U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES

INTERAGENCY AUTISM COORDINATING COMMITTEE

FULL COMMITTEE MEETING

FRIDAY, NOVEMBER 21, 2008

The meeting convened at 9:00 a.m. in the Rotunda Room of the Ronald Reagan Building, 1300 Pennsylvania Avenue, N.W., Washington, D.C., 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

DUANE F. ALEXANDER, M.D., *Eunice Kennedy Shriver* National Institute of Child Health and Human Development

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

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

LEE GROSSMAN, Autism Society of America

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

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

WALTER J. KOROSHETZ, M.D., National Institute of Neurological Disorders and Stroke (For Dr. Story Landis)

PRESENT (continued):

WALTER J. KOROSHETZ, M.D., National Institute
of Neurological Disorders and Stroke
(For Story Landis)

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
(For Margaret Giannini)

CHRISTINE M. McKEE, J.D.

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

ALISON TEPPER SINGER, M.B.A., Autism Speaks

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

OARC GUEST SPEAKERS:

PAULA C. DURBIN-WESTBY, Member and Board of Directors, Autistic Self Advocacy Network

CATHY PRATT, Ph.D., Director, Indiana Resource Center for Autism, Indiana Institute on Disability and Community, Indiana University, and Chair of the Board, Autism Society of America

NINA WALL-COTE, Director, Bureau of Autism Services, Department of Public Welfare, Commonwealth of Pennsylvania

KATHY REDDINGTON, Autism Coordinator, Division of Autism Spectrum Services, Department of Developmental Services, State of Connecticut

JEFFREY L. STRULLY, Executive Director, Jay Nolan Community Services

PAMELA BECK, Support Broker/Parent Advocate

EMILY HOMER, Executive Director, ResCare-VOCA of Maryland D.C.

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9:01 a.m.

DR. INSEL: Good morning, everyone. I would like you to take your seats, so we can get started.

We have a phone missing. Anyone want to claim it? It's a contribution to the Autism Society of America.

Good morning. Welcome to what is the fourth meeting of the Interagency Autism Coordinating Committee.

This meeting is going to be the first one that will be on a webinar. So there are many, many people who are attending, but you can't see them. That means that it will be important for you to use a microphone and also to identify yourself when you speak, which leads me to identify myself.

This is Tom Insel. I'm the Chair of the Committee and Director of the NIMH.

I think we should start by doing a round of introductions. We'll go to my left, Cindy.

DR. LAWLER: Hi. Cindy Lawler. I'm Program Director at the National Institute of Environmental Health Sciences.

DR. BATTEY: I'm Jim Battey, the Director of NIDCD.

MS. REDWOOD: Lyn Redwood, SafeMinds.

MR. VAN DYCK: Morning. Peter van Dyck, Director of the Maternal and Child Health Bureau at HRSA.

MS. BLACKWELL: Ellen Blackwell, Centers for Medicare and Medicaid Services.

MR. GROSSMAN: Lee Grossman, President and CEO of the Autism Society of America and the dad of a young man with autism.

MR. MARGE: I'm not Margaret Giannini. I'm Michael Marge, and I just became the new Deputy Director of the Office on Disability in the Department of Health and Human Services.

DR. HOULE: Good morning. I'm Gail Houle from the U.S. Department of Education, Office of Special Education Programs.

DR. TREVATHAN: Ed Trevathan. I'm the Director of the National Center on Birth Defects and Developmental Disabilities at the CDC.

DR. JANVIER: Yvette Janvier. I'm a developmental pediatrician, Medical Director of Children's Specialized Hospital in New Jersey.

DR. LANDIS: Story Landis, Director of NINDS. I apologize for having to leave at 10:15 for about an hour and a half. My position at the table will be taken by Dr. Walter Koroshetz, a neurologist who is the Deputy Director of the Institute.

MS. SINGER: I'm Alison Singer. I am the mother of an 11-year-old daughter diagnosed with autism and the sister of a 44-year-old man with autism, and I'm Executive Vice President at Autism Speaks.

DR. HANN: I'm Della Hann. I'm the Acting Director for the Office of Autism Research Coordination at the National Institute of Mental Health and Executive Secretary for this Committee.

DR. ALEXANDER: I'm Duane Alexander. I'm Director of the National Institute of Child Health and Human Development at NIH.

DR. INSEL: Dr. Raynard Kington is serving as the Acting Director of NIH and will not be able to join us today.

Dr. Elias Zerhouni, who has been on the Committee but hasn't been particularly obvious at the meetings, except for the first one, has stepped down as Director. We are in the search for a new Director of NIH, and that person will join the Committee at the time of their appointment.

Also, I would like to just introduce Dr. Susan Daniels, who has joined the autism team or is in the process of joining the autism team, Office of Autism Research

Coordination. Sometime over the next couple of weeks, we expect her to be onboard, and it is great to have you join us today.

There's lots going on. We've got a very long agenda here and a huge amount to try to take under our wings in the next few hours.

Let me just start by saying that it's been a very exciting time for the science of autism. Some of you have seen this, the recent issue of Cell that has a special section on autism. That's arguably the most prestigious scientific journal. We have photocopied the articles for you and they are available downstairs on the table. There's also two or three articles that were out the week before in Nature, which are also review papers on progress in autism.

So right now is an amazing period of time where we are seeing breakthroughs on many fronts. It is a good reminder that, as we try to complete a strategic plan, that this is very much a moving train, and that the

Combating Autism Act had the wisdom to say that this plan would be updated every year. Clearly, there are already things that we will be thinking about for updates because the science is not where we were when we started last November. So there's every reason to try to integrate all these things that are happening.

This was the week of the Society for Neuroscience meeting here in Washington. There were over 30,000 people attending. Again, more autism research presented than at any time in the past.

We counted something like 124 abstracts, and most of those were presented on Monday of this week, including a full symposium, which doesn't happen that often, around a single disorder at the Society for Neuroscience meeting.

We've got a very important agenda item here today, which is to come to some closure on the strategic plan. But before we can do that, we've got two points of business.

The first is we want to have you look at the review of the July meeting's minutes and let us know whether there's anything that needs to be revised from those minutes.

(No response.)

Hearing none, can I get a motion for acceptance of the minutes?

DR. LANDIS: So moved.

DR. INSEL: All in favor?

Any opposed?

Okay, the minutes are now accepted.

We can start to go forward for the review and decisions on the IACC Strategic Plan for Research.

Before we jump into that, let me talk about the second order of business that I would like to address, which has to do with the plan. I think before we get into the weeds here, because there are a lot of weeds to look at and there's a lot of detail, I wanted us to just take a moment and step back to see where we are and where we've come. I think it is worth talking about this a bit before Della lays out the tasks for today.

The Combating Autism Act specified that we needed to develop and annually update a plan for the conduct and support of research. It is important for us to remember that the IACC exists solely really to advise the Secretary. We are a FACA Committee. We are a federal advisory committee, and it is appointed to do that for the Office of the Secretary.

The Combating Autism Act required that the plan be submitted to the Secretary, also be submitted to the Director of NIH, and be submitted independently, which doesn't happen that often, to Congress.

So what we have in front of us is the need to get a document which may not be perfect, but which will be representative, and it needs to go to each of those three places.

In watching this process evolve over the last few months, it has just been fascinating to see how it's almost a little bit of a Rorschach test. This plan has become many different things to many different people. So it is probably worth commenting on that.

For many people, this has become a kind of wish list for the science that they would like to see done. Some people have told us that they see this as a tool for lobbying. They want to use it as a way of arguing for more money for autism research.

Some clearly just see it as a tool for mandating how NIH spends its money. Although I don't know that is what the Combating Autism Act was thinking of, that has become part of the dialog.

Others have seen this as a tool for forging collaborations before different stakeholders in both different government agencies and the advocacy community.

There's just an awful lot of passion here. I think we need to be clear that some of that is perfectly understandable because what we have asked for is a plan that represents the diverse views of the community, and this is a very diverse community.

We've got the scientists. We've got clinicians. We've got family members. We've got advocates. We've got the people with autism who care a lot about what is in this plan.

It has become clear that each of those stakeholders is not homogeneous at all. In every one of those groups, there are very marked differences of opinion, and some of the differences of opinion in those groups are greater than the differences between the groups.

What I think we have to remember is that this document does not have to represent a unanimous opinion. That is, we can use the document to describe the diversity and to describe disagreement. That's okay. This doesn't have to be a simple message. It can be nuanced.

But it also ought to be an opportunity to try to identify those areas where we've got some common ground and where we do have some agreement, and to be able to convey to the Secretary and the head of NIH and the Congress what it is that we all really feel strongly about that we would see as a shared value.

In the very first, I guess it wasn't the first but maybe the second meeting we had, we talked a lot about shared values actually and we talked about the importance of cooperation and mutual respect, the sense of urgency. We talked about the need to have partnerships, and we talked a lot about the importance of scientific excellence.

I remember some of that discussion where people reminded us that this is a research plan, and at the end of the day it's got to be scientifically feasible, scientifically rigorous, and we've got to make sure that what we are directing people to is the very best in the way of science.

The mission statement that we all adopted was to focus, coordinate, and accelerate high-quality research and scientific discovery in partnership with stakeholders to answer the urgent questions and needs of individuals on the autism spectrum and their families. I hope it is still a mission statement that all of us prize and that all of us will adhere to.

So I'm not here to ask for a group hug or to ask us to sing kumbayah before we start, but I do want us to think about using this discussion in a very constructive way to reaffirm that we're all committed to identifying what the key questions are for the science and to recommending the very best science that will answer these questions.

We may not be able to get every

person's specific issue into this plan. It may be the plan will be stronger if we keep it more general and less specific, but I wanted to go forward with this kind of spirit, that we are here to work together and to collaborate and to listen to each other respectfully, but at the end of the day to come up with something that, if it isn't perfect, will be good enough for us to get forward, so that it gives us the Strategic Plan 1.0.

Okay, that was my opening prayer.

(Laughter.)

Now unless there are any comments or any further issues about that, I am going to turn this over to Della to take us through the process of where we have come from and what we need to do now.

Story?

DR. LANDIS: Tom, can you remind me when the plan is due?

DR. INSEL: There's not a specific

due date in the Combating Autism Act, but our goal is to have this completed around November 21st of 2008.

(Laughter.)

So if we don't make it today, I will request that everybody meet again in the next very few weeks, so that we get this done by the end of the calendar year.

The Combating Autism Act is a five-year authorization. It was passed in December of 2006. I just don't think it's acceptable to let this go for more than two years without a plan.

DR. LANDIS: Well, and you could also make the argument with a new Administration and new Members of Congress, it represents a real opportunity to put forward a plan that has been bought into, as you've described, for consideration as we move forward.

DR. INSEL: Yes, so this is the time. It would be really a shame if we didn't have this ready to hand over to a new Administration.

Okay, Della, take us through.

DR. HANN: Thank you.

I just want to very briefly review with all of you, as well as the members of the public who are in attendance and listening, the steps that we have gone through over -- a brief overview of what has transpired essentially since July when we last met, and then to help focus for this morning's discussion essentially by walking through those steps, and the idea that the plan that you all received by email includes ideas that were gleaned from the extensive public comment that we received as well as the Implementation Work Group that met.

So very briefly, since July -- actually, there's one step here that is not listed. When we last met in July, we had a draft before us. Through your discussions and comments, it was modified. Then you voted electronically and agreed to have that copy of the draft available for public comment. That was done in early August.

At that same meeting in July, you also agreed and voted on to convene an Implementation Work Group to look at cost estimates, which is a requirement in the Combating Autism Act that goes with the strategic plan. That Implementation Work Group, which I will spend a little bit more time on momentarily, did meet, and it met twice, on August the 8th as well as September the 10th.

The IACC also requested in the July meeting that the draft plan would be available for public comment. So Requests for Information, an RFI, was the means by which we used to gather that comment, and I will also speak to that very briefly.

Once we had the input from these two processes, the Office of Autism Research Coordination then analyzed all the comments and provided the suggestions in the draft plan that you have before you today for your deliberations and for decision.

Just as a brief review, this was the charge that you approved at the July meeting for the Implementation Work Group. They had two main issues.

One was to discuss and provide recommendations back to this Committee with regard to the budgetary requirements that were needed to fulfill the research within the draft plan.

The other thing that the Implementation Work Group was charged to do was to have a discussion and provide advice back to this Committee with regard to agencies and organizations that could be accountable for launching the various initiatives.

This is a full roster of the people who participated in the Implementation Work Group. I realize the type is very small. We wanted to get everybody on one slide. We're happy to provide this to folks.

We were very pleased with the amount of participation in both meetings. They happened rapidly, and people were very generous with their time and their expertise in terms of providing hopefully sound advice back to this Committee.

The Request for Information was posted in August, August the 20th, and it was open and available for public comment until the 30th of September. It was posted vis-a-vis the NIH Guide and The Federal Register. We also sent these links to a variety of advocacy and research organizations, so that they could inform their constituents.

There were 148 responses that we received. It was, indeed, a wide range of individuals, organizations, and opinions that were expressed.

We redacted the actual incoming for personally-identifying information, and all of these responses are now posted on the IACC website.

That leads us to today. Again, as I mentioned, the Office of Autism Research Coordination took all of these comments from the public as well as the Implementation Work Group and went through a process of analysis and tried our best to reflect the diversity of ideas and suggestions that came in from the public as forms of suggestions and ways for you to consider in terms of potentially modifying the draft plan. All of this is available to you right now and will lead into your discussions, hopefully, this morning.

I do want to point out that the themes, et cetera, that are expressed did come from the public. So if you have questions specifically about what was meant by a particular idea, we will need to go back to the RFI and see whence it came from.

That was why we went through the extensive footnoting process, so that we could actually track back the comments to where they were coming from the public. So I just have that as not so much a disclaimer, but an explanation, essentially, for where all of those ideas, and so forth, came from.

So, with that, I turn it over to Dr. Insel.

DR. INSEL: Questions?

(No response.)

Okay, let's jump into this. What I am going to suggest is that we do this by going essentially line by line. We don't have many other choices. It's our job to actually produce the document. We don't have a subcommittee or a working group at this point to do this. It's us.

So we have got documents that you would have already received. Hopefully, you have looked at them. We have received some comments back.

What we will do is to be able to look at these where the lefthand column is what you agreed would go out for the RFI back in July or early August. The righthand column we've included all comments, essentially all comments, in one form or another, sometimes consolidating when we got several comments from different people.

The task is, do you want to make a change or do we want to retain what we had? The default is, obviously, to retain what we had. We can then examine each of the changes that have been under suggestion.

We also have comments that have come back from some of you in the last two or three days. There's another sheet that is in your folders that looks like this that includes the comments from Lyn Redwood, Ellen Blackwell, Cindy Lawler, and Alison Singer. So you can also use that as a reference, and you probably should, because we would hope that each of those people will bring those comments forward as we go through the document.

I'm going to suggest that we do this the way we write scientific papers. One of the things you learn in graduate school is, when you want to write a scientific paper, you write it backwards. You start with the results and do the figures and tables and look at the analysis, and then you write the methods. Then you do the introduction.

I think because here the action items are in the questions, the one-through-five questions, what I would like to do is to start with Question 1 and work through there. If we get all this finished and we can start on the introduction, great, but I think the most important thing for us to try to get done today will be the questions where we have actual recommendations and where we need to come to agreement about what the plan will recommend going forward.

We will have a chance to do the introduction, perhaps not today, but we'll get to it. Is that okay with everybody, that we go in that order?

So if that's the case -- I see heads

nodding -- let's start here with Question 1, which is, "When should I be concerned?"

If you look at the document, you can see in the middle column there that there are a couple of phrases that have been inserted as potential changes. In the classic case, in line 9 and lines 17 and 18, added in, "Although this change may bear the risk of overdiagnosis...."

I believe there's also a recommendation here from others. Lyn, you had a comment here?

MS. REDWOOD: These were mainly just general edits, Tom. I guess the first one had to do with "appear to regress". I think there is enough information now from Geraldine Dawson that there definitely are children who regress in autism. So that was one of the suggested edits that I made.

Also, I think that we have such a dramatic increase and prevalence over the last two decades that, regardless, we need to treat this as an epidemic, and that it may very well represent progress in identifying a core set of developmental symptoms that allow for more accurate diagnosis. So I just wanted to throw that out there as text for the Committee to consider.

DR. INSEL: So if I understand your comment, you want to take out this revision. You would go back to the original language because there's no reason to make the comment about this change may bear the risk of overdiagnosis.

Any other comments about this first page?

(No response.)

I hate to be really pedantic about this, but we're really going to have to get your conclusions about what you want to do. The recommendation that we have here is to include "in the classic case", as a change, but to remove the revision about "this change may bear the risk of overdiagnosis."

Can I get a sense of the group? All in favor of doing that?

So we would take out -- we would basically go back to the original, but we would put in "in the classic case".

Lyn, you also wanted to take out the word "appear" before "regress", but my concern is that actually will become too restrictive. You may want to have "appear to regress", so that you could include children even when you don't have the full documentation for that. So it may be better to leave it in its original, but I'll look to the group for what they want to do on this.

DR. LANDIS: So one concern that might arise as a consequence of not allowing attention to be called to the change in diagnosis is that what we have learned about certain developmental issues could get lost.

I was just at a meeting, a Child Neurology Society meeting, and there was a whole session on cerebral palsy. It became clear that children about whom we have learned a lot in terms of their cerebral palsy are now being put in some cases under the umbrella of autism. To the extent that you lose the information that you knew about the kids with cerebral palsy and the causes and potential treatments, and they now are labeled primarily or only as autistic, I'm not sure that that is the optimal strategy.

So I don't know if the point is clear, but by putting everyone under a single umbrella with just one identifier, children who previously would have been identified as something else, and we know a lot about them because of that identification, now we lose that information.

I recognize it is a complicated issue and some that people feel passionate about.

DR. TREVATHAN: Yes, I --

DR. INSEL: We are going to have to ask everybody to say their names.

DR. TREVATHAN: Oh, I'm sorry.

DR. INSEL: I'm sorry, I've forgotten to do that.

DR. TREVATHAN: Thanks, Story.

Ed Trevathan, CDC.

As I was at the same meeting, I think you addressed some of the complexity of the diagnostic criteria that currently exists that we use in which there are these major overlaps. We certainly see that in our surveillance systems.

But we think of them as co-morbid conditions. If you are sitting with the cerebral palsy community, they would talk about autism as co-occurring with cerebral palsy. When we sit here, we talk about cerebral palsy co-occurring with autism. Yet, we obviously know that both are critically important for the child, and I think important from a research point of view to retain those details, but it does make it complicated. But these are the Venn diagram with multiple overlapping circles.

I didn't read this to exclude that phenomena, but I don't know, if it does, I agree that needs to be corrected.

DR. INSEL: So would a lot be lost if we went back to the original here, which is the sort of default, and we didn't make the changes? It is up to the Committee, but I see heads shaking.

What I am going to do, because we are going to have to move this along, I would like to take a vote on this first paragraph. The possibilities here are to retain the original. The second possibility is to make the changes that you see in front of you, and the third would be to make some of the changes, which would be perhaps to include the classic case -- this is really wordsmithing, but to alter the final sentence.

Can I get a show of hands for who wants to go back to the original? All in favor?

Who wants to take the changes as they are now, the revised version, and who wants a hybrid model?

Any abstentions?

MS. REDWOOD: Tom, I'm a little unclear with regard to what you are calling the hybrid model and which are the accepted revisions. Could you --

DR. INSEL: I think we have a majority saying that we're going to go with the original. There won't be any revision of this paragraph from what we agreed to in July.

MS. REDWOOD: Is this including lines 22-23 as well or just the very first lines, 8 through 18?

DR. INSEL: Just to 18.

MS. REDWOOD: Okay.

DR. INSEL: But now that you bring that up, let's move on to the next section on the diagnosis of ASD may be reliably made by age three. So we are going through lines 19 to page 2, line 7.

Here the addition is "Some children at risk may also begin to experience co-occurring medical conditions such as gastrointestinal disturbances."

Again, we've got comments from Lyn and Ellen. I am sure others may want to weigh-in here.

Do you have the comments from Lyn and Ellen in front of you? Are people looking at those? Okay.

MS. REDWOOD: Tom, the reason I included this is because in the past few years there's been much larger recognition of these co-occurring medical conditions in autism. That is why I thought, just singling out one or two, it would be nice to describe the entire realm of abnormalities that we are seeing, whether it is metabolic, inflammatory, mitochondrial.

I think initially you just had auditory, and that is why I chose to include sensory disorders as well. So I just sort of expanded that language.

DR. INSEL: Yes. So this comes up over and over again. As you look through the plan, there are many places where the issue of the non-behavioral, non-affective symptoms are asked to be included.

What I wonder is if we shouldn't have a kind of generic approach to this where we find some way to say it that everybody is comfortable with without each time having to spell out nine different systems that would be involved.

One way to do it would be to say that some children at risk may also have significant medical symptoms. We can define what those are in the introduction at some point and actually have a list of what the various medical aspects are, but not bother to reiterate that each time.

Again, I see heads nodding. If we were to change the wording in that way -- are there any other changes that people want to make to this paragraph? We don't have anything else recommended.

I think, Ellen, you brought up about epilepsy as well, but, again, that would be covered by that change.

All in favor of accepting this, then, with that single revision?

Opposed?

Abstain?

Okay. Is someone -- you're keeping a tally? Okay.

We are moving on to page 2, lines 7 through line 15. There are no changes and I don't think we have received anything in addition. So we are ready to move to the "what do we need?" section at the bottom of page 2.

Here we have from the public changing the word in line 23 to make it "five issues have limited the use of early interventions", and then the addition of two items that come later in that section.

Ellen, you also had a suggestion here?

MS. BLACKWELL: It's minimal.

DR. INSEL: So you would like to change the word in line 18 on page 2 from "can" to "may"? "Early intervention may have a critical influence."?

I don't see anything else in any of the recommendations.

Any other comments from the group?

DR. TREVATHAN: Tom, it is Ed Trevathan again.

So we are down at the bottom of page 3, right, down here?

DR. INSEL: Right.

DR. TREVATHAN: So it might be worthwhile where it just says, "four, pediatricians and other healthcare providers", I mean the healthcare providers we are interested in reaching out to, obviously, are a lot more than pediatricians. In some cases, the real needs are outside the pediatric community, family practice, primary care, nurse practitioners, and so forth, that need to know more about autism, not necessarily making the diagnosis, but certainly understanding symptoms.

So I don't know that it is deleting "pediatrician"; just sort of emphasizing that this is a broad primary care, that these are healthcare provider issues; specialists and primary care physicians need to be aware and providers might be useful.

DR. INSEL: Do you think it would be helpful just to say, "healthcare providers"?

DR. TREVATHAN: Yes. I think we just do that.

DR. INSEL: Lyn, you had a comment here on including the recommendations of the American Academy of Pediatrics?

And, Ellen, I think you had a comment as well? Can you locate that?

MS. BLACKWELL: I think my comments are at the top of page 4.

DR. INSEL: I think the bottom of page 3. So you wanted to take out the early warning signs?

MS. BLACKWELL: Well, I'm not sure if parents are aware of early warning signs or just signs of ASD.

DR. INSEL: Christy, yes?

MS. McKEE: Christine McKee.

I did have a comment about changing "can" to "may". Just in the back of my mind, we are finally moving forward in the states on the insurance issue and getting the ABA therapies covered by insurance. I am afraid watering it down a little bit to change that early intervention from "can" to "may", it just waters it a little bit right as we are getting some progress in that area. I don't know; just a thought.

MS. BLACKWELL: I'm more comfortable with "may".

DR. INSEL: Well, this will be one of those things we bring to a vote, but it is good to hear the different opinions on this and what it "may" mean or what it "can" mean.

(Laughter.)

Anything else within this section that people would like to comment on? Then we will just walk through it line by line.

(No response.)

All right, so let's start with the first question about line 18. There is a different meaning between "can" and "may". Can I see a show of hands who wants to change it from the original, from "can" to "may"?

That is, so who's voting for "can"? Let's see the hands.

And voting for "may"?

Okay, we're moving on.

The next line, two lines down, where it says, "moving from three to five issues", that really means that you are interested in accepting the comments from the public on the two additional issues. We can work on the wording of them in a moment.

But all in favor of including this as five issues and not three, can I see a show of hands?

Anyone opposed?

So let's go to those issues. We are now halfway down or below the last third of page 3. "Greater clarity is needed in identifying three different trajectories."

Now the questions are on the fourth item. So it is line 18, whether to strike out the words "pediatricians and other" and just to say, "healthcare providers", which is one option.

A second option is language that Lyn has provided. I would like to read this because I think it is really helpful to hear.

It says, "In recognizing the early warning signs of ASD", "or fail to use existing screening tools at well checkups, as recommended by the American Academy of Pediatrics, to more effectively screen and subsequently diagnose children with ASD."

So that is some alternative language which could be inserted here as well.

Discussion? Concerns? Questions?

Yvette?

DR. JANVIER: I have a problem picking on the pediatricians. I think there have been failures in many arenas, including particularly the early intervention system. I think there's been huge progress, actually, in that area by a year ago the AAP coming out with their recommendations, and I do see implementation. So, again, I don't think it is fair to pick on the pediatricians in this issue.

MS. REDWOOD: If it was edited where it was just "other healthcare providers" and the "pediatricians" was stricken, would that meet with your approval?

DR. INSEL: I guess the question is, do you want to include the American Academy of Pediatrics recommendations in here? Is that helpful or not?

I would really be interested, particularly from clinicians who think about this.

MS. SINGER: Well, I'm not a clinician, so --

DR. INSEL: Alison? Oh, okay.

MS. SINGER: I'm in favor of striking out -- just focusing on healthcare providers in a general sentence, but I happen to like Lyn's wording here of recognizing that the American Academy of Pediatrics actually is now recommending that children be screened twice before two. I don't think that that line really targets pediatricians. I think it is actually laudatory in that the AAP has finally stepped up and recognized that this needs to be done. So I would be in favor of including that language here that Lyn has recommended.

DR. INSEL: Ed?

DR. TREVATHAN: I would, I think, largely agree with what Alison said. I think that what we may need to be careful about, and I think Lyn's addition is nice, but we may need to be careful about suggesting that we are recommending to non-pediatricians that they in some way are obligated to follow the recommendations of the American Academy of Pediatrics. That can be sometimes a little complicated.

So if there was some wording here that says something like that, for example, "as the American Academy of Pediatrics has recommended for pediatricians", I have no doubt that it would be likely some of the other primary care specialties would look at this and maybe want to make recommendations themselves, perhaps being informed by the AAP.

So just the wording, I think -- and maybe it should be done offline -- some wordsmithing to make sure that this Committee is not recommending that or trying to impose on family practitioners or internists or nurse practitioners that they follow the AAP guidelines. I mean we want to be careful about that, I think.

I don't know if Duane --

DR. INSEL: Duane?

DR. ALEXANDER: I agree with Ed on this. I would favor deleting "pediatricians and other" and just leaving it as "healthcare providers", and then making the recommendation of the Academy as an example rather than sort of a mandatory standard. I think that's okay.

DR. INSEL: Again, I see a lot of heads nodding. So why don't we got ahead and put this to a vote?

So if I can read what this might look like, it would say, "Fourth, healthcare providers may not have received training in recognizing the early warning signs of ASD or fail to use existing screening tools at well checkups as recommended, for instance, by the American Academy of Pediatrics for pediatricians.", period.

But we could probably stop at that

point and get the full meaning.

MR. GROSSMAN: Yes, I would like to make a little friendly amendment here to also add "other professionals" because there could be OT or speech or other types of professionals that are treating these children as well.

DR. INSEL: So I'm not sure I follow that. You would put the "other professionals" -- is that different than "other healthcare providers"?

MR. GROSSMAN: I believe so. I think it broadens it somewhat.

DR. LANDIS: But this is diagnosis.

MR. GROSSMAN: Yes.

MS. REDWOOD: I think they might be subsumed under healthcare providers.

MR. GROSSMAN: In many cases, it is the pre-school teachers that are identifying that there is something wrong with this child or speech or OT. I think if we limit it to healthcare providers only, that -- well, I would rather in our strategic plan process to be much more broad than to drill down. I think just putting "other professionals" in there would address that.

DR. INSEL: I just got a note that we are not doing a good job identifying ourselves.

(Laughter.)

So that was Lee Grossman.

And Gail Houle.

DR. HOULE: One suggestion might be to have "healthcare and other service providers", which includes the related service providers, the developmental specialists who are not medical professionals as well.

DR. INSEL: With that addition, if we say, "healthcare and other service providers", can we put this to a vote with the new language? This is incorporating Lyn's language about using the American Academy of Pediatrics guidelines, and as Ed and Yvette have suggested, not in some ways limiting this, but using it as an example.

All in favor?

Opposed?

I see no abstentions.

We have one opposition, but okay, ready to go. We are moving on.

Okay, so the final line on page 3, "Fifth, parents and caregivers may be unaware of the early warning signs of ASD."

Ellen, you had concerns about using the term "early warning signs"?

MS. BLACKWELL: I think I was just trying to express that professionals and other healthcare providers might be looking for early warning signs, but parents are noticing signs and symptoms, just a very small difference. I'm okay with it the way it is.

DR. INSEL: Okay. Let's leave it, then, as is.

The only other thing I see here is then moving on to page 4. So we are into the next section.

Ellen, you had two suggestions, in line 7 and line 14, but it looks like the "community-based setting" should be plural?

MS. BLACKWELL: Yes, it's just a typo.

DR. INSEL: Okay, thank you.

MS. BLACKWELL: Then the latter --

DR. INSEL: We're really getting into the weeds here.

And on line 14, yes?

MS. BLACKWELL: The latter suggestion is just that we continue to embrace person first language, which would change the word "individuals" to "people".

DR. INSEL: Okay. Does everybody see those two sections or two changes? Any concerns about those?

