U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES

INTERAGENCY AUTISM COORDINATING COMMITTEE

STRATEGIC PLANNING WORKGROUP MEETING

MONDAY, MAY 12, 2008

The Workgroup met in the Rotunda Room, 8th Floor, of the Ronald Reagan Building in Washington, DC at 9:00 a.m., Thomas Insel, Chair, presiding.

PRESENT:

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

ANN WAGNER, M.D., Executive Secretary, National Institute of Mental Health

DUANE 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

JEFF BUCK, Ph.D., Substance Abuse and Mental Health Services Administration (for Dr. Larke Huang)

JOYCE CHUNG, Ph.D., Autism Team, National Institute of Mental Health

MARGARET GIANNINI, M.D., F.A.A.P., U.S. Department of Health and Human Services

PRESENT (continued):

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

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

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

CHRISTINE McKEE, J.D.

PATRICIA A. MORRISSEY, Ph.D., Administration for
Children and Families

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

CATHERINE RICE, Ph.D., National Center on Birth
Defects and Developmental Disabilities
(for Dr. Edwin Trevathan)

STEPHEN M.SHORE, Ed.D., Autism Spectrum
Consulting

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

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

SAM WILSON, M.D., National Institute of
Environmental Health Sciences

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PROCEEDINGS

9:04 a.m.

Dr. Insel: Looks like we still have a few people who will be joining us.

Thanks to everyone for making it here through awful weather, and for those of you who had to fly in from someplace far away, double thanks. I had to do that yesterday, and I know what a miserable time this has been to travel. Lots of flights have been canceled, and the ones that actually finally make it here, it's quite a bumpy ride, at least if you came in last night or this morning.

So thank you for braving all that to participate. We have a pretty full agenda today. We're going to move around the schedule a little bit. So we'll do the coordination part, that is, the discussion about the various things that agencies and individual organizations are doing, we'll save that for the afternoon, because we want to really plow through the heavy lifting part of the meeting in the morning when everybody is so energized and cheerful. So let's do that first.

Let me start, though, by doing, we'll do a quick round of introductions, so those of us who are around the room will know who’s at the table.

And I'll start. I'm Tom Insel, the Chair and Director of the NIMH.

Christine?

Ms. McKee: Christine McKee. I have an eight year old daughter on the spectrum.

Dr. Trevathan: Ed Trevathan. I'm a pediatric neurologist and Director of the National Institute on Birth Defects and Developmental Disabilities at CDC.

Dr. Lawler: Cindy Lawler. I'm Extramural Program Director at National

Institute of Environmental Health Sciences.

Dr. Janvier: Yvette Janvier. I'm a developmental pediatrician from Children's Specialized Hospital in New Jersey.

Dr. Shore: Stephen Shore, Board of Directors of the Autism Society of America.

Dr. van Dyck: Good morning. Peter van Dyck, pediatrician and Director of the Maternal and Child Health Bureau in the Department of Health and Human Services.

Dr. Huang: Larke Huang, Clinical Psychologist, Senior Advisor on Children and Families to the Administrator in the Substance Abuse and Mental Health Services Administration in the Department of Health and Human Services.

Ms. Redwood: Lyn Redwood. I'm a parent and co-founder and Board Member of Safe Minds in the National Autism Association.

Dr. Alexander: Duane Alexander. I'm a pediatrician, and Director of the Eunice Kennedy Shriver National Institute of Child Health and Human Development at NIH.

Dr. Landis: Story Landis, Developmental Neurobiologist, and Director of the National Institutes of Neurological Disorders and Stroke.

Ms. Singer: I'm Alison Singer. I'm Executive Vice President at Autism Speaks, and I'm the mother of an 11 year old daughter with autism, and I also have a 42 -
- 43 now year old brother with autism.

Dr. Cooper: Good morning. I'm Judith Cooper. I'm the Deputy Director of the National Institute on Deafness and Other Communication Disorders.

Mr. Grossman: Lee Grossman, President and CEO of the Autism Society of America, and the dad of a 20 year old young male with autism.

Ms. Blackwell: Ellen Blackwell.

I'm a social worker from the Centers for Medicare and Medicaid Services. I'm also the mother of a 21 year old son with autism.

Dr. Wagner: I'm Ann Wagner from NIMH, and I'm the Executive Secretary here.

Dr. Insel: Okay. Thanks, and welcome to everybody.

We have minutes from the March 14th meeting. There's a lot of stuff in your packet, so it may take awhile to search through and find those, but I'd like you to take a quick look at them, and see if there are any changes that you want to make to the minutes before we vote for approval.

Everybody found them? Okay. Comments? Changes? Revisions? Do I hear a motion for approval? Participant: So moved.

Dr. Insel: All in favor?

All: Aye.

Dr. Insel: Anyone

opposed? Good. Done.

The last, one of the things that's in the minutes that we talked about last time was setting up a Services Subcommittee to begin to explore this whole area that's come up at each of the previous two meetings around the need to have the committee much more focused on the urgent need for better services, and to figure out how to take the things that we know are useful, and make sure that they're available. And we charged Lee Grossman and Ellen Blackwell with putting a group together, and beginning the process of thinking about how the Subcommittee could function.

So I'm going to ask them if they'll give us an update on where we're at.

Ms. Blackwell: Okay. I guess I have the lead here.

In your packet, you will find the minutes from our first meeting, which was held on April 30th, as well as two copies of the roadmap developed by the previous Services Subcommittee, the long version, and what I believe is affectionately known as the short version.

At this first meeting were Lee and I. Also Larke, Pat, Gail, Christine, Cathy Rice, who was sitting in for Ed, and Bonnie Strickland, who was sitting in for Peter.

Dr. G, Alison and Stephen have also agreed to join the Services Subcommittee, but they were not present at that call.

So if you have a few minutes, take a look at the minutes. I'll briefly review what happened at the meeting.

Lee talked about the roadmap that was developed by the previous Services Subcommittee that was formed under the other law.

And one of the things we talked

about was the need to build and expand upon the work that was already done in that roadmap, especially in terms of covering life span issues.

The second issue that came up is that we will be looking at the roadmap in terms of identifying the easiest and most identifiable goals that are in this document that already exists.

Lee, do you have anything to add?

Mr. Grossman: No, that's it.

Ms. Blackwell: Okay. One thing I wanted to mention to folks is that the HHS representatives on the IACC can appoint designees to attend these Services Subcommittee meetings. So if you haven't joined, is there anyone who would like to join and appoint a designee? Okay.

Another thing that we talked about at the meeting were the projects that are stemming from the National Defense Authorization Act. Gail mentioned a woman named Rebecca Pisanta, and I'm not sure I'm pronouncing her name correctly.

I have also spoken with Captain Robert DeMartino, and both of those folks are working on dual projects at DoD. And we talked about the possibility of bringing them in to talk with us at a future meeting.

One of the other items that was on the agenda was the possibility, with your permission, of issuing a second request for information. This one on services and supports only divided into children and youth issues. We would like to tie this new RFI to the previous roadmap and the previous RFI that garnered responses under treatment.

One of our goals is to learn more about standards and models of care for comprehensive services delivery. So we need to know if everyone is okay with us issuing a second RFI on services.

Dr. Insel: Everybody's very quiet this morning.

Ms. Redwood: Ellen, I think that's an excellent idea. And I was also wondering, would it be possible to get back with you regarding the possibility of having somebody be on the Committee from our Board.

Ms. Blackwell: Unfortunately, my understanding from our Federal Advisory Committee Act representative is that only Health and Human Services representatives can appoint designees, not public members. So you would have to participate, Lyn. But we tried to make it as easy as possible, and you could participate by phone, if you like.

Ms. Redwood: Okay. Let me get back with you. Thanks.

Ms. Blackwell: Sure.

Mr. Grossman: What you're going to hear from Ellen and I are a series of, kind of asks. So hopefully, somebody is making a list of these so that -- no, they're all easy. They should all get a positive response, we hope.

Ms. Blackwell: I think one of the things that we talked about was the fact that we want to make sure that we didn't miss anything in that RFI that was issued with a lot of other things. So if we focused on services, we might pick up something that we didn't get before.

We also talked about the fact that we'd like to have a couple of town hall meetings, at least one electronically. And we need to know if everyone is okay with that plan.

Dr. Insel: Well, I saw the heads nodding for the idea of doing an RFI. In terms of town hall meetings, is there a way we might be able to integrate that with other things that we're doing? Because we will be doing, I suspect, other town hall meetings around the research plan.
Maybe what we could do is use the same format, and integrate these in some way.

Ms. Blackwell: That would be

fine with us.

Dr. Insel: But I see heads shaking again. So it looks like, I assume that's a yes.

Ms. Blackwell: We thought maybe we might want to do one by phone, so that even people who can't travel can participate.

Well, I'll raise this last. But Lee and I both came back Friday night from Nashville. And I'll pass around the program from the National Association of State Developmental Disabilities Directors Meeting. We're both a little bit tired from this meeting.

NASDDDS, which represents all of the state developmental disabilities directors, held its midyear meeting exclusively on the topic of autism. There were 170 people there. Representatives from most states were present. The leaders of several national groups were there: National

Association for the Dually Diagnosed, Human Services Research Institute, the University of Massachusetts Center for Full Inclusion, the Association of University Centers of Excellence, the Council on Quality and Leadership, the National Conference of State Legislators, several Medicaid directors, and some national consulting groups.

Several themes came out of this meeting. And they're not particularly very positive, but I thought I needed to mention them.

The first is that, essentially, I did not hear that there's any new funding for services through the states. States are experiencing the fact that more people with autism and spectrum disorders need to be served, and they expect that already long waiting lists for home and community-based services will get longer.

There was a lot of discussion about the quality and effectiveness of present supports and services, and the need for evidence-based services and supports.

System capacity; the possibility of fostering partnerships within the larger developmental disabilities advocacy community, and the development of regional systems of care within states.

That said, there were a lot of positive things going on, too. A lot of discussion about really neat little programs that are existing in states. One of them, we published a Promising Practices paper on, a little program in Connecticut that serves adults with Asperger's Syndrome; a program in Oregon that goes out and targets children and adults with very severe behaviors, and some other really interesting things.

Lee, you co-chaired this, or you were sort of the force behind this meeting. Do you have anything to add?

Mr. Grossman: Well, it was a very interesting meeting, because these are exactly the people on the service side that we need to be in front of. These are the individuals, on a state-by-state basis, that are implementing the programs that our families and individuals with autism need.

One of the most interesting aspects of the meeting for me was the first day, which was a closed door session with all of the state directors and me and a couple of other people, and it was about five hours of grilling and drilling by them to get a better understanding of autism.
And it was a tremendous prelude, because
then we had the experts presenting for the next two days confirming everything that we had talked about.

What were the more positive aspects of this meeting was this very honest dialogue that we were having so that we can understand the issues that they were dealing with, because they're getting overwhelmed and inundated by autism. They feel a lot of pressure from the advocates, and it's something that makes them not very comfortable. But they were able to better understand why that's happening, and what we can do to address that.

They were also able to better understand how they could program autism within their current programming. And as a result of being better able to serve the autism community, they will then be able to better address the entire disability community.

One of the greatest aspects I think that came out of this meeting was the acknowledgment, finally, and it was something that we had set out as a goal, is that they would understand that they, as a unit, as an agency on a state-by-state basis, can't address the needs of the community in a vacuum, and that they needed to reach out to their fellow agencies and organizations so that they can combine and look at this from a multifaceted approach to be able to address the needs of the autism community. And there was a strong commitment coming out of that, particularly since many of the other organizations had representatives there, that this would happen.

I would like to say it was a great first start, but it went well beyond that. I think it was beyond a first start. It was, we were actually moving towards how we're going to set up programs and pilots, et cetera. And with that said, when we expand on the Services Subcommittee, and start bringing in outside groups to consult on an ad hoc basis, it is those organizations that definitely need to be at the table, because whatever -- we feel, Ellen and I have discussed this, that it's very important to have those people at the table that are actually going to be the ones that are implementing the services, and that are going to be the direct recipients of whatever it is that we say that they need to do. So they should be there from the get-go, providing their input, as well.

And I guess the other aspect, there was quite a bit of misunderstanding about what autism was among these state directors. And it was clear, at the end of the three days, that they understood -- they had a much better understanding of what autism is, and how to address the needs. And for that reason, I think it was a tremendously successful conference.

Ms. Blackwell: Well, another thing I got out of it is that I think the state developmental disabilities directors are struggling with how to deal with autism in the context of the larger developmental disabilities network, and perhaps how to fold services for people with autism into existing waivers that serve people with mental retardation and developmental disabilities that -- in lieu of developing separate products for individuals with autism. So I think that's sort of an ongoing piece that nobody really has the answer to yet. But it's really interesting and exciting to see the dialogue, and that they’re interested. But they really are struggling, especially in this fiscal environment, with the numbers of people who have ASD, and the resources that are dwindling.

We talked about having our next meeting on Friday -- I looked this up last night, Lee, it’s Friday, June 13th. Okay. And our next meeting we would like to have at the Autism Society offices in Bethesda. And we'd also like to schedule regular meetings of the Services Subcommittee prior to the meetings of this larger body.

We plan to do it electronically, but we would like to have this meeting on June 13th as a face-to-face meeting, so we

can sort of spend the day figuring out where we're going, and how we're going to get there, and we think that's important. So
that is our plan.

So again, we invite everyone to join, and if you don't want to jump in today, you can always me or Lee an email, and send that designee.

Dr. Insel: Questions or comments?

Can I ask a few things about -- from the meeting, one of the points that was made here in the minutes was about this national survey of children with special health care needs. And now that has questions relevant to autism, is that something that we ought to be thinking about also for the research plan? Is there an opportunity there to use this for population monitoring, or for a kind of screening effort? Do we know more about that?

Ms. Blackwell: I think Bonnie

brought it up. Tom?

Dr. Insel: Right. From HRSA.

Ms. Blackwell: Yes. Dr. Insel: Peter, is something we should know about this?

Dr. van Dyck: The National Survey of Children With Special Health Care Needs is a survey conducted every four years, a telephone survey of 40,000 or so children with special health care needs that allows data gathering at the state level, as well as the national level.

For the first time, the survey in 2005/2006 had diagnostic categories, which did include autism, as well as a number of others, 13 or 14, I believe.

Those data are now available in a public use file. And there are, I think, multiple agencies and groups looking at various aspects of that. But it does allow some beginning look at children with autism, and their family characteristics, and community characteristics, and medical home use, and some other things that I think are very interesting. And we're just beginning to analyze the data.

Dr. Insel: So will there be another wave, then, in 2009/2010?

Dr. van Dyck: There will be another survey in 2009.

Dr. Insel: Is there the opportunity --

Dr. van Dyck: The 2001 survey did not include information on diagnostic categories.

Dr. Insel: So is there some opportunity now to have a discussion about what will end up on the next survey, whether there are questions --

Dr. van Dyck: We've just had our first technical advisory committee planning that next survey, and they'll be meeting for about a year to determine what would be the elements on the next survey. For the sake of having some continuity between surveys, we don't want to change a lot, but we will accept input.

Dr. Insel: How might we do that? Because I do think that this whole community probably would be very interested in certainly getting the same questions again, but there may be an additional couple of questions that would be really critical, especially with respect to service utilization. How would we be able to have any input into that discussion?

Dr. van Dyck: Maybe one way would be for me to tell you who the members of the technical advisory committee are, but certainly anybody can submit information to me. I make the final decisions on the questions that get on the survey, so --

Dr. Insel: So you're the man?

Dr. van Dyck: I'm the man after

everybody else has done the hard lifting.

Dr. Insel: Excellent. They're already on it. I can tell they're going to work on it.

Dr. van Dyck: So we'll be happy to work with folks on it.

Dr. Insel: That would be great. And so the time frame we have is about how many months now?

Dr. van Dyck: I would think the next six months, within the next six months.

Dr. Insel: Okay.

Dr. van Dyck: It's a good time for --

Dr. Insel: So, I would think this is something that the Services Subcommittee might want to put on their agenda to be able to at least look at the questions, and to determine if there's anything additional, knowing that it's going to be constrained, because it can't be too long, and it can't be too different.

Dr. van Dyck: And Bonnie, who is representing me on the Committee, is a member of the technical advisory committee, and also could represent us well.

Dr. Insel: Terrific. Okay.

The other question I have is, just as a sort of a point of experience, we do a lot of work with states through the NIMH, because all of mental health care is through states, not at the national level. And one of the things we've been trying to do, it might be of some value here, is to actually set up some of the state efforts in a comparative way. So we think of them now as 50 independent laboratories where, if five of them make a particular change, and five don't, we can actually do comparisons.

So even though I know you're focused on the services piece of this, there are some really important research questions that will emerge about how to implement evidence-based practices, how to deal with payment for services; a whole bunch of issues which this, as much as it sounds like it's overly chaotic and confusing, it's also an opportunity, when states begin to make changes, for us to build in the kinds of evaluations that will help other states to make the right changes. So we've been doing that in other areas. And I think we ought to look at this, and see whether there's a chance to do something like that here, as well.

Mr. Grossman: The person that was getting drilled and grilled with me that one day in the closed door session was Brenda Smith Myles, who’s the second most referenced person in autism and applied research, and that was one of the aspects that she was discussing.

There were 70 people in that meeting that was representing, I think, 42 states, and we were talking about how we can

pull the information together in a repository of what's happening at each state, develop models, get their data, so that we can put it together in a thoughtful research manner, so we could, hopefully, get some sort of evidence-based information out of that. Or at least to establish what is a good model that others can replicate,
instead of trying to recreate the wheel.

Ms. Blackwell: One of the things that I mentioned on our call, and I sent
folks that were present, was the link to the National Core Indicators Project. And when I was in Nashville, I missed the first day. They didn't let the federal folks come, but I was really excited to see that the National Core Indicators Project actually has core indicators for satisfaction for home and community-based services associated with people with autism. And it's in draft right now, but they will be publishing it over the next few months. So that is really

an interesting project, and something we can look forward to sharing at a future IACC meeting.

Dr. Insel: But I think one of the things we ought to plan for is, maybe not at the next meeting, but the meeting after, to really take a lot more time, and dig into some of these issues, and maybe get some people from the state system to talk to us about what the issues are they're facing.

I have one last question, and something that you mentioned that sounds like at the meeting, but I wanted to hear more about your thoughts on going back to the roadmap from the previous IACC, which did a lot of good work, but never really tackled the implementation questions. And whether there was some discussion at this Subcommittee meeting about how we could begin to do that going forward. Because I think that's kind of been the barrier in being able to actually have any impact here.

Mr. Grossman: Well, yes, I think that's the critical question that we're facing right now. So, in looking at how to move forward on this, the next meeting in June 13th, Friday the 13th, is to get the Subcommittee much more organized. And that's why it's only for the Subcommittee members and their designees to be there. And from that, we want to start exploring ways to relook at what's been done, because the roadmap is an excellent document. Ellen and I have promised the Committee that we'll do this as a Committee. We’re not, in any way want to dictate or direct it. We want to make sure that this is an open process.

And Ellen and I are also stumbling and fumbling through this, as well, because of the fact that we're under the FACA rules, and we don't want to do anything that is not working under those rules. But we're not experts at it, also.

And we feel, at that next meeting, we'll be able to have a better understanding of how to proceed.

For example, we're talking about: These town hall meetings, doing one electronically, and perhaps doing one at the ASA conference in July;

Issuing the RFI;

Scheduling a series of meetings of the Subcommittee;

Expanding the Subcommittee to include ad hoc consultants, which would include these national associations of state directors of many different types of agencies;

Bringing in the USADs, adult service providers, et cetera, to look at convening, perhaps, policy forums, which would relook at the roadmap, take ideas out of that, expand upon them so that they can be implemented in terms of policy, and perhaps policy reform.

And I had talked to Ellen. And, unfortunately, we haven't had a lot of time to look at this, but I wanted to put some kind of structure behind this, and possibly look at, there's a very significant meeting happening in the third week of November, in Columbus, Ohio, that will bring together the leading educators and behavorialists, and many state agencies together. And looking at that as kind of a goal for us to really have looked at the roadmap, convened the consultants, hashed it through, had the town meetings, had some of these meetings, and then have a full discussion among, again, most of the people that will be implementing, there will be about 2,000 people there at this meeting in November, as a time frame, or as a goal to rollout what our plans going forward will be.

Unfortunately, Ellen and I have just been limited by time, and how much we can spend. And again, these are some of the topics for discussion at the Subcommittee meeting on the 13th.

Dr. Insel: Well, great. This is really wonderful the two of you have taken this on. And I think everyone on the Committee concurs that your leadership is going to be really helpful here.

It's a marathon, so we're not expecting a huge amount in the first meeting, but over time, we're hoping that this will become a really important arm for the IACC.

Unless there are any other questions? Larke?

Dr. Huang: I just wanted to commend our Co-Chairs on that Services Committee, because there's a huge amount of work to be done.

And around your question about an implementation plan, that did come up. Because in that roadmap, there's specific recommendations under each of the subsections. And we were going to sort of do an alignment, look at those, go one-by-one over those recommendations, and see what's been done. See how we can align it with some of the other activities going on.

I also just want to mention, around the National Survey of Children With Special Health Care Needs, that there is a public use website now which is geared toward families, and providers, and states, that displays the data state-by-state on the previous ones. So it's a nice model for getting the survey data out to the public, not just in public use files, but there are things that are graphed. You can go and query around your state information, too.

So as we think about getting survey data, not just there for research, but also so people can access what's being collected by state or substate areas, I think that's a very useful model.

Dr. Insel: Thank you.

Any other comments?

Okay. Let's move on. The next item on the agenda has to do with the town hall meeting. And Cindy Lawler, who did so much to organize that, and is going to give us a report.

Dr. Lawler: Good morning. I'm going to take the next ten minutes to share with you the good news about the town hall meeting that we held on behalf of the IACC on May 3 in Sacramento, California.

We had great attendance; 125 to 150 members of the public attended. We heard diverse views and perspectives.

Joyce Chung circulated to you a summary of the meeting on Friday, so I'll just use my time to make some very brief remarks.

The purpose of this meeting was to gather additional public input for the IACC as we continue our work to develop the strategic planning process. We decided to focus this particular town hall meeting on autism treatment research. The initial RFI suggested that this was an area of particular interest to the public, and one that was probably under-represented in our current portfolio of research funding.

This meeting was planned in a very short period of time, so it required hard work from a number of individuals. The NIEHS and NIMH provided federal leadership for this effort in partnership with two public members of IACC. It was Lyn Redwood and Lee Grossman.

We also got a lot of help from local autism scientists and clinicians in the Sacramento area.

In addition, as many of you know, we called on others for help in publicizing the event, and for suggestions for panel members. So we contacted other IACC members: Stephen Shore and Ellen Blackwell, for instance; my program staff colleagues of the

Autism Coordinating Committee; my colleagues from Autism Speaks, and the National Autism Association, as well.

We held this meeting in Sacramento for a couple of reasons. First of all, we wanted to hear from the west coast. Given that the IACC meetings are held in D.C., this makes it very difficult for people to travel and provide public comment at these meetings.

And second, the Sacramento area has a nice concentration of autism research, and this provided us with an infrastructure that could be used to support the meeting. NIEHS and EPA funds a children's center for environmental health and disease prevention that focuses on autism, and this center includes a strong community partnership component that we mobilized for this town hall meeting.

The NIH also funds an Autism Center of Excellence, and many other autism studies at U.C. Davis and the M.I.N.D. Institute, and all of those were key elements to the success of the program.

The agenda for the meeting consisted of me providing a very brief introduction to the strategic planning process to ensure that members of the public who attended understood what we were asking them for, and how the information that we collected from them would feed back into this planning process.

Most of the day was devoted to a series of panel discussions. Each panel was composed of individuals that represented scientists, clinicians, parents, and advocacy group representatives, and each panel began with a very brief introduction of panel members, short remarks from the panel members.

The majority of the time during the day, a total of more than three hours, was reserved for comments and questions from public members who attended.

The theme for the first panel, the morning panel, was ASD treatment in young children, and the afternoon panel focused on older children, adolescents, and adults. The final panel tried to summarize the recommendations that we thought we had heard from the first two panels, and provide an additional opportunity for public to interact with IACC members.

All three of these panels were intended to stimulate discussion about the range of treatments that are being used, or considered for use currently, with the goal of allowing us to extract research recommendations from what we heard.

I've listed the panel members for the first panel here, which included moderator Michael Chez, a pediatric neurologist who treats individuals with autism; Sally Rogers, a well known autism treatment researcher; Randy Hagerman, from the Fragile X field; Lynn Mielke, a practicing DAN physician; Nancy Duley, who is a parent advocate; Claire Bothwell, a parent advocate, and past Board Chair of the National Autism Association; and Lyn Redwood, who was the IACC representative for this first panel.

So what did we hear? We heard a lot about medical issues that coexist for many individuals with autism, and the lack of research to understand how to treat all of these comorbidities, and research to understand how they may be related to autism spectrum disorders.

Another key theme was autism heterogeneity. The differences among individuals and their behavior, their biologic and physiologic markers, the need for research to understand how to use information about those differences to tailor treatments.

