from peer reviewed research supporting the ongoing concerns of parents and the scientific community.

In closing, the strategic planning process has taken a considerable amount of the IACC Committee's time and not allowed for performing other mandated duties, such as monitoring all federal autism activities. As possible solutions, the IACC's mandated responsibilities, we respectfully request that February's agenda address mechanisms for

oversight, review and evaluation, and include establishing a strategic planning subcommittee and an autism advisory board and adopting a grant review model similar to that of the Department of Defense as possible solutions.

Thank you so much for your time.

DR. INSEL: Thank you.

And just as a follow-on, you should have received a Hertz-Picciotto paper in the preparations for this meeting. So I will refer you to that as well.

The next and final public comment is from Paula Durbin Westby.

MS. WESTBY: The autism research agenda has been near exclusively focused on causation and cure, two priorities out of step with the needs and desires of the autistic community. In the year 2008, only approximately one percent of the NIMH autism research budget was allocated to services research.

Research that focuses on discovering and eliminating autism both enters the dangerous and unethical realm of eugenics and avoids addressing the social barriers that autistic people face that prevent quality of life and full participation and inclusion in society at large.

Balancing the autism research agenda to focus on quality of life will pay dividends by providing evidence on the most effective methods of delivering services and providing for an effective education across the life span. Such a research agenda would complement other aspects of federal disability policy, such as the institutionalization mandated under *Olmstead v. L.C.* the IDEA and No Child Left Behind requirements for evidence and research based methodologies, the IDEA of least restrictive environment right, and increased numbers of individuals with disabilities, including the

autism spectrum in the work force.

We recommend the following.

Require that no less than half of the federal autism research budget across all departments and agencies, including NIH, CDC, HRSA, HHS, the Department of Labor and others be allocated towards services research.

Pursue a vigorous quality of life autism research agenda focused on issues such as improved service delivery methodologies, social barriers to full participation and quality of life, effective systems change models, means of effectively and respectfully addressing social behavioral, emotional and other challenges, empowering communication and other priorities.

Mandate that the interagency autism coordinating committee include representation from autistic self-advocacy organizations, such as the Autistic Self-Advocacy Network, and that there exists parity between the number of parent provider

and self-advocate representatives in the public membership to the IACC.

Include a specific recognition in the strategic plan of the perspectives of autistic adults who do not want to be cured of autism and who see severe ethical issues with the cure agenda. People on the autism spectrum are not the only ones concerned about a possible prenatal test and selection out of autistic fetuses. In recent interviews researcher Simon Baron-Cohen has raised concerns about the possible negative consequences of prenatal testing. He asserts caution is needed before scientists embrace prenatal testing so that we do not inadvertently repeat the history of eugenics and inadvertently cure not just autism but associated talents.

Neurological diversity adds in a positive fashion to general human biodiversity. To reduce it may lead to unintended negative consequences.

Fund research into augmentative and alternative communication options for autistic people across the life span, including assistive technology so as to empower many more autistic people to communicate meaningfully.

Allocate no less than one-third of the federal autism research agenda towards the needs of adults on the autism spectrum, addressing the near total lack of research funding towards the needs of this population to date.

Fund community based participatory research models, including autistic self-advocates as full partners at every stage of the research process from topic selection to study design, and implementation to existing projects as models such as the academic autistic spectrum partnership in research and education.

Provide for student loan forgiveness for services related and quality

of life participation-based researchers that is comparable to the loan forgiveness offered for researchers who work on basic science research.

And finally, look to research funded by the National Institute of Disability and Rehabilitation Research as a model for autism research priorities.

Thank you.

DR. INSEL: Thank you.

Your comments, as well as those from the other public commenter will be included in the record for the meeting.

Della, I have no other names.

Anything else before we wrap up?

Well, thanks, all of you, for coming in for this additional meeting. We got our work done ahead of time and under budget, and we'll look forward to seeing all of you on February 4th. We're adjourned.

(The meeting adjourned at 12:59 p.m.)