In favor?

Opposed?

Moving on.

So we are now moving up to page 6, I think is the next place where there are any recommended changes.

So we're now getting into the research opportunities. There was no suggestions about aspirational goals.

Under "research opportunities", we're looking at the top of page 6 about wording that has to do with how variations relate to "underlining pathology" -- "nutritional deficiencies" is the addition -- intervention strategies, and outcomes."

Ellen, you raised the question about nutritional deficiencies: why do we make the change? This, again, was from public comments.

Comments from the group?

(No response.)

So let me just, again, let's put this to a vote, people who want to include that and those who would delete it. So to, again, go back to the original form.

Who wants to include the change? Can I see a show of hands?

And who would like to delete it?

Okay, we are moving on to further down the page.

Was there a question about the votes? Did you get the votes?

So we've got now a series of additions that have come again from public comment. There are two. One is on bioethics considerations and the other is outcome studies that evaluate the impact of early diagnosis on long-term quality of life.

Looking for your comments about whether those are ones you want to retain or whether we should go back to the original.

DR. LAWLER: So I support having -- this is Cindy Lawler -- having specific language related to some of the ethical implications.

I am not sure if all of what is stated here in this addition belongs in this particular objective because there are ethical issues related to the diagnosis, especially with respect to genetic screening, but also this addition speaks to the ethics of potential risks with some of the untested treatments that may be tried. So that aspect may belong under a different objective.

DR. INSEL: Other comments?

(No response.)

I think people are saving themselves for other discussion points. So let's not spend a lot of time on this.

Let me get a show of hands for who wants to include the first public comment around bioethics considerations as an addition to the plan.

And who would leave it out and go back to the original?

MS. REDWOOD: Tom, what about also Cindy Lawler's recommendations that we include the first part, but take out "and potential exposure to interventions with more than minimal risk" and put that in another section, as a potential vote?

DR. INSEL: What's the sense of the group? So we have a third option here. We could revote on this.

Lyn, why don't you restate your proposal? Or Cindy's proposal? Cindy might be able to even restate it.

DR. LAWLER: So if we take out, if we end the sentence with, "including consideration of the implications of genetic testing", period. So that would be an addition under Objective 1. Then we can talk under the treatment objectives about making sure that there's some --

DR. INSEL: I apologize, I actually didn't quite understand what you were saying before, but that is much clearer to me.

So is that clear to everybody else?

So we split this up and we move the bioethics consideration about interventions to question three -- or four. Thank you. So we have an alternative proposal.

How about that as the option? So we

would stop the sentence after "genetic testing".

In favor?

Opposed?

Okay, and we'll delete the last part of that.

The second bullet, "outcome studies that evaluate the impact of early diagnosis on long-term quality of life". Now, remember, here we are talking about research opportunities. So this is not an initiative, but an opportunity.

I think, Ellen, you had a comment about that?

MS. BLACKWELL: I think this actually had me a little confused. I wasn't sure if it is the outcome studies or what happens between the child is diagnosed and the end of life. It may just be the way that the commenter wrote the comment, but I'm not sure exactly what the person meant.

DR. INSEL: Jim?

DR. BATTEY: Yes, I also had a difficult time interpreting what that meant. Are they talking about a prospective study where they take a cohort and follow them for decades and decades in different groups, depending on when they were diagnosed? Is it going to be a retrospective study where somebody goes back and uses historical information to try to infer some conclusion? And those studies are notorious unreliable.

First, the prospective study is notoriously long and the retrospective study is notoriously unreliable. So I don't know that I favor putting this in at all.

DR. INSEL: Other comments or thoughts about this?

Lee?

MR. GROSSMAN: I guess I would support that we do some sort of outcome studies because there is anecdotal evidence that shows that early diagnosis/intervention clearly does work. So I would support any measure that is in there to confirm that.

I think there are enough studies about lifespan costs being $3.2 to $3.5 million per individual. I guess it would be a retrospective or a comparison study. We need that data.

DR. INSEL: Other thoughts or comments?

Mike?

MR. MARGE: Hi. Michael Marge.

I think that the person intended to not look at the diagnosis, but what occurred during -- what treatments were applied to the individual and its impact on long-term outcomes.

The diagnosis by itself would not answer to all of the possible variables that could have impact on that individual that led to the quality of life. So it's got to be restated. I don't think it should be included.

MS. BLACKWELL: If we do restate it,

I did have some suggested language here, which was: "How early intervention services and supports and other factors impact long-term quality of life."

DR. LAWLER: This is Cindy Lawler.

I think, based on the two previous comments, this could be easily subsumed under, I guess, objective four, because you are certainly going to look at the age at diagnosis as a factor in predicting treatment, outcome, long-term outcome, and so on. So it may be a case where we just need to make sure when we get to that objective that the diagnostic age as a predictor is included.

MR. GROSSMAN: This is Lee Grossman. From my perspective, if these outcome studies are included elsewhere, then I would be happy with that.

To respond to what Michael was saying, I think it is important, if we are going to include under the diagnostic section, that it is done -- my thinking is that it is to evaluate the age factor. Most kids in the U.S. are diagnosed at about four and a half if they are not a minority or underprivileged, which is at about after six years old.

We should get a comparison here of what the outcomes are for somebody that gets a diagnosis at two years or earlier versus what's currently happening. But if it is covered elsewhere, I would be satisfied with that.

DR. INSEL: Other comments about this?

(No response.)

So the motion here is (a) either to accept the change as stated, or (b) to retain where we were before, delete this addition, or (c) to change the wording as Ellen has suggested.

Let me just get a show of hands for who would just delete this altogether and go back to the original version.

Okay, ten. So we've got an

acceptance, a majority who want to just delete this altogether. We will go back to the original version, and I think you will see it does come up later. I think the same issue gets handled more from the standpoint of interventions, less from diagnosis.

Okay, we're moving into now short-term objectives. This takes us to page 7 and the next discussion point, which is listed as Discussion Point 1.2. It is the one around: develop with existing tools one efficient diagnostic instrument. The only difference really here is changing from 2011 as the delivery date to 2010.

Discussion?

DR. BATTEY: I'm not sure it's practical to try to do it by 2010.

DR. INSEL: Other ideas or thoughts about this?

DR. LAWLER: This is Cindy Lawyer.

I have concerns as well, given that we may not have the people around the table that could even let us know whether bringing that forward would be feasible. My sense is it probably wouldn't be and that's too short of a time, and that we had the experts around the table to give us the initial estimate that we could probably do this by 2011. So I am concerned that 2010 is inconsistent with the earlier recommendation that we received.

DR. INSEL: So you would go back to the original plan.

Alison?

MS. SINGER: Maybe we could just put language in that indicated that we wanted to try to accomplish this by 2010 with urgency and indicate that it is a priority and we would try for 2010.

DR. INSEL: So would you want to say, going back to the original language, "for use in large-scale studies by 2011 or earlier"? Would that meet the spirit of what you're talking about?

I think you are hearing a

feasibility question here and the concern that, if we are now currently in --

MS. SINGER: I would rather see it say all efforts made to do it by 2010 but continuing to 2011, something that reflected that our hope was that it could be accomplished by 2010.

DR. INSEL: I'm just thinking that we are meeting next week to plan out our 2010 initiatives that will actually be done in 2011. So it just, in terms of feasibility, at least through the peer review process and the solicitation process, it would take a year, if we did it tomorrow, to get the project funded and it will take a year, hopefully, to get the project completed. So I don't know how one could do this at least by fiscal year 2010 anyway.

Yvette?

DR. JANVIER: Yvette Janvier.

I seem to recall that Catherine Lord had commented on this and that she felt the true timespan would be three years. I think they are already working on something like this, but, again, we should stick with what is written there, not put an unrealistic goal.

DR. INSEL: Yes, Duane?

DR. ALEXANDER: The only way this could possibly be done, particularly validity assessment in diverse populations, is if it is already almost done by 2010. But if you are going to start or even if it is in early stages already, there is no way to get it done with diverse population validity by 2010.

DR. INSEL: Again, Yvette had said this. This did come up. The timeframe was discussed in great length in the Implementation Group because we were pushing on the urgency side. I think that we might have even started further out and ended up with 2011 as where we ended up its being feasible.

But I hear you, Alison, your concern about getting this done as quickly as possible.

Any other comments about this?

(No response.)

Okay, let's put this to a vote then. The question is really whether we want to change this to 2010 or retain the original estimate of 2011.

All in favor of the change, please put up your hands.

Two -- three.

All opposed?

And in this case, the change doesn't carry. So we will go back to the original date.

We are moving on to the next paragraph.

DR. LANDIS: Actually, Tom, I think there's a change from one to two, at least one to two, or am I wrong about that?

DR. INSEL: You lost me.

DR. LANDIS: Or I guess that's just in the financial consideration.

DR. INSEL: Yes, that comes out in the wash. Okay.

So in the next paragraph, we are looking at changing the wording to include "new or existing screening tools" because we wanted to open up -- or someone wanted to open up the possibility of having a new tool as well as testing or validating the sensitivity and specificity of existing ones.

All right, that is a good point. That came from the Work Group, that wanted us to consider that.

Then there's an additional comment which shows up on page 8. There may be a typo here. I think what it says is, "Conduct active screening prevalence studies in a number of U.S. locations and use a variety of sampling approaches to compare adults born before 1987 to those born after 1987."

So we've got those two to consider.

First of all, let me just quickly see whether anyone has a grief around looking at new tools as opposed to just existing ones. Can we go ahead and just accept that, as the Implementation Group thought? Okay.

And then the addition, let's talk about that. Thoughts about this one?

DR. LAWLER: This is Cindy Lawler.

I am concerned, in addition, we may not be able to do those studies until we have the screening tools that are going to be developed as a short-term objective also for use in diverse populations. So I am not sure how those two short-term objectives can be happening in parallel. It seems like one is dependent on the other.

So the addition, if it is important, it probably should be moved to a long-term objective because it does depend upon having the right kind of screening tools that you could use an in older population and diverse populations.

DR. INSEL: Ed, this is likely to be an issue.

Can you explain, what do you mean by or what does somebody mean by an active screening prevalence? What is that?

DR. TREVATHAN: It is Ed Trevathan.

Those weren't our terms. So I don't know that I can say what they were referring to with that.

I think I echo Cindy's comments. I think the other substantial comments are I think specifying certain dates. I mean I would just exclude the dates because, until you get down into the details of the study design and what instruments are available, what populations we are looking at, I don't really think that we need to box ourselves in with certain dates in terms of comparisons. But I think that the tools are important.

Also, looking at this addition, and this is just on a preliminary looking at this comment, I think the cost is also significantly underestimated here. So we would recommend this is at least probably a

$12 million, not $6 million, endeavor if we are doing it actually in a number of U.S. locations. It is a sizable project.

DR. BATTEY: Yes, this is Jim Battey.

Until somebody can explain to me what an active screening prevalence is, I'm not in favor of putting it in the document.

DR. TREVATHAN: Yes, I think that is an issue. We don't have a definitive understanding of what they mean.

I don't know if whoever made the comment wants to describe it, but we are talking about actively going into communities and screening children with a diagnostic instrument.

DR. INSEL: No, I think it is screening would be adults. So you would be comparing 40-year-olds to 20-year-olds.

DR. TREVATHAN: Or for adults. I think that the problem is we don't know what that means. I think if you took out the "active screening" and just said, "conduct prevalence studies", and then took out the dates and increased the budget to something -- it could be $12 million. I mean $12 million would be not going and actually administering screening tests to everyone in a population. I mean doing something like that would be enormously expensive.

DR. LANDIS: This is Story.

It seems to me that there are a number of hypotheses which have not been articulated but are embedded in this addition, and that given that we don't necessarily understand the hypotheses to make this a high priority commitment of such a large sum, I think we could come back and look at it a year from now because this is a living document, but to commit to it now, with not more understanding, seems risky to me.

DR. TREVATHAN: Yes, I agree, Story. I mean this did not come up with the Committee that was looking at the epidemiologic studies, as I recall.

So before we commit to doing something of this magnitude without really having a chance to sort of vet the methods and really have a good understanding of what the costs involved are, I think is unwise.

Perhaps we could bring this up in the next round and really look at it in detail and vet it and develop methods and then come up with an appropriate cost.

DR. INSEL: Lyn?

MS. REDWOOD: Yes. I think what they are trying to get at here is, when this dramatic increase in autism actually occurred. It seems as though it appeared in the late 1980s. So I think that is why the number 1987 is included in there.

There's also concerns about whether or not we are just doing a better job at recognizing children with autism and that there is a large section of adults who also would be diagnosed with autism.

So I think it is to get at that question: if there is an adult hidden horde of people with autism or is this truly the tenfold increase in prevalence over the last decade is real? So I think that is what they are trying to get at with this question.

I don't know that this type of research is reflected anywhere else in the document. I would think that the researchers that looked at this strategic plan and put this together would be the ones responsible for how they would conduct this and whether they would do active screening or a prevalence study. So I don't know that those types of things need to be ironed out right now, but I do think it is an important initiative to move forward.

DR. INSEL: So, Lyn, are you suggesting that this would be one that we look at in the 1.1 document or is this something you think we should try to work out right now and begin to move forward for this original document?

MS. REDWOOD: Now.

DR. INSEL: Other thoughts about this?

(No response.)

All right, let's just get a show of hands, then, from the group of who would like to include this at this point and who would -- the three options.

Della?

DR. HANN: Yes, what I heard -- and correct me if I'm wrong -- I heard three options.

One is to accept the changes that have been proposed. So that's one.

The second is to do a modification changing the words similar to what Ed, I believe, had proposed, which is to "conduct prevalence studies in a number of U.S. locations and using a variety of sampling approaches of adults, and not necessarily specifying the date, and compare with prevalence of teenagers, again not specifying the date, using the same diagnostic criteria and assess whether" -- and then it continues on as is. So that would be the second option.

And the third option is not to include at this time, at this point in time.

MS. BLACKWELL: I'm sorry. This is Ellen. I have a question.

Are we just, then -- because we've put this whole new thing back on the table. Are we just going to look at youth and adults or are we going to look at prevalence of children, youth, and adults?

DR. INSEL: Well, this is to look at, it sounds to me like, adults born before 1987, or before whatever date is put in there, and teenagers born during or after.

MS. BLACKWELL: Well, if we define the ages of the people that we're looking at, would we just be looking at teens/youth and adults or would we want to look at children, teens/youth, and adults?

DR. INSEL: So I think your question begs this issue of, do we know enough here to know what this -- this is one that wasn't vetted by an Implementation Group. There wasn't a full discussion of the experts around the table about feasibility, and it raises the question of whether it is ready to go forward or it is one that we take back to a group of epidemiologists who think about how to design such things and cost them out.

Someone once said to me, don't run the Institute out of your back pocket. Sometimes that is good advice, that on things that you don't know enough, it may be better to learn more.

But let's put this to a vote. Della, you've given us three options.

DR. HANN: Correct.

DR. INSEL: So the first one, then, would be to accept as is. In favor?

To accept with Ed's recommendation that we remove the date, but we keep this as a concept of comparing -- well, Ed, maybe you can give us the language.

DR. TREVATHAN: I think that that is not as -- I mean, if I'm making a proposal, I don't think that that is as appropriate as deleting it and then taking this up in a planning process for the next year.

DR. INSEL: So we're now down to two options. So the second alternative would be to defer this and look at it in the next round for a living document. Who would want to do that, to defer it?

That motion passes.

Lyn, comment? No? Okay.

We're moving on to long-term objectives here and the next discussion point, which is 1.4.

We've got a series of additions. One is to "continue to validate and improve sensitivity and specificity of new or existing screening tools through studies of the following community populations", and then provide some specificity to that.

Comments?

Thank you, Dr. Landis, and welcome to Dr. Walter Koroshetz who will join us for NINDS.

Comments on this change, on the proposed change?

Jim?

DR. BATTEY: I'm concerned about whether or not the cost estimate is realistic. I mean I just don't know. It looks like a very expensive study to me, but I'm not an epidemiologist. So I'm not in a position to make any kind of definitive statement other than I'm not sure we know what this would cost.

DR. INSEL: Ed?

DR. TREVATHAN: I think that is a valid concern and one we would share. I mean I think some of these additions are really worth pursuing and considering in the next round, but I am concerned about committing to something when we really haven't had the group of epidemiologists sit and debate and hammer out appropriate methods and look at whether this cost is actually appropriate. It may or may not be the right cost, I think.

DR. INSEL: So I would say that, if the cost is the only hangup here and you are really excited about the concept, I wouldn't want that to get in the way of providing a really spectacular scientific idea. But if you have concerns about either the feasibility or the value of the idea, that is a different issue.

Any other thoughts about this? We are not getting a lot of enthusiasm for this addition.

DR. BATTEY: Tom, this is Jim Battey again.

If you are going to stratify this by age, socioeconomic status, race, ethnicity, and level of functioning, I can tell you that the "N" in this study is going to be enormous.

I can say that without being an epidemiologist.

DR. INSEL: Okay. So with that comment, can get a show of hands for who would like to include this addition to the plan? We've got one hand going up.

Who would exclude it and go back to the original? Okay.

We've moving on. Now this one is actually a little bit out of order because of the way this got formatted. So the next change is actually a single word change at the bottom of page 8.

Originally, the proposal had been to validate a panel of biomarkers, and the Implementation Group pointed out that validation has a very specific meaning to the FDA and to others, and what they thought would be more important would be to identify a panel of biomarkers. So they wanted to make sure we didn't use the word "validation", which is a term of art here.

Any concerns about that change? We can vote on it, if you want, but I think it is really semantic and it is mostly a local joke. It is not an issue probably that -- okay. So we are going to be identifying, rather than validating, at the bottom of page 8.

Then we are moving on to page 9. Here we have simply the suggestion to go from saying, "Five measures of behavioral or biological heterogeneity" to "at least five measures". These are fairly minor changes. Then including the language below that that says, "can be used by practitioners and/or parents to assess response".

Are there any concerns about these? They seem to us not worth a long discussion, but if there are people who are concerned about these changes, we can talk about them.

(No response.)

All right. So if I can get a show of hands for all of those together, this would be the change to identify for at least five and for practitioners and/or parents.

All in favor?

Anyone opposed?

We're moving on to the last discussion point, which is the final alternative wording. The point was, should we delete this objective on dissemination? "Effectively disseminate at least one valid and efficient diagnostic instrument". The alternative was, unless it is going to be changed to dissemination, research should not be part of the research plan.

Jim?

DR. BATTEY: Yes, dissemination is not research, and this is a research strategic plan.

DR. INSEL: Other comments or thoughts?

DR. LAWLER: This is Cindy Lawler.

Dissemination is critical. So I would support just changing it into a dissemination/research objective. So we could certainly evaluate the effectiveness of disseminating at least one valid and efficient diagnostic instrument.

DR. INSEL: Other comments or thoughts?

Ed?

DR. TREVATHAN: I agree with Cindy. I think that instead of the range of the cost, too, that the cost of this is going to be more than we might guess. So I would just eliminate the range and just put $10 million instead of 5 to 10.

DR. INSEL: Do people understand what you're suggesting? So this is research on the dissemination, but not dissemination itself?

DR. LAWLER: Right, it would be on, I guess, the methods of dissemination or however that may be designed.

DR. HANN: Right. What I heard you say was to evaluate the effectiveness of disseminating at least one.

DR. INSEL: Jim?

DR. BATTEY: That's okay. That's research.

DR. INSEL: So, Della, could you read what you just said or say what you just said again, and we'll have something that we can then vote on in terms of final language for this?

DR. HANN: Right. So the changes, the proposed changes, were to "evaluate the effectiveness of disseminating at least one valid and effective diagnostic instrument in clinical practices involved in diagnosis by 2016", and then a change to the estimated cost to be $10 million over five years, and that was it.

DR. TREVATHAN: If I could just add, I think this is inferred, but we just want to make clear that we are really looking at screening in diagnosis here, dissemination, not just diagnosis.

DR. HANN: Okay.

DR. INSEL: So when we add those words in -- so it is really explicit then.

So I'm sorry to force the issue, but could you again say this one more time --

DR. HANN: Sure.

DR. INSEL: -- and we'll have it?

DR. HANN: "Evaluate the effectiveness to disseminate at least one valid and efficient" -- right? -- yes, efficient -- "diagnostic and/or screening instrument."

Do you want to say "screening and diagnosis"? Okay, "screening and diagnostic instrument in clinical practices involved in diagnosis".

DR. INSEL: And we're changing the estimate for budget requirement to $10 million.

Michael?

MR. MARGE: What I am confused about is, what's the rationale for identifying one instrument? I mean, has that been decided by this Committee, that we are going to work to identify one valid and reliable instrument, and we are going to propose it nationally as the magic bullet?

DR. INSEL: The Committee felt that we needed at least one. We don't have any now. So that is the wording, was to begin there, but knowing that there would probably be multiple instruments that would be developed over time.

MR. MARGE: The issue would be, if you test the dissemination, test the effectiveness of the dissemination, it all relates to who is identifying or certifying the methodology or procedure as the effective, most effective or one of the most effective instruments.

Has that been thought through, in other words? Who is going to do this? I mean, which organization or what group is going to say, well, this is the certified methodology, and that now we are going to disseminate it and we're going to test whether dissemination works? Because the organization or the certifying body is the one that is going to have an impact on whether that has been disseminated and accepted and utilized. So it is a little confusing to me.

DR. INSEL: It is. We had some discussion about just some of these issues in the Implementation Group, and there was a real sense that we needed both a tool and we needed a tool that was widely used, so that we could compare across many different studies, including international studies, so that we would have the kind of population base that we needed.

Alison?

MS. SINGER: I may be remembering wrong back from the Scientific Work Group, workshops, in January, but my understanding, when we talked about this, was that it was not to be dissemination research, but that the scientists brought up the need for a briefer, less-time-intensive screening tool that would be widely disseminated so we would be able to compare, as you were saying, across different labs, including internationally, but that this was not really intended to be dissemination research. It was intended to be a new tool.

DR. BATTEY: This is Jim Battey.

But I thought the new tool we've already incorporated earlier in the discussion, if I am remembering right.

MS. SINGER: I just remember that one of the things, one of the points that consistently came up during the Scientific Workshops, when we were talking about urgency and what held up the science, what slowed down the science, we consistently heard feedback that the diagnostic instruments were very long and arduous and hard to get completed, and that that was what was holding up the pace of research and progress. That is really where I'm remembering that this item came from. It was part of the goal of increasing the speed with which we can get the studies done.

DR. KOROSHETZ: That is on the bottom of page 6, I think, line 22.

DR. INSEL: This is Walter Koroshetz.

DR. KOROSHETZ: Walter Koroshetz.

This is develop the tool, briefer, less time-intensive, has valid and diverse populations. This one, I think, is hooked, but the question is, are we doing dissemination or are we doing dissemination research on that tool, on how to bring that tool out? I think it is the latter. I mean it is a fine point.

DR. INSEL: But I guess it does raise the question of whether those on the Committee feel that it is important to do dissemination research or whether this is just something we should get out there and worry less about studying how we get it out there.

Is that an issue worth clarifying here?

DR. KOROSHETZ: Well, I think if you don't think it through and do some research to know what is the best way of getting it out, you could end up not being very effective at getting it out.

DR. INSEL: I understand that. It is just, cognizant of Alison's point about the urgency, and this is one of these objectives that wouldn't happen -- the research wouldn't be done until 2016. So that is not what you would consider a very fast timeline for at least finding out how to disseminate it, especially if you developed it in 2011.

DR. TREVATHAN: I wonder if we really can address both Alison's concerns as well as Cindy's and Jim's together, in that at least I think some of us may think of this doing research on the dissemination. We are really looking at how effective is our dissemination. So disseminate, how effective is it, and then have the feedback from a research point of view, how effective is the dissemination; what are the methods that work/fail? Then feedback to improve future dissemination.

So the research I think can actually be a component, and should be a component, of the dissemination process, which needs to be continuously improved.

DR. INSEL: Well, you are not going to get a break until you figure this one out. So are we ready to resolve this and go forward with a motion?

DR. KOROSHETZ: How about as an option say, "in concert with dissemination of at least one valid diagnostic instrument, research will be done to determine best methods" -- "best practice of dissemination", I guess.

I'm trying to get "dissemination" out of it twice.

DR. INSEL: But I think that Della gave us that language, didn't she, already, by changing it to be both screening and diagnostic instruments and to evaluate the effectiveness of dissemination, which is essentially dissemination research?

Michael?

MR. MARGE: The reason I brought up the other issue is because maybe we are not talking about dissemination. Are we more interested in utilization of the instrument? Dissemination, the process of providing the information about the instrument and encouraging people to consider it is one thing. Having them utilize it is what we really want. Is that true?

If that is the case, what's the most important question, the utilization of the instrument or the dissemination, the process of informing people about it?

DR. INSEL: Gail?

DR. HOULE: I want to go back to Cindy's suggestion.

It is Gail Houle.

If you are evaluating the

effectiveness of the dissemination efforts, you could include the impact of the utilization of the instrument as well as the efforts. It could be pretty broad dissemination research with various outcomes. What's the population using it? I mean I could see refining it. How effective is the methodology of getting it out there?

And you could even take it as far as the impact on the user of the instrument and the referrals and the child, and all kinds of other things.

So I think that Cindy's wording would cover several aspects of dissemination evaluation, including impact.

DR. HANN: This is Della.

So I'm trying to make sure I understand what you just said, Gail.

So we would have "evaluate the effectiveness of the dissemination, use, and impact of at least one...."?

DR. HOULE: "Effectiveness of

dissemination initiatives" -- "effectiveness and impact of dissemination initiatives", and at least one would be fine. I think you would have already decided before you disseminate through the earlier objectives which one or at least one or two you were going to disseminate. Now we're down to dissemination.

DR. INSEL: Alison?

MS. SINGER: I'm still confused. Do we want to evaluate how effectively we get it out or do we want to evaluate how effectively -- whether it is good.

I mean I think what we want to know is, after we have created it in the short-term objectives, in the long-term objectives after it has been used, we want to go back and say, was it good, not did we mail it right. I just don't -- maybe I'm misunderstanding what dissemination means.

DR. INSEL: Yes, I think there is enough confusion around the table about this. This doesn't kick in until 2011 at the earliest. Is this one you want to defer and discuss further in the next round of the plan, at a point when we actually would have an instrument that we could think about? So we could actually just take this off the table.

Duane?

DR. ALEXANDER: Yes, this really falls in the category of the topic that we deferred already this morning. I think we are talking about something we don't have in hand yet, and we don't lose anything in time if we are going to be doing a manual revision anyway. So I would just defer this.

DR. INSEL: So can we put that as a nomination?

All in favor of deferring this one for further information?

Opposed?

Okay, that motion carries, and you have earned a break.

So let's take a very brief break. We've got a lot to do. Five minutes, which I know means seven, but please let's stay on track here.

(Whereupon, the foregoing matter went off the record at 10:31 a.m. and went back on the record at 10:40 a.m.)

DR. INSEL: We are on to the second question. There is nothing from page 1. There are several questions on page 2 related to lines 10 and 11, and they are a little similar to what we have talked about before, around the medical symptoms or conditions and how much detail we want to specify there.

So we have comments from Lyn and from Ellen, and around the middle section, because there was a public comment about adding in auditory impairments. What I heard from the group before was that on these sorts of issues you would like to say, "co-occurring behavioral and medical symptoms or conditions" without going into the specifics of what those might be. Is that correct?

Okay, Lyn?

MS. REDWOOD: But, Tom, in the introduction, were you saying as well that these specifics would be identified then?

DR. INSEL: I think what we have to have is some part of the document we have to lay out -- and I must say I don't think it is clear whether they are part of autism or whether they are co-occurring. I think we have to clarify, and we will get to this when we talk about the introduction, the confusion about this.

But there's some place in the document we have to talk about a range of symptoms and syndromes that are seen within the autism. I just don't know that we want to repeat it every time that this comes up.

MS. REDWOOD: Agreed.

DR. INSEL: So there is this interesting language that you have recommended. I think it would be worth having the group think about it because it does provide something that is not in here already, mentioning the Autism Treatment Network, which is documenting medical features in academic centers.

Do people think that is worth including?

MS. REDWOOD: Tom, the reason I put that in there is because oftentimes these types of co-occurring medical conditions are completely overlooked because many of our children are non-verbal. So I think it is important for that to be on the radar screen, and that oftentimes parents report, when these underlying medical comorbidities are diagnosed and addressed, that the behaviors actually improve.

DR. INSEL: I thought the other thing that you put in here which is worth taking a look at is that, as you have said, they are either comorbidities or they could be manifestations which have just not been understood because they have some underlying mechanism.

A lot of us are looking at the recent data on lung cancer and smoking, which apparently, amazingly, have completely independent underlying mechanisms that, when you get back to one level, are shared. So who would have thought? Or nicotine dependence and lung cancer share the same mechanism.

So do we want to include this additional language, taking out the specifics of auditory impairments, motor and sensory impairments, seizures, mitochondrial dysfunction, all of that, simply encapsulate it as medical syndromes and then include the language about the ATN and the clarification of whether these are going to turn out to be co-occurring or whether they are actually systemic manifestations.

So let me put this to a vote. Those who would like to actually put in the additional with deleting the specific medical issues, but to provide generic language about medical symptoms or conditions, but add the section on the autism treatment network.

In favor of that addition?

Opposed?

Okay, motion carries.

We're moving on to lines 12-13, "Healthcare services to treat this co-occurring symptoms are often limited."

Ellen, you had a concern about that?

MS. BLACKWELL: I think if we are not going to define what the healthcare conditions are, we should probably not say that the treatment is limited. That just doesn't make sense to me. So we should probably just delete that sentence.

DR. INSEL: Yes, although we will have some definition of this in the introduction, ultimately. But I take your point.

Others have a sense of this? For or against?

(No response.)