The issue of vaccines was cited

many times, and is important with questions about timing and number of vaccinations, and suggestions for research that compares ASD rates in vaccinated versus unvaccinated populations.

We heard from many individuals who’d had very good success with the DAN approach, and there was a lot of frustration that research is not being conducted to follow up on the reports of this success.

The role of toxicants was mentioned a lot. And with suggestions that more research should address how biomedical aspects of autism spectrum disorders may be related to environmental exposures.

And finally, we heard a lot of different suggestions that fell into categories regarding research infrastructure, capacity, training and education.

Isaac Pessah served as moderator for panel 2. Isaac's a neurotoxicologist and Director of the NIEHS Children's Center at U.C. Davis.

The other panel members for that panel included: Pellar Burnall, who is a Kaiser physician, and directs an autism treatment program; Ruth Christ Sullivan, who is an advocate with many years experience, who has worked to address the needs of older individuals with ASD, particularly in the area of housing; Dena Gassner, an individual on the autism spectrum who provided us with a unique perspective on the needs for higher functioning individuals with an ASD diagnosis; Rick Rollens, a well known advocate for ASD and parent co-founder of the M.I.N.D. Institute, and our own Lee Grossman, who served as the IACC representative on this panel. So what did we hear from panel 2? Well, this panel focused on older children and adults. We heard we don't have good baseline data on the characteristics of ASD in older individuals, so research is needed to better characterize this population.

We heard that the need for treatments and interventions in older children and adults are very complex, and they cut across multiple domains, including education and employment, so intervention research needs to use outcomes that can reflect this complexity.

Quality of life as a metric was mentioned time and again. Again, it's not clear what constitutes a good quality of life for individuals with ASD. We need better ways to measure quality of life. We need to develop treatments that improve it.

We need to be looking ahead to quality of life issues as an adult. Even as we develop very early interventions in young children, we need to know what we're aiming for.

Biomedical concerns don't stop at

childhood. So these are chronic conditions, and they need study in older populations with ASD.

We heard many concerns from individuals with Asperger's. There is very little research to identify and assess the efficacy of interventions or supports targeted at this population.

And as we expected, we heard a lot more, and some of what else we heard doesn't fit neatly into research recommendations for treatments or interventions, but they really do reflect the urgent need of families for services and other supports, particularly for adults.

And while these comments may not have direct relevance to the autism strategic research plan, they have been summarized in the report that was circulated to your earlier, and I suspect will have use in the Services Subcommittee, and for consideration in the context of other IACC activities. And it's telling that, in many cases, families and individuals who attended saw the need for services and supports as much higher priorities than research.

So overall, I think what we heard at this town hall meeting reinforces the hard work that's been undertaken thus far in the strategic planning process, particularly the guiding principles that we've established of urgency and consumer focus, making a difference in the lives of families now.

Most of the research recommendations that we heard fell somewhere within the broad range of initiative ideas that we have before us. So this is very encouraging. So while the meeting comments do not necessarily suggest completely new initiative ideas, I think they can be of prioritize and refine the initiative ideas that we have before us.

And as one example, we have on the table an idea to conduct clinical trials of treatments that are in common use, but have not been studied in controlled clinical trials. While we heard at this town hall meeting about all the challenges of conducting clinical research with some of these treatments that target multiple systems. So maybe we need to keep that in mind as we further develop that initiative idea, and perhaps we also need to develop novel clinical trial design methods that can sort of capture and accommodate complex interventions.

In another vein, there is an initiative that targets co-morbidities, but we heard at this town hall meeting, this is persuasive, so maybe we can think about ways to consider encouraging collection of biomedical information as an element of
other treatment initiatives that we
consider.

Finally, I think the results of this town hall meeting can help us as we think about strategies for how to evaluate progress. The parents told us they don't know what to try, so they're trying everything. The clinicians told us they can't predict very well what's going to help this specific individual, so there's a lot of trial and error, and valuable time is lost.

In five years, I think we need to be able to ask and answer the questions, such as: Do parents have better information about treatment choices, and are clinicians better able to tailor treatments to the characteristics of an individual with ASD?

So to summarize, I think the meeting was a great success. We had excellent attendance. We listened to a wide range of opinions, and captured those for your use.

Many of the members of the public

who spoke expressed gratitude that the IACC had provided them with this opportunity to be heard.

This is just one meeting, but I hope it can provide as an example of how we might thinking about starting a more sustained program of actively engaging the public with IACC activities.

And I'd like to call on Lyn and Lee to provide you some feedback from their perspective on this meeting.

Ms. Redwood: Well, I agree with Cindy, it was a huge success. It was my first time ever participating in a town hall meeting, and it was a real honor to serve in that capacity.

I think Dr. Lawler really deserves acknowledgment for pulling this together in such short notice, and bringing everybody together, and conducting such a successful meeting.

I wish every IACC Member would

have had an opportunity to attend this, because I really think it makes the work that we do here a lot easier when we're able to hear from the public. And I think it was very therapeutic for the public, too, to sit and be able to talk with us face-to-face for three hours, and to be able to listen, and to realize that we take their concerns to heart, and that we're really trying to develop the best possible strategic plan to address these issues.

So all-in-all, I think it was a huge success. I hope we're able to do more. I think we need to do some on the east coast, also in the south, and throughout the country.

And I'd like to see it be somewhat of an annual event that would coincide with the strategic planning updates.

Thank you.

Mr. Grossman: Yes. I really

don't have much to say, except to also acknowledge Cindy for her hard work. It was amazing, on such short notice, that we were able to pull this off.

Also, it was great having Dr. Sam Wilson, the Acting Director of NIEHS, there, as well. I think his presence there added quite a bit to the importance of this town hall meeting.

It is probably one of the most important things that we can do in the IACC, and that is to reach out to the public, to get feedback, to better garner their support in our activities by, in some ways, actually having them direct us in our important work. So I would strongly recommend that, whenever possible, that we take the IACC on the road, either have our meetings elsewhere, if possible - I know that's hard - but at least to reach out and have town hall meetings, as often, and whenever possible.

Dr. Insel: Thank you

very much.

Let's open this up for more general discussion or questions.

Dr. Landis: So I was interested in the description that the public, many of the people at that meeting were more interested in provision of services than in research. And it seems to me that one of the disconnects there is, if you don't know what strategies worked to help people in the spectrum that, providing services, without knowledge, is somehow -- it's not counterproductive, but it may be difficult to rationalize. And I'm wondering if part of the discussion focused on trying to convey the notion that we don't know what works yet. Kind of a catch-22.

Dr. Lawler: That's an excellent point, and one that was made repeatedly in panel 2. We knew this was going to be difficult, so we really tried to take each of the comments about services, and turn them back into, well, that means that we need more research to determine whether this particular method of delivery, or this set of services, is going to be effective. So we tried to do that. We weren't entirely successful.

Lee, do you want to -- you may be in a better position to answer that.

Mr. Grossman: Well, I think that what I pulled out of many of the public comments wasn't so much the lack of knowledge on what to do, it was the lack of accessibility of the services.

I think that most parents and other care providers feel pretty comfortable now with the fact that, for the most part, we know how to treat, and intervene, and service this community. The problem is, is that that happens in such a small and inconsistent manner throughout the country, that if, that was some of the feedback that I was hearing, was that it's not a matter of not knowing what to do at this point, it was a matter of having that available to everybody.

I think that the recommendations that were directly service related that are in the strategic plan will get us to the point where we will have much greater knowledge - and Ellen can probably better address this than I can - will provide us with the detail that we need to support some more of this evidence-based research, in terms of how to roll out the service agenda.

Ms. Blackwell: Well, again, I mean, I think we heard similar themes in Nashville, that what we are missing story to some extent is the data on what evidence- based services, in particular, benefit adults. And second, that we don't really have a grasp on what the landscape for services for children and adults with autism looks like across the United States.

So I think that we do have an

opportunity here to sort of drive our strategic plan research agenda to assisting towards some of that.

Dr. Landis: Which kind of ties back to what Tom had said relatively early on. If you had a map, or a comparison of what all the states were doing, it would offer the opportunity to make comparisons, and with a modest investment, you could learn a lot about improvements, or not, with particular strategies.

Ms. Blackwell: And that, in fact, is one of our 41 proposed projects. There is existing -- David Braddock, out of the University of Colorado, publishes a State of the States for people with developmental disabilities, and what we talked about was doing some research to create a State of the States for people with autism that would have different measures, but it would allow us to go, "Okay. Where are we in five years? Where are we in ten years?" Because we really don't know if we don't know where we are now.

Dr. Insel: This would be really a huge contribution. As a public/private partnership, it's a great place where we could bring the people, all the people around this table, and the agencies and organizations together.

The volume that you refer to, I think you handed out copies of it at a previous meeting, and it's very comprehensive. It's really an impressive body of work, but it's for all developmental disabilities. And what we'd love to do is to be able to do the same thing just for autism spectrum disorder, and give families everywhere that kind of information at their fingertips. Have it electronically available. There's no reason we couldn't pull this off in the next year, or year and a half.

Dr. Janvier: I was just

thinking, if we could maybe dovetail to some of the venues, such as, I know ASA has their annual meeting this summer in July in Orlando. Next week, in New Jersey, we have our COSAC conference, where we have over 2,000 attendees. It's obviously too short notice to pull that together, but, you know maybe the goal should be, at least three times a year, that we do have a town hall meeting, not only to get input, but to give updates on where we are through -- you know, we don't have to reinvent a location to pull families with autism into, but to dovetail out to existing opportunities.

Dr. Insel: So to follow up on that, I think that's a great idea.

Other opportunities like that that we should be thinking about, the MFAR meeting is next -- it's this week, and I'll be doing a session on the strategic plan there to get some feedback from the international research community. There's also a meeting next week at SARC in Phoenix, where we'll be doing the same thing.

But it would be great to get from all of you a listings of where you think the best gatherings are. It's a great way to leverage our little budget to be able to use meetings that are already happening, and add on a day, or add on a half day to do just this.

Dr. Giannini: I think the Academy of Pediatrics should be a vital player, because the pediatrician is usually the earliest person that a family confronts. And they're very involved in autism, as you well know. And they have their annual meeting I think coming up in -- is it September? October. So that would be a very good opportunity to have a venue there.

Dr. Insel: Duane, do you know, are you involved at all in planning the meeting, or is there a way you could help us get into that?

Dr. Giannini: Yes, I can.

Dr. Insel: Can you?

Dr. Giannini: Okay.

Dr. Insel: Okay. Yes, that's a great idea.

Others that we ought to put on the list?

Dr. Janvier: With the AAP, they will be meeting in Washington in 2009 in October, so that would be really a great opportunity, also.

Ms. Redwood: Tom, there's also several large advocacy organization meetings. The Autism Research Institute has a conference twice a year with about 1500 who attend who are parents. So that might be another venue.

Dr. Insel: Yes, I think we really ought to get those lined up, and just plan to have someone from this group at most of these major meetings, so that --

It may not have to be as

elaborate as what you've done here, Cindy, but at least to have a dialogue. Not just a presentation, but an opportunity for lots of feedback, and then to have a way to capture much of this also into a website, where people can give us additional ideas.

As we'll hear in a moment, when we get into starting to talking about the strategic plan, this is going to be a living document, which will always get new feed-in. And what we'll want to have is many different pathways for that to happen. So we ought to be thinking about just a regular series of sessions at many of these major meetings.

Dr. Trevathan: Tom, just to add a couple to the list. This fall, also, the American Neurological Association, which is a very research-oriented neurological senior group, would be good.

And then also, the Child Neurology Society, which, of course, is very interested.

Dr. Insel: Do you know when that meets, Ed?

Dr. Landis: They meet back-to- back. In fact, they almost overlap.

Dr. Trevathan: They're both -- yes, they overlap a little bit, and they’re both -- one's in Salt Lake City, and another --

Dr. Insel: Isn't that the one we just missed? Didn't that just happen?

Dr. Landis: No, that's the AAN that just met.

Dr. Trevathan: No, that was the AAN. The American Neurological Association's this fall.

Dr. Landis: And it's in Salt Lake City.

Dr. Trevathan: Yes.

Dr. Landis: And we also, NINDS funds a day symposium before the Child

Neurology Society meeting, which has looked at specific pediatric neurological diseases, which has been a very successful meeting.

And it goes all the way from, depending on the disease being considered, genetics to interventions. And it might be interesting, since we fund that, to see if it would be good. We usually get about 200 pediatricians, pediatric neurologists who come to that. And it's turned out to be a very good venue to update pediatric neurologists on the most recent evidence for particular diseases.

Dr. Insel: Why don't we do this? If we can get a roster here of the major meetings, and then we can begin to actually come up with a plan for how to roll all of this out. But as was already mentioned, and Lyn’s idea, I think, is right on, that we should be thinking about this as a regular event. It won't end in '08. It'll give you a lot of frequent flyer miles here, that's for sure. So we'll have to think about how to distribute the work. But this is a great start.

And Cindy, Lyn, and Lee, thank you for participating. I think it's getting us off to a great beginning in a process that will be long term.

We're going to move on to talk about the strategic planning process. This is the major part of today's meeting.

And what I thought we would do is, if we can have Ed take us through the first part of it, and then we'll take a break and come back for the discussion of all of the individual aspects.

Ed, you're going to take us through a kind of review of how the Strategic Planning Workgroup meeting went. This was the group that we decided on at our last meeting that we wanted to have focus on the strategic plan in terms of providing priorities, and dealing with the budgetary requirements.

Dr. Trevathan: As Tom mentioned, the strategic plan is a living document, and is currently a work in progress, and I just wanted to present today, just briefly to get us started, where we are with that living document.

What will help me go through this relatively quickly, so we have as much time as possible to discuss, let me just draw your attention to three handouts in your packet that are components of what I'll be presenting. One is, the first page has: "(1) When Should I Be Concerned About My Child's Development?" Then another that the first page outlines the "FY 2007 NIH Research Funding." And then the other's a Word document that has at the top "The Interagency Autism Coordinating Committee."

So if you have those documents out, it'll help us go through quickly, and you can refer to some of the slides that

I'll show rather rapidly.

So this meeting occurred on April 21st, and for those of you who were at that meeting, these slides will look strangely familiar. It's because you've seen them already, and Joyce Chung presented many of these.

And we wanted to just show you specifically what the workgroup saw, what they did, and what's the outcome is of the meeting, and what we think our next steps are. And also, what sort of guidance we need from the IACC.

Joyce started by pointing out the overall structure of the strategic plan, so the Strategic Planning Workgroup is then under the IACC, and then the workgroup takes information and recommendations from four workshops. And we've already mentioned the services workshop that's been added, and we had involvement, not only from folks that are federal employees, but also the stakeholders. The NIMH Autism Team did a great job coordinating that meeting, as well as all these others that we've been attending.

Joyce reviewed the completed steps to date, which were that the strategic planning process was approved by this body last November. There was the public request for information period outlined there, and then, very rapidly, and I think very well done, there were the four scientific workshops on the biology, treatment, diagnosis and risk factors held in January. Many of us were at those meetings, or some of them.

And then the initial Strategic Planning Workgroup meeting occurred in February. The progress made at that workgroup was built upon at the second workgroup meeting, but with a new Strategic Planning Workgroup formed by the IACC in March, after some input from many of you, and from partners indicating that we needed a broader representation, and a larger Strategic Planning Workgroup.

Here is the roster for that workgroup meeting in April 21st. And as you can see, it's a broad, diverse group, many different organizations, and many different disciplines represented.

In addition to those on the slide, there was wide representation and participation by various public registrants. And, of course, we couldn't get this many people into the room, so there was a teleconference link, and there was ability to view slides on the internet. You can see the average length of the call between the two meetings.

And a couple of the workgroup members, and some of the IACC members participated. Virtually, I know Van Tate from the American Academy of Pediatrics was on the phone, and had some very insightful comments.

So I think that the teleconference hookup did work well.

The values that were approved by the IACC were reviewed, and there was quite a bit of discussion here. And then also, I think at the first workgroup meeting. The sense of urgency, I think, does not have to be explained to this group.

The spirit of collaboration, I think, has been critically important for our progress. And this was, again, emphasized.

And then, of course, remembering why we're all here, which is to help those with autism spectrum disorders, and those impacted by autism, is something that is a key value, obviously.
The value of excellence was discussed on multiple levels, and I think that that value came up on many different levels. One that I'll mention that's not on the slide is the need to attract new

scientists who are excellent and do great science into the field of autism research.

And then also, the need for us to bring along the next generation of great scientists, and get them interested in neurobiology and autism research, as well.

Of course, none of us have adequate funding to do what we need to do within silos. And then, even if we did have the adequate funding, that wouldn't be the best way to approach this problem. And so the emphasis on partnerships, both within government, and then across federal agencies and the private sector is emphasized. And then, of course, accountability is key. The initiatives, and there were 41 of them that were reviewed, were framed within certain questions that, I think, helped bring us to the consumer driven focus. And these are questions that many of us, who are clinicians, have heard from our patients' families over the years.

When should I be concerned about my child's development? There were seven initiatives within that question framework.

And then, as you go down the list of these questions, you'll see in parenthesis the number of initiatives that we believe were best subsumed under that particular question.

And of course, some of these initiatives actually cut across multiple of these questions. But this, I think, is a fair representation of the various consumer focus categories for these initiatives that were reviewed.

The goals we started with the workgroup meeting are outlined here. We wanted to prioritize research initiatives within each of these six question frameworks, and to discuss the budgetary requirements for the strategic plan.

We went over both in some detail, the autism research portfolio for NIH, as well as the autism research portfolio across major federal agencies, and also some of our private partners. And you can see some of the data here.

The NIH Autism Coordinating Committee categorized a very diverse portfolio in five broad research areas that were really the same areas similar to those of the workshops that were held. So that would be biology, treatment, diagnoses, risk factors, and then other.

And within each research activity, there was one research area that each activity was placed in, and a subcategory based on primary aims and objectives of particular research funding.

You can see here the detailed subcategories within each of these five major categories, and I think see that, even within these subcategories, these are rather broad areas, so there's really no doubt that autism research is a very broad area, in and of itself, and it involves many areas that may not actually have autism on the label. Because there are many areas, for example, in clinical neuroscience and basic neuroscience, biological systems, that impact autism. And then we certainly see some of these other categories that are broad crosscutting areas, but also there's some very targeted important areas for autism research within these categories.

This projects relatively well.

You can see within here, the NIH autism research portfolio by these different categories, and if you look, you'll see that, within these categories, there's some areas that you could, reasonable people can debate whether they should be under diagnosis or treatment. And I think that it just points out that, once you're really dealing at the level of helping an individual child, that you can't really separate, for example, early diagnosis, early identification with effective treatment within the life of that child. And so there is some degree of connection between these major categories, and I think many of us believe that that's appropriate as it reflects real life in terms of diagnosing and treating children with these disorders.

Here is a pie chart just demonstrating the percentage of funding in these five major areas.

Now, here is a similar breakdown that includes, not only at NIH, which everyone can see is the lion's share of this funding, but also includes the CDC, the Department of Defense, and then, too, a large private partners; Autism Speaks, and the Simons Foundation. As you can see, the contribution by Autism Speaks and the Simons Foundation is substantial, and we really appreciate the interaction, and working together across, not only the agencies, but with federal partners, and with private partners.

Here's the same pie chart, but really includes the funding from all of these different federal agencies. Included also, I believe, Joyce, is the Autism Speaks, and the Simons Foundation within this pie chart total, as well.

So in terms of reviewing these 41 initiatives, the workgroup had a description, a brief description by two of the workshop chairs, David Amaral and Gerry Dawson, reviewed these 41 initiatives. And we discussed criteria for prioritization of these different initiatives.

They were prioritized within the six question domains, again, to try to make sure that we had coverage of each of these different areas that we know are important to the community. And each workgroup member selected the highest priority initiatives, and then distributed 100 points among their choices within each of these different domains.

The results of the workgroup scoring were tallied, actually while we were there, send the results of this prioritization was reviewed, and then that's now being forward here.

The comments that arose during this day long meeting were too numerous, of course, to summarize briefly. But what came up over and over was that this was clearly a work in progress. I think that we got a lot done, but nevertheless, it's very clear that, I think most of the workgroup did not feel comfortable saying we were completely finished with our job at this point.

One of the reasons was because we actually had quite a bit of overlap within the different initiatives, and so some of the rankings probably took into account the fact that some of the lower ranked areas may have been possible to subsume under some of the higher ranked areas, as well. So we actually, I think, have some work to do, perhaps, in collapsing some of these initiatives so that we can do a better job, and be efficient, and try to hit as many of these important areas as possible.

There was a discussion about whether or not to actually do the prioritization, and the decision by the group, after some discussion, was to take really a middle ground position. And that, although more work needed to be done, that this initial prioritization that was done that I'll share does help move things forward.

So within the different question groups, here is the list of these different initiatives, and how they have prioritized. And then, of course, the higher numbers reflect the point spread between these.

Joyce, do you want to describe just a little more about these numbers in parenthesis, and how you all came to that?

Dr. Chung: Okay. So if you look at the -- there's a list of, I think, seven initiatives in this first question domain, and they are rank ordered by the initiatives that received the most number of points.

So the first one, identify relevant phenotypes that relate to etiology symptom presentation and outcome, received a total of 550 points amongst the members of the workgroup, and 12 different people ranked this one.

Dr. Trevathan: Number one. Dr. Chung:

Not number one.

Ranked it. Because they were allowed to pick three.

Dr. Trevathan: Okay.

Dr. Chung: So if they had to choose -- they first narrow down, and then give 100 points to, or distribute them however they wanted.

Again, this is really more of a

straw poll than anything else, because we had to go somewhere, and try to figure out where people were really interested. And I think it's interesting, people kind of resisted a bit doing this, but the results are very interesting, and could promote additional discussion. And I think, again, just, we wanted to share this with the Committee so you knew where things stood at the end of the day.

Dr. Trevathan: So if you can take a look, perhaps, at --

Dr. Chung: You could pick one and give it a 100 points. But, you know, that was up to you.

Dr. Trevathan: Tom, can you hit your microphone?

Dr. Insel: Yes. So let's say the latter three there, nine, eight and three people voted. That's because they had used up their three votes on the upper ones, is that --

Dr. Chung: No. Someone wanted that one to be considered, so they might have chosen the very bottom one as one of their three. That's all. So three people chose that.

Dr. Trevathan: So this would mean three people chose this particular initiative as one of the ones that they voted for, and that the total number of points across the workgroup was 120. Is that accurate? Okay.

Yes?

Ms. McKee: I just have a question. At the end of the workgroup meeting, this was passed out as the final. It doesn't match up what's being shown on the board. I take it, when you went back --

Dr. Chung: We went back. The only reason why this is different is, there were two of the workshop Chairs, Dan Geschwind and Cathy Lord, who were not present at that meeting, so we gave them an opportunity to score, as well, blindly. They didn't the results, but they provided their points.

Thank you.

Dr. Trevathan: So while we're on this slide, just to point out, within some of these question domains, there's a clear, what appears to be a clear split between, say, the top three and the rest.

This one, there may not be quite as much of a spread. But you can see that the top three ranked fairly clearly, at least in terms of the total number of points here.

Within the second question: How can I understand what's happening to my child? You see that the initiative that received the highest total number of points, role of immune and infectious factors in pathogenesis of autism, both human and animal studies came out on top.

And another one that was very highly regarded, of course, was the Post-

Mortem Brain and Tissue Acquisition Initiative, which had more total votes. But if you look there, there really are about five that were very highly regarded in that particular group, including a longitudinal study for infants biomarkers. And then the issue of neuroplasticity, as well.

Dr. Huang: I'm sorry, can I just ask, so the maximum number of people voting in any one of these categories is 12, or how many?

Dr. Trevathan: The total number of people in the workgroup was about 20.

Dr. Huang: About 20?

Ms. Buckley: Hi. I'm Diane Buckley. I helped tally the results. There were 21 people that voted, and just to be clear, in case you're trying to sum this up, some people did assign points to more than three, even though everyone was instructed to just do three.

So some people couldn't, I guess,

force themselves down to that level. And we just respected what was on the page, and put in the points, and counted it up as submitted by the members.

Dr. Insel: Did people use more than 100 points?

Ms. Buckley: No. Although some people used fewer than 100 points.

Dr. Insel: So, Diane, what that means is that, other than the second item, none of them were endorsed by even half of them -- by more than half of the people who were voting?

Ms. Buckley: Correct.

Dr. Insel: Okay.

Dr. Huang: And so the total number of points possible is then 21 by 100? Okay.

Dr. Trevathan: I think this was not unlike some of the sessions for developing priorities in any organization, and that there were many of us that, under some of these questions, liked all of them. And so I think that there was some concern about where to draw the line.

So I think there was a fair discussion about the fact that we didn't feel comfortable that we had actually eliminated some of these initiatives on the basis of this.

Here's question number three, you can see the different scores here. Once again, the genetic environmental interplay is thought to be very important by the group, and I think that this was an example of some potential overlap, or complementary sorts of initiatives.

So for example, there was some discussion, the large scale resource of genomic data on autistic spectrum disorders, that that type of a resource could actually benefit the one that, perhaps, scored the highest. So that, again, when it comes to operationalizing some of these initiatives, we all understand that there's certain infrastructure that could be very important here.

