U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES

INTERAGENCY AUTISM COORDINATING COMMITTEE

FULL COMMITTEE MEETING

MONDAY, MAY 4, 2009

The meeting convened at 9:06 a.m. in Conference Room E1/E2 in the William H. Natcher Conference Center, 45 Center Drive, Bethesda, Maryland, Thomas Insel, Chair, presiding.

PRESENT:

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

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

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

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

JUDITH COOPER, Ph.D., Deputy Director, National Institute on Deafness and Other Communication Disorders and Director, Division of Scientific Programs (via teleconference)

CHRIS DeGRAW, M.D., M.P.H. Health Resources and Services Administration (For Peter van Dyck)

LEE GROSSMAN, Autism Society of America

GAIL R. HOULE, Ph.D., U.S. Department of Education (via teleconference)

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

PRESENT (continued):

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

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

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

CHRISTINE M. McKEE, J.D., Public Member

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

CATHY RICE, Ph.D., Centers for Disease Control and Prevention (For Edwin Trevathan)

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

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

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P R O C E E D I N G S

9:06 a.m.

DR. INSEL: Good morning everyone and welcome on this very rainy day. I hope that the new entrance at NIH wasn't too much of a surprise for people. We met here, I gather, last summer, but this is our 8th meeting and I think only the second time we've met here on the NIH campus.

But we'll probably continue to meet in this facility, so hopefully you'll get to know and love it well. The last meeting we had was on February 4th, and I just thought I would start, while we're getting the audio synched and everything ready here, to give you a few updates, and then we'll go around and do introductions and get on with the very busy agenda that we have.

First of all, the strategic plan was officially published on March the 4th, with a press release at that time. It had already been submitted, but it's one that's

now fully out there on the website and elsewhere.

April 28th, we got a new Secretary of HHS, who is the person that we are reporting to, and we're hoping that we can get her to attend a meeting in the near future. This meeting wasn't going to work for her, given her schedule. But we're looking at potentially a meeting in the summer.

We still don't have directors of NIH or CDC, but I think with the Secretary on board last week, we'll hopefully get some resolution on those positions fairly soon. There's been a lot of other changes on the autism research front over the last couple of months.

The American Recovery and Reinvestment Act was passed with the inclusion of funds for biomedical research, including about $10 billion roughly for NIH.

That has resulted in a range of new RFAS, Requests for Applications, including

one very large RFA for autism research, based mostly on the heterogeneity of autism, and includes four different mechanisms.

It's quite extensive. All of the information is on the NIH website under the Recovery Act section of the website. But it's certainly changed the game for a lot of researchers in the autism field, who felt that even though we had a strategic plan, there wasn't really, as several people said to us, there wasn't any gas in the car.

Now there's a lot of excitement in the field, and every time I, over the last month, I've gone to a meeting that involves autism scientists, they rarely stay around for very long because they keep saying they have to leave to go finish up their applications.

We have people who are submitting two, three, four applications for what we call ARRA, American Recovery and Reinvestment Act funds. So between the RFA for autism and then several other autism-specific initiatives

within the challenge grants, autism-related initiatives in the Grand Opportunity Grants, other parts of the ARRA funds, there really hasn't been a moment in time quite like this for the NIH, really ever.

I just couldn't help but say that the hard work that this Committee did to get the strategic plan out before the ARRA funds arrived, though we couldn't have known this was going to happen, but in retrospect, it looks like you did exactly the right thing, by making sure that we had a plan available, so that it was quite easy to make the argument that some part of ARRA money should be set aside for doing something that was just ready to go, where we had a chance to jumpstart a project that a Committee like this had put together.

So I think history will tell us that this was highly fortuitous, that we certainly couldn't have planned it better. We're very excited to see what comes in for

these various initiatives that are out there related to autism.

The due date for the autism RFA is May 12th, so that's coming up. It wouldn't surprise me if those of you who are going to IMFAR later this week hear a lot about people who are not attending the meeting as much as they would like to, because they have to be working on the final revisions of their proposals.

Anyway, interesting time, and we can talk more about that as the day goes on. But it's certainly an exciting time to be involved in this area of research, made all the more exciting because of recent findings.

I think again, it's kind of unprecedented. Three papers in Nature on autism in the last three weeks, one on the way that biological motion is processed, and two others, really breakthrough papers in genetics.

So it's an extraordinary moment

when a field is really opening up in lots of new ways.

Well with that as a very quick introduction, I just wanted to partly use up the time until we could get our webinar fully engaged and get everybody on the same wavelength. Let's go around and do a quick introduction.

DR. INSEL: I'll start by saying that I'm Tom Insel, chairing this Committee, but my day job is as director of NIMH, and I'll pass this off to Yvette.

DR. JANVIER: Yvette Janvier, I'm a developmental behavioral pediatrician. I'm a community member or public member from New Jersey.

DR. INSEL: You'll need to use your microphone so people can hear.

DR. ALEXANDER: Duane Alexander, Director of the National Institute of Child Health and Human Development, NIH.

MS. McKEE: Christine McKee,

parent of a nine-year-old girl with autism.

DR. DeGRAW: Good morning. Chris DeGraw from the Maternal and Child Health Bureau, representing Dr. Van Dyck today.

DR. INSEL: Good timing.

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

MS. SINGER: I'm Alison Singer. I'm the mother of a beautiful 11-year-old daughter with autism, and I also have a 44-year-old brother with autism.

I'm also now the co-founder and president of a new autism advocacy group called the Autism Science Foundation, and our mission is to support the growth and expansion of autism research, and provide funding to scientists conducting that research, really with the goal of providing more information for individuals and families.

We just launched this

organization. I really just want to take ten seconds to thank all of the individuals and families who have supported the launch and who are supporting the new organization, many of whom are watching today on the webinar.

DR. INSEL: Congratulations and good luck with this.

MS. BLACKWELL: Ellen Blackwell, Centers for Medicare and Medicaid Services. I'm also a parent of an adult son with autism.

MR. GROSSMAN: Lee Grossman, most importantly the dad of a young man with autism, and I'm also president and CEO of the Autism Society of America. I've been getting text messages from Stephen Shore. He can see us but he can't hear us. So he's on the line.

DR. INSEL: So can we get some assisted communication here for the audio? Any idea what may be going on?

I must say I think it's much more important for people to hear us than to see us, so we should try to get this repaired as

quickly as possible.

MR. GROSSMAN: He says he can hear something that sounds like a typewriter.

DR. HANN: Apparently the captioning might be working, so he's able to read it.

MS. HIRTZ: I'm Deborah Hirtz from the National Institute of Neurological Disorders and Stroke, and I'm representing Dr. Story Landis.

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

DR. LAWLER: I'm Cindy Lawler from the National Institute of Environmental Health Sciences. I'm here today representing our Director, Linda Birnbaum.

DR. HANN: I'm Della Hann, and I serve as the Acting Executive Secretary for this Committee.

DR. INSEL: Well thanks everyone for being here. This is a busy day. I know there are a couple of other high level

meetings going on that have pulled some of our folks away.

Before we go on, I want to just make sure we've got our communications working, so that people who are trying to listen in can hear. So let's just take a moment and Lee, maybe you can check back with Stephen, who we could use as our source.

Okay, all right. So we've got some updates to do here from both the Services Subcommittee and the Planning Subcommittee, and then we've got some issues that we need your help on for the Summary of Advances, and we'd like to get all of that finished.

We'll get back to the minutes, I guess, later this morning. So why don't we begin with Services. I'm sorry, Della? Della's reminding me that while everybody's here, there is a change. It's at the end of your agenda. July 15th is the new meeting date for the next meeting.

We've shifted this, so that we can

-- okay, excellent. Stephen, welcome. Glad you could join us by phone. Anyone else on the phone at this point?

Stephen, are you able to speak as well as hear? Now we just hear your typing. If you're on the phone, please mute your mikes so that there won't be any interference. But we'd like to hear from you before you do that, to make sure --

DR. SHORE: Hello.

DR. INSEL: Hi Stephen. Welcome.

DR. SHORE: Yes. I can barely hear you.

DR. INSEL: Oh, okay. Well we will try to adjust that.

DR. COOPER: And this is Judith Cooper. I'm on the line also.

DR. INSEL: Great. Welcome, Judith.

DR. SHORE: Yes. I'm not sure what the typing is all about, but there isn't any typing here.

DR. INSEL: Okay. Well thanks for joining. Thanks to both of you for joining us, and we will try to get the volume adjusted so you're able to hear, and I'll ask people in the room to speak up.

The only point of business before we start on the regular agenda, which I hope you have, is that we've changed the July meeting to be on the 15th. This allows us to overlap with the NVAC meeting, so that we can have a joint meeting that morning, as the Committee requested.

Then we will have the regular rest of the IACC meeting in the afternoon on the 15th.

DR. SHORE: I'd love to come on the 15th, but I've already set up my schedule for the other meeting time, and will actually be on the way back in an airplane from Spain at that time.

DR. INSEL: Well I'm sorry. Stephen, can you mute your mike?

DR. SHORE: I can hear, but now it's so distorted that I can't understand it.

DR. INSEL: What we're hearing from our tech folks is you'll either need to listen to the webcast or the phone, but because of the delay, you can't listen to both. Stephen, can you mute your microphone?

DR. SHORE: Excuse me.

DR. INSEL: So what the tech folks are telling us here is that you won't be able to listen to both the webcast and the audio of here.

DR. SHORE: Oh, the webcast isn't -- there isn't any audio coming from the webcast anyway.

DR. INSEL: Okay, but you'll be able to listen in and to speak if you just use the phone for now. We got the message that you have a conflict with the 15th. But this was the only time that we were able to arrange a joint meeting, which is something that the Committee very much wanted.

DR. SHORE: Right, I know that, and I'd very much like to go to the meeting, but I'd like to see what NVAC is up to. It's just I guess I hadn't prepared my schedule to leave the 15th open.

DR. INSEL: I'm sorry about this.

DR. SHORE: I committed to something quite a while ago.

DR. INSEL: We've been trying to work out a date with them since, really since February or January. So this is the best we could do. I'm having to -- I guess one thing that would helpful for us to know is to make sure that those who are on the webcast are able to get the audio.

It sounds like, from what we heard, it's coming through, but a little distorted. I'm assuming, unless we hear otherwise, that we can go ahead then with the first report, which is an update from the Services Subcommittee. I think we have both Ellen and Lee here to fill us in on where

things are going.

MS. BLACKWELL: Thank you, Tom. We just wanted to give the Committee an update, so far as our activities are going, and also talk a little bit about a future town hall meeting.

Just to revisit our vision and mission, since we're not sure how the audio and video is working today, I'll just mention that the vision of the Services Subcommittee is that all people with ASD have the services and supports they need and desire throughout the life span, to lead productive lives in the community and reach their fullest potential.

Our mission is to assess and improve services and supports for people with ASD. This is just a list of the members of the Services Subcommittee, and we appreciate everyone's participation, vigorous participation I might add.

We also wanted to talk a little bit about our request for information that was

sent out in the fall of 2008. There were 137 responses. We performed a second analysis of the RFI. There were actually almost 500 comments embedded in these 137 responses.

Twenty-one people have self-identified themselves as people with ASD, and in the second analysis, there were some priorities and emerging categories that came out, that we thought the Committee might be interested in.

These six really fell at the top of the list. The first concern is adults with ASD, and the sub-concern under this group is housing needs. The second concern is community issues, and this mostly fell into community acceptance and inclusion.

The third category that was a priority is family support, mostly the need for respite and child care. The fourth is school services, the need for more teacher training and education. The fifth is provider issues, and this mostly fell into additional

training needed for providers of services to people with ASD.

The fourth is a category that Lee and I decided to call infrastructure, and the biggest concern in that area was private health insurance. The emerging priorities are employment issues, evidence-based services and supports, health and safety issues, early diagnosis and treatment, transition to adulthood and therapies.

Then we had these categories that we sort of lumped together as other, legal guardianship issues, dental care, medical treatment, assisted technology and augmentative communication and diet.

The ones that came out at the top are really at the top, these six. So that's kind of where we have our focus right now. So after we took a look at that, we met on February 24th, and we talked about putting a new focus on the Services Subcommittee, sort of moving from the previous ASD roadmap to

what we decided to call ASD Services and Supports recommendations.

We talked about sending several recommendations regarding Services and Supports to the Secretary. These would align with our strategic plan. Alison had some very good suggestions in that area.

So we will be developing a plan and a time line. We also discussed whether or not we would need to convene additional expert working groups, which is something we did when we developed the road map.

We would consider public input in developing these recommendations, and this is a document that we thought could be updated annually.

We also made some other decisions about what we thought would be appropriate to do in our meetings, the first being that we would like to hold regular presentations at each of our subcommittee meetings, starting with the federal members, to talk about

services and supports issues and learn a little bit more, and also invite others to come and talk to us.

We thought this would help us within the Committee and also be really a good service to the public. The first presentation will be at our next meeting. We haven't set the date yet, but the CDC and HRSA courteously volunteered to talk about the Learn the Signs Act Early Campaign. So we are really looking forward to that.

Our other activity that we discussed is that we will start putting together a list of federal agencies that are or may be providing services and supports to people with ASD, and that Lee and I will make an effort to identify the lead staff in those agencies. We thought that might be very helpful in terms of trying to bundle together a list of who is where.

We also feel that both these are activities are in concert with the CAA's

directive that asked us to monitor federal activities with respect to autism spectrum disorder.

So I'm going to stop for just a second here. Does anyone in the Committee have any comments or suggestions or any input as far as what we're doing in the Services Subcommittee?

DR. INSEL: Ellen, could you go back to the slide that has the list of comments?

MS. BLACKWELL: Yes.

DR. INSEL: What is number six, infrastructure? What does that mean in this context?

MS. BLACKWELL: Would you like to --

MR. GROSSMAN: Yes. Well, as Ellen mentioned, the way they're listed is on a percentage basis, the way that they ranked out in terms of the comments, and infrastructure was more about systems and how

they are set up.

Actually, some discussion about perhaps systems change, as well as making the systems easier to navigate. Plus there's -- did I catch pretty much the essence of that?

MS. BLACKWELL: Yes. Actually, these categories -- the comments fell into these categories. As I said before, private insurance, better training for care coordinators, discussion about systems of care, additional need for parent training, Medicare/Medicaid, long term care insurance.

So we just sort of put all those together into infrastructure, because they are mostly systems issues.

DR. INSEL: Other comments or questions? Christine?

MS. McKEE: I'd just like to -- we talked about having the Learn the Signs Early Campaign. I'd like the Department of Education -- I don't know if Gail is on the line or not, but I know they got stimulus

money as well, and I'd like to know what they're doing with the money.

If they could be our next presenter, I think that would be a good idea.

MS. BLACKWELL: Sure. We'd be happy to ask Gail. In fact, she's already volunteered to talk at the next, at the one after I think the CDC presentation. So I think this will be great, and I hope everyone tunes in for our meetings as well.

The other thing that we talked about at the Services Subcommittee, and I know at the Strategic Planning Subcommittee as well was the need or the possibility of conducting a town hall meeting. Lee, I'm going to let you talk about this.

MR. GROSSMAN: It seems one of the few items that came out of our discussion that needed to go to the full IACC for your consideration was this notion of having a town hall meeting.

We had a fairly robust dialogue at

our subcommittee meeting around that. I think it came out pretty strongly that the need for a town hall meeting was something that the Committee felt strongly towards.

With that in mind, I put forth the idea of having one at the Autism Society's national conference coming up in St. Charles, Illinois, outside of Chicago, here on July 22nd, and the Committee seemed to approve that and they wanted us to bring this back to the full IACC Committee.

With that said, we were a little bit uncomfortable making a direct recommendation on what that town hall meeting would actually cover in terms of topics. So these were some of the ideas that we're putting forth for your consideration.

Would the town hall meeting be a full town hall meeting covering all issues on the IACC, or just covering services-related issues? Obviously, we have to identify the facilitators and moderators, but I think

that's more of an operational aspect of the IACC staff.

What is the objectives on it, who would be there from the IACC and what actually the topics will be. Some of the suggestions were around, again just services, looking at the strategic plan that has been recently published, potential recommendations, an open discussion on all issues related to the IACC, and certainly we're open to other comments and suggestions.

Since then, I've put more thinking into this, and I feel that since the strategic plan is published, that it probably would be best to have as the topics for the town hall meeting, looking forward for the IACC. What would the next round be? What should we add as we modify and update the strategic plan, and what recommendations will there be going forward?

The day, that Friday morning of our conference follows the keynote sessions,

which are all the speakers that we have prior to the IACC will be speaking about public policy. We will have various political figures, as well as some agency representatives there that are kind of setting the stage for the town hall meeting.

The way that our conference is set up that morning, the town hall meeting won't have too many things competing against it. We expect about 1,700 to 2,000 participants at the conference, and I believe there's only two other competing events during that time frame that's allotted for the town hall meeting. So there should be a fairly large turnout for the meeting.

MS. BLACKWELL: So I guess we should talk about what the Committee wants to do? I mean do we --

MR. GROSSMAN: What was the date that we have there? Okay. Thank you. Thank you, Deborah. It's actually July 24th is Friday.

DR. INSEL: So you need some feedback about (a) whether to do a town hall meeting in this venue, and (b), what the town hall meeting should comprise out?

MR. GROSSMAN: Well, we're throwing it out for full consideration for the IACC. I think our immediate needs or my immediate needs for my staffing would be to schedule it in or not.

I think in terms of what the topics will be, we're going to have to put this out for the public, and if we can't make a decision on that now or people want to think about it further, that we do have time to get this decided upon, and then put it in Federal Register.

DR. INSEL: Comments? Enthusiasm, lack of enthusiasm? Duane.

DR. ALEXANDER: I think this is a good idea. Town hall meetings have sort of caught on as the way of exchanging information with the public, providing access to the

government Committees, agencies, whatever, and the opportunity to piggyback this with the ASA meeting, falling right on the heels of your keynote speakers, seems like an opportunity we ought to take advantage of.

MS. BLACKWELL: Does the Committee want us to focus on services, or should we be talking about, for example, one of our major activities, which is the development of the strategic plan? I mean again, would this be a Services Subcommittee town hall meeting? I think what you're suggesting, Duane, is a full IACC meeting.

DR. ALEXANDER: Well not necessarily. I think what's proposed before us here is mainly the focus on the services sponsored by the Subcommittee. We can consider whether to do it that way, but I was referring primarily to what's proposed, I thought, as a subcommittee event.

DR. INSEL: So that we'll come back to this after the next report, because

the other subcommittee also recommended a town hall meeting at ASA. So we may want to refine the topic to I guess what's on the agenda, and we'll need to vote on this, is whether to actually go ahead.

Because this is only a couple of months away, so we need to get on it pretty quickly. Alison.

MS. SINGER: I was just going to add my support for this as well, and say that I think even if it was a subcommittee meeting of the Services Subcommittee, that could be used to inform the services portion of the strategic plan.

I would also, I wanted to ask if it's possible to have dial-in or webinar at this portion of the ASA conference, so that additional people who weren't able to travel to Chicago could also participate, and so that it wouldn't be a requirement that people physically get themselves to Chicago. Is that possible at your conference?

DR. INSEL: It's possible at our conference. Again, those are what I perceive as operational decisions by the IACC staff. But yes, the venue is capable of having those types of resources available. Lyn?

MS. REDWOOD: Yes. I was also going to point out, having attended an ASA meeting, it seems as though a lot of the parents there are specifically interested in services, and there are several large autism meetings, and they each have their own little niche.

So I think it would be appropriate for that venue to focus on the services aspect of the IACC strategic plan.

MR. GROSSMAN: Having done a lot of town hall meetings, just so that everybody's aware and I agree with you, that if our focus is on services, we can publish that, we can put that in the federal registry, we can encourage that.

But when people get up to express

their opinions, it seems as though every topic is in play. But yes, it would be great to have one that is certainly focusing on services, but I'm sure that we're going to hear a lot from just about every topic area during that town hall meeting.

DR. LAWLER: I also support the idea of a town hall meeting. I think it does perhaps lend itself to a focus on services for this particular meeting. But it might be useful to consider a larger strategy if we're going to have more than one of these, because different, you know, topics could be matched up with different meetings, so that we could make sure that we cover the breadth of what the activities of this Committee.

DR. INSEL: So I'm hearing a lot of enthusiasm for having a town hall meeting, and it sounds like most people want to keep this, because of the cohort that's there, focused on services.

Can we take a vote? The proposal

would be to do a town hall meeting on Friday the 24th of July, as part of the ASA meeting, with a focus largely on services and some of the details would still need to be worked out. But in favor?

DR. HANN: Okay. I see everyone's hand is raised here in favor. Those on the phone?

DR. SHORE: I vote in favor.

DR. COOPER: Yes, in favor.

DR. INSEL: Okay, thank you. So that passes.

DR. HOULE: This is Gail Houle. I'm on the phone now.

DR. INSEL: Oh terrific. Thanks for joining us, Gail.

DR. HOULE: And I vote in favor.

DR. INSEL: Thank you. For those on the phone, it will be hopeful if you can keep your phones muted until you have something to say, because there's quite a bit of transmission otherwise, a lot of

background. Thank you.

Ellen, any other comments or other pieces for us?

MS. BLACKWELL: Yes. We just wanted to spend one second talking about future. Back in November, the Services Subcommittee had some presentations to the full Committee. We wanted to propose that at a future meeting, we talk about applied behavioral analysis-based techniques. We thought that might be of interest to the Committee and the public.

So we thought we'd throw it out here today, as a topic perhaps for the October meeting. There has been some research that's come out recently, that talks a little bit about, you know, the different ABA-based techniques and, you know, I'm sure that we could probably get some folks to talk about the various interventions.

Does that sound like something the Committee would be interested in?

DR. INSEL: One thing that I think might be helpful for this group would be to become a forum to hear about best experiments that are happening in states. I was at a briefing that I think ASA organized on Capitol Hill last week, where we heard from people in Pennsylvania, some people in Alabama.

It's clear there's a lot going on that states are trying. But there isn't really any place where people can share that information and talk about what's worked, what hasn't worked, some of the economics of this that are really complicated but important.

I wonder if this subcommittee could be helpful around at least bringing some of those experiments to the table, so people could hear about them?

MS. BLACKWELL: Some of the research has indeed started to address the different techniques and comparative effectiveness, and what might work for who. So I think it is starting to become important.

MR. GROSSMAN: Much of what the state activities have been is around the insurance reimbursement issue, and there has been controversy around that, because the state legislation typically has been fairly restrictive, you know.

It may have monetary limits. It may be for a certain age range, etcetera. So I think when Ellen and I were discussing this, what we were trying to do, if we were bringing a presentation on ABA, is to expand the thinking on what ABA truly is, and bring to fore some of the more current thinking on any of the discrete child training, any of the behavioral types of services that are being provided, as well as to broaden the definition of what ABA is.