All in favor of including the

addition from public comment about healthcare services are often limited, can I see a show of hands?

Those who want to delete this and go back to the original language, show of hands.

So the addition does not carry. We will go back to the original language.

We are moving on to line 17. Again, Lyn, you had some language to add in here? I think you might want to read it because, for those who are listening in, it may be helpful to hear it.

MS. REDWOOD: Okay. What I had suggested be added, that is in the case of the immune system, a number of hypotheses concur concerning how disruptions might contribute to ASD and other neurodevelopmental disorders have emerged in the recent years.

For example, some recent findings suggest that inflammation may be involved in the onset and fluctuation of symptoms in some children with ASD. This comes from Carlos

Pardo's work.

These questions have been receiving increased attention in the recent years, but it is too early for clear answers. While such medical problems may not be entirely specific to ASD, treating them may have significant impact on the quality of life, symptom severity, and level of functioning.

DR. INSEL: Lyn, I had a question. There's an additional sentence in the original version which goes on to talk about maternal antibodies, "an array of fetal brain proteins..." from Braunschweig.

Are you suggesting that you would delete that or would you include that after the part that you have put in here?

MS. REDWOOD: Include.

DR. INSEL: So the language you are putting in would come before that?

MS. REDWOOD: Right.

DR. INSEL: And then it would go, "For example, research on maternal antibodies...."? Got it.

DR. HANN: Just so I'm clear as well -- this is Della. So, essentially, then the sentences that you are proposing would replace the sentence, "Some recent findings suggest that the immune system....", correct?

MS. REDWOOD: Right. I would have to go back and pull out what I sent Della to look because it had more of the actual deletions and insertions of language than this document does.

DR. HANN: Yes, I think that would make sense. It would be a little redundant otherwise.

DR. INSEL: Comments about this? Questions?

(No response.)

All in favor of including the new language, which essentially replaces the "some recent findings" sentence with new language that provides more detail? In favor?

Opposed?

So the addition carries.

And we're moving on to page 3, and here we have a lot of discussion about the language around the post-mortem tissue collection.

I am going to take the prerogative of the Chair to make a recommendation here. As I read through this, both in the original and in the revised version, I have real concerns about the amount of detail that we are putting in here in terms of naming specific places where either the collection has taken place or where it should take place. I think, going forward, we want to keep this more generic.

I wonder if it wouldn't be most efficient to just take out the whole section that talks about where those efforts have gone and the work of the advocacy organizations, and just simply say that -- well, essentially, end the sentence where it says, "preservation of post-mortem tissue from individuals with

ASD.", period. There's no point in actually talking about who has been doing that. Then say -- and, actually, you could leave it at that.

You might want to add the addition that says, "Nevertheless, the tissues currently available through these efforts are inefficient for the needs of researchers. Educational campaigns through contact with healthcare providers and the internet may be useful to increase awareness."

So that would be an addition from the public, but what I want to put on the table is the possibility of taking out the mentions of all the specific agencies and collections.

Duane?

DR. ALEXANDER: Speaking as one of the things that would be deleted, I am okay with that.

(Laughter.)

DR. INSEL: Any other comments?

(No response.)

All in favor of that change?

So we are accepting the addition of the sentence that says, "Nevertheless," but we're taking out the specific agencies and groups.

In favor?

Opposed?

The motion carries.

And we are moving on to page 5, I believe. Whoops, I'm sorry, page 4.

On lines 3 and 4, there's a recommendation, "As a result of this phenotypic heterogeneity, ASD in some individuals may affect the functioning of the whole body, not only the brain and mind."

Comments?

Jim?

DR. BATTEY: Yes, I mean I think it is probably a true statement. I'm not sure what its value-added is at that point in the document.

DR. INSEL: Is this something that would go into that section of the introduction where we specify all of the medical issues that come as part of the ASD package?

DR. BATTEY: Yes, I think that only has to be stated once upfront in the introduction, and not reiterated over and over again.

DR. INSEL: Other comments?

(No response.)

So in favor of including this addition, can I see a show of hands for including this addition?

And those opposed?

So we're going to go back to the original version.

Moving down the page, "An evaluation of differences in environmental exposures between children with and without ASD is also needed."

Discussion?

(No response.)

All in favor of this addition?

All opposed?

So this addition carries.

And we're moving on to the next page, page 5. On lines 7 through 9, "Existing brain and tissue bank resources cannot satisfy the high demand and continuously increased demand for post-mortem tissue by scientific investigators. Currently," -- it looks like they took out the word -- "Currently, the numbers of well-preserved brains", and it goes on from there.

Comments about this?

Is this helpful to have it in here?

Lyn?

MS. REDWOOD: It's definitely true.

DR. INSEL: Other comments?

(No response.)

So in favor of including this additional language, a show of hands?

Those opposed?

And this addition carries.

Moving down the page to the final paragraph, "Multidisciplinary, longitudinal biobehavioral studies", Lyn, you had suggested wording change, and then there was a public comment also about adding in "co-occurring conditions". So, Lyn, can you just quickly take us through that, how you would like to see it read?

MS. REDWOOD: Starting with the "Multidisciplinary, longitudinal biobehavioral studies of children, youth, and adults, beginning during infancy that characterize" -- I had inserted in there "neurodevelopmental and medical trajectories of development across the multiple axes of the ASD phenotype and to identify ASD risk factors, subgroups, co-occurring conditions, and potential biological" -- and then it goes on into the original text from there.

DR. INSEL: Comments?

MS. REDWOOD: There's only a couple of words that are different from what was in the original text.

DR. INSEL: And those are?

MS. REDWOOD: "Neurodevelopmental and medical" --

DR. INSEL: Okay.

MS. REDWOOD: -- and "the trajectories of development across the multiple axes of the ASD phenotype".

DR. INSEL: All in favor of that addition, show of hands?

Opposed?

That carries.

And moving on to page 6, on lines 6 and 7, there are some additional words put in. "Neuroprocessing" and "allergic" have been added to what was there from the original where we had "imaging, metabolic, and immune markers" along with "microbiomics, electrophysiology, and behavior".

Comments?

Jim?

DR. BATTEY: Can somebody clarify --

or it is probably my own ignorance -- allergy and autism, how are they related? Are they related? Is there data to support that?

DR. INSEL: So there are reports of increases in allergic problems and also immune issues in kids on the autism spectrum. There are also, as you know, huge increases in food allergies in the population.

I thought you were going to ask how allergic measures are different from immune markers, but that's a different question.

DR. BATTEY: That's the next question.

(Laughter.)

DR. INSEL: Or how neuroprocessing would be different from electrophysiology and brain imaging.

So let me get a show of hands for who wants this addition to the language.

We have one, a couple of hands, well, three hands going up for these changes.

Those opposed to these changes?

So we are going to go back to the original wording here.

Then there are two additions that are recommended from the public: studies of social cognitive deficits and outcome assessments of early intensive intervention, one that we heard about before.

Comments on those?

MS. BLACKWELL: This is Ellen. I had a couple of comments on these.

These are big initiatives. If we were to include these, I would suggest that we perhaps reword them because isn't it studies of social and cognitive deficits across the lifespan? And isn't the second one outcome assessments of particular early intervention, intensive -- or early intervention, again, across the lifespan.

But we may want to think about tabling those to 3.1.

DR. INSEL: Jim?

DR. BATTEY: I thought we already

discussed them again in the first part, an outcome assessment of early intensive intervention. I remember talking about that earlier in the morning.

DR. INSEL: Well, we talked about that it was going to be picked up in a later part of the document.

DR. BATTEY: Is this the right place for it?

DR. INSEL: Could be, yes. No, this is a research opportunity. It is not yet an initiative. It is just suggesting some things that could be done.

Certainly the studies of social cognitive deficits have been done at some considerable length. So the question is whether you want to include that as one of the opportunities going forward.

Any issues about these?

(No response.)

If not, rather than discuss them further, can I see a show of hands for who wants to add in studies of social cognitive deficits? In favor?

And who's opposed to that addition?

So we will go back to the original language there.

What about the outcome assessments of early intensive intervention? In favor?

And opposed?

Ooh, this one --

MS. SINGER: Tom? Tom?

DR. INSEL: Alison, if you can use your mike?

MS. SINGER: When we moved this earlier, I thought we mentioned that we had moved it to Section 4. This is Section 2. So are we voting on eliminating it or --

DR. INSEL: I think when we discussed it earlier, it was an initiative. This is really listed as an opportunity for research, but the point still stands, that if this is about interventions, we may not need to deal with it here.

Is that the suggestion?

MS. SINGER: I'm suggesting we deal with it someplace, but agree on where.

DR. INSEL: I think this does come up later.

Ellen?

MS. BLACKWELL: I think I can't stress enough that I think if we include it, we need to specify that we're looking at specific early interventions, because it is very broad the way this is written.

DR. INSEL: I'm going to put this back on the table for a vote because it wasn't too clear what the group was wanting to do before.

But, as written, who is in favor of including it in this place as this is written? All in favor, can I see a show of hands?

One, two, three.

And opposed, knowing that we may deal with it later?

So this will go back to the original

language, and we will not be including it here.

Then we have -- let me make sure we are on the same points here -- further down, on lines 17-18, there's a recommendation that on the research on females with ASD we characterize clinical, biological, and protective features.

This came up, I believe it was in the Implementation Group, which we told not to make comments about the initiatives, but just to talk to us about budgetary requirements. They ignored us on this one.

They said they just felt strongly that this particular objective was so narrow that it wasn't really useful to break out as a separate objective, and they recommended that we delete it. So we've included their alternative or their option here.

Comments? Ed?

DR. TREVATHAN: Yes, we obviously need to know more about ASD in females. I mean I would keep it.

It seems like the need to have a comparison with males is sort of assumed. So if it would make people feel better, you could have studies of research on females with males as a comparison group, but we would suggest keeping it in.

DR. LAWLER: I agree. Little enough is known about females with ASD that I think it does merit specific mention in the approaches.

DR. INSEL: So I think that is an important caveat. So this is now talking about a research opportunity. It is not talking about an initiative. So you might decide that you don't think this needs to be an initiative, but it would be worth building into studies that are done. So this is an area that we look at.

Other comments about this?

(No response.)

So those who are in favor of

accepting the recommendation that we delete the objective? Can I see a show of hands who would like to delete this objective?

And those who want to go back to retaining the original language, show of hands?

So their recommendation will not carry, and we will go back to the original language.

DR. HANN: Do you wish to add the idea of the comparison of males, or is that just so obvious?

DR. INSEL: As opposed to?

(Laughter.)

Moving on to page 7, where we have a discussion point at 2.3 around the addition of research on the unique strengths and abilities of individuals with ASD. Again, an idea that came in from public comment.

We have comments from some people on the Committee who have already written in.

Your thoughts as a group? What

would you like to do with this?

(No response.)

Hearing nothing, I am going to go ahead and put this to a vote.

Those who want to include this additional research opportunity, can I see a show of hands?

Those opposed, who want to go back to the original language?

Okay. Thank you.

So, in this case, we will include the new language.

We are moving into the short-term objectives. So here we've got the actual initiatives.

The first discussion point comes on the issue of the international network of brain and tissue acquisition sites.

I must say I'm not sure I see where the change is in the first alternative.

DR. HANN: They dropped the --

DR. INSEL: They are dropping the

skin fibroblasts.

DR. HANN: Correct, right.

DR. INSEL: So instead of saying, "other tissue" literally, it just makes the change to say, "systemic tissue" and it leaves out skin fibroblasts as an example.

I think the skin fibroblasts came about from the Implementation Group -- or I'm sorry, from the Scientific Consulting Group that felt that the advent in induced pleuripotent stem cells would be an extraordinary advance for autism.

We've just in the last couple of months funded the first such grant at Stanford to do this at a very large scale.

So I thought that the Committee wanted us to feature that to remind the community that we are in a whole new era where we can begin to use stem cells to understand the pathobiology of autism.

Actually, before we go to this, as you can see, there are other recommendations on this same point. Maybe without reading them, if you can just take a look.

We've got two choices here. It's either this one or to do several biobanks managed by a variety of institutions.

MS. REDWOOD: Tom, does that have to be an "and/or"? Could we have both of those?

DR. INSEL: Both of which?

MS. REDWOOD: The alternative language or would that be too redundant? It just seems like we need both.

DR. INSEL: I guess I don't understand the difference between a network for tissue acquisition and biobanks managed by a variety of institutions. Those sound like the same thing to me. They are just different words I think to describe the same thing.

Actually, I can't tell how they are different from the original wording in reality. I don't know what they would do that the original wording doesn't do.

MS. REDWOOD: I guess, to me, I was

just thinking biobank sounds more extensive, just my own read of the terminology.

DR. INSEL: Michael?

MR. MARGE: Well, the first alternative refers to an international network, and the second one is silent about where the biobanks are.

DR. INSEL: Does the Committee have a preference for whether to keep this, the word "international" in there? Because having just had the meeting this week in Washington from the Society for Neuroscience, it is clear that there's going to be a major program underway in Bangalore very soon on autism that has this as probably its primary focus.

Would we want to leave that out? Or should we specify that we would like to support an international effort?

(No response.)

Okay, I see heads nodding. I want to move this along.

What's your pleasure here? We've

got three very similar issues. The only thing that I think that stands in the way is whether to put "international" in and whether to use the term "biobanks" versus "international network of brain and other tissue sites".

Then there is a difference also in the budgetary requirements. So the second alternative bumps the budget up to $40 million, which is quite a difference from the $5 million that the original or the first alternative recommends.

Walter, do you want to give us a read on this, since you are probably the closest expert to these issues?

DR. KOROSHETZ: I mean I think it's always go with the sexy name. So I think establishing a "network of biobanks with brain and other tissue acquisition sites" would be fine. "International" I think, certainly, if we can leverage any investment we put in to get more tissue into the network, that would be great.

DR. INSEL: What about the budgetary issues here? Between 5 and 40, where should we be?

DR. BATTEY: It depends on how big the network is, right?

DR. INSEL: Alison?

MS. SINGER: I think we heard over and over at the workshops about the need for tissue. As Sophia likes to say, what matter -- I mean we need a whole variety of tissues, not just brains, but brains are also important.

So I would like to see the budget be closer to 40 than 5.

DR. KOROSHETZ: I think with five, you're not going to be able to do much. That is what we spend just on DNA at Coriell a year. If you are going to do brains and other tissues, it is going to be more expensive.

DR. INSEL: Duane, since as I recall, it was NICHD that said they would be accountable for this one.

(Laughter.)

When we start talking money, all eyes will turn to you. What do you think?

DR. ALEXANDER: We don't have $40 million, but clearly five is a low estimate. That is over just two years. The other doesn't specify two years, I don't think. Yes. So we have a difference in timeframe, accounting for part of that.

I think international is important. I would leave it in. I would leave skin fibroblasts in.

I don't know whether you need to call these "biobanks". It is a little bit different terminology than we are used to using for brain and -- or for tissue banks. I think that is really what we are talking here as the resources, brain and tissue banks, more than biobanks.

I would be happy with the original language, keeping in skin fibroblasts, probably doubling that budget.

DR. INSEL: So that would be an option. Does the word "biobank" -- Walter suggests that it may be sexier and more interesting. Is there an advantage to using that, from your perspective?

DR. ALEXANDER: Does "biobank" imply living tissue to be made available as opposed to dead tissue, for the most part? If you are going to have skin fibroblast, you want that alive.

DR. KOROSHETZ: I think it is just a more general term. So there's fibroblast cultures, white cells that have been frozen, ready to be brought out again; brain. So it is just a more general term.

If you do a collection of brain and fibroblasts, you may want to have some other things that match it. So blood that you can do proteomics to kind of correlate the brain findings with the more easily accessible stuff.

So I think it is just a kind of more

general term, but you would specify brain and tissue, skin fibroblast, under the biobank, so you don't lose anything.

DR. INSEL: I think the $5 million price tag may have been tagged to the 2010 delivery date, thinking that this would be essentially a one-year effort because it was felt to be so urgent to get this going. We already have -- as you saw above, there's a lot going on. So this was partly a matter of coordinating the current effort and ramping it up considerably.

Would it make since to double the budget but to give it a 2011 or would that actually defeat the purpose of getting this done quickly?

DR. ALEXANDER: Efforts are already underway to do this. So it is going to get done relatively quickly.

You could make it -- you know, leave the 2010 in, so that it is going to be up and going, expanded, but not -- ultimately, expanded. This is a process that is going to take time to get it enlarged, to get international sites established, and so forth, and to develop the capacity for dealing with living tissue, not just pathological or autopsy tissue. So that is going to take a while.

DR. INSEL: Okay. So there is a two-year timeframe on it, even though it says, "by 2010". I'm not sure that those two are going to be on the same path.

But let's see if we can come to some agreement then about some final language that we could put up here for a vote, where we can bring all three of these together.

Della, do you want to try to help us with this?

DR. HANN: I'll try.

So what I have been hearing is to establish an international network of biobanks, and then what I am a little fuzzy on is perhaps a parenthetical around the issue of what's to be included in the biobanks. I could use your help on that.

Then the rest of it would read as follows then: "with standardized protocols for phenotyping collection and distribution of tissues by" -- right now it's 2010. I have also heard you all talk about potential 2011. And then with an estimated cost then potentially up to $10 million as opposed to five over two years.

DR. INSEL: Walter?

DR. KOROSHETZ: I think the wording, just wordsmithing, but you could say, "biobanks for collection of brain and other tissues; e.g., skin fibroblasts", and "the acquisition sites would have standardized protocols for phenotyping collection and distribution of tissue."

DR. INSEL: And the timeframe?

DR. KOROSHETZ: It's up to Duane.

DR. ALEXANDER: Well, clearly, part of this is already operational. It is going to be expanded. But if you are going to increase that budget, it ought to be by 2011 rather than 2010.

DR. INSEL: And what is the budget, Della, that you are recommending.

DR. HANN: What I heard the group discuss was $10 million as opposed to $5 million over the timespan.

DR. INSEL: What does the group think about this new wording?

Lyn?

MS. REDWOOD: Yes, Tom, I think that sounds great, but I just want to make sure that this is a continuing process and that we continue to put, I heard $40 million on the table, and I think this is something that we need to keep this sense of urgency, but at the same time make sure that it is maintained over time. So we are constantly adding new tissue.

DR. INSEL: Yes. So that is a really important point. We don't want this to be misinterpreted that this would be done for two years and then closed.

So how do you put that language in? It says, "establish".

MS. REDWOOD: Would it be "establish and maintain"?

DR. HANN: Another possibility is that the maintenance part of it you could move into the longer-term area. You want to establish it, as I am understanding it, establish it quickly, but then, obviously, it has to be maintained. So it is sort of like two components. So one could put the maintenance essentially of the biobanks in a longer-term objective because you are going to have that over the longer haul.

MS. SINGER: I think that would be fine as long as maintenance is specified to include continuing collections, not just maintenance of existence samples.

DR. INSEL: Yes, I mean all of these things are run that way. So it is probably why the language didn't reflect it, because it is usually assumed. But I hear Della's comment that for the short-term objective, we really would be focused on establishing this.

Would it be a problem, though, to add the words "establish and maintain"? So it is understood, after it is established, that it keeps going?

DR. HANN: I think you would also, then, want to have it as part of the long-term. I think you would want it both places, to be clear.

DR. KOROSHETZ: You could put in "long-term", the word "long-term" to modify "phenotyping collection and distribution of tissue".

DR. INSEL: Okay, give us something we can vote on, because we are going to move on.

DR. HANN: Yes. So here's what I have distilled from this: that we keep in the short-term objective "establish an international network of biobanks for brain and other tissue; e.g., skin fibroblasts; acquisition sites with standardized protocols for phenotyping collection and distribution of tissue by 2011." Estimated cost of $10 million over two years.

Then in the long -- so not in short-term any longer, but in a longer-term section, to essentially take that language, but not to have it be established any longer. Have it be to maintain and continue the collection of these tissues and brains for the biobanks over some period of time and with some amount of money for a longer-term.

DR. INSEL: Are we ready to vote?

In favor of that recommendation, hands?

Opposed?

So the motion carries.

We are going to be moving on to the next discussion point, which has to do with, on page 8, are we supporting at least four research projects to identify mechanisms of metabolic and/or immune system interactions, or is it going to be ten research projects, or is it going to be 25 studies, to include projects to understand the biology of autism that can inform causality and lead to treatments?

So those are three quite different choices. Tell me where you stand.

Jim?

DR. BATTEY: It isn't clear to me that there would be 25 individuals that would come in with applications that would have decent peer review scores. I mean the research community has a certain finite size, and it can grow over time, but it can't grow over a year, two, or three years. It takes a longer time than that to expand the research community to accommodate greater numbers of projects.

So I like the original at least four; if we got in ten good applications, then we would fund ten applications.

DR. INSEL: Other comments?

MS. REDWOOD: I think if we set our goals high, whether or not we get them in is a different issue, but we will start to entice researchers to move possibly from other fields into this area of research.

So I guess I feel differently. I think it is important to set our goals high and try to attract new researchers to this field.

DR. INSEL: Lee?

MR. GROSSMAN: Lee Grossman.

I'm wondering why there is a number at all. I think we can establish a minimum, but not look at a maximum. I know that we want this for budgeting purposes, but I just see somehow that we are limiting ourselves. I doubt if in the course of the four years we are going to get hundreds of them, but I think, if we're going to do anything, let's not establish a maximum number.

DR. INSEL: This is really just to

set the floor, and the question was whether the floor would be four, ten, or 25.

Alison?

MS. SINGER: I thought the floor could certainly support at least 10.

And I would add in the words, "scientifically rigorous", which is used elsewhere and just not here.

DR. INSEL: Walter?

DR. KOROSHETZ: Walter Koroshetz.

I have the same idea as Lee has. Anytime we put in numbers and just don't know what the right number is -- it might be 50. I mean I don't know.

I think the goal was scientifically rigorous and promising studies, is the key thing, and the numbers should float depending on what we get.

There's multiple times where this comes up, and I think we should have kind of a generic -- do we really want a floor or not?

DR. INSEL: Let me just clarify: we

have two issues on the table. One is the number, and the second is to add in the term "scientifically rigorous", whatever the number should be.

MS. BLACKWELL: This is Ellen.

Can I just make one additional point that every time we raise the floor, we raise the budget, and we have that 2010 number in there. So we need to bear that in mind when we talk about the numbers.

MS. SINGER: Can I answer this question?

DR. INSEL: Yes.

MS. SINGER: I think the reason we put in floors in so many of these was really to say that this is a priority area, and we didn't want to let it go through another year without having any. I think we can recognize that there are a good number of scientifically rigorous, promising projects, and we just want to make sure that we do at least four or ten.

DR. INSEL: Are there other comments

in this arena or are we ready to go to a vote?

MR. MARGE: Michael Marge.

DR. INSEL: Michael?

MR. MARGE: I think the important factor here is, who is the audience? Who are you trying to influence and who are you trying to communicate with in terms of identifying a floor?

It should be at least, as you move into new areas, somewhat realistic, as realistic as possible. I think we have to be somewhat pragmatic about this. If it is a wish list, that is a different thing, and that is not going to capture the interest of Congress and other decisionmakers.

So I think having the floor is a good idea, like at least four, unless there are good arguments to have ten or twenty.

DR. INSEL: Other comments?

MS. REDWOOD: Regarding Alison's comment about scientific rigor, I think that that could be addressed in the introduction, but I hope that all of the research coming out of NIH would have a certain level of scientific rigor and that it wouldn't really need to be specified; it's assumed.

DR. INSEL: All right. So we are going to do this in two parts because we've got two issues on the table. One is the number, and the second issue is the addition of the term "scientifically rigorous".

Can I get a show of hands for who wants to retain the original language of at least four research projects? All in favor of retaining that language? Let's see who would like to do that. Hands up.

Those who want to go to at least ten research projects?

And those who want to go to at least 25?

We've got one.

So the motion carries that we will go back to the original language of at least four.

Now the question, do we want to add the language "scientifically rigorous" before -- well, Della, maybe you can read it to us. How would that read? Or Alison?

MS. SINGER: I'll actually agree with Lyn. If we can stress that in the introduction and then it is assumed that it is carried throughout, I am fine with that.

DR. BATTEY: Yes, I agree with that. Because if you put it some places and not others, you are actually implying that maybe we are going to support some stuff that is garbage, and I don't think we want to make that implication.

DR. INSEL: So we are moving on to page 9. The next discussion point has to do with launching three studies that specifically focus on the neurodevelopment of females. We were just there in the scientific opportunities section.

So one alternative is to delete this. And your sense about that? Do we want to have specific projects on neurodevelopment of females by 2011?

DR. TREVATHAN: Delete and just merge with that one that we did just a little while ago, I think 2.2.

DR. INSEL: Okay. That is the motion on the table, is that we would take this one which had been in the plan originally and take it out of the plan.

Any comments?

(No response.)

In favor --

MS. SINGER: Can I ask a question?

DR. INSEL: Yes, Alison.

MS. SINGER: If we agreed to include it in the research opportunities, why would we take it out of the objectives?

DR. INSEL: I think what Ed is saying is that it comes in later down below, under the first long-term objective. We can specify that that would include females as well as males and emphasize it there. It doesn't need to be a separate objective in that sense.

MS. SINGER: But I thought here it was included in the short-term objectives and there it is long-term.

DR. INSEL: That is right. So that is the question, is whether to take it out of the short-term objectives as a separate initiative.

MS. REDWOOD: And that was also the recommendation of the Implementation Panel as well, Della?

DR. INSEL: Yes, this was where the Implementation Panel felt that we could make this a little tighter. They didn't think that it made sense to include this as a separate initiative.

So I want to move this along. A show of hands for those who would accept the deletion? So this is the alternative that is on the table, that we would delete this objective, merge the idea into the first long-term objective.

Those in favor of deleting this, hands up.

Those who want to go back to the original language, hands up.

So the addition carries, and we will delete this objective.

There are two other additions here: identify the ways to increase awareness among the autism spectrum community of the potential value of brain and tissue donation to further basic research, but there is no cost estimate for that yet, and launch human and animal studies that examine immune, infectious, and environmental factors in the occurrence of ASD.

Comments? Do you want these added in? Are these things that are already covered elsewhere? Is there value here?

Alison?

MS. SINGER: I thought the identifying ways to increase awareness of the importance of brain donation is important.

We have seen in our research that there is an awareness issue with regard to people thinking that brain tissue was included when they become an organ donor, and in fact it is not. So there is some work that could be done there to potentially increase the number of people who make donation.

DR. INSEL: Other comments?

DR. KOROSHETZ: Yes, I would agree.

DR. LAWLER: This is Cindy Lawler.

DR. INSEL: Cindy?

DR. LAWLER: I think the second addition will be covered sufficiently under objective three. So I would recommend not including that.

DR. INSEL: Okay. So let's take on the first one around, we'll call it, tissue awareness, donation awareness.

All in favor of including this in the plan, let's see a show of hands.

And those against including it?

So this will now be included.

What about the human and animal studies that Cindy suggests are going to be showing up later?

Question?

DR. HANN: So with that addition of the identifying awareness -- this is Della -- so with that addition, there will need to be some way to estimate cost as well as number of years.

DR. INSEL: I don't think that is going to happen right here right now, but we will get some addition to that offline.

For the human/animal studies, whether to include it as a short-term objective in this area, in favor?

Opposed?

So this one will not be included in the plan.

The long-term objectives, this is where we now add male and female children. I think someone asked, "Are there any other, kinds?"

(Laughter.)

So there may be a way to word this that just emphasizes that female children need to be part of the studies.

Comments on the change in wording here?

(No response.)

If we could improve the wording so that it just somehow clarifies that, maybe parenthetically, something like "including females" --

MS. BLACKWELL: Could it say, "with a special emphasis on females", Tom, or something like that?

DR. INSEL: Right. I see a lot of heads shaking. So let's assume that the wording will be changed to reflect a special emphasis on females.

I see no other changes for this section, but someone else may see one that I'm not picking up.

Then there is the addition at the bottom of the list: "Launch human and animal studies that examine immune, infectious, and environmental factors in the occurrence of ASD."

Again, we don't have a cost estimate for that, but comments on that addition?

DR. BATTEY: Yes. I think Cindy's argument applies here as well. This will be adequately addressed elsewhere in the plan.

DR. INSEL: Okay. So comments about that?

Lyn?

MS. REDWOOD: I agree, but can we be sure that it is addressed elsewhere in the plan when we go through the remaining sections? Because I think this is an important initiative and I just want to make sure it is spelled out the same way.

DR. INSEL: An even better reason to move on quickly, so we get to those other parts of the plan.

So can I get a vote then on these two, on the motion which would be to change the language to say, "an emphasis on females" in the previous paragraph and we will delete this addition, and we'll go back to the original language?

In favor of those changes, hands up.

Those opposed?

Okay, that motion will carry.

We are at 11:30. This is the point where we had agreed that we would stop the process of discussing the strategic plan.

We have two presentations, one on updating the strategic plan, but I would recommend that we don't talk about that until we actually have this completed. So we are going to table that discussion.

We have also asked Paula Durbin-Westby to talk to us about ethical concerns in autism research, something that has come up here.

Let me make a suggestion that we --

I think it is important that we get through more of this. I also think that it probably would be helpful for us to take a break to hear about something other than the choice of words in this plan.

How about if we stop at this point, go to Paula's presentation, and we can then break for lunch?

Is there a way that -- Ellen and Lee, can we take some time in the afternoon? Or how would that work with your schedules?

MS. BLACKWELL: In a word, no. We have a really busy schedule this afternoon, and we have brought in a lot of folks.

Lee, do you have anything to add?

I think people are really tight this afternoon.

DR. INSEL: Lee?

MR. GROSSMAN: Well, I think there's a lot of work that needs to be done here. We did in bring speakers here that have given up their time. I think, in deference to them, that we have to respect that.