And this is also another issue that, I think, many of us think deserves more discussion. Which treatments will help my child? There was a very strong interest in the interventions for older children and adults, and I think that that was discussed fairly eloquently by those that were proposing that that be a priority.

And you also can see the breakdown of the other different initiatives here.

The fast track mechanisms to facilitate translational research is an interesting one, I think, because we often think of all these initiatives as costing money, or going directly to research, when some of these initiatives are actually infrastructure or organizational issues that we think can move things along very well. So it is worth pointing out that the difference in cost between some of these different initiatives is substantial, but the cost hasn't necessarily always reflected the importance that the group perceives, because just some types of research and some activities are just more expensive than others.

And then where can I turn for services? This is an area that I think all of us feel is important. It's been discussed. Ellen and Lee have discussed this just recently, so I won't go over it. But you'll see that, really, there was an impression that all these four were important, but there's the list of the priorities.

And what does the future hold? You see the top two there that really seemed to be very, very strong in terms of their support. On the other hand, the understanding developmental trajectories of children and families affected by ASD, enhanced tracking, for example. Those are things, when you really get down to operationalizing these particular areas of emphasis, probably these initiatives overlap to some degree, and overlap somewhat, perhaps, with longitudinal cohorts.

There was also discussion of the fact that, some of these areas that are important initiatives are, in part, already being done, but then we need to sort of demonstrate support for ongoing activities, such as the National Children's Study, for example, and similar projects.

So here's some of the comments. Again, there was quite a bit of discussion on the results.

The overlap, I think, is the area that really had the most discussion, and our need to address in more detail how we're going to address the overlap in terms of the actual development of the strategic plan was discussed. Budgetary requirement issues were discussed, and again, as I mentioned, the treatment of the funding percentage is relatively small, for example, compared to others. But there are other areas that inform treatment, such as the early diagnosis sort of feeling that we needed to know more about biological mechanisms.

There was, before we get into some of the treatment opportunities, there was a particular interest in making sure that we have broad representation of these initiatives, that we don't starve one area to feed another. And I think there was agreement on that within the workgroup. And then I think this comment, the last bullet on this slide, was really, sort of came up in the discussion of how it's important, as we move forward with these initiatives, that there be the ability of NIH and others to reapportion within funding domains to take advantage of opportunities that come up.

There's some major infrastructure issues that were brought up, and I think that, especially under the treatment area that was discussed, we brought up the fact that there really needs to be better clinical trial infrastructure in pediatrics in general, but also, especially in neurological, neuro-developmental disorders. And the efforts by various groups, including Autism Speaks, was mentioned.

The fast track mechanisms for high risk/high yield studies was also thought to be critically important.

And the fact that we don't want to judge priorities necessarily by percentage of funding, because of the different costs of doing different types of research, was discussed.

The usefulness of the strategic plan was discussed. I think I'll just let you all read that.

I think that the last bullet was an area that there was, not only discussion within the meeting, but of course in the hallway during breaks, that we want to take the people doing excellent science, and attract them to this area. And if we can do that, that really will help us move quickly, as quickly as possible, and probably take advantage of their already existing expertise, given the fact that we all feel a sense of urgency here.

So I'll stop there.

Dr. Insel: Great. Terrific summary.

Let's take a five minute break, and then we'll come back, and really dig into this.

(Whereupon, the above-entitled matter went off the record at 10:30 a.m. and resumed at 10:37 a.m.)

Dr. Insel: So what we

wanted to do in this next session was to provide some time for discussion of what Ed has provided as well as to begin thinking about the next steps for the strategic plan. And Joyce has a set of slides that will take us through that.

Maybe, Joyce, before you start on the slide set let's see where the discussion goes in terms of what we've just heard from Ed. Comments, Story?

Dr. Landis: So I would say that we ran a, the Neurology Institute, a stroke planning review group had a five year meeting. And I think stroke research is as broad. Prevention, early treatment, rehab, different age group. And I'm struck by the similarities between the breadth of interest reflected here and also by the difficulty with a broad based group each of which has specific interests in focusing on a small number of initiatives. So I know it was probably frustrating for you all at the meeting that it wasn't clearer what was the top priority and was not a high priority, but I would say it exactly reflects the difficulty of planning and priority setting in diseases which have a very broad spectrum of symptoms and treatments and opportunities.

Dr. Insel: Alison?

Ms. Singer: First, I want to say thank you to Ed. That was a great summary.

I attended that meeting. And what I really came from thinking was that while it was a good discussion, a lot of the time was spent discussing the process for prioritizing as opposed to really focusing on the 41 initiatives themselves.

I also was fortunate enough to attend all four of the workshops, so I was familiar with the priorities. But even still I felt that some of the titling might have been confusing and some of the write ups really didn't enable us to drill down on what we were prioritizing. And I think we talked about that a little bit at the workshop when we got into the discussion of trying to consolidate. And that there was some unusual voting patterns and that biomarkers were scored very high in one area and very low in others.

So I think that there's more work to be done in terms of the prioritizing. I think that we want to continue to pursue the value of urgency. But I do think that it would make sense for the group to meet one more time and really have more opportunity to do as Denise Resnick suggested at the meeting, have a SWOT analysis, look at the existing portfolio to determine where are the holes, what needs to be filed in. Think more about what are the boulders, what are the rocks and what are the gravel; take a look from that perspective.

But really also have a little more discussion of each of the 41 initiatives, which are strong and I was very happy to see that the Services Subcommittee actually made recommendations that were contained in the 41 initiatives. But that it might make sense for the group to convene again, focus a little bit more on the actual content of each of the priorities and then look at how we could consolidate across the six domains.

Dr. Insel: For those of us who weren't at the meeting, was there some discussion about any of the 41 that people said let's just take this off the table, this was a mistake? Was there anything that came up at the meeting that wasn't within the 41 where people said "Oh, the workshops just really missed something critical here. There ought to be a new initiative added." Was that brought up at all?

Ms. Singer: I think if the group did meet again, it might be worthwhile to spend more time reviewing the actual initiatives.

I think David Amaral was present and he was able to discuss the initiatives from that workshop. But two of the workshop Chairs were not able to attend, as Joyce pointed out. And Dr. Dawson, unfortunately, was only able to participate by phone which is never as good as actually being in the room.

So it would be great if this group did meet again to really make it a priority to have the workshop chairs present so they could discuss within their area at that workshop what came up so that we would have that input from the workshop participants as well.

Dr. Insel: Also, it seems like the other thing that wasn't, if I understand what you're saying, wasn't available was a way to crosswalk between the initiatives and the portfolio. As you say, a SWOT analysis that would let people know what actually was already done or being done would probably be helpful and also recognizing where the gaps would be. Because you might to put something at a higher priority if it's something that's simply not be addressed at all that everybody recognizes as a need. And if I'm understanding it right, that kind of information didn't go into the conversation. Okay.

Ed wants to respond.

Dr. Trevathan: Yes, I agree with everything Alison said. I think that the detail that she described would be very useful.

Now the term "crosswalk" didn't come up at the meeting, but for those of us that know what that really describes, I think having those sorts of data in front of the workgroup before a meeting so people could study it would really be very useful.

I think on sort of move it up to sort of a higher level, I think the workgroup wanted a little more direction from the IACC on exactly what was the framework in which we should think of this prioritization. I know I see a couple of people that are on the workgroup, they're nodding their head.

But I thought Lee Grossman had a great sort of off-the-cuff presentation he did near the end that was very useful.

But one of the questions was are we really prioritizing within these domains based on a big vision of where we think we should go independent of resources? And I think some people vote with that in mind. And then I think some others voted with the notion of, okay, so where are the resources that we have now, which of these different specific areas are things that we can most likely achieve and what can we be successful doing sort of the relative amount of resources that we have now.

And there were some sort of thinking more along the lines of we have a basic research infrastructure in some areas that is, frankly, difficult to maintain and is critically important. And so what do we need to do to maintain that infrastructure so we can then build.

So there was actually, I think probably more differences in terms of how people approached the question of how to prioritize. I don't know if you agree, Alison. There wasn't necessarily what was important, not important. And I didn't hear anyone ever say "Oh, that particular initiative is just not worth not pursuing at all." I think that there was a general agreement that given unlimited resources that all these initiatives were very important.

Dr. Insel: Other comments? Ellen.

Ms. Blackwell: I guess one of my concerns is that I'd like to know when the strategic plan is due to the Secretary. I think Dr. Foote indicated that we have to start our strategic planning process for the next year in July. So what is our timeline as far as turning this in?

And my second concern is that amassing this group again might -- you know, it's a lot of resources. So where are we in terms of our IACC budget and moving forward as we pursue all these different plans?

Dr. Insel: Well, we should talk about this as a group. My own bias is that we need to have a completed draft I would say by the 1st of July. I mean the Combating Autism Act asked for this in December of 2006. It's a five year effort, and at that point we'll be 18 months into a five year effort. And even then you have to remember that this strategic plan is going to inform 2009 at the earliest budgets. We're already working on our 2010 initiatives. So we can't really put this off much longer without making it completely irrelevant.

There is no required date for submission to the Secretary. And even when I say July 1st as a completed draft, I think we still need to go through another passage for comments and for making sure that there's an opportunity to get some feedback. But knowing that it will take a while to get it through HHS, that I think is kind of where we ought to be. We ought to have a document that we can being to really share at that point.

Story?

Dr. Landis: So to what extent, I've heard it described as a living plan and that there need to be annual updates. And I know for our Parkinson's planning actually we have routinely gone through, checked off what we've accomplished, crossed off what's no longer relevant and added new things on actually a two year basis.

So since this isn't the only ever plan there will be, but it will be constantly added to and subtracted from. Maybe just getting started is a critical issue.

Dr. Insel: Yes. That's kind of where we were trying to focus this. And part of it goes back to the urgency idea, is trying to get something that we can begin working with knowing that it's going to take a while to put any of this in play. Although, some of it's already happening and I can talk more about that later. But it's surprising looking at the list of things on here how it actually begins to inform changes that are already taking place, that people aren't waiting for the plan to get finished. So that's good news.

But in this case the Act requires annual updates. So that gives you some idea of the churn that should be present.

Before we get into Joyce's comments, Lyn, did you have anything else?

Ms. Redwood: Yes. When I was looking back over the minutes to the last meeting and we decided what the charge to the workgroup would be, we were going to ask them to develop a proposal about how to proceed with strategic planning process. And then Alison had suggested that they look at the 41 initiatives, prioritization. And then also Allen suggested that those be consolidated.

And so I guess I'm just concerned that that really didn't happen at the meeting as much as we would have liked for that to happen.

And I attended the meeting as well. And what I was hearing was that the members didn't feel like they had enough guidance for us with regard to what we really wanted them to do. And that they were more than willing to come back and continue to work on this process. They felt as though it was critically important, but they needed more time to work on it effectively, they needed more resources, they needed to know a little bit more about the research inventory. IT would have been nice to also know of the projects that are being funded, as they in their first cycle of funding, their fourth year of funding; what of that percent of funding is going to be falling off this year.

So there was a lot more information that they were asking for to be able to do this effectively. So I would like to see the workgroup meet one more time and for us to be able to give them some clear guidance about what we would want as an outcome, and maybe even schedule for more than just one day. Maybe this requires two days. But I think we had a good group of people at the table and I think they're willing to help us move forward with this.

So I would like to propose that we continue with that workgroup and have them meet again. And I have suggestions for what type of guidance we should give them with regard to the product we would like at the end.

Dr. Insel: That's a perfect segue to Joyce's presentation, which is about what we should be telling them and how we want to guide them for actually taking us to this first draft.

Dr. Chung: Okay. So these next steps for discussion really follow directly from the workgroup meeting and also from the last IACC meeting, at which time there was a discussion, as you may recall, when the IACC approved a values and began a discussion about the mission. And Diane had taken us through a number of other organizations who had mission statements and vision statements to stipulate some discussion amongst the members here.

So really what we want to do is maybe take this. Roll up our sleeves as a Committee and try and tackle some of these larger frames for the workgroup to understand what they will be working with.

So there's some discussion we need to have this moment. So if you look in your packets there's a six page status report that members here will have. And I have some slides for the public here. There's a six page status report with a little structure of the Committee on there.

So in the very back of that six pager is some of the draft language for the mission, vision and so forth. So if the Committee members could grab that particular document. That's the one. Yes. On the very, very last page will be some draft language that we're going to look at together here.

So we'd like to review the draft

vision, mission and aspirational goals for the plan. And also then take a look at also a draft template for how a particular section of the plan might look like. Because we actually have to think about writing this document and how to go about getting those sections completed and written.

And then, again, we want to talk a little bit about a SWOT analysis. And that refers to strengths, weaknesses, opportunities and threats. So these are ways in which you can look at information and analyze what is there.

I think what would be critical to do is to look at what you saw as the research portfolio. We have detailed grant listings in your packets as well. But those details of which kinds of grants, what types of grants, who are the investigators; that could be paired with the initiative to see what we're already doing, where the gaps are and what kind of initiatives or infrastructure would need to happen in order to advance those. Especially the high priority ones.

So just as background. For vision we mean to say what do we aspire to achieve in the next five years. And mission is our reason for doing the plan to begin with. So if you look at the draft vision, this is the language that we formulated based on discussions at the IACC meeting. And I just wanted really an open discussion about this. And then, again, you'll see a mission statement and then aspirational goals.

So I'm not actually quite sure how to get this going. Maybe you, Dr. Insel, can move on this. But, yes, anyone in the Committee can take this. I just wanted to start off with this particular discussion.

Dr. Insel: And this reflects the discussion from last time. So this was the attempt to bring together ideas that you heard from the last IACC meeting?

Dr. Chung: Right. There was a lot of discussion, particularly led by Stephen Shore around making sure that there was -- there was a discussion here about not just health but well being and having it be much broad and really looking across the life span and really thinking about kind of the broader vision for what we want to achieve. So what do we aspire.

Again, and there was some confusion at the Committee level about is this for the Committee or is this for the strategic plan. And here we're just talking about the strategic plan. This is what we aspire to achieve with the strategic plan over the next five years.

Ms. Blackwell: Joyce, you were good enough to distribute this before Lee and I left for Nashville last week. And I told Joyce that I would take it with me, and

I did. I had little handouts with our mission and draft mission and vision.

And I think they're excellent. And I got almost universal onboard with these. These look really, really good. So thank you so much for your hard work.

Dr. Chung: So I'll just up to the mission now so people can see it.

Ms. Redwood: Hey, Joyce?

Dr. Chung: I'm sorry. Yes?

Ms. Redwood: I had a comment. Would it be possible after well research that we'll rapidly advance and profoundly improve to sort of reinforce that sense of urgency.

Dr. Chung: Okay. And Diane Buckley is back there taking notes. So edits, changes that you want to make, she'll just be putting them into the slides. So this is exactly what we want you to do. To provide some suggestions for modifications to this.

So the mission here is the purpose of the strategic plan is to focus, coordinate and accelerate high quality research and scientific discovery to answer the urgent questions and needs of ASD individuals and families.

Ms. Redwood: Can we put "meaningful" before research? So high quality meaningful.

Dr. Chung: Okay. Other suggestions?

Dr. Huang: There's just a small thing here that in terms of people first language, we usually say individuals with. I don't know if that's commonly used here as well.

Dr. Chung: Okay. Sure. That's good.

Dr. Insel: That's a great point.

Dr. Chung: Yes.

Dr. Insel: I think

that's very important.

Dr. Chung: Okay. I'm going to move on.

Ms. Redwood: I have one more, Joyce.

Dr. Chung: Okay.

Ms. Redwood: I'm sorry. Could we also add to that statement improving diagnoses, treatment and prevention somewhere?

Dr. Chung: We have aspirational goals for each of those areas. We might want to keep it a little briefer here. I don't know, what do you think?

We had had a bulkier one and you had trimmed it down. So I don't know if you thought it needed to be shorter?

Where would you put that, Lyn?

Ms. Redwood: Right at the very end "improving diagnoses, treatment and prevention." But if it fits down in the other categories, that's fine too.

Dr. Chung: Let's look down at the aspirational goals then. So what we did was we looked at --

Dr. Insel: And, Lyn, we can come back if it's not there.

Ms. Redwood: Yes.

Dr. Insel: Then let's come back to it.

Dr. Chung: Yes, we can come back. So we looked at the different questions that were posed in the six question format. And we drafted some aspirational goals. Again, these are just big picture kind of goals around each of these questions.

So in the question when should I be concerned about my child's development, the aspirational goal could be all children with ASD will be identified at an early age and receive care appropriate to diagnoses. So that might be the diagnoses topic, maybe not.

And then how can I understand what is happening with my child? Discovering how ASD effects development will lead to targeted and personalized treatment.

What causes to happen and can this be prevented would be causes of ASD will be discovered that lead to prevention, preemption of ASD.

I'm going to keep going.

For the other questions, which treatments will help my child: Best practices for treating children, adolescents and adults -- oh, it should be with ASD -- will be developed, tested and disseminated.

Where can I turn for services? Communities will implement high quality evidence-based and cost effective ASD services across the life span.

What does the future hold? Advances in treatment and public understanding will enable individuals on the autism spectrum to lead fulfilling and productive lives in the community.

And picking up on language and discussions at the last meeting was how we developed a lot of this. And from the workshops and workgroups is how we developed these draft goals.

Comments?

Dr. Insel: So the idea is that each of these will match up with one of the six. And so the idea would be that there'd be four each theme within the strategic plan there will be some introductory language that might actually emerge from the SWOT analysis, right? So kind of what do we know, what do we need sort of thing. Then there will be the specific initiatives in some order that would be based on what people thought was their highest priority. And then you'd go to these aspirational goals. And then to specific objectives and timelines and the accountability piece would come in after that?

Dr. Chung: Right. Right. That's in the template of the section that we have.

Dr. Insel: Okay.

Dr. Chung: So really, again, that workgroup, I mean the fact of the matter is the 20 people in the workgroup were really people at different stages of familiarity with the planning process. Some had been involved all along, some were new to this. And so there was a bit of inefficiency in that meeting. I think they are much more posed to work. But they needed something like this. They need kind of the big picture from this Committee. And this is the place where it should happen. This is the Committee that's responsible for this.

And so the question was how much does the IACC need to do and how much does the workgroup need to do. And we're asking you as a Committee to really work at this level; the big picture level to help guide the next workgroup meeting.

Dr. Janvier: I had a comment.

I didn't participate in that, but I did participate in the diagnoses workshop. And I think there was a lot of effort on many people's parts internationally to create the priorities in each of those areas. So I would hate to see it, and I think Dr. Insel pointed out, that no one said oh this is really not something we need to pursue.

So, first of all, I don't see what's wrong with keeping the 41 initiatives.

Two, I don't think there's anything wrong with prioritizing them, but you know I know in my group that I participated in there were some that were, I would say fairly minor or quick and easy or much less expensive. So I think it would be helpful maybe at the next workgroup meeting to identify with regard to each priority where there is funding, where there needs to be funding, what's a kind of a quick fix or a quick and easy item that could be kind of quickly checked off.

And, you know, I really applaud the coordination of both public and private funds to address this issue. Because clearly there are many centers that have been funded by the NIMH that we certainly want to continue. But I think we may have better flexibility opportunities on the private sector to push forward with some of the areas.

Dr. Insel: I think you meant funding by the NIH, but that's fine.

Let me just follow up on that, because this is a question I had, too.

I thinking about the prioritization process when -- I don't think we were that clear, now that I look back on it, with the workgroup with how we wanted them to do that. Whether this was priority in terms of short term versus long term verses quick or versus something that was low impact versus high impact, or what to do first, what to do most. I guess there are lots of different ways of defining this.

When we did the autism matrix, we used to call it a Zerhouni-gram. It was one of these templates where you kind of went from short term to long term and low risk to high risk. And we staged everything along those lines. And we started off by going to the upper right hand corner and saying what was the most important, sort of high impact long term goal that we had. And then we worked back from there to figure out how to get to that goal, what would we need to do in the short term and the intermediate term.

I'm not sure that the 41 would really lend themselves to that. But it might be worth our thinking a little more clearly about if we are asking within these six themes that people begin to prioritize or list them, what we really want that for and how we want them to do it. And is it even really going to be that useful to us, or do we want mostly a sense of how to get each of them done and work on the accountability piece more?

I'm just throwing that out there. But as I think about the discussion we had last time, I'm not sure we were that clear about what we wanted.

Ms. Blackwell: If we wanted them to rank them for us, Tom, which is what I thought we were sending them to do, then I guess I see their mission as accomplished. I mean, they did that. And it seems to me that at this point if we want to move forward, it's our job to sort of rank them or group them.

I mean, do we really need to convene another meeting of experts to tell us how we should be ranking them?

Ms. Redwood: When they met, I

think in the report -- and, Ed, you can back me up on this, that they sent this as a draft and there was quite a bit of discussion, probably a good 30 minutes, about whether or not they could even move forward with that during the meeting, Ellen.

So they weren't comfortable with the way that they were told to categorize these. They couldn't categorize across categories. There were some overlaps in the initiatives.

So I think it would be worthwhile to move forward the second meeting of that group. Because they weren't all present and they didn't feel as though they had the information that they really needed. They didn't have any types of guiding principles or goals from us for mission statement in terms of how they should prioritize these, as Tom mentioned.

So I think with more guidance they can do that.

We also had asked at the last meeting to go back and look and at all the RFI again to see if there were any that had been missed. And I know of several ones that were presented in addition to the 41, and I didn't see those reflected, or I was just curious what the status of those additional initiatives that were presented?

Dr. Insel: Joyce, do you want to respond to that?

Dr. Chung: So what we did was we went back to all the workshop participants once the initiatives were developed and asked them to go back again to the RFI to make sure that the ideas in the RFI were incorporated into initiatives as written. And we received comments from about half of the people who were in the four different workshops.

And so the workshop chairs actually went back to the initiatives and retooled them, edited them, modified them slightly to incorporate the feedback. So they were embedded within the initiative language.

But when they discussed the ideas that came in, they didn't not feel that there was any feedback that constituted a brand new initiative. So there wasn't a 42nd initiative written on the basis of the feedback. And that was what the workshop chairs decided together on a conference call.

Dr. Insel: It sounds like, though, the central question that we have to grapple with is Ellen's question, is how much are we going to do and how much of it are we going to outsource to the workgroup.

And you've given us a vision and the mission, and it's sort of a way forward with the template.

Where's the sense of the group on this? Do you want to take this on? This is in some ways just consolidating what we talked about last time. But are we ready to go ahead and accept these and then go back to the workgroup for some very specific kind of final tweaking of a plan that we largely put together with your input?

Christine?

Ms. McKee: One of the things that's kind of interesting is I went back and took the ranking from the first strategic planning workgroup. And set it into the ranking of the second. And things line up really nicely in the second category, how can I understand what's happening to my child and in which treatments.

What stands out when you rank them is how much are 5th and 6th categories weren't even touched, the ones about services and what the future holds by the first strategic planning workgroup. They didn't make it into the top 20 except for just one of them.

What I really like about this group is its balanced membership. We were created in a balanced way. And I'd like to have us go back, and now that the scientists have ranked a lot of us and given us guidance, let us take a shot at it. And then if we don't understand something or we're stuck, then I think it's worth the effort to go back to the experts, so to speak, and see how they can help us out.

Ms. Blackwell: So, Christine, are you suggesting that we, say, each get our 100 points and then vote some more to how they did? Or like how would we do that?

Dr. Insel: I think we've got an initial set of votes from that group. And I had forgotten but Christine brings this up, that if that's well aligned with the earlier kind of voting that we got, maybe we're much further along than we realized.

If I understand what you're suggesting, we could go ahead and take what we've received. We could do the work of actually setting this up in terms of what would be within the six themes.

I think it does, as Ed mentioned, it requires a little bit of tweaking. There's some redundancy still. There's some things that -- you could see it in the way they were ranked that were ranked lower because they kind of incorporated in an earlier idea. Some of these things are boulders and some of them are more gravel. And I don't think there's any sand in here. But the size is different. Some is infrastructure, some are projects. So there would be a way I think of sort of organizing slightly so it's a little easier to follow.

But the question I think is who should do that. Would the IACC like to have the autism team pull this together and come back to them with a document which we could then ultimately take? Either we could use the workgroup or not. I mean it's up to us how we want to use this group.

They clearly really got engaged in the task. And I think they'd love to do everything. They were excited about, from everything I heard, being involved and wanting to run with it. The question is how much we want to let them do that.

Alison?

Ms. Singer: Well, I think it's commendable how involved the workgroup got.

One thing, Christine, that was different in terms of the way the priorities were ranked in the first workgroup versus the second, is that in the first workgroup all 41 were ranked against each other. Whereas, in the second workgroup they were ranked already divided into the six categories.

And so what we didn't get sense of from the workgroup is whether there's prioritization to be done among six. And I think that would be an interesting question to put before the workgroup.

I don't think that there's really any reason why we can't ask the workgroup to prioritize in a number of ways; within the six, across the six and then to come up with even some additional options.