You can ask ten experts in the field of ABA, and they'll probably give you different -- certainly every one of them would give you a different opinion, in their minds, of what it truly is.

I think that -- having these differing opinions and certainly not having a common definition on what good treatments are or behavioral interventions are, has contributed tremendously to the controversy and certainly the struggle that states are having with providing this as a reimbursable intervention for autism.

I think if we can -- our last Journal of the Autism Advocate was entirely devoted to this subject. We had varying opinions on there, with the lead article being on what the future should be for what we define loosely as ABA. It is truly just behavioral intervention.

DR. INSEL: Yes. What I was thinking about was something a little more general, which is the nuts of what I said. When I said "experiments," I meant really experiments in policy, that different states have different policies for waivers, for coverage.

They have experiences with that that are sometimes better or worse, and it always strikes me that there's not an opportunity often for them to hear the whole universe of what people are doing. There are some states that are clearly out in front with trying to get better coverage.

Now maybe you already know about that through CMS, Ellen, but I'm not sure that so much of this goes on at the local and state level. I'm not sure how much of that is transmitted to people who most need to hear about it. So it's just a suggestion. Yvette, you had a comment as well?

DR. JANVIER: I'm stuck on the stakeholder priorities.

DR. SHORE: And I have a comment as well, when you're ready.

DR. JANVIER: I guess I was thinking, I mean it's a great list from 137 people, but if you have 2,000 folks. Maybe a survey could be developed from the initial

information that you have, so we get better statistical priorities.

I don't know if you have more of a paragraph about each of these priorities. I'd be interested in seeing, you know, what folks were concerned about, just not -- doesn't give me enough information.

MS. BLACKWELL: We actually do. We've had a few go to our website. The document that shows, you know, every comment and which category it fell into is on the IACC website under the Services Subcommittee link.

DR. JANVIER: Okay.

MS. BLACKWELL: So you can take a look at that and see where every single comment fell.

DR. INSEL: Thank you. Stephen?

DR. SHORE: Yes. When we're thinking about interventions, loosely termed as behavioral interventions, but I'd like to think of them more as developmental behavioral educational interventions. Given the great

diversity of the autism spectrum, that's going to mean that different approaches are going to work better or different people.

Instead of confining things to just one approach, I think it might be a good idea to take a look at some of the more promising approaches that we have, such as TEACCH, the Miller method, daily life therapy and floor time.

MS. BLACKWELL: There are some research papers that came out earlier this year, that talk about a systematic review and look at different types of interventions based on applied behavioral analysis.

So I guess that's kind of where we were thinking we could do the greatest service, have some of those folks come in and talk about that work. Not any particular type or service or intervention that operates under the umbrella of applied behavioral analysis.

MR. GROSSMAN: Yes. I certainly want to support what Stephen just said, and

that's the stance that we've taken, is that most of the legislation is built entirely around this notion of applied behavioral analysis. We've been talking to state legislators to have them look at this as a broader behavioral intervention, because there are, as Stephen just pointed out, other methods that seem to be worthwhile pursuing and probably the best system is one that's the most eclectic, so that it can pull from the best of all these different methodologies, to respond to the individual.

That was also what Ellen and I were discussing and what we were considering presenting to the IACC.

DR. INSEL: Any other suggestions for the subcommittee about future topics?

Okay. Well Thank you for this update. Certainly, if we can get the Secretary to the next or some subsequent meeting, it will be important for her to hear about the range of activities in the services

arena, and the issues that are most important from the IACC's perspective, that she know about.

We're going to move to the next item in the agenda, which has to do with the Planning Subcommittee, and I can take you through those slides very quickly. Thank you.

So this was the report from a single meeting that was held on March 17th. This goes back to the charge from the Combating Autism Act, that we have to annually update the strategic plan.

Now that we have a plan it's, as we've been saying all along, that's 1.0 and we're thinking about what 1.1 will look like. At that last meeting, you asked a group to form a subcommittee to begin thinking about the process for this.

So not to update the plan, but to convene a series of meetings to figure out how this would be done. The federal members who

volunteered are shown here, Ellen Blackwell, Tom Insel, Story Landis, Ed Travathan, and the public members, Lee Grossman, Lyn Redwood, Stephen Shore and Alison Tepper Singer, all who put up their hands when the question was put on the table.

The meeting that was held in mid-March, looked at these three topics. What would be the right approach to update it, what would be the time line, and then they came up with a few recommendations, which they wanted to bring back to you today to vote on, because they need some direction from you about how to go forward.

So we'll take you through that very quickly. In terms of the possible approaches, a portfolio analysis needed to be redone. Remember, we did something like this as a kind of, I think we called it a gap analysis in the beginning, before we did the strategic plan. So about a year and a half ago.

The point of this now was to renew that and to revise, to look at the impact of funded research was another possibility of thinking about ways to identify gaps, maybe through workshops or conferences, or even satellite meetings at IMFAR or other major national research meetings like the Society for Neuroscience, and then to solicit public input as well.

Once again, the town hall meeting format was discussed at some length, or the possibility of doing an additional request for information. So those were the various things that we chatted about. If others who are on this subcommittee have anything to add, feel free to jump in here and put that on the list as well.

The time line we talked about looks like this. We were thinking about if we could get a vote today on a planning process going forward, that as you can see, we'd have a portfolio analysis done by our next meeting,

which would be in July, and we could report out about that.

Then potentially to then have either scientific workshops or town hall meetings or an RFI over the course of the summer, to be able to conclude this by September, with the idea that we could bring back to you in October the recommended updates.

Then the update itself would take place probably in November, by a process that we still need to work out. Then the final vote on the Version 1.1 or maybe it will be 2.0 by then, would be in January of 2010, so that we can meet our statutory obligation to have this done on an annual basis.

Is that clear? Look right. Okay. So, we said we needed a portfolio analysis that needed to look at what's happened since the last time we did this, and we asked you by email whether you would authorize us to go ahead and begin that process, and we have

begun that process.

The other recommendation was to have another meeting of the subcommittee, to actually look at that portfolio analysis, so we could begin to figure out where the major changes had happened and what needed to be thought about in terms of the strategic plan.

We also needed to figure out, based on the discussion today, whether to do a town hall meeting or an RFI, and to think about the workshops and to figure out whether the time line will actually hold.

Finally, we're hoping that the subcommittee will be authorized to review the data gathered and recommend any updates, so that we can actually begin the process of doing the updates, at least in a draft form, to bring back to you.

On the portfolio analysis that you gave us the authority to go ahead and pursue, we've sent this to 19 agencies and private funders. What we're asking for is dollars

spent and then we're asking people to categorize their grants by the strategic plan, question and the objective.

We hope to have all of that in hand within the next four to five weeks. So this is the list of federal funders, and I hope these should all look familiar. These are the list of -- whoops, there's even more. So this includes SAMHSA, NIH, SSA, HRSA and then private funders you can see here.

So the decisions for today that we need to go through is this one. The first one will sound familiar. Do we want to do a town hall meeting, and if so, where and how and when? What would be the purpose of this?

Should we put out another RFI at this point? It's been about a year since we did the last one, maybe less than that. Yes, last summer. The third decision point is whether to do scientific workshops.

I'm sorry, we couldn't hear you. Could you ask the question again Stephen?

DR. SHORE: I didn't ask a question.

DR. INSEL: Oh, okay. Well, we had -- am I the only one hallucinating, or was --

DR. SHORE: I did hear somebody say something.

DR. INSEL: Okay, all right. So this is our day for tech problems. So what we're really asking you here is what do you think would be the best way for our subcommittee to get input, both from the scientific community and from the public?

The other decision point that we'll need is a vote to authorize this Planning Subcommittee to go ahead and review and analyze whatever comes in, and to begin to make the recommendations to you for the updates. So that's a real quick rundown of what we'd like to hear from you.

So maybe what we'll do at this point is first of all let me ask those on the

subcommittee, whether they have any additional points to add to this very quick summary?

MS. SINGER: I think one thing that we talked about at the subcommittee was that there were several times during this year's strategic planning process where we tabled items to discuss for Version 2.0, and I remember that we talked to the subcommittee about making sure that we went back to each one of those. I think that should be somewhere in this process.

DR. INSEL: Right. So we could add that into this list of things that the subcommittee should work into their conversation about the updates. Let me ask you then. In terms of getting input, both from public and from the scientific community, we've got essentially three options here: town hall meetings, RFIs and workshops.

And you can see that the time frame, if we go back to that, is fairly tight, because we want to do this revision in

January, before January. It's due then. One question that we talked a little bit about at the subcommittee was how realistic is it to revise a plan that you've just put out, when most of the grants haven't yet been funded that are related to that.

The RFAs that were specifically related to the strategic plan, and in fact, in the Recovery Act, there are RFAs that say specifically this is money for implementing the major points of the strategic plan for autism.

So those are not going to be funded until probably late summer or early fall. So people will begin that work in the fall. Is this the time to begin to get input about this, or are we being a little overly-reactive here, to try to update a plan that has not yet been implemented largely?

So that was one of the questions that was raised by the subcommittee. Others felt that well, we've got, as Alison just

mentioned, there were things that we tabled. So there were plenty of things that needed to be worked into this already. But then do we need workshops? Do we need town hall meetings or an RFI for all of that?

So I'm just trying to reflect what some of the conversation was around the table back in March. Here we are almost two months later. I'm not sure that there's that much more that we can say, in terms of where the research base is. There's been a lot of recent exciting science published, but it's not clear that any of that would shift the strategic plan in any substantial way. Alison?

MS. SINGER: But I was actually going to refer to the new material that's just come out. There's been a lot of new studies being published, and I think we don't know yet whether those studies or other studies that are likely to come out in the next few months would shift the strategic plan.

I think if we waited for the results of the studies that we're funding in this version of the plan, that's not really reflecting the sense of urgency that so much a part of the spirit of the strategic plan.

So I think it's critical to convene the scientific workshops and get an update from the scientific community about where the new thinking is, where the new facts are, and use that to inform Version 2.0.

DR. INSEL: Duane?

DR. ALEXANDER: Yes. I'm not real enthusiastic about using the town hall meeting for this particular purpose. I think the RFI could be utilized effectively, because it does reach out a national audience and provides a mechanism for anybody who wishes to comment.

It also would provide a vehicle for us to highlight the things that we did kind of put off, because you could include in the solicitation within the RFI specific requests for information about those

particular items.

It would give us additional input for the things that we have specifically put off for consideration for the next time. So the RFI gives you a mechanism for doing that.

Maybe one scientific workshop to provide input in that way might work. But that's what I would suggest, that we go with the RFI, not a town hall meeting, and maybe one scientific workshop.

DR. INSEL: Yvette?

DR. JANVIER: I was thinking that the chairs of the workshops that were held really could determine or help us determine if there's been a great breakthrough and a situation has been resolved or moved forward. But again, I also think that we're not going to see significant progress in the goals that we just set.

I agree with Duane completely. I don't see that a town hall meeting would be helpful with this.

DR. INSEL: Other thoughts?

MS. BLACKWELL: Having participated in the development of the previous plan, I thought that the scientific workshops were very, very helpful, and we, because of the condensed schedule, we got a lot done in a very short period of time. So that seemed to work really well for the previous development of the 1.0 version.

DR. INSEL: How about for those on the phone? Recommendations about this?

DR. SHORE: It's hard to hear. I think the sound has gone out again.

DR. INSEL: Can we get some help on the sound for those on the phone?

DR. HOULE: Yes. This is Gail. I'm having the same problem as well. I can't hear. The discussion fades in and out. Sometimes we get clarity; sometimes there's nothing, and so there's great gaps, and it's difficult to make a comment, because we don't have access to the whole debate or

conversation.

DR. INSEL: Well hopefully you can hear me. The conversation now is about the best way to get public and scientific input for revising the plan. The question is whether to do an RFI, a town hall meeting or scientific workshops, or which of those to do?

We've got a fairly tight time line, because we want to be able to bring back recommendations to the October meeting.

DR. LAWLER: I like the idea of doing the science workshops informed by an RFI. So similar to what we had done previously, put out an RFI and make that compilation of those comments available at the workshop.

MS. REDWOOD: I agree. I just sort of side with Duane. I don't need that we need four specific workshops. I think that was important in the initial development, but I think we could bring back those workshop chairs and some leaders in the autism research

community and also include stakeholders, and have it be open to the public as well.

I think the meetings we had previously were not open to the public. So I'd like to see that expanded, where they're a little bit more accessible, along with having the scientists there.

DR. INSEL: If we were going to do workshops, we did four before, to kind of cover four big areas. That might be just strategically not possible to do between now and October, although I think we could do it if it's something the Committee really wants.

Is there an area in particular that you would focus this on, if you were going to choose one of the four areas?

MS. REDWOOD: Did we not combine them Tom? You know, I'd hate to just pick one area out of those four, because they're all important.

DR. INSEL: Yes. What we could do is have a single workshop, but instead of

taking a whole day for each topic, which is what we did before, we could really focus this on what needs to be changed, and therefore maybe have much briefer comments.

So we could have a much more focused discussion and try to wrap that up in one to two days, something like that. If this is what -- I'm just trying to reflect what I'm hearing from the group.

You know, I have to say that there is something to getting people sitting around a table, talking about the science that is not published, that is quite different than what you'll get from an RFI.

So if what you're looking for is what is the most exciting thing that is likely to change the course of science, and you want to get that sooner rather than later, I think you have to bring people together to do that. Jennifer?

DR. JOHNSON: Yes. I wasn't a part of the process. So could you just

identify the four topic areas that were the focus of the workshops?

DR. INSEL: It originally was done as, I think it was diagnosis, biology, technology and intervention. Not technology. Biology, risk factors, treatment and what was the other one? Diagnosis.

Any other comments that we can take back to the subcommittee? So let me take you back to what we need to vote on. So I hear little enthusiasm for a town hall meeting. Speak now if anybody wants to revive that idea? That's off the table. We will do the town hall meeting for services, but at this point not for the science.

Some enthusiasm for an RFI and some enthusiasm -- well, considerable enthusiasm for the workshops, which would be probably September or something like that, or maybe probably September.

The other thing that I show on this slide is that the subcommittee thought

that we should probably get into a routine here. It's too late to do it this year, but perhaps to use IMFAR or some meeting like that on an annual basis, to update or to have some kind of input from the scientific community.

I don't know of a better meeting right now than IMFAR, where the autism community gets together. There will be 1,300 people in Chicago on Thursday and Friday of this week. So the thought from the subcommittee was to do this in the next meeting, 2010.

So let's take number -- we'll assume number one is off the table, unless anyone disagrees. So we're talking about RFI and/or workshops. Is there enough enthusiasm to do an additional RFI? All in favor?

MS. REDWOOD: The vote's unanimous at the table.

DR. INSEL: At the table it's unanimous. What about on the phone?

DR. SHORE: Yes.

DR. INSEL: That's one.

DR. HOULE: Yes.

DR. INSEL: Okay, two. Anyone else on the phone? Okay, and Duane.

DR. ALEXANDER: Yes. Again, I would encourage us, since we've agreed to do the RFI, to try to focus it on the issues that we put off, because we really are going to need information on those that have not been addressed in the past.

DR. COOPER: Yes. This is Judith. Yes.

DR. INSEL: Okay. That sounds like we've got some clear direction on that. Then let's talk for a moment about the scientific workshops.

Again, what I'm hearing from you is you'd like to have a workshop that doesn't focus on only a single topic, but brings many of these together, with perhaps a particular focus on those areas that we said we would put off, because we need to get more input about

those before we can revise the plan, and there were several.

So in favor of holding a workshop then? This would be within probably late summer-early fall of this year. Can I see your hands if you want to go ahead with this?

It's unanimous at the table. On the phone?

DR. HOULE: Yes. This is Gail.

DR. INSEL: Thank you.

DR. SHORE: Yes, this is Stephen.

DR. INSEL: Okay, thank you. Judith, are you still with us?

DR. COOPER: Yes, but delayed, and so I don't know whether to wait until I hear it on the videocast, because I have the phone turned down. I apologize.

DR. INSEL: Okay. Well, I've been told for the volume, for those of you on the phone, has been increased. But it's still going to be important for those of us at the table to speak right into our mikes, so that

you can hear clearly.

Okay. So we have an agreement that we'll do an RFI, we'll do a workshop, a workshop, at least in 2009, and then the other question was whether the subcommittee wanted some direction from you about whether they can go ahead and actually begin working on this.

What they heard from our first meeting was go forth, meet and think about the process. They were happy to do that, but they want to go beyond the process now and actually do something that will be substantive.

So they would like to come back. They'd like your support in being able to actually begin to make changes to the plan, that they can bring back to you, so that in that October time frame, they can bring back a draft.

We have actually not authorized them to do that yet. So can we get some comments about that particular request? Everybody okay with having this subcommittee

begin to move forward with actually using the comments that come in to revise the plan? In favor?

DR. SHORE: Yes on the phone.

DR. COOPER: Yes on the phone.

DR. HOULE: Yes.

DR. INSEL: I think that's unanimous then. Thank you very much. Anything else that you want to reflect back to the subcommittee before we move on?

(No response.)

DR. INSEL: Okay. Thanks very much. We actually are at the time when we had -- we're well ahead of schedule. We had planned to take a break after this, but I think since we're doing so well, if we're ready to go ahead, why don't we talk about the Summary of Advances, and we'll be able to focus on that as well.

Della, you're going to do that presentation. Thank you.

DR. HANN: Okay, good morning.

When last we met in February, we brought back the idea that we, as is indicated in the law, another requirement for the Committee is to do an annual update, a Summary of Advances, for autism, including such topics as cures, prevention, treatment, screening, diagnosis, intervention, services and supports.

When last we met, let's see if I can make this work -- okay, good. We discussed the methods by which we would try to do that update. Following actually fairly similarly to the methodology that had been used the prior year, the Committee decided that they would focus on original science and reviews that were being published in peer reviewed journals.

We would focus on the previous year, which was calendar year 2008, using terms such as autism and autistic, and then doing the search, and dividing it into six categories that roughly correspond to the six chapters that are currently in the strategic

plan.

We identified multiple sources that could be significant, and all of these were discussed at the prior meeting, and this was the methods that we used in terms of identifying a list of potential articles and reviews that could be used for the summary.

Having decided on that, we also discussed at the February 4th meeting an initial process by which the Committee could begin to review all of this information. The first phase, which has been completed, is that we proposed and sent to the Committee a list of 257 unique articles that matched the methodology that I just reviewed.

The Committee took a look at that and made some additional suggestions and deletions. Excuse me, the 257 are what resulted from that process.

We then moved to a second phase, which you all will remember I sent to you, in terms of requesting your ideas in terms of

what should be the articles in which to highlight in the summary. We heard from six members, three federal members and three public members.

What I bring to you today are the results of that and your help, essentially, to determine which way we should go in terms of identifying the list of articles to summarize.

What I have and will walk through with you are options for the Committee to consider. We have articles for the summary that are based on selection of at least one member of the IACC who wanted all articles to be reviewed, that is 257.

At least two members agreed on 120 unique articles, and at least three members agreed on 41 unique articles. The breakdown of those are presented there. For the IACC members, you will also have in your packets the actual listing of those articles, that match Option 2 and Option 3.

So for Option 1, as a way to be

helpful, we looked at Option 1 in terms of the 257 articles, and broke it down according to the various categories, and here's the distribution that resulted.

You will note that the numbers in the distribution do not actually exceed or they actually exceed 257, because there are some overlaps. So sometimes an article would be appropriate for both biology as well as risk factors, okay. So the categories are not necessarily mutually exclusive.

But this is the distribution by Option 1, with about 107 of them following in biology, 116 in risk factors and the remainder falling in the other categories.

For Option 2, which was -- corresponds to 120 articles, this is the distribution that resulted. For Option 3, which were three or more members and it involved 41 articles, this is the outcome. This is the distribution that it would look like.

Now in our further pursuit of the articles, in terms of actually going through and doing the analysis, starting to look and read in-depth, we realized that there were six articles that actually were already covered in the 2007 summary.

These were articles that were published in January and February of 2008, and somehow they slipped into the 2007 Summary of Advances. So this is the listing; these are the first three and these are the following three. They generally fall in the Risk Factor and Biology section, is where they are falling.

So what I request today, in terms of bringing this to the Committee so that we can proceed with the Summary of Advances, is to get an idea from you which of the options you would like OARC to pursue, in terms of actually drafting out a summary of the advances.

I'd also like to hear from you

with regard to whether we should include or not include those duplicate articles. I think there can be arguments made either way. So it's up to as to which way you would like to proceed with that, and then depending on which of those options are selected that will have an impact then on the drafting of the report and the time line by which the draft can be returned to you. So I open it up.

MS. REDWOOD: Della, I have a question. Can you explain a little bit about the purpose of the Summary of Advances? Will this utilized specifically by NIH, by the autism advocacy community? I think that will help us to decide what articles should be moved forward.

DR. HANN: The only information I really have is the information that's in the Combating Autism Act. The Act requires that we produce this Summary of Advances, and since most of the actions that are conducted by the Committee are for the public as well as for

the Secretary, as well as Congress.

MS. REDWOOD: How will it be distributed?

DR. HANN: Last year, once you all completed the Summary of Advances, that was then forwarded to the Secretary, and I do not believe it was sent -- it's not required by the law to be sent on to Congress, which is what the strategic plan requires. The strategic plan requires it also be given to Congress.

So it went as far as going to the Secretary, and then we posted it on the website. So it was available to anyone and everyone who was interested.

MS. REDWOOD: One of the things we also discussed was actually identifying which articles had been funded by the federal and private. Was that done as well?

DR. HANN: We have not done that yet. Once we get the listing of which articles you wish us to pursue, then we can do

that. We can provide that information, if it's cited in the research articles. Sometimes these articles don't tell us.

DR. INSEL: Duane.

DR. ALEXANDER: Just as a starting point in the discussion, I would endorse Option 2. Option 1 is just too large really to be manageable and report on. Option 3 cuts the number down very low. It also provides a very skewed distribution.

Option 2 provides almost the same distribution as the overall one in Option 1, but Option 3 is just very, very different and very skewed. Option 2 provides a reasonable number, and I would think that that's a good way to go.

I would also suggest that we include the ones that we also included the previous year, just because -- well for two reasons. Because it corrects an error that was made in the past, and these really do qualify as in calendar year 2008. If we don't

include them, people will say "How come you didn't?"

DR. INSEL: Other comments? Let me clarify that part of what the question is here is what is the policy we want to adopt going forward, because we're going to do the same thing every year?

The more that we can specify how this is done -- for instance, one way of specifying in some actions like this is people will say "Well, you only accept journals with an impact factor of over 3. Anything else doesn't count." I'm not saying we should do that, but providing that kind of specification helps us for the subsequent years, so that we can maintain a consistent approach to this.

Because going back to Lyn's question, one of the values of this will be for someone in 2013 or 2014 to look at these Summary of Advances and say "Oh, so this is when the strategic plan kicked in. So this is what happened in 2010 and 11 and 12."