I don't understand, or maybe there's some other reasons, why that we have to adjourn at a certain time. I mean if it means we have to go longer, we go longer. We can cut lunch shorter and do some other -- rework the schedule. As far as I'm concerned, if we have to be here all night, I'm here already.

DR. INSEL: What's the wish of the group? How do you want to proceed?

I know people are eager to get this finished. Chapter 6 is a quickie. So that won't take us a long time. But 3 and 4 are still to come, and they are major.

I think it would be a mistake not to address those as soon as possible, but I am also aware that we have invited Paula. I think it is important for her to have an opportunity to speak.

So there's not much time. There is an hour lunch break. We could go grab things quickly and bring them back and work through lunch. Then if we started at either 12:45 or 1:00 with the Services Subcommittee, we may be able to get a little further through this.

I must say that if we're not going to finish today, I don't want this to go on forever. So if we are not going to do it today, what I want to think about with you is how we can get together over the next couple of weeks to be able to get the rest of this completed. December is never an easy time for people to get together, but I don't want this to drag on into January.

What's your pleasure? Ideas about how to proceed?

DR. TREVATHAN: Very short lunch. Those of us who don't live in Washington don't have the luxury of staying all night, and the flights out of D.C. on Friday afternoon, Friday night, are pretty limited. We will be stuck here all weekend, some of us, if we don't get out. So I think we probably should cut lunch and cut whatever we can to get done.

DR. INSEL: Lyn?

MS. REDWOOD: Tom, I would also support another meeting. I'll come back anytime, any day, to get this done. I think it is important to get it done by the end of the year.

We could possibly do this via a webinar, like we did some of our other meetings that were very successful. But I don't want to lose the momentum we have going today and I don't want to lose all the wonderful insight from the Committee members.

DR. INSEL: Yes, I think heads are nodding here. I think everybody would agree with you about that.

So let's do this: why don't we have Paula do her presentation now? We may want to abbreviate that a little bit.

We will quickly grab something to eat, and maybe we could have people bring things back here rather than hanging out in the cafeteria for that hour.

We will take on Chapter 3 over lunch, and, Lee and Ellen, we will still get to your program on time. We won't finish this. So we will still have to come back, but I would like to get more of it done today. Okay?

Paula, it's all yours.

You can sit here. What would you rather do? You can manage the slides from here. It's up to you.

It will take a moment to get the slides up.

So let me introduce Paula, whom some of you have met before. She is a member of the Board of Directors of the Autistic Self-Advocacy Network.

You've heard various comments from members of the group in the past. Some of their points have shown up in the strategic plan as well, and we have discussed some of them today.

But we felt in meetings that we have

had offline that this is a group that hasn't had a seat at the table, and they wanted to make sure they had a chance to be with us at some point in this first year of the IACC.

So we are going to have them have a few minutes before we can get back to talk about the plan.

MS. DURBIN-WESTBY: Can you hear me okay?

I'm Paula Durbin-Westby.

The Autistic Self-Advocacy Network is an international nonprofit organization run by autistic self-advocates. Our focuses include public policy advocacy, community-based research, social support groups and other initiatives.

The Autistic Self-Advocacy Network is here today representing the International Autistic Self-Advocacy community's concerns about research ethics for autism. In general, we are pleased to see language in the strategic plan that focuses on community settings and services research funding. We have additional ethical concerns that should be addressed in the strategic plan.

Among the most important ethical concerns are these: expanding the focus of research to the whole individual, including a lifespan focus and a more balanced view of autism spectrum conditions, additional members on the Interagency Autism Coordinating Committee, quality-of-life issues, inclusion of people on the autism spectrum in all aspects of research, and funding considerations that have an ethical impact on the overall state of autism research.

In addition, there is an ongoing concern with the lack of mention within the strategic plan itself of potential ethical conflicts in genetic research, although I saw some of that put in today, including eradication of autism and possible unintended or detrimental effects of genetic and pharmaceutical therapies.

Expand research to the whole individual across the entire lifespan. Ethical research will value and, therefore, address the entire life of the person with an autism spectrum condition, including individuals of varying abilities and disabilities.

Contrast the all-too-prevalent devastating disorder rhetoric which is not limited to any particular subset of people on the autism spectrum, and with literature about other disabilities where there is more of a positive lifespan focus. For example, the ARC of the United States asserts, "The ARC is devoted to promoting and improving supports and services for all people with intellectual and developmental disabilities."

The National Institute of Neurological Disorders and Stroke refers to cerebral palsy not as a devastating or puzzling disorder, as so much of the material in published autism research does, but asserts, "Cerebral palsy isn't a disease. There is no cure of cerebral palsy, but supportive treatments, medications, and surgery can help many individuals improve their motor skills and ability to communicate with the world."

While NIMH and the IACC are obviously not first and foremost service-delivery organizations, the goal of all scientific research into any disabling conditions should ultimately be the application of that research to real-life situations in ways that directly benefit the subject of that research.

People on the autism spectrum are a major stakeholder group. Yet, it is felt by many that autistic adults have been effectively excluded from the process by virtue of our organized constituency not having had a seat at the table.

The strategic plan should remain open to additional changes until the issue is addressed and more members on the autism spectrum are appointed to the work groups and the IACC itself. If the one member on the spectrum is absent during voting and discussion times, the concerns of people on the autism spectrum may not adequately be represented.

In addition, include autistic adults who have perspectives other than prevention and cure. We are an important stakeholder group, and recognition of our concerns and policy goals must be included in any ethical undertaking.

Quality-of-life issues: although the domains here are aspects of quality of life in regards to health according to international standards, with only about 1 percent -- that's a May 12th figure -- of the NIMH budget for the year 2008 devoted to the quality-of-life issues, which are priorities for anyone on the autism spectrum, they will remain unfunded or underfunded.

Ethical research will study areas valued by people on the autistic spectrum; for example, employment, education, societal attitudes, economic and health disparities.

One among a number of models for including people on the autism spectrum in research projects is community-based participatory research. There are other models as well.

Ethical research seeks to understand firsthand perspectives. That is, people on the autism spectrum themselves should be asked about their lives, experiences, opinions, values, rather than primarily having others speak for them.

In addition, we do not find it ethical for the research community or the professional community to treat autism like it is just a disease or illness. Autism is a developmental disability and not a condition that stands alone. Autism is often discussed in a quite different manner than other developmental disabilities are, as I already mentioned.

Researchers and community partners each contribute their own strengths to a project, as seen in this diagram. The academic/autistic spectrum partnership in research and education is one example of a community-based participatory research team. Their current research focuses on improvement of healthcare and healthcare access for adults on the autism spectrum.

The May 2008 figure that I had of 1.6 out of $127 million toward research and to support some services across the lifespan is a somewhat disturbing statement about the priorities of NIMH and the private organizations that partner to fund research.

Choice of topic studied is driven by funding. If little funding is available for research that can have an immediate impact on the well-being and life chances of individuals on the autism spectrum and support of their families and the community, researchers will turn to other areas where funding does exist and away from the research that might make the most difference in the lives of individuals.

We consider supports and services research to be of utmost importance to people on the spectrum. We, therefore, urge a shift of funding away from a narrow focus on causes, cures, and the recovery concept, which has been shown to be invalid in other populations once thought to be curable, such as homosexuals.

The focus should be on maximizing skills like communication and not on reducing autistic traits, especially when those traits do not seem to be well-understood by non-autistic researchers or the general population as of yet.

Move, instead, toward a focus on services and supports, including alternative and assistive communications technology and affordable communications technology, which will be much more effective for a larger number of people on the autism spectrum.

We also urge replacement or removal of language regarding cost impacts or burden on society. Since true costs are often in terms of an inaccessible society, a comparison would be saying lack of employment among African-Americans means that their presence somehow costs society.

Change sometimes comes in the form of laws that attempt to change inequalities in the structure of society. In the case of people on the autism spectrum, societal changes come in the form of effective service delivery and supports.

We request removal of prevention-oriented language and goals in general throughout the strategic plan. Funding, services, and supports might, indeed, be more cost-effective than a focus on funding used to prevent what in all likelihood may be a legitimate part of natural human diversity.

This presentation is a collaborative effort between the individuals listed above and a number of other members of the autistic community and non-autistic supporters.

Thank you for your attention.

Are there any questions? Do we have any time for questions before lunch?

DR. INSEL: Or comments? The floor is open.

Paula, I think you wowed everybody. Either that or it's lunch calling. But I don't see a lot of questions, a lot of hands going up.

Thank you very much for joining us for this. You have picked the worst-possible day to do this because there's so much else on the agenda, but I think it is helpful for us to hear your comments, especially at this point in time when we are trying to close the loop on many of these issues in the plan that are relevant to what you have just been talking about.

So we appreciate your joining us for this and for representing your colleagues from the Self-Advocacy Network.

I believe it is time for us to take a very abbreviated lunch break. What I would like people to do is to race down to the cafeteria, pull something out of there if you can, if you must, and come back as quickly as you can, so that we could start within about 10 minutes.

(Whereupon, the foregoing matter went off the record for lunch at 11:48 a.m. and went back on the record at 12:12 p.m.)

A-F-T-E-R-N-O-O-N S-E-S-S-I-O-N

12:12 p.m.

DR. INSEL: The first item that shows up here is on page 1, line 16, 15 and 16.

We are having a little bit of technical trouble with the webinar. We will get this back up in just a moment, but I will read through this, so that people who are listening in know what we are talking about.

We are at the very beginning of Chapter 3, "What caused this to happen and can this be prevented", under the section, "What do we know?"

The first sentence, "As with many complex disorders, causation is generally thought to involve some forms of genetic risk interacting with some forms of non-genetic environmental exposure."

There's a parenthetical comment there which includes not only hormonal and reproductive factors and paternal age, which had been in the original version, but it now adds, "the maternal age", deletes "birth weight", and adds "dietary factors, medical exposures", and then several other items.

Comments about that?

DR. KOROSHETZ: You could just use parental age to get both maternal and paternal. They are both important.

DR. INSEL: Is there good evidence for maternal age being a factor? The Israeli study only found paternal age and not maternal.

DR. KOROSHETZ: Yes, but two recent studies, one from Kaiser and another big one, showed both.

DR. INSEL: Right. So there's the Bierman work that the maternal age effect is very weak. It is, again, mostly paternal. But I would agree that, in the absence of evidence, that making it parental age would be one way to handle this.

In terms of the others, does someone

want to explain medical exposures? Does that mean thalidomide or what does that mean?

If we don't have a good explanation, it is hard to defend making the change.

And dietary factors?

MS. REDWOOD: Tom, I would think that other things that have been under investigation, like possibility of ultrasounds or in vitro fertilization --

DR. INSEL: So you think that's what medical exposures means?

MS. REDWOOD: I don't know. I am just tossing out things that we assume are safe that might have some consequences long-term.

DR. INSEL: So I just wonder if we need to find a different term, since that wasn't clear. I notice somebody else wrote in as well that they didn't know what medical exposures meant. Is there a better term for that we can come up with?

(No response.)

Again, since this is parenthetical and it is simply examples, maybe if we were to say, "and other exposures", leaving it open.

I do worry that medical exposures, since I thought it meant thalidomide, and other people will think it means other things, it may be misleading. As with dietary factors, whether it is worth simply keeping this less specific and whether we would be better off with a more generic approach?

Any other discussions about that?

MS. REDWOOD: I just worry that with a generic approach that things might be overlooked. I think if you get some clues, like "plus other", but at least put some of the things that are high on the radar screen for potentially being problematic.

DR. HANN: This is Della.

This is part of a set of examples. So it is an "e.g." It is like "such as". So we have hormonal and reproductive factors. I hear parental now as opposed to the two. You are discussing dietary factors, medical exposures, stress. We could always add an "etc." at the end of the toxicants to say that there's many that could be considered, but this was just a partial listing to give examples of the types of things you all were considering.

DR. INSEL: Lyn, I agree that there is some value in providing examples. I also worry, though, about constraining possibilities by providing examples. So I think you want to find some balance.

Sometimes when you put in too many things, it actually becomes a list that is constraining rather than opening up possibilities that we are not currently thinking about. So I wonder about actually limiting this more rather than putting in too many things.

I believe that the one environmental effect or the one non-genetic effect, and maybe it is genetic, where we have extremely good data now from three or four different studies, is parental age, where the risk goes up 17-fold for girls with autism. So that would be one that one might imagine, although it is not clear that that is truly environmental exposure.

What is the sense of the group? How do you want to -- because the wording here, one option would be just to take out all the examples. The other would be to list a couple and say, "etc."

Jim?

DR. BATTEY: Yes, I would favor taking them out, because paternal age really isn't an environmental exposure. It's paternal age or maternal age.

DR. INSEL: Other thoughts or ideas here?

MS. BLACKWELL: I wasn't even sure what a medical exposure is.

DR. INSEL: Yes, we just talked about that. We are still trying to figure it out.

Walter or anyone else?

DR. KOROSHETZ: I would go without the list, I think. It is just too hard to do.

DR. INSEL: All right, so there are three possibilities: delete the list, go back to the original list, or the third possibility is to add in "maternal age, dietary factors, medical exposures, as recommended".

Can I get a show of hands for who would delete the list altogether?

Who would go back to the original?

Okay, so that idea has carried. So it will just say, "environmental exposures", and we are moving on.

The next change is "may or may not vary with severity", and there was a comment there. I think, Ellen, you weren't sure. You said this doesn't make sense. Severity of exposure, severity of symptoms, it wasn't clear what they were referring to.

DR. HANN: Just to clarify, this one

I do remember. This is severity of ASD. That is what they were referring to.

MS. BLACKWELL: So you are saying it refers to the severity of the symptoms, of how the autism impacts the individual? Okay. I think we just need to put something in there to clarify what it is.

DR. INSEL: Any other comments about this?

If we added that to it, "may or may not vary with the severity of symptoms", is it useful to have this in or is it simply more wording?

DR. BATTEY: Well, most "may or may not" statements don't add very much information because either they do or they don't, right?

DR. INSEL: You mean they do or they don't add information?

Okay. So in favor of including this with the addition of severity of symptoms? In favor of including the addition?

And those who would delete it and go back to the original?

So we are going back to the original.

Moving on to the second page, top of the page, there is the first discussion point. There is an addition from the public. "Yet, progress in identifying robust susceptibility genes has been slow, further highlighting the complexity of ASD."

Is that something we want to include? Comments?

DR. KOROSHETZ: I don't think it's true.

DR. INSEL: Walter?

DR. KOROSHETZ: I mean I wouldn't include it. I don't think it is true. I think we have made a lot of progress in identifying susceptibility genes. So I think it is actually a big plus to what happened the last couple of years.

DR. INSEL: Other comments?

DR. BATTEY: Yes. I agree with that. Two or three years ago, that statement would have been a true statement, I think, although there may not, in fact, be any robust susceptibility genes to identify. It may, in fact, involve allelic variation in a lot of different loci, in which case none of them are necessarily robust.

But if you look at the progress made within the last six months to a year, using the whole genome association studies, the progress has really been quite impressive.

DR. INSEL: Any other comments about this or thoughts about is it worth including this comment?

(No response.)

Let's go ahead and put this to a vote.

In favor of the change, can I see a show of hands?

Going back to the original?

So we will delete this comment and

back to the original.

There is an additional comment at the bottom of this paragraph. "However, what causes this spontaneous deletions and duplications is not clear and possibly could be due to environmental exposures."

Comments about that?

DR. KOROSHETZ: I was trying to think of what they were thinking, but I think if it is the idea that it could be related environmental effects that affect the sperm and the egg or something in utero, that would be possible.

DR. INSEL: Yes. Well, what I interpreted this to be was that we know that there are these now de novo large-scale structural changes in the genome that are about ten times more common in children with autism and potentially in adults with autism as well; we just don't know that yet.

Those are meiotic events. They happen most often through something that has taken place in male sperm.

So what they are recommending here is that this could be due to an environmental exposure in addition to male paternal age or something like that.

So other thoughts about this? Actually, I think the hot area here is to look at piRNA, which seems to be the key for taking these things out of the spermatogonia, and it fails in some cases.

So issues about whether to include or exclude this phrase?

DR. KOROSHETZ: I would include then, yes.

DR. INSEL: Okay. Those who would be in favor of including the wording here?

And those who would go back to the original?

So we will include this additional sentence at the bottom of this paragraph.

Now, Lyn, you have a whole section here. It is hard for me to tell, because of the coloring, how much of this is the same or how much of it is different.

So, Lyn, yes, you will need to use your microphone.

MS. REDWOOD: Tom, the part in green is new suggested text, and the part in black is the existing text, if that makes it easier.

DR. HANN: Except for the phrase, "high priority for discussion". That was something else on your thing, right?

MS. REDWOOD: Oh, I'm sorry.

DR. HANN: Yes.

MS. REDWOOD: That was supposed to be over in the other column.

DR. HANN: Yes.

MS. REDWOOD: This, again, goes back to saying that a lot of the genetic research has not been that fruitful and we still have not identified this susceptibility gene, despite all the money --

DR. INSEL: So the first part of that I think the group voted clearly against.

So we are down to the middle and the lower paragraphs. I am trying to just see how it fits with what is there.

MS. REDWOOD: It is pointing out, Tom, that some of these studies that point toward a highly heritable disease are based in older studies in twins, and that that data may not be as accurate today because it was prior to the increased numbers --

DR. INSEL: If I can just interrupt, we have the most recent data still not published from the largest study ever done at Stanford by Joachim Hallmayer, 130 monozygotic pairs, as well as a whole series of dissects, and the data are really better than ever.

I know this isn't available to the public. It is a project that we fund, and he has been willing to share the data with us. He has done such careful phenotyping out of the California birth registry and the twin registry; I just can't imagine that that won't make it even more likely that there's a very high heritability here, certainly higher than any other of the complex genetic disorders that we think about, like diabetes or asthma.

So I guess the question is, does the group want to include any of this language in the text now?

DR. TREVATHAN: Tom, there is so much. Can you specify exactly what part of the text we are voting on?

DR. INSEL: This is in the pages that you have on the side --

DR. TREVATHAN: Right.

DR. INSEL: -- and it's --

DR. HANN: Page 8.

DR. INSEL: It connects with page 8.

DR. HANN: Well, it is also in the --

DR. INSEL: I'm sorry.

DR. HANN: Right. What page do you have?

DR. INSEL: Page 5.

DR. HANN: Five, okay.

DR. INSEL: Yes.

DR. HANN: Page 5. Sorry.

DR. INSEL: So there are two paragraphs. There are three paragraphs. The first one I think we have gone ahead and voted against. The second two are variations on what's there, talking about new technologies that reveal gaps in extra copies.

I guess the question is whether this really adds information to what we now are looking at or whether it is highly specific and maybe more specific than we need to be for this introductory section.

And to my way of thinking, the key point is the first line in the third section. "However, what causes these spontaneous deletions and duplications is not clear and possibly could be due to environmental exposures." And you just voted to include that. So the only question that remains is whether you want to include the rest of it.

So can I get a sense from the group?

Those who want to include this extra language, could I see a show of hands?

Or those who want to go back to where we were?

We have include the first line, but not the rest of it.

DR. HANN: Actually, I think the rest of it is picked up somewhat in the next section, in the next paragraph.

DR. INSEL: Oh, you know what? It is my mistake. You're right. So it actually goes into the next section. So I don't think we even need to -- if I am looking at this right, I don't even believe we need to vote on it.

Lyn, what you have done, you have actually given us the language that is here with I think one addition.

Can I suggest that we just continue to move on, and if people feel that there is anything in this additional part that they want to insert, they bring that up?

Okay, then maybe the easiest thing is to vote on it.

Those who want to make any additional changes based on this suggestion, can I see a show of hands?

And those who want to keep moving?

All right, so we will go back to the original language with the exception of that line about environmental causes for de novo mutations.

We are moving on to page 4, because there is nothing for page 3.

You can see at the top that it says, "Research on environmental risk factors is also underway" instead of saying, "less developed". Then we go down to the next discussion point.

By the way, let me just see if you agree with that language, or do you want to go back to the original?

Okay, to change it to be "also underway"? Show of hands for that change?

Those against?

The motion passes. So we will make that change from the public.

Now under discussion point 3.2, "These data as well as subsequent research indicate that the link between autism and vaccines is unsupported by the research literature. Some do not agree and remain concerned that ASD is linked or caused by vaccination through exposures...." -- and you can read the rest of this.

Well, let's just take that piece of it first. How are you with that additional language? This was one of the attempts to try to provide the diversity of opinion, knowing that this is a place that we are not going to be unanimous. Actually, there have been a lot of places where we haven't been unanimous, but this was one where we felt it important to give a flavor of what the public input had been.

Cindy?

DR. LAWLER: I think it provides a fair description of the sentiment around this issue. So I like the idea of including differences of opinion on this. I would support the rewording.

DR. INSEL: Now Lyn has also provided quite a bit of wording which is shown in this attachment. So it is not integrated because it just came, but you should take a look at that additional language and see, because that would be an alternative to what you have in front of you.

Are there other thoughts or comments about this?

Lyn?

MS. REDWOOD: Tom, there were actually several -- there's actually four areas in here where I had proposed alternative language. I know when you sent out the request to the Committee, you offered us that option. So I took advantage of it.

DR. INSEL: So do you want to take

us through that, what you would like to see in here? Then what we can do is come back and really have three options, going back to the very original version, the version that is on the second column up here, and then what it is that would be in a third version that you are suggesting.

MS. REDWOOD: Well, there's four different areas where I had suggested language be added. The first one, which starts with, "The high priority for discussion: progress in identifying susceptibility genes has been made possible due to collaborations and resources, both public and private.

"Progress in identifying environmental factors which increase autism risk has also been made through this area of research and has been chronically underfunded."

This was information from when you reviewed over the research matrix a few years ago and identified the environment as an area that was underfunded.

"How existing research resources and toxicology could be tapped into to provide important infrastructure for studying some forms of environmental risk while other resources need to be created.

"Environmental risk factors may be pertinent not only to brain development, but also to chronic systemic features of at least some subgroups of ASD, such as inflammation and oxidated stress."

That was the first addition of language.

The second language was from the Institute of Medicine Workshop that was held in 2007, which summarized what is known and what is needed in the field.

One of the things that came out of that workshop that was discussed was mercury being identified as having a potential role in autism. These came from several studies, Palmer, the Windham study, DeSoto and Hitlan, Holmes, and it was a finding that received support in animal studies as well and in the general literature of mercury effects. So I inserted that.

The third insertion comes after the reference to the Immunization Safety Review Committee report that says that the epidemiological studies had found no relationship between ASD and vaccines containing the mercury-based preservative thimerosal.

What I added here, Tom, is actually in the report. However, the report also acknowledged -- and I could put quotes here; I took out the quotes -- population-based studies would not be able to detect subpopulations that could be genetically more vulnerable to mercury at lower doses than normal. The majority of children with these genetic susceptibilities would dilute out the minority of susceptible children, and that the Committee actually recognized this line of reasoning as a theoretical explanation for the data presented in the report.

So it was a caveat that was on like page 64, buried in the report. I think it is important when we look at susceptible populations. So that is why I added that in there.

There is also some more clarification with regard to looking at vaccines in the next part. "Many remain concerned that ASD is linked or caused by vaccination through exposure to thimerosal, the measles, mumps, rubella vaccine, imposing challenges to a weakened immune system, or possibly due to mitochondrial disorders.

"Congress has expressed a wish for studies on vaccines, mercury, and autism to be continued", and this came in the report language that was attached to the combating autism bill. So that is why I added that in there.

Also, the addition, "Recent studies

suggest factors such as paternal age, maternal age, mothers potentially exposed to rubella whose children were born in the 1960s during the rubella epidemic." That was the only other suggested added language.

DR. INSEL: Comments?

(No response.)

Now, remember, this is the section on "What do we know?". There is another section coming up on "What do we need?", but this was trying to capture what there would be mostly agreement about.

Discussion?

MS. REDWOOD: Tom, one other thing is that there have been several studies since the Institute of Medicine study in 2004 that have found associations between thimerosal-containing vaccines and adverse neurodevelopmental outcomes, like ADD, ADHD, autism. So the 2004 report is somewhat dated.

Those were not referenced in the strategic plan at this time.

DR. INSEL: Further discussion?

DR. TREVATHAN: I think one of the questions at this point is how much detail to put into this introduction. I mean there's very obvious on this Committee difference of opinion of what the science is telling us. I think that a lot of us would take an opposite view, that the bulk of the evidence actually shows there isn't a relationship between MMR, thimerosal and autism, and that that's actually the bulk of the scientific data out there.

I don't think we are going to come to an agreement on that at the Committee level. I think the question is how much of that debate needs to be in here, I think especially given the fact that there is an Immunization Safety Review Committee and a whole other group of folks that are looking at vaccine safety research. This issue is part of that mandate; whereas, we don't really have, we haven't had the experts in vaccine safety research on our Committee.

So it seems like a strategic point, and I thought we would address this, actually, before. Is this IACC doing vaccine safety issues or that we need to leave that to the vaccine safety committees?

DR. INSEL: So for this part of the plan, because we are not even close to the initiatives -- it is just trying to capture for many audiences what do we know, and in those areas where there is real disagreement, laying out what that disagreement might look like.

So let me suggest that we've got really three choices. We can go to the original language which doesn't reflect the diversity. We've got language that came from the public comment that sort of represents both sides of the argument, saying that everybody thinks they know, but, in fact, there's real differences of opinion. Then there's the third option which Lyn has provided, which is a lot more detailed, and to be fair, I think both sides of the discussion, and what the references might be, to get more information.

So unless there's further discussion, I would like to go ahead and put this to a vote and see what people want to do.

The first option would be the original version of this, which is in the lefthand column.

Those in favor of going back to that or retaining that?

DR. LAWLER: So are we voting on all of these additions? Because Lyn has proposed four additions in this paragraph. So it might be helpful to go through each of them because --

DR. INSEL: Well, we could do that, but --

DR. LAWLER: As one example in the first one, "Progress in identifying has been made...." --

DR. INSEL: Can I interrupt for a second?

DR. LAWLER: Okay.

DR. INSEL: We could do that. It is going to take us the time we have left if we start to do that. If the group really is satisfied with the other option, which is what is in front of us in the right column, I don't want to spend the time going through each line of the potential additions.

So if it is okay with you, let me get a sense of the group. If people feel that they like pieces of Lyn's to be integrated in, then why don't we ask if that is the option that you -- we will make that a fourth possibility, and then we can go back and we will spend the rest of the time working on that. But that is as far as we will get today.

DR. LAWLER: I just want to make one comment. I think this is well-supported. We did do a fairly comprehensive evaluation of the research matrix, and there was consensus that the role of the environment really had been sort of underrecognized and sort of understudied. So I would agree that is folded into her first comment. So I don't think that is really very debatable. I think we have got good backing for that part.

DR. INSEL: Right, but doesn't that sound like the point you would put in; you lead with that under "What do we need?" rather than "What do we know?"

DR. LAWLER: Okay.

DR. INSEL: Okay. So we've got three options?

DR. HANN: Four.

DR. INSEL: Four options.

DR. HANN: There are four options.

DR. INSEL: Okay.

DR. HANN: One is the original.

DR. INSEL: Who wants to continue the original language?

We've got one vote there.

Who would go to the language in the right column?

And then who wants to consider -- well, is there a point --

DR. HANN: Could you please hold your hands up again, please? Thank you. For the second?

One, two, three, four, five, six, seven, eight, nine, ten.

DR. INSEL: Do we need to go on?

DR. HANN: No.

DR. INSEL: Okay. So we're going to move on to further down the same paragraph --

MR. GROSSMAN: Tom, I know we voted on this, and I did vote favorably for it. I don't want to do it here, but I think that some of the wording here could and should be changed though. I would like to defer that. If we are going to meet again, that this is a point for further discussion to clean this up because, even though I did vote for it, I am still very uncomfortable with just kind of how it rolls out because I don't think it is truly reflective of how many people feel about this.

I guess that was one of the understandings, that we were going to meet again. I would like to have that.

DR. INSEL: Well, Lee, I think rather than coming back to it, because I was hoping that whatever we do here, we can move on from here. So let's take a moment and figure out what part you are uncomfortable with, and we can figure out a way to address that. If it is simply wordsmithing, we can maybe do that very quickly.

MS. REDWOOD: Tom, part of this isn't even accurate. I guess that is the problem that I have with it.

When it says that, "These data, as well as subsequent research, indicate that the link between autism and vaccines isn't supported by the research literature", there is research literature that supports a link, and that's not being acknowledged. That is not a balanced statement, and it doesn't cite at all the research literature that does support a link. Then it just says, "Some do not agree", but it mainly appears like it is "some do not agree" in parens, however.

So I think to be fair and balanced, you need to cite both the literature that does find a relationship and the ones that don't.

MR. GROSSMAN: Yes, and what is cited here through the exposure to MMR, for example, is very limiting because you can't address the concerns that people have just by that short clause there.

MS. REDWOOD: And this is hugely on the radar screen of the public, and I think not to acknowledge this in a balanced way does a real disservice to all the public comments we have received on this issue.

DR. INSEL: Well, we have received public comments on both sides. I must say it is striking, the number of comments that implored us not to get into this issue and made it very clear that vaccines have no place at all in this report.

So this was an attempt to try to speak to both issues. As I said at the beginning, we are not going to find -- this is an area we are not going to find common ground, but the report can reflect both perspectives.

I'm not sure I quite understand your comment, Lee. So are you saying that the MMR mention is too specific or it is too --

MR. GROSSMAN: Yes, I think it is just not a broad enough statement, and we don't have to get into specifics. When we look at the rest of the document, this is just kind of an overall global picture of what caused this to happen and can this be prevented.

The less specificity that we can put in this document, except for short- and long-term objectives, I think the better.

The argument that people are out

asking us to avoid this topic altogether, well, we can't, and it is not being avoided here. So I would rather, if we are going to address it, let's address it in a way that reflects fairly both sides.