So I shared with Ellen the sense of urgency. I think I've expressed. Our need for a sense of urgency, but I think that there's a lot of willingness and eagerness and tremendous expertise vested in the workgroup. And I think it would be worthwhile to have them take one additional look at this before we move forward with writing. Particularly I think it's really important for them to have a SWOT analysis. I think a lot of the data came to the workgroup just before it met. And I think that that was really reflected in the conversation or the lack of conversation among the group about what was contained in each of the 41 initiatives.

So my feeling would be to ask this group to meet again to really urge the workgroup chairs to participate more actively in the conversation. But to have this group meet again.

Dr. Insel: Joyce, do you want to say something about this SWOT analysis, since that was an earlier slide. Thoughts about how to get that done?

Dr. Chung: Well, see, I think that we're looking at about six weeks before July 1st or maybe seven weeks. And I think that we have some constraints on this Committee in terms of things like getting things out in the Federal Register and having adequate time to notify people of our activities. So we really need to think about how to do this very efficiently.

So, I mean I think we can have a workgroup meeting possibly in June, but it's going to mean that we start planning it today and make sure we can get on people's schedules, which is going to be challenging enough.

So as much as I applaud that we'd love to do that, and we have been able to kind of work miracles, I think it's going to be tough.

And I would like to think about how to do some things as tasks before them; smaller groups working on things. So one of the ideas we had about the SWOT analysis if you saw that the table of funders was NIH, CDC, Department of Defense, Autism Speaks and Simons Foundation which contributed a large number of funds to autism research yearly, that perhaps the program staff who administer those grants and know those programs well could provide some input, analysis, could do that SWOT analysis for the workgroup or in the Committee. If that could be something that could be allowed. I think that could be done.

I've talked with Ann Wagner, Chairs NIH ACC about the possibility of doing that.

We'd love to do that in partnership with these other organizations. So that some of that could be done outside of the workgroup, per se, with 20 people getting dumped together versus getting -- I mean, it's still going to be challenging, but it could be a medium step that could take us further.

The workgroup chairs could also do some of this consolidation. They've talked about doing that. They've been constrained from doing that because we didn't want to collapse until people saw everything. This might be the time. So that maybe we can ask the workgroup chairs to work on that. Again, preparatory step for the workgroup meetings.

So these are ideas that we had

about trying to advance these things, continue to advance them knowing that getting a workgroup meeting together will be challenging, but we'll try.

Dr. Insel: Maybe it would be good to go through the template so people could turn this into something that's actually operational and you could see what the vision was for how this would look and then think about who would do which part of it.

Dr. Chung: So is there any need to approve these draft vision, mission goals? Do we move off of this?

Dr. Insel: Well, we can take a reading from the group now. Are people comfortable with the vision and mission statements that we see?

Lyn?

Ms. Redwood: I just have a few more just minor wordsmithing to do. And I don't know if this would be the time to do.

In the section understanding what's happening to my child, it talks about discovering how ASD effects development. And I would like to see something broader than just development. Because we've heard that these children also have a lot of physical issues as well. So maybe physical and psychological development or define what kind of development. Because just looking at development sort of disregards their health issues.

And then I think somewhere putting prevention in there, because I don't see prevention anywhere in any of these statements.

Dr. Chung: That's in the what causes to happen, can this be prevented.

Ms. Redwood: Okay. Thanks.

Dr. Landis: I would be concerned. If you start saying physical and psychological, you end up losing cognitive. As soon as you constrain that term development with any descriptors, then I think you end up in trouble with things getting left out. Psychological to me would not necessarily include cognitive, which would be a very important issue.

So I can understand your desire to have it specified, but to the extent you specify then you exclude, which is very difficult.

Ms. Singer: What if we say development and health?

Dr. Huang: Or you could say comprehensive development.

I have a question. I guess in terms of the prioritization, and I'm concerned about our time frame here and not drowning ourselves in process also. And when I look at this chart of prioritizations and it was an expanded stakeholder group at this strategic planning group, there seems to me that there's some natural breaks if you look at the votes. And that those natural breaks would probably signify that there's some sort of consensus level as well within each of the six domains.

So in the sense of moving ahead with this, I feel relatively comfortable moving ahead and not further outsourcing some of the decision making. It's always hard to prioritize. And I think we just have to just get down and do it.

But the question I have about the vision and the mission and the draft aspirational goals in the six question framework, and I like the vision and the mission. I guess one of the things that I feel is not really captured there is kind of what we're struggling with today; that it's really a lot of people and a lot of voices and a lot of stakeholders coming together to really create this shared vision mission piece. And I don't like wordy mission or vision, but that was just one thing that I wasn't sure if it was really there.

And then I had a concern in terms of the six domains. They're all focused on about my child's development or about something happening with my child. Whereas, the vision and the mission talk about every individual with an ASD across the life span or individuals and their families. And then the six domains fall into from the family perspective only, not the individual with the ASD.

So I didn't know if we needed consistency there. You know, it seemed a little bit of a disconnect for me on that one.

Ms. Blackwell: I guess when I read this I thought about substituting. I felt like you did, Larke. But I thought about using the words "my family member's development." But, you know, that's sort of lets out that it could be the person with ASD, you know, themselves. But I also agree.

I feel strongly that there should

be some emphasis on these life span issues. And when you read the word "child," even though it could certainly be an adult child, it sort of shifts you back into that child realm.

Dr. Insel: I had exactly the same reaction in looking at these. Because there is this weird disconnect. And we talked about it at the last meeting that we wanted to be focused on adults with ASD as well. And yet all the first five – I think the sixth one gets into the life span.

I had a thought about it, which was that maybe what would be useful would be to have an introductory section before you get into these specific themes that explains how these questions were derived. Because we didn't start here. We started, you know, with biology, diagnoses, risk factors. And to say that we got to this point by having a discussion about what were parents asking, what were we hearing about, and then say it within the same context that we recognize that that's one perspective. It's not the only perspective. And that even though we're framing in this way, we also recognize that there are very large issues which we're also hearing about that have to do with what we provide for adults. And also what adults with ASD are feeling about the opportunities that they have.

That piece just isn't integrated that well into this. And I'm not sure how else to deal with it in this first draft.

The other part, though, it does seem like we could -- I mean, if you can look at the top one there: Which treatments will help my child. And then we stay: Best practice for treating children, adolescents and adults with ASD.

So it may be that on some of these we could actually shift the language a little bit. I think the first couple don't lend themselves to that, but this one certainly does.

Dr. Morrissey: Tom? Dr. Insel: Yes.

Dr. Morrissey: I was looking at the last two questions and then looking at the first four. And it seems to me that if you take out "my child," take that out, you can say how can I understand what is happening, what caused this happen and how you -- I mean, you basically take out the reference to child and then you cover anybody's concern. A parent's concern, a grandparent's concern, a service provider's concern and you don't lose anything in terms of the organizational structure.

Dr. Insel: Steve?

Dr. Shore: Just replace "my" with "a." "A child's development."

Dr. Insel: But do you need it at all? Could you just say when should I be concerned.

Dr. Shore: About development.

Yes.

Ms. Singer: Yes, that could be done.

Dr. Morrissey: And I think that you can still have the preference material that you were going to put in the introduction to talk about how you got the questions and maybe even reference the importance of not limiting to child. Because we dealt with it in ADD with a program announcement issue, who are we talking about. And that's one way to deal with it.

Dr. Insel: Okay. Great. So let's go back then to the central question. We've got a mission and a vision and there's some suggestions for how to move forward with this. Where's the group with these two statements? Let's at least get that piece locked down.

Are we okay on the mission and the vision?

Dr. Giannini: I wanted to make sort of follow up to what Pat said but in a different way. That maybe it wouldn't be such a struggle if we looked at these different initiatives here according to life span. Because some of these fall into different milestones of a person's life and their milestones. And maybe it be easier to categorize how you prioritize what's important with the infant and young child than probably the adolescent and then the young adult and so forth and so on?

I mean, it would be a little harder, perhaps, to do all that. But it might be easier in the long run.

Dr. Huang: If I can follow up, Tom.

So not answering your question about the vision/mission yet, but I was thinking about these six aspirational goals. And to how to make it more of an inclusive community perspective or all multiple stakeholder perspective.

IT could be phrased like how can I understand what is happening with an individual with ASD. When should I be concerned about the development? You know, what caused this to happen? Which treatments will help an individual? And then it's not just placing the total onus on the family or just from the family perspective, but it's broadening it. And I think that makes it feel more inclusive that we all, everyone might have a role in trying to understand these questions. And it takes out the "my."

I like these questions or the intent of these questions to really sort of translate the research into what's really happening to me and my family or someone in their family. But I just think they need a little bit rephrasing.

Dr. Insel: But I'd be curious from the parents and the group whether that makes it less personal or less actionable to say that? What's your sense? Are you comfortable with that?

Ms. Blackwell: We use the word "person" a lot at CMS. And I was going to suggest that maybe instead of using the word "individual," can we talk about person center planning? So it's really six, half dozen of the other but I think "person" is a little bit more family friendly.

Dr. Insel: I guess what I'm thinking, though, is the difference between when should I be concerned about my child's development versus when should I be concerned about the development of a person with ASD or an individual with ASD. Does that actually cut it for you as a family member?

Mr. Grossman: Well, I would want anybody that's involved in this person's life to feel engaged, including professionals and the public agencies providing the services. So the broader we can make it so that people do feel included, the better.

I think as a parent that would be the best approach to take. Too often everything is defined by the parent or the individual. And I know from talking with a number of professionals or agencies they feel like they're cut out of the process.

Dr. Insel: And if you go back to Pat's original suggestion, just saying when should I be concerned is that too general or not? Does that not capture what you want?

Ms. Singer: I like that suggestion. I think that reflects the breadth that Lee was discussing. And because it's coming with the context of an autism spectrum disorder, it's very clear that it's referring to autism spectrum disorder.

Dr. Huang: And then if we go that route and I think that something should be in the mission statement then that this is a very collective effort of parents, researchers, professionals, individuals. And then I think those aspirational goals fall out from that base.

Just a suggestion. I'm not adamant about it.

Dr. Chung: Something in this slide about working in partnership or with diverse communities, or however you want to put it.

Dr. Huang: Well, I would kind of build on what Lee was saying, that we want professionals to really focus on this and to understand when they should be concerned about an individual's development as well. And I think if we're going to have that implied in the draft aspirational goals, it needs to be said somewhere I think also in the mission without making it an overly lengthy mission statement.

Ms. Singer: So I think we can

maybe now move forward with agreeing that all of the values, vision, mission and aspirational goals should be included in the opening statement and move on to the next topic.

Dr. Insel: Larke, I'm wondering if we can add something to allow us to move on. Because I do want to keep the mission statement pretty tight. But I wonder the whole piece around values, we talk a lot about collaboration and the joint effort. At one point we actually had just what you were commenting on in the mission statement. We kind of took it out at some draft because it got kind of bulky. But it is so important that it seems to me we could build that again into the text.

Because remember, this will be a document that will have several things in it. It'll probably actually start with this as the living document that is a result of discussions between all of the stakeholders who were on the IACC with input from clinicians, scientists and others through all these mechanisms.

I think there will be probably at least a paragraph or even maybe half a page about the process right at the front end of this that will clarify how we got here, then lay out the mission and the vision.

Would that work for you to kind of capture that? Okay.

Given that --

Dr. Huang: It would work keeping in mind that lots of times people just read the mission and the vision statement. That vision, that needs to float on its own also.

Dr. Janvier: I mean, it doesn't really sit well with me. I mean as a pediatrician I think what Dr. Giannini was saying. too, I think you have to mention children. I don't view every child I see as an individual. I don't know. I just doesn't sit right with me that we take out the word "children" from this.

Dr. Alexander: I would go along with that. We're denying biology and development and everything else if we try to eliminate children. And after all, at the time we're trying to identify these is in early childhood, as early as possible. Why not put "child" in there. You can depersonalize it if you want from my child or I be concerned, why should we be concerned about a child's development; if there's concern about that. But we want to identify this in childhood. And to take that out and just leave out any reference to children I think is a disservice and a misinterpretation of biology and development.

Dr. Insel: So, again, what you'll see when we get to the template is that there'll be a paragraph. So let's take the first one. If it were "when should be concerned" not only would the aspirational goal be about children, but the introductory paragraph will all be about infants and early diagnoses. You know, how do you distinguish normal from abnormal development in the first 18 months and what are the tools that we'll need to be able to do that. So it's very, very focused on not just childhood, but very early childhood.

I don't think you'll miss it there so much. The only question would be whether in the title itself it becomes in some way exclusive if you focus -- maybe not that one, but on the other ones on my child as opposed to just saying how can I understand what is happening. Would it be better to leave it opened ended. And then in the text you can begin to provide some context for who you're talking about.

Dr. Janvier: I think it was fine the way it was. Honestly. I think it touches on the life span by making the further questions generic: What does the future hold? You know, I think that you are talking in number two about children, and I don't think you need to change that.

Dr. Giannini: And that's where it begins. So if you miss it there, you've missed a lot of time.

Dr. Landis: So it seems to me that there's a concern that's been brought up about not restricting the intentions and needs for research to children and that to try to edit that with however many people are sitting around this table is probably not the best use of people's time. But that the group, the NIMH autism group with input from people on this panel and others could try to incorporate those desires to have it be more broad and then feed back to this group.

And I know Lyn had some additional comments. And the NIMH group could serve as a coordinator. And then the next draft could go out with those things incorporated.

Dr. Insel: So that would be a great way for us to move forward. If you would want the team to tweak the mission and vision, maybe not the vision but the mission very slightly given the comments from Lyn and Larke. We could tweak some of these titles in the way that we've been hearing about and then provide some of the text. Some of that will come, I think, out of the SWOT analysis. Because there will have to be a piece built in right after the question when should I be concerned. You'll want to say something about well what do we actually know here and what's missing. Where are the opportunities and then we can get to the initiatives.

Dr. Shore: I have just one more comment.

Dr. Insel: Steve? Dr. Shore: And that was I understand the importance of focusing on children, but also at the same time development through the life span. So what if we had some language in there about when should I be concerned or we be concerned about development from childhood onwards? Then we get it all in.

Dr. Insel: Well, is there a comfort with letting the team struggle with this and getting something back to you that looks like a real draft. And then we would take your comments on that and then go forward with that to the workgroup. Is that what I'm hearing as a plan? Okay.

Can we look at the template? Because I think that will be helpful for people to see.

Dr. Chung: Okay. So in your packets there's I think it's maybe 3 pages. It starts with this questions: Which treatments will help my child. So the Committee members will have this in their packets.

And this is something that might serve as an example of a section, one section of the plan which deals with this particular question. And we'll again change the title of the question accordingly.

So starting off with a section on do we currently know, then what are the gaps in what we know. Laying the aspirational objective from the previous slides we've looked at. And then really getting to very specific short and long term objectives below that.

And this is the type of sort of framework for the individual sections for the questions that we'd like to float by you. This is a draft. This is something that actually Dr. Insel just quickly wrote up and gave to us.

We think we just wanted to begin to think about our task of writing. If we want to get a draft plan to you in July, we need to kind of get a sense of what these different pieces would look like. So, again, we wanted to provide you this template.

So, again, this is the aspirational goal, a draft goal from before. We'll be using this for an example right now.

And then, again, the short term objectives. These are just, again, draft. These could be done at the workgroup level, perhaps. This is something maybe the workgroup could do. I guess it's up to you decide who would be formulating these objectives. But this would be an example of some of the short term objectives. So:

Completing phase 2 randomized controlled trials on novel medication compounds;

Targeting course symptoms by 2011;

Test advocacy and safety of the three widely used biomedical and/or nutritional treatments by 2012;

Demonstrate through intervention research that employment can be increased by 40 percent for adults with ASD;

Test four methods to improve dissemination of interventions to diverse communities by 2013.

That types of very specific measurable goal, this is the level of the kind of objectives we'd like to have in these annual updates and plans.

So these are short term, and then longer term would be:

Develop interventions for children at risk for ASD with the goal to preempt autism in 90 percent of younger siblings;

Develop a range of treatments with individual specificity reducing disability, for instance, and;

Effective means of dissemination.

So, again, these are examples.

Just to give you a sense of how this might lay out. And you see the document in front of you that kind of has it in all one document.

So the other thing we did in this document was I did this for Cindy for the town hall meeting. I took the treatment initiatives, there were nine of them, and I tried to put them into lay language. Because the titles are problematic. I mean, they were developed by the scientists and members of the workgroups. And they were great working titles, but sometimes they're very dense and hard to understand. So I tried to take all nine. And in the template I listed out the kind of lay version of the title. It had a little more description at times, and then underneath I put the original initiative title so it would not be as confusing.

So, again, this is what we did in the template to make sure that it was understandable to people. So, again, the nine research opportunities in lay language form that we would like to have to develop this language for the plan itself.

Ms. Blackwell: I have a comment. Because at the very first meeting we elected to put services and supports under treatment, I'm just a little bit concerned that that's getting lost in this language.

Dr. Chung: This is just the treatment one. There's a whole another one on -- remember what we're going to term for services.

Ms. Blackwell: Okay.

Dr. Chung: That will have its own set of lay language ones in specific goals and so on.

Dr. Insel: We chose the treatment one because we thought: (a) it was the kind of great opportunity. You remember the budget, that was the place where there had been the least investment.

So it's clear that that's got to be a big part of the plan, and;

(b) it was a little bit easier to say what would be the way forward. You could list the studies, you could -- you know, as opposed to try to define how you're going to get a biomarker for autism, which was a little harder to do.

So we thought we would try it out with this and just take it out on the road at this point. The same thing, we're working on the same thing for the other five themes.

Dr. Chung: Again, we just wanted to push forward to try to refine a little bit more of what we have so that we can have some guidance from the Committee about whether this is the right path to go forward with.

Dr. Insel: If we are going to go back to the workgroup, we don't want to waste their time wordsmithing.

That's not really the best use of their time. And if you just take a quick look at these initiatives that we have, some of them are not understandable in the language that has been applied. So they need to be put into language that's consistent that is also clearer for anybody reading it, either scientist or non-scientist. And as you look through some of these, it's just so striking comparing what the original language was to what Joyce has up here. The new language is just a lot more understandable.

So this would have to happen for all of the six themes. And could be done very quickly. I'll take the "very" out. Could be done quickly.

Judith, did you have a comment?

Dr. Cooper: I was just wanting to clarify, Joyce. That we would do for each of the six, we would list whatever 41 in language that you would modify, right?
The six areas, there are 41 total

initiatives. So that they would be rather than eliminating and saying this is the number one priority and then we just don't even mention the others, we'll now have research opportunities in whatever was in that six?

Dr. Chung: I think it's very clear that no one wanted to eliminate anything.

Dr. Cooper: Right.

Dr. Chung: There's so many good ideas. They can be prioritized, and that again needs to be refined.

Dr. Cooper: Right.

Dr. Chung: But when we roll this out we can't have those titles be part of
the plan. So this is what I wanted to draft for you all to see that we could take this language that's a little difficult understand and bring it down to a level that would be a lot more comprehensible to everyone.

Dr. Cooper: And I really like that. Because what it does is even though we may identify some priorities, there may be some other research opportunities that individuals in the research community can hop on. And if it's highlighted, it'll be very helpful. So I like not eliminating.

Dr. Insel: Duane?

Dr. Alexander: I think this is a good model. It's something that we have some experience with. It has a nice flow to it. It's one that comprehensible both to the scientists and the public that we're used to dealing with. And I think this model that you've done for one of these is one we could replicate for the other five and go with it.

Dr. Insel: Is there a comfort with, even though we wouldn't lose any of the 41, in clustering them? Because as I just read through these, just to give you an example in the first item, the first theme, there's one that's called characterizing and improving the diagnostic process in the community. And then screening and diagnostic instruments in under represented populations.

So if we start to cluster these together and make it a little more thematic and a little more conceptually organized, that's okay. Good.

So it may not be 41. I mean, all the ideas will be there, but they may be clustered in such a way that it'll look more 26 or something like that.

Dr. Landis: Twenty-six is a whole lot less daunting than 41. And I think as long as you don't lose sight of the complexity, that having it small it's still daunting, but a smaller number; 41 just sounds really depressing.

Dr. Insel: Because it's a prime number. We will try to get a prime number out of this, one way or the other. So maybe 29 would be the place.

Okay. So let's see where we're at. So we've got an agreement that we'll pull together the mission/vision. Values we've done already. We've got that. Aspirational goals you've got and then we've got this template that people seem to be pretty comfortable with.

Joyce?

Dr. Chung: So this Committee needs to decide on a very important question, which is your interpretation of -- in the law, the strategic plan has to have proposed budgetary requirements. And that was discussed and Ed presented a couple of the discussion points brought up by the workgroup. We didn't solve that problem for you if you wanted to punt that to them. They didn't figure it out. But it's a big question and it really belongs to this Committee in terms of your interpretation of that language. And it's complex.

And one of the things that wasn't

done, you had asked at the last meeting to have the research funding portfolios collated, and we've done that in the interim. But this Committee hasn't really reviewed that and had a discussion about that and how that might inform this interpretation of budgetary requirements. But if we're going to write the plan we also need to know what we're writing around that issue. So we're somewhat silent still on that point.

So I can provide the information again in slide form up here when you direct me to, but I think that's a discussion for the Committee.

Ms. Singer: Well, first I want to thank you for providing that data. I know many of us have been asking for that budgetary data for a long time. And I know that a lot of work went into compiling and assembling and distributing that data. So many thanks to that.

When you talk about reviewing the data, it's true that this group has not had a chance to review the data. But at Autism Speaks we asked our professional science team to review the data. And our review of the data showed that approximately only $80 million of the $127 million counted by the NIH as autism spending was in fact direct autism research and training.

So this means that of the $127 million only approximately 63 percent of the dollars were pertaining to autism. And we reached this figure by applying the following test to each grant: if the grant contained the word "autism" in the title, we counted it as direct autism research or if in the opinion of our full time professional science team the study abstract clearly related to autism, then we counted it as direct autism research.

We also included funds related to training and conferences as direct autism spending.

And using this criteria 63 percent of the grants reported by the NIH as autism spending related directly to autism. And applying the same methodology to our own science portfolio, 93 percent of the grants pertained directly to autism.

So I've talked at this committee level several times about the fact that our charge from Congress and the President in the Combating Autism Act is clear. And it's to see that direct autism spending reaches the authorized levels and is applied to autism research.

In the Combating Autism Act Congress authorized and in the Omnibus Budget Act it appropriated $114 million specifically and exclusively for direct autism spending. And according to our analysis with spending currently at $80 million there's an additional $34 million that under the law must be directly applied to autism research. And this is what we talk about when we in the advocacy community refer to the new money authorized and appropriated by Congress under the Combating Autism Act.

So, I know that at the last IACC meeting and the Strategic Planning Workgroup reference was made to the fact that no specific autism line item appropriation existed in the budget bill. And this is true. But it's important to realize that there's no specific line item appropriation in the budget for any disease, any disorder, or any condition. But, in fact, Congress has singled out autism as needing special treatment.

The Combating Autism Act is the first and only disease-specific bill, and it was signed into law in conjunction with the NIH Reform Bill.

The coinciding policy statement also gives clear indication of Congress's and the President's intention that autism should and needs to be treated differently than other diseases, and that direct autism spending should be at the legally authorized limits.

So when we look at funding the strategic plan we need to look to increase the spending levels by no less than $34 million.

Dr. Insel: Alison, just a point of clarification. I think the 114 is 2008. And the budgets that you're looking at here are 2007 dollars. So the 2007 authorized but not appropriated figure was 100. So there is a bit of a gap between '07 and '08.

Ms. Redwood: Tom, with regard to the budget, my idea was that the plan that we would develop will be based on the need of the community and on good science and that we would come up with the projects that we felt were necessary for us to have to be able to address this problem. And that we shouldn't be inhibited by budgetary requirements.

Then we take this back to Congress and actually let the advocacy community use this document, use this strategic plan to get the money we need now to help these children and adults with autism.

So I personally think being constricted by, okay, you only have a $100 million to spend isn't our job. I think we need to come up with the best plan that we can.

Dr. Insel: The point of having the inventory is not so much to say what we can do. It really is just to get a sense of what we're currently doing and where the funding falls within this current, whether it's 127 or 80.

I think it is important, though, for us to come up with a figure that people feel confident in. And the 127 is the official NIH number. But if there are real concerns about the credibility of that, we ought to dig into that and figure out how to fix that credibility problem.

And one thing that occurs to me that might be very useful is actually to, since we have the people that we need in the room to help do this, is to put the program people together who were talking about having to do the SWOT analysis, to have them look across the two portfolios and get a very clear idea of what parts of this, for instance, your team at Autism Speaks thought doesn't really belong.

It's critical if we could do that soon. And the reason is because, and I think you know about this, that NIH is going through this new coding, is moving to a new coding system. It's still possible to tweak that between now and I think the next few weeks. We could still make changes in how we define autism in the coding system. But I'd much rather get it right and get it to a place that the community is comfortable with rather than having to have this discussion every year about whether the numbers we're reporting are really credible or not.

So I wonder if we could set that up as an action item coming out of this discussion today. Rather than saying it's not right or it is right, figure out what are the 30 or 40 or 50 grants that your team felt shouldn't be counted and see if there's a way we can capture something about them that either we want to include or we don't want to include. And maybe by looking at your portfolio we could get also a good sense of how you've made those decisions for Autism Speaks.