Hopefully, you'll see growth. But that growth only means something if you use the same metrics every year. So we need to have some clarity. One could argue that just simply doing this by the number of people voting is maybe not something that is entirely reproducible, because next year you might end up with three different people agreeing that you need now 400 articles.

So I think we do need to think carefully about what we're adopting before we put something in play. I don't want us to change the way we do this every year.

DR. HANN: Not to change the subject, but I just wanted to also say I was just informed that those duplicate articles for this year, really what happened is that they were e-pubbed at the end of 2007, but then the actual publication in the journal appeared in 2008. So that's the reason why there is this overlap.

DR. INSEL: Comments from those on

the phone? Any interest there? There are two different questions on the table. Maybe we should take the simpler one first. What about the duplicates? Do you want to include the January-February 2008 publications or not?

So let me put this in a policy framework. So the policy would be that going forward, the year for publications will be determined not by electronic publication, but by actual formal publication on the article, which is usually the date that this comes out in the paper version of the journal.

So the American Journal of Human Genetics papers were January, even though they were e-pubbed available in December. So can we get clarity on that? Does the Committee want to use formal publication date or e-pub dates for this? All in favor of using the formal publication date?

Okay. It's I think unanimous at the table. On the phone okay with this?

DR. HOULE: Yes.

DR. SHORE: Same here.

DR. INSEL: Okay, thank you. So that's an easy one. So we will then include the ones that were mentioned in 2007. We'll see if anybody notices. What about this bigger issue, about the number of papers to include?

MS. BLACKWELL: Tom, could you talk a little bit more about stratifying them based on their impact value?

DR. INSEL: So the one way that scientific publications are graded is by what's called the impact factor, which is looking, this is by journal, so different journals compete. They compete viciously to have higher impact factors.

So those journals like Science and Nature and Cell have very, very high impact factors, which are determined by the citations for publication. So a paper in Science or Nature is perhaps 10 to 20 times more likely to be cited than a paper that's published in

a lesser-known journal.

That's not a perfect way to do this, but it is something that could become consistent, and it's the way that some academic departments manage their portfolios. They say to their junior faculty, we only count papers that are published in the following level of journal.

The reason for that is because there are so many scientific journals now, some of which don't even come out in paper form but are just electronic. The result of that is that virtually anything can now be published.

Now we've tried to set the standard by peer review, but peer review also has a universe of things that vary tremendously across journals. So that is why you can end up with so much variance, and what I would recommend for the Committee is I think if this is a place where you're probably better off setting a high bar rather than a

low bar, because you want to maintain confidence in whatever the Committee says is a scientific advance.

If we start sending things to the Secretary as scientific advances that have no credibility or that are coming out of journals that by themselves have little credibility, that's not where you want to be, I wouldn't think, in terms of our role.

So I would probably encourage us to try to, if anything, set the bar as high as possible. When I have groups report to me on things like this, I always say to them either you can do this with a scalpel or I'll do it with a hatchet. But someone has to be very careful in deciding what should be included and what shouldn't. Duane?

DR. ALEXANDER: Tom, my understanding of this is that this is the second cut on this. The original one was made by the group that reviewed the universe and picked the 257 or whatever the number is, to

be considered.

This is the first cut. But just doing the further analyses and summaries of these papers is not necessarily, I thought, a commitment to include that, but to give the Committee more information about these papers, to decide whether this group of about half of the original, from those, which should be in and which should be out.

Not necessarily a commitment to include everything that's in here. Is that the way we operate?

DR. INSEL: No. I think from this point, the hope was that there would be enough clarification so the group could begin writing. This is a huge document that someone's going to put together, and it would be unlikely that somebody wants to summarize 120 pages just -- it was hard enough to get this Committee to read just the titles and the authors list.

I can't imagine that we're going

to come back and study -- this would be probably a couple hundred pages of text that many people from this Committee are unlikely to really dive into and then to further refine.

DR. ALEXANDER: Okay.

DR. HANN: Also, given the vote that you just had, some in the list, okay. So for Option 2, there's 120 and for Option 3 there's 41. It's possible that some of those were e-pubs from December, meaning that the actual official publication date wouldn't have been until 2009.

So it may affect those numbers, given what you all just decided, because we weren't using that as a rubric in terms of the first wave of information to you.

MS. BLACKWELL: Do we know out of the 200-some how many would have a high impact value?

DR. HANN: We did not examine that in terms of this list.

MS. REDWOOD: I guess I have some concerns about setting the threshold at what the impact value would be, and that there might be some new, emerging science that's not published in Nature or Cell, that we would want to know about and replicate.

So I think that's a good way to be able to capture that type of new emerging science. So I would hate to set the threshold that it has to be a certain impact level to be included. If it's something that we as a Committee feel as though was important, and needs to be acknowledged and replicated with future science.

DR. INSEL: Yeah. There's a very interesting paper that's in this list. I think it's in the list of 41, maybe it's in the list -- I'm sure it's probably in all of them, but I believe admitted into the final 41, which has to do with melatonin and a melatonin synthesizing enzyme as being so highly abnormal in ASD that there's no overlap

between the two groups.

It was published in not a great journal, Molecular Psychiatry, which probably has -- I don't know what the impact factor is. I think that's probably an impact factor of around 7 or 8. So it's certainly above 3. But that's one of those findings which comes out of nowhere, and it certainly would need to be replicated.

But you might want to capture that as something that's quite interesting. But generally, I think one of the things that separates out -- not always, but sometimes the lower impact journals are publishing work that is not that entirely novel.

It's actually the other way around, that the most novel ideas are usually the ones that these journals will compete for. It's the fourth replication that winds up in a third tier journal. But not always.

Well, we need some clarification from the group about what you want to do here.

MS. BLACKWELL: I would certainly support some measure going forward that can be replicated on a standardized basis, other than, you know, just who happens to be at the table and who voted for a particular article.

MS. HIRTZ: I would agree with that, but perhaps there could be an additional section, that deals with new ideas of note or that require -- or that would -- where it would be nice to have follow-up and see where they go, some sort of additional section that doesn't have the same weight as the rest of the body, but where there will at least be an option to note kind of new and interesting ideas that need follow-up. That might be a compromise, so that we don't lose track of those.

DR. INSEL: Do you want to make that a nomination or a proposal? This would be something that OARC could put together and send out to the Committee for approval, is that right?

DR. HANN: I'm sorry. I'm just a little lost now, I will admit. So what I heard was first of all whether or not people wanted to use some sort of journal impact factor as one of the cuts for the future going forward.

Then a second one has to do with new and emerging ideas, but who would make the decision on what's new and emerging. I guess that's what I'm trying to understand.

MS. HIRTZ: Well, it would have to be the Committee members who are involved.

DR. HANN: Be able to determine what would be new and emerging to go in that. So --

MS. HIRTZ: I'm not sure of the best way to title it. I think we need to think about that a little carefully, because I don't -- it shouldn't be an endorsement, but it should also be just at least an awareness of note kind of thing, and we'd have to figure out how to best title that section.

But it would allow the option of including new research that seems to be of interest and a potential that doesn't have the imprimatur of the high level journals.

DR. INSEL: Alison?

MS. SINGER: I would also suggest not for this year unfortunately but for the following year, if we're talking about convening a group at IMFAR in May, the timing on that works out nicely for this as well, where we might be able to get additional input from the scientific community with regard to the scientific advances.

I am a little concerned about the Summary of Scientific Advances being compiled by six people, and only six people. That's a little concerning to me at this point.

Am I not understanding the process? The 257 was just a database search, and then is it true that only six people?

DR. HANN: Well, I guess it is a database search, but we used the methodology

that we described in February. Let me go back, to do that. It wasn't just a complete dump. We used multiple sources to help us. So we did use Pubmed and Scopis.

We looked at sections of major journals as well as science news. We also looked to see what had made it in the papers, in terms of what was being publicized to the public, as another means in terms of trying to make sure we were capturing what was attracting attention, essentially, throughout the year.

So it wasn't just a random sort of go in and dump 257 articles. There was some sifting that happened at that moment in time, and then -- but the decision was to bring it back here. Since this is a product of this Committee, it was important for the Committee to determine how best to approach all of this.

Yes, you are correct Alison. There were six members who provided input during the second phase.

MS. SINGER: I think that's just a little disappointing, that only six people chose to participate in what is such an important document that the Committee produces. Maybe next year we can look for additional ways to get more input in building this document, so that it's not the collective wisdom of six people.

DR. JANVIER: I mean I could comment on that. I mean I was personally overwhelmed by the number of articles, and to take the time to actually obtain each article, which I'd have to do on my own, and then try to read them, I honestly found it completely overwhelming.

MS. SINGER: And given that, what I'm suggesting is that not for this year, because we have to complete the document, but for subsequent years we look at additional ways of gathering input for this document, so that it's not so overwhelming that people feel it's too hard for them to contribute.

DR. LAWLER: So if we go back to the issue of using impact scores as a potential way to sift through these, are you suggesting or one way to do that would be to apply that before we even see this list. So rather than seeing 250 this year, maybe we'd see 180 or something.

Another way would be to proceed in a similar fashion to this year, and then, you know, if we went back to Deborah's suggestion, apply an impact factor, but then we'd at least have before us the listing of other publications that made it onto this list.

Maybe they weren't, the impact factors weren't high enough, but we could sift through those and there may be ones that would be of note, that could be provided in another section of the report.

DR. INSEL: This kind of goes back to Lyn's original question. So what's the purpose of this anyway? There is what it says in the law, which is that this is a

requirement that we provide this to the Secretary.

There's also the value of using it ourselves for getting a measure of how we're doing. The whole point here is to try to coordinate and accelerate progress. What we have in 2008 will essentially be baseline, and we'll want to use this to find out how we're doing by 2011 and 12.

So you might want to think about it that way as well, and I think Lyn's comment about using this also to look at where the funding for the science came from would be really helpful, if we can identify what science is most important.

That's going to need, I believe, some standard measure, which nobody ever wants to make. But there has to be some cut that we decide on, is a definition of substantial progress.

MS. REDWOOD: And if there's a way, Tom, to take that list of scientific

advances and then retrofit it back into our strategic plan, to see where the gaps are in the science, I think that is what would really make this document be useful in the future.

I agree with Duane's concerns about if we go with just the 41, it's very warped and it will look like we really didn't accomplish much in those other areas of the plan, because it was so heavily weighed on what was it?

DR. INSEL: Risk factors.

MS. REDWOOD: Risk factors.

DR. INSEL: Yes, and then that's a really interesting comment. I was thinking the same thing, but from the other side, that if you look at this, the figure for Option 3, this may be a really interesting baseline to follow, because there are only four in the treatment bar and four in the services and supports bar, and two under diagnosis, even though that is actually the number one part of the strategic plan, is to develop better ways

of doing diagnosis.

So I don't think this is a reflection of us, because we didn't have a strategic plan for 2008. That came out in 2009. Even the e-pub version was 2009. So what we'd want to look at is if this is where we're starting from, what does this look like in 2009, 10 and 11?

And hopefully, we'll see a somewhat different organization for this. If we don't, then we've got to ask ourselves what are we doing wrong, and how do we move the bars around here?

Well, I sense we're stuck, because we're not clear on how to take this forward. Deborah's made one recommendation, that we have sort of two sections to this, one that sets this very high bar and another one that mentions other advances that may not have made it in, but that the Committee feels the Secretary and others should know about.

How do people feel about that? Do

you want to take that on as a recommendation and try to take that forward? Then we'd have to decide what the high bar would be for those things we include.

MS. HIRTZ: I'm confused, Tom, because I thought we were voting on like Option 1, 2 or 3. So this sounds like something different.

DR. INSEL: Well, I'm concerned that if that's the way we go, Option 1, 2 or 3, I want to know how we'll do it next year, or if you want to do it next year in the same way, by having whether two or more members of the Committee or three or more members of the Committee think it should be included, and if so, does that provide the stability of consistency and reliability that you want.

MS. HIRTZ: I thought that what you meant -- I'm a little confused, because I thought that you brought out the option of using the level of the journal as the determinant, rather than having the two

members of the IACC choose it. Was that one of the things that you offered?

DR. INSEL: Yes. So I mean what we could, and you could decide initially if you want to take of the three options, we could ask to see how this would stack up against some standard metric like impact factor.

Since I was one of the three most likely, I can tell you that as I look through, I mean the way I would read these kinds of things, because as Yvette says, it's really hard to pull out all 250 papers if you haven't already read them.

So you tend to look at the papers that are in journals that are known to produce the most significant findings, where most of the major discoveries have been published in the past. Those are the ones I tend to track. Those are the ones that have the highest impact factors.

So I would assume that that's

probably going to map pretty well onto that variable. But maybe not. We haven't actually done that.

MS. HIRTZ: So the question then is can that list be established, that can be reproducible from year to year and have some objective criteria? Do we have a list of journals that can be what determines the articles that are reviewed, as opposed to the people selecting them?

MS. BLACKWELL: I would suggest that we move forward with, I guess, what we are calling Option 4, which is to base the list on the impact scores and then perhaps have a subsection on novel or emergent research, and say, ask for suggestions from the Committee members, say capped at three, or put some limit on it, so that we can have this subsection where members can actually contribute.

DR. LAWLER: I'm a little bit concerned about whether the journals that

would represent all these different areas are going to, you know, have comparable impact factors. So I don't know if there's some way to do maybe a ranking by impact factor within the categories, as opposed to just, you know, overall, because we may end up with even more biased representation.

Because some of these areas may be very important, but they just, you know, have a smaller cadre of investigators in that area and subsequently fewer cites.

MS. REDWOOD: This Committee is relatively stable, correct? We all have appointments for several years? So I would think that if we're all reviewing it each year, there would be some stability there in our decisions.

MS. SINGER: I would also say, in trying to respond to the point that Yvette made about just the quantity of information that we're going to be including and wanting people to actually read the document, the

Secretary to read the document and other people to read the document, that even cutting it down to 120 might be too much.

People might look at that and feel the same sense of bulk that members of the Committee described. I would like us, if we're going to invest the time and energy in producing this, to have something that people actually read and benefit from.

DR. HANN: Just for perspective purposes, the first version included about 55 articles for 2007.

DR. INSEL: And how was that done, Della? How were those chosen?

DR. HANN: I will have to draw on the wisdom of others who worked with me, to help with that. Diane?

MS. BUCKLEY: This is Diane Buckley of NIMH. It was primarily done in-house at NIH. It was really relied on -- well, it started with similar kind of library search, as was used this year, and then really

relied on a collaborative effort of program officers within NIH to review the materials and point to what they thought kind of the top findings were.

Then we brought those to the Committee and they reviewed it at that level, once we had identified, excuse me, the top ten advances from that year.

DR. INSEL: Yes, go ahead. Further thoughts on this? Duane?

DR. ALEXANDER: Yes. We're really kind of at an impasse here. I think we need to get this decision back maybe with the Committee again. I would suggest that maybe we ask them to start with Option 2, and do some selective pruning, based on their own knowledge and some information that they can get from program staff or other scientific equivalent, and pare that list back to what they consider a reasonable list to present, and what people figure, with a combination of impact factor and diversity of the science,

and importance of the findings, that they make a determination of what the number and the inclusion should be.

Whether they have to come back to the Committee by a mail ballot or whatever, I don't know. But I don't know think we're really ready to make a decision as a whole group here, from the options that we have presented.

So I would suggest that we put this back to the Committee. Maybe with -- whether you go with the whole 239 or the 120 or 42 or whatever, and ask them to do a scientific analysis of those and give us a proposal, maybe by mail ballot. Then we can decide whether to do it that way.

DR. INSEL: Yes. The only people working on this are Diane Buckley. So there's no group, and what we're really talking about is they've already done part of what you said, which is they've taken what you had asked for and they sent this all back to the Committee.

The Committee's given them feedback. What they're really asking for now is they're going to write up summaries of all these advances, which is a very extensive undertaking. Before they start on that, they want to know are they starting on 270, 120 or 41 advances.

Because it's going to be a lot of work to decide which one of those, for any of those. I guess my alternative would be to say they're going to have to bring this back to us anyway, right, when they've got the whole thing written up.

The other argument one could make is have them do the 41, and if there's something that people on the Committee feel was a really important breakthrough in 2008, that really was a game-changer for autism or for families with ASD, then we should ask them to include it.

But if you look at those 41 breakthrough discoveries and you don't see

anything missing, you've got it. The other possibility would be you look at this 41 and you say you know, half of this is not that important. We decided to cut it down even further. We can do that at a later stage.

I am a little remiss to ask them to do this for 120, having already done a bit of that work myself and knowing that there aren't 121 major, substantial significant breakthroughs in 2008. I just don't want to make them do the work. So that's where I'm coming from. Jennifer?

DR. JOHNSON: You know, I think what might be helpful to this discussion is to help define the term "advances," because how you define that will really depend on how much you include. If we define it broadly, then you would include 120 articles.

If you are really strict in your definition, then and you talk about high impact, then you might end up with five articles. So I think that's maybe part of the

challenge here, is that since it is a document that talks about the Summary of Advances, how are we defining "advances"? I think that would help put some parameters on what's included and not.

DR. INSEL: Chris?

MS. McKEE: I just want to know what really falls off the spectrum between Option 2 and Option 3. What gets hit rather hard are treatment, services, supports and outcomes. We've received many comments since we published the strategic plan about the rather small percentage of funds that have gone towards service-related categories.

So I'm just uncomfortable looking at this, as going from Option 2 to Option 3, that like once again, what happens to treatments and services and outcomes?

DR. INSEL: But so just to be clear, isn't that really telling us what the public is saying, which is you guys aren't doing -- there are no breakthroughs in those

areas. There are no advances. This captures that in a way that we may feel uncomfortable with, but if it's the reality, why wouldn't we want to share that?

It hopefully is what we're trying to change. Remember, this is the baseline. This is what we want to be able to show in 2013 that we worked from.

MS. McKEE: Right. I think it goes both ways. As long as it's explained that there is an absence here, and we're aware of it and we're working on it.

DR. INSEL: Yvette?

DR. JANVIER: I agree with Duane. I think we should go with Option 2. I mean not having read all of these articles, but looking through every title, I mean it seems to me that, you know, in these articles one sentence may explain what they found.

So I think it's a more balanced view. It does take into consideration the spectrum of issues we're supposed to be

addressing, and you know, if MMAR doesn't have anything to do with GI symptoms, you can summarize that in one sentence.

But I think it would give us, you know, kind of a more balanced approach than this Option 3.

DR. INSEL: Other comments?

DR. JOHNSON: Well, I want to go back to my comment about defining advances, because I think that you can include as many articles as you want to. But if you don't know about the quality of the research, then is there a benefit to including it?

We might be endorsing something by including it in this list, but it may not be research that was conducted in a valid and reliable manner. So that's where I'm stuck, is beyond looking at each of these articles and determining the quality of the research, it's hard to know whether to go with Option 2 or Option 3 or Option 1.

DR. INSEL: Well, so one other

possibility here is that we could have you go back to the list, because only six people responded, as was pointed out, and those who haven't looked at this could take the time to actually go through it and give us a sense of what, of the 200 and some, which ones they think, based on the titles and the journal and what they know about the field, look like they are real advances.

MS. BLACKWELL: Could we also have the list sorted by impact scores, if we are getting the list back?

DR. INSEL: We can give you the impact factor for each of the journals. That's not for the articles, but for the journal. So that would give you some sense of what would be considered a first tier, second tier and third tier journal. All of those are in this list.

MS. REDWOOD: Tom, we also have created really sort of a nice document with what we have now, and I think there's some

usefulness to it. I don't know if just having all that research in one area that parents and go and look for this year these were all the things that came out, with links.

I think that's helpful. Not that that be presented to the Secretary as the advances, but somewhere on the website to say "These are the things the IACC looked at, in coming up with the summary of advances." So they're acknowledged in some way, and if there is a parent who's awake all night and has an appetite for research, they can go and look through this.

DR. INSEL: So we can actually make all of this available, so people can see the full list.

MS. SINGER: I think that's a great compromise between Options 1 and Options 3, where Option 1 gives people an opportunity to see the full scale of what was published. I love that idea, Lyn. I think there are parents who are up in the middle of night and

really want to read the studies, and some of us do read the studies.

I think to Jennifer's point, we also want to be providing some information about what really were the significant advances. Again, I think for the other, I don't want to say end of the spectrum, but for the other group of people who don't want to read even 120 studies, the idea of you can just look at the summaries of these 40 and you'll get a good flavor for what the advances were, I think, is also an important piece of information to convey to people.

So I love Lyn's idea. I think that really helps us to strike a balance.

DR. INSEL: And one other thing to add to that. This is a different purpose than the Summary of Advances. But if we are going to put out the 240 or whatever the list of articles would be, is that any of them that were funded by NIH are now required to submit the article to Pubmed Central.

So it's not just the title, but you should be able to actually get the original article, without having a subscription or anything else. Those are all required to be publicly available within, what is it, six months or nine months of publication, something like that. Okay.

So it wouldn't be available at the end of 2008 or 9, but by 2010. All right. So let me try to summarize what I'm hearing from you. There is the -- one option is to not make a decision today, but to go back and actually have additional people look at this list.

We can provide you with the impact scores for the different journals, so you have an idea of how the journals themselves would be ranked. A second option would be to make a decision between 1, 2 and 3 here, and a third option would be to tell Diane and OARC to come up with an Option 4, which would further break down what's in any of these by

impact factor and only take the highest impact factor journals.

So those are three potential ways forward. Am I leaving anything out?

MS. SINGER: Maybe we'll call it Option 3.1, where we combine 3 and 1, publishing the full list as Lyn suggested, and then shortening the ones for which we -- that we described as advances.

DR. INSEL: When you say "shortening it to Option 3" --

MS. SINGER: Going from 120 to the 40, so that more people looked at those articles. There's not two people --

DR. INSEL: So in a way, this sort of, if I hear what you're saying, it kind of separates out the two roles here. One is to put out a long list for anyone to use, but then to have a very refined list for the purpose of the Secretary, which is what's in the statute. Is that clear? Okay.

DR. HANN: So that just to be

clear, Option 1 was around 250 articles. So that's the full list, and then Option 3 is around 40-ish. Okay.

DR. INSEL: All right. So why don't we make that one of the proposals. The second proposal would be to use, just to go with Option 2 at this point, and which kind of the alternative 120, and we can come back to you with the summaries from 120 articles that then we'll ask you to look at.

Before we vote on those, let me just check. Is there a sentiment that people really want to go back and do this again, that there are more people beyond the six who have done it, who now want to participate? Or is that something that I don't see a lot of enthusiasm for taking this on. Chris?

MS. McKEE: Was it that six people suggested additional articles, or only six people voted on ranking them?

DR. HANN: Six people, using your words, voted. Six people went through the

list and sent back to me a shortened list or a recommendation for all of them. But anyways, six people responded back to me.