I'm not sure if this truly reflects the strong ideas or points of either side, but I think that it doesn't do justice to either argument. So, to me, it is just all very confusing, and I think it just can be cleaned up, which is why I was suggesting, if we are going to meet again, I think just a little bit of wordsmithing and we can get this so it satisfies all, because right now it is just in there. I can tell you it is going to be a bull's eye for a lot of people to come after.

DR. INSEL: Well, I think it is a bull's eye no matter what. I mean this is clearly a place where we got a huge amount of public comment and there's a lot of passion on absolutely opposite sides of this issue.

We don't do this -- it is not a

political question; it is a scientific one. So it is not going to be done by how many public comments we received on either side.

What I would suggest is that, if you think this needs wordsmithing, we not do it later, that we come up with language now. Because once we have made an agreement here, this isn't changing unless we come back and revote on it all over again.

So if what you are suggesting is that we put in language that is less specific, we can do that, and we can agree to do it right now, if you think that would be helpful. It might be simply ending the sentence with the word "vaccination" and not going into any specific vaccination or any particular relationship to the immune system.

I'm not sure if that is what you are saying though.

MR. GROSSMAN: Yes, I'm not sure what I am saying either because I am not taking a position on either side of this issue with this. It is just the way it sounds just doesn't seem to be clear enough.

To ask me to come here and reframe it right now, it is just not going to be possible because I am probably going to come up with something that is equally as confusing as this appears to me right now. That is why I was suggesting just to table this one section because it is important to a later discussion when we are looking at the other when we come back as a group.

I mean I will support whatever the decision is of the Committee. I am just stating what I feel, that it is just very unclear and it doesn't seem to be truly representative of both sides.

MS. REDWOOD: Tom, I just have to reiterate again it is not accurate. There are studies, and the way this reads is that it is completely unsupported by the research literature, and that is just not true. I will be glad to provide the studies.

DR. LAWLER: So how about we could say, "The weight of available evidence does not support a link between autism and vaccines. Some do not agree and remain concerned that in susceptible individuals ASD is linked or caused by vaccination."? Then in parentheses give some examples of "e.g., through exposure to MMR or mercury in thimerosal-preserved vaccines". That would make it more general, but it may be sort of other features of vaccination there's still concerns about.

It puts in there the susceptible subpopulation issue because I think that is critical to the concern.

MS. REDWOOD: Tom, also, the studies that were relied on by the National Academy of Science were all these large epidemiological studies, three of them done in Denmark, funded by the Statens Serum Institut as a for-profit vaccine manufacturer.

Also, NIEHS actually looked over the

VSD database published by Dr. Verstraeten and said that the database couldn't be utilized to even ask that question; it was an administrative database. There wasn't links to the records.

So there's been a lot of investigation since that time that has really created more questions than answers. It is not reflected here in the way it is worded.

DR. INSEL: Is Cindy's wording helpful in finding some common ground?

Cindy, do you want to -

DR. LAWLER: Yes, something like, "The weight of the available evidence does not support a link between autism and vaccines. Some do not agree, however, and remain concerned that in susceptible individuals ASD is linked or caused by vaccination". And then --

DR. INSEL: Stop right there.

So does that provide the balance we are looking for?

MS. REDWOOD: I guess I have a problem with "weight" and how you apply weight to something. I think the more recent research is finding problems. So I think it should be that more current research or developing research has found links.

DR. KOROSHETZ: I think we are not going to get consensus in terms of the weight of the evidence. I think there's been recent studies that show thimerosal has not any effect on brain development. So I think it is a complex area and there are lots of people doing different things, reporting different things, but the absolute weight of the evidence is that there is no tie-in. I think it is important to state that here because it has import not just for autism, but it has got import for the health of millions of kids.

So I think we should say that the "weight does not support". I think we have to be honest and say that there are scientific studies that don't agree with this, because that is the way it always is when you weight something, and that there may be some populations that we haven't gotten to, as Lyn said, because they are going to be swamped by the huge numbers who have specific susceptibilities, like a weakened immune system or mitochondrial.

So I think we can wordsmith it by just leaving the door open, but I don't think we should skirt the issue.

DR. INSEL: I guess, listening to what you said and what Lyn is saying, and hearing Cindy's version, it seems to me that Cindy has given us the language that you are looking for.

DR. HANN: You need to do it again. Go, Walter.

DR. KOROSHETZ: The only thing I have was the date, blah, blah, blah. "It's unsupported by the weight of the research literature. However, some scientific studies do not agree and many are concerned that ASD is linked or caused by vaccination, especially in those with special susceptibilities such as a weakened immune system or possibly underlying mitochondrial disorder."

Is that okay?

DR. LAWLER: I like that.

DR. INSEL: Della, can you --

DR. HANN: I'm trying.

(Laughter.)

DR. INSEL: Okay. We'll get this --

DR. HANN: We had better move on.

DR. INSEL: Well, I don't want to move on until we've got some agreement here because I could see that Lee is uncomfortable, Lyn is uncomfortable.

DR. HANN: Okay, let's just do this one sentence at a time. If we could do this one sentence at a time, it would help me to make sure I'm getting it.

What I heard Walter to say was: "These data, as well as subsequent research, indicate that the link between autism and vaccines is unsupported by the weight of research literature."

I'm stopping there. Okay? I got nods on that one.

Then the next one: "Some scientific studies" -- oh, "however"? Okay. "However, some scientific studies do not agree" -- and we have to have a "people" in there.

DR. KOROSHETZ: "And many remain concerned."

DR. HANN: Well, the studies don't remain concerned, but people remain concerned that ASD is caused or linked by vaccination. Studies aren't concerned.

MS. REDWOOD: The word "parents" is removed.

DR. HANN: Is it just "parents"? That's what I thought.

So let me start over with this sentence again.

"However, some scientific studies do not agree."

DR. INSEL: Now do we actually have that from the discussions we had with our expert panels, with the work groups? I mean if we are going to put in evidence about scientific studies, I wonder whether this is the place and time to do it. At least it wasn't in the original -- I'm just going back to the original language of what we had agreed to before. The language we had was that parents remain concerned, not scientists remain concerned.

DR. HANN: Well, we don't have scientists right now. Right now all I heard was, "However, some scientific studies do not agree." And then I said to put a period after it. I haven't moved on to the people part.

Are we okay with that statement? "However, some scientific studies do not agree."?

DR. INSEL: I think it is a risk to go there unless we have a chance to really flesh out those studies. After you have just said that the weight of the evidence doesn't support this, to then turn around and say scientific evidence does support looks like --

DR. KOROSHETZ: I think studies disagree. I mean there are some reports where they claim that there is something. I mean how do you weigh them is at issue.

MS. REDWOOD: Tom, I guess I am agreeing with Lee. I would be more than glad to prepare a reference sheet and provide all of the research since then.

DR. HANN: You have.

MS. REDWOOD: And if we could come back to this, I can provide those studies and the Committee could review them.

DR. HANN: She has.

DR. INSEL: Yes, but I think we have a bunch of references here. Some of us have been through this literature.

I think there is really a fundamental disagreement here about how people read this literature and the quality of the literature that we are looking at. I can just tell you that there are many people -- and as you saw, a majority of the people around this table, a vast majority, accepted the language that was in here already. So we are going back to revisit it because Lee felt that in some way it was opening us up to unhappiness from some parts of the community.

I don't think we are going to find a way to please everybody in the community. There's no language here that is going to work, except to clarify that there is a really fundamental disagreement both in the way that people interpret the literature that is there and in the way that they feel about the results that have been published so far.

So we could come back to this many, many times. I'm not sure that we are ever going to get to a point where we can get a unanimous decision about this. We don't have it yet, and I am not convinced that we will.

I can tell you that, if we -- well,

let me stop there. We are getting past the time. If we can't reach an agreement, we will come back, but I thought we had an agreement.

MS. REDWOOD: Can we vote on the proposed language that was just drafted?

DR. INSEL: Do we even have -- Della, do you want to go ahead and finish reading it?

DR. HANN: Okay. This is Della again.

I'll start from the top.

"These data, as well as subsequent research, indicate that the link between autism and vaccines is unsupported by the weight of the research literature. However, some scientific studies do not agree. Therefore, some people remain concerned that ASD is linked or caused by vaccination...." And then I had lost the rest of Walter's comments at this point.

DR. KOROSHETZ: "In specific subpopulations with susceptibility related to weakened immune systems or possibly due to underlying mitochondrial disorder."

DR. INSEL: Are we ready to vote on this?

So the vote would be whether to take these additional changes versus going back to the language that we had 10 minutes ago.

So in favor of these changes, the new version, hands up.

Retain what we had 10 minutes ago?

DR. HANN: One, two, three, four, five, six, seven. Seven.

Could you raise your hands again for the new language?

DR. INSEL: New language?

DR. HANN: One, two, three, four.

DR. INSEL: We will go back to where we were 10 minutes ago.

I think, given the time and our commitment to Ellen and Lee, we are going to have to stop at this point on page 4, and we will figure out a way to continue on another date.

But we are now going to move on to the next part of the agenda, which is to discuss the report and update from the IACC Services Subcommittee.

MS. BLACKWELL: Okay, it seems like a good time to change gears here.

The Services Subcommittee met on October 10th. Our minutes are on the new and improved IACC website. If anyone hasn't seen it, it looks much better than it did. Congratulations to the team.

Anne Sperling, who is here today, walked us through a summary of the public responses to our other RFI, the one on services, which Lee is going to talk about for just a very few minutes.

We will be meeting on December 10th to talk more about those responses and how they might inform an updated services roadmap.

In that call we also talked about the agenda for today's meeting and our hope that IACC will continue to be receptive to presentations regarding services and supports at future IACC meetings.

The next Services Subcommittee meetings will be December 10th and February 24th at NIH and on the afternoon of March 26th at the Humphrey Building in Washington.

At that meeting we plan to hear from Captain Robert DeMartino, who is Director of the Behavioral Medicine Division at TRICARE. Dr. DeMartino will be talking with us about the ASD services demonstrations underway at the Department of Defense.

I would also like to note that our guests today include Ann Kohler, who is the Director of the National Association of State Medicaid Directors, and also Nancy Thaler, Executive Director of the -- I have to say this quickly -- National Association of State Directors of Developmental Disability Services.

Hopefully, at some point it would be

great to have Nancy and Ann talk to us a little bit about the state perspective on services and supports.

I would also like to say thank you to our guests today, and last, but certainly not least, the staff of OARC, which has given the Services Subcommittee such great support throughout our endeavors.

So, with that, I turn it over to you, Lee.

MR. GROSSMAN: Azik is going to pull up some slides.

My talk is limited to just reviewing the RFI that we have put through. As Azik is putting up the slides, I will just make some comments here.

I want to thank the IACC Committee for allowing us to proceed with the Services Subcommittee presentations this afternoon. We had many people under some fairly severe conditions come here, and in deference to the speakers here, I think that we had to honor the time that they were here.

I would suggest in the future that, when we schedule the agenda or put the agenda together for the IACC, and when we are discussing issues of such great importance as finalizing the strategic plan, that it probably was not, in retrospect, a great idea to have our presentations today, but they are here.

I also want to acknowledge Paula Durbin-Westby and thank her for her excellent comments. Hopefully, what we are doing in the Services Subcommittee is reflective of the issues that she brought forth, which I think were entirely right on and ones that we intend to follow.

Let's see here. Here we go.

The RFI was put through, and it was the input from everybody in the autism community. We asked people -- we addressed state agencies, private agencies, anybody that is affected by autism to participate in this

Request for Information.

We set the priorities in this to be around issues and concerns of services and supports, and we emphasized those supports being lifespan in their perspective.

In light of the fact that it probably was issued at the second worst time of the year -- the absolute worst time of the year would have the holiday seasons at the end of the year; we issued it during the time that people are normally on vacations and then preparing for the beginning of their school year -- we did fairly well on the responses.

We received 137 responses which addressed 368 various issues. Of those 368, there were 75 research initiatives that were addressed in there as well.

Now the Committee has been tasked with reviewing the responses. The questions and issues that came out, those 368 that were presented, broke down into these various issues, and I won't go through those individually because it would take hours. But this is the task that the Services Subcommittee will be addressing.

At our next meeting on December 10th, we will be looking at all of the responses. In some ways, we will be reviewing even how the responses were framed. For example, education and awareness, although there were 60 questions and issues raised, when you look at how it is framed, we are not sure if it was for education specifically or if it was education of professionals. So we are going to have to drill down much greater into the detail of how these responses came in.

DR. INSEL: Lee, can I ask a question? If you can go back one slide?

So for that range of responses, do you know who was responding? Did people self-identify whether they were on the autism spectrum, whether they were providers or they were family members?

MR. GROSSMAN: Della?

DR. HANN: This is Della.

It was a wide spectrum again. We had organizations that wrote in. There were individuals.

I'm trying to remember, but I am pretty certain that there were also individuals who self-identified as having autism. So I do believe it was across the board.

MS. BLACKWELL: I think we had state representatives reporting in, too.

MR. GROSSMAN: Yes, I think it was, from a cursory glance on it -- we're obviously going to dig much deeper into this on December 10th -- it was a fairly broad cross-section of the community. In the cursory review I did, I didn't see any group as being left out.

DR. INSEL: I was more not thinking that people might have been left out. I am more interested in whether, as you look at that range of issues, whether they will track with different groups, and whether there's actually different concerns about such things as transitions or education awareness, depending on the group you talk to, and whether we are getting that kind of evidence coming out of the RFI.

So, as you look at it, besides just understanding the categories, I think it may be helpful to look at how these different categories track with different parts of the community.

MR. GROSSMAN: Yes, I think the first thing that we are going to tackle is just looking at the categories themselves to see if they were broken out correctly.

Ellen and I raised questions and concerns regarding the first one, healthcare and treatment, because it just seemed as though it was too medically-oriented, whereas some of the responses were coming back in terms of more educational, psychosocial, and behavioral. So they might have all been glomed into that first category.

Again, I have to apologize because we are spending too much time on this because we really haven't done the work on this, and it will be done on December 10th at that first meeting.

Just to conclude this, the primary purpose of this is to update the services roadmap that was done in 2004 and presented to the initial IACC in 2005. Then we are going to come back with those details. I think at the next meeting we will have those particulars worked out and there will be a full report on the RFI then.

MS. BLACKWELL: Can everybody hear me? Yes. Okay. Well, I'm just going to use this, Azik.

I am going to go through really quickly a lot of very complicated slides about how the services system in this country works.

Can everybody see okay?

Generally, services sort of fall

into two buckets, the child bucket and the adult bucket. So there is some method here.

Just for a second I wanted to talk about the history of services in the United States. In the beginning, as most of you probably know, people kept their family member with a disability at home, and it wasn't until the beginning of the 20th century that states decided that it would be a better idea to create large institutions and send people with disabilities to those.

During the 1960s and 1970s, there was really a realization on the part of families and the Congress that it would probably be better to keep people at home and in their community. So some things started happening. Congress passed the Education for All Handicapped Children Act. Congress created a program in Medicaid called ICFMRs, which I will talk about in a minute. Things started leaning a little bit more towards where they are going now.

Many, many more states are closing -- in fact, most states have closed many of their large institutions. In 1981, Congress added the Home and Community-Based Services Benefit to the Medicaid law. All of these things started accelerating and continue to accelerate to this day, keeping people with autism as integral members of the community.

So where does the money come from? These are the major funding streams for autism services. Some of these ones under "government" might look a little odd, but, in fact, the justice system does support a lot of people with autism.

Here we go with the child part of this portion. I am going to talk in a few minutes about the Rehabilitative Services Act, but the real key to the special education system in this country is what we now call IDEA, the Individuals with Disabilities Education Act, which underwent a significant reauthorization in 2004. It is a grant program. It is not an entitlement program. It authorizes grants to states and many, many other grants, as Gale can attest.

This is a very high-level view of IDEA here. What does it say? It requires that states provide a free and appropriate public education -- we call that FAPE for short -- in the least restrictive environment for children with disabilities ages 3 to 21. That is Part B of IDEA.

Part C is the part that Gail is most familiar with, the early intervention services for disabled infants and toddlers ages birth through two and their families.

So a child enrolled in Part C -- well, let me back up for a second. Each state's governor decides who the lead agency is for Part C. It is usually the health and human services arm or, typically, the education arm in the state.

A group of family members and professionals develop what is called the IFSP.

The IFSP includes services, defines goals, describes criteria for progress, and there's always a service coordinator. In Medicaid, we call that a case manager, but in IDEA it is called the service coordinator.

Part B is really the bulk of the services that come through the Department of Education. Part B is led by what are called LEAs, local education agencies. Probably you are more familiar with these as school districts. It requires that the free and appropriate public education be provided in the least restrictive environment.

Kind of an interesting piece of this part of this statute is that some states still serve children beyond age 21, and also that autism wasn't added as a disability category until 1990. So many children were labeled with other disabilities. It was, I believe, Disability Category No. 13.

So what is a free and appropriate public education? The law says it is designed to meet a particular child's needs and must provide access to the regular curriculum, and that it provides the child with an education that is going to prepare him or her for the future.

What is "least restrictive environment"? Well, when the Congress wrote this law, it really wanted to make sure that children were not taken out of their neighborhood schools and communities unless there was just really something associated with the nature or severity of the disability that just made it impossible to educate a child in his or her home school.

So where are children with autism educated? Special classrooms in their home schools. It could be in a general ed classroom for all of the school day or part of the school day. It could be in a center-based program, a special school, a private school, or kids could also be home-schooled.

What is an IEP? This is the plan

that drives a child's education. It describes annual goals. They are both functional goals and academic goals. I think that is important.

Parents and professionals are part of the team that writes the IEP. The IEP also talks about what supplementary aids and services -- for example, a school bus or a personal care aide -- a child might need to function in that least restrictive environment. It might require that a child go to school longer than the typical school year. A child could get extended-year services under some circumstances.

It mandates now the transition needs be met at age 16. It has to be looked at regularly.

I think this last bullet is really important. It is constructed to enable a child to receive educational benefits.

What is Section 504? Section 504 is actually part of the Rehab Act of 1973. It is a civil rights statute, but it could also be the venue for some children with autism to receive services in a public school. These students must also have a disability that limits a life activity.

School districts also have to provide the free and appropriate public education.

A 504 plan would substitute for an IEP. It is generally aimed at kids who need adjustments made to their environment. It doesn't measure goals and objectives along the way. It talks about accommodations.

Most of you are already familiar with the Americans with Disabilities Act. It is a civil rights act. It guarantees that people with autism can be accommodated.

If you are not familiar with the Olmstead decision -- some of you are -- this was a Supreme Court ruling that passed in 1999. There were two women in a Georgia hospital who wanted to live in the community, and the State of Georgia did not agree, although their professional staff felt that they could certainly be supported in the community.

They won, indeed, the right to live in a community. This case had a huge ripple throughout government. To this day, we still are making major efforts to assist states and people to live in home and community-based settings.

I am just going to talk for a second about private health insurance for children with autism. Typical medical insurance covers medical services. Some insurance companies have been denying coverage based on an autism diagnosis.

Many coverage debates are aimed at these three therapies, ABA treatment, and speech and occupational therapies. ABA is a treatment philosophy that could include certain services and supports that are designed for a particular child.

These states -- thank you, Alison, for giving me a list -- are ones that require private insurers to cover applied behavioral analysis treatment. The ABA usually has some sort of a maximum yearly or lifetime cap.

DR. INSEL: Question about that?

MS. BLACKWELL: Sure.

DR. INSEL: Does the passage of Mental Health Parity change this at all?

MS. BLACKWELL: We are still analyzing at CMS, Tom, the impact of the Mental Health Parity Act. It applies to private insurance policies, but it also has some intersection with the Medicaid statute in terms of managed care.

So what the Mental Health Parity Act says is that, in addition to receiving parity with payment for services, people must receive equitability with physical health services. Because the law is so new, we are still in the process of taking a look at what does that exactly mean.

How does health and medical treatment equate with -- you know, it is easy in terms of a hospital visit, but it is harder when you try to talk about parity and, for example, case management. Where does that fit in terms of the hospital? So a lot of questions.

Social Security is important. There are two types of disability benefits that come through Social Security. Most people with autism receive the Supplemental and Security Income Benefit. It is paid monthly to low-income disabled children and adults. Disability definition and qualification is extremely complicated. Ask anyone who has ever gotten through a Social Security office.

The impairment listing for autism, I've got the site up here. You can take a look at it, if you like. It is also very complicated.

Most people on SSI also are eligible for food stamps. They also typically qualify for Medicaid.

The monthly benefit for 2008 for a single person is $637 a month, and that is meant to cover all of the person's expenses. The couple benefit is probably about, I think it is about $900 a month. So we are talking about very povertized people.

The resource limit is $2,000. So a person with autism who is on SSI cannot have any property or cash worth more than $2,000. Otherwise, they would lose, for example, their SSI benefits and their Medicaid eligibility.

Medicaid is Title XIX of the Social Security Act. It was actually passed at the same time as the Medicare law in 1965. Unlike Medicare, Medicaid also provides long-term care services.

It is a joint partnership between states and the federal government, and every state has a different program. Some services are mandatory in Medicaid and others are optional. I can't stress that point enough.

In a moment I will show you a slide showing what the mandatory benefits are, but you may be surprised, if you are not familiar with the Medicaid program.

Each state operates a state plan. There really is a state plan. It lists all the covered services and who the people who are covered are.

States decide who is eligible for the most part, what services they will cover, how much they are going to pay for them, and what the provider qualifications are. States also decide how much of a service a Medicaid beneficiary can get.

Services must be medically necessary. CMS does not define medical necessity; our states do.

Generally, services delivered under the state plan have to be available everywhere in the state, except under some circumstances.

States can't deny service to a person who has autism or any other illness or condition. States can also request that the Secretary waive certain provisions of the Medicaid statute, and I will talk about what can be waived. It could be statewideness, who gets what, who provides what. It gets a little bit complicated.

I thought we would talk for a second about this partnership between the states and the federal government. The federal government pays for at least half of every state's Medicaid program under something we call FMAP.

Every year FMAP changes and it is based on a rolling three-year per-capita formula. You can look it up online. No state gets less than 50 percent. The maximum rate, matching rate, under the statute is 83 percent.

This is the 2009 FMAP rates, and I just kind of tried to pick out the states that get the highest FMAP. These are the states with the highest poverty levels.

What that means is that, if a state applies for a service and they are at a 70-percent match rate, the federal government pays 70 percent of the cost of the service and the state pays 30 percent.

There are certain exceptions. Administrative costs related to the Medicaid plan are always paid at 50 percent. American Indian services receive 100 percent FMAP. There are some other exceptions, but generally most states have about a 50 percent match rate.

This is a good slide. These mandatory services on the left are the only ones that are in the Medicaid statute.

So take a look at the list of optional services for a second. Home and community-based services, which aren't even listed on this slide except for ones that come through the state plan, are all optional services. Dental services are optional. Speech, physical therapy, occupational therapy, case management, personal care, hospice services, all of these are optional services in Medicaid that states are not required to provide.

There is a place in the Medicaid statute where it actually intersects with the Education Department. In 1988, the Congress passed the Medicare Catastrophic Coverage Act, and most of it was repealed except for this little piece, Section 1903(c), which says that, in the Medicaid program, Medicaid has to pay for Medicaid-covered services that are included in a child's IFSP or IEP before education services.

So what that means is that Medicaid pays for a lot of services that a Medicaid child could be getting in school, say speech therapy, occupational therapy, mental health services.

So these Medicaid services can be delivered in school settings, but they also have to be delivered according to Medicaid rules. So Medicaid pays for many, many services that are included in our statute in school settings.

That happens partially because of a benefit that the Congress in 1965 in a statute called EPDST, the Early and Periodic Diagnostic Screening and Treatment Service. This is a really important service that offers protection to kids from zero until the month they hit their 21st birthday. So any Medicaid child can receive any of these benefits, screening, vision, dental, hearing, physical and mental health services, whether or not the state has elected to include those services in its state plan.

So, again, I can't stress the importance of this benefit to the health of all the children enrolled in the Medicaid program.

So how do you become eligible for Medicaid? It is so complicated. We have a whole team of people at CSM that talk about

Medicaid eligibility, and I am not one of them.

States pick groups. So there are some financial criteria attached to becoming a Medicaid beneficiary. There are some non-financial criteria. Some groups are mandatory; others are optional. Every state determines eligibility on its own. So it is very complicated.

Almost all groups include these people: aged, blind, disabled, under 21 pregnant or parents and caretakers of children.

This is an important population. These are people under dual eligibility who can actually be dually eligible for both Medicare and Medicaid.

Medicare pays first for their physician/hospital care. Because Medicare doesn't cover long-term care, Medicaid picks up their long-term care.

There are about 8 million people

enrolled in both of these programs. They are our most expensive and most frail beneficiaries. About half of them live in nursing homes. Most of them are very, very poor. You can see that they represent about 40 percent of all Medicaid costs a year, which is about $310 billion a year, 25 percent of Medicare costs which are over also $300 billion a year.

So I talked a little bit earlier about what is a waiver. You guys have heard me talk about waivers before. 1915(b) waivers are generally managed care waivers or waivers that permit a state to deliver services through managed care or to also limit providers through selected contracting.

Section 1915(c) of the Act allows states to provide home and community-based services.

We also operate many 1115 demonstrations. Arizona never participated in the Medicaid program until the early 1980s.

Since then, it has run an 1115 demonstration, a managed care demonstration that provides all of its Medicaid services. Vermont, more recently, and Hawaii, even more recently, have turned over almost all their Medicaid programs to managed care.

So what is a home and community-based waiver? It was added to the statute by the Congress in 1981. It is now the foundation of all long-term care for many, many Medicaid beneficiaries.

What does it do? It provides community-based alternatives to institutional care. It is undergoing gradual addition of self-directed service opportunities, which you will hear a little bit more about today.

Also, this last bullet is very important. All of these home and community-based services are optional. States are not required to provide them.

So what could you provide in a home and community-based waiver? This is a list of the services that can be provided: case management, homemakers' services, I mean a lot of services for people with mental illness.

The last is probably the most interesting service, other services to avoid institutionalization. These are just some examples what another service could be that might help a person with autism stay out of an institution. There are many, many more. CMS has approved about 300 other services.

So how do states operate these home and community-based programs? They have to ask CMS. We approve a waiver for three years, then five years. People participating in waivers have to meet an institutional level of care, and there are only three in the statute They have to be eligible to enter a nursing facility, a hospital, or an ICFMR.

What is an ICFMR? Well, the level of care for a person with autism typically is an intermediate care facility for the mentally retarded. I'll talk in a second a little bit more about what that is.

But the person with autism would have to be able to choose between living in an ICFMR or living in a community-supported through Home and Community-Based Services. So ICFMR under the statute serve people with mental retardation or related conditions, which is a pretty broad term.

Congress added this benefit to the statute in the sixties because there were some pretty horrible reports coming in about what it was like to live in a large institution. There are about 6400 of them now in the United States. Most of them are actually pretty small. As I said earlier, states have closed most of their large institutions. Alaska doesn't have any ICFs.

The average cost of an ICF in this country is about $118,000 a year a person. In Maryland the comparison cost in its MR/DD waiver is $188,000 a year per person.

So to participate in a waiver, it

has to be less expensive than staying in an ICFMR.

I put up this slide because sometimes you might hear the term IMD. What is an IMD? An IMD is a mental hospital. Mental hospitals have never been included in the Medicaid statute for people ages 22 to 64, although we added, Medicaid added something called the PRTF benefit in fairly recent years. So children ages zero to 21 can receive mental health services in PRTFs.

So waivers, they can't duplicate services that a child could be getting in his IEP or IFSP, and they also can't duplicate these 504 plan services, nor can they duplicate services that a person could get through the Rehabilitation Act.

CMS is extremely interested in the quality requirements associated with home and community-based waivers because we want to make sure that our beneficiaries are healthy and safe in the community.

Medicaid does not pay for room and board. So that $637 that I mentioned earlier, that has to cover a person's room, board, and all of their incidental needs.

Again, it has to cost the state -- if a state wants to get a waiver approved by CMS, it has to cost less than the cost of institutional care. We call that cost neutrality.

States have to tell CMS who the target group is. These are the three target groups that we have in our regulations right now.

States have to tell CMS how many people they plan to serve each year.

States can establish waiting lists. The federal government just asks that the waiting list be fair.

Services in a particular waiver that serves people with autism may or may not meet every need that that person has. They are just the services that are included in that particular waiver.

As states move more and more toward managed care options to save money, they are starting to operate more and more 1915(b) managed care waivers concurrent with 1915(c) waivers to use managed care to save money on these home and community-based delivery systems.

Right now about 65 percent of all Medicaid services come through managed care. There are about 350 active waivers in this country. I counted them one day. I think about 100 of them could serve people with autism. Most states have very long waiting lists, indeed, for home and community-based waivers.

Are we going to get stuck? I think I'm stuck, Azik.

Okay, thank you.

The State of Maryland nicely agreed to let us look at its waiting list numbers on the three waivers that could serve people with autism. The State of Maryland can serve about 13,500 people on these waivers. There are over 20,000 on the three waiting lists. There are four priority categories. You can see that the highest priority category are the people that need help in 30 days. Those people are waiting an average of about four years for services.

So, again, these are all optional services. I can't stress that enough.

The self-direction options that CMS and states have started to build into these waivers, I think they have really made a difference for people with autism. What that means is, instead of having care delivered through an agency-based model, families actually have the ability to pay, hire, fire, recruit, and really take their family member services into their own hands. This especially works well for people who may not have been served very well in the old agency-based model.

One of the challenges in self-direction is that $637 a month. You know, it is pretty tough to pay for rent and food anywhere in the United States on a very low income. So that continues to be a challenge that we are trying to overcome.