Would that be a way forward here?

Ms. Singer: I think we would be happy to participate in that.

Dr. Insel: Okay. Let's

plan to do that. I mean we talk about urgency all the time. I have to tell you we really would have to do this within the next couple of weeks because I think the NIH coding process is going to be drawing to a close. Story may know more about it than I do, but I would assume it's going to be in the summer for sure because they want to have this in place for the 2008 budget.

Lee?

Mr. Grossman: Yes. I have a couple of points I want to have clarified. Because I'm not sure what's being asked of us right now.

Are we being asked now to come up with a budget for all the priorities? And I say that because I think that's something that we should undertake. It's my understanding of what we've been tasked with is that once we decide on what our priorities are, that we should be able to come up with the appropriate figures that would be to fund that, and we shouldn't be limited by what is either congressionally mandated or within the funding levels of NIH, at least at this point obviously. We want to know what the portfolio should be.

And who knows? When we go through that analysis, it could be $10 million, it could be a billion dollars. But at this point I doubt it's $10 million. But I think that that's a worthwhile exercise that we need to go through to see what our actual needs are to fulfill the promise of what the strategic plan should provide to
the community. And then turn the advocates
loose to go out and get it.

Dr. Cooper: I would concur with Lee. But I'd also point out that we don't need to stay focused just on the NIH budget either because, I mean, we're many federal agencies here. And many folks in various agencies will be supporting some of these priorities. And so we don't want to be narrow in our focus of the budget.

Dr. Insel: And it's also, as it says in the Combating Autism Act, it's a public/private effort. So it could become a mandate for Autism Speaks also, or for Simons or any of these other organizations up there to try to raise funds.

A different sort of question is whether we have enough information to know how to do this. I usually use the example of the biomarkers. There's both a predictive biomarkers and biomarkers for treatment, I think that's in this list of 41. Do we know what that would cost? Do we know how to put a budget on that?

We could probably put a budget on treatment trials because we have a sense of how to do that. But there are some more discovery based efforts here. And I'm not sure that we would even know where to begin.

Well, we could ask experts to

give us an estimate. But I wouldn't want to be constrained -- I wouldn't want to take something out of the list just because we don't know how much it would cost.

Larke?

Dr. Huang: Well, I don't have an answer anywhere near to that question. But I have a question about the framework here.

We seem a little bit inconsistent. Is the services scientific group separate from treatment or within treatment? Sometimes we talk about it as separate, sometimes it's within,

Dr. Chung: What is your question?

Dr. Huang: Is the services within these research areas, we talked about these four -- that reflects the four workgroups that's going throughout.

Dr. Chung: Yes. So in this detail--

Dr. Huang: Is services within -- sometimes we talk about it as separate, sometimes within.

Dr. Chung: Yes. Yes, services research is in here, and it's $1.57 million in the NIH budget. That's one of the line items here, it was broken out. It was within treatment as it's currently organized. I mean it's in here.

Dr. Huang: Okay. So are we consistently going to have it within -- so these things are reported within the four workgroups, the scientific groups?

Dr. Chung: Yes.

Dr. Huang: But then there was something earlier where we said well that's going to come out in the services workgroups.

Dr. Chung: So the initiatives were separated out. Part of the problem was that, you know, when we looked across these -- when the first workgroup ranked and gave some initial scores for the initiatives, the services ones were not getting a whole lot of support amongst the workgroup members. So there was a real need to kind of try not to orphan them off. So that's why we developed these question framework so it really gave broad coverage to these areas. So that's why it came out.

There's been some discussion as to whether this portfolio should also be aligned with that six question framework versus this four bin thing. It was a lot of work to get to this point, and we did it across organizations. So maybe in the next iteration there could be changes. But I think for this year it's pretty clear this is the effort that we've been able to accomplish in terms of just, you know, categorizing things. But services is still in the funding organization within treatment.

Dr. Insel: Peter?

Dr. Huang: So then just in attempts of that, the breakdown and hearing what we've heard earlier in terms of the priorities from some of these Strategic Planning members about services, then we could look at this budget portfolio and look at it as sort of a gap analysis in terms of some of the other information coming in?

Dr. Insel: Exactly. That was the --

Dr. Chung: The SWOT analysis, right.

Dr. Insel: It was the reason for getting this started was to figure out where was the current portfolio invested.

Peter?

Dr. van Dyck: I'm a little confused about this discussion about services because the strategic plan is research, and the budget we're talking about here is labeled research. There's discussion around the table about other organizations or agencies providing money for autism, and that's true. But when we were asked if we provided money for autism research, we said not but yet we have services dollars.

So services may be appropriate up here if it's NIH or CDC. But I'd feel uncomfortable putting our services dollar within the research framework.

Dr. Insel: I should clarify.

Dr. van Dyck: I'm not sure that’s what --

Dr. Insel: Yes, this is not services. Where it says "services research," it means something very specific, which is why the number is so low. And it's essentially implementation science or implementation research. It's actually what Joyce does for a living in her real job. So it's the kind of research that looks at both cost effectiveness and a whole set of issues that NIH and CDC do. They don't do a huge amount of it, but it's not the provision of services at all. In fact, we wouldn't count that.

Dr. van Dyck: And I'm perfectly comfortable with that. But services was being thrown around here a little bit.

Dr. Insel: Right. So this is --

Dr. van Dyck: I just wanted to clarify that.

Dr. Insel: This is research, not --

Dr. van Dyck: So that if the attempt is to include what other agencies do, it would have to be separately or parallel or some other way?

Dr. Insel: And we would only include it if was research.

But the question here is that it's actually a really tough one. And that is how to address the budgetary requirements that are in the Combating Autism Act. It says that very specifically, but it doesn't tell us how to do it. And one idea is to simply take your best estimate of what each of the 41 or however many initiatives we end up with, how much they will cost. The other would be to -- I guess that the workgroup, if I understood you right, you said there was something about looking at percentages or proportions. Or how did the workgroup, did they have any advice for us about how they would do this?

Mr. Grossman: We didn't get into that specific discussion at all. No.

Dr. Insel: So as Joyce said, they're not going to help us. So we have to do this. And we have to think about a way to do it that both satisfies what the law requires and yet has some rigor and credibility to it. And I'm not sure that -- like the Parkinson's plan, was that done there?

Dr. Landis: There were requests

to come up with a cost. And Dr. Gerry Fischbach was the Director at the time, and he was very expansive in his views of what we could do and should be doing. And it was about a billion dollars.

Dr. Insel: Now he can do that at the Simons Foundation for us.

Dr. Landis: Right. And isn't it nice he's turned his attention to autism?

I think the difficulty, of course, is coming up with realistic numbers and balancing them with numbers that other diseases might envision for their needs.

I would also say that one of the particularly difficult things is as discovery proceeds, you can find that there's a body of research that you would have never thought of as being autism relevant or related which suddenly because you get a gene or you get a pathway or you get a biochemical compound, suddenly you can build upon research that other institutes have been funding for other reasons.

And I've often found that in Parkinson's that genes get discovered and it turns out there's a huge investment that NIGMS had been making in something that we just never thought of as being relevant. And trophic factors which we thought would be incredibly important for Parkinson's turn out only to be important for therapeutics and not for development of the disease.

So a very complicated issue. And it has to be scientifically credible to the extent that you can do that. And probably projected, not just what do you need year. But if you get this next year, what do you need the year after.

So we have not made a good effort since Gerry's departure to do that for Parkinson's. But we get requests all the time. Not in language like that, but we get requests all the time to come up with professional judgment budgets.

Dr. Insel: Yvette?

Dr. Janvier: I just had a thought. You know, and I think I had sent to Joyce in the beginning we were asked to kind of think out of the box and just throw out whatever crazy idea came into your head. And not being a member of a government agency, sometimes I do that.

And I was just sitting here thinking well I don't know what the budget was for the development of the Manhattan Project or development of an atomic bomb. But, you know, NIH and NIMH, whatever I get all my acronyms mixed up, you know you do things in a certain way. And then we've got all these dollars spread out all over the country. Well, you know, maybe if we created an autism research institute somewhere and brought some of these people together, we could look at what that would cost instead of throw some dollars here, throw some dollars there and really make some major inroads into this. And, you know, come up with some sort of, who knows, off the wall dollar amount budget.

Dr. Landis: So let me just say that's not the first time that suggestion has come up. Parkinson's would very much like to have a Parkinson's institute. And what we've done is to create the Udall Centers, which are now 13 centers. And I think there are significant analogies between actually the autism centers and the Udall Centers, Although the autism centers are much more clinically based than the Udall Centers.

And to put all your eggs in one basket makes me as an institute director very nervous. Because if you don't have the right people there, you've spent all your eggs. So I think the autism centers are actually an effort to create centers of excellence and are doing a good job.

Dr. Insel: But maybe you

meant something a little different, which is -- and the IACC could have a real role here, which is to coordinate -- look at all these different efforts going on, which have been really in silos.

I found it really fascinating to look at the Autism Speaks portfolio and to look at how many people were being funded through Autism Speaks that were being funded through the NIH. I don't think either agency knew what the other one was doing.

You could imagine a kind of virtual institute or virtual program in which all of these five sit down together and figure out one should have a list of what needs to get done, who is going to do what and what it will cost and who is going to spend what. And that, I think, is really what the spirit of the Combating Autism Act was all about.

If indeed we are being truly redundant, then we're stupid. And then we've been played by the grantee community that has allowed this to happen because we haven't bothered to find out what each other is doing.

So we ought to make sure that that $188 million that's being spent is really being spent in a way that is coordinated and is much more efficient than what we've been doing now.

And, hey, we've got everybody in the room except for the Simon -- well, we don't have Department of Defense. That we can fix. And we don't have the Simons Foundation here. But we ought to have all of those people together.

So this leads actually to a proposal, which is to think about whether the question of the budgetary requirements ought to be wedded to the question of implementation and accountability. And whether once we actually have the plan we want to charge, I would think it would be the members of these five groups, to sit down together and figure out how much this is going to cost and who is going to do it and who is going to be held accountable for whether it gets done or not. And that's a separate group I think from any of the people we have now because, for instance, I don't believe the Simons Foundation or Department of Defense are involved in the workgroup at all, even though they are going to be major funders.

Story?

Dr. Landis: So can I just say the identical situation exists in Parkinson's disease. Defense, Michael J. Fox, a couple of other foundations, NIH, and a number of institutes. And if you could actually get aggregated planning for autism with coordination of efforts of all of these groups, it would be a truly groundbreaking effort which would set a principle for every other collection of funding organizations. I mean, you could really make an impact, not just for autism but to provide an example for every other group.

Dr. Insel: Let's do that.

Dr. Janvier: But I thought that's what part of the Strategic Planning Workgroup was. You have a member from the Simons Foundation there. You clearly have Autism Speaks there.

Dr. Insel: Actually I don’t -- there isn't anybody from the Simons Foundation on the workgroup.

Ms. Singer: Not the current one. Dr.

Janvier: I thought there were.

Dr. Insel: Not on the current one?

Ms. Singer: Not the current one.

Dr. Insel: No. We had an earlier group where Gerry Fischback was there, but not in the one we have now.

Larke?

Dr. Huang: I think that's a really exciting proposal.

And I have to say that in my markup on the draft vision I had something like that that is really inspiring and exhilarating. But also a coordinated research plan. Because to me we can inspire research, but a lot of other people can inspire research. We can try to accelerate it. But it's not just the purview of this Committee to do it. But what really can this Committee do that is going to be unique with the players that it has at the tables? And to me that is a master plan coordinated building on each other, collaborating which would to be to me, it would make it a less siloed whole agenda more efficient use of funds. So I like that idea. That was the kind of thing I was struggling to say might even be in the vision or mission. How is it unique? How is this IACC really doing something that's going to move the field?

Dr. Insel: Lyn?

Ms. Redwood: Tom, the other thing that I think would really be a contribution that we could make is when you look at this overall portfolio, to me what really stands out is the lack of financial resources that is going towards treatment. And even when you look at the whole breakout on the budget, I only saw like $1 million out of this, you know, over $100,000 budget focused on like biomedical treatments for autism.

So if there would be a way that we could leverage this research agenda.

Even when you look at this treatment, it was just 14 percent. And this whole category of other was 14 percent. Treatment was the largest area that we received RFIs from, and it's what the community is really begging for.

So I would actually advocate for

a reallocation of this. When we started this process we gave each of these four categories the opportunity to write ten initiatives. Maybe we should have looked at what we already had and said we have an over abundance of biology, so they're going to only have five initiatives and we're going to increase maybe treatment to 15.

We need to figure out some type of mechanism for being able to sort of rationalize the money that we have in a way that's effective and make sure that all these bases are getting covered adequately and that it's leveraged and prioritized. And I think that's something, too, that the Strategic Planning Workgroup could help us with in really digging into with this document that we're going to develop with Autism Speaks to be able to figure out exactly what of this money is going toward autism research. And then look at really if that's adequate in those areas or if we're overspending in some areas and not doing as much as we could in others.

Dr. Insel: Joyce, could you go to the next slide? Yes. I thought this was so telling. Because as you just said, it's such a contrast to the comments that we've gotten in if you look at both the RFI and also the discussions we've had, whether it's at town hall meetings or in other venues.

Most of the questions and most of the interest is on the treatment side. There's some on diagnosis, but it's much more in the area which has the smallest segment of this pie, which tells you that one of the greatest uses of a strategic plan is to then reprioritize, rebalance. And it may not be so much that we're going to have new money to work with. One hopes that there will be new money. But even in the absence of that the strategic plan can help you to make decisions about how you take the money that is part of the regular churn and how you make your next set of investments.

So this one of the things I think we can count on coming out of this effort.

Have we solved the budgetary requirements issues? We're punting it, it sounds like, to yet another subgroup that would look at the implementation and at the cost.

Lee?

Mr. Grossman: Yes. I guess I would want more clarification on that subgroup that it's being punted to. Do you have an idea of its makeup and who that would be?

Dr. Insel: No. You know, I think what's going to happen here, I think from this discussion what I'm hearing is that you and others don't want the plan to be constrained by costs at this point. You'd like us to come up with the best ideas that people will find inspiring and that meet the vision and mission. And then there will have to be some -- and that I think we can do by July 1st. I think the problem of putting numbers and figuring out who will do what is going to take longer. And I suspect that will be -- that will come some time after that.

Dr. Landis: But I think if you look at some of the specifics that were derived three phase two trials that do whatever, it's possible to put a price on that. It's possible to put a price of the creation of animal models. It's possible to put a price on genetic studies. I think for each of those things NIH staff and foundations have ideas about how much it costs to do each of those pieces. So that once you know what the specific pieces that are your specific benchmarks, you can put prices on them. It's just until we have those specific benchmarks, it's a little hard to do that.

Dr. Insel: Let's ask Dr. Wagner. As an Exec Sec, but as a program officer is this something that program could do? Could you begin to give us ballpark estimates of costs?

Dr. Wagner: Well, I think Story's right. When you get to the level of saying we're going to do three clinical trials or we're going to do so many studies on biomarkers, then you can. So it doesn't necessarily tell you how much it's going to cost to answer the question, but it can tell you how much -- we can get a ballpark of how much it would cost to launch the initiatives or the studies that would go toward that.

Ms. Redwood: How do you make the decision to do three or 300 studies?

Dr. Landis: So in Parkinson's, and I keep harkening back to this, there's been a lot of pressure on the institute to be doing intervention trials, and we set up a whole new network to do that. And the thing that we're now learning, responses from the community, why are you doing a trial on coenzyme Q10 and why are you doing a trial on creatine, and why are you doing a trial on minocycline. Why aren't you doing trials that we think will actually come out of what we've learned about the science?

So there is this incredible tension, which I know you and every other person involved in this field feels, which is the urgency to have trials versus the tension between having trials that aren't actually sensible.

And we've now done minocycline trials in every neurogenerative disease and have had no positive results. And had we known more, we probably wouldn't have invested the money in that. So that the complexity of running a trial now because people want to know an intervention versus not running that trial and investing the money, I don't have an answer. I'm just saying it's hard to know where to put your dollars until you have a compelling biological reason for doing a trial.

We're doing trials on nutraceuticals and recycle antibiotics for neurodegenerative diseases, and none of them are coming up with results that actually informing what patients should be doing.

But the best intervention is deep brain stimulation, which actually comes out of some very sound biology and a neurosurgeon who in Paris thought, gee, this would be a really interesting thing to try.

So it's very, very hard to know where to put your dollar.

Dr. Janvier: I was also thinking comparatively that clearly living in a state where one in 60 boys has autism, I mean this is a major concern. But how many dollars are spent this year on children's cancer? How many dollars are spent on other developmental disabilities that if we are the priority, then we need to be at least equal to that. And I've seen those graphs, but not too recently that we might come up with all these different maneuvers to say okay we need $100 million or a billion dollars, but how much is being spent on other things that we should equate to?

Mr. Grossman: I just want to say something here, and at the risk of being inappropriate as well. Because it seems when we start talking about dollars, those devils are in the details. And actually everything we've done prior to that discussion will
seem easy I think as a comparison.

And with that, because the devil is in the details, is that we can run of
risk if it's not done well and does not have a broad tent, where many different parties are privy to this, that it could really sabotage all of our efforts to this point.

And I'm saying that because right

now I'm so unclear in terms of how we're going to move forward on that that I want to raise that as, perhaps, a real caution.

Dr. Insel: What I'm concerned about is that if we allow this to trump the discussion about what we really want to do or to constrain it, then we won't get the best plan. So I think there is some logic to moving the budget discussion to after you eat the dinner. You know, you don't usually talk about whose going to pay the bill until you've already ordered. You think about it,, but you don't talk about it.

So it might make sense for us to go ahead and try to get everything else locked down. And we can do that in the next six weeks, I think. And then come back to you as a group and figure out.

I think we could turn to program, as Story is suggesting, and get on some of these things get, just as we've done here, some templates. Give you some sense of what this will look like, what the bill could be. But there does need to be a kind of implementation discussion that has to take place sometime in the near future that says this is what we think it will cost, and this is who will do it. And I don't think it will all be NIH. I think the really exciting piece here will be figuring out as we're doing -- I think it's okay to talk about this.

We have one of the items in the plan under biology is the need to have a new tissue repository that's better. Because we have such a limited brain bank. And so Autism Speaks has come forward saying let's do this. And we have already within two weeks a partnership developed that's going to bring together some of their efforts, our efforts, and the Simons Foundation will contribute as well to make this happen.

Not waiting for the plan,

although it will be one of the things that we'll probably take credit for in the strategic plan.

So that's just a model of what we would like to see going forward. And I think once we have the list of what it is we most want to do, then we can use that to inspire those kinds of partnerships.

Story?

Dr. Landis: I would also say that I think not just NIH program staff looking at price tags, but also foundation staff. We often hear that if NIH would just put a little more money in, it would actually happen more quickly. And foundation staff I think will have views of how to put a little more money in to make it happen sooner rather than later. So I think we can poll all of those sources for the best possible price tags.

Dr. Insel: Yes.

Dr. Landis: And there's a risk

of low balling. And there's also a risk of high balling. Because if the price tag comes out to look unachievable there may just be oh my God, we can never spend that amount of money and so let's not even try to generate those research opportunities.

Dr. Insel: So is what you're suggesting that this same team that does the SWOT analysis, actually once they get that done start to look at this and begin to at least give us some ballpark numbers that we can work with? And it would be really interesting to know how people in foundations would price things out relative to how it's done in the government. I think it will be educational for everybody. Yes.

Okay. Joyce, what else do you need from us?

Dr. Chung: I guess the last thing to do is for this Committee to define what the Strategic Planning Workgroup meeting should do. The charge to that workgroup

Because that is a meeting that needs to take place in the near future and that agenda and material, or whatever needs to be done for that, has to be defined by this Committee. So some ideas we had here was that perhaps the workgroup could review the input from the town hall meeting, which has not had a formal way of being folded into this process, that maybe they could do the development of the short and long term objectives. I don't know who should do this, but this has to be done. It was things that we did for the draft plan.

Consolidation of priorities could be done, perhaps, by workshop chairs or someone else. And then maybe the group could refine the prioritization better after consolidation. I think a SWOT analysis will say a lot about infrastructure and mechanism needs.

And then we need to talk about public input for the draft plan. If we were going to present this in July, it's probably good to start planning now for how we're going to get public input. Because that needs to be planned now as well.

So I think those are some of the loose ends. Some for the Committee, but some for the workgroup. And we just need to define this.

Ms. Redwood: Joyce, I liked all the things you had on there. I think some type of framework for defining priorities would be helpful, too, that we could use in the future when we go about this next year.

The other thing, I don't know if this might be useful, but we established a committee to look specifically at service because services that I assume will be ongoing. Might it be beneficial within the IACC to also establish a committee that would work specifically on strategic planning throughout the years? I don't know, I'm just throwing that out, because it might be easier if there was a committee that was meeting that came back and reported to this overall Committee, since I don't think this is going to be our complete focus as we move forward. This was just the first thing that we had to accomplish initially. So I just wanted to make that suggestion, too.

Ms. Singer: I think that's an excellent idea.

I would just add to the points that Joyce made in the charge to the workgroup. I would love to see them prioritized not only within the six categories, but across the six.

Ms. Redwood: And could they also maybe help us with some recommendations regarding implementation of the plan.

Dr. Chung: So, again, you know, there's a lot to do with a group of 20. It's really hard. It was hard to get them to focus on the tasks.

I think there's been some discussion about an implementation workgroup of some kind, or something that's different from this one, this particular workgroup. That might be a different kind of thing because, for instance, we don't have DoD in this group, nor Simons. So it may be important for this Committee to consider a different kind of workgroup. This Strategic Planning Workgroup can meet one more time to finish out the prioritization and have something else happen. So there's other moving parts.

Dr. Insel: I am a little concerned, though, because we kind of went to them with some of the same charge last time, and we didn't get exactly what we were hoping for. We got something. They did give us this attempt to prioritize.

Well, what I would hope we could do is to give them a document that's pretty close and use them as a kind of sounding board about, you know, is this going to work or are there pieces of this that need to be changed and either redefined or reprioritized before we take it public.

I'm just concerned if we go back and we ask them, I guess it depends on what you mean by the word "refine." But if we ask them to prioritize something that we haven't done, we'll end up back where we started, and we'll have a discussion like we did today.

I'd like to think that we take them what is really almost a finished draft, and we use them as kind of the final edit group to say this looks good, or this needs a little more of this or that.

So I guess I'm very comfortable with one and three, especially on the refining. And I'm not sure how much we want them to put in the objectives, because I think we can do that, as you've done here with this example. You have the short and long term objectives already built in. But I think we need to show them what we've got and see whether they can buy into that.

Dr. Chung: But who would write those? I mean, those are pretty specific. And I don't think that our team internally has the expertise to be able to write that level of detail of short and long term objectives. So, I don't know.

Dr. Insel: My concern, though, about the 20 people in the workgroup is we don't have the scientific clout there that we might need. There are very few people who actually do experiments on that workgroup. And I wonder if it would make sense to go back, at least to get the draft, to get something to work from, to go back to the workshop chairs to get some help with that if they're going to be looking at the consolidated text anyway, if they could help us with that?

And then you could get -- again,

the workgroup could help to refine those objectives. But I'm just concerned about asking them to do any of this de novo, because it's just too difficult in that setting, particularly when they're not involved. I think they haven't been involved up until now, many of them. So it's kind of like from our perspective we're kind of getting into the ninth inning, and they're just being called into the game. They will have to want -- I would want to do this, I would want to change all the rules if I were just starting, and that's not where we want to go. We want to get this finished, at least for this round.

So I wonder if we could actually provide them with everything that we think would be a kind of draft document and then ask for their edits and refinement of it?

Ms. Blackwell: What if instead of reconvening the 20 people, because that is sort of a burdensome exercise, we ask the chairs to attack this for us?

And I have another question. When we talk about refining, are we going to ask them to flag the 20 or so that we talked about earlier, or just rank, I mean, because we're still kicking around 41 pieces of research. I mean, do we need to say can you red flag 20 or 25, or whatever that number is?

Dr. Insel: What’s the sense of the group?

Ms. McKee: How many of the workshop chairs were involved in the second Strategic Planning Workgroup? I know Gerry was there.

Dr. Insel: Yes, Gerry wasn't in the room. It was David Emerald was in the room, Gerry was on the phone, Dan Geschwind wasn't able to attend, and Cathy Lord was unable to attend. One option would be to bring them back to the table and get them to do some of the heavy lifting here.

I did hear a lot of enthusiasm for going back to the workgroup at some point and giving them a second chance to look at a document and get their blessing on it or get their refinement of it. But I think what I'm concerned about is if we ask them to put the document together, it's going to be moving backwards instead of forwards.

Ed?

Dr. Trevathan: Yes. I think you're likely right. I think Ellen's idea of going back to the workshop chairs and getting them to take it at this point and try to refine this a bit. And then trying to get closer to a draft that goes back to the workgroup will likely be more productive.

I think also in the context of doing that other draft if the members of the IACC can weigh in on it and sort of in doing so frame it a little better so that the workgroup feels like they've had more direction in what they're supposed to do, it'll be more productive.