DR. INSEL: Okay. So I'm going to, prerogative of the chair, knowing a break is long overdue, we're going to have two choices. The choice will be 3.1, which is to have a long list that would be published on the IACC website.

We'd go with Option 3 for refining for the Secretary, and the second option would be Option 2, which is to have the summary of the 120. Can I get a show of hands for the 3.1 notion?

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

DR. INSEL: And for Option 2?

DR. HANN: One, two. Two.

DR. INSEL: And for those on the phone, 3.1 versus 2?

DR. HANN: I'm not sure they're able to hear you right now because of

technical difficulties.

DR. INSEL: Well --

DR. COOPER: This is Judith. I vote for the first option.

DR. HANN: Thank you, Judith.

DR. INSEL: Anyone else able to hear us on the phone?

DR. SHORE: Yes. I'm going to go for 3.1.

DR. INSEL: And we still haven't heard from Gail.

We'll check in with Gail at a later point. So Duane?

DR. ALEXANDER: Just one additional comment. Both for purposes of reviewing the articles when they are originally circulated to us, and for purposes of the list that we're going to provide of these, it would be very useful, I think, if we could include the abstract, rather than just the title. That's legitimate to do. Is that --

DR. HANN: I'll check into that with regard to copyright issues.

DR. ALEXANDER: Because if we could, certainly we can do it internally next year, when these are circulated.

DR. HANN: Certainly.

DR. ALEXANDER: That would help us with our own decision-making. But if we could include it with what we put out here for the non-summarized articles, that would be useful.

MS. SINGER: I think on PubMed, you can get the abstracts now. So if you link, it's not a copyright issue.

DR. HANN: Right, if we link. But if we publish it --

MS. SINGER: But if you can't get the copyright, then I think the second best solution would be to provide the link, so that people have quick access to the abstract.

DR. HANN: We're happy to provide the link. The link is fine. But actually taking it and publishing it on our site, I

think it would probably wander into the copyright issues.

DR. INSEL: Okay. Any other issues about summary of advances? Della?

DR. HANN: So what I hear then from the Committee that there were nine votes to go with what is now referred to as Option 3.1, which is the full listing, and then with a written summary of the 40-ish, which was in Option 3 articles. That seems to be the vote that will carry.

DR. INSEL: Okay. With that, we will take a break, and we'll reconvene. It's five until 11:00. So let's reconvene at 11:05 to hear from Dr. Swedo on the intramural program.

(Whereupon, the above-entitled matter

went off the record at 10:59 a.m.,

and resumed at 11:12 a.m.)

DR. INSEL: Everyone come back to the table. It's a great pleasure for me to

introduce Dr. Susan Swedo, who is a pediatrician, who works within the NIMH Intramural Program, and who is leading a relatively new effort.

It's about two, two and a half years old effort around what we call Developmental Neuroscience Branch, but it's largely focused on autism and autism spectrum disorder and she has, in that relatively short period, put together a large team with some outstanding projects.

We thought it would be helpful for the IACC to get a quick update on where that effort is going. So Sue has agreed to take us through a rather quick overview of what the branch is doing and some of the projects that have completed and some that are underway.

So Sue, I won't take any more of your time. Thanks so much for joining us here.

DR. SWEDO: Thank you so much for the invitation. It's a really great pleasure

for me to be here, and to represent my colleagues in the intramural program.

As Tom mentioned, we are a relatively new program. But we're actually quite excited and as we put the slides together for this presentation this morning, I think we got even more excited about how much we're doing and have already accomplished.

I want to point out our mission statement to you, because even though it looks somewhat casual and frankly was, the words are very carefully chosen. We are very focused on autism rather than the entire spectrum of autism spectrum disorders.

We are looking at the more severely affected individuals. We believe in a cure. We're using leukemia as our model. When I was in my pediatric training, it was the era in which the fatality rate of acute lymphoblastic leukemia was about 95 percent.

By the time I finished my training

and some practice about five years later had turned completely around, to the point where the survival rate was 90 to 95 percent, and in fact that those individuals not only survived but were cured of their cancer.

We believe that the same thing is possible for at least some cases of autism, and as in the leukemia model, our group is aiming to find two to three percent. That may sound like a demotivational activity for us, but it's actually quite a challenge to think about that subgroup of individuals that might respond to a specific treatment.

As we keep our eye on the long-term prize, it's also very important to us to be able to help those children and families that are affected today. So that's the second part, the conducting meaningful until-then research.

Many of our treatment trials are actually designed towards alleviating suffering at the present time, even if we

don't understand the mechanism behind the treatments. We hope that they will be helpful, and I'll share more about that in a moment.

As I said, we are aimed at looking at the causes and cures. As we learned from our studies of obsessive-compulsive disorder, you need to model these diseases and try and understand better how things are happening.

In our experience with obsessive-compulsive disorder, we found that by doing very careful clinical observations, we were able to identify subgroups of patients in which we could then generate a hypothesis of ideopathogenesis, test it and actually we now have demonstrated not only that we can determine how it's caused, but can prevent it and in many cases eliminate the symptomatology.

I want to point out that environmental triggers for us includes the entire environment that affects the child.

That includes maternal antibodies; it includes exposures in utero as well as in the neonatal period.

It may be things like advanced paternal age. When you start to think about all of the compounds, all of the changes that have occurred in the past two to three decades, it's somewhat overwhelming, and so you have to keep your focus on small bits at a time.

Genetically susceptible host. Certainly, the papers published this week in Nature would remind us how important the genetic underpinnings of autism are. It's very clear that some individuals are susceptible, while others are resistant to the disorder, and trying to find out not only those susceptibility genes, but the protective genes, is a very exciting challenge.

Dr. Mady Hornig has pointed out the fact that we actually have an even more challenging job to do here, and that is that

it's sort of not just the environment and the genetics, but it's also the timing.

The child who's exposed to that same environmental trigger when they are two or three years old, might have a very different response than a child who is six or nine months of age.

We do believe that everything ends up happening through and to the brain, and that is that they'll either be abnormalities of brain development, structure and/or function, that eventually lead to the symptoms of autism.

Again, those symptoms are behaviorally defined, which creates problems in sort of narrowing that focus, but also provides us with some good homogeneity in terms of responsivity. As Tom mentioned, we have a true multidisciplinary team in the autism program in the intramural NIMH, multidisciplinary M.D.s, Ph.D.s and other professionals.

We have ten full-time staff and then we have approximately 12 trainees working with us, everything from post-doctoral fellows to post-baccalaureates IRTAs or, as we like to call them, our indentured servants. No. They're actually an amazing group of young people who are often the ones responsible for some of the most novel approaches to our patients.

Well, in this slide you can see where we are today, in the Natcher Building. Our office is on the fourth floor of the old part of Building 10, in the condemned portion of the north wing. But our patients don't go there. They stay, as I'll show you in a minute, in the new part of the clinical research center.

Then Cedar Lane, which is one of the streets bordering the campus, on the other side of that we have a wonderful screening clinic, which allows the families to meet us in a much less intimidating setting the first

time.

We have established a lot of collaborative relationships, and as I learned from Dr. Judy Rapoport, our strength lies in our ability to do clinical evaluations, clinical observations, behavioral assessments, and then to find the best and the brightest, wherever they might be.

Within the NIMH, we're collaborating with eight different laboratories, about 15 different individuals, on everything from executive function, MRI scans, MRS and proteomics. Within the NIH, we've actually had the privilege of being able to work with folks in NCI, NHGRI, NIAID, we got the AIDS team involved in looking at some of our lymphocyte phenotyping and immune markers.

And one of our most strong collaborations currently is with Dr. Owen Rennert and Dr. Margarita Raygada in NICHD, the Child Health Institute, who are working

with us to establish a new protocol. We'll be able to examine stem cells derived from skin biopsies, and hopefully be able to turn those into normal cell lines that will --

UNIDENTIFIED SPEAKER: I know I'm connected. I can't hear a thing.

DR. SWEDO: Can you hear me now?

UNIDENTIFIED SPEAKER: I can hear you now, yes.

DR. SWEDO: Okay. I will talk much closer to the microphone. I apologize, Stephen.

UNIDENTIFIED SPEAKER: I don't know why I'm even connected so that you can hear me.

DR. SWEDO: I don't know either, but thank you for speaking up.

UNIDENTIFIED SPEAKER: Thank you.

DR. SWEDO: Whoever that was. All right. Now I lost my place. We were talking about Dr. Rennert and Dr. Raygada and the fibroblast investigations, but also a huge thank you to ASMA IDRIS and the CTDB team,

which has provided us with a wonderful clinical trials database, which allows us to collect these 2,000 and some data points from each of our children in the subtype study, organize it and actually pull it back out to analyze.

Extramural investigators are all over the country, and actually we have international investigators as well. And again, these are scientists specializing in various things, from behavioral colleagues who are helping us to think about the aspects of regression and the behavioral symptomatology, to Dr. Carlos Pardo and his colleagues at Johns Hopkins, who are looking at our CSF and blood for immune markers, but also a number of genetic collaborations with UCLA, Vanderbilt and others.

In addition to the academic collaborations, we are also collaborating with Autism Speaks and the two networks there, the Autism Treatment Network and the Clinical

Trials Network, as an opportunity to take the novel findings we're working on here in the intramural program, and to rapidly translate them into the community.

We get our spinal fluid from healthy control children, through a collaboration with D.C. Children's Hospital, and then in addition we have a number of collaborations with folks such as Keith Hyland at Medical Neurogenetics, to look at neurotransmitter concentrations.

So for all of our studies, the screening study is our entry point, and this is a comprehensive, diagnostic and behavioral evaluation. Dr. Audrey Thurm heads up this team that does an ADOS and A-DIR, but also a number of other behavioral and I.Q. testings.

That clinic opened in the fall of 2006, and since then they've done more than 400 in-person screenings, with more than 200 subjects being found eligible for participation in our PDN studies.

I can't begin to tell you how much that actually is. 400 subjects sounds like a lot, but when you multiply that by the fact that doing that evaluation takes a minimum of eight hours, it's really a tremendous investment that our team has made.

We have three basic types of investigations. The mainstay is our subtype study or the phenomenologic investigation, where we're really looking for those subgroups that will give us a clue into the etiology and pathophysiology of autism.

Therapeutic trials vary from those in which we have a hypothesis, and we're trying to either test it or generate additional windows, or symptom-specific therapies, and we'll talk more about those in a moment.

We also have hypothesis testing experiments, and those tend to be second generation. As we begin to find things within the phenotyping study, for example, then we

move on to a hypothesis testing investigation.

The FMRI study that Dr. Marta Gozzi, one of our new fellows has written and is taking through scientific approval, will be looking at the effects of oxytocin, vasopressin and placebo on emotional processing, and this will be measured not only with behavioral testing, but with FMRI.

In collaboration with Dr. Jim Shannon of the Intramural Program, we're going to be using magnetic resonance spectroscopy to evaluate the response of individuals treated with riluzole, a glutamate antagonist.

So we couldn't do our work without being located in the clinical center, and that's because in this mammoth Building 10, we actually have access to pretty much everything we need, from the state of the art MRI scans that are in the back of the building, overnight electroencyphalography, with an amazing technical team that's been quite effective in getting leads onto the children,

not an easy task, and inpatient and outpatient clinics within the new clinical center.

So the phenotyping study. How are we going to get at that black box and begin to understand more? Our hope is that by choosing either particular known etiologic variability or clinical phenotypic variability, we'll be able to trace it back through and look at mechanisms.

This is called variably the 50-50-50 study, the subtype study, the phenotyping study, the phenome study. It has a lot of names, because it's a lot of things. Probably the most comprehensive is the phenotyping study.

This involves a comprehensive baseline evaluation with very extensive behavioral and medical workup. The children are followed longitudinally for three or more years, and at the present time, we are enrolling children who are ages 12 to 16 months, one to four years of age.

When the study was started, we thought that maybe one of the most obvious subgroups to look at was the regressive subtype. So we are enrolling 50 children with regressive autism, 50 with non-regressive autism, 50 typically developing age and sex-matched controls, and then 25 children with non-autistic developmental delays, in order to do comparisons for specificity of the findings in the children with autism.

In the regression subtype, as I said, the original hypothesis was that there would be children who have regression and children who didn't have regression. If you had no regression and no early signs, you would be typically developing.

If you had early signs, you would have classic autism. But in actual fact, it's not that simple at all. It's a continuum rather than a dichotomy, with the majority of children actually having some early signs, as well as some signs of regression.

It's rare but not unheard-of that children will have absolutely completely normal development, and then lose skills, either in an acute and dramatic fashion or more subtly over time, and it's also quite clear that some children have no regression at all, that they just have slow development from a very early period.

But the majority of children are in that box in the middle, where you have some early signs and some degree of regression.

So within the subtype study, we actually started this study two years ago this month, and to date we've had 143 participants, 77 with autism, about half and half regression and non-regression, 19 with developmental disabilities, and 48 children with typical development.

We've actually come so close to finishing Phase 1 that we're moving into Phase 2, and recruiting an additional cohort of children with autism, as well as children with

known genetic disorders, with and without autistic symptoms, and then obviously a new cohort of typically developing children to match them.

All of the children undergo comprehensive medical evaluation that includes not only a history, family history, physical and neurologic exam, but also phlebotomy, MRI scan, overnight EEG, LP for the children with autism to obtain spinal fluid, and dysmorphology camera.

Our dysmorphology findings will be reported this week at IMFAR, and in general I can give you the bottom line, is that children with autism do not have a specific pattern of dysmorphology. I think people in the field already knew that. Parents already knew that, but it's nice to have it be able to be documented, so we can move on to the next question.

In the EEG study, we've done 107. I'm showing here the preliminary findings from

the first 50 children with autism but without epilepsy. What we found was that they had abnormalities on their EEGs much more frequently than expected.

On routine EEGs, or the 40 minute study that's done immediately after lead placement, we found about 1 in 5 children had abnormalities, and surprisingly nine of the children had epileptiform activity that had not been previously noted.

Sixty percent of the overnight EEGs were found to be abnormal, including 25 children with epileptiform discharges. Those epileptiform discharges may provide a new therapeutic target. There are some case series in the literature to suggest that use of anti-convulsants for these epileptiform discharges may be helpful, but it's actually quite controversial, as you don't want to use these drugs on children if they're not going to be of benefit.

So one of the trials that we're

considering is a trial of use of anticonvulsants to treat the epileptiform discharges.

Sleep abnormalities were another very exciting finding of the first 50 children. In this case, we've now done 74 sleep studies that are continuing to confirm these findings. We used modified polysomnography, and what that means is it's the regular sleep study without the respiratory leads.

Since sleep apnea is not a problem for these children, we wanted to make sure that they slept as well as possible, and that we were measuring their best night's sleep. So unless they have a history of potentially loud snoring or other respiratory problems, they don't have the respiratory leads.

But we were able to get everything else, and from the first 50, we found out that the children with autism had decreased sleep efficiency. They have to spend a lot longer

in bed at night time to get any sleep. It takes them a long time to get to REM sleep, and they actually have a marked decrease in the total amount of time spent in REM sleep.

I think it's really important to note that these children did not have reported sleep difficulties. So these were occult sleep problems in these children, and perhaps because they're so young, as they became older, they might develop the kind of sleep problems that parents report. But these children were not reported to have difficulties with middle of the night awakenings.

Here are the findings from the mean REM percentages. On the left two bars are the non-regressive autism group; on the far left, the autism regression group. Next to them, you'll see that their means are identical. The standard deviation varies a little bit, but in general, both groups are markedly decreased from children with

developmental delays for the typically developing children.

I also want you to notice that in the autism non-regression and regression group, that the mean is about 5, with the typical mean being above 10 in our findings. But nationally, the mean being about 20 percent of time being spent in REM.

Among those children with autism, a number of them actually had no REM sleep during the entire night. Those findings led one of my fellows, Dr. Ashura Buckley, to design a trial of Donepezil or Aricept, to treat these sleep abnormalities.

Donepezil has anticholinergic effects that actually increase REM sleep. This was an accidental finding among the adults with Alzheimer's disease, but we thought we could use it to our advantage in these young children with autism, who are having REM deficits.

We had originally designed a

double-blind placebo control trial to start, but on the advice of the IRB, because of the young age of the children, we moved to a dose finding study. So this is an open-label trial with three different doses of Donepezil and a repeated overnight sleep studies, the polysomnographies, to evaluate whether or not the Donepezil is helpful.

We're titrating the dose upward to maximize the response, but to minimize side effects as well as to ensure sustained effects, so that they don't have rebound.

Here are the dose response curves from the first two children. Both of them started very low, one at zero percent REM and one at three percent REM, and initial PSG. Over the course of the treatment trial, they moved up to having normalization of their REM at 2-1/2 milligrams, and into the normal range of five milligrams of Donepezil a day.

If the remaining eight patients in this open label trial have a similar dose

response curve, we'll be able to choose the dose for the placebo-controlled trial. As I mentioned, our collaborations with extramural investigators. This is one where we would want to get a large population of patients together as quickly as possible, to get this answer soon.

Minocycline and treatment trial is sort of in between. It's somewhat hypothesis-driven, but it's also hypothesis-generating, in that we're using minocycline not for its effects as an antibiotic, but for its effects to block NF kappa-B, and to block the initiation of the inflammatory response.

This study was based on work done by Carlos Pardo and Diane Vargas at Johns Hopkins, demonstrating that individuals with autism had chronic neuroinflammation. We know that minocycline has been shown to be of benefit in other neurodegenerative conditions, as well as autoimmune disorders such as rheumatoid arthritis.

This is an open label trial in 15 children, ten of whom actually went through the six month trial and had pre- and post-treatment LPs done. Our primary outcome variable is not actually behavioral change, since it's an open label trial. We were concerned that many things work in open label studies.

But instead, we were looking to see what the effects are of the minocycline on the patterns of cytokine and chemokine distribution within the CSF. We have collected all of CSF. It's now with Dr. Pardo, and we're anxiously waiting to find out if there are interesting results.

Our hope is that there will be a subgroup of children in whom the CSF cytokines changed more, and they tended to have more behavioral response. Then those would be the children that would be entered into a placebo control trial, rather than using it indiscriminately on a larger number of

children.

The riluzole treatment trial is actually an outgrowth of a study that we were doing with children with obsessive-compulsive disorder. Riluzole is a glutamate antagonist that was used in Lou Gehrig's disease or ALS, and was found to be able to forestall the progression of the disease.

Glutamate is the primary excitatory neurotransmitter in the frontal cortical striatal circuit, which has been thought to be involved in OCD and tic disorders. Thus, it's thought to be involved in repetitive behaviors, fixated interests, obsessional thoughts.

Dr. Paul Grant of our group did an open label trial in six children with OCD and found strikingly positive results. On the two graphs to the right, the CY box is the children's Yale-Brown Obsessive-Compulsive scale. In the CY box, higher scores are worse, and the baseline is shown in lavender,

the 12-week rating in maroon and the current, which at that point was six months' follow-up in the lemon color.

You can see that in all patients they had improvements during treatment with the open label riluzole. When we designed the placebo control trial, we determined not only to examine the group of children with OCD only, but also individuals with autism and obsessive-compulsive symptomatology.

As you may know, many of the stereotypies and fixated interests of autism can meet criteria for obsessions and compulsions, but in addition, the children need to have more classic OCD symptoms.

We finished the first 30 subjects, about 15 in each group, and the interim data analysis was positive enough to continue. So if recruitment picks up, we're hoping to have the results of the second half and be able to publish the final results of this trial in a year or so.

Our most recent addition to our portfolio is a study of remittent autism. This trial actually grew out of conversations with Lyn Redwood and Laura Bono, as well as parents at the DAN and Autism One meetings, where they were convinced and I became convinced that we would be missing an opportunity if we didn't look at children who had had dramatic responses or improvements in their symptomatology, either following behavioral interventions, biomedical interventions, or in some cases, almost clearly spontaneous improvement.

So in this study, we're trying to look at what it is that distinguishes those individuals that respond from those who do not have a similarly robust improvement. We'll be enrolling 40 children whose symptoms have remitted, and 40 children, similar baseline, who retain their symptoms of autism.

And as you might imagine, the real difficulty here in not in during our current

evaluations, but in trying to establish that retrospective history, to make absolutely certain that the child actually had autism to begin with, and not an expressive or receptive language delay, which they outgrew.

So there will be an extensive review of medical and developmental records, as well as a comprehensive medical and behavioral evaluation.

Then the remainder of the protocol is very similar to the subtype study, in that they'll have two-day inpatient stay, with an overnight EEG, an MRI scan that would include not only structural measures but also measures that assess neuroinflammation and diffusion tensor imaging, to look at track changes, as well as very extensive neuropsychological testing in this group of individuals, to look at executive functioning.

We are actively recruiting for that study, so I was very glad to hear that the slides will be posted and we would greatly

appreciate referrals. You don't have to know whether or not they'll meet criteria. Just go ahead and suggest that they give us a call, and we will do the evaluation from then. Thank you very much.

(Applause.)

DR. INSEL: We have some time for questions.

MS. BLACKWELL: Sue, thank you so much. That was a wonderful presentation. You mentioned that you -- it sounds like you're primarily working with children, but I'm curious to know if you're working with young adults or adults at all?

DR. SWEDO: Yes, we are indeed. In fact, the remitted autism study is moving into adolescents and young adults. The FMRI study is exclusively young adults. We haven't actually moved into adults as our target population. We tend to use them more as grown-up children, but we have no problems with that.

In fact, in the study that we'll be doing with Dr. Rennert, we'll probably be using adult individuals in order that we can get siblings to donate skin biopsies as well.

MS. SINGER: On the Donepezil study, on the two children for which you already have data, in those kids when you saw an increase in REM sleep, did that translate into improvement in their behavior or in any symptom reduction?

DR. SWEDO: It did, but again we're very hesitant, because (a) of the relatively intensive nature of the study, they're admitted four times to the NIH Clinical Center for the sleep studies, as well as medication administration.

We do our ratings and the parents do their observations, and it does appear that they have improved. But we thought with this relatively short time period, that we weren't expecting dramatic changes.

MS. REDWOOD: Sue, with the

recovery study that you're doing, is there some criteria for enrollment with regard to location, where they live, so we can share that with other families?

DR. SWEDO: Absolutely. For that study, because we don't know how common or how rare the phenomenon is, and because we have the privilege of being able to provide travel for families, anyone in the United States is eligible for that study.

We would pay all travel expenses. All clinical care at the NIH is completely free. That's actually been a good drawing card for many of our younger children and their families, who find that our waiting list is shorter than a lot of folks, and that they can get a very comprehensive evaluation.

DR. INSEL: Just to put in a plug for that, it's an amazing bargain, because the NIH has the ability to -- it may be the only place in the country that can do rare diseases.