What does home and community-based services look like today? We spent last year in Medicaid $28 billion on home and community-based services. You can see that the weighting is still a little bit more toward institutional services, but year after year we see more states leaning toward home and community-based services because they save money.

Total Medicaid spending last year on long-term care was $101 billion. As I said before, Medicaid spending last year was $312 billion.

This is a list of the waivers that CMS has approved that are directed specifically at people with autism. You can take your time studying this, but you can see that the numbers of people are actually pretty small.

There is only one waiver -- Pennsylvania is here today and they will tell you a little bit about this waiver. It serves 200 adults. But the rest of these waivers are pretty much targeted at children with autism.

We have some other items under review at CMS, but that's it. Most people with autism are served in waivers that serve people with mental retardation.

The Rehab Act of 1973 also helps a lot of people with autism get jobs and support them in terms of their employment. So I mention that today because it is an important support.

What does the future hold? Well, we know that most people with autism need services and supports throughout their lives. About half of our states now, at least half of our states, are facing significant budget shortfalls and slow anticipated revenue growth.

What happens when more and more people become unemployed? More and more of them lose their health insurance and end up as Medicaid beneficiaries.

States are continuing to use managed care along with home and community-based services to save money. We certainly believe that this economy will have some implications for autism services and services to all people with disabilities.

Okay.

DR. INSEL: Thank you.

Questions?

I've been saying to Della that it is easier to follow a biochemical intracellular pathway than to understand how you negotiate this very complicated landscape.

(Laughter.)

MS. BLACKWELL: It is a very --

actually, I didn't even scratch the surface today. Okay? But I hope that, having heard that, our successive presentations will make a little bit more sense to you.

DR. INSEL: We may ask you to reprise this in six months. Now that we have a new Secretary of HHS, or we will soon have a new Secretary of HHS, and we think we know who that will be, it will be -- I think we sit as an advisory group to him. He should be here to hear about this, and we should make sure that, as the Services Work Group gets further into their tasks, that we can lay out a set of priorities for him to hear about fairly early in his tenure. So I don't know if we will get him to the February meeting, but certainly for the April meeting we ought to think about getting that on his agenda, so he can hear about this directly.

MS. BLACKWELL: Well, our Medicaid Directors met in Washington last week. Although Ann was telling me it wasn't quite as bad as I had anticipated after listening to some of our discussions which were actually surrounding mental health, we think that there are going to be some changes made very quickly to state Medicaid programs, and they will not be expansions. They will probably, most likely, be contractions. So you see all of the optional services that are up there on the table, and it could be very, very scary.

DR. INSEL: Jim?

DR. BATTEY: I can tell you from firsthand experience that to get Medicaid benefits in the State of Maryland you've got to be broke. You can't have anything. If you've got anything at all, they will find any excuse they can to exclude you.

MS. BLACKWELL: We do believe that states have mechanisms -- I mean when you talk about waiting lists, we do believe states have mechanisms to serve people who are in crisis. They can reserve capacity for people. So that it is likely that people that need services immediately will probably get a waiver slot. But, as you can see, it takes a while.

DR. INSEL: Yvette?

DR. JANVIER: I had a question. I mean I understand the 504 plan. That is a plan written for a particular child. The waiver I am a little bit fuzzy on. I have had children that have had a waiver bed or slot, but are the waivers given to a program to provide a certain type of service?

MS. BLACKWELL: Waivers are operated by states. There are lists -- states pick a list of services out of the services that are on that one list, Yvette. So a person would have to qualify. They would have to meet an institutional level of care, and then they could qualify to get any of the services that a state had elected to put in that waiver. But, again, they are not mandatory services. A person has to meet institutional level of care.

There is a new option in our statute

to provide some of these home and community-based services to people who don't meet institutional level of care, but it is a little unwieldy. It doesn't allow states to target, and it has some other -- I mean without getting real deep -- actually, not very deep -- into the weeds, but very few states have used that option to serve people. So it is hard to get home and community-based services. It is very different from entitlement programs that come through Education.

MR. GROSSMAN: Yes, I think what you mentioned, Tom, at the very beginning after Ellen's remarks is very poignant because it is much easier -- as complex and as difficult as it is to go through what we have been fighting with and trying to come up with in the last year, the service sector is that much more complex by probably tenfold. Almost every one of those slides that Ellen had, you could put a whole strategic plan behind that.

With that said, I believe as we go through here, I am not saying that we are going to come up with more clarity for anybody here. Sorry to disappoint everybody in the audience. But our point today was to emphasize the importance of this. It is what we hear as what the community is asking the most for, and that is for lifespan services. And it is also to present the picture that this is complex, but there are ways to deal with it.

MS. BLACKWELL: I think our next speaker is Cathy Pratt, who is with us today from the University of Indiana.

Thank you so much for coming, Cathy.

DR. PRATT: Let me put a little bit of perspective on the Medicaid waiver question. In Indiana, where I am from, we tell parents that at the age of 16 if they are contemplating having a child with autism when they turn 30, to sign up for the waiver, because the waiting list is so incredibly long.

The reality of it also is that, when families do, indeed, get their children, their sons and daughters, on the waiver, it is a lifesaver, and it is not just a lifesaver for that child, but it is a lifesaver for the entire family as well.

I appreciate Ellen's work in really working on these waivers. We continue to learn and grow in this.

Okay, can you advance me? Go back a slide. Can you do that? This is going to be the most difficult part.

I have been coming to these meetings for quite a while. It is very apparent that the population of individuals that we are talking about continues to increase.

In my State a year ago, our child count data showed us that the incidence of autism for students in our Department of Education was 1 in 128. This last child count data showed us that the incidence of autism is now 1 in 113.

The incidence increases every year so dramatically in terms of the categories that Ellen was talking about. Autism is one of the categories and it is the fastest-growing category in our special education services. Every year, by about 20 to 28 percent, we see an increase in these children being served.

The other difference -- and I have been in the field of autism for over 30 years now -- is that the individuals that we see come to us with a whole host of very complex needs. Probably the group of individuals who challenge us the most are those individuals who have autism and a mental health issue.

The challenge for those individuals is, when they go to the DD system, the DD system says, "I'm sorry, but you have a mental illness." When you go to the mental health side of the equation, they say, "I'm sorry, but you have a DD", and the individual falls right in the middle.

So we have individuals who are very complex, who come to us with a whole host of challenges, which for families what that means and for the individuals what that means is that they have to access even more services than we did a number of years ago.

That makes the service delivery system very challenging. One of the things that we heard early on in the IACC process, as we looked at the services roadmap, is that families talked about the fact that services are very siloed.

I know very sophisticated family members who have a difficult time negotiating services, especially when they get into the adult arena, because they speak different languages. For each service delivery system that you go into, you have to learn a different set of words, a different set of language.

We also realized that autism is a

lifespan issue. We were talking earlier today about the fact -- and, Colleen, you're probably so aware of this -- some of the initial individuals that you really used in those prevalency studies are now heading toward adulthood. For folks to perceive that autism is an issue around childhood really misses the boat. I think we really have to look at the adult issues because that is the population that economically is going to put the greatest pressure on us, and socially put a great pressure on us.

We know that there are evidence-based methods and evidence-based practices, and we probably could spend an hour talking about what is an evidence-based practice and what does that mean, and how many studies, and how do you know it exists.

But what we find in our State is that many of those evidence-based practices are only available to families or to programs that have access to the universities that are engaged in that type of research or close to hospitals that are engaged in those kinds of activities.

So the services roadmap that we looked at a number of years ago still has issues that are relevant today. That is, that we look at family and professional partnerships, that we come together on these very complex issues; that, obviously early and continuous screening is important in early intervention, but, yet, I continue to hear that the average age of diagnosis is 60 months.

In my own State, I struggle with our zero-to-three providers being willing to put the label of autism on a child because they say they may give the diagnosis, but then where do they send the family, because there are no services that are available. So we know that families are missing that opportunity to really intervene early on.

We know that there are in various

states an array and diversity in the quality and the number of education services. One of the phone calls that I will oftentimes get from families is, "Where is the perfect state to move to that has the perfect services?" The reality of it is that there is no perfect state.

I know in terms of education, you will look for that perfect teacher, and then you pray that that teacher never leaves, and realize that if anything changes, that your son's or daughter's program will change as well.

We know that we need to have community-based services that are available for easy use, that families have to have access to those services.

Let me just explain to you a little bit of where I come from. I represent a statewide program, in addition to being Chair of the Board for the Autism Society of America. My goal in my State is that every family member have equal access to services regardless of their level of income or their education level or their race or their background, or whatever, and that simply doesn't exist today for our families.

We also know that, as individuals grow, that we have to look at transition and we have to look at work. I recently heard a figure that 90 percent of our folks are unemployed. While it is so important to focus on early intervention, if we spend a lot of money in the area of early intervention and in educational programming, and we prepare people for nothing, then what have we done? What is the job that we have done ultimately?

Then this has to be a partnership. Stuart, you and I have for many years been working on issues around Medicaid waivers. I'm proud to say Indiana was the first state, and we continue to strive to improve that and work on that, but to realize that this will take multiple funding sources.

Very simply, if we are content with the fact that we are simply passing insurance bills in states, we are missing the big picture. Funding these children is going to require a lot of funding coming from a lot of different resources: the educational issue, rehab, the mental health community, other organizations, and it can't be just borne by that.

So what we need to look at is taking research to practice. I am phrasing it this way because you are individuals who look at research.

I think the outcome always of our research is, are we really able to influence what happens in people's lives? Again, is there a broad impact, that these services are available to everyone?

So some of the research can address services, and instead of looking at single-subject research, why don't we do things based on performance criteria?

Gail, I am going to give a wonderful example of something that OSEP has funded. OSEP has funded a grant to basically change the systems in 12 states to look at implementing evidence-based practices in school districts. Indiana is fortunate to be one of the first states.

What they are doing is that they are implementing evidence-based practices, and they are rating the value of those evidence-based practices not by how much money they put into them or how often people implement them, but by looking at, are we able to help children achieve their IEP goals? Are we able to help children meet educational outcomes? So tying that research to real-life practice is making a tremendous difference.

We know what those evidence-based practices are, again -- but I am not touching it, I promise you. It must be the aura, huh?

But the other issues are that oftentimes these aren't being implemented. So what are the systemic issues that support the implementation of evidence-based practices? What are the systemic issues that we need to look at in order to make sure that what we all talk about and what we see as best practice are implemented across settings?

And the reality of it is that professionals will typically utilize those tools that are the easiest for them to use. So how do you balance ease of use with fidelity of implementation? What are the factors that lead to that?

So I also believe that research can and should drive policy. We have been doing in our State, we have looked at our Medicaid waiver. I'm embarrassed to say we found a few people who were still being served who are now deceased. And I don't think that that is that unusual.

But looking at our states and looking at our policies and trying to figure out what people really need, and making decisions based on that, and the needs not only of the family members who have the means to come to meetings like this, but listening to the silent majority that we oftentimes don't listen to.

A couple of months ago, I spent a day with a family in their living room, talking to them about their daughter, who was only in school for an hour a day because of her violent behavior. For that family, the most important issue was to make sure that their daughter had the right services, that we put together supports in place that would help her to be successful.

That required that we locate a psychiatrist who was willing to treat her. We couldn't. We could not find a psychiatrist in her area. I had to dig far and wide to find one because of the challenges she faces.

We had to also get her back into school because the family, going through economic turmoil, is not able to afford to take their daughter to a specialized dentist or take their daughter to a specialized doctor. And they needed to get back to work, so that they could afford to do this.

I think, again, what are the context and policies that create these systems that will accommodate our folks? So research should lead to real change.

We talk a lot in practice about how much money we are getting. We really applaud ourselves when we are able to go to Congress and get millions and millions of dollars for whatever. But I would question us, and I would really challenge us to say, instead of focusing on those inputs, I think we need to be focusing on those outcomes.

One of the differences that we are making in people's lives is because of the work of all of us sitting at this table. Are we going to be able to say in five years that the employment rates of people with autism are better than they are today? Are we going to be able to say that families are not struggling? Are we going to be able to say that families have access to the resources and services they need? Are we going to be able to say that children, young children, no matter where they live, in what part of the United States, have access to quality child care services? Those are the issues that I am concerned about. That is what keeps me up at night.

In education, we talk about this as generalization. When you are a teacher, you know that your practices, you have only been effective as a teacher if what you have taught a child is generalized to other settings.

I would challenge all of us to think about that also. I would say that what we research in our clinics, in our hospitals, in our universities, is only effective if it can be generalized out to the broader public, and it is equally available to everyone that we serve in the United States. As Lee so well puts it, that is a human rights issue.

Thank you.

(Applause.)

MS. BLACKWELL: Thanks, Cathy.

Our next speaker is Nina Wall-Cote. Nina, as I mentioned earlier, works for the State of Pennsylvania, the only state that has elected to create a Medicaid waiver just for individuals with autism. It certainly does not mean that we don't serve many, many other people with autism in other home and community-based waivers, but Nina has a rather special waiver. She is going to explain to you why the State decided to do that and more.

MS. WALL-COTE: It is a great pleasure to be here today. I would love to be able to say, coming on Cathy's heels there, ditto, ditto, ditto.

It is really a great pleasure to be able to come and to talk to you about what is underway right now in the Commonwealth of Pennsylvania to address all of the issues that

I think Cathy articulated and Lee articulated so succinctly.

We have had a mammoth process underway for the past three years to begin to design models to support children and adults living with autism across the lifespan. I wear a couple of hats in this respect. I am the parent of an 18-year-old living with autism, a social worker, and now the Director of the Bureau of Autism Services. So I wear many hats and look at this through many lenses.

I have to share with you in terms of outcomes. We were very pleased recently that our 18-year-old voted. There's an outcome. That passes the "So what?" test. A lot of families talk to us about that "So what?" test and we think about that. That informs so much of the work that is underway and the models that we are developing.

In 2003, Secretary Estelle B. Richman, who is the Secretary of the

Department of Public Welfare in Pennsylvania, brought together the Autism Task Force, which was a group -- and we are going to jump around here because I realize we have limited time. She brought together a group of about 300 people, family members, professionals, folks from the system, to talk about what in Pennsylvania's system was working and then where we needed to do some work.

What was interesting is she said, you know, you can talk about the problems, but you also need to come up with some recommendations. This group did. They generated a 1,000-plus-page report and made five recommendations with respect to what we needed to see happening in our system.

I would say, as much as this is very, very much a Pennsylvania document, I think it generalized wonderfully when we are talking about what is needed in the system right now overarchingly. We have had the great pleasure of interacting with colleagues in other states and talking to them about their work and their challenges and our work and some of our challenges.

You have in this PowerPoint an overview of what our five main Task Force recommendations were. It probably will surprise no one here that the group spoke clearly to the need to begin to develop some models to support adults living with autism.

Seriously, we all know at the age of 21 many folks with autism fall off the cliff, and there are not services available where there were entitlements up to the age of 21.

We have spent time trying to think about what it is adults with autism need. In thinking about the two models that we have developed to support adults living with autism, we have focused on some very specific things.

I'll just emphasize what these two models, our 1915(c) waiver and our ACAP 1915(a) waiver, both emphasize. They are a little bit different in terms of the funding mechanism and the structure, but some of the things that are in kind, that they share in common.

When we were designing these models, we thought about what it was adults with autism needed to be successful. What did a positive outcome look like?

We also thought an awful lot about what we were seeing in our work day to day with respect to some of the negative outcomes and the kinds of things that we want to avert. We do an awful lot of crisis managing in our system, unfortunately. We are seeing folks with autism winding up in the criminal justice system in droves. We are seeing people at home with aging parents without services. We are seeing some very, very tragic outcomes.

So we literally started with two large pieces of paper on the wall and thought where did we want to see adults with autism going in successful, positive ways and the things we wanted to avert.

We thought about the need to link outcomes to support planning and to think about assessment as an ongoing, fluid process that tells us about individual strengths and vulnerabilities and needs, and to find ways to link assessment to support planning and to outcomes, with an assumption that all folks can progress and can throughout the course of their lives lead more productive, independent lives. So I think that is very important to emphasize.

A third theme I want to underscore is training. I think this was touched on today. There are a dearth of professionals in this arena who know how to work with this population. We can find some masterfully talented folks working with children, but when we start talking about adults with autism, it is very, very difficult to find folks who understand the unique needs that adults present.

So we thought about training as an integral component. So with respect to our (c) waiver and our (a) waiver, training is built in. Folks who are providing support through these models will have completed our training. We have done extensive development of training protocols, web-based training, and I think that, obviously, is critical.

So those are some things that the models share in common. We're looking to serve adults 21 and older.

We struggle, and I know Kathy Reddington from Connecticut is going to talk a little bit about some of the challenges when you are looking at the complexity of folks across this broad continuum and those individuals who may not meet level of care.

I sort of shy away from the high-functioning/low-functioning lexicon. People are differently complicated, and I do worry so very much about those individuals who may not meet level of care. This is something as a system we really do need to focus on. I am pleased to see that our colleagues in Connecticut are looking at that.

You can see here some of the services that are included in our (c) waiver. I think the need to have behavioral support planning in there is critical. Functional behavioral assessment is a key assessment we conduct at the front end.

Crisis intervention, I talked about the crisis management that we are doing. There is a crisis support service in both ACAP and in waiver.

That will give you an idea of the array of services. We have family counseling built in there as well.

I think what we really tried to do here was to finetune this, again, to the unique needs of adults living with autism.

We can probably go forward.

I also want to emphasize -- and here is the challenge, and we see this in the kids' arena -- no one size fits all. So when we are thinking about designing models to support adults with autism, we recognize, when you look at the different complexity across that spectrum, that we are going to need to look at different models and to be very creative in thinking about how to support our adult population.

I think we are just going to fly through these -- if we want to just jump ahead.

I want to touch on -- it was very interesting to hear the discussion about the complexity of the Medicaid system and the response from folks here when Ellen had completed her presentation, and I think about what families experience as they navigate all of this, too. So, again, the need for the family support here is critical.

The next slide touches on another initiative that is a key recommendation of our Task Force, and that is for the development of regional autism centers. We have for the past three years been basically designing a model, a regional center model, which we will announce within the next two weeks.

There are four legs to the stool of our regional centers. Obviously, we are looking to have services provided in the centers, education.

Families talk about the experience of being launched into the system and trying to figure out, you know, where's Waldo, and how do I pull the services together and navigate all of this at a time when my life has become incredibly complicated?

We are looking to develop statewide materials that also have a regional focus as well to help families navigate our very complex system in Pennsylvania and to identify where resources are.

Again, in the research area, we are looking at, through our regional centers, funding applied research. That gets me back to the "So what?" again. This is the research that will inform practice and help us begin to define standards around diagnosis and assessment and treatment and training. These will be conduits, clearly, for all of the training we are developing in the Commonwealth and we hope to get routed out around the State.

We are a large State. We are dealing with the challenge of meeting the needs in rural areas. Having traveled around Pennsylvania a few times, you think about what is autism for a family as being an inherently isolating experience. When you are geographically isolated, that complicates this immeasurably.

So these are our ASERT centers. You might also have heard recently that we now have autism parity legislation passed in Pennsylvania. This is what our Act 62 looks like. It mandates private insurers to begin covering autism services, beginning July 1st, 2009, up to a cap of $36,000 a year. Medicaid will remain for us in Pennsylvania the safety net for our families.

We are in the process right now of defining what this will look like as it rolls out. Implementation is incredibly challenging. We have our Department of Public Welfare working with our Department of State and the Department of Insurance to define what this will look like when it hits the road, and we have families at the table helping us with that process as well.

This is crazy. This is the Cliff's Notes version. I think I have done this in 10 minutes, but I really do want to finish up on a few things here.

This is but a snapshot of the work that is underway. I do really want to emphasize that, looking at some of the other initiatives that we are struggling with, this is mammoth macro-systems overhaul, and the complexity of what we are doing here cannot be emphasized more stridently. We have lots of wonderful people looking at how to take our system and begin to craft something that is more responsive to the needs of this incredibly complicated community.

We are struggling though and we are frightened at a time when resources are becoming increasingly scanty. This is, indeed, a very challenging time to begin the process of developing models and supports for an extraordinarily complicated population.

You can see here, though, as we sort of scroll through the list, in looking at some of the other challenges facing us and all of you as we move forward, we are in the process of crafting a strategic plan that will see us through the next two years of the Rendell Administration and also looking three years out.

We have our best-case scenario and we have our worst-case scenario. We are calling this sort of the "daughter of Task

Force report". It is an important document because it is talking about the future. A great foundation has been established, but, clearly, looking at our challenges going forward.

I would encourage all of you just to look at the Task Force report. There's really good thinking in there, and we would be pleased to speak with any of you about some of our experiences, as we have been taking that document and implementing it, operationalizing it. Any interaction with you is welcome.

I would have to say we have been very, very humble in that we have, I think, moved some incredibly great work, but recognize how far we have to go here.

I do want to emphasize, though, that one of the things as a parent that is incredibly poignant now is seeing such a huge emphasis on autism awareness and what we are seeing in the media, just tremendous, and all the great work that has been done. But we have to remember that kids with autism become adults with autism.

Having been through our State centers and also seeing the complexities of autism in aging, adults with autism become senior citizens with autism. If we are going to look at this, I think we have to look at it authentically in all of its tremendous complexity.

So thank you. Thank you for your time.

(Applause.)

MS. BLACKWELL: Nina, thank you so much.

Our next speaker is Kathy Reddington. Kathy hails from the State of Connecticut.

It's not a Commonwealth, is it, Kathy?

MS. REDDINGTON: Pardon me?

MS. BLACKWELL: It's the State of Connecticut?

MS. REDDINGTON: It's the State of Connecticut.

MS. BLACKWELL: Okay. Kathy is in charge of a very interesting program that she is going to tell you about, but it is not a Medicaid waiver. It is a State-funded program, and it's really neat.

MS. REDDINGTON: Thank you. Thank you for having me here.

This clicker seems to have a mind of its own. As Nina was talking, it kept flipping to Connecticut.

(Laughter.)

So I am from Connecticut. I'm Kathy Reddington. I work for the Department of Developmental Services which is a DD agency in Connecticut. We have a Division of Autism Services in that agency, and I'm the Director of that Division.

Now I can click, right? Oh, it's a slow clicker.

Just so you know, I'm talking about

a very small pilot, a very small service delivery. We have many things going on in Connecticut. I'm just going to focus on this one little project.

When we are talking about autism spectrum disorders, for the purposes of this pilot, we are including autistic disorder, Asperger's disorder, and PDD-NOS, which some states do exclude Asperger's under their DD services.

The purpose of the pilot was to develop a program model to provide services to adults with autism spectrum disorders who do not have mental retardation. Connecticut is historically called an -- they call it an "MR" State. The DD agencies serve people with mental retardation only, meaning an IQ of 69 and below.

So what happened with people with a 70 IQ and above is that they didn't have a service delivery system in which to go to other than voc rehab services.

So a lot of these people graduated from high school. They exited school services. Maybe they stayed until age 21 because they had special needs, but at age 21 they really got nothing.

So where were they? They are in their homes. They are in their bedrooms. They are on the computer. They are not doing anything.

So families were the driving force behind the legislation in Connecticut. They really did lobby the legislature and educated the legislature in terms of these are very needy individuals in our State and we really do need to do something about it.

So we designed the pilot to deliver supports using a home and community-based waiver model. We do not have a waiver. We expect to apply for a waiver, but we are using that same model in terms of the service delivery.

I'll go real quick.

We got a million dollars in funding in July of 2006. That is annualized funding. We were funded for two and a half years. It is now switched to three years.

We focused on a small geographic area in Connecticut. I had a 40-member steering committee, which is now an advisory council. We had representatives from advocacy groups, advocacy groups with differing opinions and priorities because we felt everyone needed to be at the table. Families were there, individuals on the spectrum were there, State agencies were there, and professionals with expertise in the field were there.

We did get an additional million dollars in funding in July of 2008, which we think is going to be our last funding for the next couple of years. That was for new Division staff and starting another geographic area in Hartford. The Division staff positions are frozen.

I did contract early on for an outcome study through the University of Connecticut. My charge was to write a report of the results of the pilot. I didn't want to write my own report, so I contracted with the University of Connecticut to do an outcome study and they have researchers that are looking at the outcomes. That report will be ready in January. I don't have all the data compiled yet to give you a lot of information, but I have some snippets I can talk about.

The purpose of the outcome study was really to document the program implementation of the pilot. We describe participants' -- they are going to describe participants' early experiences and subjective outcomes, both positive and negative. They do that through an interview process with the individuals and the families.

Am I talking too fast? I'm trying to get through this in time.

That's through an interview process.

They have just completed their post-interview. We may try to extend this study for another year to get a little more longitude in this very small study.

We are describing participants' objective outcomes. Those are the outcomes that are documented on their individual plans. We are looking at progress of those outcomes, and we are looking at cost estimates, cost-effectiveness of the pilot. We are going to look at our educational and training component of the autism pilot.

So right now we are currently providing services to 50 individuals. That is with our original group in New Haven, which is one geographic area. We added the Hartford group this August.

We have 16 provider agencies, and I have two service coordinators who will do the case management function.

What does service delivery look like? We have service coordination/case management. We do assessments on individuals. We use the scales of independent behavior, which is an adaptive rating scale. People might be more familiar with the Vineland, which looks at adaptive skills. This has a little more comprehensive information which we can get out of it and helps us with program planning.

It also documents people's delay in development. We also have a tool called LON, a level of need, which was funded by CMS to Connecticut. We developed this tool to look at people's needs and risk areas, and we can eventually assign dollar amounts based on your score in different areas and what kinds of services. So that we have an independent way of assigning money and budgets to people, and it is an objective measure.

We do an individualized service plan. They are all individual plans. We also have individual budgets. Every person has their own budget to meet their service plan.

Our individuals sign off on the service plan and they sign off on their budget. They can switch their budget as their needs change and as their desires change.

Provider selection, they can select an agency or they can do a direct hire, which Ellen was talking about. They can direct their own services. Direct hire, they can hire someone, a neighbor, someone they know. They can advertise in the paper for a graduate student who is specializing in autism to help them with their supports.

We require service documentation in the form of daily contact sheets. They fill out a form that talks about their individual outcomes, what happened during that visit, and some followup.

So what is the individual who has autism going to do between the next visit? So we give them a signed sheet -- they sign off on the sheet, and with their commitment of what they are going to be working on until the next visit, and also what the service provider is going to do.

We have an entity called Fiscal Intermediary.

You're rolling your eyes. All right, I won't go into that.

MS. BLACKWELL: It's really complicated.

MS. REDDINGTON: It's very complicated. A Fiscal Intermediary is somebody who really pays the bills. These individual budgets get pretty complicated and pretty onerous because it is 37 hours of this and two hours of this for this person and this agency, and all this service documentation gets submitted to this Fiscal Intermediary. They basically pay our bills.

We also have clinical consultation. We have a group that meets with our individuals every six months to a year. The individual attends, their family, their service providers, and this clinical group of people with expertise in the area meet to look at, are we on the right path? Is the person happy with the services? Are we making progress?

The supports and services we offer at this point are a life skills coach, which would be the people working on all your independent living. Can you budget? Are you safe in the community? Do you know what happens if the lights go out at night and you're alone? Can you cook? A variety of things.

Community mentor -- a lot of our individuals have been in the house for a long time. They don't know how to access community activities. They would really love to, and it is someone to attend those activities with them.

We have job developers, which we try to -- gee, I'm not even looking at my notes -- we have job developers, which really we need to look at creative ways of finding employment for individuals. Not everybody wants to stock shelves, although some of our individuals do, but we need to really be creative in terms of looking at meaningful work for people.

We have job coach. Job coach can be done on the job or it can be done after work. Some of our guys have a pretty high IQ. They don't really want someone at their workplace, but if someone can talk to their supervisor or them, meet with them after work, as to what's working well, what's not working well at work, we can help them that way.

We offer social skills groups weekly, and that's a hot item. People seem to like that.

Sometimes social skills groups are done out of context for what's really happening in their lives. So what we do is we try to have a big connection between what's going on with the life skills coach and what's happening in social skills groups.

An example would be we had a young

woman who was in a waiting room for employment. She ended up talking about some biological functions that were getting people upset in the waiting room. That became a topic at life skills class, coach, at the life skills group of what do you talk about in a waiting room and different types of waiting rooms, and some of those social skills that people don't know. You know, people are friendly in the waiting room, and they were talking about this. Well, this is where you need to stop in your conversation or people are going to get upset.

We just started offering respite services. We have a mother who was able to go home to Ireland. She hadn't been to see her family in 15 years, and we were able to provide some supports.

It's respite in the house. Somebody went, took the young man out to dinner. They stayed with him overnight, but they left him pretty much alone during the day. There was an emergency number. So we are able to offer that.

And we do have consultative supports in terms of behavioral, nutritional, OT/PT, speech.

This was the original 28 participants of the outcome study. The age range was 22 to 55 years when we started working with people. IQ range was low, 70s to 140s. We now can say we have low 70s to 160s. I have two people with over 160 IQ.

Gender of the original 28: 20 male, eight female. Race/ethnicity: two Hispanic, two black, one Asian, 24 white. Primary diagnosis: 11 with PDD-NOS, 11 Asperger's, and six autism. Ten of the individuals have a secondary behavioral health diagnosis.

And you can see some of the diagnosis that people had. I'm not going to read them all.

Employment: eleven were employed or said they were employed. I think some of the employment was that they had been on a working assessment through voc rehab and were getting paid for that working assessment for a month. So they were reporting as employed. But 11 were employed, two full-time. Twelve were not employed, and five had never been employed.

We have a lot of variables that we looked at. I just pulled out some that were kind of interesting, to me at least.

We looked at the daily hours of TV watching, and the operative word is "daily". So the high was 12 hours; the mean is 3.29.

On top of that, daily hours of computer use. Daily: 18 hours; mean, 3.32.

I think I can read the numbers.

Then on top of that, daily hours of video games: eight high and the mean was .93.