I do think that it is risky just to go back to the workgroup right now because I'm afraid we might go back and there may be some slight change in the order of these priorities. But I'm not sure that it's going to be significantly different than what we've got now, frankly.

Dr. Insel: How about the idea of having a standing Strategic Planning Workgroup? What's the sense of the group about that?

Mr. Grossman: I mean, it sounds like a great idea and makes a lot of sense. It just is a matter of what we're going to task them with doing.

I'm not really sure who the oversight will be other than the full body of the IACC over how we're achieving the goals of the strategic plan. And if this is a committee that's made up of the IACC members, then I think that that's something that can be easily convened. If it's going to be an ongoing ad hoc, then that would need the approval of the IACC to do that. But I think either way as long as there's something that's kind of holding our feet to the fire, that would be a great suggestion on a way to move forward.

Ms. Redwood: Tom, what about the suggestion of having a committee within IACC because we're going to have to evaluate the strategic plan annually and provide updates. So I guess I would want to sort of call the question on whether or not that would be something that we could consider in addition to the workgroup?

Dr. Insel: So maybe I misunderstood. So you were thinking about have a subgroup of this Committee that would really dig into this? Okay. That's separate from the current workgroup that we have.

Dr. Landis: I don't know if we know exactly what we want this working group to be doing long term and to institutionalize a working group when we don't have a specific set of tasks. I mean, different from your subcommittee of IACC, but to have a standing workgroup without a set of defined responsibilities and tasks seems to me-- it makes me nervous. And I would also say that NINDS did not have a representative on that. We were offered the opportunity and just the timing was horrible. So institutionalizing that strategic planning working group as it’s presently -- all of this is making me nervous. Sorry.

Ms. Singer: Maybe I'm misunderstanding what Lyn was saying, but I don't think she was talking institutionalizing that group. I think she's talking more about having a subcommittee of this group similar to the Services Subcommittee that would really focus on the research strategic plan in an ongoing way since we're going to be doing this for the next five years, evaluating what we've done and amending it.

Dr. Landis: Is that what Tom suggested? Or was Tom's -- two suggestions.

Dr. Insel: So there are two -- Lyn has two suggestions. One is to keep the, if I understand you right, the workgroup going as a regular working group that's separate from the IACC and then to have a subcommittee of the IACC.

Ms. Redwood: But I wasn't really suggesting forever and ever. I think we could probably use them one more time to look over this. And then, you know, maybe evaluate it then and see whether or not that was a useful way to do this and whether or not we want to do it again.

Dr. Insel: Okay. So

what if we were to follow through by -- I want to make sure we manage expectations here because I know some of the people on the workgroup really want -- are really motivated, and they really want to be helpful. And some of them are very skilled and committed. But I don't think we want to give them the impression that this a long term commitment. We're really at this point talking about a single meeting to finish up this task. Hopefully, we could do it before July 1st. And then we could evaluate I think at our next IACC meeting whether we want to go back to them for some additional help in the future.

But I think we'd better be clear with them that this is very time limited and very structured and very well defined around at least one and three. And we will provide them with outcomes, so that could be -- number two could be incorporated in three.

At the same, this other idea

about having a workgroup just like we have the Services workgroup of the IACC it seems to me that's got to be essential. It's too painful to try to do this with all of us. And so having a group that can really hammer away at the language and come up with things like these objectives and the priorities will be essential going forward. But since we've made it this far, hopefully we can continue to work in the way we have, at least to get to the next draft. And then we can figure this out.

Dr. Chung: So a couple of points of clarification. I think that if it's a group of Committee members only, it would actually be technically a subcommittee, and then no one else outside could be technically on that committee. But the government, the federal representatives could send a proxy. So that could be done in the future. So that's how we do it on the Services Subcommittee.

And I guess part of this is that the Autism Team has done a lot of the background work, and whoever continues to be on the Autism Team will continue to do a lot of this work in between the meetings to draft and develop things for you. And so that will continue as well. So you'll have that effort going forward.

Dr. Insel: So it's time to break for lunch. So before we do that, let's make sure we understand what we've done here. Joyce, maybe you can walk through it?

We've got the vision and mission? Dr.

Chung: Vision and mission, aspirational goals. We have a transcript of this meeting. We have a note taker who has been taking notes on the fly with people's comments. And we'll have those turned around very quickly for you to see again and to approve electronically.

We have a template of the plan, a

section of the plan which sounds like people like, and particularly the lay description of the initiatives. So, again, we can change those as we need to, but I think that will be helpful for everyone. So we're going to continue to draft all the 41. Even if they're consolidated, we'll have at least more comprehensible language, and we'll go forward with writing those sections right away. And then the priorities can be laid in within those once they are done by the workgroup.

We’ve discussed budgetary requirements and decided that there needs to be a further refinement of the plan before that can be done. And there needs to be some sort of implementation, discussion, or a group of people who discuss that. And that has yet to be defined.

And then lastly, the charge to the workgroup will be to try to meet between now and July to do kind of a polishing off and really kind of getting this plan in good shape for this Committee for the next meeting July 15th.

Dr. Insel: Judith, last word.

Dr. Cooper: Did we agree that for the short and long term objectives we would go back to the chairs of the working groups?

Dr. Insel: Of the workshops.

Dr. Cooper: Of the workshops, I’m sorry.

Dr. Insel: They'll help us with getting objectives.

Dr. Cooper: We can do that. That will not be the working groups' responsibility.

Dr. Insel: So they're going to do some of the heavy lifting with program folks as well.

Okay. Good work. We got a lot

done here. Let's take a break for lunch, and we'll reconvene at 1:30.

(Whereupon, the Committee was adjourned at 12:36 p.m., to reconvene this same day at 1:39 p.m.)

AFTERNOON SESSION

1:39 p.m.

Dr. Insel: So, we're back to the agenda.

The next item is the summary of advances. But before we start on that, I wanted to say a little bit about some changes that are taking place in the Autism Team.

As I think most of you know Dr. Joyce Chung agreed to lead this effort for a year, taking off from her funded research at Georgetown. And we were lucky to get her, and we've been lucky to have her but the year is drawing to a fast close. I have in denial about this for as long as possible. But June 30th is her last day. So it may be no accident that I said I want to get this done by July 1st. Actually I want to get it done by June 30th, to be really precise.

She's been a spectacular leader in every sense of the word for the Team. And even though she's only been doing this on a part time basis, it's really gotten us off to a great start. My only regret is that she's leaving just at this critical moment, but she has other things that she's obligated to do. And this was the original deal that we struck when she joined us last June.

So I wanted you to know that this will probably be her last meeting. If she's here on the July 15th meeting, it will be in the audience instead of having to do all the work to bring us altogether. And I wanted to thank her for everything she's done.

And Steve Foote, who is not with us today because his father is ill in Tucson and so he was unable to make it back. And, actually, he's just canceled out on going to MFAR as well. So he's missing this meeting altogether.

He was also signed on for one year and May 15th -- but we've gotten him to extend to the first of June. But he will also be rotating off this month.

So we're in the process of recruiting some additional people into the Team, changing the structure a little bit. We want to have people who will be full time because we think this is going to become and continue to be a lot of effort here that needs to go into coordinating and into running the IACC. And we'll probably be bringing people -- people we've had recently, Joyce and Steve and Diane who you'll hear from in just a moment, have all been with us on an IPA basis. Meaning that they joined us on a part time basis with having a position elsewhere. But we'll be bringing, I think, the next set of people who work on the IACC issues as federal employees so they will be with us full time.

And if any of you have people you'd like to recommend, please let me know. Because we're looking for the brightest and the best to continue on in this process.

And we will move forward to hear from Diane Buckley, who is a part of the

Autism Team and who has been helping us with reports. And her task has been to respond to the Combating Autism Act request for an annual summary of advances.

We also need to get your conflict of interest forms signed. They're in front of you. If you can sign them and send them down this way, then we cannot have to bug you
about this later.

Ms. Buckley: Thank you, Tom. So I'm here to kick off our afternoon of updates. And so I'll be starting by telling you about where things stand with respect to the summary of advances in ASD Research. To do that, I'll remind you of the legal requirement for this summary. I'll tell you about the steps that we've taken so far to get our information. The advances that we've identified and the status of our preparation of the summaries of those advances. And then we can talk about next steps.

So the Combating Autism Act in the

section where it establishes this Committee and its responsibilities states that the Committee shall develop and annually update a summary of advance in ASD research. And the language presented here is the language in its entirety. So there's not further guidance on this, but as you can see it really points to the full range of topics in ASD research.

So in terms of gathering information, we really took a two pronged approach. The first was requests for research accomplishments that we issued in December of 2007 to 19 federal and private organizations that support ASD research. And most of them responded and provided us with the most significant research accomplishments in calendar year 2007 that their organization supported in some way. And those materials actually a key input to the scientific workgroups that we held in January. And I'm sure all of you saw those materials at that time.

To supplement that request we also worked very closely with the NIH library. NIH as an organization has an internal library service filled with wonderful informationists. And we worked with one who is a neuroscience and familiar with the area of autism. And he went through all the materials that came in from the 19 organizations. And he also went using all of his expertise and supplemented those materials by really looking at the peer reviewed literature in 2007. He looked for items that made the news in major journals. He reviewed relevant websites.

By the end of this real two pronged approach we ended up with a really nice list of 140 publications that come from over 50 journals. And although I think we did a good job in taking a broad approach to this, our overall purpose in the end was to be selective, not comprehensive in that the purpose is really to try to identify significant stories or clusters of publications that would constitute an advance in ASD research. In some cases recognizing important advances might be relevant and reflective in just a single publication.

So that's kind of a summary of the process we took in terms of what we put on the table and what we considered.

And in reviewing all of those publications we were able to identify 10 areas of advance. And the way we have it organized right now is under the six question framework. And, of course, these slides were prepared before so they're not reflecting the discussion you had earlier about the framework.

But I would say from this point forward what you're looking at are draft materials. So even the placement of these in the framework is our first cut. And the ten advances that we found you have the titles here for the first six. The next slide will have the other four. And your packet of materials in the right hand pocket you'll find a document that gives you a draft text for three of these advances. And they are the ones that are marked with the stars.

So just to run through these, we saw certainly findings about the ability to diagnose ASD earlier than previously established.

In terms of understanding what is happening, we see progress in understanding brain anatomy and head growth, understanding the role of face processing deficits and increasing emerging understanding about the role of the immune system. Certainly a lot of important findings that came out at the end of 2007, and then we see some confirmation early in 2008 about changes in different genes that night contribute to autism.

With respect to treatment progress in terms of model organisms that point to new treatments and interventions that can reduce symptoms.

In terms of services a very clear documentation on indication of the costs involved on a societal level for autism. And also, of course, the findings that came out confirming the high prevalence of ASD.

So in terms of where things stand and our next steps, what we anticipate doing is finalizing drafts for all of those ten advances. Soliciting feedback. Right now we've been working in a collaborative way, I'd say really primary within NIH so we have been working across institutes. But I think this feedback piece it would be nice to hear from some of the other partner, and at least a confirmation of how we've reflected these advances, revise it as appropriate and bring it back to you for a final review and approval.

Dr. Insel: Diane, when are these due to HHS or --

Ms. Buckley: It's not specified.

Dr. Insel: Comments?

Dr. Janvier: Are summaries of these studies advances going to be put on the IACC website or how is that going to be handled?

Ms. Buckley: I would anticipate once the report is final from the Committee and submitted to the Department that that would become a report that would be publicly available.

And we haven't talked about this, but it's listed as a separate requirement for the IACC, but at least in my view in thinking about the annual cycles of strategic planning, I mean I think we can think about this as a

key piece that on an annual basis, maybe even in a more timely way next year if we can, to really look at the year in review and use that as a key input to tweaking our strategic plan for that next year. And hence, the desire to try to fit it within whatever our strategic plan framework.

Dr. Insel: Right. So

that's actually the new twist on this was to marry this to the strategic planning framework so that ultimately when we get into cycle this will just be sort of the results of what the investments in the plan have been,

Alison?

Ms. Singer: I'm just curious. How did you choose the ten and did they naturally fall into the six areas so that there were a few in each, or is that a consequence or did you specifically look to find the most promising advances for each of the six categories?

Ms. Buckley: No. When we did this work even the six categories were still quite in flux. So the first look through this was just looking at the publications and the sciences and seeing where those areas are.

And you can even see the way they fall out, maybe just one in several areas and then a lot coming out in terms of our general understanding with what's happening.

Really it was a qualitative process. It was extramural program staff and science advisors reading through and really just seeing where the main themes were.

I mean several of these topics I think will be very familiar to all of you. And they track the news because they really are certain things that made the headlines, with all of it always being driven by there needing to be the basis of the peer review literature behind it.

Dr. Insel: Larke, you had your hand up?

Dr. Huang: Actually, I think Diane sort of answered my question. I was just wondering how these might track onto the strategic plan objectives, the short term and to immediate term objectives in the strategic plan sections?

Dr. Insel: Of course, the many other implication of this is that in the future some of these advances also will drive the changes in the plan. Because the hope is that you'll make discoveries that no one would have suspected that will cause you then to put new goals and new elements into the plan going forward.

Dr. Lawler: I think just to follow up on that, I think it terms of how it might track with the plan it is going to be important to sort of understand that anything new that's funded as a part of the strategic plan we're not going to start seeing this advances for, you know, maybe a lag time of five years or so. So how to make sure -- if this is being reporting annually, and it looks like there's still no advances in areas two, it may not mean that there's not -- we haven't made investments. So it will be most useful in the area that Tom suggested where if there's a new advance that suggests there's a new opportunity that we should now include in the plan for the next year, but it's not going to track nicely with -- at least immediately with the new investments that we make. There'll be this lag time. And I am a little concerned that the use would be made of this, that it'll sort of serve as a proxy for whether we're making progress or not, which I think can be problematic because of that lag.

Ms. Buckley: I think that's an excellent point. My view on that would be that it would be an important input, but it by no means would be an adequate replacement for really measuring progress on the specific short term, especially in longer term objectives. And I think that was really the part of that discussion that was earlier about wanting to really make those objectives measurable. And I think that's a very different endeavor in terms of the accountability from this.

Given this is a requirement under the law, the Committee has to do it anyway. I think it's worth considering trying to use in a way to just inform those other efforts.

Dr. Insel: Duane?

Dr. Alexander: Did you decide in advance to just sort of do a top ten advances, or why ten? It seems from all the sources that you called from to some people ten might not look like very many.

Ms. Buckley: We did not start with a fixed number. I think individuals started with different ideas wondering could we have a list of 20 or whatever, and others thinking well no, there might only be five. But there was not a fixed number. And it was really just based on the review of the materials and seeing whether -- again, I think all of these maybe except for one have multiple papers behind them. So that you start to see some confirmation or a clustering of findings to kind of raise it to the level that would make it on a list like this.

Dr. Insel: And it looks like some have a science or nature paper that would drive them. Is that fair to say? I guess not every one of these, but many of them have very high profile papers that lead to press releases.

Ms. Buckley: Certainly. Again, a qualitative indicator of importance or significance.

Ms. Redwood: Tom, is there a way to take these articles and then look at the recommendations at the end to see if it is something we might want to pursue further in our strategic plan? Because I'm looking at several of these that I'd be curious to know what the next steps would be in terms of taking that information and then turning it into an actual potential treatment or taking it the next step to get to that point where it can be intervention for autism.

Dr. Insel: Yes. It's a good point.

I think most of these are associated with investigators who are on our workgroups. So we had people I think in almost every case as I look down this list who have been involved with the strategic plan. Almost every -- at least all of those, certainly. I don't know whether the next set. Yes.

So I think we're pretty well capturing this population of scientists to already feed into the plan.

But your question reminds me that what we did with the previous IACC is that we would put aside time at just about every meeting to hear from the people doing the science. To bring them in and to really probe in much greater detail about what they had discovered and what would be next and to make sure that the IACC was also fully informed, especially around new areas that were emerging. So we had at various times people come to talk about neuroimaging or David Amaral who came to talk about primate research. And there was a whole range of people who came through the IACC almost at every meeting.

And my hope would be that once we get past this next phase, we'll actually begin that process and we'll put aside time at each meeting to have a scientific presentation. Or, as we talked about earlier, have a presentation on the services agenda.

Ms. Buckley: Okay.

Dr. Insel: Larke, yes? Dr. Huang: Can you just show us the next slide, what's under the four or five?

So right now these don't really track onto the priorities in the six categories, particularly in four, five and six? I'm just looking at the previous presentation on that.

Dr. Insel: Yes. I mean, they weren't done in response to that, so it wouldn't be surprising. This is just a way to organize it. And I think really the take home from Diane's presentation is is this a model that you want to continue. Because there's a required report and we want to get this report aligned perfectly with the strategic plan. Does this format work for you as a group? And it'll be up to Diane and the Team and program to pull together what the items ought to be.

Ms. Buckley: And that's especially relevant to the samples that are in packet. So that you could take a look and give us an indication of what would meet your expectations. We tried to, with the help of a skilled science writer helping us try to translate the science into lay language and also to do in a concise enough way so it gives enough richness, but it's not too long. So they're about one page summaries.

Dr. Huang: I guess my concern was on number five, where can I turn for services. And the key study was there was a cost on -- I'm not sure what the implication of that. I mean, I'm not sure if it's trying to retrofit studies into categories that --

Ms. Buckley: And I think this goes back to Cindy's point earlier of -- and I think this is the key question for the Committee to consider is would you like to

see, does it make sense at this point in time for the summary of advances to be organized in a way that corresponds to the framework of the strategic plan or is that appropriate at this point possibly.

Again, they weren't developed, we didn't go and seek and search for things that would answer each of the six questions.

Dr. Insel: So, again, the sense of the Committee? Do you want to follow this model? Does this look for format? I'm not going to ask for a vote unless somebody's really uncomfortable with this. And then we're going ahead with having this group of people who are working for the IACC to come up with a list. You'll have a chance to vet the final and we'll make sure it's posted on the website.

I think it's a good idea to use this document as something that can be seen as kind of a return on investment ultimately. But we're not at that point yet.

The main piece here was just getting the format so it matches what the Committee wants.

Okay. Very good, Diane.

Mr. Grossman: I just wanted to make a quick comment on that. Because, Diane, I think that it would be important not to try and retrofit things into certain categories. Because for example like that number five that was up there about services, I'm not really sure if the Michael Ganz study is appropriate for that one just at first glance. And the reason I say that is because it's almost more telling if there's nothing under that category if it's a big goose egg. That will show that perhaps it's a priority we need to develop research around that.

Dr. Insel: But it sort of

addresses the question about cost outcome studies. It's not an outcome study, per se,
but it is a paper that got a lot of attention. It is I think an advance in the sense it tells us something we didn't have before.

And I don't know where else we would put it. It doesn't fit with any of the other five. So I think you've got to have some way to put it within the format of what we say is important to do.

But I wouldn't get hung up so much on any of the specific items.

Okay. I think we're ready to go forward. We want to go back to what we normally do at the beginning of the meeting and just go ahead the table and just get updates so everybody knows. This is our coordinating effort, what's going on at the different agencies and organizations.

And Ellen asked if she could switch with Larke, so we'll start with you.

Ms. Blackwell: Thanks again,

Larke.

I wanted to talk for a second about -- again I'm from the Centers for Medicare and Medicaid Services. Talk for a second about home and community-based services since that's what everybody seems to be interested in.

I counted our waiver programs recently and we are running about 350 approved home and community-based waivers. Over a million people participate. We're looking at an outlay of about $25 billion a year out of our budget of $301 billion a year in Medicare.

I also went into the waivers and looked at them recently to see how many of the 350 appear to include populations that could include people with ASD. And it's very difficult to do that. So this is a very unscientific guess. But I looked at target populations like mental retardation, developmental disabilities, autism and mental illness. And I came up with about 135 of the

350 waivers could be serving individuals with autism.

We have approved 11 waivers for children and adults with ASD. We have one waiver pending, it's about to be approved I believe from the State of Pennsylvania that serves 200 adults with autism. And Pennsylvania has also developed sort of a companion piece. The waiver that we're about to approve is a fee for service item, but they also have another program that uses managed care to serve the severely behaviorially challenged adults with autism.

So they're doing some really interesting things.

The other states are Wisconsin, Indiana, Maryland, Maine, Colorado, South Carolina, Rhode Island, Illinois, Massachusetts and Kansas. We're also talking to several other states about their autism proposals. And we've experienced substantial increase in requests for technical assistance over the past year.

We have some experience now. The Deficit Reduction Act put a new piece into the statute where states can provide home and community based services absent a waiver. Only one state has this coverage, it's Iowa. We're still experimenting with it. We issued a notice of proposed rulemaking on April 4th.

I think it could be used to serve people with autism. It's a little bit unwieldy because there's no ability to target services at people with autism. The services themselves actually have to be targeted. So there probably are some opportunities.

Another nice thing about this piece of the statute is that it permits states to target people who are not at institutional level of care. So that would be, for example, people with Asperger syndrome.

So, you know, again no state. We have very little experience with it but I think it does hold some potential.

We are getting ready to finish up with our Money Follows the Person grants. It's almost $2 billion, a project that permits states to get people out of institutions and back into the community.

We're finishing approval of our operational protocols now and they're very, very interesting. I've read several of them. And states get additional money once a person is de-institutionalized. And I'm sure that there are some people with autism that will be reentering the community.

As many of you may know, we have issued have several regulations this year. Probably the ones that impact people with autism the most are a notice of proposed rulemaking on rehabilitative services, a regulation on case management which is now final and another rule on school administrative and transportation services.

The waivers that I mentioned before, we think about 90 of the 350 have some element of soft direction in them, which is really a great step forward for us where families and consumers are controlling the opportunity to hire and fire their staff, manage their budgets. So states are moving more and more into that arena. And it's really a great opportunity, particularly I think for families with an individual with autism who may have trouble finding folks or agencies to work for their behaviorially challenged family member.

We have some money this year in our Real Choice Systems Change grants, we'll be issuing that solicitation fairly soon. It's to continue to support state efforts to address long time care reform, including support services to people with autism.

Some other artifacts of the Deficit Reduction Act that are still in play includes self-directed personal assistant services, the buy-in to Medicaid for disabled children, which is part of the Family

Opportunity Act.

We have another grant program that takes kids out of psychiatric residential treatment facilities and brings them back into community settings. And there's also something called the Long Term Care Partnership Program.

So overall state flexibility, additional opportunities for choice and control by consumers. And the changing demands of the market are continuing to impact state decisions about their Medicaid programs.

Dr. Insel: Great. Thank you.

Let's go on. Larke, do you want to go next?

Dr. Huang: Okay. I'm at the Substance Abuse & Mental Health Services Administration, referred to as SAMHSA in the Department of Health and Human Services. We are not a research agency, we're primarily a services agency, services administration.

Across the life span with a primary focus on mental health and substance abuse issues.

We don't have any designated program, per se, for individuals with ASD, children or adults. We do have a number of services programs, services grant programs where children with autism are part of the service population. That program is primarily our Children's Mental Health Initiative, which is a congressional legislative program. We've had it since 1993 and it's been pretty much in the last five years level funded at $105 million per year for services.

About five percent of the service population there are children along the autism spectrum disorder.

That's one of the programs I pick out in particular as relevant here. Because as I listen to the discussion here the structure of that program, which is an infrastructure and services grant program which is now funded about 125 states and/or communities, served over 95,000 children and their families, I think aligns very well with the complex needs and services for children and families with autism disorders.

It's to prevent children from going into institutional care. It's focused very much, as Ellen was talking about, about home and community-based services that are individualized to the child and family that are least restrictive environments, community- based and implement evidence-based practices. So it's a model for complex service delivery across multiple service sectors. And that has been successfully evaluated and continues to be funded by Congress since 1993.

We do have another dissemination mechanism and sort of more in the area of translational research. Our National Registry of Effective Programs and Practices is a searchable database of evidence-based interventions and promising interventions as a decision making tool for selection of interventions.

I did search on that tool. We have over 100 interventions now that have been cleared and posted on that. And when I searched for ASD or people with autism, we actually did not have any interventions turn up. So as the research proceeds, that's something that we would certainly want to partner with in terms of getting the translation piece out on that.

That's pretty much it in terms of ASD.

Dr. Insel: How do we fix that? Because there evidence-based practices in autism?

Dr. Huang: Yes. The way that's done is it needs to get -- you need to advocate for getting it to be a priority for the next panel review of practices. And that we're about a year behind in getting practices up into the mechanism. But it would probably be talking with -- probably you talking with

Dr. Klein and saying can this become a priority for interventions that could be fast track reviewed and put into NREPP.

Dr. Insel: Can you help us with that? Is that something that you can do from within?

Dr. Huang: You know, I can certainly try to do it within, yes.

Dr. Insel: Okay. Good. Thank you.

Peg Giannini?

Dr. Giannini: I'm the Director of the Office on Disabilities for Secretary Leavitt and President Bush. And I cover the whole gamut of disabilities and, of course, autism is a large part of it. And my responsibilities are many, mainly I am responsible for the President's New Freedom Initiative, which cuts across all domains that we've been talking about today. And as I said, all disabilities which includes autism as well.

