U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES

INTERAGENCY AUTISM COORDINATING COMMITTEE

FULL COMMITTEE MEETING

FRIDAY, NOVEMBER 30, 2007

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

PRESENT:

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

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

DUANE F. ALEXANDER, M.D., National Institute of Child Health and Human Development

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

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

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

LEE GROSSMAN, Autism Society of America

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

LARK HUANG, Ph.D., Substance Abuse & Mental Health Services Administration

PRESENT (continued):

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

WALTER KOROSHETZ, Ph.D., National Institute of Neurological Disorders and Stroke

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

CHRISTINE McKEE, J.D.

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

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

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

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

EDWIN TREVATHAN, M.D., M.P.H., National Center on Birth Defects and Developmental Disabilities, Centers for Disease Control and Prevention

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

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

ELIAS ZERHOUNI, Ph.D., National Institutes of Health

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PROCEEDINGS

[9:03 a.m.]

DR. INSEL: Good morning to everyone. For those of you who served on the previous IACC, it looks like we have come up in the world. These are very different digs than what we are used to meeting in. I'm glad all of you have found the place. I want to welcome everyone to what we see as a new chapter in autism research.

We are delighted this morning to have Secretary Leavitt with us. I'm going to turn the meeting over to him and let him launch us on this very interesting journey.

SECRETARY LEAVITT: Tom, thank you. Good morning. Welcome to all of you. I know that many of you traveled a great distance to come. I too have been traveling all week. I wanted to make sure I got back for this, and I'm feeling a little breathless.

I'm glad that we are together. I have met many of you. I know many of you and work with some of you, but I understand that some of you may not know each other. It might be a good idea if we just took a minute or two and went around the table. I would be interested to know, as I suspect those of you who don't know each other might be interested to know a little bit about how you became interested in this subject. I suspect if you all take 30 seconds we could accomplish that. There won't be a timer, but I would be interested to hear a little bit about you.

Patricia, could we start with you?

DR. INSEL: If you could use your mics because this will all be recorded.

DR. MORRISSEY: I have been commissioner of the Administration on Developmental Disabilities in the Administration for Children and Families since August of 2001. I was one of the lucky people that was on the initial committee. Many of the grantees that we fund are involved directly in all aspects of autism work: basic research, applied research, training people. So I feel like I'm a voice for them. I know some of the characters around this table quite well, so I'm excited.

SECRETARY LEAVITT: Patricia, I don't know that I know where you came from before Washington.

DR. MORRISSEY: I have been in Washington since 1976, and I spent most of my time either working for the House or the Senate. Right before I took this job, I worked for Booz Allen Hamilton. I had a chance to go to China in this job to give a keynote address at a special ed conference in Beijing in 2004. So it has been a great opportunity for me.

SECRETARY LEAVITT: Where did you grow up?

DR. MORRISSEY: My dad was in the Army. He was a sergeant in the Army, and I had a chance to live in Panama, Germany, and most of the East Coast.

SECRETARY LEAVITT: Wow, what a life. Thank you. Yvette.

DR. JANVIER: My name is Yvette Janvier. I am a resident of New Jersey. I'm a developmental pediatrician, and I'm a new community member to the board. I work with children and families with autism every day. I don't know if we have a cluster. I live in Brick, New Jersey. I'm glad to hear that the CDC tested my water and I can drink it safely.

I'm definitely in the thick of things, working with children and families with autism every day. I'm on the New Jersey COSAAC Autism Council and Referral Center, and I'm very glad to be here. I have worked collaboratively with Sue Swedo and Audrey Thurm before the current program was up and running. So again, I'm very glad to be here.

SECRETARY LEAVITT: Who inspired you to be a physician?

DR. JANVIER: That is a good question. Well, it was definitely predestined. My grandfather didn't have the money to go to medical school. My grandmother in those days also could only be a nurse. So I feel like I'm the prophecy of unfulfilled dreams in my family.

SECRETARY LEAVITT: You made good on destiny, then. I'm glad you are here.

DR. JANVIER: Thank you.

SECRETARY LEAVITT: Duane.

DR. ALEXANDER: Good morning. I'm Duane Alexander. I'm the director of the National Institute of Child Health and Human Development at NIH, one of the major institutes that funds autism research. Like Yvette, I'm a developmental pediatrician.

SECRETARY LEAVITT: How long at NIH?

DR. ALEXANDER: Since 1968.

SECRETARY LEAVITT: There was a before that. What was it?

DR. ALEXANDER: It was training in developmental disabilities at the Kennedy Krieger Institute at Johns Hopkins, and medical school and residency in pediatrics there.

SECRETARY LEAVITT: You are fortunate to have spent that much time with that great institution.

DR. ALEXANDER: That's right. Even though it was before Dr. Zerhouni was there.

DR. ZERHOUNI: You are lucky.

[Laughter.]

SECRETARY LEAVITT: This is one of my colleagues and one of the great people on the Earth.

DR. GIANNINI: Only because I'm the oldest in this room, I think.

[Laughter.]

DR. GIANNINI: I'm Peg Giannini. I have

devoted my entire professional life, which is over 50 years, for disabilities. [I started] when "disabilities" was a very unpopular word and not acceptable for the lofty profession of medicine, and if a physician dealt with the area of disabilities, there had to be something wrong with you. Fortunately, I was a pediatric oncologist. That had made some credibility to my going into disabilities.

I am the director of the Office on Disabilities with Secretary Leavitt, which was created after I was appointed by President Bush after he gave the executive order of the New Freedom Initiative. One of my responsibilities is to make sure that that is executed and that all of our agencies, especially within HHS, abide by it. I won't go through the domains because you know what they are.

Autism has clearly been one of my priorities all through the years of my professional career. I think some of you know that that are in this room. I can foresee that with where we have come from and where we are going that we can be very optimistic.

We need to partner more. We need to have common ground. Now we have the myriad of autism which we didn't have when I first started. We just put it in one lump. It was something different about these kids and maybe it was autism. We didn't have human subjects committees then, so we could try anything we wanted, and I did.

SECRETARY LEAVITT: I hope your word "optimism" becomes the watchword of this group. Lyn? Thank you.

MS. REDWOOD: My name is Lyn Redwood. I'm a nurse practitioner by profession. I'm also a founding board member of the Coalition for SafeMinds and the National Autism Association. I serve in the Department of Defense Autism Spectrum Disorder Research Program. I have a 13-year-old son who suffered with autism.

SECRETARY LEAVITT: Department of Defense, how did that happen?

MS. REDWOOD: I think you would have to ask some other people in the room how that happened.

[Laughter.]

MS. REDWOOD: Evidently there is a little pot of money over there to do autism research. It has just been a wonderful program so far.

SECRETARY LEAVITT: I'm very pleased that we have connected up with you here. Thank you. Go on.

DR. BATTEY: I'm Jim Battey. I'm the director of the National Institute on Deafness and Other Communication Disorders. I'm a pediatrician, a molecular geneticist by training.

SECRETARY LEAVITT: Now, the background on genetics, where did that start off?

DR. BATTEY: That began with my graduate work at Stanford.

SECRETARY LEAVITT: Interesting. Thank you. We are glad you are part of this.

MS. SINGER: I'm Alison Singer. I'm the executive vice president for awareness and communications at Autism Speaks. I'm also the mother of a beautiful 10-year-old daughter with autism and the sister of a 43-year-old man with autism. My brother was diagnosed back in 1969, and my mother was called the "refrigerator mother." We have come a long way since diagnosis in the '60s, but we still have a tremendous road ahead of us and a long way to go.

I want to thank you, Mr. Secretary, because by your attendance here today you are recognizing that autism is an urgent global healthcare crisis in need of a very intensive and coordinated response. So, thank you.

SECRETARY LEAVITT: Well, thank you. It does appear that autism has been a defining feature of your life as well. Thank you for being willing to do this service.

DR. WILSON: Good morning. I'm Sam Wilson, the acting director of the Institute of Environmental Health Sciences at the NIH. My career in biomedical research is in the area of genome stability and the topic of DNA repair. I have been at the EHS now for 12 years as the deputy director.

SECRETARY LEAVITT: Where did you grow up?

DR. WILSON: Well, I grew up in Texas, and after graduating high school, moved to Colorado to take my undergraduate training and some post-graduate training in the area of chemistry. That is actually what led me to decide that I did not want to be an organic chemist during my career. I thought that medical school would be a nice general way to find out really what I wanted to do with myself. So then I switched and went to medical school.

SECRETARY LEAVITT: Was there any particular person that inspired that decision?

DR. WILSON: Well, I think the main reason that I'm in research is the professor I had in my junior year in college. He came to me and invited me into his laboratory to do research and get some hands-on training in chemistry. That experience basically molded me for the rest of the way. I haven't actually been able to shake the education that I got during that brief period, maybe two years or so, the rest of my career.

So the experience in medical school was more an educational experience in the broad range of diseases and human biology, but I think that early experience in the research lab made an imprint on me that I never was able to outgrow or shake, fortunately.

SECRETARY LEAVITT: Probably some people in that environment that affected you a lot that didn't know they were doing it at the time.

DR. WILSON: That's right.

SECRETARY LEAVITT: Thank you.

DR. LAWLER: Good morning. I'm Cindy Lawler.

I'm program director in the Extramural Division at the National Institute of Environmental Health Sciences, and I have responsibility for the autism portfolio. I have been at NIH about eight years. In my former life I was a Tarheel. I had a faculty position at UNC Chapel Hill, and I was a dopamine receptor pharmacologist and focused primarily on neurodegenerative diseases.

Autism was something new for me. At the time that I came on board, we had very little investment and I had very little to do as a new staff person at that time. So it was given to me, and it has been very rewarding to see our involvement grow over the past eight years.

SECRETARY LEAVITT: It sounds like in a way you have trained to do this but found your way into this specific category almost by happenstance. It sounds as though it has taken with you, however.

DR. LAWLER: Yes, it has.

SECRETARY LEAVITT: That's great. Thank you. Ellen.

MS. BLACKWELL: Good morning, Secretary Leavitt. I also fell into this by accident. I represent the Centers for Medicare and Medicaid Services. I work in the Disabled and Elderly Health Programs Group, where most of our services for people with autism generate.

I'm here today because I also have a son with autism. He is 20 years old. He is a Medicaid beneficiary, so we experience Medicaid programs in our family on several levels. But I hope that I can inform my professional career with my personal knowledge.

I also founded an Autism Society chapter many years ago.

SECRETARY LEAVITT: Thank you. As we listen to our conversation, I become increasingly persuaded that autism seeks people out. It is not something that generally they start off choosing. We are all here for different reasons or with different paths. Stephen.

DR. SHORE: Yes, I am my own autistic child. After being recommended for institutionalization at two and a half, I recently completed my doctoral degree in education. It is my goal to use my personal experience with my academic studies, along with practical experience in directly working with people in the autism spectrum, all over the spectrum at all ages, to help people with autism lead fulfilling and productive lives.

I spend most of my time aboard airplanes, traveling between conferences and consultations, but I do have an address in Boston.

SECRETARY LEAVITT: Stephen, I am really pleased that you are able and willing to spend time at this. I think this will be among the more important things you could be doing, aside from all of the other demands that are there. Your perspective will be extraordinarily helpful.

DR. SHORE: It is my honor to be included. Thank you.

DR. MORRISSEY: Larke.

DR. HUANG: Good morning, Secretary Leavitt. I'm Larke Huang. I'm here representing the Substance Abuse and Mental Health Services Administration. We don't specifically do research on autism or autism spectrum disorders, but we are the services end and look to take what the NIH has discovered and developed and move it into the field. I'm pleased to be part of this Committee again.

SECRETARY LEAVITT: Thank you. We are really glad that you are here. Your contributions are well known up to this point, so we will look forward to more as time goes on. Edwin.

DR. TREVATHAN: I'm Edwin Trevathan. I'm representing the CDC. I'm the, I guess, still new director of the National Center on Birth Defects and Developmental Disabilities. I now have been in that job, as of today, for four months. I'm a pediatric neurologist and have a long-time interest in developmental disabilities and neurological disorders in children.

In retrospect, my real interest in this area probably started as a child because my mother was a special education teacher. So I grew up surrounded by children with autism and developmental disabilities who frequented my home.

SECRETARY LEAVITT: Would you say that was the defining point in terms of your own interest in these areas?

DR. TREVATHAN: Oh, yes, most definitely.

SECRETARY LEAVITT: Is your mother still living and in good health?

DR. TREVATHAN: She is. And if this is

recorded and transcribed, I'm sure she will read it.

[Laughter.]

SECRETARY LEAVITT: You should be very proud. Thank you.

MS. McKEE: Hi. I'm Christine McKee. I'm one of the community members on this Committee. Prior to the birth of my daughter, and I'm a little nervous to admit this in a room full of doctors and scientists, I practiced law --

[Laughter.]

MS. McKEE: -- with a firm in Kansas City and then later with the United States District Court for the Western District of Missouri.

After the birth of my daughter, who is now eight, I have been a stay-at-home mom and I have been very passionate about her care and education. She was diagnosed as being on the spectrum at age two, and I run her home program and network with moms and dads in the community to provide the best care that we can for our kids.

SECRETARY LEAVITT: Thank you. Did your legal practice focus at all on the healthcare sector or is this a brand-new industry to you as well?

MS. McKEE: I was an employment discrimination attorney, for the defense. I'm not a plaintiff's lawyer.

SECRETARY LEAVITT: Interesting. Thank you, Christine, for being part of this.

DR. van DYCK: Good morning. I'm Peter van Dyck. I'm director of the Maternal and Child Health Bureau in HRSA, the Health Resources and Services Administration. [I am a] pediatrician. We provide a large range of services, education, and training programs for mothers and kids but also children with special healthcare needs, including those with autism. We work in partnership with states and universities, mostly.

SECRETARY LEAVITT: Your presence at this table, and others of my colleagues, remind me of the coordinating nature of this panel. It is a place where so many different things can come together. I'm glad that you are a part of that. Walter.

MR. KOROSHETZ: I am Walter Koroshetz. I'm the deputy director of the National Institute of Neurologic Diseases and Stroke. I came down in January. Prior to that, I was at the Mass General Hospital in Boston, where

I worked for about 25 years in many different jobs: basic neuroscience, clinical research, training. I actually helped train Ed, so all the good things he said I will take credit for.

SECRETARY LEAVITT: You have to share them with his mother.

[Laughter.]

MR. KOROSHETZ: So I came to NIH because I saw it as a real amazing opportunity to try and push the science forward and also to kind of tease it towards getting treatments for different bad neurologic diseases. In the past, I took care of mostly patients with stroke, Huntington's disease, and head injury. There are a lot of bad things out there, but the science seems to be the thing that is needed to push the envelope forward in many, many different areas.

SECRETARY LEAVITT: You have obviously devoted your professional life to this, so we are glad you are here to get your experience. Lee.

MR. GROSSMAN: Good morning. I'm Lee Grossman. I'm president and CEO of the Autism Society of America. I'm also the father of a 20-year-old son with autism.

It is an honor to be here, Secretary, and to be part of the IACC redux. I'm the only public member to carry over from the preceding IACC, where I was appointed by your predecessor, Secretary Tommy Thompson.

It really is an honor to be here. I guess because I paid my dues and maybe I'm a little bit more tenured, my placard was always at the back of the table and it is moving up here.

[Laughter.]

MR. GROSSMAN: I guess maybe Tom is starting to get comfortable with me now.

SECRETARY LEAVITT: Or wants you very close where he can make certain --

MR. GROSSMAN: That's probably it.

[Laughter.]

SECRETARY LEAVITT: We are glad you are here. Ann.

DR. WAGNER: Good morning. I'm Ann Wagner. I'm with the National Institute of Mental Health. I'm a clinical psychologist by training. I'm on the scientific program staff that manages the autism research portfolio. I function as the executive secretary of this Committee.

SECRETARY LEAVITT: Thank you. I think all of you know Tom and Elias, but there are probably some things about them you don't know. Surprise them, Tom.

[Laughter.]

DR. INSEL: I should have guessed. Well, it did occur to me when you were asking people about their past, especially those who had been at NIH how they got there, I may be the only person who was at NIH before Dr. Alexander. I came as a high school student. I have tried to leave many times.

[Laughter.]

DR. INSEL: But I either can't get a job anyplace else or, when I do get a job, I decide that I would have actually been much happier back at NIH. So I keep coming back, as Elias knows. A fact from the past that I think no one knows.

SECRETARY LEAVITT: Thank you.

DR. INSEL: I should also mention, in terms of revealing secrets, that Lee Grossman's proximity to this end of the table was not of my design.

[Laughter.]

DR. ZERHOUNI: I will just say a few words. I will add a little bit what Tom just said because one of the most important jobs I do is to identify potential directors for institutes that I then present to the Secretary. When there is a candidate, we narrow the list to about two or three, and I like to visit them in their own quarters.

So I visited Tom in Emory, and the way I knew he was going to be the next director, and I wanted him to be the director of the Institute of Mental Health, is two things. One, you may recall, one of our main topics of discussion was actually the strategies related to developmental disabilities and autism and the fact that he felt that NIH was not doing a great job at putting together all aspects of it, from basic to delivery and research.

The second is, I went to a room where there were all post-docs. The room was magnificent. It was books and great carpet and so on. I said, "I have never seen a post-doc room as pristine as this one. They must treat you very well around here." [They replied], "Sir, you don't understand. That was to be Dr. Insel's office and he gave it to us."

I went to see Tom in his office. It was a tiny office. I said this is the man we want: selfless, focused on the total problem. That is how we ended up nominating him for the post.

I'm the director of the National Institutes of Health. I have to look at the total picture, and I can already say that this Committee is going to be close to my heart because there are so many pediatricians on the Committee. I have to tell you, I have a personal attachment to pediatricians. My wife is a pediatrician. She teaches me about the issues of pediatrics. I get private lessons every day about what needs to be done.

I see Dr. Gary Goldstein from the Kennedy Krieger there. He knows that one of the things that we worked on when I was dean of research was in fact breaking barriers between disciplines. I think the autism crisis will require that and will require us to actually enter in ways not entered into before in terms of organizing and stimulating the research we need. So that is why I'm here.

SECRETARY LEAVITT: Good. Thank you. Well, a little bit about me. I'm going to confess to you that I lived the first 40-plus years of my life completely oblivious to this. It sought me out in different ways.

When I was elected governor, I began to feel the impacts of this from other people. There was a woman by the name of Carmen Pingree [ph] who was a neighbor of mine and who was very active in the State of Utah because of her own experience. [She was] just a crusader. She was just relentless, and it was in a very thoughtful, steady way.

Not long ago, a school was developed for children with autism just a few blocks from my home and it bears her name and is a very rightful symbol. I'm guessing some of you know Carmen.

Then, not too long after I was elected governor, a childhood friend of mine called me. Alan Jones is his name. We had actually worked together. He is a little younger than I am. He is my brother's age. He wanted to see me. He told me that their daughter they had just discovered had autism and that they were needing to learn about it and wanted me to know more about it. He wanted to start a group down in our hometown in southwest Utah. There was no money available and he was looking for the State to help.

I sort of followed this through Alan. He told me at some point along the way years later -- I think his daughter, Elaine, now is a senior in high school -- "There is no question that this has been the hardest thing my wife and I have ever faced." He used the phrase, "It has defined our life together," which I thought was a really interesting characterization. He said that in a very positive way, that they have grown in the context of this difficulty. Through him I have been able to see how this affects people in very direct ways.

One of the great things about being the Secretary of Health is you have wonderful teachers. Tom and I had occasion to, on an assignment that we got from the President after the tragic thing at Virginia Tech, travel all over the country together to talk with people in communities who had suffered in similar tragedies, trying to figure out what we could learn from it.

So we spent a lot of time on an airplane together. In the context of it, much of our conversation actually focused on this subject. I got a chance to learn from one of the best about it.

So I want to tell you that I have been fortunate in one respect in that I have not had to deal with this personally, but I have certainly become aware of the distress and the suffering and the sorrow that comes with it and the love that it generates among people and families. So I hope that both of those things can be represented in the context of this conversation.

I do have five children. I now have three grandchildren, which has been fun. At Thanksgiving I was with my daughter, who has a one-year-old and a very active two-year-old. I have been conscious of how we all watch every step of their development and all the little things. They turn over, they sit up, they are responding to things, and how difficult it is when something doesn't happen that you expect should and then the sense of worry that that creates.

I have come to connect that with everyone who has their own experience discovering that they are challenged by this.

So I'm glad that we have parents here, and it looks like we have a good collection of them, who have been through that experience. I'm glad that Stephen is here, who can give us the experience from his point of view.

There are lots of aspects to this. There is the human side of it, there is the economic side of it. I think we are all conscious that this has a tremendous impact economically both for the families and for society in general. But I think what has become eminently clear is that it is not hopeless. It is treatable. It may be even preventable. I think that is what this is about.

We still have a lot to learn here. While we continue to see an increase in the investment and the awareness, there is still a lot of new research that has to be done. There is a lot of research that currently exists that has to be better shared. We have to do a better job of listening to one another. I hope that that is what this panel can be about.