This isn't a rare disease, but you could take a rare subtype or a rare phenomenon and bring people in from all over the world, really free of charge, with comprehensive care which, as long as someone's involved in research, doesn't have any other constraints.

DR. RICE: Just to follow up, you mentioned adolescents being enrolled in that study. What is the age range?

DR. SWEDO: For the remitted autism study?

DR. RICE: Remitted autism.

DR. SWEDO: At this point, we're going up to 18. If we don't find enough subjects within the next six to nine months, we may expand that further. But right now the age range is 8 to 18 years of age.

DR. LAWLER: This is really an impressive body of studies that you have ongoing, and I think it provides a great example of the kinds of studies that intramural scientists at NIH can do, that

might be more difficult to do in other arenas.

I'm not sure how much sleep you get. Probably very little. It's really breathtaking scope, and thank you for the many issues that you're trying to address in a very rigorous and careful way.

DR. SWEDO: Thank you, Cindy. I appreciate that. I also have to express my personal appreciation, as well as that of the team, to Tom for suggesting that an intramural program would be useful. I think I was a bit skeptical at the outset.

DR. INSEL: You were a little bit skeptical. I don't think I had to twist your arm for more than about a month, and then it finally happened.

DR. SWEDO: It was scientific skepticism, and I am so grateful, because it just was the right place at the right time, and I think Dr. Gallin is really focusing right now on the intramural program being the laboratory for clinical studies for a number

of different people, and that's one of the things that's most gratifying and exciting, is the number of extramural collaborators that we have, folks who haven't had an opportunity to get the patients and get the patient volume that we can do. So we're welcome to that.

DR. INSEL: Duane.

DR. ALEXANDER: I just want to echo what Cindy said about the appropriateness of the intramural program for doing these studies. These are not easy studies to set up and to get done, or to recruit patients for.

You've got a whole group of them here together now, assembled for testing different hypotheses, different groups of kids, different approaches. You've set that up in a relatively quick time as these things go.

So congratulations and I really look forward to the ongoing results of these.

DR. SWEDO: Thank you.

DR. INSEL: Deb?

MS. HIRTZ: You've clearly shown that one of the major advantages of the intramural program is to be able to get pilot studies going that could potentially lead to Phase 3 trials. So I was wondering, these look so promising. What is the plan for moving forward to Phase 3 trials?

Can the intramural program collaborate with centers across the country, where many more patients are going to be required? It makes it a lot easier if people don't have to travel to Bethesda, so can we then expand to multi-center Phase 3 trials?

DR. SWEDO: Absolutely, and we're working on sort of two fronts. I mentioned the Autism Speaks and Clinical Trials Network, which I'm now one of their advisors, but also the Autism Treatment Network.

For those of you who don't know, Autism Speaks has been able to put together a network of 18 different sites, each of which is responsible for recruiting and evaluating

comprehensively 100 subjects each year.

We hope to be able to expand those if funds are available. But those 1,800 children or adolescents, young adults a year are potential subjects for such studies.

Secondarily, the ACE network, some of the NIH-funded centers, would be ideal places, and the collaborations are not easy, but they're much more possible than they used to be. We know that it works. So at the present time, a number of intramural investigators are actually PIs on extramural grants and contracts. Thank you.

DR. INSEL: Okay. Well thank you very much, Sue. This is very, very helpful, and I'm sure that the group will want to have you come back in a couple of years, when you're up to 800 subjects, and we'll see what the latest research shows from that point.

DR. INSEL: Before we break for lunch, we wanted to focus your attention on something we haven't done in the last couple

of meetings, which is to go through the minutes, which you have in your packages, and you should have received ahead of time.

This is the minutes from the November, December and January and February meetings. So we're open to comments about revising or changing the minutes in any form.

MS. REDWOOD: Tom, these minutes will be on the IACC website, along with the transcribed minutes as well.

DR. HANN: The minutes will occur, be available off of the website and then the transcripts of the meetings also will be available.

We're having some -- technical difficulty seems to be our theme today. Prior to this meeting, we were having some technical issues with that website. So we hope to get those ironed out. But yes, both will be available.

MS. REDWOOD: Because I think the summary minutes, I think you've done a great

job in capturing what transpires at the meetings. But at times, it's really difficult to do that. So having the actual transcribed minutes, I think, is very useful too.

DR. INSEL: Any changes recommended?

Hearing none, we need to take a vote, and if there are no recommendations. Alison?

MS. SINGER: There's one little change. On the January 14th minutes on page ten, line 23, it should be BBD&O instead of DDB&O. The ad agency is BBD&O.

DR. INSEL: I'm certain we can make that change. Any other recommendations?

MS. REDWOOD: Can we -- we just received these sort of late. I think it was toward the end of last week.

If we could get them a week or so before the meeting and vote on them at each meeting, I think that would be helpful, than having four sets of minutes to try to review

at one time, a day or two before travel.

DR. INSEL: Does the group feel comfortable voting on these, or do you want to have more time to review them?

I don't see any concerns about that. Can I see a show of hands for approval, and then we'll look and see if there's disapproval?

Approved. Any disapproval, abstentions?

One abstention. On the phone?

DR. COOPER: Approve.

DR. INSEL: Anyone else on the phone?

DR. HOULE: Yes.

DR. INSEL: And anyone else?

Okay, thank you. We're actually at a point where we can break for lunch. We're going to reconvene at one o'clock to hear about augmentative communication, and also to hear about complementary and alternative medicine, and particularly hear

from the head of that particular center. See you at one.

(Whereupon, the above-entitled matter went off the record at 11:49 a.m., and resumed at 1:01 p.m.)

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

1:01 p.m.

DR. INSEL: We are ready to reconvene for the afternoon session, and welcome to those on the phone. We have Judith. Anyone else on the phone at this point?

(No response.)

DR. INSEL: Well hopefully we'll have others joining us fairly soon, and Judith, it sounds like you're able to hear us okay?

DR. COOPER: Was that you Tom?

DR. INSEL: Yes.

DR. COOPER: Yeah. You're like a minute behind the video or ahead of the videocast. Yes, I can hear you fine now. Thank you.

DR. INSEL: Okay, great. Well, we're going to start the afternoon session, which is on augmentative communication, and we have two people joining us for this. The

first is Dr. Joanne Cafiero, who -- we're getting --

DR. HANN: Judith, can you go on mute?

DR. INSEL: Thank you. Whose work with autistic children and individuals dates back to the mid 1980's, wen she trained -- we're going to need to have someone mute their phone. Thank you.

If only all problems were so easily solved. When she trained and worked at the Bittersweet Farms autistic community in Whitehouse, Ohio. Later she taught adolescents with autism in the Montgomery County, Maryland public school system, where she developed and implemented a program for non-verbal children using state of the art communication technology.

She earned a Ph.D. from the University of Toledo in 1995, and she was appointed to the National Academy of Sciences Committee on Education Interventions for

Children with Autism.

Her current research focuses on how children with severe communication impairments in autism learn language, which models of instruction are most effective, and how to take this information from research to practice.

She's authored many articles and books on augmentative communication for people with autism, including Communication Power for Individuals with Autism, and A Parent Guide to Picture Language. Dr. Cafiero, it's a pleasure to have you here with us, and I'm going to turn the microphone over to you.

Speaker - Dr. Joanne M. Cafiero

DR. CAFIERO: Thank you. I'm very happy to be here today, and to talk about my favorite subject, autism and augmentative and alternative communication for individuals with autism spectrum disorders.

I'm going to talk about the research, but I'm also going to discuss some

promising practices, because this is a very, very early stage of really exploring how AAC works for individuals with autism. So I don't want to avoid those promising practices that are so important.

I'm going to talk a little bit about the features of ASD and AAC, and how they have an interesting feature match, and then look at evidence-based practices, functional communication training, picture exchange, visual supports, activity schedules, the augmented input strategies, speech-generating devices and then keyboard communication systems.

There are many myths about autism and AAC, and hope that my little half hour talk today will dispel some of those. First, that AAC will inhibit the development of speech. If an individual with autism has speech, they don't need any AAC. If you provide AAC, the person will automatically use it, and if they don't use it within a specific

time frame, that means it's not a viable intervention.

And finally, that no tech or low tech interventions are a better way to start. I'd like to talk about those issues as well. We know the learning characteristics in autism. I'm not going to go over that with this group.

But I would like to talk a little bit later about how there's a feature match between the characteristics in autism spectrum disorders and AAC.

Just to build a little bit of a framework, Meredith Edelson did an interesting review of the literature on autism and cognitive impairments, and she found that 74 percent of the claims on cognitive impairments were from non-empirical sources.

I think this is extremely important when we're talking about communication. If we make the assumption that a large percentage of individuals with autism,

70 percent which is what's stated in the DSM-IV, do have cognitive impairments, there's going to be a qualitative difference in the kind of intervention, communication intervention we provide for someone with autism.

What she found was that many of those scores were on adaptive functioning scores, not cognitive assessments, and of course they were language-based and providing a language-based assessment to someone with a language disability doesn't seem to be exactly scientifically sound.

So that is the framework for where I think we all need to go, where we need to be in terms of AAC and autism.

In addition, autism and motor impairments are something that many of us have not thought about, and there's a new body of research that's addressing that. Leo Kanner and Hans Asperger in 1943 and 1944 stated that their clients that exhibited those qualities

that they called autism or Asperger's also had motor impairments.

In another study by Provost, Lopez and Heimer in 2007, found that 100 percent of the sample children with autism had fine motor deficits. Another study found that 41 percent of children with autism, two to six, had oral, motor and hand-muscle apraxia.

This has a critical effect on an AAC intervention. If there's motor planning difficulties, then how can they access a device effectively? That really makes all of us who are in this field be much more cognizant of that, and provide interventions that really enable them to use their skills and to address those motor deficits.

Some more research on difficulties with the reach to grasp movements done by Rhinehart. Atypical motor preparation, movement preparation, impaired motoric preparation and impaired movement towards goals. These are all studies that are showing

that individuals with autism have motor impairments and motor planning difficulties.

We also know that there's a link between autism and comorbidity with affective disorders, which also may affect communication. All this creates a framework to make the intervention with AAC much more critical and much more complicated.

We know that individuals with autism, 50 percent of whom don't have functional language, and it may be limited to requesting and refusing, and early AAC interventions seem to focus on requesting and refusing only, and once a child or a student or an adult can request or refuse, they consider the intervention successful and completed, when we really need to go much deeper.

We know that individuals with autism have unique developmental sequences of language skills. Sometimes symbolic language does not emerge until adolescence. But we do

know that functional spontaneous communication, more than any other skill, will define the quality of life for individuals with autism, which is why it's so critical that we consider AAC.

What is it, exactly? First of all, there are no prerequisites required for an AAC intervention, and I'll talk about that in a little bit. It compensates for and replaces speech. But for someone who has some speech that is not commensurate with someone their own age, a typical developing child or student, AAC may be a viable option.

It is also multi-modal. It's not meant to replace existing speech or existing appropriate gestures or body language. It's to supplement and enhance what is already there.

What's extremely important, we are finding that AAC supports the development of language, not just unlocking language that maybe not able to be expressed because of

these motor difficulties, or some of the other complex issues in autism, but providing an AAC intervention is a tool for developing language, as well as for unlocking language.

AAC includes manual signs, low tech such as picture language boards, and I'll show you some of those, as well as high tech sophisticated computer devices. So we talk about aided AAC, which is AAC that requires any tool or device, and unaided AAC, which is you use your body -- sign language, gestures, facial expressions.

Here's the feature match that I spoke about. Many people with autism are visual processors. AAC uses a visual medium. Motor planning is an issue for individuals with autism. Using AAC requires less motor skills than using speech.

Difficulties with multiple cue responding, which we know is a feature of autism. With an AAC intervention, you can provide the scaffolding to include more and

more complex cues for the person to process and then to generate language.

Social difficulties are also an issue in autism, and an AAC device can be a buffer between two people and a bridge between two people. The interest in inanimate objects we see in individuals with autism, AAC uses inanimate objects. So there's an interesting feature match there.

Millar, Light and Schlosser in 2006 and Pat Mirenda in 2003 did a comparison of aided and unaided AAC, aided meaning using a device, a tool, a computer, a picture language board and unaided, gestures, body language and sign language.

In comparing the two, obviously unaided is more portable. There's an unlimited vocabulary. However, we find that it requires very, very sophisticated fine motor skills, which many individuals with autism don't have.

So we see many children and adults

that are using sign language, and the signs are idiosyncratic, sloppy signs that are understood by familiar communication partners, but not understood by anyone that is not a familiar partner.

Aided AAC requires less complex fine motor skills. It's more readily comprehensible, but it's not readily portable. But what Millar, Light and Schlosser and Mirenda found was that there is -- none of these is superior to the other. Aided and AAC, there's no research that has shown that sign language is better than graphic symbols, or the other way around.

Oliver Wendt and Ralph Schlosser completed a study in 2008, in which they reviewed all the research that they could find from 1975 to 2007 on AAC and autism, both aided AAC and unaided AAC.

They had a very stringent criteria for their inclusion in their meta analysis. They looked at the calculation of percent of

non-overlapping data, which is what we do when we're looking at single subject design.

And 20 of the 22 datasets that they looked at, the percentage of non-overlapping data was between 80 and 100 percent. So many, many studies were discounted unless they fit that criteria.

The data was taken from both peer-reviewed and approved dissertations, and in approved single subject and group design. When they looked at all those studies from '75 to 2007, they found five that fit the criteria that were PECS studies.

One was a manual sign study and three utilized speech-generating devices. So you see that we are really in a very, very early stage of looking at AAC for individuals with autism.

What he found was AAC does not inhibit speech production, which is extremely important. We find many parents will say "I don't want to provide a device for my child,

because I don't want that child not to speak." But they found that it does not inhibit speech production, and in fact showed modest increases in speech. So this is very, very important.

What are the evidence-based practices in AAC and autism? The oldest one is functional communication training, and there are many, many studies in the Journal of Applied Behavior Analysis showing functional communication training is an effective strategy, which uses both aided and unaided AAC for individuals with autism.

The second is the Picture Exchange Communication System, PECS, which uses graphic symbols and there are many studies supporting the validation of that.

The augmented input strategies are a somewhat different approach, in which the speaking communication partner uses the device him or herself, and provides augmented receptive input to the child with autism or

the student with autism.

Then fourth, speech-generating devices. Now the augmented input strategies, speech-generating devices and functional communication training, they all have an overlap. So I treat them that way, but many of them overlap. Picture Exchange Communication System is more of a separate strategy.

When we look at functional communications training, Mirenda did a review of the literature in 1998 and she described it as using PCS, Picture Communication Symbols, objects, speech-generating devices or any sort of ideographs.

In FCT, all behavior is viewed as communicative. So that's the approach. When a child does a difficult behavior, what are they trying to communicate?

FCT replaces aberrant behavior with communication, and the FCT intervention must be as efficient, acceptable and

recognizable as the aberrant behavior is, in order to be effective.

And what she found was in all her studies that she did and her meta analysis, was that functional communication training produced immediate, substantial and sustained decreases in aberrant behavior.

This is just an example of some of the picture symbols we might use as a replacement for aberrant behavior. If a student engages in aggressive behavior because they need a break, then we teach them to ask for a break using that symbol, or using the sign for a symbol, a sign language asking for a break rather than the aberrant behavior.

"I need help" would be a symbol that they use if their behavior is attention-seeking. "I want chips" would be if their behavior is a desire to ask for a tangible thing, or "I want the quiet room" if they're on sensory overload. So it's simply replacing a communicative behavior for an aberrant

behavior.

Picture Exchange Communication System is a very systematic ABA strategy with sequential protocols, in which the student exchanges a symbol of an item for the desired item. It is an expressive language strategy only. It's a way for the child to express what they need or what they want or what it is they want to comment on.

It acknowledges the communication partner. So the child or student has to approach the communication partner, hand them the symbol for, for example, if they needed a break, and that's an important part of PECS. It requires the person to person contact. Approximately one-half of the children who were in a PECS intervention developed speech.

All right, speech-generating devices. This is where we get in some exciting and sophisticated areas. A low tech device can involve one location, one cell, up to 32 cells or single and multi-level cells.

It can be a high tech sophisticated communication device, much like what we see the individual with ALS -- I'm trying to think -- that Steven Hawking uses.

We have people with autism that are using devices that are very sophisticated. The speech output or voice output device, speech-generating devices, summons the attention of a communication partner.

So if a child is using a no tech device, where they have to point to something they want, or hand over a symbol for something they want, they might not get the attention of their communication partner, whereas a voice output device does.

A speech-generating or voice output device is a model for speech. It can be used alone or with other AAC. So it's not necessarily used by itself. Again, AAC does not replace any functional language that's already in existence. It's to supplement, it's to enhance it.

Schepis, Reid and Behrman and Schepis, Reid, Behrman and Sutton did some studies on speech-generating devices with children with autism, and found that they were effective. Then Romski and Sevcik have done some really wonderful work on the augmented input model, where the speaking communication partner is using the device, paired with their own speech, as a model of how do you use the device, and they have found that that is also extremely effective.

So the augmented input model is another overlay of how to address an AAC intervention with someone with autism, where the speaking communication partner is an essential user of the device.

Using speech-generating devices was found to really affect some other behaviors in autism that are significant. We're seeing in the work that I'm doing, children are shifting attention from the device to the communication partner. They're

engaging in joint attention when they have a speech-generating device, or an AAC intervention.

Dattilo and Camerata and the others that I'm citing found that the use of the speech-generating device was done spontaneously, not immediately preceded by a prompt, and that also using speech-generating devices increased other communicative behaviors.

Some of those pre-linguistic behaviors that we don't see children with autism engaging in, such as gestures, shared attention and shifting attention, making vocalizations.

The augmented input strategies are important to note. In these strategies, the communication partner is essential, and it involves an receptive and express language intervention, not just an expressive language intervention where the child or student is provided with a device, and then they are

trained to use it, without the communication partner using it him or herself.

Using the augmented input strategies means that the AAC is viewed as a language that is shared between the communication partners. Some of the augmented input strategies are natural-aided language, the system for augmenting language. Some visual routine schedules can be augmented input strategies.

If you're pointing to something that just is done, the next thing that's going to happen, you're providing augmented input and -- language modeling. So these are all part of -- a way to address an AAC intervention.

We found they are effective in increasing spontaneous communication, based on my work, Mark Dexter's work on storybook-aided language, Marcia Acheson from the University of Cincinnati, Janice Light and Drager and Romski and Sevcik.

All of us who have done this work agree that the communication partner needs to model using the device naturally, rather than providing a device and expecting the child or student to use it without the modeling of the communication partner.

This is an example of communication placement board that we use with many of our children in autism preschool programs. When you're using a communication board like this, if you're talking to the children, you'll say "You want to share your cookies," for example?

You point to the icon and you pair that pointing with using speech. So you are giving augmented input. So if you say "Do you want more cookies," you would say the word as a communication partner and you would point to both of the icons indicating that. That's really what the augmented input strategy is all about.

In a study that I did in 1995, I

found that when the parent gave augmented input, the child tended to give more output, and there was a correspondence between the input given by the parent and output generated by the child.

In another study that I did, I found that if you increase the input that you gave to an individual with autism, you got more output.

So this is just a nine symbol no tech communication display, but when you increase it to a larger number of words, including nouns, verbs, comments, descriptors, we found that we got -- that we were able to affect greater communication, longer mean lengths of utterance, more spontaneous language.

So the more input we gave, the more output was generated. This is a study that I did, actually an action research project that I did when I worked in Montgomery County Public Schools. But it does -- I'm

sharing it because it does mirror the augmented input strategies that my colleagues have done.

Again, this just indicates at baseline the number of spontaneous initiations at the intervention. When we increase the number of vocabulary words that we use to converse with the child, they generated more language. After extended school year, when they weren't getting a lot of input, the spontaneous language decreased. After extended school year, it went up again.

So we also found that if the individual with autism doesn't get continuous augmented input, their output decreases. Interestingly, as this student was able to generate more communication, the difficult behaviors decreased.

This is a study done by Romski, Sevcik and colleagues from Georgia State University. It's a retrospective analysis. They did this study in 2006 with 60 toddlers.

They were randomly placed in one of three groups.

Now initially, there were no individuals with autism in this group. As they looked back, they found there were actually 11 children with autism in the group. What they found in this study -- first they trained the parent in helping these children generate speech.

In Group 1, and it was randomly placed, they had no AAC provided. Romski and Sevcik used speech-generating devices and the augmented input model. So in Group 1, the parents were trained to stimulate speech in the children, but no device was used.

In Group 2, they did aided AAC. A device was provided, where the focus was on giving augmented input. So the parents learned how to give input to the child without expecting or providing the scaffolding for the child to give any output.

In Group 3 was an aided AAC again,

but the parents were trained not only to give input, but to help the children generate output. The model was they used a speech-generating device. They selected a relevant lexicon or vocabulary and used visual graphic symbols. They taught through natural exchanges.

Actually, each of the sessions were 30 minutes long, and there was ten minutes of play, ten minutes of storybook reading and ten minutes of snack time in which the parent worked on language.

The communication partners integrated the speech-generating devices in Group 2 and 3 into their own spoken language. Here's the results of that study. There's many more graphs I can show.

But I'm just going to show this one, in which after 18 weeks and after 24 weeks, the children in the AAC group were generating a larger percentage of the target vocabulary than the speech-only groups.

What's important about this is at the end of the study, we found that both groups of children were using speech, but between the 18 and 24 month period, we found that the children that didn't have a device had no way to express themselves.

You see they were using only about one and four percent of their target vocabulary. So they are telling us, Marianne Romski and Rov Sevcik, that children who receive augmentative communication input, or augmentative communication output interventions were able to communicate using symbols after 18 sessions, and generalized and maintained this language at home.

Children in the SCI, which was the communication without an AAC device, could produce only few words by 18 sessions, and had no conventional way to communicate while learning to speak.

The results of related studies in natural-aided language, aided-language

modeling, assistant for augmented language provide preliminary support for suggestions that language modeling with symbols and natural context may be a viable intervention for children with ASD.

Let's talk about non-activity specific communication displays and devices, and I know that I'm putting a whole body of AAC knowledge out there, and I know I'm not giving you enough background. So I'll be available to talk with you afterwards if there's questions you have.

But when we're looking at devices that are not activity-specific, what do we look at? Motor planning, core vocabulary. We want a device that can increase and grow with the child, in terms of vocabulary and communicative function. We ask ourselves what's the access mode? Are these children requiring the use of visual discrimination or motor memory?

Those are questions we really

haven't answered yet. Preliminary data shows that there may be groups of children for whom motor memory is the way to go, and they need a device in which every icon is in the same place at all times, so that their motor movements are always the same to access the device. Not all, but there may be a subgroup of children for whom that's the way that's most effective.

When we're looking at AAC, we're also looking at core vocabulary and fringe vocabulary. Core vocabulary is more open-ended, applicable to many situations. Fringe vocabulary is very specific to a particular activity.