And one of the other major responsibilities is to be sure that there's partnership and collaboration within our own agencies and with other federal departments and private entities. And many of my partners

are sitting around the table here today. ADD, and NICHD, SAMSHA, CMS. And that's really the way that I'm able to accomplish any of my initiatives. Because I don't have resources. I have what you call authorization, but no appropriation.

Dr. Insel: We know about that, actually.

Dr. Giannini: Sorry? Dr. Insel: We know all about that. Yes, The life of the autism –

Dr. Giannini: And I'm very grateful to my partners that are here today and those that are not here today because it's allowed us in partnership to accomplish many important initiatives. And one of the areas that I was responsible for was the Surgeon

General's Call to Action for Health and Wellness for Persons with Disabilities, of which again many of the things we're talking about is in that publication. But particularly the initiatives that the partners were extremely involved in and important, was for instance in the initiative of youth in transition for 14 to 30 which includes, which I keep repeating, autism. So that it became a seamless operation.

We worked with six states and four tribes. And initially for the states to be selected the governor had to make a commitment that he would fulfill whatever had to be done, and we were successful with the six states and the four tribes.

I'm just going to tick off some of the initiatives that worked out this way.

There's another one in employment of adult or young adult, adolescent. We worked with the Department of Labor and particularly with ODEP so that we not only worked with the consumer, the employee in a certain organized way, but also with the employers so that they would understand what an autistic or an Asperger's kind of individual would be and how productive they could be and so forth. So that's been very productive.

And we have another nationwide programs that I won't go into detail. But the other is that it was important for us to also partner with other federal departments, such as Department of Education and Social Security. And we do that with our co-occurring initiative of disabilities, which autism was an important part. Particularly that was HRSA, ADD and Department of Education.

I just wanted to finally say that it's important for this kind of relationship because in this way we can impact policy. We can impact, perhaps, legislation. We can do many things that perhaps individual agencies cannot do. So that's important. But the other impact we have is not only on a federal level, but on a state level which we're working very closely with on emergency preparedness and, again, other partners like ADD, and I could name a few others, which is so important to take care of our persons with disabilities. But also not only with the state level, but then also on the local levels.

So it kind of pulls it altogether. It takes on the federal level what I've described. On the state level it's really persuasion because we can't tell states, we can't dictate to states what they have to do, but we can kind of make them understand where the common ground is and how it would be beneficial for both sides of the aisle, so to speak, in terms of disciplines. And then on the local level just really getting the networking of services to work together.

So I can go on, but I'll stop.

Dr. Insel: Thank you very much. That was great.

Story Landis has morphed into Deb Hirtz for NINDS?

Dr. Hirtz: I'll be real quick so we can catch up a little bit. I just want to mention a few things.

One is that the NINDS is undergoing its own strategic planning process right now. So that the work of this Committee is really timely in terms of integrating what we are trying to do at NINDS.

We have four different modules of our planning process at basic clinical and translational groups and then what we're calling a disease group. And I'm actually the chair of that group. So one of the things that we'll be doing very shortly is coming to find some representatives of the autism community to talk with us about what we need to be doing and what we've been doing so clearly. This is work that's already in progress here.

The study that I want to mention

is just an update on what we consider one of our really important and existing studies in autism. And this is a study in Norway that is being funded through Columbia University where we're looking at 100,000 pregnant women that are enrolled in a Norway birth cohort and screening the children when they're 18 months and then again when they're older. Trying to basically ascertain all the children in this population that might have ASD.

The reason that it's such a good rich resource for us is that we'll be able to have cases of ASD and controlled children from this perspectively gathered population. And they have exposures from pregnancy, they have blood samples from the mothers from pregnancy, we have cord blood from the children. So we'll have a lot of information that we will be able to use to compare risk factors and biomarkers and exposures in children who have ASD and children who don't.

It's a long process because it

takes -- the birth cohort is enrolled over several years or even longer than that. And then in order to ascertain all the children who have ASDs in this population, we're trying to get them by screening but finding that it's probably going to take waiting until they get to school age until we really know that we have all the population.

So the study's in progress. It's going to be another few years. And we think it'll be really a terrific resource.

We're very excited about our new ACE centers. But I think Tom is going to talk about those as a group. So I'll let him take over.

Dr. Insel: Thanks. Maybe just one other thing to mention that Walter Koroshetz from NINDS has been very involved with Ed from CDC, with me at NIMH and with people in the Department to organize a meeting on mitochondrial disorders and their relationship to autism, which we're hoping will happen in June. So that is not quite finalized. We can let the Committee know more when that happens, or Ed may know more about it than I do. I think as of Friday we were still trying to clarify whether --

Dr. Hirtz: Still working on it.

Dr. Insel: Okay. So it's still up in the air.

Dr. Hirtz: It will happen. It's really just a question of when.

Dr. Insel: When? Okay. From the NIMH perspective, yes a few things to mention.

As Deb just mentioned we have four new awards for Autism Centers of Excellence. One is to what we call a program center to look at very early social interactions and developments. These are in children at risk from 12 to 24 months.

There are three additional awards that are for what we call networks. So these are centers specifically but they're virtual centers across many different sites. One is to Diane Chugani from Wayne State who has got a network that's going to begin to look at the effect of a particular intervention buspirone in promoting normal growth and development of the brains of children with autism.

Dan Geschwind at UCLA has a network which will build on the AGRE, that is the Autism Genetic Resource Exchange, to increase the number of simplex families. There will be 400 more families added, including 200 African-American families.

And Craig Newschaffer from Drexel University, actually both Dan and Craig were very involved with our strategic planning effort, has received one of the other networks to look at risk factors and biological indicators during the prenatal, neonatal and early postnatal period. So this is much more of an environmentally-based effort. Actually it's called EARLI, which is an acronym for early autism risk longitudinal investigation. So it's E-A-R-L-I. And we're pretty excited about this because it's taking us into an area that everybody says we need a lot more information about but haven't been able to do as much as we'd like.

This combined with what Deb was just talking about with the Norwegian study has, we think, a huge amount of promise. Now here there are 1200 moms and babies as opposed to 100,000. But it's a start.

Just a couple of other things as recent findings or recent studies.

Last month we funded a multi-site collaboration between Amy Weatherby and Cathy Lord to look at an intensive parent implemented early intervention for children with autism. This is a manualized program which builds on some earlier work that both of them had developed. And we're hopeful that this could actually be disseminated broadly to the autism community.

And it would remiss not to mention that there have been some very high profile papers recently, particularly around genomics where remarkably it's been now about three months, but three different groups from completely different populations and different approaches ended up finding the same gene associated with autism. And that gene is one that we had not heard much about before. It's called contactin-associated protein 2. And what makes it particularly striking is the biology of the gene is that it sits within the synapse adjacent, kind of one protein away, from neuroligin-3 and SHANK 3, two other candidates that have come up from genomic studies.

And this extends the list now of interesting genes that seem to be associate with risk for autism. They're not diagnostic by any means, but they continually point us towards synaptic proteins suggesting that that may be a place that we'll need to know a lot more about going forward.

And finally, I should mention that a group at MIT and the Autism Consortium in Boston had reported now about three months ago a new causative mutation, that's chromosome 16p11 mutation which adds to Fragile X and Retts and tuberous sclerosis and 15q23. So we have now yet another one that explains about one percent of children with autism. So it doesn't explain much, but it means that that one percent probably needs to be taken out of other studies that we're doing because they have something that's very much like Fragile X. It doesn't have a name yet, but this is clearly penetrant mutation that is probably defining a separate disorder which we've been lumping together autism, but it's probably something quite unique.

I think I'll stop there and turn it over to Cindy.

Dr. Lawler: Thank you. I'm from the National Institute of Environmental Health

Sciences.

And one of the gap areas we've heard about in the planning efforts as being the lack of understanding of how environmental influences and gene environmental interactions may contribute to autism risk. So in response to that we recently developed a program that I spoke a little bit about at last November's IACC meeting. And of course, this is NIH and it's a program, so I had to come with a cute acronym. so the acronym was ENHANCES, which is sort for Explore Novel Hypothesis In Autism Networks and Centers Through Environmental Science.

And the goal of this program is really to help develop new collaborations between what has been largely two separate fields, environmental health sciences and autism researchers.

And the strategy was the NIEHS supports (P30) Core Centers at a number of institutions across the country. And these

Core grants provide centralized facilities and services for environmental health scientists who have funded research projects. Well, if you overlay the map of where there's an NIEHS Core Center with where the institutions that were going to be awarded an ACE, you see there's some overlap. So we targeted three places that had a Core facility funded by us and that were slated to receive an ACE award.

And what we did is we provided at the very end of last physical year infused money into our Core Centers for a special pilot project solicitation that had to involve a collaboration between an environmental health scientist affiliated with that Core Center and an investigators that was part of the ACE network or center at that same institution.

So even though we start with the same institution, these are usually groups of people who do not speak to one another.

So this money was provided at the

very end of the last fiscal year and subsequently over the last couple of months the solicitation has gone out and applications were received and have just been awarded recently. And I'll just give you one example.

The three institutions that were targeted, University of Washington, UNC Chapel Hill and Wayne State University.

So one of the pilot awards that was made recently to the University of Washington is to support a new collaboration between an assistant professor in environmental epidemiology who has been a very active member of the NIEHS Core Center and an assistant professor in psychology who is director of one of the ACE Core service facilities.

And these two investigators didn't know each other at all in the past. They're from very different fields. And this pilot funding has allowed them to come together and they're designing a study to investigate the potential role of plasticizers like bisphenol A and phthalates in autism risk. And they're doing that by adding an exposure component to an existing baby sibs study.

In addition to funding that, you know the planning for that particular pilot study the Core Center Director told me he's had very lengthy discussions himself with the ACE PI at that site, who is now Brian King trying to brainstorm of ways to really further integrate these two centers. And one idea that they've been kicking around is to establish a bio repository from some of the autism families and that baby sibs network that would provide materials to look at other potential environmental factors in the future. So that's just one example of how with a small amount of money you can really begin to leverage existing efforts.

Another just minor point I want to make, these supplemental funds that were provided last fiscal year with FY '07 dollars showed up on this listing of funds. But if you go through them and looked at the abstract of the Core Centers, there's nothing about autism on there. So this would be one example of why it's really difficult. Even though the supplemental funds are noted here, you wouldn't realize they were specific for autism if you just looked at the abstract for that Core Center. So it's kind of an imperfect science.

So we're hopeful that pilot projects such as the one I just described will really help provide some seed money to jump start the integration of these two fields.

Dr. Insel: Okay. Thanks, Cindy.

Judith?

Dr. Cooper: I'd like to share with you an ongoing activity that's between the NIDCD and Autism Speaks. But I want to give you a little bit of background of why we're doing it.

We're all familiar with research studies that have shown that early intervention can have an impact on language acquisition in children with ASD. And we know that this is a significant finding, because we also know that early language acquisition is a real strong predictor of outcome in children with autism. And it's become really important, therefore, that we can identify the strategies and the programs that have the strongest impact on language acquisition.

Well, there are lots of intervention programs out there and they have different philosophies and different approaches, but we really need to try to pinpoint which ones have this -- we want to be able to compare the language outcomes. And the problem is that we can't that right now because the intervention programs, even though many of them have been published and we have strong research papers, very often use different measurement tools to assess language over time in these programs, and they use different terminology.

Some of these intervention programs use the term "functional speech" as a goal. But the problem is they don't define it and different people mean different things by functional speech. And so we're in a quandary because it's really hard to talk about long term efficacy across these programs.

So, to address this situation, NIDCD assembled a group of leading researchers in child language disorders and in language and communication in autism spectrum disorders. And we asked them to take a look at these issues. And through a series of conference calls and correspondence and culminating in a meeting sponsored by Autism Speaks last December, we have focused the group on two goals which are going to be presented in a summary paper, which will be published soon and I'll tell you about that in a minute.

And the two goals really were these: To have this group of experts come together and say what are the recommended measures that we can use to evaluate efficacy of intervention, and also to come up with some kind of common terminology for describing the levels of language ability. To set up some benchmarks for determining a child's language level and then to use those benchmarks to compare across different intervention studies.

The paper will be primarily for researchers, but we think it will also be of great use to clinicians and professionals who service children with autism spectrum disorders. As they have to chart language progress and they have to assess these children. So it'll be a nice bridge between the researchers and the clinicians.

And we also think it'll be helpful to parents and to individuals who are involved in early intervention and who are looking for efficacy and effectiveness data and trying to interpret clinical reports and research studies.

So the paper will be published in the Journal of Speech Language Hearing Research sometime soon. We're not quite final, but we're close. And once the paper is available, we'll certainly let you know and make it available to the Committee.

Dr. Insel: Super. Thank you.

Peter van Dyck?

Dr. van Dyck: Good afternoon. I'm going to talk about some money we received from the legislature this last year for some service delivery programs and not talk about existing or ongoing programs this time.

We will be expanding to a number of our, what we call lend projects, which are centers, 35 centers across the country for diagnoses and training, diagnoses and treatment of children with autism and other developmental disorders. And for training folks on how to improve care for this population. And those additional supplements to some of those lend centers will be for activities which focus specifically on autism and other developmental disabilities and/or document how they'll provide services to new a geographic area and how they will collaborate with other entities in the state, such as Title V, which is the MCH program, autism research grants and other grants that will be funded other these initiatives that I'm talking about.

In addition to supplementing some of the existing 35 lend programs, we will fund several new lend programs in areas across the country where they now don't exist. And, again those programs will provide diagnoses and treatment for children and families with autism and other developmental disabilities and for training as well.

In addition, we'll fund a

technical assistance center to these new programs or supplements I just mentioned to help with autism training, guidelines, collecting and disseminating promising research and practice models and data collection and analysis efforts to assess the impact of these new investments and how they relate to training.

We will then also fund two autism intervention research network centers. They are multi-site centers. They focus on intervention research guideline development and information dissemination and which cover the areas of both physical health and social mental cognitive and behavioral health interventions.

We'll also be funding a handful of states in what we're calling state autism demonstration grants. And these demonstration grants will implement state interagency autism plans with a key role for the head or lead Title V or MCH program in the state to develop models for how to develop systems and services for children with autism and other developmental disabilities. And to coordinate state-wide efforts with others in the state that provide services to children with autism and other developmental disabilities such as Head Start, Healthy Start, Medicaid, EPSTD, child care, WIC, MCH program.

And we'll be also funding a coordinating center, a state public health coordinating center to help provide technical assistance to that handful of states, but to also develop and implement a strategy for defining and supporting and monitoring the role of state public health in ensuring that children with autism receive early and timely identification diagnoses and intervention. And the center will complete assessments of the Title V or MCH agencies -- actually use the same Title V, equate it with MCH and the maternal and child health program in the state.

The center will also complete an assessment of the MCH agencies and partners activities related to autism spectrum disorders, convene the state MCH agencies and partners to develop a public health framework or monograph for addressing ASD and other developmental disorders, develop and maintain a database of state public health activities related to ASD, and to provide technical assistance to public health agencies to enhance services and supports to children youth and family.

And I think I'll stop there. These are new activities.

Dr. Insel: Great. Thank you. That's really interesting.

Duane?

Dr. Alexander: Like many of the other NIH institutes, we're involved with some collaborative activities with Autism Speaks and some other organizations. Let me mention just a couple.

One of these is the Baby Siblings Research Consortium that's been going on for several years taking advantage of the known fact that siblings, younger brothers and sisters of children diagnosed with autism, have an increased likelihood of developing autism themselves. Thus, it's an enriched population for studying early signs and symptoms of development of autism and ways that we can pick up these kids earlier and earlier. And so this is the goal of that study, and that's continuing to go well.

A brand new activity is the Pan America Autism Research and Services Training Initiative that Autism Speaks put together with the Carso Health Institute in Mexico City and the Canadian Institutes of Health and NICHD is a partner with this as well.

The goal of this is to try to increase the knowledge of and services for persons with autism in Spanish speaking Americans.

The first workshop is going to be focusing on increasing autism awareness in these countries.

A third activity is continuing to maintain our brain and tissue bank for researchers in autism and other neurologic disorders where we provide, not just a tissue from effected individuals, but also normal tissue and children with neurological disorders above and beyond autism.

We currently have discussions underway to try and expand this brain and tissue bank as a resource for more research related to autism.

Number four is the National Children's Study. This is a study that's been going on in planning since about 2001. It was a study mandated by Congress. And I think most of you are familiar with it. This is a study of environmental influences on children's health and development in which we will study 100,000 children recruited over four years, during pregnancy or even before pregnancy with environmental and genetic measures of the children, their family, their home, their school, other surrounding community so that we will be able to look at different environmental factors and exposures in relationship to their health and development.

One of the major outcomes that we're focusing on in this study is autism. By age 3 we expect to have all the autism cases identified so that we'll probably have 700 to 800 children with autism identified prospectively with all the background information on exposures during pregnancy, DNA on the child and the parents and be able to look at gene environment interactions in relationship to the development of autism.

So we're very excited about that particular study. And we are moving along. We got the dollars that we need from the Congress for the study. And the OMB approval to proceed. We could be in the field recruiting the pilot sample of 1,000 children by September this year and the full sample starting next summer.

Finally, I'll just mention that we are partnering with the other NIH institutes, four NIH institutes in funding the Autism Centers of Excellence and the networks for the Autism Centers of Excellence.

And that's the major activities to report.

Dr. Insel: All right. Thank you.

Gail?

Dr. Houle: Good afternoon, and thank you. I'm the only non-HHS agency represented here. And I'll give you an update and just try to put it into context of what we do at the Department of Education.

Our congressional mandate is mainly as a service provision agency, not a research agency.

In the area of special education

we get about -- well, somewhere over $11 billion of funding. Most of that funding flows from the U.S. Department of Education to the states based on the child count of how many children with disabilities they have identified and provide services to. It may sound like a lot of money, it may not sound like very much money. If you take this amount of money overall, the federal proportion of education for a child with a disability is about 17 percent of the total cost. The rest of the cost is made up through the state and through your local school districts and your local education agencies.

There are probably between six and seven million children served under the Individuals With Disabilities Education Act throughout the country. If you're interested in a particular state breakdowns, how many children are served, how many children in each disability category you can go to a website, which is ideadata.org and look up your state and see how many children are identified with autism or any other particular disability within your state.

So that's where the bulk of the money that Congress gives to the Office of Special Education within the U.S. Department of Education, that's how it flows down to your local school district. But we also have, and this is the area that I work with, is a small pot of IDEA money in the Part D program. And that approximately $200 million is divided among all the disabilities, which probably are maybe 12 in the IDEA legislation, autism being one. And with those funds we have the authority to fund professional development activities, which are teacher training programs that go to universities. And we have a fair percentage of those programs now that are training professionals, either speech language pathologists, teachers even para-professionals to become certified in the provision of services for children with autism. That's grown. The proportion of the universities requesting and receiving those funds has grown tremendously over the past, say, five years.

We fund technical assistance provision. We fund regional and state providers to provide technical assistance within their state or region for people who are employed at local school districts to enhance their ability to provide services for children with autism and families.

And one of our biggest investments, it's directed -- we call it directed funding as opposed to non-directed funding. Directed is the Professional Development Center in Autism. Sam Odom is the principal investigator. And it's at the University of North Carolina. They're just finishing up their first year. And on their website they have applications for state education agencies to apply to send teams or to have institutes go out and provide training for teams of professionals for each state. So if you're in a state that is looking for some technical assistance and training to provide enhanced and better quality services for children with autism, you might want to look at that website and see if your SEA or any other organization you know is interested in collaboratively having teams trained. It's a training the trainer kind of model.

We also have our parent training centers. There's at least one in every state. Usually more than one in every state. And they serve parents of children with all disabilities, including autism.

There's also specialty parent centers. One for parents who are military, members of the military and have children with disabilities, one for parents who are Native Americans who are having trouble getting cultural sensitive services for their children. So we do fund the parent training centers and we're getting ready to refund those

And we also have some assistive technology awards that we're getting ready to make in the area of advancing communication disorders and the ability to communicate and use assistive technology more effectively for school children.

The other thing that we're doing is new is this week we met with a Department of Defense representatives. The Department of Defense has a new mandate under the National Defense Appropriations Act to provide additional services or at least to insure appropriate and adequate services for children of military families with autism spectrum disorders. So they're working with the Department of Education because the children are either in military schools or they're in school districts scattered throughout the United States, but still are dependents of military families and active military duty members. So we're working with them with their new mandate that they have to actually evaluate some of the services that are provided, make some recommendations that would impact whether or not a family is stationed in a certain part of the country or not, depending on what services are available.

We are in the midst of our own grant review process. Our fiscal year ends September 30th. So we don't have any of our new awards awarded yet, but we will be doing that with our 2008 funds, and then we'll be getting right into 2008. So at the next meeting I could probably more succinctly provide you with a handout of the new grantees in the area of autism. We'll know by then who is getting the awards.

Thank you.

Dr. Insel: Okay. Thank you.

Ed?

Dr. Trevathan: Briefly, our Learn The Signs, Act Early campaign at CDC in which we partnered with American Academy of Pediatrics and state and local health departments and a variety of organizations has continued its work. And there have been groups set up around the country now actually in all the major reasons in the country and most states actually to look at more detailed mechanisms for implementing the Learn the Signs, Act Early campaign which we hope can help us to identify children with autism earlier in the general population.

And the significance of that is underscored by the fact that we still don't have methods for doing population-based surveillance to determine the number of children in the population with autism before the age of 8 yet. And we're doing better getting down to ages 6 and 5. But we clearly need to do a better job with ascertaining children in the general population earlier, both for epidemiology and determining prevalence and also really being able to intervene early with the interventions that we hope will be effective.

To that end, we also have funded some centers to develop better methods for early identification in the general population of children with autistic spectral disorders with the hope that we can implement those methods and our surveillance systems. And hopefully we'll have some methods developed by those centers soon.

We should be reporting prevalence rates, again out of our ADAMS site, our surveillance and epidemiology sites within the next several months for the 2006/2007 years.

We have a collaborative effort with Denmark looking at prevalence of autistic spectrum disorders in Denmark. We're starting to get some interesting data from Denmark and hope that those data will be available soon for publication.

Just throw in a couple more acronyms from the government.

Our Centers for Autism and Developmental Disability Research and Epidemiology have been developing over the last several years a large and complex case control study to look at risk factors for autism. And that study known as SEED, or the Study to Explore Early Development, is starting to enroll patients or study subjects. And we're very optimistic that that will continue to go well.

It is a case control study, so it's not a prospective study as the National Children's Study. But the power, in a sense, is quite large because we'll be enrolling hopefully about 2700 children. So we'll be able to hopefully do some nice analyses and look at risk factors for development of autistic spectrum disorders there.

We have had historically over the last several years at CDC an autism workgroup that's been a group of investigators from multiple centers at CDC. And we are restructuring and actually reforming that workgroup in the context of a much bigger neurological disorders workgroup that has started to meet.

Our hope is to bring in people that haven't heretofore been working in the autism world. We're working more with, for example, our Office for Public Health Genomics, National Center for Environmental Health laboratories and others to really look at ways to sort of bridge and take some of the new science that's been developed by NIH and others and try to look at how we can apply that to larger populations.

Dr. Insel: Thank you. Pat, you get the last word.

Dr. Morrissey: This will be short and sweet.

We do not have any specific projects on ASD right now, but we have two initiatives that probably will benefit some children with autism. We're about to fund in this next two months three one stop centers for military families that will bring the relevant service providers to the table to help families plan for their children. And we think because of the National Defense Authorization Act of 2008 that a high percentage of those kids that will be served will be children with autism.

And the other thing is something that Congress gave us, a $2 million initiative to fund a national clearinghouse and technical assistance center on family support. That family support is the name that we've given to our one stop initiative in the last five years.

And the approach we want to take is to basically try to create a cadre of people across the country in every state that will have a better understanding of how to bring about service integration for the benefit of families and kids.

Dr. Insel: Great. Well,

thank you. That's a lot going on.

Let's take a five minute break and then we'll come back for the public comment.

(Whereupon, the above-entitled matter went off the record at 2:54 p.m. and resumed at 3:03 p.m.)

Dr. Insel: Okay. As we've done in the past, we have a number of people who have written in ahead of time that they'd like to make a public comment, and we'll have them do this in alphabetical order. So we have got about eight people listed here.

Because of the late hour, we want to be done by 3:30 at the latest, it would be great if you could keep your comments to less than five minutes, maybe closer to three or four.

The first person on the list is Vicky Debold.

And we have a microphone up here, and an empty chair.

Ms. Debold: Good afternoon. My

name is Vicky Debold and I represent SafeMinds, a private charitable, nonprofit organization founded to investigate and raise awareness of the risk to infants and children of exposure to mercury from the environmental and medical products including thimerosal in vaccines.

We appreciate the opportunity to provide recommendations to the IACC on its strategic plan. To that end, eight recommendations are offered.

The first is to acknowledge autism as a national emergency, an epidemic, with at least one out of every 150 children in the United States effected. We respectfully request that the NIH respond to autism as a national emergency and appropriately allocate the critical resources necessary to respond to this pervasive epidemic before it effects an even greater proportion of the nation's children.