There are things that the federal government can do and should do that it is uniquely able to do. One of them is bringing the kind of researchers together, and the clinicians and the parents, and I hope that is what this represents.

I have been aware of the two-day workshop that was held at IOM. I think that was a good start. I understand that has most recently now been made available, so hopefully we can build on it in the development of this agenda.

But let's just get down to work. I want you to know that I do understand and hold this as a priority. I'm anxious to learn from what you produce. I mentioned earlier that the dozens of different departments and agencies of the federal government need a place where they can come together, and I think that stands out to me as one of the most important things we can do, just get people at the same table.

Things will happen at the breaks that will be more important than a lot of other meetings. Somebody will say, "Something you said triggered a thought in my mind," and I would encourage you to organize your meetings in a way that will allow that kind of spark to happen spontaneously.

You may have some things that you would like to say to me. I'm very anxious to hear them. I don't want to spend so much time that you can't get onto the organized agenda. But, are there questions or advice you would like to provide the Secretary of Health and Human Services? If you would, this is a good time. Any thoughts?

DR. JANVIER: I have some advice. The last time, or the first time I came to this meeting was in 2003. That was in conjunction with the National Autism Summit. I have to say, much of the changes and tools that I have been able to implement in my practice came from that summit. I was able to meet Wendy Stone from Vanderbilt and implement her tools.

I would strongly suggest that the Committee consider such an event again. Washington was wonderful, but again, I think it should be accessible throughout the country.

SECRETARY LEAVITT: Thank you. Those are the kinds of ideas I hope will be advanced and organized into a communications agenda. Collaboration and communication and organizing into a proactive, thoughtful agenda is what I think the product of this needs to be.

Well, Tom, thank you very much for letting me spend some time and get acquainted with all of you more. I am going to excuse myself, with the anticipation that

I will get a full report and we will have other interactions when you have a little more momentum.

DR. INSEL: Thanks so much for joining us. I know you have been in something like 11 cities in last five days, and so I hope this feels like coming home. You are certainly welcome to come back to any additional meetings we have in the future.

SECRETARY LEAVITT: Thank you very much.

DR. INSEL: Let's take just a moment, and then we are going to have Dr. Zerhouni present an overview perspective from the NIH. Maybe we can get the slides up while we are waiting for him to come back up.

I guess there is really no need to reintroduce Dr. Zerhouni, but it is, again, a real privilege to have you launch this meeting. We are delighted to have you here.

In the past, Elias, we have always met in Building 31, and I think, as you look around, you will realize that we have progressed.

[PowerPoint presentation.]

DR. ZERHOUNI: I can tell, I tell you. The voice resonates, too. I hope this will be a resonating committee that will really direct efforts across not just NIH but the entire apparatus that needs to be energized and has already been stimulated.

I think the key question to me as the NIH director is to try to share with you the philosophy that might be considered by the Committee in terms of where to go and how to go about being effective in a committee like this, which is diverse, large, and obviously ties into a very complex underlying reality: a reality of science, where many things are not known; a reality of administrations, where have to coordinate between different agencies; a reality out there with the children themselves, who need to be at the center of the focus.

I happen to suffer personally from dysgraphia. I have never been able to write. People don't know that about me except those who see my handwriting. I was a little bit like Steve. I was pronounced unfit for many academic career tracks. Therefore, I personally felt many, many years ago the need for a child to really be supported and not identified as insufficient in any way, shape, or form.

The second thing I would like to share with you is my sense of how strategy works. I come from a very mathematical family. My brother used to always give us teasers. One day he asked the following question. He said, if I gave you a vase containing large stones, pebbles, and sand, and you knew that the amount of stones and pebbles and sand I gave you fit that vase exactly, then you emptied the vase and I gave you the large stones, the pebbles, and the sand, what would be the best strategy to refill the vase completely? Would it be to put the sand first, the stones second, the pebbles third; or to be the pebbles first, the sand second, and then the stone; the stone, pebbles, and sand?

You could show mathematically that there is no strategy that works better than the one that says first the large stones, second pebbles, and third sand.

What I have noticed in committee after committee and strategy session after strategy session, both in this job, my previous job at Hopkins, and my previous job at my laboratory, is that committees often move between sand, pebble, and rocks at very, very different rates. All of a sudden, what you end up with is you have no sense of exactly how to build that vase that will contain all the elements of the strategy.

So one piece of advice that I always give at the beginning of complex committee work like this is that at some point don't forget the rocks, pebbles, and sand theory of coordinating committees. If you do, what then happens is, at the end, false expectations are created and different perceptions are created. I think that the most important thing here is to be very, very comprehensive and transparent but also strategic.

In that context, I would like to basically give you the broader sense that we have at the NIH of where things are going and how in fact, when I mention Ton's vision of a comprehensive system, that is not a linear system between basic translational research, clinical research, all the way through practice. This is really not a linear system. This is an interacting system where in fact lack of effectiveness at one level enlightens scientific questions at another, and vice versa.

That context is driven in the 21st century by the sense that we have made progress to the point where we can change the old paradigm of medicine, the paradigm of waiting for something wrong to happen to then intervene. This is true for all conditions. This is more true, I think, for developmental disorders and autism spectrum disorders.

When I became director, I used this slide. I said, there is a need to transform medical strategies in the 21st century from treating disease when symptoms appear and normal function is lost, to intervene before symptoms appear and preserve normal function, recover normal function for as long as possible.

Why is it that for the past 5,000 years medicine has adopted the reactive paradigm? That is because knowledge wasn't there. We did not understand the molecular and cellular events that led to disease. Understanding these pre-clinical molecular events, our understanding is increasing.

When I became NIH director in 2002, I asked my staff how many genes do we know for sure are currently known to be of importance to a complex disease. We knew a lot of genes were very, very monogenic diseases but not complex diseases. There was one called PPAR gamma, the enzyme.

In 2002, no discoveries were made. In 2003, two discoveries were made about Crohn's disease and two genes which related to the immune response. In 2004, no discoveries were made. In 2005, five discoveries, all of a sudden.

The one that was really remarkable was the first discovery made by what we call genome-wide association studies, where you are taking a group of patients and a group of controls that don't have the disease and then you see if there any difference in their genome. That became the first discovery in age-related macular degeneration that gave us a sense that in fact this disease may not be degeneration, it actually is an inflammatory disease. It changed the theory of the disease and it changed our approach to the disease.

In 2007, every single week I have received a report of a significant association, and the year is not over. Clearly, we are understanding that better. The risk factors are better identified. More importantly, what we are realizing is that we may not have all the tools needed, nor the strategies, the rocks that I talked about, that are needed to in fact go along that continuum of knowledge to detect the disease and intervene before it is too late.

Hopefully, as I tell Congress, it seems that in this century, unless we find a new paradigm for medicine, it is hard for me to see how we sustain the cost of health care with the trends that we know.

Very much like this meeting, I convened many meetings in 2002, and they ended up being known as the NIH Roadmap for Medical Research. That wasn't the name we wanted to have, but our people in Communications thought it was a good idea.

What we did is we started to use the rock, pebble, and sand strategy and said, wait a minute, let's just make sure we understand where the big rocks are. Those three rocks are here. First, it was very obvious at the very top that there were pathways to discovery that A) were not developed, or B) not exploited. We needed to have a comprehensive approach to in fact open new avenues of understanding and research in all diseases.

The second leg of the Roadmap was the sense that the way you conduct research in 2002 is just not going to be the way research is conducted in 2025. It is thoroughly clear that we will need a different concept of how research teams organize along lines of disciplines that are currently a little too rigid to a world where interdisciplinary research will be required. [That] is actually emerging currently in terms of being able to address a complex medical problem like autism. Clearly, a change there.

The third leg was the sense that there was a disconnect between what we knew in the laboratory and what we had learned in the laboratory, what our scientists were able to do, and the ability to leverage that knowledge into real translation at the population level, the patient level. That is what we call Re-Engineering the Clinical Research Enterprise.

Those are the three big rocks. When people talk about the Roadmap, there are really two things. There is a fundamental vision that says we are shifting from a medicine that was curative to a medicine that is much more preemptive. We need to do this through three very fundamental poles of action, which relate to working real hard [on] what tools we need to understand the diseases that we are talking about, what teams we need to do that, and how we prevent the disconnect that always occurs between lab research, which is very intense, very complex, and very difficult, and the need to humanize it to the child, to the patient. At the end of the day, that is where our value is.

We came up with this concept that medicine of the future will be what we call Four-P format. It will be Predictive based on discoveries, as we are seeing them today and as we are predicting will become much more frequent, at the very fundamental molecular level.

What that means is that in autism spectrum disorders, as you know, we are describing and diagnosing the disease more accurately. As you can see, the Academy of Pediatrics has recommended screening at 12 and 24 months. But we do realize that our tools are incomplete and our tools are insufficient. We need to in fact go further than we have, but more importantly, we need to unravel the scientific mystery of exactly what this is.

It may be that it is not one thing, as we all can imagine. It may be multiple things. I predict that in the 21st century we are going to go through a phase of reclassification of diseases. That has happened. Every century with new knowledge we tend to reclassify diseases. In the 17th and 18th centuries, it was by organ. If you had something in the head, it was something related to the head. There was no understanding of the subcategories of disease. Today, with molecular signatures, we are able to in fact subclassify even the same type of cancer into several subtypes.

This movement, if you will, towards a better understanding and classification of diseases at the molecular level is going to be a driving force, and it should be, in this context.

We need to, obviously, understand that once we can predict and subclassify, that ipso facto means a personalization of the delivery of care. Preemption is absolutely essential because it is not possible to think of the diseases that we deal with without being able to intervene years before they strike. If you can do that, you then achieve a result that is remarkable.

The fourth P, which I don't think is as appreciated by scientists and by the community at large, is what I call the "Participatory P." That is that if you look at every disease process that we are dealing with at the National Institutes of Health and you ask what is the fundamental gap, what is the fundamental problem that we have, what you will hear is patient participation, community participation, the ability to study the disease in its natural environment easily, effectively, with a commitment by the patients.

Yesterday, the Secretary and I were in Boston. We visited the Framingham Study participants. We had over 600 participants, from father to son to grandson, there. It was just such a heart-warming exercise to talk to every single one of them. Their experience being part of a cohort that basically, since 1948, has contributed to world history is a remarkable event.

I dream of almost every complex disease having a Framingham Study of its own kind. That is what I mean by active, collaborative participation.

So those four factors, to me, are going to be the big rocks of exactly what we need to do.

Now, I'm just going to be very quick in terms of the specifics of autism research. I think Tom is going to cover that much better than I can. Clearly, in the predictive category, earlier diagnosis is the order of the day. There is nothing you can study unless you know it is there. You have to do it in prospective terms.

I'm really pleased that the Academy of Pediatrics has joined us in this recommendation and really used the signs that were developed, as Dr. Janvier was saying.

One tool that we knew was going to be absolutely critical is something that I understand a lot about, and that is imaging. Dr. Gary Goldstein, who is here, from the Kennedy Krieger, and I were talking [at the time] I was chair of radiology. It was very obvious that the Kennedy Krieger needed to really break into imaging, MR imaging, at the time because you could not really understand brain development unless you had a standard, normalized database.

The vision to me of the future in all imaging is that instead of eight imaging specialists looking at an image and trying to make some conclusion based on a subjective and semi-objective science, that in fact what you will see is your child will be compared to a normal database at all ages so that the reading will be not against the knowledge base of a single individual and its imperfections but the database that the NIH has developed through NIMH so that you can tell exactly where the discrepancy is, if any, so that you can focus on a better characterization of the disease process in vivo.

That is one example of investments that need to be made, but clearly, the personalization of the treatment is going to be something that is way beyond the NIH's mission. We will need to involve CMS, we will need to involve communities, and there needs to be a new compact around the disease of autism. There needs to be a social change in the understanding of what autism is and its impact on our society.

So it is clearly a challenge. It is not going to be easy. It is going to be a long road, but the longest stretch starts with the first step.

Research on phenotyping and the autism phenome projects are going to be critical. Then, the Genes and Environment Initiative of the Exposure Biology Program that Dr. Wilson is leader of is going to be essential. When we measure exposures today, we measure them on a general basis. We don't really have good measures of individual exposure.

One of the major components of a program we launched in 2005 was to develop new technologies to measure exposure at the individual level and go from there to have a composite view of exactly what happens in terms of diet, physical activity, environmental exposures. [We want to] develop the technology and the biomarkers that will allow you to do that so that you can in fact use that data set against the gene variance. We need a molecular understanding of autism as a either single condition or autism as many conditions, whatever it is.

At the end of the day, that is the golden rule. You have to understand the fundamental mechanisms of the disease.

Participatory means what I said. In other words, I don't believe we can make progress in complex diseases as we know them without a new form of social organization and collaborative. That will require commitments from all parties and not just a one-way commitment. It is going to require an interactive, bidirectional commitment from all involved.

As Tom has always told me, the most important thing is that the longest journeys start with the first step. You need to communicate effectively about exactly what you are doing. You can have the right strategy of the right rocks and the right pebbles and the right sand, but if nobody knows about that, that strategy will really not be leveraged as effectively as it needs to be.

I think that the effort of communicating accurately with the public is going to be essential to the success of this Committee. Obviously, it has to be subtended by some structures. That is why the autism centers of excellence are going to be essential to this integration that I'm talking about.

We need to make sure that in fact over time the science improves and it doesn't become a structure without substance or a structure without performance.

That we are always concerned about. Any time you create an administrative infrastructure, the risk of sclerosis increases. That is my experience. So we need to make sure that there is a continuous flow of flexibility and no barriers should be allowed to be erected between the different disciplines and the different fields.

No one knows where the answer may come from. Therefore, everyone is entitled to a seat the table.

With that, I would like to basically thank you all for your willingness to take the time. I know it is not easy to come to Washington and spend days on things that are process-oriented. But at the end of the day, I think the Committee here is going to be essential to this new vision.

With that, I will turn it back over to you, Tom.

DR. INSEL: Thank you very much, Elias. I know your schedule is tight and you are going to have to get out of here in just a moment. We will take a break when you do that.

Before you leave, any questions, comments, or remarks that you think Dr. Zerhouni should hear?

[No response.]

DR. INSEL: I think that is a surprising silence from this group, but we don't know each other well enough, probably, yet. The next time you come I'm sure they will pepper you with lots of interesting questions.

DR. ZERHOUNI: I think they are reserving their questions for you.

[Laughter.]

DR. INSEL: I think I get the rocks and you get the sand. I think that is how it works. Thank you very much.

Why don't we take 10 minutes, reconvene, and then we will go on with the rest of the program.

[Break.]

DR. INSEL: Let's get back to our seats and we will try to catch up a little bit on the agenda. We have an awful lot that we want to cover. As Secretary Leavitt said, some of the most important conversations will happen during the breaks, so we want to make sure that we don't preempt all of the time you have to interact outside of the formal part of the meeting.

What I'm going to do is just take a very few minutes to review what our job is here based on the Combatting Autism Act. I know many of you are very familiar with this, but I think it is important for us to take a few minutes and just get us all on the same page. This is the work that we are really here to do.

The Combatting Autism Act was signed on December 19th of last year. "The Secretary shall establish a committee to be known as the IACC to coordinate," as Secretary Leavitt said, "all efforts within Department of Health and Human Services concerning autism spectrum disorder."

I point out that Gail Houle is here, joining us a little bit late today, who is from the Department of Education as well. So even amongst the federal partners we stretch outside of DHHS.

Our responsibilities. Really, there are five things that we are charged to do. Here are the first three. First, to develop and annually update a summary of advances in ASD research. The emphasis there is on "research."

Second, to monitor federal activities with respect to ASD research and services, and to make sure that there is coordination thereof.

Third, to make recommendations to the Secretary regarding any appropriate changes to the federal activities, and in addition, to monitor public participation in decisions relating to ASD and to make sure that there is sufficient public participation at every level. We will talk more about that in a few minutes, but one of the things that we as a Committee need to do is to ensure that there is sufficient public participation. If we feel there isn't sufficient public participation, there is a charge to report to the Secretary with some ideas about how that can be improved.

The last two charges are really going to be the meat of what we will work on initially. To develop and annually update a strategic plan for the conduct of and support for ASD research -- again, the emphasis is on "research" -- including proposed budgetary requirements. Finally, to submit to the Department of HHS this plan. They are then to submit it to Congress and they are also to submit any updates.

That is what we are here for. It doesn't sound like it should take so much work that it will take a tremendous amount of labor. Much of what we are going to talk about today is the strategic plan and how we will be able to pull this together in a very, very short time frame.

In the spirit of people talking about off-the-record issues today, let me just say that amongst at least the federal partners who have been involved in this effort, this last nine or 10 months seem like they have been forever. There was actually an effort to get the strategic plan going the second week of January, and we were ready to rock and roll with this as soon as we had gotten the language from the Combatting Autism Act.

But it takes a while to get all of the delegations of authority and to get all of the membership. All of you who have become special government employees know what you had to go through for that purpose. This is what is called a FACA committee, a Federal Advisory Committee Act committee, which means that you have to go through a lot of hoops to be able to serve on the Committee.

So this has been a much more delayed process than we would have liked to get to this November 30th date. I promise you that going forward the sense that I have from all of my federal colleagues is that time matters and that there is a real urgency here. We will, I hope, be much more on the front of our agenda rather than something that we only feel through frustration. I think that we can finally begin to move very quickly.

That is not to say that we haven't accomplished much already. I wanted to just take a few minutes to pay some homage to the previous committee, the IACC, that had met twice a year from 2001 until 2006. As Lee mentioned, he served on that. I think you were the only person who provides the consistency from the previous committee to this one, Lee.

There were many things that came out of that. You heard a little bit from Yvette about the Autism Summit, which was in 2003. One of the tasks of that committee was that we didn't do a strategic plan but we did this research matrix which had a research component that was launched in '03 and then a services report, which looked a bit like a matrix as well, in May of '05.

The research matrix was evaluated just about a year ago, and our last meeting, which was in November of '06, was to look at that evaluation, to take stock of what we had accomplished, and to figure out what we needed to do more of and what might have been missed in the original 2003 plan that we would want to now do a mid-course correction on.

It is going to be difficult for you to read this, I know, but this is familiar to so many of you. I throw it up here as the matrix from 2003. The different colors represent different topics that we were following through. The key thing for you here is to understand the thinking that we had at that point. This was kind of a rock, pebble, and sand effort.

On the left, going from bottom to top, are the low-risk, medium-risk, and high-risk efforts. That is, each of the efforts was ranked on the basis of risk and, on the bottom, from one to three years. The next block is four to six years, and then seven to 10 years. So the upper right-hand corner represents what the vision was for the things most important to accomplish over the 10 years from 2003 to 2013.

As I mentioned, when we did the evaluation of this about a year ago, we got I would say a mixed report card. There were some places where we had clearly had some successes, particularly in building capacity. Some of the initial things to do were to put together a twin registry. We have 130 twins, most of whom are concordant for autism and have been very well characterized both in terms of zygocity -- that is, genetics -- as well as in terms of their symptoms.

The lower left-hand corner effort was to build the tissue repositories, DNA and brains. In the Autism Tissue Program, which is a collaboration with Autism Speaks, we are up to 91 brains as of this point, and we are going up at about 20 a year. When we did the matrix, my memory is, we had 32 in 2003. So we are even accelerating based on the increase in capacity there.

On the level of DNA and cell lines, as of the last count in our repository, almost 4,000. Within about another two or three months, because of a new release, we will be up to almost 8,000 cell lines and DNA samples. Those are from families. If one looks just at cases, we are around 1,600 or 1,800, something like that, by the middle of January.

With other opportunities that are now going on through the Simons Foundation and through the AGRE effort and others, we see these numbers going up perhaps to something like 8,000 cases within a year from now.

This is all building very quickly. There is a lot of acceleration around building capacity, but that, I think, has been the real success. One of the things that the matrix recognized was the most important thing to do was to have the tools there and to have the resources there for the discoveries to take place, a little bit like what you already heard from Dr. Zerhouni.

What was missing from that plan, at least when we looked at this a year ago, was insufficient attention to environmental factors. That was one of the things that we addressed at this IOM meeting earlier this year. Many people felt there was insufficient attention to developing treatments. Yes, there were some treatment studies that came out of the original matrix, but there was a thought that we needed to do far more, particularly treatments that might be focused on the core symptoms of autism.

There was also a sense, as Dr. Zerhouni mentioned, of this idea of going from "autism" to "autisms," that being able to identify the various subtypes of this disorder hadn't been fully realized, and that we needed a lot more activity on that front.

I thought, just to get people up to date, I would do a very quick summary of some of the what I would call milestones over the last four or five years, some of which were related to the matrix, some of which were not.

Just to very quickly go through this, beginning in '04 with the expansion of AGRE and ATP, giving us the DNA samples and brain samples. Some of the first imaging studies that suggested abnormal brain development in terms of the trajectory of both white matter formation as well as of ultimate brain growth.