For example, if we look up here. Now this is an overlay for a mid-tech AAC device. Core vocabulary, this might be core vocabulary for a variety of cooking activities. But all this language is appropriate for any cooking activity, whereas the fringe vocabulary is specific for making

waffles, for example.

This is an eight location device in which we're using phrase-based core vocabulary. So you see that this vocabulary may provide the vocabulary needed to access a communication effectively across multiple environments. It's very limited, but we have to understand that's really where we're at. We are really at the very beginning stages of understanding AAC and autism.

So we know that individuals with autism do have strong visual processing modalities. We know that visual discrimination supports literacy learning, but it requires a huge number of symbols.

A motor memory device. Speech is motoric, so AAC maybe should be a motor act. Promotes more automaticity and training in the device is essential for communication partners, because many of our devices that rely on motor memory are extremely complex.

Okay. I'm going to just go

through a brief case study. How am I doing on time?

DR. INSEL: Well, we can take a couple more minutes. I think what we'll do is we'll have some time for discussion at the end. So maybe we'll take two or three minutes now and we'll come back afterwards.

DR. CAFIERO: All right, I'm going to go through. This is a brief case study of a little five year-old, who was provided with a very high tech device. He had no means to communicate. This is the overlay of the device that he used, and he was able to navigate from this page to other pages, and effect from communication.

Actually what happened, this was a little guy who was a head-banger. Head-banging stopped once he had that device. So the communication partner viewed it, his device, as his real voice. The navigation strategies were modeled naturally the incidents of self-injurious behavior decreased

over the course of seven weeks.

Also what we found is as his vocabulary increased, his SIB decreased. I'm going to move on here. There's a variety of devices. There's a new device out now that loads onto an iPhone. If any of you have heard of that, it's called a ProLoquo2Go. It's inexpensive I think something that we really need to think about doing research on.

This is another overlay picture word power that's put on a variety of devices. I'm just going to skip this one. I want to talk a little bit about the autism advocacy movement, which is critical.

People that are diagnosed in the autism spectrum have a lot to tell us about their experiences as someone with autism, and their experiences with the assumption that they did not have cognitive and communicative potential.

So we want to really focus on getting information from them on how we

approach AAC interventions. Assessment tools should be open-ended. We don't look at what a student can't do; we look at what he needs to do to be effective in the environment and to have the best quality of life, and what assessments address those.

The research questions. Entry level AAC. Do we start with no tech, low tech or high tech? Do we look at visual discrimination or motor memory? Do we do structured-direct ABA approaches or more natural language approaches.

And for a maintenance AAC device, where do we go, low tech, no tech or high tech? Communication partnerships are essential. The speaking communication partner has to view that device as the ears and the voice of that student.

The goal is spontaneous novel utterance generation. That's what we want for all our individuals with autism. The ability to say anything about anything at any time.

So to recap, augmented communication, communicative input is the key, regardless of communicative potential.

Assume communicative potential regardless of and perhaps because of behavioral issues. AAC helps develop language. There should be no arbitrary time lines, and functional spontaneous communication is critical.

Pat Mirenda describes it very well, in the immortal words of Mick Jagger. "We can get no satisfaction" until we figure out how to provide every individual with ASD with a viable, robust, flexible and generative communication system that will support long-term language development." That was a crash course in AAC and autism. Thanks.

(Applause.)

DR. SHORE: I have a comment when people are ready.

DR. INSEL: Well, we have another speaker, Stephen. I think what we'll do,

given the time, is we'll move on and then we have a half hour scheduled for discussion with both Dr. Cafiero and with Dora Raymaker, who is on the line and waiting to join us as well.

DR. SHORE: I'll be gone at about two o'clock, because I have to teach a class.

DR. INSEL: So go ahead and make your comment now, and the rest of us will have a chance to talk about this in more detail later. Go ahead.

DR. SHORE: All right. I think the importance of alternative communication devices, augmentative communication devices cannot be overstated, and as was suggested many times through the presentation, there are many situations where a person on the autism spectrum is considered to be almost a non-person, and not having much in the way of cognitive ability until --

And sometimes this even happens by mistake, when they're in close proximity to a device, such as a computer keyboard for

example, and then they start typing something out, and we find out that they have at least as much cognitive wherewithal as we do.

I think the presentation was just great, and the more we can do to assist with communication, the better off we'll be.

DR. INSEL: Great. Thank you for joining us and for sharing those thoughts. Now we're going to go on to hear from Dora Raymaker, who's going to join us by phone, as I understand. I'll just quickly introduce her as the co-director of the Academic Autistic Spectrum Partnership in Research and Education.

She's a board member of the Autism Self-Advocacy Network and a member of the Self Advocates as Leaders. She's a Master's student in System Science at Portland State University in Portland, Oregon, where she studies complex systems.

She's an autistic self advocate and a user of augmentative and alternative

communication.

DR. HANN: Dora, please start your presentation now.

MS. RAYMAKER: I want to make sure you can hear me well. How is this volume?

DR. HANN: This is good. Thank you.

MS. RAYMAKER: Okay, thanks. Hello, and thank you all for giving me this opportunity to address you on the important topic of augmentative and alternative communication.

My name is Dora Raymaker. I am co-director of the Academic Autistic Spectrum Partnership in Research and Education, AASPIRE, and a Board member of the Autistic Self-Advocacy Network.

AASPIRE is an academic and community partnership between research professionals at Oregon Health Sciences University, Portland State University, University of Wisconsin-Madison and the

autistic adult community.

AASPIRE conducts community-based participatory research on issues that are of importance to the autistic adult community. The Autistic Self-Advocacy Network is a non-profit organization run by and for autistic people, whose activities include public policy advocacy and social support groups.

It is a community-based participatory research, in partnership with AASPIRE, advancing autistic empowerment and culture, maintenance of a speaker's bureau and increasing public understanding about individuals in the autistic spectrum.

I am also a Master's student in the System Science program at Portland State University, and a member of Self Advocates as Leaders, my state, Oregon's branch of the National Self-Advocacy Organization, self-advocates becoming empowered.

I am an autistic person and an augmentative and alternative communication or

AAC user.

Next slide, Why we care about communication. The autistic self-advocacy community cares about communication. The following are quotes from autistic individuals.

From Joel Smith, "One of the biggest keys to an autistic person getting the life they want is for that autistic person to be able to express, in a way that allows the largest number of people to understand, their own desires and thoughts."

From Alberto Frugone, "Communication freed me from the pain of compressing my human dimension into empty silence." From Donna Williams, "One of the most important pieces of ammunition people have for their own self-protection is the ability to act and the ability to explain. Communication means empowerment. It means the ability to communicate one's self determination. Communication is necessary for

self-advocacy."

Next slide, Overview. I am talking with you today to emphasize the need for your support in enabling autistic individuals to have the greatest number of opportunities for communication possible. For some of us, communication involves speech. But for others, speech may impede or even prohibit our ability to communicate.

So I'll start now with communication versus speech.

There are many ways to communicate without speech. Augmentative and alternative communication devices and technology can provide a wide range of options. Your support of research and programs related to devices and technology will substantially benefit both autistic people and other AAC users.

A device alone, however, isn't the ticket to effective augmentative and alternative communication. Access to devices and attitudes regarding the use of AAC are of

equal concern to the self-advocacy community, and equally necessary for effective communication.

Your support will also be welcome in evaluating and removing access barriers to alternative communications and ensuring service, supports, therapeutic and educational programs related to AAC operate effectively.

Next slide, what is communication? Communication is a process that occurs between at least two entities, and can be visualized by this model, called the Shannon Weaver model of communication. A sender has a message, which she transmits through a channel to a receiver.

During transmission noise may distort the original message. The receiver decodes the message and then he feeds back to the sender an effective communication, meaning equal and symmetrical exchange between the sender and receiver. There is a dynamic that occurs through the feedback, where the sender and receiver actively influence each other.

In order to have reciprocal communication, both the sender and receiver must play an active and equal role. While this is a former model, it is considered inaccurate, a simplified representation of communication between people.

Communication is not something a single person can sort of not do. Communication is a dynamic interaction, a dynamic process.

Next slide, elements of communication. Communication is not speech. Communication is made up of a message composed from perhaps English or maybe compressed binary code, or maybe something that can be touched. Both the sender and receiver need to be able to encode and decode the message.

The mode of communication relates to the channel the message is transmitted through. The mode may be sign and speech and hearing, but it doesn't have to be. The mode could be reading and writing, or any number of

other possibilities.

Communication also involves time. In the case of a telephone conversation, transmission and reception occurs synchronously or in real time, meaning that the message passing between communication partners is synchronous send-receive send-receive send-receive.

If instead of the telephone, that you communicated by using email, message passing would be asynchronous. The receiver may respond to subsequent messages from the sender before he decodes and responds to the first message sent.

Next slide, communication, an autistic experience. As you know, autistic people may experience the world differently from people who are not autistic. These experiences may affect communication. Some reported sensory differences, such as difficulty separating foregrounds and background sounds that cause noise distorting

the person's ability to decode auditory information.

Think of this exactly like too much static on a phone line. The same sort of noise could occur for other senses, like visual or tactile. Movement differences, such as apraxia or dyspraxia are experienced by some. This can make planning or execution or a normal type of movement such as speaking words painful or impossible.

Some autistic people record a slower rate of processing information, where message exchanges happen -- they can understand them. Some autistic people may also experience differences in comprehension or use of language.

For example, difficulty understanding the pragmatics of the social context in which language is used. A particular type of message and coding or mode may be difficult or impossible for an autistic person to use, much the same way -- may encode

his messages would be for someone who is blind.

Please note these experiences are by no means universal. Not all autistic people have these experiences.

Next slide, AAC and building bridges. AAC can assist with reducing or eliminating these sorts of barriers to communication, because it changes the elements of communication involved in an exchange.

AAC can change the type of message and tagging, for example from English to American Sign Language, or from English to picture.

AAC can change the mode. For example, from sight and speech and hearing, to reading and writing or to kinetic, motion-based or tactile mode. AAC can change the timing, for example from real time to asynchronous exchange, or perhaps simply slow down the rate of a real time exchange to a more manageable speed.

Further, AAC has been known to serve as a bridge between one type of communication and another. For example, Jamie Burke started out with typing and used that as a bridge to speaking. Speaking, however, should not be assumed to be an appropriate or desirable goal for everyone, communication is. This one style of communication are a natural part of human diversity.

Next slide, AAC devices. AAC is not strange or new, as a need for augmentative or alternative forms of communication have always existed. As the advances you're not aware of in modern communication, technology continues to explode, more and more AAC devices are being developed.

AAC devices can use a wide range of different types of message and coding, like the device I'm talking to you with now requires literacy. Others, like the hospital communication board on this slide allows for both pictures and words to be used. They

might have pictures only.

Still others use symbolic languages for encoding, such as Blissymbolics, which you can see an example of at the top of the slide. Devices make use of all types of technology, and must have paper such as a cardboard communication board or -- to high-tech computerized voices like this one I'm speaking to you right now, and everything in between. That's prerecorded messages. There are many, many available options.

Next slide, other AAC and communication systems. A communication device, however, is not the only form of AAC. Gesture, body language, sign languages and consistent idiosyncratic behavior, like shaking one's head when overjoyed, are alternative or augmentative forms of communication.

Device alone is also not a communication system. Communication systems, what people actually use for communications in

day-to-day life, can involve any combination of devices, other forms of AAC and typical spoken or written messages.

Some devices are used in my communication system that is a speech synthesizers, speech synthesis software on my iPhone, or low tech note pad and pen, a talking picture frame, and make communications hard and non-disability related technologies such as email, Internet chat and SMS.

My communication system also includes non-device parts such as speech, gesture, live speech forms, specific behaviors, and using other people as interpreters.

Next slide, variable roles for AAC. AAC can serve different roles for different autistic people. Some may use AAC method most of the time; others, part of the time. Still others only in certain situations.

For example, when under stress or

communicating with strangers, just because an individual may not need or want to use AAC at one time, does not mean that an individual won't ever need or want to use AAC at some other time.

Thus, AAC users do not use one single method of communication all of the time. Everyone, not just people with disabilities, use AAC. You use AAC when you smile by saying "I am glad to see you," when you send an email and when you hold up a finger for someone to wait, instead of saying "hold on a moment."

Next slide, "Understanding autism-specific needs." Even though AAC has been around for a long time, there may be some autism- specific needs which have not been well-addressed yet. Technical needs, like device design, is one area.

One example is that often devices are designed with the assumption that the user will be seated in a wheelchair. So

approachability may be one area in which autistic people have different needs from the majority of other speech device users.

Strategies for AAC users is another area. Like considering autism-specific abilities and disabilities in the development of AAC training.

For example, my speech therapist once gave me a lovely article that included strategies for how to use socio-cultural norms to compensate for the strangeness of my device. Needless to say, it wasn't very useful to me, except perhaps to illustrate this point.

A third area of consideration is examining autism-specific cognitive needs. For example, the need to examine assumptions about autistic people cognition and communication before presuming a particular type of device would be useful.

As one example, the notion that we all think in pictures may lead to the mistaken

belief that picture-based AAC devices, like those that use the picture exchange communication system, are appropriate devices for all autistics.

This may focus funding and research on those devices, while solutions that may be more appropriate for other autistic people, particularly those who may have difficulty with visual processing or who are blind, remain unexplored.

Next slide, examination of disability bias. Since AAC has such a rich history, there is a lot that can be learned from AAC using other populations that can be applied to autism. One area of concern to self advocates is that viable AAC strategies for autistic people may be discounted, due to incorrect assumptions about autism.

So the incorrect presumption of mental incompetence close communication doors are open to people with other types of disabilities. For example, the use of

communication assistance. Another area of concern is that the realm of speech is over-emphasized for autism. This is an issue that has come up for people with other communication disabilities in the past.

For example, a system that deaf people learn to read with and speak English and not use their native sign languages. While these old ideas have fallen by the wayside for others, as they should, they remain a firmly entrenched paradigm for autistics.

What doors might open by thinking about autism in a new way, and looking at communication instead of speech and their applying the lessons learned already from people with other disabilities to the autistic community, through a communication device that works on brain waves, like that recently developed at the University of Wisconsin, benefit an autistic person who has severe difficulty initiating -- movement.

Next slide, improving technology. Some additional areas which could use funding, support and examination regarding AAC device technology is speech synthesis improvement and application of new technology into AAC equipment, incorporating current advances in technology into AAC projects.

Developing new technologies in the end -- need for devices, and developing more affordable devices, a critical access issue, are all areas that could use attention. These sorts of investigations would also have benefits for a far larger population of AAC users, as well as potentially having applications for the non-disabled population.

Next slide, evaluation and inclusion. Evaluate a wide range of AAC devices, AAC systems and AAC-related therapies more thoroughly. This includes both existing technology and new technology.

New technology doesn't have to mean new devices. It may mean evaluating the

use of an existing device developed with a different disability in mind, such as the brain wave communicator.

Most importantly, however, include autistic people in the development process of communication solutions that are intended for us. We know what works and what does not work. Ask us. Historically, the success of assistive technology depends enormously on whether the technology was designed with direct inputs from the end user or not.

This can be seen, for example, in the wild success of ultra-light wheelchairs, as well as in the success of the ultra-light AAC device, which was designed by man who lost his ability to speak at age 21.

Next slide, Access to communication is a civil right. The American Speech Language Hearing Association makes the following position statement: "It is the position of the American Speech-Language Hearing Association, ASHA, that communication

is the essence of human rights and that all people have the right to communicate to the fullest extent possible.

"No individual should be denied this right, irrespective of the type and/or severity of communication, linguistic, social, motor, sensory, perceptual and/or other disability." If I may present, like accessible buildings, accessible communication is a civil right.

Communication-related accommodations, such as use of a communication device or sign language interpreter, are protected by disability law. Focus on speech instead of communication may deprive autistic people of their right to communicate.

Next slide, price barriers to access. Price of devices or AAC-related training is a formidable barrier to communication rights. Dedicated speech devices cast out into the gutter; picture or language libraries, 500. being evaluated for

or trained on an AAC device or communication system incurs professional costs.

The ability for a person to test out a device in natural environment before committing to purchase may be limited. Insurance, if a person has it, is typically not helpful.

Next slide, institutional barriers to access. ASHA represents that my right to communicate is at issue, again exemplified by the inappropriate emphasis on speech rather than on communication.

This may come from the social stigma associated with disability in general, that it somehow better to suffer to appear non-disabled, no matter what the cost, than it is to appear at all disabled, even if the person is truly not functionally able to look less disabled without this facade.

This is a problem with socio-cultural attitude, not with the disabled person.

Next slide, other barriers to access. Finally, some systems may limit individuals' access to AAC. For example, some schools will not allow an AAC device to be taken out of the school. This effectively means the student is only allowed to communicate for several hours a day.

Not only is this understandably very frustrating, but it also reduces the amount of time the person can learn to improve their communication skills. A person should be able to communicate and learn how to improve communication all of the time, not just when it is convenient for others.

Lack of understanding of how disability accommodations work is another barrier to access. I heard a story just last week of an autistic boy who communicates using American Sign Language. He has limited speech and limited literacy.

His schools have refused to provide an interpreter for him on grounds that

he not deaf. But legally protected disability accommodations are not tied to a specific disability. They are tied to individual needs.

Next slide, evaluating service delivery and therapy. When are going to have research that would help autistic people access their right to communicate an evaluation of the service delivery system that provide AAC devices and training to autistic individuals, including medical facilities, schools and therapy centers.

Research on whether the federal, state and educational programs that provide AAC are doing an adequate job. What can they do better? Develop interventions to improve the delivery of AAC technology to all who could benefit from it.

Another area to evaluate more closely and scientifically is therapy that focuses on AAC, and especially on multiple kinds of AAC, not just picture cards. Are

these therapies beneficial?

A third area to evaluate is what sort of communication or behavioral improvement occurs from therapy that focuses on the process of communication, rather than the mechanics of speech, and that means actively including communication partners in the therapy.

Communication partners are required for the requisite dynamic of communication.

Next slide, summary. Augmentative and alternative communication devices and other technologies can help autistic people communicate. We would like better understanding of technology needs, improvements to technology to meet those needs, and to be included in the dialogue with developers and end users and primary stakeholders.

We would also like some assessments of access and attitude, including

more rigorous understanding of access barriers, interventions designed to remove those access barriers, and more involvement of communication partners and the community in communicative activities.

However, in all cases, we want communication that actually works for us, not communication that others think should work for us. There are so very many ways to communicate.

Next slide. There are many ways to communicate. But in some cases, an autistic person may want to speak. If that's so, then they should be given every opportunity to learn. However, a lot of us have other ways of communicating. I learn a lot more than I do talking or being expected to talk or -- communicate adequately that way.

There are other times where I don't use language at all, and I am having a really hard time finding assistive technology to deal with that. But the fact that I am

having a hard time finding that technology doesn't mean I shouldn't have a right to communicate in whatever mode is possible for me to communicate.

Not only do I have that right, but I have the right to choose what mode of communication is appropriate for me, and blend. There are many forms of communication, and all of them are okay and all of them should be open to all of us, because communication is so very important.

Next slide, why we care about communication. The self-advocacy community cares about communication. We cannot express our needs without it. Adam Keith and Cheryl Smith, "One of the biggest keys to an autistic person getting the life they want is for that autistic person to be able to express, in a way that allows the largest number of people to understand, their own desires and thoughts."

I would not have been able to give

this presentation today without augmentative and alternative communication. I would not be able to express my needs, my desires and my dreams. AAC will begin this necessary shift to more quality of life and discussion around others and research.

Please encourage Secretary Sebellius to bring someone from the organized autistic advocacy community, such as a resource from the autistic self-advocacy network under the IACC.

This will ensure the concerns of the self-advocacy community, such as the critical important path of communication can be fully addressed. Thank you all so much for listening. It was a privilege to be able to address you today.

(Applause.)

DR. HANN: Okay. We're going to open it up now for questions. Before we go on, I want to thank you Dora for a wonderful presentation, and also to ask the members of

the Committee that if you have questions for Dora, to assist in her ability to communicate with us, if you would please, you have note cards in your packets, to write your questions on that, and then Susan will type them and send them to Dora.

We may have a little bit of a delay in getting her response, but that would be the preferable way for communication.

DR. INSEL: Well thanks to both speakers. We have some time. We've scheduled nearly 30 minutes for some discussion. So is Dr. Cafiero still with us? Yes. So if maybe we can have you join us at the microphone, and we'll open this up to a conversation with the committee.

MS. McKEE: I thought you did a wonderful job presenting about an hour and a half worth of information into a half an hour. I'm curious about what you're most excited about right now, as far as research, or what's going on right now?

We've had the introduction of the ProLoquo through the iPod touch, which my daughter's using. What else is out there that you're excited about?

DR. CAFIERO: I spent three days in Arkansas with a community of people with autism who have been using a particular device for 15 years. It happens to be a Prentke Romich device, and what I am most excited about is seeing the kind of novel communication that's coming out of these individuals.

I saw children as young as six and an adult who has had a device since he was 16. He's 27 years old, and what I found was most compelling and most upsetting to what I thought was typical for people with autism is I saw people looking to say something novel, and when they couldn't find the vocabulary, they were putting together pieces of words to say what they wanted to say.

Now I had always had the

assumption that phonemic awareness was not a venue for teaching language. However, I'll give you the example of a little girl who had a device for about a year. She was full included in her second grade class, and her teacher had put up an alphabet chart.

She's using Avantage, which is a very sophisticated device that uses a coding system in order to communicate. So in other words, she had to learn to use a language code for the English language, for somebody who has difficulty with English.

It's something that I did not think she could do. She was sitting in the classroom and the teacher put up an alphabet chart. She raised her hand and she said on her device "Your window looks just like my window," which was -- I was completely startled by that.

So she was basically saying that that alphabet chart on the board looked like the overlay on her communication device. I

saw another young man who was working with his teacher, and he wanted to tell the teacher something, couldn't find the vocabulary.

He wanted to talk about a tree that was blown down in a tornado, and he said "Fix the tree on the golf horse," H-O-R-S-E. What he wanted to say was "Fix the tree on the golf course." He couldn't find the word "course." He used the word "horse."

This is something I had not expected anyone with autism could do. That's actually taking chunks of words or words that sound like other words and putting them together to say something, to make a comment. And also it was a comment; it was not a request and it was not a refusal.

So this is an area that I find very mystifying and very exciting. If you give someone a device, a very sophisticated device that enables them to say anything about anything at any time, is that going to be the kind of device that is really going to be the

springboard for our kids with autism, to be able to communicate spontaneous, novel utterances, which is what we want?

Right now, we're giving them devices or low tech things in which we pick out the vocabulary. So they're saying things that we've decided we think they want to say. Whereas with these devices, they can create novel utterances.

Then of course the whole idea of keyboard communication is very compelling, because then you say anything about anything.