So that's how people are spending their days.

Forty-six percent had never or almost never participated in community activities.

Scales of independent behavior, which is the adaptive skills assessment I talked to you about earlier. Twenty-three of the 28 individuals scored two or more standard deviations below the norm in overall independent skills. So I want you to think about people with IQs of between 120 and 160 who score two standard deviations below the norm in independent skills. These are people with disabilities. IQ is not a measure alone for disability.

Independence is measured in four subtests: motor skills, social and communication skills, personal living skills, and community living skills.

The SIB also measures general maladaptive behavior. Seventeen individuals are marginally serious to serious in the General Maladaptive Index

I interviewed a family two weeks ago. I interviewed a young man and his mother. He has a job working in a grocery store. He's new to our program. He was pointing to answers because he was having a hard time answering me directly, and it turned out during the course of the interview he assaults and bites his parents one to six times a week, elderly parents.

As he was pointing this out to me, his mother froze, and I was trying to be very light about it. I said, "Thank you for sharing this information" to this young man, and I looked at his mom and said, "So have you talked to the service coordinator about this?" because I didn't see anything in his plan.

She said, "No, no one knows about this. No one does know about it. We haven't told anyone about it."

I said, "Well, you know what? It's time we can start working on this." I kept it as light as I could, although I was devastated, but it is tough on families.

Maladaptive Index is measured in three areas: internalized behavior, asocial, and externalized behavior.

Considerations: when we were developing the pilot, we really had to deal with a workforce that had little experience with this population. A lot of misconceptions and a lot of misunderstandings.

"Well, he can fix my computer. Why can't he go shopping and make a grocery list? Why can't he make change at this store? He can add software. He can add hardware to a computer. He can do all these other great skills. He must not want to do it. He must be manipulative."

I think that that's not just the service provider population. I think it is the population in general. They see someone with so many talents and they really wonder why they're not doing it, are not able to do it, and they are looking at it that it must be volitional, that there is some reason that they don't want to do it, so they are not doing it.

We are developing a DVD training series. We have our first part completed. We used a trainer and then we used footage of purchase events in our pilot. So she will demonstrate the concepts and strategies which are good to use, and then we have individuals who are also filmed supporting those strategies.

It was difficult to motivate individuals to seek services. If you remember back, my numbers, you know, you think, oh, as people talk, we'll open a program; people will come. Well, if you've been in your room on video games or on the internet and you have not accessed the community, and I come along and say, "Great. Wouldn't you love to change your life? And I'm here from the State and we will help you change your life", well, it was really hard and it is really scary for them.

So we really had to take it slow, which was hard for some people in our State to understand, saying, "You have a million dollars. You mean you can't get all these people up and running in four weeks?"

So we are fully operational now after two years, but it did take a long time and we had to start very slowly with services. We do things like, you know, "You need to try something three times, and if you don't like it, then we won't go to that place again or do that again," but we really do need to give people experiences and safe experiences.

So we are working now with advocacy and support groups and school transition planners to get people prepared to another service delivery system.

Successes: we've had a lot of new jobs and volunteer opportunities. We have a young man who was pretty much in his room all during the day. He would be up on the computer all night. His family never saw him. They did know he went to get food from the kitchen because food was missing and he would bring it into this room. He only came out to feed the dog.

His affect was really depressed when I met him. You know, cap, you couldn't see his eyes or his face, no smiling, very stiff.

He was able to get a job at a company that -- and I'm not technically savvy, so I won't know what I'm talking about, but it's to put racks together of recording and audio/visual equipment. It's some computer thing where they talk to each other, these parts. If anybody has a better description, go right ahead. But he does that. I don't know what he does. He loves it.

He was doing it for about three months and his mother called me up and she was crying and I said, "What's wrong?"

She said, "He called." She said, "Jeff called me this afternoon or yesterday afternoon and said he was going to be late from work; he was going to be home late from work."

She said, what happened is the guys

asked him out for a drink, and she was absolutely thrilled because here's a man who had gone to college. He was in his thirties, and his colleagues had asked him out for a drink.

He has, because of the issue with the budget of many, many companies, he has been laid off with his entire division. So we are trying to scramble to see what else we can do for him.

We have another young woman who was unable to leave the house. She has a job now. She works for a company that produces puzzles and word games for newspapers. They mail her the puzzles. She does the editing and correcting at home, and she mails it back in and she gets paid piecework for that.

She's in her thirties. It is the first job she ever had. She loves it. We are not stopping there. It is an initial job for her. We are getting her out into the community more.

What else? We have a woman who is doing an internship at a frame gallery. She is learning how to frame.

A pharmacy tech, somebody at a movie theater -- I won't go on.

People are learning cooking skills. We have people who don't know how to use burners of stoves. All they do is heat a frozen dinner in a microwave. They were having secondary medical issues related to the frozen foods and had obesity, high blood pressure, high cholesterol, diabetes.

So we have a number of individuals working with nutritionists and their life skills coach to learn how to cook healthy meals. They go to the library. They take out a recipe book, and we go through the whole thing with them: shopping, planning your purchases at the grocery store.

Artwork, my husband said my presentation was pretty boring, so I threw in some holiday cards.

(Laughter.)

We have several very talented artists. This is the second year they are doing holiday cards. I thought I would share some of the cards with you.

The Greater New Haven Arts Council did sponsor an art show last February for six of our individuals. It was really a wonderful experience. It was a regular art show. It was on a first Friday, so it was the whole art community at different galleries. They chose the name of the show and called it "The Full Spectrum".

And it was very touching as they had sent out invitations to their family members. Family members came in with bouquets of flowers for this young woman who is a great artist. You know, it was just very touching for people. It was a good success for them.

One of our young men that we work with, he is very theatrical in his affect. He is not stiff as you might guess, some people might think. If he doesn't hear me, he's like this (indicating). You know, he's very expressive and makes it tough for some people in the community to accept what he's doing.

We were able to get him a volunteer position reading to children at a library, which he initially said he hated children, but we said, well, why don't you try it?

(Laughter.)

So he started reading Dr. Seuss, but he acted out Dr. Seuss, and these little kids -- I wasn't there, but the provider said these little kids had their mouths open because he was so great. He just acted the whole thing out. Their families loved him. He loved it. He did it for a whole like semester and said, "You know, that was okay; I don't want to do that again though."

So now he's teaching an art class after school, and he actually makes $50 an hour. He doesn't do a lot of art class teaching, but he has that small job.

People are taking advantage of community and recreational activities. They're socializing with colleagues, and families report fewer meltdowns.

I have some very preliminary results of the outcome study. More people are working. The average wage is higher. People are significantly happier with the pay they earn from their jobs and with the environment of their jobs than they were at baseline.

What I was surprised about is the amount of TV, internet, video watching did not decrease. In my own mind, I had thought, well, if we are getting them out in the community, getting them better jobs, those things will decrease. It probably is not. That was my erroneous -- that was my mistake. It is probably not going to decrease. That's what they like to do.

The future: one of the things I started doing this July is working with our Department -- we have a separate -- we have lots of separate State agencies in Connecticut because it's that Yankee thing. Everything is separate. So we have our own Department of Mental Health and Addiction Services.

I started working with that Department because they have a number of young adults who have autism, a diagnosis of autism spectrum disorders, but also have a major mental illness. They were having difficulty with using some traditional mental health methodologies to work with these adults that wasn't really working.

So we are developing profiles on them. We are, hopefully, going to be developing a multi-agency program model that will include individuals with the ASD and a major mental illness.

We are finalizing a feasibility study for Medicaid-funded services, and we really hope to apply for a Medicaid waiver within the next year. Ellen has been waiting.

(Laughter.)

These are some comments from the outcome study that the researchers gave me.

"Have gone on some adventures."

"Excellent."

"Excellent."

"Very happy with it."

"Some services. She still needs more. A housing component would be great. She could live alone or with a roommate."

"Gave him new opportunities."

"Art projects. Helps with self-esteem."

"Glad he's in the project."

"The service provider has helped a lot. She gets out of the house and opens up a little more."

And the last one is my favorite. This is from an individual. "Glad to be in it." And it wasn't to me; it was to the researcher. "Glad to be in it. Helpful for me. Can learn to be independent and feel like I will have the life of my dreams because of this program."

That is the end of Connecticut.

(Applause.)

MS. BLACKWELL: Thanks, Kathy.

It's a little program, but it makes a big difference. Again, a State-funded program, serves very few people, but you can see a big difference for them.

So, Lee, we've got our panel.

MR. GROSSMAN: If we can have our panelists come forward?

We've made up a lot of time. We're only a little bit behind, which is great. So we're going to keep that on track.

So we have about 40 minutes in the panel presentation. I am hoping that there will be about 10 minutes left at the end, so the panel can discuss among themselves and take questions from the audience. So I will be prompting you to maybe hurry up a little bit.

DR. STRULLY: My name's Jeff

Strully, and I'm the Executive Director of an organization called Jay Nolan Community Services.

I'm honored to have that position because I get the opportunity to spend time with about 550 people who live with autism and the challenges and the impact that has on them.

I am going to, hopefully, provide two pieces of information for you today. The first is, in my mind, hope that all -- and I want to be very clear here -- all people with autism spectrum disorder can have valued, desirable lives, not just some, all, including the people with the most significant disabilities. So that is the first issue.

The second issue, the vast majority of the money that Ellen talked about is going to segregate, congregate, isolate, and hurt people with autism spectrum disorder. That is what you are funding today. That is the reality.

When I first met Jim, he was in a State-operated institution with two-on-one staffing because of high levels of aggression. Today, living in his own home -- because all people should live in their own home, not in facilities, not in community-based environments, but in their own places. All people should be working, not in enclaves, workstation industries, not in segregated workshops, but in jobs that are meaningful, jobs that produce money.

Now there are exceptions to that rule, of course. The Paris Hilton rule comes to mind.

(Laughter.)

The Paris Hilton rule is, if you grandparent gave you $375 million, you can do whatever the hell you want to do. Except for that, the rest of us poor schlubs should be working.

(Laughter.)

So the question is, was that where

we came from, and the answer is no. Jay Nolan was founded in 1975 by the Autism Society of Los Angeles. Between that and 1992, we tried to do good for people. We didn't. We congregated them. We isolated them. We hurt them. We victimized them.

We decided in 1992 that is not the way people should live. So in 1992, we decided to close group living, day wasting, day services, going to the park, the mall, the zoo, the museum, which is, by the way, how adults with more significant disabilities spend their lives.

People who are generally segregated, we decided to close everything and everyone should live in their own place, and they should control who touches them, who assists them, who supports them, and how they are supported. We believe that people should stop doing wasting, which is what, again, most day services for adults with disabilities in this country do, day wasting. That's how it is, and the reality is that is not the way people should live.

We decided we were going to change that. So now we decided, as I said, people should own their own businesses or work, or whatever.

What we have discovered right now in our supportive living program is we are currently supporting 97 people in 96 places of their own. Two people with autism decided to live together, and we said, why? Why do you want to live together?

And the mother said, well, because they had a DSM-IV diagnosis.

We said, well, that's no damn reason for people with disabilities to live together.

And the two kids said to us, well, we like the Lakers; we like the Dodgers; we like the Kings.

Well, we could agree that people with autism don't have good inspirations of good decisionmaking -- (laughter) -- but in fact that seems like a reasonable reason to live together. You have some commonality. There's some interest that people have. So we decided on that.

We serve a very unique group of people. Half our people used to live in a wonderful place called Camarillo State Hospital, which at one time was the largest institution for people with autism in the world, 6,000 people all on one campus.

We serve folks now that got out of Camarillo, went into the group home, and now are living in their own places. Eighty-nine of the folks we support live with a housemate. In our words, a housemate is a non-disabled person who lives with a disabled person, so that the disabled could live in their own place. The fact of the matter is eight of the 97 folks need just walking support.

Oh, by the way, we do this course-neutral. Anything I say is not a Cadillac service. It is using wisely monies from the

State and federal government as compared to what is done generally, in my opinion.

What is an interesting fact here is I discovered something. Forty-eight percent of people who have housemates have been living with the same person for nine years. Right, a non-disabled person has been living with a person with significant degrees of autism for more than nine years.

What does that tell you? People with autism are as good as the average American couple.

(Laughter.)

And I thought these people don't like relationships. I don't think that is true. That is not what we see. We see that people are dying to have relationships. People are dying to have lives that matter. The question is how to do that, of course.

Just real quickly, because we don't have enough time, we think everyone should be working. Right now we are trying to get people to own their own business, work in whatever jobs they think makes a lot sense to them, and definitely earn some money. Then we will figure out how to deal with Social Security through PASS plans, and so forth.

Just an interesting thing, when people left our group homes where we had high turnover, high special incident reports, high property damage, we don't see that when people are living in their own home.

As a matter of fact, let me tell you something. When people have lives that matter, people don't have challenging behaviors. Environmental change itself eliminates most acts of aggression, property destruction, and self-injurious behavior, not everything, but when you put people in crazy things, you get crazy stuff.

When you have people have control about who is involved in their lives and what their schedule looks like and who makes decisions, we just don't deal with all the craziness that exists in our country right now.

Ellen just kept on with her facts and facts.

(Laughter.)

Let me just end and turn it over to my colleagues here.

Just let me end this way: you have the ability not only to push the research question on all the good issues you talked about, but I would like some issues addressed. What is a wonderful direct support worker? What are the traits and characteristics of people who are really good at supporting people out there day-in and out?

Help me provide better supports by looking at things that actually touch people and how to support them, so that they have more friends, they are more involved in the community. They have more control in their lives. They have more income, and lives are truly desirable. That is the information I need.

The second and last point I want to make is whoever tells you money is the sole problem doesn't know what they are talking about. You could do good with the money that exists. That is not to say we don't need more money, but we also have to start looking at how we are spending our money because we are wasting tons of money for people with autism that are not getting the outcomes we want.

Thank you.

MS. HOMER: I would like to add this is not a slide, but this is a tough act to follow. I want to grow up to be just like him someday.

(Laughter.)

MS. BECK: I'm your parent of a child with autism. He's 24 years old. I am going to try to describe to you what it has been like for 24 years.

Statistically, when my son was diagnosed, it was 1 in 10,000. So this is wonderful to see you all here and talking about it. It's great.

Anyway, there he is right there. His name is Brandon and he's 24. He has autism, and he also at the same time contracted juvenile diabetes, which was an interesting phenomenon. It was like within the same six months, and we didn't even know he had the diabetes until later.

But imagine trying to deal with a child who couldn't communicate and his blood sugar was low or high. You just didn't know what you were doing.

Currently, he is on an insulin pump, but in those days when you gave shots, you had insulin levels that were going every which way. It was an interesting time to live through.

One note about my son: he is very skilled at the piano. He has an ear for it. So we have been capitalizing on it, and you will see further in on my talk about it.

Plus, he's got very strong computer skills, which is an asset for him for work.

I'm not going to go over it, but these are just a few of the things that we tried back in the day when autism was just a new word in the vocabulary. We tried all of these things.

There was one thing that really helped our son, which was a diet change. We took him off wheat, corn, casein, gluten, yeast, and sugar. Interesting to try to do that when you have a diabetic son who has to constantly eat. So it was also challenging, but we worked it. We made it work. We made it happen.

Also at that time, there were no products on the market. Coeliac disease didn't come out with all their products. So I had to kind of create my own, make my own food for him, and constantly stay at it.

So we tried different drugs on him and nothing worked. These are just a few. We tried chelation, which was just a disaster, and we almost lost my son trying to do that piece of it.

So, currently, we are just doing those three pieces at the bottom, which is this diet we are continuing with. We have some Lexapro and Novolog to keep him ticking.

This is just kind of an overview of some of the things that we found were helpful to us. Early intervention, of course, was really important, but we didn't have an early intervention program in the school that he attended. So I had to do that myself.

I remember taking him into a small closet with toys and moving his mouth to get him to talk and repetitive things to get him to move forward. So we were starting at the ground level.

I wasn't educated in special ed. I have an art degree. So this was totally different for me.

But we found, in mainstreaming, some

of the kids were very, very open. They wanted to be a part of his world and embraced him and made him part of their world as well, which was so wonderful.

Teachers and administrators -- now we are talking, we didn't have programs. I am talking 20-some-odd years ago. So this was all new for all of them, and you had some teachers that were really willing to make it happen for him and some administrators. It was wonderful.

We had to advocate at every meeting, every IEP meeting. Anything that we needed, we had to make happen and be a part of that. The bottom line is you had to be persistent. But at the end, Brandon did earn a diploma, which was to us a miracle.

So now I am going to talk about waivers. He is now in the transition state, and we were lucky enough to -- we live in the State of Maryland. We were lucky enough to be fifth in the State to get the New Directions

Waiver. It is a self-direction model, which I guess everybody has been talking about that.

I am his support broker in a sense, where I get to hire staff. Everything is done at home. It is a home-based program. I hire staff. We have a full-time coach. We have staff that comes in the evening. Because of this special diet, we have a cook that comes. All that is supported under the waiver. He takes piano lessons. If he needs speech, we can do that. Respite.

I do want to make mention -- and this is a little off the topic, but at 20 Brandon was able to fluently learn Hebrew and have a Bar Mitzvah. That was really wonderful to watch and very moving for everybody who participated.

Currently, he has a part-time job at our public library. He attends piano classes at the Peabody Preparatory in downtown Baltimore and has had recitals down there.

They embraced him. I never told

them that he was autistic. It was just wonderful to see him up on that stage playing piano just like everyone else and loved it.

Brandon has a girlfriend, which is very exciting. He also plays in a rock and roll ensemble.

The bottom line is that this enables him to have a real life and to participate and be a part of the community, not to say that it is easy. We still have challenges trying to get people in the world of work to understand that Brandon is capable of doing more than what they assume he can do. So that is a constant challenge. Social skills, getting folks together with him is always a challenge.

The complications with diabetes is always going to be a challenge to him, although we have tried so hard to get technology to keep up with him. That has helped a lot, and he manages his own diabetes. He does his own blood tests. He has an insulin pump. He takes his own insulin.

The future, which is coming up very quickly, is to live independently.

I guess, in closing, are employers really ready to make it happen for people with disabilities? We've hit up against some resistance a little bit.

Are neighbors willing to have disabled folks live in their community? Because property values change as well.

And how to stop the stereotyping and discrimination, and really move forward and be a part of the community.

I just wanted to show you Brandon and his girlfriend.

And that's it.

(Applause.)

MS. HOMER: Now it's my turn.

My name is Emily Homer. We are a waiver provider here in Maryland.

Just to touch a little bit before I go to my slides, when I came to Maryland to do services for adults with disabilities as well as persons with autism, the agency that I came to was not in good shape and was failing because we were doing things traditionally versus kind of thinking outside the box.

So we have kind of changed from having some major issues to really being a thriving agency and moving forward with some new ideas and some new innovations to serve people.

I just want to touch briefly on the company description, the services that we provide, immediate and ongoing challenges that we have here in the State of Maryland, long-term challenges such as staffing, training for staff, trying to buy staff into innovative ways of doing things instead of using the excuse they just don't want to or they just don't know how to, or they are too disabled to learn. Then suggestions for future directions.

Who is ResCare? ResCare is ResCare-VOCA. We merged together. We are a human services company dedicated to helping people to live to the maximum of their ability and to live independently. We are an international company that is owned out of Louisville, Kentucky. ResCare originally came from "respect and care".

More than 45,000 ResCare employees work in thousands of locations, and we serve 65,000 people every single day across the United States.

ResCare provides services in 38 states, Washington, D.C., Puerto Rico, Haiti, Bahrain, Great Britain, Netherlands, and Germany. So a pretty big company.

We provide workforce development for one-stop career centers, transitional assistance for TANF programs, residential employment and supports for individuals with intellectual disabilities, developmental disabilities, and acquired brain injuries. In-home supports for senior citizens with disabilities, so that they can remain in their homes. Academic training, vocational skills training, technology-based home support services, alternative educations in schools that seek to stabilize children with emotional and behavioral difficulties, in-home therapeutic services to support children with emotional and behavioral difficulties and their families.

VOCA of Maryland has been in operation since 1983, and ResCare merged or purchased them in 1999. VOCA is funded by the State of Maryland, and we are up into the waiver, community-based waiver. We function on about $1.9 million a year, and we have about 80 staff, management and direct support.

We provide residential supports to 25 men and women with intellectual, developmental, and mental health disabilities. We do a variety.

I know we had some speakers up here talking about dual-diagnosed people. They don't fall on the DD side; they don't fall on the mental health side. They kind of fall in between.

Out of the 25 that we have, probably 23 of the 25 are dual-diagnosed in some kind of way. They have dual diagnosis.

We have nine locations. Twenty percent of the people that we serve are labeled ASD. Another 20 percent of the individuals that we support in our program have autistic-like tendencies, have autistic-like behaviors, but have never been diagnosed with autism. They tend to fall in that 40-plus age group where there wasn't a lot of knowledge, there wasn't a lot of wherewithal when it came to diagnosing that population.

We support individuals to live in and participate in their communities. We support individuals to exercise choice about their preferences and interests. We support individuals to acquire skills and behaviors to maximize their independence.

These are some of the immediate

challenges that we face. The majority of the service providers are unwilling to support individuals with significant behavioral changes or behavioral issues. Specifically, the last four of the five consumers that we have actually taken into our program and we are currently serving now are autistic, have been labeled with autism. No other provider in the southern Maryland area would provide services to these people.

Receiving calls from the State, from the regional office, saying, "We really need your help. This is a very challenging person." Facing such things as one of the guys that we serve has autism. He also has severe pica. He also has elopement behavior. So he is constantly trying to elope. So a lot of challenging things that are going on in trying to provide an environment that will balance all of that at the same time.

Limited options for support employment. For the people that we serve, the challenges that we are facing, and it kind of goes on here to say that, that 28 percent of the individuals that are receiving services at our agency right now do not have any kind of meaningful employment. They are not engaged in any kind of day programming anywhere. They have no place to go.

We are providing what we call "in lieu of day services". So we are providing supports in home via through the community, trying to get them out into community activities and getting them out during the day, because nobody is willing to support and serve anybody in any kind of work setting.

We have actually taken some of our individuals through supported employment. We get there and they are like, well, you know, we'll get back with you, and then we never hear from them again.

So some real significant challenges that we are facing to support people in the community as a whole.

Limited psychiatric service options for people who do have a lot of dual diagnosis going on -- whether that be because the big story that we hear is that, well, we don't accept Medicaid. They will engage you in conversation. The minute that they find out that they have a disability and a mental health issue, usually that means that they are not going to serve you.

So we have a limited group of psychiatric service and supports out there that will assist us in therapeutic services as well as counseling services, as well as just some behavioral services, to combine that all together to support people in the community.

We have slow payments and low reimbursement to try to make all of these things happen. When providers are not being paid in the medical field, they are not being paid, they begin to pull out of the Medicaid program. They are not wanting to participate in that. So we have a limited selection of physicians that will even serve our people, which then leads me to the next issue: that most of them don't have a clue, until we walk through that door, what we do or the population that we serve.

So you are trying to educate people as well as trying to advocate for the services that our individuals are in need of. For instance, you walk in there. The doctor says they are going to give one of your consumers or one of your individuals a physical exam. That may or may not happen unless you push it and push it and push it. They are going to just write some stuff down and say, okay, we'll see you in three months from now or we'll see you in a year, and not taking the time because, No. 1, they don't have the knowledge; No. 2, they just don't really know where to even begin.

A lot of our consumers or a lot of our individuals may not respond to questions. They may not be able to respond to questions.

Inadequate SSI/DI's contribution to the cost of the room and board, I know earlier we talked about $637 is what they get a month. Two hundred and sixty-two of that actually goes back for personal spending each month, and the rest of that is for room and board. So about 34 percent is actual cost and the rest comes back to the provider to have to take care of.

Staff recruitment and retention. Low provider reimbursement rates directly impact the quality of staff recruited and their longevity. I think around here in the State of Maryland we are paying anywhere from, I know I have heard some of the providers say that they are paying anywhere from $7.25 an hour to maybe as much as $9.00, $9.50, sometimes $10.00 an hour.

We are literally competing with your local McDonald's, Burger King, Checkers, those places that do not require for that person, No. 1, to be responsible for another human life and, No. 2, to deal with the behavioral issues and the challenges that we deal with via the community and as well as in their home.

Some of the long-term challenges: according to the United States Department of Health and Human Services report, the cost for long-term care and home and community-based waiver services for individuals with intellectual disabilities increased from $10.5 billion to $25.5 billion from 1992 to 2003. The same report projected that the federal share of Medicaid outlays would likely approach $2 billion in 2006.

Then some kind of very alarming statistics here that say that, according to this same report by the United States Department of Health and Human Services, by 2020, the demand for residential services for individuals with intellectual and developmental disabilities is projected to increase from $359,446 to $687,938, almost doubling by the time 2020 approaches.

During the same period, the need for direct support professionals is expected to nearly double from 406,175 to 770,370. The workforce that typically fills these positions, workers between the ages of 20 and 39, is expected to only grow 7.2 percent, which is an alarming rate.

We are saying that our need for direct support workers is going to increase by 50 percent and the typical people who serve our consumers is only going to grow by 7.2 percent, which then leads us to the fact, how are we going to fill these positions? How are we going to make sure that the people that we serve out here in the community are actually taken care of and they are supported?

We are going to have to turn, typically, to workers that are immigrants coming in that we then will be facing some challenges such as language barriers, cultural differences.

How are we going to approach that in the next 12 years, which is not really that long? 2020 sounds like a long way away, but it is not that far away. How are we going to approach that? How are we going to look at being able to meet the demands of direct support staff, educate and train our staff to actually come in and do a good job, and find the monies to make that happen and come together?

In conclusion, this is why we do what we do, because they live in their own homes. They decorate their own bedrooms. They can relax when they want to, ride bikes, and even knit.

That's it.

(Applause.)

MR. GROSSMAN: Thank you, Jeff, Pamela, and Emily. We appreciate the discussions from all the speakers this afternoon. It is an amazing dichotomy between this morning's discussions.

I think it is important to note how everybody from a state level, from a private provider, or individual, these various agencies have been able to overcome the challenges that they have been presented with and still have successful outcomes. That says quite a bit for all of you, and thank you very much for what you are doing.

We will open the floor to questions in I guess the four minutes or so we have left. I am going to take moderator privilege by asking the first question.

The first question is: since you are sitting around in front of representatives of federal agencies, and this is the coordinating body to advise the Secretary of Health and Human Services, I would like each one of you, what would be the singular most important thing that you would want to advise the HHS Secretary?

Then I have a followup. What would be the most important aspect that you would like to see changed on any level that would help you to do a more effective job?

MS. HOMER: Speaking from a provider's point of view, I think it comes down to training and recognizing that our direct support staff are professionals, that they carry some kind of clout here. They have a very important job. But giving them ways to train so that they can increase wages, so that our turnover isn't as much.

We develop relationships between the persons that we serve and the staff that are there one day, and the next day they come in and those people are gone. So I would say for us it has to do with training to make better wages, so that there is not that major turnover.

MS. BECK: I would have to say coordination, making it easy for parents to navigate through these systems and have access and know what is available to them.

DR. STRULLY: Leadership, it would

be nice to see some inspiring leadership sometime.

DR. INSEL: Can you come up to the table and we'll give you a microphone, so they can hear you better? This way, people on the phone would be able to hear as well.

MS. KOHLER: Okay, thanks.

Hi. I'm Ann Kohler, and I'm the head of the National Association of State Medicaid Directors, but I also work -- under me is the Center for Workers with Disabilities Program.

I would be interested in knowing how much any of you know about that. We provide lots of technical assistance to states to encourage employment of people with disabilities. Also, if you are familiar with the Medicaid buy-in program that lets people who become much more gainfully employed in voc rehab continue to receive their Medicare and Medicaid benefits?

DR. STRULLY: I'm somewhat familiar

with all of that. I mean, to be real honest with you, I come from a state that is seamless from a funding point of view. So I don't pay attention to the State and where they get the money. I just kind of play with my folks. So I don't know who is Medicaid and who is not Medicaid because you can't tell in California.

MS. HOMER: I am familiar with those programs. I think the biggest issue that we run into right now is finding gainful employment, finding somebody who is educated, employers who are educated to understand, whether that be through a buddy system where you have one of the persons that we serve sharing, maybe not a paid staff person, but a person who is volunteering to kind of buddy up with that person at that job and be kind of their caregiver without -- it is kind of that social connection without being paid to do it.

But the big issue we find is that, and even more so as the economy gets worse, as jobs become slimmer, that employment opportunity becomes less for the people that we serve.

MS. BECK: I just know from our experience in one employment situation that we have been met with a lot of resistance. We have tried to say, well, maybe we can carve this job out and emphasize the strengths that he has and work around some of the other issues, and we have met up with a lot of resistance with that.

MS. KOHLER: Because I kept hearing all day the theme of jobs. Maybe, Ellen, we can sort of work together.

I know we have a Department of Labor grant to expand job opportunities for people with disabilities. We feel very strongly that it is inexcusable that one group of the population has a 70 percent unemployment rate, and that once baby-boomers, like me, if we ever get the chance to retire -- (laughter) -- there will be a tremendous need for workers out there. So it is an area that we would like to continue to work on.

DR. STRULLY: And your point is really a very important point. I mean let's be honest. It falls into several categories. One is expectations. Parents have low expectations; providers have low expectations; state officials have low expectations, and, obviously, federal officials. So everyone has low --

MS. KOHLER: You're absolutely right.

DR. STRULLY: No, no, I'm being -- if we want truth, we should at least speak sometimes the truth.

There's low expectations. Medicaid pays for segregated programs with low outcomes, and it is about time someone says this is not acceptable. You guys are funding this stuff.

MS. KOHLER: We urge strongly trying to change those expectations to say, "Don't tell your child to grow up and be on SSI."

DR. STRULLY: I agree.