In '05, we got some of the first baby sibs results, looking at children at very high risk and being able to identify for the first time some of the most important behavioral features for predicting. Again as Dr. Zerhouni was saying, this very important aspect of prediction and preemption.

The launching of the public awareness campaigns through CDC: Learn the Signs, Act Early. Something that was then done with Autism Speaks and got a tremendous amount of pickup from the Ad Council campaign.

The first quantitative neuroanatomic study. Walter Koroshetz, who is here, probably would think that this is impossible that this hadn't been done earlier, but that is the state of this field relative to much of the rest of neurology. We actually didn't have a single quantitative study of the brain, at least at the cellular level, until early in 2006.

The first development of some behavioral strategies on joint attention and play skills showing that by putting these in place in a randomized control trial between 18 and 24 months you could get significant recovery compared to treatment as usual.

The study from Cathy Lord showing diagnostic stability beginning at age two and following these same kids to age 12.

The opening of our NIH or NIMH Intramural Program, which in some ways came about as a function of the matrix and realizing the difficulty of getting some of these goals met through the typical peer review, RO1 mechanism. It was just taking too long. We wanted to have some place where we could move rapidly. This was a program that is largely focused on studies of the immune system in autism and included both characterization of the immune system in regressive versus non-regressive autism, but also looked at treatment studies. So, developing the first studies that were carefully controlled of anti-inflammatories and other factors that have been carried out by Dr. Sue Swedo, who I believe is here with us, or was here earlier.

So there is a lot going on in the Intramural Program. You will hear more about that, I think, over the next few meetings. I only learned this week that in their first 18 months they have screened over 152 children and have about 108 that have already been enrolled in studies. So this is a very rapid and very exciting project.

Last October, or I guess it was the end of '06, the FDA ultimately approved the use of Risperidone for autism. I believe that was about October of 2006. Of course, the Combatting Autism Act being signed at the end of December 2006 was very much a landmark.

Finally, just the MMWR report from CDC about the one in 150. Predicting autism at 12 months has become something, as Dr. Zerhouni said, that we have seen several reports on in this past year. Both work from Becky Landa and Hopkins and the work from Sally Rogers at UC Davis. Really very exciting work where prospectively children at risk were followed. We are finally able to now identify some of the ways in which these kids can be clearly detected at either 14 months or, in some cases, at 12 months with significant sensitivity and significant predictability.

This past year has been an extraordinary time for the genetics of autism in ways that perhaps none of us would have expected. We thought it would come earlier. What came really was sort of a wave. We are still in the middle of that wave. Many of these papers are not yet published. Much of this was presented about three or four weeks ago at the American Society for Human Genetics meeting in San Diego, a meeting which, by the way, five years ago had virtually nothing on autism. This year autism was one of the main topics both for the plenary sessions as well as for the poster sessions.

Finally, just recently, the AAP guidelines that you heard about from Dr. Zerhouni which I think also must be seen as a landmark for the ways in which now research is beginning to inform practice and to change the way that pediatricians across the country will be increasing awareness and increasing detection of autism in the community.

Finally, as of today, we will be launching the National Database for Autism Research, which is, I think, also a very exciting new effort. I will tell you just very briefly about this. This is something that was generated over the last two years here at NIH to try to pull together in one place all of the efforts that are going on [that are] both NIH- and CDC-supported but also much more broadly throughout the community.

The hope is that this will ultimately be a kind of one-stop shop for the entire research effort, whether it is in terms of the clinical studies of phenotyping, whether we are talking about imaging studies or genetics. All of the data will be linked to this data base through what we will call a federated system.

I'm not going to take you through this in great detail. There will be an opportunity, I think, for us to talk about this much more in the future. I do want to mention that we are at a point where we have already had this running for the past few months through our Intramural Program. We have used them, as we do for so many things, to sort of kick the tires on this and to make sure that it is actually going to work. The report from them is that this has really made their lives in some ways easier, not more complicated.

So we are at the point where we are ready to roll this out, initially to the ASE network. Over the next few months, we are going to go much broader than that, ultimately to pick up archived data from the AGRE studies from the start and CPEA network as well as from AGRE fairly soon.

The hope is that about a year from now we will have this as a fully federated database that will interact not only with the NIH-supported research community but also with the private community that could bring in the work that is being currently supported by Simons Foundation, Autism Speaks, and others.

Last comment here is, with all of this going on, we realized soon after the Combatting Autism Act was passed that we needed to do much more on our end to get proactive about all of the opportunities that were out there and to push forward with a lot more focus, I would say. So starting in the spring and summer, I brought in a number of people to form what we are now calling an Autism Team. All of the team I believe is here with us today, and I wanted to take a moment to introduce them.

Their job is going to be to work with all of you. They are here to staff these IACC meetings and to work to bring all the information that you are going to need for developing a strategic plan and for making the reports that are necessary that will go back to the Secretary.

They will be, in a little while, telling us much more about what they are doing in terms of the strategic plan. We will have the team actually walk us through that and what it is that you will need to do today to get that launched. They are going to be organizing a number of scientific workshops for that, and they have already started that process.

Finally, this is the group that will also be helping to organize and oversee this database for autism research. They will be managing that and pushing that forward to make sure that it comes out on time and that it is perfectly integrated with everything else that is going on across the country.

When I said "perfectly integrated," I saw the team all look at their shoes. Excuse me for putting you on the spot.

Let me introduce the group very, very quickly. Dr. Joyce Chung, who is on the side here -- thanks for standing up, Joyce -- is leading the Autism Team and comes to us as a psychiatrist. She was at Georgetown University before in the Department of Psychiatry. She was funded by NIMH and has jumped into this with a huge amount of passion, a lot of interest in trying to move things forward very quickly, and has been really an important person in pulling all the different pieces of this together.

Dr. Steve Foote, who is in the back of the room, is well known to many people here. Steve had been at NIMH and actually had autism as one of the areas in his division. That was his specific program. He retired from NIMH much too early. I think that was about 18 months ago. We brought Steve out of retirement to help us really pull together the strategic planning process. He is somebody who has a lot of experience in both public-private efforts and in also knowing how to get the federal effort working very quickly. Steve has had an important role in designing this, and you will hear more about that in a few minutes.

Diane Buckley, who was working in Dr. Zerhouni's effort overall within the Office of Science Policy for NIH, has joined us to help with the report-writing and to make sure that we have all of the requirements in the Combatting Autism Act completed with all of the facts that they are going to need.

Finally, Dan Hall. Dan had been working on the caBIG project. This is a huge database effort for the National Cancer Institute. We were able to persuade him a few months ago to leave caBIG and to join the NDAR effort to lead that for us in a way that would, again, meet all of the milestones and be well integrated with what is going on in other efforts to that it would be fully federated.

Finally, Takita Herbert, who I saw earlier and don't see now, is providing support to the team and will be around as well. You will get to know all of these people very well. These are people who are going to be working with every one of you. I think you will find them to be as competent and as passionate as I have. I must say that it has been a real pleasure having this group join in this effort.

I should also tell you that many of them, in addition to being passionate about the science, are also parents of children with autism and have left other things that they were doing very well, as many of the members on the Council you have already heard, so that they could give of themselves and give back in an area which touches them personally as well as professionally.

I will stop with that comment and see if there are any questions about our charge and about what we will be planning to do. What we are going to do after we do a round of introductions is to hear much more detail about the strategic plan. Lee.

MR. GROSSMAN: Thank you, Tom. I wanted to ask a couple questions out of clarity and kind of to manage expectations of what we are doing here at the IACC. We have been asked a lot of questions at ASA regarding how the services fit in. In reading the section of the bill authorizing the IACC, it refers quite a bit to research, but there are also these gray areas. For example, monitor federal activities with respect to autism spectrum disorder, coordinate all activities.

So I want to see how the services aspect of this fits in. I just want to clarify that. If it is, then how you see that moving forward.

DR. INSEL: You are absolutely right. There is some ambiguity in the law. That is why I took the time to actually put in the words that were there. It says to update and provide the summary of the research. It doesn't say anything about services at that point. But then later it says that our job is to monitor activities with respect to ASD, including, I would presume, services.

We kind of danced around this a little bit in the previous committee. We started off with a real focus on the research and then what we heard from people was that is great. Actually, I think it was when Ellen joined the group that we really got a sense of the urgency of trying to get a better picture on questions like Medicaid waivers. I remember we had meetings where there were lots of questions about the variations between states and policies, especially Medicaid policies.

As you will remember, at that point we said we need to know a lot more about this, and we brought together a group -- you were part of it. Ellen was very active in this as well -- to give us a sense of the landscape. I think that was helpful.

I would recommend that we not take that off the table. I think that it would be a mistake for this group to ignore some of the urgent issues around services. Certainly, we have an opportunity here because we have most of the people at the table that would have that information to bring this out and to make sure that we coordinate appropriately.

But we can do that. I think the language allows us to do it. It doesn't mandate it, but I don't think it tells us we can't. So I'm hoping, if there is interest from the rest of the Committee, that we would engage in that issue.

I should clarify that the strategic plan, though, specifically says research and not services. So our first order of business, which will be around this plan, is going to be on that part of it. We could still do something with services research, but it is going to be around research.

What was your second?

MR. GROSSMAN: Again reading from the law, these are all clarity issues. I was happy to see that it said "The Committee shall receive necessary and appropriate administrative support" from the Secretary because that was the problem in the first IACC. Is that something that you feel confident about?

DR. INSEL: "Necessary and appropriate." We read that as money.

[Laughter.]

DR. INSEL: I'm not sure how other people read that. There is a comment in the NIH-HHS appropriations bill that would provide financial support for running this Committee, but that bill has not been passed. It is in limbo. If any of you want to contribute to running the Committee, you are more than welcome to do that. That is a joke. We are going to have to wait and see how we do.

MR. GROSSMAN: We are working on the money issue on our end.

Then the last question I had was just regarding the subcommittees, because it does allow the Committee to establish subcommittees. Is there any plan to do that?

DR. INSEL: Right. We are authorized to be able to do subcommittees and workshops, and even a workgroup. We have the opportunity to do that. I think at this point we are going to build the strategic plan around those kinds of recommendations -- you will see this in a few minutes -- where we will have workshops and a workgroup that come under that kind of authority.

Anything else?

[No response.]

DR. INSEL: If not, I know we are way behind schedule. I apologize for that. I would like to take a couple of minutes -- I know originally we said five, but maybe we should cut that down to try to save some time -- and just go around the table. Part of today really is just getting to know each other. We are going to be working together a lot over the next few years, and I wanted to start by making sure we are all getting familiar.

So if we could take a couple minutes for people to talk about what their agency does with respect to autism, I think it would be useful to get a sense of what that federal landscape looks like.

I know that there is a roster. I don't have it in front of me. Cindy, who is the first one up for that discussion?

DR. LAWLER: Pat Morrissey.

DR. INSEL: Pat Morrissey. So, Pat, why don't you start?

DR. MORRISSEY: I will try to do this in two minutes. The Administration in its work on disabilities funds 67 university centers, many of which are funded by NIH institutes and do work in applied and basic research in autism, as well as focusing on the service side of things. We fund other grantees that also interact directly with people with autism.

Protection and advocacy system. They provide attention to human and civil rights of people with all types of developmental disabilities, including those with autism. We fund state developmental disabilities councils which basically advise governors as to how service systems need to change and advocate for people and train people to advocate for themselves.

Every one of these types of grantees have advisory groups, or the council itself is, obviously, an advisory group to the governor. They include people with autism or parents of people with autism. So there is a direct connection there to what we discover on this committee that we can share.

So I guess the thing I promise all of you is that we will be very proactive in sharing information with our grantees, who will then be in a position to affect people with autism and their families in every community in the United States.

I think that is important because I got the impression from your list that making sure everybody knew what was going on and transparency was a key factor in what this Committee does going forward. We will be glad to help with that.

DR. INSEL: Thanks, Pat. I think it is very helpful. I know that even people who work in the government sometimes can't figure out what all the agencies do, so there is an opportunity here, since we are coordinating, to figure out which pieces of the puzzle fall in which agency. Ed.

DR. TREVATHAN: Thanks, Tom. It is a pleasure to be here representing CDC. Secretary Gerberding wanted to me to be sure and say that she was sorry she was not able to attend today but realizes the importance of this issue.

Describing the CDC in two minutes is a bit of a challenge. I think perhaps one of the things that is worth pointing out is, from a research point of view as we think about going forward, public health and population-based emphasis research are our ability to shine.

I think, to add to all the great work that is being done here going forward, can really be the fact that we have the ability to do large-scale population-based community studies that really aren't subjected to the concerns we all have and work toward as clinical investigators in terms of referral bias and so forth. We really have the ability to look at snapshots of the population.

We have also large numbers of people within our agency that have not been involved heretofore that I think we could call upon in the future as we identify potential risk factors. Especially, if we think of environment broadly, some of our infectious disease expertise in the general population could be called to bear.

Then our Office of Public Health Genomics, for example, that is really focusing on looking at genomic risk factors in large populations, has potential to contribute, as well as our National Center for Environmental Health Laboratories, that can do large numbers of evaluations.

At this point I would say our activities to date have been focused on, say, three broad areas. One, population-based surveillance and epidemiology to identify estimates of prevalence of autistic spectrum disorders. We have heard the numbers today already a couple of times: the estimate of one in 150 children with an autistic spectrum disorder, or the term that I'm warming to as well, the "autisms." That number that really encompasses all those areas has come from our surveillance data.

[We also do] etiologic research from a public health point of view, as exemplified by our CADDRE centers that are now enrolling patients and collecting data. There will be about 2,700 children involved in studies looking at a variety of different potential risk factors.

Then, also, an area that has been emphasized is early intervention or early recognition to enhance early intervention. In our Learn the Signs, Act Early campaign we have worked, as has been mentioned, with the American Academy of Pediatrics to encourage screening children on a universal basis early for autism and related developmental disabilities. We think that those areas are going to be important going forward.

I think our challenges in the future are going to really be continuing our surveillance to look at prevalence estimates in the population using standard definitions. What we hope to be able to do as we go forward is to get into estimates in younger age groups as we are able to identify children earlier, to be able to get population-based prevalence estimates on more homogeneous autism syndromes. We hope also to be able to use some of the genetic environmental capabilities to look at etiologic risk factors going forward. Thanks.

DR. INSEL: Thank you. Ellen.

MS. BLACKWELL: Hi. It is going to be hard to explain everything CMS does in three minutes, Dr. Insel, but I will try. We are the agency that administers three major programs: the Medicare program and also the Medicaid and State Children's Health Insurance Program.

I would say that the latter two programs are probably the ones that have the most impact on children and adults with autism. Medicaid is a huge program. Medicaid and SCHIP last year expended over $301 billion.

Today I wanted to mention a couple things. In the previous iteration of this group, we made a promise to the Services Subcommittee, which was to produce some promising practices papers about how Medicaid funds could be expended to help children and adults with autism, and we did in fact publish these papers, I am so happy to say. They are on our website under the "Promising Practices" link. There are three of them. One is a study in California of young children who are being diagnosed, the other is a pilot program in Connecticut for young adults who are trying to get work, and the third is a supported employment program in Delaware.

So it is really nice to be able to actually finish a project that we promised this body. I brought a few copies of them with me, and they are also on the CMS website.

Most people with autism are served through home- and community-based services waivers or through our Early and Periodic Diagnostic Screening and Treatment Program. CMS is also a big funder of educational services in the United States, as I have talked about before.

Presently, we have seven approved home- and community-based waivers for children and adults with ASD that serve about 7,000 individuals. I was telling Dr. Insel this morning that it seems like such a small number because these waivers serve over 1 million people, and 7,000 folks is kind of a small number.

Many states, though, are starting to get engaged in autism. Because Medicaid is a state-driven program, CMS is really the receptor for states. In fact, I received this nice report from Utah this week which I thought was kind of cool.

We have several states that have actually set up state operational units to focus on autism. It is less than a handful, but it is becoming a little bit more of interest to states.

We also have many grant programs that operate. One of the new ones is a program that is going to be looking at youth who are living in psychiatric residential treatment facilities. We think some of these youth, who go up to age 22, may have ASD. We are going to try to take a look and see if this program is going to be benefitting any of those kids.

We also have a very new grant program. It is huge. It is $2 billion in the money-follows-the-person grants. We don't think at this time that they are going to include many people with autism, but I am asking folks to keep a look on that.

A couple other things happening in CMS that I think will impact people with autism or that have certainly gotten the attention of the autism community are a regulation on rehabilitative services that we issued. We took comments until October, and one of the topics that that regulation addresses is the difference between rehabilitative services and habilitative services. There will be more on that, I'm sure, as we move towards the publishing of the final regulation.

We also have a regulation on case management services in clearance that may have an impact on services for people with autism.

The only other thing I would like to mention is that we have an increasing emphasis on self-direction in Medicaid. Families of children with autism are particularly interested in self-directing their family member services, and more and more states are getting engaged in that activity.

That is about it for me today.

DR. INSEL: Great. Thank you. Listening to you reminds me that in the previous committee we had Ellen actually give us kind of a short course in a bit of a workshop at one of our meetings. It was very memorable because this is such complicated stuff.

Jim Battey and I and others are used to looking at complex cellular networks, but to understand the way in which these networks work for services was actually more complicated than understanding the cell, I think. Actually, the diagrams aren't that different. It is just the labels are changed.

It may be the kind of thing that, as we go forward, we will want to do at some other point because most of us, even those of us who thought we knew or understood some of this, discovered that there is a lot of complexity here, and some of it is changing.

MS. BLACKWELL: We gave a presentation recently to state mental health directors with our SAMHSA partners trying to teach state mental health directors about Medicaid. It was amazing to me because the lexicon is so different between evidence-based practices and the Medicaid program. So we really are trying hard to make that link. I hope that continues.

DR. INSEL: Right. The point is, though, that in addition to a coordination function what we used this Committee for before was educating each other. It is great to have you as part of the Committee because this is a piece that I think all of us need to learn much more about.

Let's go on. Gail, you weren't here for the original introductions, so why don't you say who you are and where you work and a little bit about the Department of Ed.

DR. HOULE: Thank you very much. I'm Gail Houle, and I'm associate division director for programs in the Office of Special Education Programs. My particular area of expertise is speech language intervention programs, early childhood programs, and parent information and training programs.

I hope that, as you had mentioned, Tom, maybe sometime we will have an hour to present to the Committee with some visuals to try to explain how some of our programs work and how the financing, the money, and the services get from the federal government to the level of the child and the family in the schools or in an early intervention program.

We implement IDEA, the Individuals with Disabilities Education Act. Our office implements Part B, which is six through 21 services, special education and related services. Actually, excuse me, Part B is three through 21 and Part C is birth to the age of three. So we have those two programs.

We also have a small discretionary grant program, which is Part D of IDEA. It is a smaller pot of money that we use for competitive discretionary awards. Many of those awards recently have been in the area of providing technical assistance and personnel training to meet the needs of children with autism.

We are primarily focused as a federal agency on providing funding and services to states, who are then in turn charged with monitoring and providing services to the local education agencies or the local early intervention agencies.

It is somewhat complicated. The federal special education funds provide approximately 17 percent of the cost of providing services to a child with a disability, in general. That is an interesting fact to remember with this. A lot of the funding is made up from state and local funds combined with the federal appropriation in special education.

We fund a formula grant program, which is our largest program in Part C and Part B, where we fund states based on child count or census population of the state. That flows a little over $11 billion from our Office of Special Education Programs directly to the states to combine with their funding to provide special education services. We have investments in the discretionary program as well.

Some of our priorities in the area of autism are early and accurate diagnosis and classification of children on the spectrum, early intervention services for children on the spectrum, educational programs and approaches, including evidence-based practices and ensuring that practices that are used do follow the most current and most compelling evidence for interventions.

We are interested in additional communication and speech interventions, sensory and motor development interventions, those that also promote and facilitate social interaction and address challenging behaviors, and we are interested in the measurement of the personnel training impacts and how we can provide better models for universities and colleges to use in effectively preparing personnel to specifically work with children with autism.

We are also interested in facilitating the collaboration among the educational personnel, special education and related service providers, and families at the national, state, and local levels. We have a pretty full agenda, and we have some recent investments that I look forward to presenting.

DR. INSEL: Thank you. The challenge will be now to coordinate much of that with what is going on elsewhere. That is one of the things we can do here. Peter.

DR. van DYCK: Good morning. I will try to be brief in describing three or four programs. Under education and training type programs, we have an investment called the Leadership Education in Neurodevelopment and Related Disabilities -- it is much easier to call it "LEND" -- and Developmental Behavioral Pediatrics. We currently fund 34 LEND programs in 27 states and the District of Columbia. The money goes to universities. It is an annual investment of about $19 million.

We have nine Developmental Behavioral Pediatrics Training grants in seven states to universities, for a total investment of about $1.5 million.

These LEND programs provide long-term training to pediatricians, OTs, PTs, nursing, nutrition, communication disorders, audiology, speech, et cetera. In the Developmental Behavioral Program, long-term training is provided to developmental behavioral pediatrics fellows.