The second thing I wanted to say is providing literacy instruction for people with autism is critical, regardless of behavior, regardless of whatever cognitive scores, literacy is critical, because literacy and AAC are irrevocably woven together. You can't separate them out.

DR. INSEL: Can you talk to us a bit about the role of age here? Does it matter whether someone is an adult with

autism? Is there an age that's too early to begin this?

DR. CAFIERO: No. Janice Light at Penn State is starting with 18 month olds using devices, and what Romski and Sevcik found was that when they worked with children and gave them a device in the toddler study, those children were able to communicate before speech developed.

We see in the programs that I work in, I work in several counties in Maryland, that there seems to be a trajectory of behavior development that I'm seeing in the youngest children. I don't have the research to back it; it's observation.

They will come into a program at age three and be relatively quiet little guys and girls. Around age five and six, we begin to see some serious behavioral difficulties with the kids who don't have a way to communicate.

So my thinking is we give them a

way to communicate immediately, not ignoring speech. You can work on speech and you can work on AAC, and the research tells us that AAC does not inhibit; it actually supports the development of speech.

So I would say it's never too young and it's also never too old.

DR. INSEL: And as a follow-up on that, both you and Ms. Raymaker made a very clear statement about separating communication and speech.

You actually said at one point that the presence of speech was in some cases, I thought you were implying even possibly an impediment or sometimes didn't make this any easier.

Is there something about the presence or absence of speech or any other variable that predicts who's going to be most successful in the use of AAC?

DR. CAFIERO: I think that there's a philosophy that if a child is echolalic,

that they're probably going to develop speech and there's a hesitancy to provide AAC. I think that AAC needs to be provided from day one of diagnosis, without ignoring the speech development. I don't know if that was your question, Dr. Insel, or not.

DR. INSEL: Well, I guess what I'm getting at is you had some outcome data, and in the biomedical world, we're increasingly trying to personalize interventions to identify who's going to be the best responder, and who may need a different kind of intervention than the one we're offering.

Is there anything that you have been able to discern that would predict who's going to respond best to --

DR. CAFIERO: To an AAC intervention?

DR. INSEL: Yes, yes.

DR. CAFIERO: No. I think that we're providing it -- well, we engineer our classrooms with a no tech AAC, so that

there's visual supports everywhere, and we provide literacy from day one. Literacy, as I said, literacy and AAC are so connected that we don't want to ignore that.

Many of our kids and adults will become keyboard communicators. So we don't know which people will be most successful. But we're making the assumption that, especially with No Child Left Behind, we need to have literacy interventions in place.

That literacy will support the development of either conventional speech or augmented communication. But no, we don't know. My perspective is provide those supports to everyone. Kind of a universal design, a universal design in learning for the classrooms.

DR. CAFIERO: Yes.

DR. RICE: I have somewhat of a follow-up question to what Tom just asked, and I'd love to hear from Ms. Raymaker as well.

But if both of you could address

it in terms of are there guidelines for assessing what type of AAC should be used with what type of person? How do you go about picking what system that you use and what's the most appropriate communication for that individual?

DR. CAFIERO: We are in the trial and error phase. Sometimes the intervention is decided by the budget of the school system, sorry to say. But now that we have the ProLoquo2Go, which is on the iPhone, if anybody wants to see it later, I'd be happy to show it to you.

I think you have one too, don't you Christine, which is -- this costs about $400, which compared to the $8,000 devices is really a Godsend. But we don't know, and it's often defined by budgets and insurance companies.

I was involved in actually an insurance company, that was I believe a class action issue, where insurance companies were

denying devices for people with autism and actually we were able to overturn that.

So it is considered appropriate and insurance companies are covering devices. What's important to note, though, is if a parent requests a device, they have to make sure that that device is the device that's most appropriate, because insurance is not going pay for another device in two years if that's not the correct device.

I don't even know what correct device means. I do know that the learning curve for AAC for kids is very different between children, and sometimes it takes several years of using the device. The communication partner uses the device to provide input before they get any output.

So I encourage people not to give up. It is teaching language as well as unlocking language. I think that's an important piece. Maybe Dora has a comment about that?

DR. INSEL: We're sending her some questions. She'll be responding, I think, in a moment. One of the things maybe we could just draw you out on this in the meantime.

Listening to both of the presentations, which are fantastic, really tremendously interesting, how much, as you look into the future, do you think of the impediments are going to be technology and how much will it be policy and how we use them and all these other things? Is there still a big technological hurdle that we need to overcome?

DR. CAFIERO: We have some big questions that I discussed earlier. One is is it visual discrimination or motor memory that we have to be targeting, to help people with autism generate language, for those that do not use a keyboard communication?

There's four or five major AAC devices, and their architecture is all different. If they could get together, it is extremely difficult for practitioners to learn

the architecture of the device.

If you're going to be a communication partner, you have to know the device like it's your own voice. That has to be a second language for you. I'm struggling myself learning some of the devices. You know, when you're my age in your 60's, it's a lot harder. Some of the young practitioners just learn it in a snap.

But I wish that the companies that are making these devices would get together and come up with a common architecture, because they're all very different. So you have to learn that before you can be a good communication partner.

Interestingly, when I was in Arkansas and I saw the dozen or so young people that are using these devices, the teachers were not using them because they didn't know how to use them. They introduced the device to the student and the student was navigating all through that device in a way

that I could not do.

That's another thing that I found extremely compelling, the little boy that I was going to talk about in more detail today, Jacob, can navigate around his device with much more facility than any of his teachers can.

He finds things. One day he has a lot of sensory needs, and he wanted to be tickled. He couldn't find the page for body parts, but he found the page for Mr. Potatohead, and it did the job. So he got tickled on his head and his nose and his ears. He was able to do that.

These are things that we had never expected people with autism could do. I think AAC is humbling all of us about autism. I think technologically, I wish the companies would come up with a common language and a common architecture, because learning it is hard.

Then transitioning a child from

one device to another, from Picture Word Power to Minspeak to what's on the ProLoquo2Go, you are actually learning a whole different language and language structure.

DR. INSEL: So we have comments? Is that right, Susan?

MS. DANIELS: We have answers to one of the questions. What type of device did you use today? The answer is , I used ProLoquo as the speech software, and the a capella voice Heather for voice on my Mac.

DR. INSEL: Any other questions or comments? Christine?

MS. McKEE: One more comment. One of the big drawbacks that I found is that the companies sell their software on their own devices. So you pay $8,000 if you want a warranty 10, 12 thousand, and you get this one device, a four or five pound device. Then try strapping that to your child.

It just doesn't work. So there is one company that has gone and they're selling

their software separate, so that you can put the software on the computer in her bedroom, on the laptop in the kitchen.

So as they move around the house, they have opportunities to communicate. I hope that the companies continue in that vein as well, to make it more accessible.

DR. INSEL: I raised this issue about the technology barrier, because it does seem that from the research focus, there's really an opportunity here. One of the things that NIH does by law, we're required to spend, I think it's 2-1/2 or 2.3 percent of our budget on small companies. It's called the SBIR grant.

That may be a place where a lot of this could be developed, and we could think about what the next generation of technology might look like, and figure out how to make it most accessible. Because there's quite a bit of funding that could be put into this.

Okay. Well thank you very much to

both of our communicators for this last session. We'll take a ten minute, let's say 15 minute break at this point, and we'll come back to hear from Dr. Briggs about the National Center for Complementary and Alternative Medicine.

(Whereupon, the above-entitled matter

went off the record at 2:18 p.m. and resumed at 2:34 p.m.)

DR. INSEL: Before we go to the open session for public comment, the last presentation is by Dr. Josephine Briggs, who is the Director of the National Center for Complementary and Alternative Medicine, affectionately known as NCCAM, and Josie has been in that role for what, two years, a year?

DR. BRIGGS: No. A year and two months.

DR. INSEL: Okay, and will be taking us through kind of an overview of what NCCAM does and how NCCAM could be a useful

partner for some of the things that we've been talking about.

DR. BRIGGS: Well thank you very much, Tom, and to the Committee. I'm really delighted to have this opportunity to meet with you. I've been aware of this body.

I've read your strategic plan with substantial care. It's a very thoughtful document. I've seen many strategic plans, and I think this is extraordinarily well done.

I'm really very delighted to have an opportunity to begin discussion of potential partners of NCCAM with the autism community. I've met with a couple of autism organizations already, and I very much welcome furthering these contacts, and learning from you, learning from the Institute partners who've been the leads and experts in this area, and thinking together about how we can contribute to moving this forward.

I'm a kidney doctor. I'm actually reasonably new to the field of complementary

and alternative medicine. But I've spent a good part of my professional life taking care of people very heavily burdened with chronic disease, which is also very familiar to all of you in this room.

In the process of being a dialysis doctor and transplant doctor, I really learned how high tech medicine didn't always have the answers. It's key and life-giving in the care of end stage renal disease, but at the same time is often depersonalizing. It loses the human touch.

I do see the world of complementary and alternative medicine as encompassing some practices which offer some potential promise to impact on life with chronic disease, life of caretakers with chronic disease, and all of us at the NIH have been very aware of the autism impact on our communities. So I'm eager to be part of the solution.

I'm going to run you through a set

of slides that talk about NCCAM and what we've done, and my year of learning this field, and what I see as some of the promises. Then I'll talk about a few implications for the concerns of this interagency coordinating Committee.

So NCCAM is ten years old. I'm going to show you just a little bit about its mission, and then tell you about the current data on use of complementary and alternative medicine in the United States, then review briefly some of what I see as the main lessons and achievements of the first ten years of NCCAM's life.

Then sum up by talking about some of the challenges of the CAM research, and one area which has come up in CAM research but may have a little relevance here.

The legislative language that created us in '98 said we had responsibility for the conduct and support of basic and applied research, to investigate and validate complementary and alternative treatment,

diagnostic and prevention modalities.

That mission was translated by my predecessor into three major pieces: explore complementary and alternative healing practices using rigorous scientific methods to develop the evidence base, for safety and efficacy of CAM approaches; to support the development of a trained scientific community; and to disseminate authoritative information to the public.

I hope all of you will look at our website. It is the most widely-accessed site on complementary and alternative medicine on the Internet. As I think most of you are aware, there's a lot of information and some misinformation on the web about complementary and alternative medicine, and we take our website responsibilities, our public information responsibilities very seriously.

Our website, for example, was just updated this morning with the FDA advisory on Hydroxycut, a widely-used supplement that

turns out to be dangerous for weight loss. So it's an important part of our mission is making sure there's valid information.

We're pretty small. Our total budget is $125 million. It's only .4 percent of the NIH total of $30 billion approximately. So we have to be a little cagey in how we spend these resources, but I think we've had enormous impact in ten years, largely because of the wonderful partnerships we've been able to build across the NIH.

This is the history of our appropriation growth, following our founding in '99. There was a few years of rapid growth; then we paralleled the doubling and we were stable, flat or really declining purchasing power through '08. We enjoy, with the rest of the NIH funding, a little tiny uptick in that year.

NCCAM is a team player, and what we've been able to accomplish has happened because we have partnered with institutes and

centers across the NIH with specific expertise in other disease areas.

We have just published a very major study on gingko for prevention of Alzheimer's disease. This was published about three months ago in JAMA. It's a 3,000 patient study, the largest study ever performed at NIH or I believe in the world, for prevention of Alzheimer's.

It failed to demonstrate any benefit of gingko on preventing cognitive decline in people at high risk for cognitive decline. The major funder, together with us, has been many of some of the people in this room, as well as the National Institute of Aging.

Some of you may be aware of prominent studies we did together with arthritis and musculoskeletal on glucosamine. That was actually a little more ambiguous. The glucosamine has a little bit of benefit for certain subgroups, but did not show clear

benefits.

A number of years ago we partnered with NIMH on a study of St. John's wort for major depression. That study also failed to demonstrate the benefit of St. John's Wort, and at about the same time some major safety concerns arose about the interaction of St. John's Wort with other medications.

These are just few examples of how key partnerships are for NCCAM. We have, in my superb staff, still do not have disease-specific expertise, so everything we do we work hard to partner with the Institutes at the NIH, who know the details of research on specific diseases.

I just want to take a few minutes to show you some data on what the public is actually doing, and the data I'm going to show you comes from the National Health Interview Survey. This was done in 2002 and again in 2007. It's actually implemented by the CDC but we helped pay for it.

This is a very important health survey, which is done using census methodology and in fact census personnel, who in the years when they're not doing the census and many of them work for the CDC to do this survey.

It's done with person to person interviews. They're quite lengthy. Potential respondents are identified by putting a grid over the entire country, and then choosing households so it's truly representative, and the surveyors go up to five times to each household until they get answers to the very long survey instrumentation.

So we think it's as valid as any of the surveys that exist. In this last survey, we collected information on 24,000 people and 9,000 children. Consistent with other surveys that have been done before, about 40 percent of Americans are using some form of complementary and alternative medicine.

One in nine children, we're seeing

increasing, we believe, use of complementary and alternative medicine by children. It's widespread in all demographic groups, women more than men. That's been consistent in all the surveys. About 60 percent of women and about 30 percent of men use complementary and alternative medicine.

There's very big geographic differences. The Pacific Northwest, the usage is about 15 percent higher than the rest of the country. Use is lower in the South. Very strikingly, in all the surveys that have been done, the use is greater in people with more education.

So many of my physician colleagues are surprised by this result, but in fact people with college degrees use this more than people with high school degrees and people with advanced education use complementary and alternative medicine more than those with just college degrees. That's true, even if you try to account for income effects.

This is the bottom line of what modalities are most used. The highest bar to the left is natural products. This is defined as non-vitamin, non-mineral dietary substances. Mostly it consists of herbals and other supplements. These are used by about 40 million Americans.

The other major categories are relaxation techniques, including deep breathing and meditation.

Manipulative therapies are also used by a lot of people, as is yoga. This slide shows the changes between 2002 and 2007, which I think aren't very surprising.

I call these meditation, massage and yoga are kind of Main Street complementary and alternative medicine. If you walk down any Main Street in America, you'll find these are more common.

You'll note that the therapies that often cause concern, like Ayurveda and chelation are used by very few people.

This is the data for children. Again, the pattern for children differs in some significant ways from that for adults. The use of non-vitamin, non-dietary supplement.

This is percent among those who are using some form of CAM. This is still the most common form of CAM, meditation. Not surprisingly, it's hard to get kids to meditate, but manipulative therapies and yoga are being used increasingly for children.

Why? Why do people turn to these forms of health care. The dominant reason that they tell interviewers is that they want to be healthier. But it's also used to treat specific healths and conditions, specific conditions, and it's mostly used as an adjunct to convention care, not instead of.

The dominant reason why people tell interviewers that they use these practices are back pain, and in fact other kinds of pain, neck pain, joint pain,

headaches, anxiety and other modalities also.

And this is the reason among children. Again, very similar. Colds is up as a common reason, but back pain and neck pain is also common.

We did ask about autism in this survey, but the numbers were too small to be analyzed separately in our sample of 9,000 children. There were 54 who were -- whose parents reported that they had been given a diagnosis of autism.

That very much fits with the sort of 1 in 150 numbers that I think you're all very aware of. Use of complementary and alternative medicine is not uncommon in children who carry the diagnosis ADHD.

This shows the top dietary supplement used in 2002, and I just wanted to point to this slide, to tell you that NCCAM in its first ten years of life, has done studies on many of these agents.

The studies on echinacea.

Echinacea was the subject of two large studies looking at the impact of echinacea on duration and frequency of colds. It failed to document clear benefit of effect.

Ginseng we have not studied extensively. I told you about the gingko study. Garlic supplements, we've looked at bioavailability but not studied. Glucosamine I've already talked about. St. John's Wort we've talked about.

Peppermint is used for gastrointestinal symptoms and some other indications. We have a few pilot studies on it, and fish oil and Omega-3's have been studied both by us and other parts of the NIH, and have, I think, reasonably well now documented effect on cardiovascular risk.

So that was the data in 2002, and this is what we see now in 2007. We're struck at the pattern of changes, and in fact so is the dietary supplement industry. So right after the publication of the results with

echinacea, the trade journal of the supplement industry published figures showing sales before and after that study.

The study was published in July, which they noted was fortunate, since a publication in flu season might have had a larger impact. The studies of St. John's Wort and the safety concerns have resulted in very marked fall in the utilization and sales of St. John's Wort. I think it's not only the negative study but also the safety concerns.

Fish oil and Omega-3's are now the most highly, most frequently sold single supplement. So at least tentatively, we interpret this data as suggesting that the public is listening and paying attention to this research. And in fact the media coverage of this work is enormous, and people really do care about this.

So we feel that this work, this is one indication that with some investment in this area that's so widely used is worthwhile.

But I will tell you there have been a lot of challenges and a lot of lessons learned in implementing these studies, and as one looks back at ten years of experience, one has to say that there's a lot that one can think about doing differently in the future work.

The first thing I've already mentioned that NCCAM is small. We have a small staff, I think a very expert staff, particularly in the area of natural product composition. But we don't have the kind of disease expertise that is represented in this room. The conditions that we are talking about today are ones where that expertise is absolutely critical.

So I feel very strongly that anything that NCCAM is eager to be part of solutions here and part of the NIH team, but this is something we have to do in partnership.

The product characterization

issues can be really tough in this area. Unlike drug studies, these compounds often don't have identified biological targets, and that has posed interpretation problems. I'll mention one.

The echinacea studies, echinacea is believed to have immune modulatory effects in preventing colds, and in fact there's a good number of rather large European studies that in fact suggest that it may have effects on cold frequency.

But we sure didn't see it. However, I have to say we are not totally sure, in looking back with benefit of the retrospectoscope, that we studied the ideal preparation, because echinacea differs very markedly in how you extract it, and some people believe it enhances immune responses; others believe it dampens them. Both could potentially help in symptoms of colds.

But it's an example where with the benefit of retrospection, one wishes one knew

more before the study was done. As I'm sure you're not surprised to learn, the studies have been criticized for that reason.

I think the other big lesson in our studies is the need for really strong preliminary data, so that the population, some of these interventions may only work in a small subset of people.

One would like to have the kind of preliminary data that would allow one to identify the target population most likely to benefit. The glucosamine studies are a good example in that arena.

So this is the kind of preliminary data that we would like to have before undertaking another major randomized clinical trial of a CAM intervention. We would like to have a strong biological hypothesis, a well-described intervention, proof of concept, preliminary clinical data, chemistry of any natural products, and very sensitive outcome measures.

That was certainly, in your fine strategic plan, the need for improved measures of assessing disease severity was a goal that I could very much empathize with.

I will also say that another key tool that we need to have is ways to identify interventions that -- and populations and symptoms for which they have the most promise. CAM interventions are often expressed by the believers a very high level of hope for what they can do to the disease process.

I told you about some of the negative studies, and I will tell you in a few minutes about some of the positive studies, which have largely come in the arena of symptom management like pain management and stress management.

Overall, I see a lot of the promise of CAM intervention as not being for the core symptoms of Alzheimer's, but for help with management problems and perhaps for help with the stress of caretakers.

So that's something that I'm eager to learn from this group about -- and this slide just reiterates that we need to support research at all levels from the basic science to the tools for human subject study, specific effects, and in some cases, where the data is strong enough, into the real world of effectiveness.

There are lots of excessive claims, and we're very attuned to that. This is one that I'm sure you've all seen, but one of the things that we think about in hunting for areas of promise is what truly looks biologically promising, and we are very attuned and nervous about claims that seem to us to go too far.

These are a few kinds of things where we had some very positive results. The benefits of mindfulness meditation for stress reduction in quality of life, for example, for Alzheimer's caregivers. The quality of the caregiver is so important.

The quality of life of the caregiver is, as I know you know, better than I can speak to, is incredibly important for the well-being of patients, and this is something that we need to talk about.

Yoga and tai chi are very helpful for balance and avoiding falls in elderly people. We've also invested heavily in placebo research and how reassurance and expectancy leads, for example, to pain management. Pain is an area of major focus for us.

I think I'll skip this for time. So to turn now to autism, numerous provider and patient reports, and I've been reading them with substantial interest since I've taken this job, and I've certainly heard testimonials that CAM practices are being widely used by autism families in their search for help for their children.

I think that it's certainly one reason for all of us collectively to think how

can -- which of these show the kind of promise that we should now work to develop the scientific evidence.

In all of this, we have to view safety of the child as paramount, of course. We have developed the kind of expertise, through some of the positive and negative lessons that I've already talked to you about, in doing some research in practices that are already in real world use.

In any research that involves a CAM practitioner, an acupuncturists, an practitioner of stress reduction techniques and so on, it is very clear that these have to be done with the CAM practitioners helping in the development of the approach.

The final bullet point is perhaps the one that I would want to stress most here, which is that the evidence base has to be incremental. Just because something is in real use currently doesn't mean that the right approach is to leap in and do a large RCT.

I think we've learned through the experiences I've talked to you about--but what's well known to all clinical trialists--is that the large randomized clinical trial is the ultimate gold standard of evidence, but it is a rough instrument, and it detects large effects or it detects effects on well-targeted populations.

When you try to bring it to bear to a complex problem, many of which subjects may not benefit or in fact might even be slightly harmed, and try to detect an effect, you will be left with no clear answer. The worse thing that can come out of research like this are large randomized trials that still leave the question unsolved.

I would have to admit that that may be the case, looking back, at our echinacea studies, that we still are not sure that echinacea doesn't affect cold frequency. In some ways I've talked about the echinacea data and our impact on sales of echinacea

quite a bit.

Just two weeks ago, Jane Brody, who's a columnist in the New York Times writing on health issues, really as knowledgeable a health consumer as you could hope to find, commented that whenever she goes on a plane, she takes echinacea. I sort of scratched my head. Jane, didn't you read the studies?

But it was an example that we can end up putting a lot of resources into a topic, and still not have an answer. I think, particularly in the setting of autism, where you appropriately and desperately want answers, the worse thing for us would be to leap into a randomized trial without the level of evidence to make sure we were designing the experiment just right. I guess that's one of NCCAM's main lessons.

So we need to build a way to move from anecdote to evidence, and it's a path. My predecessor, Steve Straus, a very esteemed

person here at the NIH, used this quote: "The plural of anecdote is not evidence." And that is absolutely true.

Anecdotal evidence can be very misleading. I think all of us are vulnerable to hope and expectation, given a pill or something to take, and I'm sure that is true for the struggles of people trying to help their children with these disorders.

So one does need to figure out strategies that will provide objective approaches, and I would say that we have to view this as a step-wise process.

One small pilot study that NCCAM is currently funding looks at the effect of Omega-3 fatty acids compared to a placebo in children with autism spectrum disorders.

This is a study led by Sherri Novotny, a psychiatrist at Robert Wood Johnson. She's looking at aggression and irritability. It's a small study. It's a pilot, and certainly the kind of study that

might provide one of the kind of building blocks that we need.