MS. KOHLER: So, hopefully, we can get some movements.

DR. STRULLY: Being on SSI means you are living in poverty. Boy, that's a real American outcome.

MS. BLACKWELL: Kathy has a comment to make.

MS. REDDINGTON: I have to disagree with you. Connecticut has very good Medicaid for the employed disabled. People can make up to $78,000 a year and have $20,000 in income.

I don't think our Medicaid programs are segregated programs. They are mostly home and community-based programs. People live at home with their family or in their own apartments.

So I have to say that, as a State official, I disagree with you.

DR. STRULLY: Nancy (sic), go out -- whoever -- come out to California. Look at where most of the people who are --

MS. REDDINGTON: There's a State travel ban in Connecticut because of our budget. So I can't come out there right now.

DR. STRULLY: Let's just think about this for a second.

MS. REDDINGTON: Okay.

DR. STRULLY: Most of the adults with developmental disabilities aren't working.

MS. REDDINGTON: I agree with you.

DR. STRULLY: Okay. Two, most of them are in day hab, workshops, work activity centers, or sitting at home. I don't see celebration in the world.

MS. BLACKWELL: Well, but I would have to add, as the Medicaid official in the room, that, as I said earlier, states design their own programs, and many, many, many more states have put service opportunities in their home and community-based waivers that may or may not be used, depending on a person who is enrolled in the waiver.

We see most of our states are moving toward self-direction, participant-directed opportunities. We are making a vast effort at CMS to try to change these ingrained systems.

So I hear what you are saying, Jeff, but I would still tell you that there are more and more opportunities going into the waivers to create meaningful days for people --

DR. STRULLY: That is true.

MS. BLACKWELL: -- based on their individual needs.

DR. STRULLY: Ellen, that is, of course, true. I'm telling you, just go out and spend time with people with substantial disabilities and tell me where they are at.

It is not a blame issue. It is not a CMS -- fed versus state versus provider. I am just saying, all the stakeholders, if they want better outcomes, better start working together. Or, as Einstein said, to keep on doing the same thing over and over again is the definition of insanity. In fact, that is what we have.

We have pockets of excellence, but those are the exceptions. I know everyone is trying to do it. I am just saying people with disabilities have waited long enough. It is about time they start -- this interesting conversation this morning of 2010 versus 2011 was fascinating until you know that there's real people out there who are going for the next five years to be isolated, lonely, poor. The question is, I think it is time we start working to change that.

MR. GROSSMAN: I think we should be ending about now.

Let me just conclude by saying thank you, all of the speakers. I think it has been a fabulous afternoon.

(Applause.)

As all of you can see, the Services Subcommittee has our work cut out for us. We will be calling on many of you to join with us to participate in this process.

What we tried to do this afternoon was to give you a snapshot of the complexity of service development in the U.S. today and how difficult it is, but also to highlight the successes out there.

I am a firm believer that we know enough right now today to significantly improve the lives of everyone affected by ASD. The problem is that these minimal successes that we are seeing in these few people that are getting the proper access to these incredible workers out there and providers that are giving these services and changing these lives is at single-digit percentages.

The issue today is not knowing what it is that we need to do; it is the accessibility of those programs. That is what we hope to accomplish in the Services Subcommittee, is to provide that accessibility, so that 100 percent are receiving and having the successes that the very few are receiving at this point.

Thank you all.

DR. INSEL: You will get the last word and then we are going to break. So let's make it quickly.

MS. THALER: I want to make a comment about the pockets of excellence. My members are the directors who run the DD services and most of those waivers.

You're right, most of the day services are segregated services, and my members struggle with that all the time. We have a huge project in support of the pilot leadership network, trying to figure it out, trying to make that conversation relevant to this group.

My directors struggle with services, particularly for folks with autism/autism spectrum disorder, because they don't know exactly what works and how much of it works.

So when you open yourself up to enrolling everybody, you've got to manage costs and you want to be effective in what you do. Our members struggle with what types of services work for which people and what is the amount and duration and frequency with which those services should be delivered.

Thank you.

DR. INSEL: That is an important message to end on and, actually, will be dealt with when we think about where the research can help in this endeavor as well

I wanted to thank you, Lee and Ellen, for your leadership on this.

This is an introduction. We are going to take a lot more time in this arena, and there's a lot more we have to learn about it.

I think, going forward, it will be very helpful to understand where the traction is, where we can really begin to make some change. But what I heard today, which I think is so important, is that we really need to raise the bar, that we need to really increase expectations.

I was serious. I think one of the ways that this Committee can be helpful is to bring the Secretary into this discussion, the new Secretary, so he can begin to hear the gap between what the intention may be and what is actually happening on the ground.

Let's break here, reconvene in 10 minutes. We will go into the public comments session.

(Whereupon, the foregoing matter went off the record at 3:23 p.m. and went back on the record at 3:33 p.m.)

DR. INSEL: We would like to move into the public comments section. So if we can have people take their seats?

We've got a number of people who have written to us about wanting to make public comments. We have about 30 minutes scheduled for this. I have six names on here. So we will be asking people to limit themselves to five minutes.

We will start with Eileen Nicole

Simon.

DR. SIMON: Thank you.

Can you hear me?

DR. INSEL: No. You may need to bring the microphone a little closer.

DR. SIMON: All right, I will just hold it.

This first slide is just to show you I have been at this for a long time, and it hasn't been fun.

Our whole family is in such a disaster mode because Anders, our oldest son, is due for a jury trial on December 14th. I have no idea what is going to happen with him, but I have been working since he was a baby to understand what might be the cause of developmental language delay.

I hope I'm going to do that correctly. Which key is that I push? Oh, I've got it.

In October of 1969, The Scientific American arrived in my mailbox with an article by William F. Windle describing the brain damage caused by asphyxia at birth. To me, that was an "aha". Well, that explains the problems with language development. I just, for the life of me, can't understand why this research is so lost in the dustbin of history and not paid attention to anymore.

Therefore, I have actually two points here. I feel that the IACC research plan must include investigation of brain impairments that can result from oxygen insufficiency during birth or a lapse in respiration during birth. I think professionals tend to not understand the biochemical basis of respiration, and I could go on for an hour on that. Auditory nuclei in the midbrain, the inferior colliculi, are selectively damaged by a lapse of respiration of six to eight minutes.

These two pictures here are from the article by Windle in The Scientific American.

My second focus for research that I

think should be important is to investigate the midbrain auditory system as the possible final common pathway which everybody talks about affected by all causes of autism. These small nuclei in the auditory pathway have higher blood flow and metabolism than any other area of the brain.

This was discovered more than 50 years ago by the former head of the NIMH, Dr. Seymour Kety, who was very interested in blood flow and metabolism in the brain. They did experiments with radioactive tracers and found, to their great surprise, he and his group, that blood flow and metabolism are not uniform through the brain. It is not the cerebral cortex that is most metabolically-active, but nuclei of the auditory system in the brain stem have the highest blood flow and metabolism in the brain.

I have done a lot of research on this. Dr. Ladislav Fisch -- I don't know if he is still living -- in England pointed out that the auditory system is the vigilance center of the brain. It is the one center of the brain that can't go to sleep unless we stone it with drugs or something.

The auditory system is continually active even during sleep. That is why we use alarm clocks to wake up.

The high metabolic needs of the system make it very vulnerable to not only oxygen insufficiency, but, for instance, pesticides, mercury. Mercury is known to be harmful to this area of the brain.

Well, because I keep looking, looking, looking, I found at least 13 case reports of loss of the ability to comprehend spoken language following injury of the inferior colliculi. I have listed them there.

I have also posted this online on my website, which I will put up later. It is probably in the IACC document somewhere.

But my question is, how much more serious such an injury should be for an infant who has never been exposed to language? There may be a reason why this is happening more often.

I put up a website and I got immediately emails from all over the world asking me, do you know how soon after birth your son's umbilical cord was cut? And I said, well, clearly, before he was breathing, because he was on the other side of the room, white as a ghost, and I asked, why isn't my baby crying?

Now I find out -- I have had to do a lot of research on obstetric practice now, and I find this policy that they published in November of 2006 that immediately after delivery of the neonate a segment of the umbilical cord should be double-clamped, divided, and placed on the delivery table pending assignment of the five-minute Apgar score.

How many of us as prospective parents have any idea that this is a standard procedure in the delivery room? On the other hand, how many of us or how many parents today are encouraged to bank their baby's umbilical cord blood, which means clamping off that lifeline to the mother as soon as possible after birth, and if the baby --

DR. INSEL: I'm sorry, Dr. Simon, but it is six minutes, and there are lots of other people in line.

DR. SIMON: Oh, okay.

DR. INSEL: So I'm going to have to ask you to wrap up in the next 10 seconds.

DR. SIMON: Okay. Well, I just have one more thing. Vaccination after asphyxia may be double trouble because asphyxia disrupts the blood/brain barrier and allows any kind of foreign material circulating in the blood to get into the brain. I think that autism might be a variant of kernicterus, which is bilirubin staining.

Then this is just --

DR. INSEL: We are going to have to

stop because we have so many other people waiting.

DR. SIMON: Okay. All right.

DR. INSEL: Thank you very much for joining us.

DR. SIMON: All right.

DR. INSEL: We are going to move on to Maribel McIntyre.

DR. SIMON: This is online and I hope people will read it.

MS. McINTYRE: Good afternoon.

I am just going to read my statement.

First of all, thanks for having us here.

"Your child has autism." After hearing these words and going through the stages of grief, we asked ourselves, what options do we have? How can we help our children? How is science looking at this condition?

In 2007, the IACC invested about $35

million on characterization of genomic studies. Although I understand the genetic studies are very important, I also think that questions on the environment, the genetic gene environment interaction in children's development are very urgent questions that need to be addressed and properly funded.

I am positive that my experience with autism might be different from some of yours. I live with autism 24/7.

When I look at my son, I see how autism affects his whole body, not just his brain. I take notice on his developmental challenges and his health, and specifically, his gastrointestinal issues.

Usually, these children's GI issues, many of them develop yeast, parasite, bacteria, and viral infections throughout their gut. I encourage you to visit the gluten-free, casein-free blog to see what the majority of us have to deal with on a daily basis. Let me warn you, it is very graphic.

But there is more to autism than just gut issues. A lot of these kids are highly sensitive and get easily overwhelmed by their environment. So activities such as going to the movies or the pool are very stressful or just simply out of the question.

Due to their extra sensitivities, getting them to try new foods looks very much like a high-protocol negotiation or a wrestling match, which leads us to another question: can a child consume and absorb enough calories and vital nutrients from a so restrictive diet while experiencing constant diarrhea? I asked this question to my pediatrician, but I didn't get a satisfactory answer.

I also asked for some tests to be performed to see if my child was allergic or sensitive to some foods, but she said that it was just a phase. Well, it lasted for two and a half years.

Now I would like to take you back to

the spring and summer of 2007. My son Christian was about two and a half years old, and this was the heart of his self-restricting diet phase. He only ate cheese, yogurt, milk, bread, and fruit.

I painfully remember that his eye contact had diminished to almost nothing, and he wouldn't even respond to his own name. He looked like he was in a fog and seemed more interested in spinning toys than interacting with us. He lost most of his social skills and words by then.

We were very worried and thought that his behavior was very odd, but the word "autism" hadn't entered our minds yet.

When my mother-in-law decided to teach him to drink milk from a sippy cup, he threw a fit. He had refused to learn and he quit drinking milk altogether.

Then, within three days of his milk strike, he started using his words again. We were very surprised. He also learned how to use a spoon and he was interacting more with us. It was fascinating to see these changes in him. Although he was still engaging in behaviors and was still suffering from GI issues, we noticed that he was learning, that he was imitating, that he was connecting with us.

Within months, our child had gone from being almost non-responsive to wanting to learn and repeat everything. We were thrilled by his progress, but puzzled what caused his development to slow down and even slowly regress. What triggered his development to initiate after a regression? And most importantly, what does milk have to do with it?

It was not until six months after his milk strike that we learned about the benefits of the gluten-free/casein-free diet by medical interventions and the role of a doctor.

We finally found a doctor who was

open to testing, just testing, for food sensitivities, and also understood the severity of Christian's GI issues.

Our doctor ordered two specialized tests. You probably have heard of them, the urine peptide test for casein and gluten and the organic acid test or OAT.

The peptide labs showed high levels of casein -- at this point he was still eating yogurt and cheese -- and moderate levels of gluten. It appears that these unbroken protein chains have an opioid effect when they reach the brain, but I will leave that to you, that answer, for you to answer that question.

And that would explain, also, that stoned-out look that he used to have. You call out his name and he was just looking at la-la land.

The OAT test showed high levels of bacteria overgrowth, yeast, Krebs cycle, and other markers.

Anyway, he has been doing wonderful

with the diet and probiotics and supplements.

I know that his story is not unique, and you can go to websites such as TACA or Age of Autism to actually read more about stories of families dealing with this issue.

I think that my question is that we need more studies to validate, expand, and deepen our knowledge on biomedical interventions with dietary manipulations and other therapies.

I know in 2007 the IACC only spent 1 percent of the whole budget on biomedical intervention. My question is, why don't we spend a little bit more?

Thank you.

DR. INSEL: Thank you.

The next speaker is Katherine Walker.

MS. WALKER: Hi. Good afternoon. I am very humbled to be here today.

I am a mother of a young child with PDD-NOS. It has been very enlightening, this discussion, especially listening to the mothers of the older children. I don't know whether I should be hopeful or scared.

But there's many cats in the room, and it seems like this Committee is really trying to deal with herding a bunch of cats, but I am going to focus on what is important to me and my child right now. So I am going to go ahead and read my statement.

It says, good afternoon. My name is Katherine Walker. I'm not a doctor or a scientist or a member of a pharmaceutical company. I am a mom of a boy who has PDD-NOS. I am an advocate.

You could say I represent thousands of families who couldn't be here today. I am here to tell you a story.

Two summers ago, I took my son Adam to a water park. My son loves the water and was getting more adventurous with the encouragement of his teenaged cousin.

As the two boys ventured further

into the water, things got bad very quickly. The cousin went a little bit too far. Adam followed, but could not reach the bottom and panicked. A lifeguard right next to Adam kept looking at him, but did nothing, even as Adam screamed and cried.

Being nonverbal, Adam couldn't say, "Help." Adam was up to his ears and barely keeping his head above the water. I ran toward them yelling, "He needs help. Help him."

When I reached Adam, I was nearly chest-deep in water. I looked up at the young lifeguard, who was supposed to be watching for swimmers in distress. "Didn't you see him?", I yelled. The young lifeguard said nothing.

I got Adam out of the water, calmed him down, and Adam soon went back into the water. It just wasn't a big deal for him, but it was a horror for me and a harsh awakening to reality.

As parents, we must realize that no

safety system is foolproof. We are the ones that must advocate for our children when the safety system is failing or does not have a broad enough scope.

Many, if not most, of our ASD children can't tell us when they are in distress. They can't tell us that their tummy or their bottom hurts, even though they have continual gastrointestinal issues and diarrhea.

Perhaps some of you understand that, and I hope that at least some members of the IACC and those who finally determine what studies get funded experience this daily battle.

Parents are in the trenches every day fighting ASD. We know our children. We see what works and what doesn't work.

This is why I find it inconceivable that the reports of parents regarding causes, symptoms, and treatments is labeled as "anecdotal". The last time I checked the scientific method, it was form a hypothesis, conduct research and experiments, then come to a conclusion based on the results.

For example, my son Adam has responded well to the GFCF diet, and I have seen great improvement in real terms of attention, verbal communication, temperament, and interaction with his family and peers. He is generally a calmer and happier little boy.

I have had my experiments with the diet, like the pizza he recently ate at Chuck E. Cheese on a holiday. His symptoms flared, especially behavioral symptoms, screaming, agitation, sleeplessness. It is unreal how gluten and casein affect my son.

The medical establishment should no longer tell parents that our everyday experience with ASD is not adequate enough to merit and trigger formal clinical unbiased studies.

Thomas Jefferson said, "It behooves our citizens to be on their guard, to be firm in their principles, and full of confidence in themselves. We are able to preserve our self-government if we will but think so."

The Combating Autism Act originally included support of the study of vaccine safety and biomedical interventions. This is clearly indicated by the legislative history, such as the comments made on the Senate Floor by Senators Enzi and Dodd. I know that portions of the bill were stripped out, but the heart of the issue is still there, and we parents are on guard. The fact that I am here this year is proof of that.

The IACC, NIH, CDC, AAP, and other groups have no choice but to see the new paradigm of autism. This is a whole body issue. This is not simply a neurological issue.

There is a direct relationship between the gut and the brain. What we put in our children's gut, especially when the gut is being attacked by fungus, bacteria, and even viruses, has a most serious impact on how their brains function. Even the most well-known institutions aren't looking at the whole picture.

While at a follow-up visit to a prominent institution in Baltimore, Adam's pediatrician was supportive of the GFCF, but when I informed the doctor of recent biological testing ordered and supervised by another doctor, I even shared the printed results that revealed high levels of toxic metals and Candida in Adam's intestine, this doctor showed little interest and moved on. Apparently, heavy metal toxicity and a raging yeast infection were not important.

That summer day at the pool a young lifeguard was not paying enough attention to my son. He did not look close enough to see Adam's source of struggle, even though the outward signs of distress were evident. I had to save Adam.

I reach out for help for Adam even

when conventional medicine may not approve. When the typical safety system does not work effectively or efficiently, when the lifeguard is not paying attention, for whatever reason, I must act.

The NIH, CDC, IACC, and the AAP all have roles as lifeguards in protecting our children, in discovering all possible ways to help those dealing with ASD. Your mission and core values must include an authentic commitment to uncover and curb the causes of ASD. It must be done without bias to any industry or government interest or initiative. It must be fair and balanced.

I thank the IACC for allowing me the opportunity to speak, and I will conclude with one more quote from Thomas Jefferson. "The force of public opinion cannot be resisted when permitted freely to be expressed. The agitation it produces must be submitted to."

Thank you very much.

DR. INSEL: Thank you.

The next comment is from Jim Moody.

MR. MOODY: Good afternoon. I am Jim Moody, and these comments are on behalf of the National Autism Association.

The strategic plan for autism research is the heart of the Combating Autism Act as it charts a course driven by scientific research and clinical medicine to find the cause and treatments for autism.

The community has an extraordinary opportunity with this plan coinciding with the beginning of the Obama Administration. This plan must bring to bear the best we have in science and medicine to combat autism, but it also must be remembered that this plan embodies the hopes, prayers, and dreams of tens of thousands of families that are dealing every day with autism, that this will bring home their stolen children.

Autism must be declared a national health emergency that justifies a crisis-level response from the White House. A crisis-level response is justified by the rapid rise in ASD prevalence, the extraordinary burden on families and society, and the opportunity and answers provided through research that have an immediate impact. Epidemic denial is no longer possible, given the tenfold increase in prevalence during the past two decades.

Some claim that the rise is not real but rather an artifact of better labeling and services-seeking behavior. But the precautionary principle demands that the rise must be presumed real and drive policy until proven otherwise by rigorous evidence.

In a questionnaire answer on the subject of the autism epidemic, President-Elect Obama said, "These numbers can no longer be explained solely by increased awareness or changes in the diagnostic criteria. It is a health crisis and I will act accordingly."

Determination of environmental triggers can lead to rapid reduction in new cases of acquired autism. Recovery of function and loss of diagnosis is possible, but interventions, both biomedical and biological and behavioral, must be introduced at the earliest possible time to maximize their effectiveness.

For the plan to work, it must be more than words. It must justify the expenditure of a substantial increase in research funding, based upon a cost of disease analysis and the opportunity for science and medicine to perform high-quality work. It must reprioritize significant resources to research by environmental triggers, biological mechanisms, and treatments, both biomedical and behavioral. It must ensure continuity and accountability with an autism advisory board composed of scientists, clinicians, and advocates.

It must ensure transparency and accountability by involving the community in decisions regarding both scientific merit and relevance to the plan and its goals. And the plan must re-engineer the funding process to provide for rapid innovation and decisionmaking and metrics that ensure that the program and goals set forth in the plan are being accomplished.

Congress and the community have repeatedly called for research on the role of vaccines and their components in the etiology of autism. CDC's claim last July that the science on this is done and it is time to move on is contradicted by a growing scientific consensus that vaccines do play a role in the autism.

The government has conceded in vaccine court that vaccines can cause autism and, famously, in the Poling case and at least 10 other cases. The open question remains, how many children have been vaccine-injured and what can be done to help them and prevent new cases?

CDC's original Verstraeten study found statistically-significant associations and reported them in industry conferences in Simpsonwood. These signals were subsequently concealed through post hoc protocol manipulations and included an exclusion criteria.

Following revelation of this manipulation, Verstraeten published a letter in Pediatrics in 2004 retracting any interpretation that the CDC study proved no causation, stating in part, "The bottom line is and has always been the same. An association between thimerosal and neurological outcomes could neither be confirmed nor refuted, and therefore, more study is required."

The most recent analysis of CDC's Vaccine Safety Datalink by Young, published last June, confirmed a statistically-significant association between several neurodevelopmental disorders and mercury in vaccines.

Frank DeStefano and colleagues at

CDC, in a 2002 published paper, also confirmed an association between the age of MMR and the onset of autism, although dismissed this as an artifact.

I am going to sort of skip over a few things to just finish up here.

DR. INSEL: Jim, it's been five minutes.

MR. MOODY: Right.

DR. INSEL: If you can just take another minute --

MR. MOODY: Sure. All right.

The one-size-fits-all vaccine schedule has never been proven safe by the ordinary method in animal/human trials. The schedule, therefore, must be presumed unsafe and experimental.

In the absence of adequate safety data, is it any wonder, then, that the public is voting with their feet not to take the vaccine schedule? The crisis in confidence is growing with many citing autism as the reason not to take the routine vaccine schedule.

DR. INSEL: Jim, I'm going to need to ask you to bring it to a close.

MR. MOODY: Okay. Sure. In conclusion, the plan must express a meaningful commitment and process to achieve the congressional goal of treatment and prevention. Change is in the air. IACC has an extraordinary opportunity to adopt a muscular and aggressive plan that uses the tools of science and medicine to make an immediate impact on the lives of those with autism.

To paraphrase President-Elect Obama, yes, we can implement treatments and recover kids and provide them, those on the spectrum, with full and meaningful lives. Yes, we can discover any flaws in the vaccine schedule and correct them. Yes, we can work together as a community to achieve these goals.

Thank you.

DR. INSEL: Thank you.

The next speaker is Vicky DeBold.

DR. DEBOLD: Good afternoon. My name is Dr. Vicky DeBold, and I am the parent of an 11-year-old boy with autism.

I represent SafeMinds, a private, charitable, nonprofit organization founded to investigate and raise awareness of the risk to child health due to exposure to mercury from the environment and medical products, including thimerosal in vaccines. Additionally, SafeMinds supports research on the potential harmful effects of all forms of mercury, including thimerosal.

We appreciate the opportunity to provide recommendations to the Interagency Autism Coordinating Committee's strategic plan for autism spectrum disorders research and recognize that the plan's focus is intended to enhance the quality, effectiveness, and overall benefits of autism research spending within HHS agencies.

Many organizations, ours included,

have articulated concerns with the August 15th draft plan being considered today. Specifically, we note that the August version, one, lacks a sense of urgency; two, overemphasizes genetics-only research; three, underemphasizes environment and gene environment interaction research; four, omits oversight and accountability mechanisms, and five, reflects inadequate representation of the autism community throughout the planning process.

Integral to improving the IACC's strategic plan is to clearly communicate the urgency needed to address the alarming rise in autism prevalence and the failure to date to realize the potential of recovery and gains in quality of life through promising treatments.

This language is needed to set the tone for the entire plan and to frame the government's response and allocation of resources at levels commensurate to the obvious crisis at hand.

We strongly recommend that all language failing to acknowledge increased prevalence be removed from the plan and that language recognizing the potential for recovery from disability be inserted.

Funding for environment and gene environment interaction research must be considered relative to genetic research. Although funding levels for environment-oriented research have increased, an inappropriately large proportion of the August 15th budget is allocated to genetic research.

IACC funding initiatives were intended to complement non-governmental initiatives, thereby creating a balanced national research portfolio free of wasteful duplication.

Fiscally-responsible recommendations require that funds earmarked for genetics-only research, already well-funded in the private sector, be shifted to the environmental research sector and adequately funded in all sectors.

Additionally, research related to environmental triggers explicitly detailed in the Combating Autism Act legislative history, namely, vaccines and mercury-based vaccine components, is conspicuously missing from the August 15th plan.

I can't emphasize enough the need for rigorous research that establishes whether causal associations between exposure to vaccines and autism exist cannot be overstated. Townhall meetings conducted throughout the planning process demonstrated the extent to which this topic is important to the public. I want to mention that Congress feels that the vaccine issue is unsettled, and the topic really needs to be investigated.

Provisions for accountability management and evaluation of research spending also continue to be absent from the plan. Oversight and evaluation mechanisms similar to the Department of Defense's grants review model should be developed and implemented by an autism advisory board composed of diverse community representatives, as required by the CAA.

The board, composed of scientists, clinicians, and advocates, would not, in fact, duplicate the IACC's broader work coordinating all federal autism activities, including those related to provision of services. Rather, the board would focus on the scientific research agenda and the CAA provisions related to annual performance measures and strategic plan updates.

DR. INSEL: You will need to --

DR. DEBOLD: Thank you very much for your time.

DR. INSEL: Okay, thank you.

And we have one more speaker, and that is Mike Frandsen.

MR. FRANDSEN: My name is Mike Frandsen, and my website is coachmike.net.

Most of the focus on autism is on

research for children with autism, but less is discussed in the way of research on services for adults on the spectrum. So the presentations of the last hour, it was good to see that.

NIH, HHS, and other agencies need to do a better job of ensuring that people with autism and other disabilities can contribute to their missions. NIH and other agencies have virtually ignored the Schedule A hiring authority, a federal program used to hire people who have a severe disadvantage in getting employment.

Schedule A was developed by the government to help reduce the more than 70 percent unemployment rate of people with disabilities. These are people who want to work and are more than capable of working.

Several years after NIH and other agencies were made aware of their lack of action on the Schedule A issue, there has been little, if any, action taken.

I submitted Freedom of Information Act requests to all federal agencies asking how many times the Schedule A was used to hire people with disabilities. According to my survey, most federal agencies underutilize the Schedule A program or did not use it all.

In almost all cases in which the hiring authority was used, hires of people with physical disabilities outnumbered those with cognitive and psychiatric disabilities by a very wide margin.

A couple of examples: HHS reported that it hired 213 people with disabilities through Schedule A from 2002 to 2008. One hundred ninety-eight had physical disabilities; 15 had cognitive disabilities, and not one had a psychiatric disability.

The Department of the Interior, which has 75,000 employees, used the Schedule A to hire exactly three people with disabilities.

From 2003 to 2008, the Department of

Commerce hired 36 employees with disabilities under Schedule A. All were in the physical category except for one in the psychiatric category. None were hired with cognitive disabilities. Commerce has 36,000 employees.

And there are most statistics at coachmike.net.

The government needs to be proactive in hiring people with disabilities, including those with developmental disabilities. In the hundreds of pages of responses I received from government agencies, not once was there a mention of someone hired who had autism. In the descriptions of disabilities listed by agencies in their responses, the term "autism" never came up, although some agencies did not go into specific detail, other than listing the three major categories.

The classification of disabilities under Schedule A excludes most people on the autism spectrum. The government lists people with disabilities in three categories under this program. The first, severe physical disability, would only sometimes apply to a person with autism. The second, mental retardation, may apply to a percentage of people on the spectrum, but it is now believed by many experts that far fewer people with autism than previously believed have mental retardation, a term that, incidentally, is being phased out in favor of intellectual disability or cognitive disability, though the government is still using it.

Finally, the third category, psychiatric disability, does not cover all those with autism, which should be classified as a developmental disability, a term that would be much more accurate and inclusive under this program.

So the government should ensure that people with autism and other disabilities are adequately represented in federal agencies, and NIMH, NIH, and HHS should be leaders.

It is disappointing that an

organization whose mission is to work to improve mental health, the NIMH, does not have an equivalent program to ensure that those with disabilities can contribute to advancing that mission.

So I would suggest that you just spend one minute of your time, go to coachmike.net when you get a chance, click on the special report, and take a look for yourselves. You may say that it costs too much to include people with disabilities in the workforce, but, in fact, in the long run it costs too much not to do it.

Thank you.

DR. INSEL: Thank you.

We've come to the end of the public comment section, and I want to thank all of those who prepared comments. They will be entered into the record. So even for those who weren't in attendance, they will have access to them.

We need to talk a little further

about what we are going to do from here. We've got a lot more work to do. It is not going to happen right now, but we have to think about how we are going to be able to get together. I am very serious about getting this done before the end of December and certainly before the new Secretary arrives, at the very latest.

So the regulations specify that for a FACA committee we have to have 15-day advance notice in The Federal Register. That would put us somewhere after the first week of December, would be the very soonest we could get back together.

But I do want to put this on your calendars, and we will get back in touch electronically about trying to get together probably in the second, third week of December. We have also talked about the 24th of December, Della, right, as a perfect day?

But we want to try to figure out a time when we can get as many people together around the table, and those who can't can join by webinar, so that we can make some progress on the other half, at least, of the strategic plan that we didn't get to talk about today, and we still have to do the introduction as well, which is a major part of this. So we will be back in touch with you very quickly.

I wish that there were a faster, easier way to do this, but I am afraid it just isn't going to happen except going through it line by line. We need all of you to help us in getting this done.

Okay, thanks for your help today. Thanks for everybody's attendance, and particularly Lee and Ellen for putting together the services discussion, which was outstanding.

We will look forward to getting together in the very near future to finish the strategic plan work.

(Whereupon, at 4:12 p.m., the meeting was adjourned.)