Both the programs not only do training but they do service, so in both training programs screening, diagnosis, and treatment services are provided to kids. Continuing education and technical assistance is provided to local providers and families, as well. Autism is included in the training and service provision in those programs.

Surveillance. Data from the 2005 National Survey of Children with Special Healthcare Needs has just become available. Actually, it was earlier this week. Yesterday, I believe. It is now available at the HRSA, Maternal and Child Health, and the National Center for Health Statistics websites. This national survey is the first ever national survey of children with special healthcare needs using a common definition to establish prevalence estimates at both the national and state level. It helps us monitor children with special healthcare needs and their families and how they function or move within the healthcare system.

There was a previous survey in 2001. This gives us a chance to do some follow-up from 2001 to 2005, but importantly, in this last survey, which was just released, children with special health care needs are surveyed by functional limitation and by selected health conditions, and autism is one of those selected health conditions. We should be able to have data in the next couple of months on children with autism, families with autism, access to services, functional limitations, impact on the family, and other items.

First, the Maternal and Child Health Services block grant that I mentioned earlier provides money to maternal and child health programs and children with special healthcare needs programs in each state. Thirty percent of the $600 million that states get for the block grant has to be spent on children with special healthcare needs, including children with autism. States match this money, so it grows into almost $2 billion that are serving children with special healthcare needs across the states.

Data from the survey estimate that about 14 percent of children have special healthcare needs, which is about 10 million kids in the United States who have a special healthcare need. In these children with special healthcare needs programs in the states, children with autism are served.

As part of the previous IACC, we worked on a subcommittee, in fact co-chaired the subcommittee, of services, the Services Subcommittee, and worked on a set of guidelines for medical home primary care practices through the National Medical Home Autism Initiative at the Waysman Center at the University of Wisconsin. These guidelines developed by the ASD Service Guideline Workgroup include service guidelines for the medical home which are consistent with the recent clinical reports and toolkit just released this last month by the American Academy of Pediatrics.

The guidelines go beyond the medical home to focus on the action steps needed to support the child and the family in the broad system of care. They will be beginning to be used in a series of regional meetings beginning next week in Chicago as a discussion and planning tool for state teams to develop action plans for implementing responsive ASD services.

I happen to have a draft of that here if anybody wants to take a quick look at it.

I think I will end there in the sake of time, other than to say the charter does suggest that research is important but we don't think it is sufficient. There is still a need to implement research findings in the practice community. We need to be better at implementing evidence-based services. The Maternal and Child Health Bureau is here to represent these training and service needs in the community. Thank you.

DR. INSEL: Great. Thank you very much. There are 27 institutes at the National Institutes of Health that Dr. Zerhouni talked about. Five of them are represented on the IACC. Maybe we can just go quickly through them so that you will get a sense of the somewhat different portfolios in each.

Duane, do you want to start?

DR. ALEXANDER: Part of NICHD's mission from the beginning has been to try and help people have healthy babies and help those children reach adulthood as free of disease and disability as possible. Developmental disorders has been a major component of the research that we support, including autism.

This grew considerably a little over 10 years ago, when we joined with the National Institute on Deafness and Other Communication Disorders to fund 10 collaborative programs of excellence in autism. That markedly expanded our research support and helped increase the work in autism and provided some of the leadership in autism research over the last decade.

Last year, these CPEAs, along with the STAART Centers in Autism, evolved into the autism centers of excellence. Seven of these were funded, supported by five different institutes, and more of them will be funded in 2008.

But the majority of our research is investigator-initiated research grants that we support, many of them conducted in one of the 14 developmental disabilities research centers that we support around the country.

We also support research training to train new scientists and investigators in autism and other developmental disability research. We also are involved with research outside of the NIH. Alice Cowell from our staff, for example, sits on the group that is coordinating NIH and Department of Defense Research Activities in the new congressionally directed Medical Research Program, which includes autism for the first time. She is involved with that.

Our major feasibility activity for the next several years is probably going to be the National Children's Study. Dr. Zerhouni talked about the Framingham Study. This in many ways is an environmental Framingham. It is a coalition of many federal agencies led by NICHD, the National Institute of Environmental Health Sciences, the CDC, Ed Center primarily, and the Environmental Protection Agency.

This study will recruit, over the course of about four years, 100,000 children, beginning during pregnancy and then following them through infancy, childhood, adolescence, to age 21. [It will] look at environmental influences broadly defined; not just physical and chemical environmental exposures but also the social, cultural, and educational environment that these kids grow up in. [It will] look for environmental factors that influence their development and whether or not they develop certain disorders or diseases.

This will be a major effort. It is about to kick off. We anticipate the recruitment of the first kids into this cohort in 2008.

Autism is one of the major outcomes that we will be looking at in this cohort of 100,000 kids. We expect we will have about 700 children with autism, and 99,000 controls. So we will have a prospective look at children with all this information gathered before diagnosis of autism was made that we can go back and look at, and also look at it in relationship to their genetic constitution. We will have DNA from the kids, both parents, and siblings, to the extent that we can get that.

So we won't have to wait 21 years for the answers because most of these kids will be diagnosed by age three. We can start doing the evaluations of the environmental exposures that relate to autism.

In addition to this, NICHD supports a brain and tissue bank for developmental disorders, with an increasing emphasis on autism. We also are partners in the coalition that is working on the Baby Siblings Project and a number of other disorders. I will stop there.

DR. INSEL: Thank you. Jim.

DR. BATTEY: Yes, Tom. Thank you very much. I will try to be brief. NIDCD's interest in autism is in supporting research that studies the consequences of autism for communication and language development. We are pleased by a number of developments over the last five years. We are supporting an increasing number of trainees and career development awards which will hopefully train the next generation of scientists to continue the important work in this area.

Our portfolio of investigator-initiated research has more than doubled between 2001 and 2006, which we also think is a very positive development.

We are very pleased that we have had an opportunity to collaborate with other NIH institutes to support the autism centers for excellence, and we were delighted to work together with NICHD over the 10-year period that the CPEA network was in place. That was very satisfying.

Finally, we are working together with Autism Speaks to develop a small meeting. The goals of this meeting will be to figure out what criteria one can use to establish the acquisition of functional speech in children with autism spectrum disorders and to develop a set of recommended measures that can be used as outcome measures for evaluating interventions that target language.

DR. INSEL: Thank you. Sam.

DR. WILSON: Tom, thank you. I will be brief. Cindy, of course, is a member of the Committee, and I will pass the mic to her in just a few moments.

I look forward to working with this Committee as we move forward over the next months and years. I'm here today to affirm the commitment of NIEHS in autism research.

In our research at NIEHS, we work closely with committees like this one and with advocates and with groups out in the general community. We are used to listening and responding to the views and needs and research ideas of the communities. That is an important point that I would like to get out on the table.

Finally, as this effort in autism research builds capacity, we at NIEHS would like to partner across the entire research effort as we move forward.

I will turn the microphone now to Cindy.

DR. LAWLER: Thank you. We had no investment in autism in the year 2000, and that has grown to almost $3 million in 2007, which is, I think, a significant success story.

The main focus of our efforts in building a program at our institute has been developing strategies to engage environmental health scientists in the autism arena. I think we have been fairly successful. We now have routinely autism and the environment sessions as part of international neurotoxicology meetings and Society of Toxicology meetings and also the international meetings for autism research. That is a sign of success and movement in the right direction.

I think the best example of our success in this arena has been the CHARGE study at UC Davis. That was initiated in 2001 and took advantage of a Children's Environmental Health Centers Initiative, a broad initiative at our institute. CHARGE is the first population-based case control study of environmental risk factors.

In 2001, the CHARGE investigators were top scientists in environmental epidemiology and toxicology, but they were new to autism. So that has been a huge success. It is an ongoing study, and we are now beginning to see some of the very provocative results that are emerging from that study.

In the same vein, I will just mention an initiative that we have recently developed, and this has been, again, to try to encourage collaborations between scientists in the environmental health community with autism researchers. We developed the ENHANCES Program, which has provided funds for pilot projects that involve ace investigators and established environmental health scientists to begin to develop collaborations and preliminary data and strategies for addressing environmental etiologies in autism.

I think I will stop there.

DR. INSEL: Thank you. I will put my NIMH hat on for just a moment. To give you something of the landscape of NIH, the 27 institutes, some of them are involved with developing resources or are focused on a particular approach, like the environmental health sciences. Some are really focused on life stage. We have a National Institute of Aging, and as you heard from Dr. Alexander, the National Institute of Child Health and Development.

Others are much more what we sometimes call disease-specific. We are one of those, as is the Neurology Institute, more disease-specific. We are focused on a number of mental disorders. Those are usually mood, anxiety, psychotic disorders.

Autism is one of those that we have a real interest in, and that interest has ramped up considerably in the last few years. In 1997, the NIMH investment in autism was about $9 million. In 2006, the last year we have final numbers for, it was $61 million. So we have gone up almost seven-fold since 1997.

This is an investment that has gone in a variety of ways. It is interesting; the NIMH covers everything from genetics and imaging, which is a high priority for us, to working out the biology of the disease and finding biomarkers and early diagnostic tools, to the other end of the spectrum, where we do research on service delivery. What are the healthcare disparities for autism; how do states compare; what are the best practices for the delivery of services, using state and Medicaid data, and can we figure out from that whether the science that we are doing actually is having an impact and are we actually seeing the dissemination of evidence-based practices.

The flip side of that is trying to get a sense from the service data about what the scientific needs are. What are the kinds of projects that we need to be focusing on in terms of the more basic and less applied research.

We have a very broad portfolio. I should mention that Ann Wagner, who is part of our program in autism, also chairs something called the NIH Autism

Coordinating Committee. So we have, even within NIH, a kind of smaller group. Of the five institutes that are involved in autism research, the program officers meet once a month or something like that to make sure that we are working together.

So when you hear about something like these autism centers of excellence that Duane mentioned, everybody is at the table to figure out how to fund those. They come in as a single program. I think NIMH took some, NICHD took others, depending on what the focus of the grants are and what their major interests are.

Just to give you a flavor of that for the NIMH centers, the one that has been funded this past year is a study to look at brain development through serial neuroimaging at high resolution in a baby sibs approach, so in children at very high risk for developing autism, to see if we can pick it up very early on. This is a study at UCSD by Eric Courchesne to see if we can detect what is it about brain development that may be changing before the symptoms emerge or before there is even a diagnosis. It starts very early.

Another kind of study at one of the centers that have picked up at NIMH is looking at psychosocial interventions also very early. [There is] work from Sally Rogers at UC Davis trying to figure out whether an intensive behavioral approach, getting children at 18 to 24 months, will have a greater impact than either starting later or starting with a less intensive approach, doing this in a very well controlled, rigorous way.

That latter experiment, I should mention, is part of a network. One of the things that we have put in place is that many of these sites work together across the country using collective approaches to diagnosis and intervention so that we get more data than we could get from any given site.

That gives you, I think, a sense of the kinds of things we are involved with. I did mention earlier that we have an intramural effort through NIMH which is very focused on immune mechanisms as well as trying to do novel kinds of treatment development. As others have mentioned, much of our work on the extramural side is investigator-initiated, where we hope to have the very best ideas, including a lot of encouragement for young investigators to move into this field.

That is a very quick run-down. You will hear much more about that, I think, as time goes on. Walter.

MR. KOROSHETZ: Thanks. The NINDS supports a broad range of research in autism and neurodevelopmental disorders. Deb Hirtz is here, our program director, and Laura Ramunez, who works in genetics and autism for NINDS is here. With the other institutes, we support the autism centers for excellence.

A lot of work at our institute is targeted at brain development, and there has been some really amazing new science that has come out of the study of brain development. I don't know if people know, but the Nobel Prize last year was given to scientist Craig Mello for finding how small pieces of RNA actually affect gene transcription in worms. It turns out, I think, that the last couple of years we have seen that that is amazingly important in how the brain is developing. It is a brand new area that has opened up in this kind of broader scheme called epigenetics.

With the other institutes, we are involved in the mass attempt to try and get the genes that participate in conferring risk for autism. There are a couple of little things I would like to point out. There are a couple of clever little projects.

Duane mentioned this large population study. We have actually hooked onto one that started in Norway a number of years ago where they actually have been tracking about 65,000 births already in a very kind of organized fashion. We have attached an autism study to that big population study to get at some similar things. They have blood banked, DNA banked, and hopefully that will be profitable.

Another one was a study which is based on trying to find a population where there is not much genetic variation where we have a better chance of finding autism genes. This is a group that we are funding that is looking at autism in the Central Valley of Costa Rica, which is a very genetically homogeneous population. This is something similar to what Jim did in Venezuela looking for the Huntington's gene.

The other thing I would mention is that there are these autism-associated disorders which are monogenic and can give really interesting insights into how the brain doesn't develop normally and actually causes symptoms that are very similar to autism. Disorders like Fragile X, Angelman's syndrome, and tuberous sclerosis have genes that have been identified.

Really, one of the most important things there is that identifying these genes gives scientists tools. They now have animal models, mouse models, that they can really work with. Sometimes having the tool is what really attracts the really good scientists. People who are really smart are going to stay away from a problem until an animal model shows up that they can work with. That can be a real attraction. So we are hoping that this research will help these kids with these really bad things, but it may also pay off in the general autism research.

Finally, I would end up by saying that a lot of what I mentioned is research that is ongoing, hinting to the future. There is an attempt to try and see are there some things out there right now that can make a difference. We are planning now and working with Diane

Shegany [ph] at Wayne State in Detroit on a trial of a serotonergic drug, Buspirone. She has been able to identify with PET scanning abnormalities in serotonin metabolism in the brain of kids with autism. The hope is that this drug, which has potentially some positive effects, maybe even on behavior, may actually also affect the neurodevelopment. We are hoping that that trial will get up pretty soon.

The last thing I would say is that I think all of the NIH institutes are really invested in being persistent and just keeping the work going until we get to a treatment. Hopefully it will be soon, but we will keep working there.

I would like to thank the families and the kids who participate in this research because nothing goes forward without that. So, thanks.

DR. INSEL: Thank you, Walter. Peg.

DR. GIANNINI: Our role is a little bit different from most of you with your tremendous budgets and millions of dollars and so forth. As our office is advisory to the Secretary and to the White House, our charge is really to facilitate collaboration and partnerships and common areas of issues that we can work on. That goes not only within HHS but also to work with other federal departments and also on the state level and on the local level.

Basically, the Freedom Initiative's bottom line is to tear down all barriers for persons with disabilities throughout all the domains, so we cover all of those. Autism is part of each one of them, if you look at the particular domain and where that particular gap and barrier exists.

We are a young office. I was appointed in '01, so the Office is not as old as many of the other agencies that we have been talking about around the table. But we have been able to tear down the silos. I don't have a budget, but I have to use whatever the talents are of persuasion. We identify the gaps and the barriers, and then I meet with the various partners, [including] some of you around this table, such as NICHD. Duane has been a wonderful partner. HRSA has been a wonderful partner. CMS has been a wonderful partner.

That is how we are able to execute special initiatives in the areas. We don't want to duplicate. We just want to identify the gaps and the barriers. That has been pretty successful.

We have also partnered in the same way with other federal agencies, with Social Security, with the Department of Labor, and with the Department of Education, and worked very closely with them, as was mentioned on Part C and Part D, which concerns in some aspects children with autism.

Our concern is also life span. We go from birth to death, all disabilities, all ages. Obviously we have a large community.

The idea is really to bring to the table the policy decision-makers. I'm not critical of their staff, but unless you have the policy decision-makers at the table you cannot make plans and you cannot make decisions. We have been successful in doing that because substitutes are not allowed.

The other prominent activity is to bring to the table, besides all of us, the constituent leadership, the parents, and the advocates for disabilities, and obviously autism has a loud voice. Lee is on our Constituent Leadership Committee. We work closely with the Academy of Pediatrics and HRSA on the medical home and see where that can be met.

We also work closely on a little technical thing but important, with IT so that the personal health records include disabilities so that whatever information is important in that regard is there.

I will just mention two special initiatives that we have done. One is the co-occurring of developmental disabilities and mental health and within that also is autism. The other large one is the Communication and Speech Development Initiative, which concerns deafness, hard of hearing, and also autism. We have the partners. ADD is one of our partners as well in our co-occurring. Social Security and the Department of Education, and the whole list for the communication one.

I will stop there.

DR. INSEL: Thank you. It is great to have you here. It makes me remember that so much of what you are describing is actually a lot of what this Coordinating Committee is about, which is developing partnerships, making sure that there isn't a lot of redundancy, getting clear on who is doing what, and having the people who can actually set some policies around the table to figure out how to do things better. So it is great to have you here.

The last agency, Larke, SAMHSA.

DR. HUANG: Thank you, Tom. As I'm listening here, I'm trying to figure out whether we are like the rock, pebble, or the sand. Our agency mandate is slightly different than most of the other federal agencies around the table. We are not a research agency. We are primarily a services agency. We focus primarily on substance abuse and mental health services. We administer the mental health and substance abuse block grants to states, and then we have a portfolio of discretionary grants.

None of our programs focus specifically on autism or autism spectrum disorders. We do have programs that can interface with those populations of children and adults, and I will just mention some of those, but we don't have a targeted initiative in this area.

We do have a congressionally mandated program called Systems of Care which focuses on building interagency, cross-sector, interdisciplinary services for children with serious emotional disorders. We have about 70,000 children that have come through that program. About 2 percent of those children have a co-occurring developmental disorder or are children with ASD. That is a program that gets about $105,000 per year from Congress.

I think in terms of listening to some of the presentations today, and particularly to Dr. Zerhouni's Four-P approach, we probably come after that. Thinking about what Lee said in terms of the interventions and services, we are focused on taking what you get out of your clinical trials or out of the research and putting it into the field. We are really that link.

We do some of this with some of the institutes in what we call a blending initiative, where we work with them utilizing our grant sites in combination with their research sites and getting these interventions into the field quicker than they normally go. That is part of the focus of the blending initiative.

We also have a National Registry on Effective Programs and Practices, which is a database of evidence-based interventions, primarily in mental health and substance abuse, across the age spectrum for treatment and prevention. That is a database that is accessible to the public to look at what is the research saying about effective interventions.

We have priority areas that we focus on each year for that particular database. We have not had one particularly around ASD, but that is something that we could make a policy decision around, including that as a key focus.

Then, soliciting interventions, such as Tom was talking about: psychosocial interventions or medication interventions that could be included in that database.

We also do some limited research around services utilization and treatment expenditures, and we can do that by diagnosis. So we can get some sense of state and Medicaid expenditures for children, youth, and adults with ASD. That's it.

DR. INSEL: Thank you. I would like to go on to hear from the public members. We have a list here, so why don't we, without losing any more time, just start with you, Lee, and have you tell us about ASA.

MR. GROSSMAN: Again, thank you for all of what the federal agencies are doing. This is a marvelous endeavor. We at ASA are very much looking forward to not only the work of what is going on on this Committee but working with the agencies individually as well as some other ones that do have some other involvement with autism spectrum disorder.

A little bit about ASA, and I will be brief about this. We are 42 years young. We have approximately 200 chapters throughout the United States. We, right now, have about 200,000 members and supporters. Throughout the ASA organization, we put about $20 million per year, and have been doing that fairly consistently for probably the last eight to 10 years, back into the community for support services and advocacy.

We are governed by an elected board of directors which is elected by our membership. We feel that we have a very, very strong representation of the entire autism community through that process. I'm happy to say that with our current board that that exercise is working very effectively.

We are led by our very, very capable and wonderful chair, Kathy Pratt, and I'm not just saying that because she is my boss. Anybody that has had any dealings with her knows of her reputation and how strong she is as a wonderful supporter and a very much respected professional in the profession of autism.

Some of the things that we are doing specifically in terms of research is that we invest heavily every year through our advocacy and government relations efforts in supporting biomedical research not only on the federal level but on the state levels. Some of the active programs that we have recently started or are in process are our Treatment-Guided Research Initiative, our ongoing Environmental Health Initiative, our early diagnosis and early treatment multi-site program that is about to launch, and an Asian comprehensive medical treatment center which we hope will celebrate some of the early findings for comorbid conditions in autism.

Some of the things that we believe very strongly in is that all of our committee's initiatives, programs, and boards have people on the spectrum as fully participating representatives on those committees. We are all about life span supports. We feel very strongly that in terms of when we talk about autism and when we identify every aspect of being in crisis, the most urgent crisis that we have right now in the autism community is that for adult services and programs.

We have recently stepped up and recognized autism as a global epidemic and that it is an emerging, if not currently prevalent, global human rights issue.

Probably more than anything of the concepts that we most strongly adhere to is that autism at any age, at any level across the spectrum is treatable and that that treatment needs to be done today.

We realize that autism is much bigger than the Autism Society of America. As a result, we have reached out to other partners. In the last couple of years we have formed strong partnerships with organizations such as Easter Seals, which is a $1 billion nonprofit organization in the U.S. who is also the largest private provider of autism services in the country.