One other thing that I wanted to put on the table, because this is discussed in the setting of CAM modalities, and it's something that we're exploring for glucosamine and echinacea and other interventions, is the issue of N of 1 trials.

I wanted to clarify that this is a proposal that's been talked about for -- to guide therapeutic decisions by physicians. So if you are wondering does glucosamine help my sore knee, it is reasonable to try to work with a physician and get a placebo and a glucosamine pill, and take them alternately for two month blocks and see if your knee seems to do better.

Statistically, if you do that with appropriate intervals and three crossovers -- so three intervals on the placebo, three intervals on the active medication, the statisticians tell us that that data is

reasonably reliable.

That assumes that what you're after is symptom management, and that the effect will be reasonably prompt. It doesn't -- it only would work if an intervention can be expected to have an effect in a short enough interval and wash out in a short enough interval.

But it is a design that because people are their own controls, has sometimes the potential to get answers that will be relevant to that person, and can guide a therapeutic decision for that person.

Something I'm interested in exploring is whether such an approach could also help us get the kind of pilot data that we might use in talking about which trials could be done on a large scale.

Dr. Hirtz and I have already talked about this briefly; Tom and I have talked about his briefly. I think it's an idea that I'm interested in exploring, both

for other CAM applications and with the autism community. There are some substantial barriers.

It's not quick. It takes time and manufacturing placebos that look just like the active stuff, and when somebody bites the pill they can't guess which they're on. It has substantial costs.

So it's not a trivial undertaking, but it's something that I think is worthwhile to at least explore, whether this might be a way to get some important pilot data.

So this is to develop proof of concept data. It won't give us all the final answers, but it might be an approach that's worth exploring. And an additional benefit perhaps might be that it brings the patient, their caretaker, and the researcher into a dialogue.

So just to summarize, I want to tell you how pleased I am to be a partner in this process. I am very aware of the

incredible burden that these conditions are having.

I don't have anyone in my family directly affected, but I'm sort of of the grandmother age, although not yet a grandmother, and I do have two close friends who have grandchildren who are affected by one of these disorders.

I think all of us--and my heart goes out to them. I think that this is an enormous social problem and an enormous burden for families and patients, and I very much want to be part of NIH's contribution to answers. So thank you.

(Applause.)

DR. INSEL: Thank you, Josie. Let's take a few minutes for discussion.

MS. REDWOOD: You know Tom, in looking at the literature on autism, there's just such a high rate of alternative and complementary medicine used. In one of the studies in 2007 by Hanson, and this was in 112

families, 74 percent reported using some form of CAM, which is much higher than what you had found in the general public.

Another survey was done, 77 of 150 families responded, and 95 percent of them were using some form of CAM in association with autism, and that was in Herrington in 2006.

I think one of the things we need to be very careful about doing when we look at these complementary and alternative treatments in autism, is to define the subgroup that might respond to those therapies.

I think that's been something in the past that hasn't been done, when we've tried something like looking at methylcobalamin in autism. It was given to all children versus identifying the specific subgroup of children that had low levels or had elevated levels of methylmalonic acid in their urine.

So we really need to identify the

subgroup, and when you talked about doing Omega-3's in autism, I was just curious whether or not you had looked at the children to identify first if they had low levels, and that those were the children enrolled, or was it just all children with autism enrolled in the study?

DR. BRIGGS: I totally agree with your points, that study is a pilot, an investigator-initiated study. She has obtained samples to be able to look at the Omega-3 red cell membrane composition. But she didn't target a specific subgroup.

But your point is absolutely right, that the more we know about the biological mechanism, the more we are able to target the approaches to the population most likely to respond.

I would add that we shouldn't -- that I am open particularly to studies not only talking about the core symptoms of autism, but some of the other symptoms, where

we're really just asking practical management information.

So I understand that eating problems and digestive problems are very common in children with this spectrum of disorders. So I wanted to say that I would see promise in looking practically at: do these approaches, the dietary approaches or probiotics, for example, help with the gastrointestinal symptomatology, as appropriate as studies looking at core symptomatology.

There, of course, you'd be talking about the children who were affected with a particular set of symptoms.

DR. INSEL: Josie, when does a treatment go from being CAM to non-CAM?

DR. BRIGGS: That's an important question and one for which there isn't an established answer. NCCAM was created with a fairly prescriptive legislative mandate, but with no definition of complementary and

alternative medicine.

We tended to think of complementary and alternative practices based largely on where they came from. If they came from outside the mainstream and are moving along into the mainstream, we don't want to give up on them just as soon as they start to look plausible.

So fish oil for cardiovascular and non-cardiovascular indications, we still view as CAM, even though it has become more and more mainstream. But it has to be a functional definition. It has to be, by its nature.

Our mission has to evolve as the interventions evolve.

DR. INSEL: Some of the data, as Lyn was suggesting in autism, would say that many of the things that some people might consider to be CAM are actually pretty much mainstream.

In fact, they're probably used

more than many other treatments that people would have said more were approved by the FDA, such as Risperdal or even ABA in some cases.

DR. BRIGGS: That's right, yes. Well anyway, I did want to say to members of the Committee, outside my colleagues, that I very much welcome continuing this dialogue and NCCAM is eager to participate and be part of the team.

DR. INSEL: That's great. I think this is really helpful to us. There may be some people who will look at 0.4 percent of the NIH budget and feel like this is a small investment. But the reality is that the way NIH is organized, is that the centers at NIH provide expertise, content expertise.

So they're not disease-specific. We have many of these. I think there's eight or nine different centers, seven or eight, you know, for minority health, for complementary and alternative medicine. There are several others. They work with all the other

Institutes.

So the idea isn't that you plug a lot of money into those centers, but rather you put in people who have great expertise around trial design, the N of 1 kinds of approaches, whatever that might be, and then the Institutes, such as NICHD or NIADS or NIMH work with those people to get the best design for whatever studies get funded. Okay, thank you.

(Applause.)

DR. INSEL: We're now ready for the public comment session of the meeting, and we have four people who are scheduled to give public comment, and we'll just go ahead and start with the list that I have. Theresa Wrangham is the first speaker. Whatever you're comfortable with. You can sit, you can stand, whatever works.

MS. WRANGHAM: Good afternoon. My name's Theresa Wrangham. I'm the president of SafeMinds. More importantly, I'm the mother

of an 18 year-old daughter with autism who's benefitted from behavioral, biomedical and CAM as well.

As the IACC commences the updating of their strategic plan, SafeMinds would ask that the Committee revisit objectives already in the plan for modification and expansion, as well as the addition of new objectives to more adequately address the autism epidemic facing our nation.

The need for treatment is of primary concern. Of the nine treatment objectives in the plan, we note that four were unanimously supported by public members as needing to be quadrupled in number.

The public understands that treatment research is desperately needed to improve the lives of affected individuals as soon as possible, to assure the best long-term outcomes. Treatment is an area that requires significant expansion to appropriately address the needs of the ASD individual.

SafeMinds also acknowledges the role of research as the cornerstone in the creation of new and effective treatments for autism. NIH has historically placed a priority on inherited genetic risk factors when funding autism research.

However, these investment have not yielded the results that would provide the urgent breakthroughs needed to respond to this health crisis. It should also be noted that genetic research is well-funded privately, while environmental research is underfunded.

SafeMinds believes that now more than ever wise research investments are necessary and recommends, as did the recent UC-Davis study, shifting funding from genetic to environmental studies, as they are most likely to lead to effective treatments and prevention.

Research on environmental factors in the strategic plan has been limited to five factors. While public members of this

Committee unanimously supported investigation of 20, and the inclusion of interactions between exposures. We would ask that regular steps be taken to identify environmental factors driving autism's rise, with expansion of the numbers of factors pursued, and that they be inclusive of vaccines and their components as intended by the Combating Autism Act.

The current strategic plan contains only four research projects to identify metabolic and/or immune interaction mechanisms with the central nervous system. These objectives are likely to inform causality, that in turn leads to new treatments and preventions.

SafeMinds would recommend an expansion to 25 projects, and that they not be limited to immune and metabolic system interactions.

Little is known about possible differences between teen and adult phenotypes,

and whether subtypes of ASD change over time, as well as by birth cohort. Conducting active screening prevalence studies in a multitude of locations of various sampling approaches of adults born before 1987, compared to prevalence of teenagers born during or after 1987 using the same diagnostic criteria, would provide a much-needed assessment on possible differences in subtypes, as well as speak to the contribution of the environment relative to diagnostic changes in the rise of autism. We recommend such an objective be added to the strategic plan.

Given the rich clinical data available in successful treatments used by physicians treating our children, the number of clinical trials to determine efficacy and cost effectiveness could easily be expanded from the two trials proposed in the strategic plan.

Expansion is desirable as

information gathered will inform best practices in the treatment of autism, and assist in making treatment more widely available to those affected.

We would also request the convening of an independent panel, as recommended by Dr. Mark Noble at the last IACC meeting. To date, we are unaware of the next steps taken as a result of the last meeting in this regard, and feel strongly that this panel will signal to the autism community and the general public that vaccine safety concerns will be addressed, free from conflicts of interest and in accordance with the Combating Autism Act. I thank you.

DR. INSEL: Thank you. Let me remind people that all of the public comments are provided in your folders. You're welcome to respond to any of these things, and of course members of the public who contribute should know that all of this information does inform the process.

So, for instance, the group that will be looking at updating the plan will have these comments as well, to be able to think about as additional ideas filter in. Thank you.

The next speaker we have is Ari Ne'eman.

MR. NE'EMAN: Thank you. Members of the Committee, hello. My name is Ari Ne'eman. I'm testifying today on behalf of the Autistic Self-Advocacy Network, an international non-profit organization of autistic adults and youth, advocating for ourselves in public policy, service provision, research and media representation.

I'd like to start by applauding your decision to hear from ASAN Dora Raymaker and our friend, Joanne Cafiero. The topic of augmentative and alternative communication has been one that we've been encouraging the IACC to take up for some time, and we are pleased that the IACC has been responsive to the

requests of the autistic community in this matter.

Through the use of augmentative and alternative community technologies, autistic people across the life span can be empowered to communicate in meaningful and effective fashions.

The issue of autistic voices is one that I would like to expand on. The IACC is a body charged with making decision on autism research dollars allocated in our names and ostensibly for our benefit.

Yet I would like to remind the members of the Committee that the IACC continues to lack a representative from the organized autistic self-advocate community, despite having many representatives from the various factions of the organized autism parent and professional community.

As our new HHS Secretary has taken office, we encourage you to communicate the need to rectify this oversight in

representation as soon as possible. In respect to the IACC's upcoming work, particularly in respect to updating the strategic plan, I would like to take the time to call attention to three major issues of concern to the autistic community.

The first is the need to balance the autism research agenda, which currently drastically underfunds quality of life and services research, which has the potential to benefit autistic people across the life span.

We call upon the IACC to heed the call of the autistic and cross-disability communities message and adopt research dollar parity between basic research and quality of life/services research, recognizing that our society should spend at least as much money ensuring we have a quality of opportunity and quality of life and support as is spent on matters of autism causation, which have regrettably controlled the public arena so far.

We must move beyond the conversation around autism causation and cure, and towards a quality of life, civil rights focus, autism research and advocacy policy.

Secondly, a perfect example of the type of research the IACC should fund is in health care disparities research for autistic adults and youth. As our country prepares to embark on national health care reform, this type of research will be crucial for ensuring that autistic people across the life span have the ability to access medical services on an equal basis with the non-autistic and otherwise neuro-typical population.

Currently, many access issues relating to sensory, social communication, unique co-existing medical issues and other differences amongst the autistic population prevent full access for our people.

We urge that this research be funded, and that it be funded along participatory action research principles, that

ensure that the research is conduced with and not merely on autistic people.

Finally, I call attention to the urgent need for the IACC to address bioethical issues associated with prenatal testing and the autism spectrum. Very recent genetic research findings bring the prospect of an autism prenatal test closer and closer.

History has shown us that if this technology is developed, it will be utilized. The 92 percent rate of selective abortion in the Down's Syndrome community and similar examples across the disability community show that this issue should be treated seriously by the autism research community.

By making the focus of autism research preventing our very existences, our lives are devalued and the prospect of a world without the neurological diversity that has benefitted our society is a very real one.

I urge this Committee to consider the ethical, legal and social implications of

autism prenatal testing and the current autism research agenda, both through dedicated funding for its consideration of ethical, legal and social implications, as has been adopted by the Human Genome Project, and through incorporation of such a requirement of consideration of these implications into the IACC's existing and future funding projects, both through the updating of the current strategic plan, and potentially through the creation of an Ethics Subcommittee or workshop attached to the IACC.

The national conversation about autism has for too long excluded autistic people. Thank you for your time. We encourage you to hear our voices. I'd be glad to take any of your questions, and as always, nothing about us without us.

DR. INSEL: Thank you very much.

(Applause.)

DR. INSEL: The third speaker in this session is Katie Miller.

MS. MILLER: Okay. Thank you for allowing me the opportunity to speak today. My name is Katie Miller and I'm here representing myself as an autistic citizen. I would first like to applaud the IACC for having a presentation on assisted and augmentative communication given by an autistic self advocate.

The significance of this twofold. One, AAC is one of the most important areas of autism research, because it provides non-speaking autistics with ways to communicate. Communication is a basic human right, and no one should be denied that opportunity.

The limited numbers of AAC devices do not work for everybody. I met a parent of an autistic young man at one of the other IACC meetings, and she was furious that so much money and research was being devoted to causation and cure, because that did not help her son.

They had tried many different AAC

devices and for some reason none of those worked for him. She could describe to me exactly what kind of device he needed, but that just wasn't being developed, because the research time and money was not going there.

AAC research is vastly underfunded, leaving countless autistics unable to express their thoughts due to lack of compatible technology. The fact that this presentation was given by an autistic self advocate is also be applauded. It shows that the views, experiences and expertise of the autistic community are valued. It gives me great pride to witness an a autistic voice being heard.

While this is evidence of progress, autistic voices should be a regular, organized and consistent presence within the IACC, not an incidental occurrence. Out of 18 members of the board, only one is autistic. How can the Committee succeed if it largely excludes the people it exists to serve?

Representatives of the Autistic Self-Advocacy Network have proven helpful to the Obama Administration, as evidenced by repeat invitations to important service, education and disability-related events, briefings and exclusive bill signings.

It is time that the IACC include a presence from the organized self advocate community, such as a member of ASAN. We are here to help you understand the challenges and strengths of our diverse community. We are the experts on our autistic needs, experiences, ideas, thoughts and feelings, and we are eager and willing to offer you that insight. Please listen to us.

One of the challenges many autistics face is less access to health care and often less adequate health care than that of the average population. These disparities are common throughout the life span and affect autistics with diverse abilities and living situations.

The reasons for health are disparities are likely as varied as autistic people themselves. How then do we research solutions? We directly involve all the affected parties, most notably autistics, doctors, nurses and primary caregivers, but also friends, family, teachers, social workers, public transit operators, health care receptionists, and anyone else directly deemed relevant to a particular case.

This collaborative approach to research is called community-based participatory action research. It equitably involves all parties in the research process, combining the unique knowledge and strengths of each to produce the desired result.

Research done collaboratively is more likely to result in the discovery of concrete problems and solutions regarding improper health care for autistic people.

In addition to executing participatory action research, I strongly urge

the IACC to implement research dollar parity. For every dollar that goes into basic autism research, I want to see a dollar going into quality of life, services, supports, and education research. These are the areas that directly improve the lives of a autistic people.

While scientists spend billions of dollars searching for the causes of autism, autistic children are being abused by their teachers, who lack the education and resources to treat them appropriately.

Teenagers are shuffled from school to school, without ever getting an appropriate education. Young adults age out of the system, only to find that they were not taught independent living skills, and there are no programs able to help them.

Autistic adults are being confined to institutions because community support systems are either non-existent or grossly underfunded. Whether or not an autistic adult

needs help holding a job or brushing her teeth, the fact is that research can and must be done to develop effective supports that allow autistic people to reach their individual goals and lead fulfilled lives.

Years are spent searching for a future cure, while autistic people who are here now, who can be helped now, have needs that are not being met due to lack of research and funds.

For every dollar, for every hour that is spent in a lab looking for causes, think of how matching that time and money can make a real, measurable difference in someone's life.

Secondly, I would like to point out that language matters. Autism is not cancer. Cancer kills people. Autism does not kill people. When I hear autism compared to cancer in terms of searching for a cure or in statements such as "autism is worse than cancer," what I hear is that society would

rather that I and my people were dead than continue to exist the way we are.

I am fortunate that I am able to express my opinion, but many of my fellow autistics are not able to do so. Please do not assume that they do not understand and do not have opinions on what is said about them.

Autism is also not a disease or an epidemic. It is not contagious, infectious or life-threatening. It hurts our feelings when you describe us as a burden.

The last points I want to touch on are the bioethics concerns and eugenic applications of genetic research. I believe that science for the sake of pure research is not in essence wrong or bad in any way. It is how humans choose to use the research we have gained through science that can lead to harm.

I do not believe it is wrong to be curious about the causes of autism. In fact, I myself am fascinated by the human brain and enjoy reading about my own autistic neurology

in scientific texts.

In fact, I'd be happy to read many of those hundreds of articles that you guys didn't want to read. You should hire autistic people to do that for you. We were all discussing this earlier.

However, I am deeply concerned about how cause-based research may be used. If a prenatal test for autism is developed, up to 90 percent of autistic people may follow in the steps of those with Down's Syndrome, and never make it out of the womb.

Because autism is so complex and so varied, there is no way of predicting future quality of life of an autistic fetus, only by identifying certain genes. I'm not taking a stand on abortion, but on eugenics. Today, we are abhorred by the times in history where groups as varied as the poor, mentally ill, blind, promiscuous, physically disabled, homosexual, Jewish-- everything else you name it--were labeled degenerate and unfit.

In an effort to improve human hereditary traits, such people were institutionalized, sterilized and of course killed. Of course we now recognize these wretched acts as massive violations of human rights. Let's not go there again.

Let's not segregate people from society by confining them to institutions, when they could live in their community with the right supports. Let's not think of people as sick, disordered and unfit for living. Let's not take an entire group of people and, without their consent, attempt to prevent future generations of them from existing.

Let us respect and accept all people for who they are. Let us support and educate all people and aid them in living the best possible life. Let us develop ways to help people communicate their needs and access health care. Let us change society to accommodate all people, and let us make the world a place in which everyone can grow,

learn, work, play, love, but most of all live. Thank you.

(Applause.)

DR. INSEL: Thank you very much. We have one additional comment from Paula Durbin-Westby.

MS. DURBIN-WESTBY: Thank you for the opportunity to speak today. It looks like you now have two people who want to help summarize the 120 scientific studies. I think that would be fun.

It is gratifying to see that the Interagency Autism Coordinating Committee is addressing the critical issue of augmentative and alternative communication. Now it is time to allocate funding to AAC research. Including a presentation about AAC is an important but preliminary step.

Since communication difficulties are experienced by many people on the autism spectrum, funding research in this area should be a high priority. Advances in communication

technology and the development of AAC options that are affordable will have a practical application to the lives of people on the autism spectrum throughout our entire life span.

Because of the extreme disparity between services and quality of life funding, and the funding of basic research, funding for AAC should be diverted from the millions of dollars allocated to genetic and treatment research and not drawn from the already-minimal funding for service-related research.

I recommend using a community-based participatory research model for AAC and other research, rather than being grown up children as far as research is concerned, autistic adults must be included as collaborators and co-researchers for both practical and ethical reasons.

The community-based participatory research paradigm is one model. Others may be developed and utilized. One likely outcome of

including people on the autism spectrum as collaborators and co-researchers is that the research will be made more relevant to the lives of people on the autism spectrum, including not only adults but children as well.

Just one example from a current research area is that of eye contact research. It's been recently discovered that autistic children will get mouths more than eyes. Although this may be an exciting new discovery for researchers and others, it is not necessarily news to people on the autism spectrum. We are often aware of the reasons and motivations for our own actions.

In addition, studies have already been undertaken that show that typically developing children also use multi-modal perception to process their experiences. It has been suggested that some sort of retraining could be done to direct children to not look at mouths but at eyes.

The theory is that by looking at mouths, children and presumably adults who do not make much eye contact are missing important social cues, which we don't get through our peripheral vision.

While it is critical to understand the underlying mechanisms for human communications and processes, the design and application of scientific theories, especially when young children are involved, should have participation input and oversight from people on the autism spectrum.

Researchers should take into consideration the numerous self-reports of people on the autism spectrum about the necessity of looking at people's mouths in order to compensate for auditory processing difficulties, among other reasons, including co-researchers who are on the autism spectrum, can positively inform research so that time and taxpayer money are not wasted, and so that studies involving autistic children as

subjects do not cause additional difficulties when children are trained to look away from mouths and possibly lose a significant visual method of accessing receptive communications.

Audiovisual synchronies are important, not just because they are early indicators of autism, but because they are a critical component in how we make sense of communication inputs.

Once again, a chronic or fatal disease model or metaphor is not appropriate for autism. Autism is not fatal like cancer, and as an autism person who has kidney disease, I can tell you they are not comparable.

The Interagency Autism Coordinating Committee must promote appropriate language to reduce myth-making and stigma. The time has come for the Interagency Autism Coordinating Committee to include representation from autistic self-advocacy organizations such as the Autistic Self-Advocacy Network, which has

had a representative at all but one of the IACC meetings since November 2007.

Autistic self-advocacy organizations are an increasingly recognized stakeholder in autism policymaking, and should not be excluded from the Committee that makes decisions about federal funding for research.

The public law that created the IACC has been in place since 2006 or 2007. The newly-founded Autism Science Foundation is represented. I don't know if officially, but there's still no representative from a major autistic self-advocacy organization.

Adding a public member from an autistic self advocate organization will begin to redress the existing imbalance, and add a much-needed dimension of focus on research and policy that will benefit people on the autism spectrum across our life spans.

This will enable research into AAC, eye contact and other areas to move from the promising practices realm to a best practice

reality. Thank you.

(Applause.)

DR. INSEL: Thank you very much. That is the end of our public comment session. I should just stress that because of the number of comments about changing membership of the IACC, in terms of public membership, the authority for that is only retained by the Secretary.

We do have a new Secretary, so this may be the time for those who want to lobby for inclusion to think about that. There will be an opportunity to try to bring her to one of the IACC meetings in the near future, hopefully in July.

But if we don't make it in July, we'll do it soon thereafter, and we're hoping to have a chance to brief her about the IACC and autism more generally in the next few weeks.

Other comments from the Committee?

(No response.)

DR. INSEL: Anyone still with us on the phone who wants to make a comment?

(No response.)

DR. INSEL: Okay. Hearing none, I want to thank all of your for your participation. I think those from the public who joined us and made comments, and those from the public who didn't make comments but joined us anyway, and we are officially adjourned until July 15th. See you then.

(Whereupon, the above-entitled matter was adjourned at 3:37 p.m..)