Specific recognition of autism as

an epidemic is needed to both highlight preventable environmental causes and the urgency of needed governmental action.

Two is to allocate sufficient resources to fund autism research. The IACC strategic plan must make a case that sufficient funds need to be spent on autism research, whether derived from Congress or as part of the overall NIH funding allocation.

Three is to shift the research focus from genetics to the environment, acknowledging the epidemic demands that the research focus shift away from an exclusively genetic model to one that investigates the role of environmental factors combined with the genetic vulnerability as a potential culprit behind this otherwise unexplained epidemic. The role of the environment has been widely recognized as under-studied. And the absence of a well developed environmental research agenda impedes the discovery of etiologic factors and effective treatment strategies.

In particular, the IACC's strategic research plan must include a special emphasis on vaccines and their components as a possible cause of autism. This topic is the only specific research priority mentioned in the Combating Autism Act legislative history. To meet this requirement the research plan should include specific extramural funding for a rigorous, prospectively conducted and randomized trial that will establish differences in health outcomes, including autism spectrum disorder among vaccinated and unvaccinated children. Perhaps the National Children's Health Study can include these variables in its protocol.

Fourth is to develop a leveraged research agenda. The NIH should develop a leveraged agenda focused on prevention and treatment that will benefit the greatest number of lives and families as quickly as possible.

Five is to regard autism as a dynamic disease process that is amenable to treatment. I think that's pretty self- explanatory.

Six is to reclassify autism as a multi-organ disease. Numerous comorbid disease states need to be diagnosed. They exist in children with autism including abnormal gastrointestinal function and inflammatory bowel disease, evidence of increased oxidative stress, severely disordered serum chemistries, methylation disturbances, increased body burdens of metals and microglial activation in the brain.

Seven is to establish an NIH-driven research agenda that is not driven by researchers. The current research agenda appears to be driven by investigators seeking continuing funding rather than by the NIH to achieve specific research goals, which in turn provide the basis for funding allocations. Specifically:

(a) NIH should issue requests for applications for high priority research gaps and use special emphasis review panels;

(b) Include NIH goals as items to be scored when reviewing grant proposals;

(c) To announce NIH goals as program project grants, and;

(d) is to require Autism Centers of Excellence to address NIH goals as part of their center designation and to consider such project proposals when scoring center proposals.

The strategic planning process ought to be performed by the Autism Advisory Board which has specific recognition and legislative history.

Lastly, is to create a formal mechanism for ongoing public/private research agenda. Throughout the draft document, reference is made to a public and private partnership regarding autism research activities, establishing strategic and specific research agendas as well as funding decisions -- must have direct consumer input on both science and relevance similar to the process used by the Department of Defense to carry out the autism CDMRP program. It is essential that the NIH adopt a community-based participatory research model.

Thank you.

Dr. Insel: Thank you. The next person on the list is Paula Durbin-Westby.

Ms. Durbin-Westby: Hi. I'm Paula Durbin-Westby. Today I'm representing the Autistic Self Advocacy Network, a volunteer- run nonprofit organization run by and for autistic people dedicated to advancing advocacy and support for the autism spectrum.

ASAN urges research directed toward quality of life in such areas as service delivery, education and support services.

I spoke at the March 14th meeting

about the need for research models that include autistic people at every level of the research project. Funding should be allocated to research that will have practical applications for autistic people and our families.

As I mentioned last time, community-based participatory research is a promising avenue for exploration. With community-based research, members of the community being studied are full participants at every stage of the research process.

Since I last spoke to you, I've learned of a promising new project that exemplifies how the academic and autistic communities can partner together to conduct research to improve the lives of autistics. AASPIRE, spelled with two As, is the Academic Autistic Spectrum Partnership In Research and Education. The partnership adheres to the principles of community-based participatory research.

The mission of AASPIRE is to: Encourage the inclusion of autistic people in matters that directly effect them;

To include autistic people as equal partners in research about autism;

To answer research questions that are considered relevant by the autistic community, and;

To use research findings to effect positive change for people on the autism spectrum.

AASPIRE team members come from three interrelated communities: The autistic adult community, the academic community and the support and service community.

The autistic community partners the Autistic Self Advocacy Network.

Academic partners include health services, disability and autism researchers from multiple institutions.

Team members from all three

communities work as equal partners to design, implement and disseminate the research.

The inclusion of autistic individuals in all phases of the project ensures that the research is relevant to the autistic community, that the methods are feasible and respect the rights of autistic adults, that the questions are clear, that the conclusions are valid and that the findings will be used directly to benefit the autistic community.

A strong literature exists documenting health care disparities for people with developmental and intellectual disabilities, including increased mortality, increased morbidity, of lower quality of life. AASPIRE is currently undertaking an initial pilot project to address these disparities.

The first pilot project will examine the experiences and recommendations of autistic adults as consumers of health care and the experiences and recommendations of primary care clinicians as providers of health care services to autistic adults.

The project will use a variety of methods to obtain and analyze data, including surveys, semi-structured, open-ended interviews and data mining of information shared through public online communities. The purpose is to obtain pilot data for an NIH proposal to develop and evaluate practical tools that can improve patient-provider communication and make health care more accessible to health care consumers on the autism spectrum.

Using AASPIRE as an example, I urge high priority funding for studies utilizing community-based, participatory research. The results are based in the real life experiences of people on the autism spectrum and will have practical application.

Thank you.

Dr. Insel: Thank you. John Erb.

Michael Frandsen.

Mr. Frandsen: My name's Mike Frandsen from coachmike.net, and I tutor kids and adults with autism.

I believe that the Department of Health and Human Services, the National Institutes of Health and the National Institute of Mental Health discriminate against people with disabilities in their hiring process.

There's been some discussion that NIH should do more research on services and coordination of research with services for people with autism. I believe that they should.

One example of how this disconnect between research and real-world services can be partly bridged rather than having completely separate silos for each area is greater federal employment for people with disabilities.

I believe that one area that is

deeply ingrained in the NIH culture that needs to be changed is the insistence that NIH is solely a research organization whose responsibilities completely end at conducting research. This attitude shows a reckless disregard for doing research on the services that are desperately needed today to improve the lives of people with autism and other disabilities.

This attitude is at best shortsighted, and at worst a mind-set perpetuated by academics who sit in ivory towers rather than work in the trenches and help people with autism and other disabilities.

During each of the past five years I advocated on behalf of a person with impeccable credentials and great experience who has a psychiatric disability to get a job interview at NIH through the Schedule A hiring authority. Schedule A is a federal program used to appoint persons who are certified that they are at a severe disadvantage in obtaining employment.

This Schedule A program, specifically set aside 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 -- is severely underutilized and virtually ignored by NIH.

While the person who I advocated for does not have autism, Freedom of Information Act requests I sent to NIH have shown that, as of a year ago, not one of NIH's employees hired in the previous five years was hired using the Schedule A authority for people with disabilities. And there's no evidence that during this time frame this program was ever used at NIH to hire someone with autism.

Information was sent each of the past five years, multiple times per year, to the NIH Director, HR contacts, EEO contacts, selective placement coordinator, communications directors and the ombudsman. Even years after NIH was notified of the problem, the lack of Schedule A hires, they refused to do anything. NIH's response, I believe, has been insensitive, ignorant and dismissive and I left my job at NIH in protest a year ago, and still, this individual with 20 years of excellent job experience who has applied for jobs for more than five years at HHS and NIH has not received the opportunity for a job interview.

It is ironic and disappointing that an organization whose mission it is to work to improve mental health through biomedical research on mind, brain and behavior, the National Institute of Mental Health does not have an equivalent program to ensure that those disadvantaged with disabilities can fairly contribute to advancing that mission.

I believe that NIH and other

agencies should not only develop policy on making the hiring process as inclusive as possible, but should also be accountable to those claims by ensuring that the policies are effectively implemented in a way that will mutually benefit the agencies, the public who they represent and the employees who conduct work for these agencies.

NIH needs to be proactive in hiring people and other operating divisions of the Department of Health and Human Services need to take a role in outreach and awareness.

In conclusion, given its position as the steward of medical and behavioral research for the nation, NIH should be particularly sensitive to attracting and retaining people who are traditionally under- represented, including those with disabilities whether they be physical, psychiatric, cognitive or developmental.

Incidentally, the government doesn't even have a category for developmental disabilities in its Schedule A program developed by the Office of Personnel Management.

A failure to proactively include employees from all segments of society in the hiring process threatens to leave these people languishing with difficulties and frustrations. And this is based partly on what I've written on my website, coachmike.net.

Thank you.

Dr. Insel: Thank you. Carol Hoernlein

Ms. Hoernlein: Hi. My name is Carol Hoernlein. I am a former food process engineer who has investigated food additive sensitivity for the past 16 years.

When the genome study results were announced last February I realized the similarities between MSG sensitivity and autism. Because the genes in the neurexin 1 area of the genome code for glutamate synapse formation. And based on that, I compiled all the data that I had and put it together. And then I started to look at what symptoms also showed up in autism.

And the result of that is a flow chart that I came up with, which I brought a copy of. And you can see, it's actually quite complicated. But what I did was I color-coded

-- the things that are gold have to do with autism spectrum disorder. And basically there's so many similarities that are related to glutamic acid sensitivity. And glutamate is here. These are all the body systems that are effected by it.

This chart is available. I have a PDF of this chart. I also have hard copies if anyone would like to have a copy of it. And it's also on my website. My website is msgtruth.org, which has been up for six years.

And basically -- I don't know if they can see it.

And on the chart I have basically the parts of the body that are effected by glutamic acid, the diseases involved, what happens when certain substances that the body makes either increase or decrease.

The diseases that we have names for that -- what these things cause. And underneath that I posted all the medical treatments that we currently use for a lot of these. And what's very interesting is that most of them are glutamate blockers.

And in this investigation where I was basically putting together all of this data, I noticed that the amygdala is effected by glutamic acid. It's the target due to its importance in the sense of taste and smell. And what's interesting about the amygdala is that when it's activated, gaze avoidance is what occurs with autistic individuals because they feel threatened. It's a part of the brain that's involved with fear as well as taste and smell.

Also glutamic acid in the body is converted to GABA, gamma-aminobutyric acid, which I understand is being used to treat autistic children. GABA in a normal individual causes the pituitary to release growth hormone. This may be involved somehow with the abnormal growth seen that was spoken about before as one of the symptoms.

Glutamic acid also increases histamine response and consequently inflammation that is also found in ASD.

Now the thing that was the most striking to me was that wheat and dairy have something very much in common with vaccines, and that is a high glutamic acid content. Wheat and dairy are often used by food manufacturers to make what they call a clean label so that they can, instead of using MSG, they process wheat or diary and create -- isolate the protein and concentrate it. And so encasing the free glutamate content. The glutamate content is tens of thousands more than it is in just plain milk, which was the original ingredient.

And vaccines now use glutamtic acid as a preservative for the virus.

So that's one thing all three things have in common, And I feel that the parents who have noticed a change in their children when they change their diet have a scientific basis for that position.

PKU is a disease where it only involves one amino acid, phenylalanine. And currently the treatment for that, well, they test for that at birth, and they watch the diet of that child until they're seven years old and the brain's hardwired.

I think we may need to do something like that similar for children with autism if they have those genes that were discovered. I think that would -- you know, they should probably be tested at birth as well to find those genes. And if they do, we may find that watching their diets until they're seven would be a help.

Supplements that are reported to

help those MSG sensitivity that may also help people that possibly they share the same genes with these autistic individuals were CoQ10, taurine, vitamin B6, vitamin B12, ibuprofen which is a glutamate blocker, antihistamines like Benadryl and magnesium were found anecdotally to help those with MSG sensitivity. I'd be curious if those supplements may be of use in treating autistic individuals.

Okay. And I have one more point. Is that the heavy-metal toxicity that is found in children who are autistic often is a side effect probably of the glutamic acid because glutamic acid inhibits cysteine metabolism. Cysteine is used to make both taurine and glutathione. Glutathione removes heavy metals from the body. Taurine regulates heart beat and also bile formation. And is also found to be low in people after seizures.

So that's basically all I'd like to say.

Dr. Insel: Thank you.

John, did you have additional comments?

Mr. Erb: Ladies and gentlemen, my name is John Erb and I'm here before you today to give you an update on my mission to end autism.

November 30th, I informed you of the connections I had found between the food vaccine additive MSG and autism. I also told you that I would have MSG removed from the food supply, thereby reducing new cases of autism.

January, I received a letter from Dr. von Eschenbach, Commissioner of the FDA, inviting me to petition the FDA to remove MSG from the food supply. I have since done just that. My petition is now on the docket of the FDA and open for public comment.

I've also done further research into the connection of autism and MSG and have the following findings:

A study done in 2006 found that people with autism spectrum disorder had a significantly higher concentration of glutamate in the amygdala hippocampal region and suggested in their conclusion that abnormalities in glutamate may partially underpin the pathophysiology of autism spectrum disorders. That was done in 2006.

As far back as 1990, an article entitled "Glutamate in the Mammalian CNS" found that the neurotoxic nature of glutamate resulted in brain lesions and possibly underlies several neurological diseases and that this neurodegenerative effect of glutamate also appears to regulate the formation, modulation and degeneration of the brain.

MSG effecting the brain has been a long-known fact. Another name for glutamate is glutamic acid. Please take note of the following human studies done on glutamic acid and pay special notice of their dates. These are listed in your minutes.

The Role of Glutamic Acid in Cognitive Behaviors, 1966.

Glutamic Acid in Human Intelligence, 1960.

The Effects of Glutamic Acid on Behavior, Intelligence and Physiology, 1957.

Experimental Studies of the Effect of Glutamic Acid Combination on the Mental Efficiency of Mentally Normal Adults, 1956.

Effects of Prolonged Glutamic Acid Administration on Various Aspects of Personality, 1956.

The Effects of Glutamic Acid Upon the Intelligence, Social Maturity and Adjustment of Mentally Retarded Children,
1955.

Glutamic Acid Therapy in Intelligence Deficiency, 1952.

Improving Mental Performance with Glutamic Acid, 1951.

Glutamic Acid and Intelligence

Quotient, 1951.

An Investigation of the Effects of Glutamic Acid on Human Intelligence, 1951.

Okay. Considering the natures of these studies on humans ingesting glutamate with effects on human intelligence, IQ scores, personality and behavior, I ask that this Committee take seriously the overwhelming possibility that MSG is playing a role in the triggering of autism, even in the NIMH press release dated February 19th in the genome project they said clues emerged adding to evidence that implicates components of the brain's glutamate neurotransmitter system in autism. So even the NIMH genome study suggested this.

So, considering MSG was introduced to the public in 1950 and only after 1950 did we see the incredible growth of MSG, I'd suggest we take this seriously.

And I'm actually going to ask at this time to Dr. Insel, your autism investigative group at NIMH, I would like to volunteer to be part of that. And I was wondering how does one go about joining that little group of assisting with this program.

Dr. Insel: We'll be posting positions in the next, probably the next three weeks.

Mr. Erb: Is there an ability to volunteer.

Dr. Insel: We don't do volunteers, unfortunately. But thanks for asking.

We're going to need to move on. We've got three more people.

Thank you, John. Judith Ursetti.

Ms. Ursetti: Don't worry, I'm not seeking a position.

My name is Judith Ursetti, and I reside in Dover, Massachusetts. I'm a certified public account, but I've been inactive in the profession since the birth of my second child, Jack, who was diagnosed with severe autism just after his second birthday.

Jack's diagnosis spurred me into action. Prior to moving to Massachusetts last summer our family lived in Houston where I was a founding member of the Dallas Chapter of Cure Autism Now and was extremely active in advocacy and community outreach.

Since moving to Massachusetts, I've served as chapter advocacy chair for the Boston Chapter of Autism Speaks and have been appointed to the Steering Committee of Advocates for Autism of Massachusetts as well as their newly formed Insurance Subcommittee.

I sit on the Special Education Parent Advisory Council of Chickering School in Dover, Massachusetts and also served as a member of the Parent Advisory Council for the Development of the 100 Day Kit that was recently released by Autism Speaks.

In 2006 I ran the Chicago Marathon to raise funds for the organization for autism research, and just last month I ran the Boston Marathon to raise funds for Nashoba Learning Group, the wonderful school for children and young adults severely effected by autism that my son Jack attends.

I also write a blog for parents.com called autismville.

Admittedly, I sit before you the token autism mom, a cliché, if you will. But I would contend that the fact that I am a cliché lends credence to the notion that autism is effecting our nation in alarming numbers. Since that indelible day in November of 2005 when the pediatric neurologist scribbled the word autism in Sharpie across Jack's medical record, I've been motivated to try to make things better for families dealing with its challenges.

Sometimes, when my husband Andy is digging through the laundry basket attempting to locate a matching pair of clean socks, he rolls his eyes at me and he mumbles, you know, you can't boil the ocean. I know in my heart that he is right, but as this Committee has already recognized, the needs of the autism community are incredibly immense and diverse.

The Combating Autism Act of 2006 took a huge leap forward in addressing those needs by creating a congressionally mandated roadmap for a federal war against autism. Part of this roadmap, as you already are aware, was the re-authorization of this Committee whose primary charge is to develop a strategic plan for the conduct of autism research. There are numerous crucial issues to be dealt with, but the most fundamental issue of all remains the long unanswered question: Just what is autism? What causes it? What can be done to treat it?

This question lies heavily on the hearts of thousands of parents. In the year 2007 alone, over a quarter of a million of them walked to raise funds for autism research at Autism Speaks walk events across the country. Two thousand attended the National Conference for the Autism Society of American. Eleven hundred attended the Defeat Autism Now Conference in New Jersey.

Jenny McCarthy was interviewed by Oprah and Larry King, selling just a few books along the way.

Parents are desperate for information. Since my son's diagnosis not quite three years ago, I have searched for answers myself in any form available. I've scoured the internet, I've attended conference after conference. The results of my efforts have been much like following the yellow brick road. Even the greatest of the wizards don't possess the answers. The word breakthrough continually eludes me.

I sit before you today as the mother of a son who I love unconditionally. Our family is doing all we can to make sure he knows that and that he receives the best very care and support available. But like so many families just like ours we're worried sick. The frightening reality is that Jack, more than likely, will spend more time living on this earth without our care than with it. It's crucial for his future well-being that we identify the biology behind his disorder and develop treatments that will lead him to a life of health and happiness, the life of independence he deserves.

I leave you today with the words of Carly Fleishman, a nonverbal teenager profoundly effected by autism who recently learned to communicate independently with a keyboard. In an interview with ABC News, Carly stated autism is hard because you want to act one way but you can't always do that. It's sad that sometimes people don't know that sometimes I can't stop myself and they get mad at me. If I could tell people one thing about autism, it would be that I don't want to be this way.

My son Jack is nonverbal, just

like Carly. I suspect, if he could type, he would tell you the same thing.

The challenges before you are great, but you possess the talent, energy and compassion to see this mission through. As you work on our behalf, please be reminded, you really can't boil the ocean, but you can be wise. You can work hard and focus on setting groundbreaking priorities, develop a research plan that will serve as a gateway to finally find new answers Jack, Carly and thousands of others so deserve.

Thank you.

Dr. Insel: Thank you. Theresa Wrangham and Rachel Wrangham. I assume you're together, but no? Okay. Theresa?

Rachel Wrangham: My name is Rachel Wrangham. I am 17 years old and I have autism.

Having autism can be very hard and frustrating. Autism makes it hard for me to communicate with people. And it's hard to focus when people talk too quickly or more than one person is talking. When that happens, I feel overwhelmed and I put my hands over my ears. But there are things that have made my life easier.

Today I want to talk about treatments that have helped me and that need more research money.

It used to be hard to sleep because my body felt strange and I couldn't sleep through the whole night. My brain thinks too much and it's hard to turn it off. I try to relax, but that doesn't seem to work. So Dr. Bilica had me try inositol and it has made a big difference. Now I can sleep through the night and sometimes I can sleep in.

For over three years my menstrual cycle was irregular. There was too much pain and I was always nervous. I would also get really -- I would always really get tired a lot.

Dr. Hamilton ordered tests and said I needed a new vitamin and herb supplement called PCOS. About three or four months after taking these pills, my cycle is normal. I'm not so tired or nervous, and not in as much pain.

Since the 7th grade my reading level has been a sixth grade level. After 80 hyperbaric oxygen treatments my brain feels like it is more organized. I can see and understand more than before doing HBOT.

I'm now a junior and my reading is at a 9th grade level. At the beginning of the year it was still at a 6th grade level. I love HBOT and don't need as much help at the school to do my work now.

I want to know why my body works differently. I would like to be healthy. I would like doctors to figure out why these treatments worked for me and find new treatments to help me. The answers will help all kids with autism feel better.

Thank you.

Dr. Insel: Thank you.Nice job.

Theresa Wrangham: Good afternoon. I'm sorry, I'm a little worked up.

My name is Theresa Wrangham and I'm Rachel's mom. I want to thank you for the opportunity to speak with you today about my hopes and concerns for autism research.

My hopes spring from the fact that my daughter's health and autism symptoms have improved more in three years in pursuing biomedical interventions than they have for the previous nine years of speech therapy and social skills therapy.

Our story is one of fighting for Rachel's health, the same story that parents tell consistently in the ASA chapter I co- founded during the five annual state conferences I have coordinated and support groups of which I am a part of in Colorado.

In 1990 Rachel was a normal baby

in every way. We vaccinated on schedule and thus began her exposure to dangerous toxins like aluminum and mercury. Her immune system continued to be assaulted while living in the Middle East from Kuwaiti oil field fires and toxins from weekly pesticide fogging of our compound.

She's an example of vaccine injury and a product of her environment, an environment that is globally polluted and effecting children in the United States, as evidenced by the recent study from the University of Texas Health Science Center that was published this year, but showed an increased autism risk in mercury emissions in proximity to pollution sources.

Rachel went from being a normal and social infant to a toddler with periods of vacant stares and playing alone when surrounded by children. At three, her language acquisition had stopped and by five and a half she was echolalic.

On our return to the United States in 1997, Rachel was diagnosed on the spectrum at over six and a half years of age. All the benefits that she has received from any treatment was long after early intervention. She never had that opportunity.

Under the care of Dr. Roger Bilica, a former Chief of Medical Operations for NASA and Dr. Debbie Hamilton, medical tests indicated that Rachel suffered from heavy metal toxicity, oxidative stress, impaired detoxification, hormone imbalance, mitochondrial dysfunction, intestinal inflammation and malabsorption. These impacts to health are not unusual. Recent clinical investigations have identified numerous comorbid disease states in children with autism that also include severely altered serum chemistries, methylation disturbances and microglial activation in the brain.

You've already seen what helped Rachel; a simple B vitamin and insotol has helped her sleep through the night. Chelation therapy continues to remove the dangerous heavy metals in her system.

More recently the herbal and vitamin supplement she has taken has regulated her menstrual cycle. For three years, I couldn't get a doctor to look at it.

Her intestinal abnormalities have improved markedly with enzyme therapy and probiotics. And as she's already stated, after 80 hyperbaric oxygen treatments, and I want to state this clearly, after four months of this. It took four months to accomplish this in conjunction with methyl B12 injections her IQ shot up 10 points, her language usage improved and her reading level went up three full grade levels in four months.

My concern is that research into biomedical interventions will not be pursued. Autism societal costs are already at 35 billion annually and it's a public health crises that requires great urgency and attention.

I feel research much shift from being primarily genetic in focus to a thorough investigation on the role of the environment and vaccines in order to identify the factors driving this epidemic.

Policy must change to ensure that bias and conflicts of interest cease to invade the scientific process and that a balance of views are represented in the research agenda.

Many afflicted individuals can't be here today to tell you what their needs and desires are. And it's the charge of this body to see that one day they will.

The promise of treatment and prevention has roots in successful biomedical intervention. The inclusion of clinicians treating recovering children, scientists’ focus on environmental triggers and toxicology and family members of those afflicted is a necessary component of the strategic plan, No stone should be left unturned in finding the truth. Health must be the priority, and research into and standardization of by a medical intervention to stem this disorders disastrous and growing health consequences require your immediate action.

Rachel is proof how medical treatment of abnormalities that occur in autism have improved her health, lessened her autism symptoms and greatly reduced the burden to special education and future adult services. Her progress has given her the ability to express herself and greater self-determination. This success must be extended to all effected individuals.

My family asks that you consider the progress of children like Rachel and those who have recovered. They are a beacon for the many who struggle daily with autism, they're progress mile markers in the destination to health.

Thank you.

Dr. Insel: Thank you very

much. And it's very timely with all the discussions today about what should be in the strategic plan.

Well, my appreciation to everybody who traveled to provide public comments. I know other people wanted to, and we're simply out of time. But we are interested in getting written testimony from anybody who has something that they think the IACC needs to hear about.

Also, my gratitude to all of you, some of whom traveled from far away to get here. And our work is moving on quickly. So we'll be pretty busy. We'll keep you pretty busy over the next few weeks. But I think we've got a very clear charge from you about how to go forward.

I still want to, as much as possible, hold to a July 1st due date for, at least, a draft plan that we can being to share with the public more broadly.

Thanks, everybody. And we'll be

in touch with next steps.

(Whereupon, at 3:43 p.m., the meeting was adjourned.)