We also have a very proud relationship and partnership with the Autism Research Institute, which we share a common pedigree through our common founder. Through ARI, there is also a network of other great autism national organizations such as SafeMinds and the National Autism Alliance that have formed an MOU with our partner at ARI.

Along with that, we have partnerships with the NATAP organization, which is a technical assistance program which the LEND and AUCD groups are organized through. We recently had a tremendous conference pulling all the NATAP partners together. There were 1,500 participants at that conference. We had a peer-to-peer professional conference talking about treatments, interventions, services, and education.

Lastly, our partnership with NARPA, which is autism-specific residential providers and organizations that deal specifically with providing services to the adult sector.

That is a very, very short synopsis of what we are up to these days. We are pretty busy at the moment, as you can tell. I think we all are, dealing with this global epidemic of autism. Thank you.

DR. INSEL: Thank you. Yvette, do you want to say something? I know we did introductions before, but maybe you could tell us a bit about your experience and what is most important for you in coming onto the Committee.

DR. JANVIER: I am a developmental behavioral pediatrician, and I work in the trenches in autism in New Jersey, on a daily basis making new diagnoses with children. Unfortunately, they are not coming in very early. There is a crisis with regard to access to care. Programs were mentioned in developmental behavioral pediatrics. Unfortunately, there are fairly few relative to the 14 percent disability rate. There is a year to two-year wait to see a developmental pediatrician in the

New York, Philadelphia, New Jersey metropolitan area. How are we going to identify these children early if you are waiting that long to see a specialist.

I think it is wonderful the work that the committee from the American Academy of Pediatrics has done, with Chris Johnson and Susan Hyman co-chairing that committee. I think, unfortunately, there is a gap between wonderful recommendations and implementation.

I have been out there in the community in New Jersey for a number of years advocating for implementation of recommendations made by the AAP and American Academy of Child and Adolescent Neurology, even to screen every child with developmental delays for autism. This is the first step to push pediatricians to do that.

My organization is a nonprofit hospital. We have been in existence for over 100 years in central New Jersey. We serve 16,000 children each year. We are the largest pediatric rehabilitation provider in the country. We serve over 2,000 children with autism. They come to us for something as simple as a hearing test, for something as complex as multidisciplinary autism team evaluations. We provide specialized verbal behavior early intervention programs, and we are pleasant recipients of many of the funds mentioned here today through early intervention, Medicaid, and so on.

One of the initiatives that I'm hoping to get funding for through the New Jersey Governor's Council on Autism is to send our nurse practitioners into pediatricians' offices to work with the office staff and pediatricians on implementing the guidelines that were published, teaching them about these really basic, simple tools, and making this happen.

Again, I'm fairly optimistic we will be getting those dollars to do that. I certainly don't have 100 nurse practitioners to make that happen, but it will be a start. It might be a concept for a bigger plan nationwide.

Also, what we have done in order to address this shortage is, I have two developmental pediatricians at my site. We have six others throughout our system. We have hired nurse practitioners and trained them to work with us under our direction, and they have been excellent, I have to say.

So they are running now a developmental/autism screening clinic which is really in a pilot form. Of the first 10 children, nine were screened for autism and half of those children were found to have signs of autism. So clearly, there is a problem out there.

I just would also like to say that certainly we are fortunate to live in a country where we have great freedoms and free speech, but the impact of events like Jenny McCarthy hitting whatever channel she was on have really been very problematic to many of the families I have seen. I was asked a little bit before about some of the alternative complementary treatments, which we know many of the families pursue, but I think a lot of that had settled down over time. Now even severely affected children 20 years old, the families are saying to me, "Dr. Janvier, did you miss something? Jenny McCarthy did this and her child has recovered. What happened?"

I know that many of the research projects that the NIH group was trying to address were looking at some of these treatments that are out there. It really is a great concern.

As a clinician in the field, I would love to find the cause of autism, the cure, how can I make these children better. What I know right now is that the treatments, the speech therapy, the occupational therapy, the early intervention, the intensive school programs, that is the answer. Sending people on wild goose chases, spending thousands of dollars, is really not in the best interest of our American families.

DR. INSEL: Chris McKee.

MS. McKEE: As I said earlier, my designation on this Committee is simply as a parent of a child who suffers with autism. I have no other affiliations.

For the past six years what I have done is I manage her in-home therapy program. We started with Lovos [ph] and then we have moved on to a verbal behavior program. This program is overseen by local and national consultants. We hire and train our own therapists, and then we work with those consultants in setting up her educational program.

What this means for me is every day I go shopping for workbooks because there isn't a workbook that fits kids with autism. I start cutting and pasting and I try to make workbooks that will work for her. It is the same thing with designing play activities and designing file folder games. Everything in her academic curriculum is specifically designed for her and to keep her interested in it so that she can learn.

I also spend time every day with moms who are doing the exact same thing. They are strategizing, they are planning, they are trying to figure out how to make a difference in their children's futures. These conversations take place in the hallways as we wait to pick up our children at school and around the dinner table. I belong to a moms' group, and I have to say that the information that I get informally from my mom friends has been better than anything I have ever gotten at a conference or a workshop or any article I have ever read.

I guess it is through this network of moms and dads that I have learned about the common problems and struggles that autistic children have. It is for this group of parents that I'm eager to join in the work of this Committee.

DR. INSEL: Thank you. We are delighted to have you here. Lyn Redwood.

MS. REDWOOD: Thank you, Tom. First, I want to thank HHS for allowing me to serve on this Committee. I thought quite a bit yesterday about what I should talk about today, if it should be the National Autism Association or SafeMinds, because our role as consumer advocates is to infuse passion and urgency into the discussion of research. I really thought the best way to do that was to talk about my son because he is what brought me here today.

My son Will was born at 40 weeks gestation. He weighed in at eight pounds and 11 ounces. He had APGARs of nine and 10 and a full head of coal-black hair. He was a wonderfully sweet baby who met and exceeded all of his developmental landmarks the first year of life.

But then, shortly thereafter, all that changed. He started to get sick all the time. He had strep infections, upper respiratory infections. It just seemed like anything that came by, he got it. At the same time, his appetite decreased. He stopped eating. If he did eat, he would gag and vomit for no apparent reason. He stopped sleeping through the night. He stopped looking at us and he wouldn't respond to his name. As all of you know that have a child with autism, there is just this empty shell left of what had previously been your normal, healthy baby.

At first we thought our son was hearing-impaired and we went to an ENT doctor and he placed tympanostomy tubes and advised us to start aggressive speech therapy, which we did. Still our son was getting sicker and sicker. He developed intermittent bouts of bloody diarrhea. He would cover his ears and scream whenever there was a loud noise. He would cover his eyes when we went outside because the sun hurt his eyes.

He had intermittent fevers and rashes. His fingertips had no feelings. They would peel. All he wanted to do all day long was sit in his infant seat and rock and watch "The Fox and the Hound" over and over and over.

When we followed up with the ENT doctor six weeks later, he told us that there was something more seriously wrong with our child and he referred us to a neurologist. Fortunately, the chromosome studies for Fragile X were negative. His MRI was normal. He had some delayed myelination, which was considered a variant of normal. His EEGs didn't have any seizure activity, but there was some wide posterior temple slowing, which again was considered a variant of normal. His ADRS had some latencies in Wave 5 that might be indicative of an auditory processing disorder, but nobody really knew.

So again, we were advised to continue with speech therapy. We started an intensive behavioral intervention program. We were enrolled in the Babies Can't Wait program through our school system.

But by four years of age, our son still had no spontaneous language despite all of these intensive therapies and he was not even potty-trained. If we didn't catch him quickly, he would take the feces out of his diaper and smear it on the walls. So our lives were really bad.

In 1999, I was notified by the Board of Health, because I'm a member, that we were delaying immunization with hepatitis B from birth to six months of age because of concerns about mercury. I was, at the time, just shocked to find that vaccines contained mercury, but I was even more shocked when I started looking at the mercury literature and I realized that mercury typically caused a delayed neurotoxicity, loss of speech, developmental delays, immune system dysfunction, colitis, peripheral neuropathy, sensory disorders, rashes, peeling fingers, photophobia, slowing on EEGs, abnormal evoke potentials. It was everything my son had that was wrong, and that is just to name a few.

I was even more surprised when I looked through my medical records and realized that at 14 weeks and 28 weeks gestation I had received products because my blood type was Rh-negative that contained mercury as well, 130 micrograms of Thimerosal each dose.

When I looked at my son's vaccine records again, he was one of the highest levels of exposures. He had received 187.5 micrograms the first six months of life. To put this in perspective, at two months of age with just three vaccines, he received 125 times his EPA's allowable exposure to mercury.

I wanted to have my son tested for mercury, and again he was almost five, so it was too late. I had a lock of his baby hair from his first hair cut at 20 months of age. EPA's action level for mercury in the hair is 1 part per million. Five parts per million is diagnostic of toxicity. My son's levels were 4.8. That didn't even reflect his highest exposure because he had lost all of his hair by six months of age.

But the good news that I have is that with targeted biomedical interventions like N-acetyl cysteine to help my son make glutathione and reduce oxidative stress; N-ethyl B12 [ph], which was to treat his functional B12 deficiency, which was diagnosed with elevated methyl-malonic acids; digestive enzymes, where he gained 14 pounds in one year and I got first measurable cholesterol levels that were normal; and also chelation therapy with oral DMSA to help remove mercury from my son, [we were] able to restore his health.

Today my son is 13 years old. He does grade-level work in school. He has no supports. He is in a regular school program. He has three good friends, and he loves going and spending the weekend with his brother in college playing video games.

His improvement to date has been nothing short of a miracle, in my opinion, and that is why I feel so passionate to share this with everybody. I know that his exposure levels were extreme. I acknowledge that. There are several, as we all know, autisms. It is very heterogeneous.

But I think that mercury really needs some attention. EPA right now suggests that one out of every six women have elevated levels of mercury in their body that could cause injury to their unborn children. Our exposure rates are increasing dramatically as new coal-burning powerplants come online in China. It takes only 10 days for that plume to hit the West Coast of California. Forest fires like we had in San Diego just a few weeks ago release 30 percent as much mercury as all of our industrial sources. I just feel strongly that those things are not being looked at.

Also, pregnant women and infants continue to receive flu vaccines that contain full-dose exposure to thimerosal in spite of the IOM's recommendation that these sensitive populations not receive mercury.

I guess my passion is that I want us to start to embrace the role of the environment and look at neurotoxicants like mercury in the role of not just autism but many of the new childhood epidemics and to view children with autism as being sick and not being mentally defective. A lot of my son's obvious symptoms of mercury toxicity were completely overlooked because he had a psychiatric diagnosis. That is just not right. Children are really sick.

Dr. Zerhouni mentioned predictive. With pharmacokinetic modeling and the exposure levels that I and my son received, you could predict injury. He was well above the lowest observable effect level. So I'm asking that we come up with some policies that are protective of our children and that follow the precautionary principle, and that we initiate studies as soon as possible to investigate a lot of these comorbid disease states in our children, like abnormal gastrointestinal function, inflammatory bowel disease, increased oxidative stress, severely disordered serum chemistries, methylation disturbance, and body burdens of metals.

There have been over 1,000 parents that have reported recovery from their children doing these targeted medical interventions, and they are being completely overlooked.

So again, thank you for allowing me the opportunity to share this with you.

DR. INSEL: Thank you. Steve.

DR. SHORE: Likewise, it is an honor to be with all of you to fulfill what my mission is, and that is to help people with autism lead fulfilling and productive lives to our greatest potential by using our often considerable strengths. That is just the way it is done with everybody else. We all try to spend more time doing things that we are good at and that we like. If we like something, we are probably good at it.

Insofar as research, having just completed my dissertation, I have my mind on a lot of research. One of the things that came out of my dissertation is a real need for better subtyping, so it was good to see that word "phenotyping" at the bottom of Dr. Elias' presentation.

We need to get much better at defining what autism is. We can't agree on what it is. I think all we can agree on is that the DSM descriptors are lacking. But, what is it? I think by better subtyping, thinking about autisms rather than just autism, that will empower us to match best practices to the needs of people on the autism spectrum. So that is one area, the first area that I would like to focus on.

The second thing that I do is consult internationally to school districts, other organizations, individuals, and to people on the autism spectrum around the world. One thing that I find fascinating which Roy touches on in his book is how are people supporting those with autism around the world.

What I have found is that even in the most desolate, resourceless places, there is always at least a small cadre of people who are doing really good work for those of us on the autism spectrum. They perhaps don't even have the terminology for what they are doing but for what is happening in those areas it is best practice. So that speaks towards what Lee was talking about earlier: increased collaboration and cooperation. It is a worldwide issue and we need to look at autism as such.

Participation, one of the four Ps. I think it is important that those of us on the autism spectrum are included in the research because we can provide insight that nobody else can.

The third thing that I'm focused on is the idea of self-advocacy and disclosure for those of us on the autism spectrum. In brief what that means is, how can we help people with autism describe what supports they need in a way that other people can understand. So, how can a person with autism, for example, request to their supervisor that the lighting be changed in the office because they have a visual sensitivity to fluorescent lights, and do it in a way that is agreeable and reasonable and perhaps even come up with suggestions. How about an incandescent lamp.

With advocacy also comes disclosure. If you are going to ask for greater understanding or a change in the environment, you have to tell why. That is whole other set of decisions, ranging from not bothering to disclose at all, to disclosing a tiny little piece, to doing a whole workshop on autism. As time goes on, with more attention being paid to autism, disclosure becomes easier because more people are aware of the condition.

A fourth thing that I do during the rare times that I'm home is give music lessons to children and adults on the autism spectrum. It is different from music therapy, which is very valuable in its own right. I feel that teaching a child with autism a musical instrument provides a real-life way to develop interactions with others and get involved in the community.

Also, we mustn't forget the humanity of it all. Let's just have fun and be with our children and adults who are on the autism spectrum.

Finally, I have written three books on autism, an autobiography, another one on self-advocacy and disclosure, and "Understanding Autism for Dummies." All of that speaks to my goal of promoting better understanding of people with autism as well as empowering those of us on the autism spectrum to understand the greater non-spectrum world. In other words, promoting better mutual understanding.

I think it is important to do all of this in a way that is respectful to people with autism as a part of our greater community.

So again, thank you, Dr. Insel and everybody else, for allowing me to participate.

DR. INSEL: Thank you. Actually, the thanks would have to go to Secretary Leavitt, since he is responsible for all of the public members around the table, but I'm glad to take the credit for him.

Alison Singer.

MS. SINGER: Thank you. As I said earlier, I'm the executive vice president at Autism Speaks, but more importantly, I am the mother of two beautiful and energetic daughters, one of whom is diagnosed with autism. I'm also the sister of a 43-year-old man with autism.

My daughter Jody is now 10 years old. She was diagnosed with autism at age two and a half, and she received early intervention services through the New York State Department of Health. She currently has an out-of district placement that we fought hard to secure in a special school created specifically for children with autism, where, fortunately, she is able to make great progress because the staff there is trained specifically to meet her unique learning needs.

My brother Stephen, as I said, was diagnosed in 1969 and has a very different story. He is a former victim of Willowbrook but fortunately is now living in a group home in Rockland County, where he participates in a day program delivering meals on wheels to homebound citizens.

In the last few years, he has learned to swim and has learned to communicate using the PECK# system, proving that it is never too late for people with autism to make meaningful and life-altering gains.

It is a privilege for me to be here to continue to work to fight for the rights to which Jody, Stephen, and millions of Americans with autism are entitled. At Autism Speaks, we are committed to raising awareness of autism and to funding the science necessary to develop better evidence-based treatments as well as better understanding of the ideology and biology of autism.

Awareness of autism has grown dramatically in the last few years, leading to important and very real changes, two very recent ones being the new guidelines from the American Academy of Pediatrics urging that all babies be screened twice for autism before age two. Also, earlier this week the United Nations announced that April 2nd would be World Autism Awareness Day beginning in 2008 and continuing until we no longer need a World Autism Awareness Day.

Later this afternoon, the chair of our Scientific Advisory Committee, Dr. Gary Goldstein, is going to give a comprehensive presentation on our science program, so I'm not going to spend any time on that topic right now.

I do want to say that as we begin to develop the strategic plan for autism research and begin ensuring that it meets the needs of a diverse community, two principles will be critical. Those are transparency and, as Dr. Zerhouni said earlier, participation.

The members of this Committee need a fundamental understanding of what comprises current baseline federal autism research funding if we are to develop a robust strategic plan including, as the law states, budgetary recommendations. A breakdown of the current NIH spending by research theme rather than by funding mechanism will inform the Committee members and the public of where actual funding shortfalls may exist. Simply put, we cannot get to where we need to go if we don't know where we have been.

Secondly, in developing the strategic plan, we need to explore how best to involve a greater number of stakeholders. Exploring ideas as to how to best organize this input I believe should be a key part of our strategic planning process.

Finally, I feel the need to note the absence at this meeting of a key advocate to whom we all owe a debt of gratitude. Jon Shestak served on this board, and together with the team at Cure Autism Now, was instrumental in passing the Children's Healthcare Act of 2000 which first authorized an IACC. John played a unique role on this board, giving voice to the thoughts that many of us as attendees were unable to express, and he always did that in a unique and inimitable way.

I think it actually feels strange to have an IACC meeting without John present. I don't want this to sound like a eulogy, but I do look forward to carrying on the important activities that John started and to completing the work that we all know to be so important to the future of all of our families.

Thank you.

DR. INSEL: Thank you. This is really such an interesting group. Just listening to not only how articulate all of you are and how passionate you are about this, but how all of you come from such different perspectives. I think that is what the Secretary had in mind with bringing this particular group of public members together.

I think he also wanted to make sure that all of the federal partners who are here had a chance to hear this entire spectrum of views. Clearly, there are many places where you are not going to agree and many places you are not going to agree with many of the federal members of this Committee, but we are hoping that we can develop enough of a spirit of cooperation and collaboration and transparency, as Alison just said, that we will be able to work very well together.

Understanding there will be some differences of opinion, but those don't have to become roadblocks. We have important things to do. People are really looking to us to deliver initially on a strategic plan and that we will be able to work together in spite of some different perspectives, in fact hopefully enriched by those different perspectives.

Now, we are about 30 minutes behind schedule. Joyce, we were going to be going into the discussion of the strategic plan. Would you want to break now and do that after the break or do you want to embark on that and take us through it rather quickly? What is your pleasure?

Let's get a sense of the Committee. We could break now and come back at one or we could charge through this and try to finish by, is it possible, 12:45?

All in favor of breaking, can I see a show of hands?

[No response.]

DR. INSEL: I think we are going ahead. Dr. Chung, the floor is yours. Your slides will be up in just a moment.

[PowerPoint presentation.]

DR. CHUNG: I have a very complicated set of ideas to present, and I'm glad to do it before lunch in a way because this means that perhaps we will have a chance to digest, literally, what I have to say and have an opportunity to work it through a little more.

The idea here is to give you a sense of where we would like you to start thinking. First of all, I would like to say that I am very honored and, speaking on behalf of the Autism Team, we are honored to support the work of the IACC. Today I'm going to be presenting to the Committee and the public a draft process for the development of a strategic plan for autism research.

This process is really our team's best effort. We have been working on this over the past few months with input internally and from outside, but really, this is our best effort to try to think about how to move the process forward.

To start, we have some goals. Really, there are two major goals. The first goal is to discuss and adopt a process. We need to actually lay out the steps. What are the structures; what are the roles of the various people on this Committee and people who are very important to this process who are outside this committee. We want to make sure that everyone understands how they might have a way to contribute.

The second goal is very concrete, and that will involve the Committee voting on establishing a workgroup. This again goes back to Lee's question about subcommittees and workgroups. We would like to have a workgroup that comes out of this meeting that can move on from this meeting and take on the detail work of putting the plan in motion.

To start, we had a brainstorming meeting. When we first came on this summer as a team, we weren't really sure where to start. We all came on around July, and of course the purpose of our team is to really help coordinate ASD activities for which NIMH has lead responsibility. Of course, included in that is staffing the IACC.

We were quite aware that the Combatting Autism Act required that the IACC put together a strategic plan, but we weren't really sure how to begin to prepare because the Committee was still not formed. So over the summer we decided, with Dr. Insel's support, to organize a brainstorming meeting in August. We wanted to gather some ideas from opinion leaders just to get some ideas to get us started.

I have listed here, again, the participants. We tried to reach very far into different stakeholder groups, but again, this is not totally inclusive. We did this meeting in August after we were delegated authority to manage the Committee.

In terms of what came out of the brainstorming meeting, it was really truly a brainstorming meeting because we encouraged participants to offer their thoughts and their individual ideas. We did not want them to reach consensus. Again, this was just to get everyone's ideas on the table. Although opinions differed, the following general ideas emerged.

The first one, which has been echoed by many people in the room today, is the importance of stakeholder involvement. We know that the stakeholders around ASD are incredibly diverse and the views are very diverse, and so we needed to make sure that whatever plan we put together would be informed by multiple viewpoints at multiple points along the process.

The other idea that came out from the meeting was the need to encompass both government and private funding organizations. It was interesting to us that people who came really assumed that the plan would include not just the government, the federal government or other government organizations, but really the significant contributions and investments made by the public, really, the public-private funding.

The next item had to do with, again, the language in the Combatting Autism Act that describes budgetary requirements. There was clearly an expectation that the plan will include some type of cost estimates for what it would take to put together a really good strategic plan.

Lastly, we needed some reassurance that it would be okay if we went ahead and started getting a process drafted so we could hit the ground running. That was our purpose here, to try to not get in front of the Committee as much as to help the Committee get active right away. That is really the plan that we are seeing today.

We listened very carefully to what we heard from the brainstorming group, and on the basis of what we heard, we designed a process plan that I'm going to present that is guided by these following four principles. They are stakeholder involvement, government and private investment, responsiveness, and the last is priority-setting.

Stakeholder involvement is hard to represent fully, and so this diagram is simply showing a portion of stakeholders, including families, persons with ASD, educators, Congress, researchers, therapists, state and local programs, research funders, advocacy groups, and medical providers. Again, not inclusive but giving you a sense of how wide-ranging stakeholders are.

As I walk you through the plan, I would like to make sure that you know that we try to include stakeholder input in every phase of the planning process.

Government and private investment is based on the fact that one of the distinctive characteristics of ASD research is that it is made possible by both government and non-government private investments. The ASD strategic plan would be an opportunity for us to promote synergy between these types of funding organizations that has never really been done before. Many researchers, as we know, are funded by both types of organizations and are sometimes not clear how we relate to one another.

Responsiveness has to do with the fact that all stakeholders feel a sense of urgency about improving the lives and outcomes for people with ASD through research. This urgency we felt was matched by tremendous growth in scientific activity and discovery, but since ASD science is a fast-moving field, the strategic plan should be flexible in response to leading edge findings and knowledge.

The thing I wanted to emphasize here is that one of the things that is going on with the strategic plan is it has to be annually updated. I like to think of this first version as Version 1.0 that we will definitely update in years to come.

Lastly, as a team we decided to take a position with regard to the type of strategic plan that would be developed. There are many types of models out there, but instead of generating a comprehensive list of all possible research activities we conceived of the plan as identifying really important opportunities that we need to jump on to fill gaps that we haven't done so far and to facilitate innovation, really through a lot of cross-talk and a lot of new ideas, not doing the same old types of workshops and discussions we have had in the past.

In a word, we wanted the plan to be strategic, not just a list. That means the plan won't set priorities, to us.

Now I want to walk you through a bit of the structure, but before I do that I want to emphasize there are two very similar-sounding words I'm going to be using. The first is "workgroup" and the other is "workshop." I have to use those words because of the type of committee we are, but I have tried to do it through color coding. That might help you. The workgroup is green and the workshops are pink, and this is how it lays out. So I'm going to go through this now.

Starting off with this Committee, the IACC is the parent body and, as such, has the responsibility to fulfill the duties outlined for them in this Combatting Autism Act of 2006. That includes developing the strategic plan.

The Strategic Planning Workgroup is a workgroup that federal advisory committees like the IACC are permitted to establish to study an issue. The workgroups then have to report their recommendations to the full committee for deliberation. They really work to help the committee do additional work that it can't do on its own.

I have a proposed composition that we wanted to propose to this Committee. We propose that the IACC establish a Strategic Planning Workgroup to provide additional expertise to develop this plan. Examples of expertise that we might need would include scientific experts and representatives from major ASD funding organizations that may or may not be on this Committee. We also recommend that the IACC chair, Tom Insel, appoint the workgroup members.

The next structure that I want to talk about has to do with the workshops. Again, these are more traditionally like we do at scientific workshops where we really divide up the areas of autism research into four major domains. Again, these domains are things that we came up with in consultation with other folks, but this is a preliminary suggestion. We thought that thinking about treatment, thinking about diagnosis, risk factors, and biology might cover most of the waterfront.

We think that these workshops would be best if they were very diverse. We want these workshops not just to be scientists but we want IACC members to be involved at the discussions of what types of priorities are important in these areas and also other public stakeholders, again who might not be on this Committee but who would like to be involved.

Our lay definitions of these domains are as follows. Treatment: how to improve the outcomes for individuals with ASD. Diagnosis: how to best describe and identify ASD. Risk factors: which genetic and/or environmental factors influence the occurrence of ASD. Lastly, biology: what underlying processes lead to development and medical problems in ASD.

There is more I could say here, but included in here are ideas that we need to have a lot of interdisciplinary discussions that we want to talk about services research and, again, a lot of the things that people described earlier.

Now, as I said, we want to hit the ground running. The Combatting Autism Act does not specify a deadline for completion of the strategic plan, but because of the sense of urgency we have all discussed, really this compels us to try and get this plan executed. We are proposing a six-month time frame.

These are three phases, which I'm going to walk you through, but again, we will have to update that again next year.

This is a timeline, which is way too busy, that just gives you a sense of the six months we will be racing through. I'm going to walk you through this step-by-step.

Step A is the brainstorming meeting that I described to you earlier. That meeting took place in August. From now on, the steps of the plan are color-coded and the key for the codes are at the bottom of the slide.

In Step B, the NIMH Autism Team, the team of us who have been working on this over the past few months, developed this draft process which you are reviewing right now.

Step C is the meeting at which we are now convened, so that takes us right through to this. The goal for this meeting again is to discuss and adopt the process plan.

Step D would be our recommendation that the Committee vote to establish a Strategic Planning Workgroup.

Step E would take place soon after this meeting, probably in December. We would like to distribute an electronic request for information, or RFI, to a broad group of stakeholders asking for input about the four research domains that I talked about earlier. That would mean that workshops that we convened would start off with public input.

Step F would be the last step in the development of this first phase of developing strategic priorities. In this last step, which we think would happen in January, we would like to hold several scientific workshops, the goal of which would be to generate these research priorities that come out of each major area of autism research.

I'm going to stop for a moment and see if people have questions.

[No response.]

DR. CHUNG: So moving right along to phase two, which we call plan development and consolidation, this concerns the development of the plan itself. This phase begins with Step G, where the SP Workgroup will review all the priorities generated by the different workshops we are holding.

This workgroup will look across the entire range of autism research to begin to think about priority-setting in terms of ranking what comes first, staging where the field is ready, what opportunities there are. There could be some duplication of what people think from the different workshops, so we want to make sure there is no redundancy and that things were not missed by them. This workgroup will really think hard about the entire field.

Here we would like, again, some input about what the workgroup product is. If we have some idea about the rankings and what they think are high priorities, we would like public input about what they think about these priorities and whether they match with their own priorities.

We want to have a March IACC meeting, which is unusual. We usually have these meetings twice a year, usually in November and May. This year, because of the work the Committee must do to really make this plan happen, we are going to have a March IACC meeting. This is Step I. They are going to look at both the workgroup rankings and the stakeholder inputs and really deliberate this information at the March meeting to decide about final priorities. Because the IACC is the body charged with making this plan, they will finalize what goes forward.

In addition, I think we need to spend some time at that meeting discussing what we mean by the budgetary requirements, what kind of cost estimates people would like to include to accompany the plan.

We on the Autism Team will begin writing, with the help of a science writer, once those final priorities have been determined by the Committee. This will end phase two of the process.

The last phase will be final document approval. There is kind of a side step, which is Step K. Here, although the Combatting Autism Act does not consider issues about implementation, I think, clearly, if we don't know how to implement the things that we have talked about it is not a relevant plan. We have to have this be something that actually informs what we do.

So we recommend that this SP Workgroup then turn their attention to how these top research priorities might be implemented and then bring those ideas back to the Committee. Basically, our argument is that the strategic plan is not a living document unless there is a plan of action.

We will distribute a first draft of the plan in advance of the May IACC meeting so the IACC membership can review and come with recommendations for edits, changes, and revisions, to the May meeting. We would like Step M to be a time when the IACC will review and amend the draft plan as needed and discuss implementation recommendations which we hope the workgroup will present to the Committee.

Nothing is complete without stakeholder input, once again. We would like to solicit comments on the plan in the draft phase. Based on all the comments from stakeholders and from the Committee, we would be sending a revised plan to the Department of Health and Human Services in June of '08. Department of Health and Human Services has retained the authority to submit reports such as the strategic plan to Congress, so we will send it to them.

A final step which we recommend which can be discussed later is that we think it might be useful to form a different workgroup in the future, maybe in the May meeting, to have the IACC consider again an Implementation Workgroup for the strategic plan. Once the plan is done, we want to make sure it is actually informing action.

Again, to remind you that the plan needs to be annually updated, this slide provides some possible steps to executing the update. We don't imagine doing the whole thing over again each year but certainly at intervals, but we do need to update it so it is quite responsive to what is going on at that moment.

I wanted to end with just reminding you of the decisions for the Committee. To reiterate, the main decisions for the Committee to make today are 1) to discuss and adopt a process plan for developing the strategic plan, and 2) to establish a Strategic Planning Workgroup which will help the Committee get the work done.

Now I will turn the discussion over to Tom.

DR. INSEL: Thank you, Joyce. That was a very quick run-through of a fairly complicated plan, but this is a proposal. This is not by any means a finished document. We realize that time is of the essence. We didn't want to lose a meeting by just having us sit around and discuss what might be a good proposal, so we put this up here for you to consider and see what parts of it work and what parts of it don't work.

But, we would like to have a final launch of this. That is, we would like your coming to some consensus at this meeting so that we can get started.

First of all, let's start with just questions of clarification. Is it clear enough? Do you understand what Joyce is putting in front of us?

DR. MORRISSEY: I have a question, Tom. Step E, which is the stakeholder request for information to seek input on research priorities; could we talk a little bit more about how your staff see that happening? Is somebody going to give someone baseline information, or are we just going to assume that people out there, between now and through Christmas, are going to be able to give you their best ideas, do their own research to find out what has been done, what hasn't been done, and what is important to them, and send that in?

DR. CHUNG: We don't expect people to have to know the literature or know research. We want them to speak from their experience. What areas of research do they feel are important. So we tried to developed a lay description that is not really science language or jargon so that people can speak to what they think is important.

If the predominant thing that people are concerned with is lack of treatments or need to understand what works, they can provide that information and they don't have to be a science expert. This is a very important thing because I think if we don't get their input from the very beginning we may just start off in the wrong area with the wrong emphases. So again, this is meant to be really very user-friendly to the public.

DR. MORRISSEY: I have a second question, then. So people are going to send in what is important to them. Then is somebody going to sit down with this list of what is important and look at what is already being done by various institutes and programs and say this is covered, this isn't covered? What is the process for getting to a synthesis or a scrubbing of the public input?

DR. CHUNG: We plan to really look at the range of responses and summarize them as best we can. Part of this is there will be a parallel process where we are going to pull all the material together for the workshops that look at what is being funded now, what are some new initiatives, what are the resources in the field, looking across types of funding organizations, government and non-government.

That kind of matching will go on in the

workshops. They will look and see what people want, what we are doing, and try to understand how they fit or don't fit.

DR. INSEL: If I could just add to that, this isn't really that different than a process that we undertook a little more than a year ago when we did the evaluation of the matrix. That was also a gap analysis of what was being currently funded, what we were missing at that time, looking at a whole range of different kinds of research pretty much covering this same spectrum, although it wasn't quite divided up this way.

So we have that we can fall back on. We can fill in some of what has happened in the last, let's say, 18 months since that analysis was done.

I think almost from the beginning one of the tasks of the workshops, not the workgroup but the workshops, will be to take a very quick survey, but yet a very accurate survey, of the portfolios of all the different agencies to figure out what is actually being done and then to do just what you are saying, do a kind of match-up with the kinds of requests that are coming in from outside.

DR. MORRISSEY: So the workshops are going to be the ones that do the crosswalk between the public input and what is already being done or has been done?

DR. INSEL: Right. They are the ones who are going to be in the details enough. They will be actually dealing with sand and gravel more than rocks in each of these areas.

DR. MORRISSEY: Just one more question. I think you need more for the public than those simple definitions of the different categories for the workshops. You need to give them a context statement. Maybe you are talking about one page, but the point is paragraph one would deal with here is this law, we exist, we have done some work in the past, and we would like to hear from you about this, this, and this. We will do the crosswalk later but give us what is really important to you.

I think unless you give them a context statement that orients them and also identifies the urgency of their response, given your timetable, which I know is driven by the appropriations committee cycle, you won't get as much as you might otherwise.

DR. CHUNG: That sounds like a great idea. Thank you.

DR. INSEL: Alison.

MS. SINGER: I think that we need to consider having something be part of the overall plan. As pervasive as the focus on prioritization needs to be a focus on measurability and making sure that at every phase we are thinking about how we are going to measure the outcomes.

I think one thing that surfaced at the review meeting for the matrix was that we had difficulty actually reviewing the matrix because the items on the matrix were not expressed in a way that lent to measurability. I think we need to keep that in mind, use that as a learning from the past IACC, and as we go forward, make sure that it is considered at every phase of this process so that we don't have that same issue.

DR. INSEL: Great. Great idea. Thanks. Lee.

MR. GROSSMAN: This is quite a bit to swallow. This is my first time seeing this. As part of the IACC and being asked to make a decision on this at this point, I feel particularly challenged to do that because I do have a number of questions and some gaps here in the explanations that seem to really need to be filled in.

First of all, I wanted to ask what is happening with the matrix? Is it being canned as a result of the strategic planning process?

DR. INSEL: With the passing of the Combatting Autism Act, the previous IACC was officially abolished. The matrix lives on in a URL which I had posted earlier, so we have access to both the evaluation and the details around the evaluation. Our hope was that we would use part of that as the foundation for this new effort.

The one exception I mentioned was that the matrix, in the evaluation it was felt, had not done enough on environmental exposures and issues related to the environment. The hope was that the IOM meeting that I think was in March or April of this year could maybe serve as something of a foundation for part of that plan going forward.

We didn't want to imply that this is starting from a completely blank slate. There is quite a bit of work that has happened. That evaluation and the previous matrix can help inform this process going forward.

MR. GROSSMAN: I guess my next set of questions is in regard to the workshop domains, particularly on treatment and what exactly treatment means. It says "how to improve the outcomes for individuals with ASD," but I guess I would want more specificity on that and if that is the area where applied research can be a place where we are looking at psychosocial, educational, and behavioral research.

I'm also trying to gather from the strategic plan where we might be able to identify short-term opportunities, treatments and interventions that are currently ongoing that many parents are employing that seem to be benefitting the community. When I look at this, it screams at me that most of this is looking at long-term types of biomedical research. I think the needs are so pressing right now, and with the identifiable potential short-term opportunities, that we should put a particular emphasis on that because that is really what is needed today.

DR. INSEL: I will let Joyce respond to this as well. This is exactly the discussion that we have had as well. The point of refining these four categories was trying to lay out what we saw as broad domains, and this certainly doesn't define them adequately.

But treatment by no means was meant to be exclusively biomedical. The hope was that that would look at the entire universe of treatments, both the ones that are currently in use and then the opportunities to think about treatments that no one has even tried yet that could be really important.

That is true across all of these domains. These are much broader than might be apparent from these brief definitions. Hopefully, the discussion would be much broader than discussions that we have had up until now, even thinking about the discussions that we had on some of these domains for the earlier matrix.

Joyce, do you want to add to that?

DR. CHUNG: I was just going to say that that might be a workshop you would want to attend, Lee. We would appreciate your input.

DR. INSEL: Lee, also, there is one other point that you make which I think is really important. In some ways it goes back to Alison's question about metrics or measurable outcomes. That is how we look at short-term versus long-term. The matrix actually was designed that way so that we would have some early wins and then some high-risk but longer term efforts.

I think that is a discussion we haven't had enough of. We haven't quite figured out what, at the end of the day, this will look like, whether we have a kind of matrix display of this where we are looking at short-term versus long-term or do we want to have the priorities mostly around putting the rocks in first and then worrying about the gravel and sand later.

I think that is the kind of discussion that the workgroup will have to have. I think those kinds of issues we are going to have to work out. It is not clear to me; I don't know whether it is any clearer to Joyce or other people on the team.

MR. GROSSMAN: I guess that plays into, really, my last concern. Exactly what you are saying is that you are having these discussions and you are not sure what can fit in. That really plays into the importance of having a very, very broad and strong across-the-board representation on that workgroup so that all of the various disciplines and potential thinking on what we can do and what we should be doing for research is really represented.

Again, just seeing that now, that was one of the things that jumped out of me. Looking at how important that workgroup will be, it really needs to have a very diverse set of people that really are looking at all parts of the elephant and that can address all the needs.

DR. INSEL: This is probably the thing we have talked the most about. You could say, well, why do you even need this. There were two considerations that drove it. One was, since this group is advisory to the IACC, we didn't want to simply recreate the IACC in some other form. That wouldn't make much sense. We wanted to have a group that would include part of the IACC but would even be broader, as you are saying, so that we get a very diverse set of inputs.

The second piece was what Joyce was emphasizing, and that is we thought we needed a group here that could really push on the implementation side. We didn't really want to end up with a document that would sit on a shelf and that we might take out three or five years later and say, "So, how are we doing here?"

We wanted to put on this workgroup, this middle-level group, representatives from organizations that could actually make some serious investments in some of the priorities.

So I actually had a vision, and I don't know if this will come about this way, that it would be at that workgroup level that there could be an implementation plan that would be developed that, if we decided that a certain thing needed to get accomplished was a high-priority item, several partners would agree to take certain parts of that and we would split it up. We would divide and conquer.

Then, using Alison's idea of having some metrics built in, we would have some accountability so we would know who has taken ownership for some part of this plan and who can we go back to in six months, nine months, or a year to find out what kind of progress is there.

I wanted to use the workgroup as having an implementation group there as well, where we could get the buy-in from the people who may be paying for it. I'm not suggesting that is only going to be the federal partners but that in this area there would be foundations and others who may not be at the IACC level at all, or may not be on our Committee, and yet may have a real stake in trying to make this happen.

Is that clear? Does that answer the question?

MR. GROSSMAN: Maybe it is just me, but I still find it a little murky.

DR. INSEL: I think that is what we need to drill into, then. In Jon Shestak's absence, let me push all of you. We need to know what is murky. We want to get this clear. We want this to work. Ellen.

MS. BLACKWELL: I just want to delve a little deeper into what Lee referred to earlier. Maybe I'm just still in the mode of the old IACC, but [there is] one thing I'm noticing that is missing from the plan, or at least it appears to me that it is missing. We talked earlier about the services research. It seems to me like there are places in this plan where we should have service circles and service spots.

We are talking about, for example, a treatment workshop, a diagnosis workshop, a risk factors workshop, a biology workshop, but a lot of advocates and families are really interested in services that are mainly coming from the Department of Education and Medicaid. So it seems to me that that is sort of a missing link in this plan. I'm wondering if maybe we could talk about adding or putting some emphasis on services for children and adults.

DR. CHUNG: I'm sorry that the descriptions are so brief, but that was definitely part of the treatment domain. There are a lot of things within those domains that I didn't flesh out because, in some ways, some of these things cross-cut and we don't want them just stuck in one place. We want to make sure there is some overlap between the workshops and there are cross-discussions. We don't want them to be set off in separate places.

But services is definitely in there. Everyone hears that and knows that. I'm sorry it is not actually in the text, but it is definitely in there in spirit.

DR. INSEL: Larke.

DR. HUANG: I want to echo that comment, also. This looks like a very elegant plan, but to tell you the truth, I'm a little confused. I'm not sure how many plans I'm looking at here. I see a strategic plan, a process plan, an implementation plan. I see a lot of levels of implementation, and I'm not quite sure what that implementation is referring to.

I also think on your brainstorming session, which I appreciate that group coming together, that there isn't a services agency represented on that. I think that we are coming at this in very different ways.

I thought it was very important to Dr. Zerhouni and I really appreciate that you had him here this morning to really make us think beyond the 20th century and really into the 21st century. I'm looking at some of these categories and thinking, where are we catching the presumptive stuff here? Where are we really catching the true participatory stuff here? Do we capture it or is this another medical model strategic plan?

I think in terms of treatment we might really want to think about that more as intervention and look at it not as just medical or psychosocial treatments but what do we know about early identification, what do we know about the importance of early intervention, and then, on the other end of the spectrum, what about recovery? I think the concept of treatment doesn't take that whole spectrum of interventions into consideration. It keeps us kind of in 20th century thinking and not in the 21st.

I'm not quite sure; the implementation of the research process or the implementation of the plans or the implementation of each of the things that happens in the workgroups, were they called? I'm sorry. I found that a little confusing.

I have to say I haven't read it. I just got the Combatting Autism Act today. But it seemed to me that the developmental or lifespan perspective might need to be captured there somewhere as a guiding principle along with the importance of the broad stakeholder base.

I think also, to speak to Ellen's thing, a critical circle that is missing on your page three is service funders. I think that if we are really going to make a difference in people's lives that is a critical piece that also needs to be in the circle.

MS. BLACKWELL: I added that circle as well myself.

DR. INSEL: Let me respond to that. We went back to the Act. This is a point that we have discussed at great length. Actually, part of this discussion recapitulates the same discussions that we have had over the last two or three months.

The Act is very specific that the strategic plan is only to focus on research. We have been arguing that we could probably, under that umbrella, include research on services. So if we want to look at health disparities, that could go into the treatment effort.

But that was the reason that there was no one from a service agency brought into the brainstorming session, and that is the reason why there is no box specifically for a services priority-setting or services plan. According to the language, it is really about research specifically.

DR. HUANG: Again, I'm sorry, I haven't read the Act. Is research defined specifically in the Act, the kind of research? Is it not services research? Is that something that should be discussed here?

DR. INSEL: The word that is used is "research." This is where there is some ambiguity. I think Lee brought this up earlier this morning. The Act talks about the role of the IACC in overseeing all the activities of the federal government related to ASD, but when it talks about the strategic plan it says this is a strategic plan for research. At least our interpretation of that was that the research could include services research; that is, research on dissemination.

Actually, you may remember, we had the same discussion for the earlier matrix effort, which had the same issue. That is why we launched the separate effort around a plan for services or a matrix for services. We may need to do that here again, but the pressure we have now and what we are trying to respond to which is in the Act is to lay out this agenda for research somewhat more narrowly defined than that.

DR. HUANG: I guess you just also made me think that there is a whole science of implementation research, too, that might need to be one of those boxes.

DR. INSEL: Yes, that is what I'm suggesting. That is what we would call "services research," which is trying to understand, if you had a treatment, how would it get out there and how would you make sure people had access to it.

I'm not sure whether Ellen mentioned it in her formal remarks, but she has told me at various times about the waiting lists, even in the State of Maryland. It makes you realize that even if we had treatments that we knew were better than the ones we have now, who would actually be able to get them and who would be trained to be able to deliver them.

All of those issues I think need to be in the discussion and would also be part of the priority-setting exercise.

MS. REDWOOD: Dr. Insel, in Section 1 there on the first page where it talks about expansion of activities, it does specifically list that "The Committee will, with the availability of appropriations, expand, intensify, and coordinate the activities of the National Institutes of Health with respect to research on autism spectrum disorders, including basic and clinical research in the fields of pathology, developmental neurobiology, genetics, epigenetics, pharmacology, nutrition, immunology, neuroimmunology, neurobehavioral development, endocrinology, gastroenterology, and toxicology."

Then it says, "Such research shall investigate the causes, including possible environmental causes, diagnoses, or rule out early detection, prevention, services, supports, intervention, and treatment of autism spectrum disorder." So it is all in there.

DR. INSEL: Right. I guess the clarification here, because we come up against this frequently enough, is what do we mean by "services research" as opposed to "services." What I interpret this to mean is that it would be research on services and I think the term is "services, supports, intervention, and treatments of autism spectrum disorder." To us, that means trying to understand the science of dissemination, the science of access, the science of healthcare disparities, and the science of cost, which is really an important piece as well.

What it would not include is provision of services, only to the extent that that becomes a scientific question. This truly is about research. I don't think that the strategic plan would take on questions about which agency is partnering with which states to get which practices out there. Important issues, but I didn't see that as the charge. If other people really do, that is a different interpretation of the same language.

DR. HUANG: What you said is a ladder in terms of what agencies are doing in states as part of services research. I don't really see that in the realm here, either.

But I do see that what array of interventions are going to have the best outcomes for people with ASD as a critical piece of the research. That could be the early screening or early identification for the young children. It could be the supported employment or the supported housing for the adult.

To me, all of that is part of the research endeavor. It is part of looking at that array of interventions, each one of them perhaps being an evidence-based intervention. But, how does it get into the field; that is the implementation piece. What is the array that is going to be the personalized best outcome for a person with ASD.

To me, that would fall into it. I don't see that in this plan.

DR. INSEL: I think I now see where we are disagreeing. We are not, actually. That is precisely what I meant by "services research." It also, I think, gets to this issue of personalization that Dr. Zerhouni talked about.

I think, as we talked about with the team, that all of that was embedded in treatment. That is what I meant by these being very broad categories. We will have to spell that out much more clearly. Treatment wasn't meant to be simply randomized control trials, by any means. There is just a whole other set of issues that have to do with how do you get from research to practice. What are the barriers. That is where cost and things like that become very important.

Our institute has taken that mandate very seriously for many, many disorders. We would do it here as well. We actually have large efforts underway to look at just those issues, particularly around healthcare disparities but also around the science of implementation and the science of dissemination.

All of that I thought was embedded in treatment, but again, if other people don't think it belongs there, we should hear about that. This is a good chance to get those things out.

Walter.

MR. KOROSHETZ: Sometimes it is more semantics than anything that gets people all off track. One way of thinking about it, if it meets the group's needs, would be to relabel so that the medical drug treatment may fit well with the biology workshop and the treatment workshop may be focused primarily on treatment interventions, if that is where people think that the mix is. Certainly in terms of drug treatments, there is probably less that you could attack there. It may fit in well with the biology which is aimed at trying to provide a drug treatment. That is just a way of thinking of a compromise.

DR. INSEL: Walter, can you respond to this other issue, because this is the other end of the spectrum. What is your comfort level with having the treatment workshop also go into issues about implementation, at least the research on access, implementation, dissemination, cost?

MR. KOROSHETZ: I think there are two things. One is, there is what people feel, which is a lack of availability and access. That is a really strong chord and it is a very appropriate chord. If you are going to do this work, you have to separate that out from the work of this workshop, which should be trying to figure out what is best practice, how do you actually determine that scientifically. It is particularly difficult in a field where there may be not a lot of guidelines and people have tried a whole bunch of different things.

But I think that the idea that to serve the people who have the illness now, to try and understand what is the best intervention, what is the evidence that would provide the best guidelines going forward is probably worthwhile.

DR. INSEL: Gail.

DR. HOULE: One other way to look at this possibly is to look at the first page of the Act and your statutory language and, in that first paragraph, "expansion of activities," and then look at your workshop domains. There will be some overlap in the areas that are put forth in your statutory language. Everything is not going to fit into one of these categories or the other, but when you are crafting your definitions, to the extent that you can use these.

For example, "treatment" is there in the workshop domains that we talked a lot about. Is it semantics or what actually is involved in treatment. But if you spelled out some of your statutory requirements in the domain workshops, and some may be addressed in more than one domain workshop, you may be able to capture everything that is here and a feeling that you might have left out something that is in your statutory charge.

DR. INSEL: Good. Peter.

DR. van DYCK: To me, the treatment piece sounds like a medical model. I think more of just pure treatment. I would feel more comfortable if it were a little better explained and more defined more along the line of under committee responsibilities. In the law itself it says "develop and annually update a summary of advances in autism spectrum disorder research related to," and it lists some things, which include prevention, treatment, early screening, but also access to services and supports for individuals.

I have no problem with, and I think it is more clear to add language like that, if we need to keep those four workshops, adding it to the treatment definition and treatment language so people think of it up front rather than having to arrive at it at some process during the discussion.

DR. INSEL: Duane.

DR. ALEXANDER: I think we are getting hung up on different components of what we can consider under the rubric of treatment. There is treatment effectiveness research and then there is treatment implementation research. We really, I think, intend to encompass both of those in that kind of a workshop. The same way with the diagnosis workshop. It is developing diagnostic methodologies and then implementing those diagnostic methodologies the most effective way.

I agree with you completely. This is a research plan. What we have to encompass in this is research. We do research not just on treatment effectiveness -- and by that I mean not just drug treatments but also behavioral treatments, speech treatments, occupational therapy treatments, education treatments, whatever, the whole spectrum of effectiveness of different treatment approaches -- but also, the implementation of those treatments once we develop them.

There is a science of study of research of implementation of treatments, whatever type they may be, and how we deliver those most effectively to people affected with autisms.

I really don't think we have too much of a dichotomy here if we understand that what we intend to encompass is both the effectiveness side and the implementation side.

DR. INSEL: How about the word "intervention"? Would that make people more comfortable, or that doesn't help? Peg.

DR. GIANNINI: I agree with what Duane just said, but I think that maybe we are getting too constricted in trying to box in several concepts. I think there is a lot of flexibility in the law where the statement is "including basic and clinical research." I think that it could umbrella many of the areas of dichotomy that we are struggling with right now: basic research versus service. I think that is what I'm hearing, that there isn't enough on the service. I think under the rubric of this statement in the law that we could be creative.

DR. INSEL: Ed.

DR. TREVATHAN: I also agree with everything that Duane said. As we were having this conversation about services, some of the comments made earlier were ringing in my ears. One of the things that is obviously important and cuts across a lot of our interest is early diagnosis and early recognition. It is so critically important. We have obviously taken some steps in the right direction lately that have been mentioned.

But as we talk about access, I would just encourage, at this point in our history of dealing with the autisms, that access be connected to the issue of early diagnosis for many of the reasons that Yvette mentioned, but yet still have the emphasis on research. Those could be important research questions in terms of the diagnosis.

What can be done in communities, not just lowering rates in developmental centers, but what can be done at a community level to facilitate early diagnosis and early recognition with the goals that we have stated. We don't really know how to do that very well at this point, and that is a research question. That could be connected to diagnosis and be connected to services.

I don't know if that would help also clarify some of what is within the treatment group as well.

DR. INSEL: Other thoughts? Remember what you see here was just a first stab at how to capture this. It is clear that the sense of the Committee is we need something more on this area. We will find the language to try to capture both of those areas, both the early diagnosis and early detection, [which is] the predictive, preemptive part, and the other piece, which has to do with how to make sure we are looking at delivery and implementation.

DR. CHUNG: I have some questions about some other assumptions. The time frame, do people feel that is doable? [Would we] be willing to do that work in the next six months? There were a lot of things that I presented. Obviously we have been focused on the workshop domains. Is there any other feedback?

DR. JANVIER: I had questions about the stakeholder component. We have Autism Society of America and Autism Speaks here. They have tools in place. I don't know, maybe I'm just thinking too detailed, but without a specific questionnaire that you are sending out in your webcasts or on your websites, I wasn't clear on how that was going to happen.

I also would advocate for the nonmedical people in the room here that I do think we need to get away from a medical model. The majority of the interventions, or whatever you would like to call them, for people on the autism spectrum are not medical. We really should broaden that. You could include treatment under interventions or call it "Interventions and Services" or whatever, but I do think it is too narrow and we should move away from a medical model.

DR. CHUNG: We would rely on some of the help internally on our staff who have done RFIs to the public. I think what we would like to do is really try to push this out to as many organizations, and ask your help to help us figure out who are key contact peoples to disseminate the requests for information. We have a listserv that people can sign up for that NIMH [runs.] There is a group of people who come to these meetings or who have expressed interest, so we already have an internal list, but we could certainly push it out further to big organizations.

MS. REDWOOD: Would it be possible for stakeholders to attend some of these working group meetings and have an opportunity for public comment and have those advertised as well? If a certain stakeholder has an interest in one of these four areas that you have outlined, that might be a way to, as well, get public input in the process.

DR. CHUNG: Yes. We would welcome that.

MS. REDWOOD: I love the six-month time frame. I know I work best under pressure, so I think that speaks a lot to the sense of urgency we have facing us.

MR. GROSSMAN: I wanted to address the timeline issue. Certainly there is a strong sense of urgency. I wish what we are discussing now would have occurred 16 years ago when my son was diagnosed. I think, realistically, if I put somebody full-time on this project in my organization, they would be hard-pressed to meet these goals in six months.

Although I think that obviously this is extremely urgent, it is perhaps a little bit too aggressive. I would rather not have it pushed through and slipshod and not have all the important stakeholders and constituencies provide input at the expediency of just rushing it through. I just think that six months is probably too much of a push.

One other issue I wanted to just briefly address. It seems like we really did get into this service array of research. I was talking earlier about short-term opportunities. I would hope that the strategic plan would truly set that as perhaps its highest priority, to look at what short-term opportunities exist.

For example, I just throw this out as a pilot project. You can do research on employing adults with autism in the community. If we could apply that and find some sort of a standard involved in that, just think what impact it would make on families and individuals affected by it. I'm just raising that as a concern.

DR. INSEL: You could also do a cost analysis on such a project and show that the value of such an investment over what any of the alternatives are. We are in the middle of doing something like that in other disorders.

MS. REDWOOD: There is also a services bill that has been introduced by Senator Clinton that you may want to take a look at that addresses some of these issues as well with regard to services.

DR. INSEL: I have the sense that people might not be ready to vote on this, that you want to chew on this a bit, but I don't want to leave today without having some sort of a plan going forward. I certainly don't want to wait three months before we get this started. Do you want to talk about this over lunch? Then we can come back in 45 minutes or something like that and then see if there are additional questions and then maybe vote on it at that point, before we start the next session? Would that work better for the group?

Or, do people feel like we should just go ahead and that with a few modifications we are ready to go? What is the sense of the group? Jim.

DR. BATTEY: I think we should vote.

DR. INSEL: We are snow-blowing with this thing because we have been so close to it, so it is hard for us to see how complicated it may be to somebody just walking into it. Nothing is final here because it is an organic process. As Joyce mentioned, this is 1.0 at best. Alison.

MS. SINGER: I want to echo Lyn's sense of urgency, but I don't think waiting 45 minutes is going to slow the timeline down. I think as part of our focus on incorporating more stakeholders it would be great for us to have the opportunity to discuss the plans that have been presented to us for the first time with some of the stakeholders who are sitting in the room over lunch. I would propose waiting 45 minutes until after lunch.

DR. INSEL: Is everybody okay waiting 45 minutes? Then we can come back and do this not with an empty stomach.

If that is the case, it is essentially 1 o'clock now. We were supposed to begin the afternoon session at 1:45. We have been running a bit late all morning. What I would like to do is, from 1:45 to two, do more clarification questions if necessary, vote in that period of time, and then at 2 o'clock we will start the presentations from the non-government funding groups. We will be off by 15 minutes, but that will give you 45 minutes now to chew on this while you are chewing on other things. Let's come back and try to wrap this up.

[Lunch recess taken at 1:00 p.m.]

AFTERNOON SESSION

[Reconvened 1:55 p.m.]

DR. INSEL: We are going to start. If you will take your seats. I'm hoping we have a quorum so we can get started. If you will take your seats.

Jim Battey from NIDCD had to return to NIH and so I have asked Judith Cooper from NIDCD to sit in his chair. You will get to know Judith in future meetings. She is the autism point person for the Deafness Institute and serves on the NIH Coordinating Committee.

The plan was that we take a few minutes, now that you have had a chance to think about this a bit more, and see if there are additional questions or additional points for discussion. I want to remind you that this is an organic document. This is a process. We are going to be probably modifying some of these things as we go along. Whatever we come up with for May or June is going to be Version 1.0 and will get modified over the subsequent months as we get to Version 1.1.

For where we are now, in terms of getting your support for this process of putting this plan together, what are the other issues that we should be thinking about? Anything?

[No response.]

DR. INSEL: Who are we missing? We are missing Larke, Ellen, and Steve Shore. Let's wait another minute. I assume they are coming back from lunch.

I guess you figured it all out during lunch? We didn't expect this. We thought there would be more confusion, not less, after having a chance to talk about this.

DR. TREVATHAN: Tom, with regard to the workshops, which seemed to be where there was a lot of the discussion, I wonder if there is a way to somehow move forward and at the same time have further refinement of some of these issues that have been discussed about what is in a workshop and what constitutes research and that sort of thing. If there is a mechanism for fleshing out those details and circulating it among the members so that we can then have input on that but then agree to the framework under which that will be done, I wonder if that is a way to move forward.

DR. INSEL: This is a good point, Ed. We are, for better or for worse, going to clutter your inboxes over the next few months. There is going to be a lot of points of this that are going to need your input about some decisions. We are going to think about who goes into these workshops and we want to make these very broad-based, so we need your input about how these get staffed. We certainly need the best scientific expertise, but we need other kinds of expertise as well in the discussion.

So yes, there will be plenty of opportunities for further discussion and further, I think, clarification about what will be taken over by each of these workshops. Maybe the names would even shift a little bit. From the discussion we had earlier it sounds like that might be necessary.

I think the assumption ought to be that things are more likely to be in than out. I don't know that there are a lot of kinds of science that we would keep out of this plan. Stephen.

DR. SHORE: At the risk of possibly being repetitive, because I came in a few minutes late, I just want to say that I feel a little bit confused and overwhelmed by the plan just because I haven't had time to process it. Maybe it is just a function of being on the autism spectrum and sometimes needing a little more time to process things, but I don't have the ability to immediately process it all within five minutes or however long we had.

If we had had a document say a week before to process and maybe even Email suggestions, making this more of a capstone meeting of this is what we have discussed, this is what we have agreed on, we have a few more things to do, that would make it much easier than having to think about voting on something that we have barely seen.

Another thing that I think is important to consider is that with these different subcommittees, in the spirit of that fourth P, Participation, having people on the autism spectrum participate, in particular in the services area and diagnosis. As we get to the challenge that adults with autism face, there are very few resources for adults with autism to get a diagnosis.

I think expanding the view of what the fourth P is, the Participation, and I guess the diagnosis thing for adults. That is a little bit of a separate thing, but it is also important to consider.

DR. INSEL: So we will be thinking about this and getting your input and the input of others into how to staff out the workshops. They will be broad. I think that is a place where we can get a really sincere diversity of perspectives so that we are getting the broadest picture possible of where the scientific opportunities are and where the scientific priorities ought to be.

The question of getting this at the last minute, or even after the last minute, and not being able to see it ahead of time, I'm sensitive to that. We don't want to push people into something that you don't feel comfortable with. On the other hand, I'm feeling this need to move forward. I don't want to delay our launching this effort because we are really eager to set up these workshops for January. If we lose much time now, we will be into February, and then it is going to be really difficult to stay within this schedule.

What is the sense of the group about how people feel around comfort level of commenting on it now? I guess if there is a compromise position, one could say that we could endorse this as a general plan with the idea that some of the specifics would have to be filled in later with your input on particular points of it where you have had a chance to look at it further. Would that be more comfortable?

Is that okay, Stephen?

DR. SHORE: That feels much better.

DR. INSEL: I think what we are talking about, and what Joyce presented, was kind of a basic structure, knowing that what goes within that structure really hasn't been defined for us, let alone for you. We will have to do that together.

Can I get a show of hands in terms of who is in favor of this basic structure going forward for the plan?

[Show of hands.]

DR. INSEL: Anyone opposed, or all opposed?

[Show of hands.]

DR. MORRISSEY: I appreciate the urgency of this, and I have talked to several people that used that word. What I would like to propose is that at least we be given a couple days to think through what it is and to make some suggestions to you. For example, I think intervention would make a nice change for treatment or some other list.

I think that some other text in the plan should describe language from the law directly because there are two audiences here. One is Congress, which is paying attention to this because it is so new, and the second is the public that you want to give you input.

DR. INSEL: I'm sorry, Pat. Just to interrupt, I should have been clear. We have heard a number of comments already this morning that will go in. What I'm asking for concurrence on is what was presented as a structure with all of the suggestions that you have already made this morning.

DR. MORRISSEY: That wasn't clear.

DR. INSEL: As I said at the beginning, this was really meant as a kind of straw man. We were putting it up for you to be able to comment on because we wanted something to start working with. We heard about changing the word "treatment," which seems loaded and is not the word that we should be using.

I think your comment about putting in language both when we put out the request for information to the public as well as embedding language as we define these that come right out of the Act is excellent. We will make sure we implement those kinds of suggestions as well as many other things that were put on the table. I saw Joyce scribbling furiously as you were talking earlier, so I think you should assume, unless there was something that there really was no concurrence for, that most of what we talked about will be in the document as we go forward.

We are not ready to put anything out. Again, I'm really trying to get this fundamental structure of the workshops, whatever they get labeled as, a workgroup, and then that would be the group that would advise the IACC.

DR. MORRISSEY: I have one other process comment. I think that whatever the process plan looks like that will reflect all the suggestions everybody makes is going to influence the message you give to the public, correct? There has to be turnaround around very quickly in order for you to meet your January deadline.

Would it be reasonable, once you draft that message to the public, that people around this table at least get a chance to see that message and maybe be able to make constructive suggestions for further clarifications based on what we think we all agree to here?

DR. INSEL: I would love to do that. If you are willing to help us with this, we will put it out to the group. Again, there will be a relatively tight timeline, but let's get the wisdom of the crowd on this so we get the best document possible. Lee.

MR. GROSSMAN: My negative vote reflected the fact that I didn't know what we were voting on. What you provided to Pat just now was a great deal of clarity for me, so I feel much more comfortable about it.

I'm still murky, and I don't know what specifics you can provide, on the workgroup. I guess whatever specificity you can give on that because again, as you can tell, in the discussions today there was a very diverse opinion on what all of this means in terms of what should be in the strategic plan. Certainly the workgroup should reflect that diversity.

DR. INSEL: Great. Point well taken. I think all we have told you so far is that the workgroup would have the chairs of the workshops, one member of this Committee, and Joyce, who else? And major funders, right, who will be in the next session.

Anything else? Ellen.

MS. BLACKWELL: I liked your point about reflecting the language in the Act. I just wanted to emphasize that it does speak to services and supports for individuals with autism spectrum disorder. When we talk about intervention, maybe we could also stress that language as well.

DR. INSEL: Sounds good. Walter?

MR. KOROSHETZ: It looks like, the way it is written, you have two inputs from the stakeholders. You have one before the workshops that, presumably, the RFIs that are related to each of the workshops will help inform the workshops. I think the IACC should be a part of that. Then, also, after the workshops are done, I think it is reasonable to finish that loop and go back to the IACC and then for them to comment on whether they are satisfied or not and bring that back in. So there could be a loop both pre- and post- around the workshops.

DR. INSEL: This is a point that we might have glossed over too quickly. Joyce mentioned in her remarks that we would like to have an additional IACC meeting because we thought we needed to get everybody around the table once we have had the workshops meet and once we have gotten the public input from this first phase. Probably, we are talking February.

DR. CHUNG: March.

DR. INSEL: March, you think? The idea would be to meet in March and then again probably in May. This is just a heads-up. We have, in the past, been meeting twice a year, but we won't be able to do this without having an additional meeting before May.

DR. CHUNG: The meeting dates are actually on the agenda at the very bottom. I just want to call your attention to that. March 14th and May 12th.

DR. LAWLER: I just want to come back to a comment that Alison had made earlier, and that has to do with making sure that this process includes consideration from the very beginning as to how progress is going to be evaluated.

One of the big challenges on the autism matrix was really how to evaluate it. We were putting different projects in bins that corresponded to goals in the matrix, but there hadn't been a lot of thought up front as those goals were really being developed [about] the best way to objectively evaluate them. It would be nice to see that this new plan didn't suffer in the same way.

People who understand metrics and are thinking about how the efforts of science can be evaluated I hope will be included in these workshops that are being developed for February rather than being pushed down to more of an implementation phase.

DR. INSEL: Thanks, Cindy. We may also want to ask the workgroup, that next body up, since they are not in the workshops, to make sure that they are really clear about what the measures of success would be and what the metrics are. If it is not clear to them, then we don't want it to come back to this Committee until it gets cleared.

Anything else?

[No response.]

DR. INSEL: Thanks so much. I think as a first task this has been great to see the group coming together. This is not simple, as Joyce said at the beginning. This is a complicated process. We are delighted that we have it at least clear enough that you are comfortable with the basic structure. We will come back with some of the details.

The next session is on presentations from non-government funding for ASD research. This is one of the places where the landscape for autism research has changed a lot in the last four or five years. This has happened not only in autism but in other areas of medicine, where we have seen private foundations that have been using philanthropy and other methods to develop funding for research play a greater and greater role in how research in a disease area gets supported.

In this case, we have invited three such foundations to come to this first meeting. This was done for a very particular reason. Remember we said earlier today that the Combatting Autism Act, when it talked about putting together the strategic plan, made the point that this was for both public and private investment and that they were hoping to see -- and this is mentioned several times in the Act -- that some of these things would be undertaken as a true partnership. We certainly have some terrific partners available here.

We thought, even before we go any further into this strategic planning effort, it would make sense to hear what these other foundations are funding, what kinds of things they are doing, what their missions are, and see how whatever this effort is and whatever the people around the table are involved with can synergize with those efforts.

We have three people coming in. The first is Dr. Gary Goldstein, who is the clinical science advisor for Autism Speaks and president of the Kennedy Krieger Institute. You heard a little bit from Elias Zerhouni about Gary earlier in the day. He is a physician who graduated from the University of Chicago. Before becoming the director of pediatric neurology at the University of Michigan at Ann Arbor he served in the U.S. Army. He relocated to Baltimore in 1988 and has been the president and CEO of the Kennedy Krieger Institute since that time.

In terms of his role at Autism Speaks, he is chair of the Scientific Advisory Committee. He has many other hats that he wears, including serving as a professor in neurology and pediatrics at Johns Hopkins University School of Medicine and in the environmental health sciences at Johns Hopkins University School of Hygiene and Public Health.

Gary, do you have slides already loaded up? Yes. Good to go?

[PowerPoint presentation.]

DR. GOLDSTEIN: Good to go. It is a pleasure to meet all of you. Actually, I know a lot of you in these different roles. I thought I would just tell you a little bit. The CV is there, but I am a child neurologist. I have been working with children with disabilities for more than 30 years in a very traditional way, in the beginning of my career as a consulting neurologist.

It was an unusual opportunity almost 20 years ago when I was offered to take on the presidency of the Kennedy Krieger Institute. [The Institute] is more than a medical program for children with disabilities but is very involved in education of children with disabilities, very involved with community supports for children with disabilities, and has as its internal mission supporting the families and the children but doing this in an interdisciplinary way.

I think we were ahead of our time in having this interdisciplinary approach preceding me, starting 30 or 35 years ago. A lot of that was generated by some of the agencies that are here today. We are the Maryland Center for Developmental Disabilities, which is funded in part by the Administration on Developmental Disabilities, Pat Morrissey's agency. I'm pleased to say we were just reviewed and refunded for the next interval.

That is our working with families in the community. It is very dominated by very creative social workers and has great programs, including an early Head Start program, a day care program for children with disabilities, and a lot of outreach into the community, doing home therapies and lots of other things. That is one.

This gives me some background and insight into what I think is needed and how as an agency, that is giving the services or carrying out research or providing medical services, views all of you.

The other is the Maternal and Child Health Bureau. We were one of the very first to receive a grant from Peter's bureau for training, not just physicians but training physical therapists, speech therapists, occupational therapists, administrators, social workers, and whatever, all of the disciplines -- there are 10 of them -- that relate to caring for a family with a child with developmental disabilities. Social work is an important piece of that.

That is an interdisciplinary training program, and it wasn't focused on autism but on developmental disabilities. I have to say the first almost 10 years, half the time I have been there, autism was part of the Institute but it was such a small percent that it didn't get a lot of attention from me, anyway. I was certainly aware of it.

It has been in the last 10 years that we have really seen more and more of an emphasis [on autism], with more and more children we are recognizing and more and more children we are either educating in a school or that we are providing services for in our clinics or community needs. It has just been this explosion of whatever we are doing.

One of the things we have recognized, and that is why I mentioned the training grant, is that even though the professionals now exist -- physical therapists who know how to work with children, speech therapists, psychiatrists, neurologists, developmental pediatricians -- most of them haven't been trained in autism. It is only recently that it has become an important part of our post-graduate curriculum to really make sure that everyone who was working at the Institute and everyone we are training, all the trainees that are going out, have an autism background.

There is an absolute deficiency of people trained to provide these services. I know we are focusing here on research, but for us, research and training go pretty much together with the fellowships, whether it is research people or whether it is teachers or whether it is speech pathologists or special educators.

A survey was done in the State of Maryland among the special education teachers. Most of them are not comfortable with autism. So they are special education teachers whom you would think would be all about autism. It is not. They feel they don't know what to do with children with autism.

I'm here not to really talk about that, but with the various institutes, we have a training grant with Peter from MCH Bureau, community-based services and advocacy from Administration on Developmental Disabilities, and then a mental retardation and developmental disability research center from NICHD with Duane to provide the core to support lots of different kinds of research projects in developmental disabilities.

Today, over 20 percent of our research and clinical activities and more than half of our educational activities are with children with autism. It is an enormous event, and that is something that has caught my attention, so much so that I was very involved with helping get this new foundation, Autism Speaks, started.

I'm here to tell you a little bit about Autism Speaks. I guess it is not surprising, with the recent awareness of this problem and the magnitude of it, that a foundation would be relatively new. We feel we are old now, but this was founded in 2005.

It had two missions. One was to bring public awareness to autism. The parents knew about autism. Some of the providers who had to take care of children with autism knew about autism. There were foundations focused on research, like NAAR and CAN, but they were pretty much funded by the parents and the parents' friends. There wasn't public awareness, I don't think, about autism to a great degree. We are talking 2004 at this moment.

I had the opportunity to be in discussions with the Wrights and Bernie Marcus, who is another founding person for this foundation, saying that the public has to know about autism. The people who don't have children with autism or grandchildren with autism have to know this is going on, how much autism there is, and how little support there is relatively for research in both the public sector and the private sector, honestly, and how to influence this.

One of the remarkable things, in my mind -- for many of you in the nonprofit world I think it is absolutely remarkable -- we have to be able to merge together actually five nonprofit organizations that were dedicated to autism into one foundation, Autism Speaks. Autism Speaks began shortly thereafter.

ACRE, a New York-based, relatively small but fundraising foundation that was raising money for research on autism, merged into Autism Speaks. Shortly after that, in February 2006, NAAR merged with Autism Speaks, and in 2007, in February, CAN merged with Autism Speaks. With the CAN merger came the Autism Treatment Network, another nonprofit organization that had merged just weeks before with CAN. They came along on the ride, and so all of these people are there, [along with] all of the tradition of those organizations. They themselves were about 10 years old, the two of them anyway.

And the advocates. We have this wonderful board that has the founders, like Jon Shestak and Eric London from CAN and NAAR, and obviously the Wrights and other concerned parents. One other board member here, if she could raise her hand, is Laura Slatkin over there, who actually came from Autism Speaks when we first began.

The goal was, one, to raise awareness. We have raised awareness. This is a group interested so you probably notice all these things, but everyone I meet now knows about autism, sees the spots, and is worrying about their grandchildren or their children. I think that is good. It is too bad that we have to worry about it, but on the other hand, it is getting a lot of pressure on us. It is creating an opportunity for fundraising, and a lot of good things are happening.

This is a little history of Autism Speaks. You ought to go to the website, AutismSpeaks.org. Then you can learn a lot more about it.

This is what we are up to. Much of the money that is raised will be used, or almost all, for biomedical research. We are very active in public awareness and getting everyone to know about autism and the fact that things need to be done for it. I think that is moving rapidly.

This will look familiar to you. I hadn't seen your slides. I'm a volunteer. I'm there but I'm not there full-time. I'm a volunteer, but who were going to be the people. Fortunately, shortly after [a conversation with Tom], we had the merger with NAAR and with NAAR came Andy Sher, who was their chief scientific officer and brought a lot of skill to that. Then with the merger with CAN, along came Claire Losinchares [ph], who was over here. Not here today is Sophia Colamarino.

We have three outstanding staff [members.] You would be lucky if you had them, but you don't. We have three outstanding staff members. Their own retreat and their own thoughts about who was going to do what came up with I think almost the same outline that you [have] that we would be thinking through in terms of our portfolios.

We want to integrate our portfolios with the NIH portfolios and the CDC portfolios so that we can do something not additive but something we can spark either in the beginning or the end or something to make a big difference. I think this planning process is perfect for right now.

Now, we are raising money for research. This will all be, actually, for autism research. It won't be for research like autism. We are up to this year, I think, giving out $30 million in grants, and next year maybe $40 million in grants around those topics. I'm not going to go through this in great detail.

If I look at the other foundations, Cystic

Fibrosis, Juvenile Diabetes, certainly the Race for the Cure, you wouldn't even know their names if they weren't raising $100 million a year for research. You can't know of a foundation that raises $10 million unless you are in that foundation because it wouldn't have any public awareness. Autism Speaks is getting the awareness. I have a hard time believing we will not have the order of magnitude of $100 million a year to sponsor different kinds of research to make a difference for children with autism and make a difference for the families.

I'm not going to go through this, but if you look on the website of Autism Speaks and look for grants, you will see we have a lot of different mechanisms. Now, the reason we have a lot of different mechanisms in part is because of the merger. We integrated everybody's mechanisms, so Autism Speaks, before we merged, had some thoughts of how to do this. Then NAAR had their grant mechanisms and CAN had theirs, and we brought everything together.

I'm not going to go down the list, but there are a lot of different grants, some of which actually relate to the NIH. What if you are a young investigator and you get an outstanding score on your RO1? You don't always get funded when it is outstanding. It used to be all the outstanding grants got funded and half of the excellent grants got funded. Right now we are seeing grants that are rated [outstanding.] You get back your critique and it says "This is wonderful. We have no doubt you can do well." It has everything on it, no questions, and you don't get funded because you run out of money.

So we are encouraging some people who have those grants on the topic of autism just to send us their NIH grant that didn't make it and maybe we can give you the bridge money to help you have that grant work.

We also want to build on some of the grants that are out there. If you are an NIH researcher, you will get the good news that you were funded and then they will say "We are holding back 20 percent, and not because you are not good enough for the 100 percent."

First of all, you write your grant and the study section cuts it back to what they think [is appropriate] because you put too much in. So they cut you back. They say, "You are approved now for $300,000 a year, or $200,000 a year." Then you get the news there is an administrative cut because the government doesn't have enough money, and that is 20 percent more. So you write back and say, "I'm going to drop Specific No. 3 then because I can't do all that I said I would do."

We are open to hearing about the things that you can't do because we feel we are taking advantage of the fact that you already have the infrastructure provided by the NIH.

Then we want to target some areas. We have had workshops as well, workshops on the concern about the gastrointestinal disorders of autism. We wanted to invite gastroenterologists who have experience with children but not necessarily experience with autism to think about the kind of investigations they might do to understand what are all these complaints about that children have and that families have with children with autism and the GI tract.

A lot of concern about immunology. We had an immunology workshop that is going to lead to a call for grants.

We had a toxicology workshop not too long ago wondering about the toxicants and this interaction of gene vulnerability and toxicant triggers and how we could get at that. In fact, we have had ongoing conversations now with NIEHS about maybe some partnership grants and how we could do that.

It turns out there is something called the NIH Foundation that can mediate partnerships between a private foundation and the NIH. We really want to see more research looking at the environmental influences in autism.

The most common genetic disease is cystic fibrosis, a recessive genetic disease, and I think that is one in 2,500. This is one in 100, or one in 150. One in 100 boys, anyway. I think it is too common, with 10 percent of us are carrying these recessive genes, so the environment has to have a role. How are we going to explore it together. We have a plan there.

In addition to calls for investigator grants, the foundation is sponsoring some pretty big initiatives. One of which, to which our contribution to was just renewed, is the International Autism Genome Project, the AGP. This is a study done by very much the same geneticists who are looking for the causes of other common disorders that have a genetic propensity, and they are doing these "snip-chips."

If you have read about it in the Wall Street Journal and the New York Times recently, you can get your snip-chip now and you yourself can just send it in to 23 and Me and they will do your snip-chip for you.

This is a project where you do the trios and you get both parents and the affected child and you begin looking for those gene or gene areas that are altered among the children who have autism and then among the children who don't. It is a big project. Fifty investigators, 19 countries. We are seed money, but in Canada, they put $25 million in, I think. The MRC in England put in $10 million or something recently to have this search for these genes.

The environmental factors initiative is one just beginning. We have a committee set aside to think this through and maybe to work with NIEHS and CDC and how to proceed with this.

Epidemiology. We don't know, at least I don't know, the difference in the prevalence of autism [depending on] where you live. Forget whether you live outside the United States. I really don't know, if you live in a rural part of this country or in a city, if you live in Texas or if you live in California, is the prevalence really different. Does the climate make a difference; is it something in the air; is there something there. Most diseases you know the prevalence by zip code. Here we have a very common disorder.

CDC is beginning this, but the numbers I see still don't tell me regional differences. Maybe there are no regional differences. China is hard. What are the standards for making a diagnosis. That is one of our problems, not having the biomarker. But, is the incidence in China, like stomach cancer, 10 times here or is it one-tenth? That would certainly be a clue.

Another big event from early on has been the baby sibs. This is where you track the subsequently born children who are born into a family where there is already a diagnosed child with autism. It turns out the risk of recurrence is really high. It is an opportunity to do lots of studies, which you have heard about.

We have a clinical trials network and an early treatment research network. So these are the areas that we are pursuing.

I'm going to tell you about one more project. We are obviously interested in partners. There is just too much to talk about right now.

One project, and this is something that is a grant from Autism Speaks to the principal investigator, Paul Law and his wife Kylie Law. Some of you know about it. It is the Ian Project. I would like you all to look at it. It is a Web-based research project, www.IanProject.org, and it is an opportunity, if you are anybody, to learn a lot more about autism, but if you are a family and you have a child with autism, to participate in an online research project. You are consented. You are committing yourself, if you choose, to spend three or four hours over time answering lots of questions about your child.

In six months, 20,000 individuals have consented. We were talking about community participation. Twenty thousand participants are consented. These include parents, children with and without autism, families that have twins, triplets, you name it.

This collection of patients and all the demographics and personal observations of these families can be linked to investigators who are searching for research subjects. Say the investigator is in Houston and you are looking for the twins of Houston who have a child with autism, we can send an Email to all those families saying there is a study going on at Baylor or wherever and they are looking for twins or boys or girls or 10-year-olds, or whatever, and you are close enough that you might be interested in learning more about this study. It is like a match service or a dating service between these 20,000 people and investigators.

Plus, we are learning a lot. Who knows about autism, the details of autism? It is really the families. It is not the doctors. That is one of the problems here. No one is really responsible for autism, whether it is your family doctor or whoever. Who knows? It is really the families.

At the moment we don't do adults because of some consent issues. The very next goal in 2008 is to open this questionnaire up to adults, so we would love help in devising what questions we should ask.

That's it.

DR. INSEL: Thank you.

DR. GOLDSTEIN: I thank you for the opportunity to tell you where we are heading. We certainly want to work with you.

DR. INSEL: Great. Thanks, Gary. Can you stick around? We will have questions later. I want to march through each of the presentations. If we could get you to stay for a bit, we may have people on the Committee revisit some of these things.

The next presentation is from Jerry Fischbach, who is the scientific director of the Simons Foundation Research Institute. Jerry is very familiar with both the NIH and with this Committee, having served previously as director of the NINDS, the Neurology Institute, at a point when IACC was first formed. He left NIH to become the dean at the College of Physicians and Surgeons of Columbia University. Over the past several months he has moved to take over the directorship of the Simons Foundation, which is a new initiative which we thought would be important for everybody to hear about.

[PowerPoint presentation.]

DR. FISCHBACH: I'm a fan of the NIH. I'm going to talk a lot about how private groups can and must interact with the NIH. I always quote Louis Thomas, who said that the NIH is probably the single-most important institution for health and social advancement in this country in the last 50 years, probably 75 counting from Lou Thomas' time, and I firmly believe that.

I am the emeritus dean of medicine at Columbia, where I tried very hard to recruit Tom Insel, unsuccessfully, because Tom felt the same way I did about the call to public duty at the NIH.

The Simons Foundation was initiated by Jim and Marilyn Simons. Marilyn is the president of the Foundation. Jim is a mathematician. For many years, he funded, through philanthropy, studies in mathematics and physics. He is the former chairman of mathematics at Stonybrook.

In recent years, for personal reasons, they became interested in autism and actually did a lot of very innovative things over a period of three or four years, until they decided they had to expand. Things were growing faster than they imagined. They recruited me, and we have recruited a staff at the Simons Foundation in New York.

To distinguish our efforts in autism from the rest of the Foundation, we have coined the phrase "SFARI," Simons Foundation Autism Research Initiative. This is what we study. We are determined to understand what goes wrong during the development of the brain.

The missions are overlapping with what you have heard and what the NIH's mission is. It really is to improve the diagnosis, treatment, and prevention of autism and related developmental disorders.

Jim made a decision a long time ago. He did not want to be involved in raising awareness. We all want to speak out every chance we get, and as I will tell you, we are reaching out to many families. But the primary goal of the Simons Autism Research Initiative is research.

There are a lot of public and private efforts, and they are very similar in kind. The NIH has a similar mission. They do search for new talent and new techniques. They are interested in a diversity of approaches. They want to fund the best scientists. They are a focus for attention on autism through RFAs, through meetings, through convening power, and they have been a tremendous asset in increasing interest in this country and abroad.

Private foundations on the margin are a bit more streamlined. They are less centralized and constrained. I can call investigators anytime I would like and encourage them to apply on the spot for a grant, come to New York, talk to them, cajole them, educate them. Scientists need a lot of education about what their work means for autism.

We give large awards. Our last RFA was up to $500,000 per individual award and up to $1.5 million for consortia projects, and $250,000 for pilot projects.

Now, we don't have anywhere near the money the NIH does and I suspect we won't be able to raise -- we are not raising money at all -- the amount of money that Autism Speaks and others might have. But it is a matter of how you want to spend it. We want to invest it in relatively few, high quality projects.

The NIH does take risks, but I think we can take higher risks. We can do intriguing things with scientists who certainly, even through innovative grant programs at the NIH, would not have a chance of being funded. If there is time, we can go into some of them. As I said, we are more involved with the individual investigators, almost on a daily basis.

The synergies here I think Gary mentioned. We can provide seed funding for later NIH support and supplemental funding. We are probably going to supplement a major imaging grant as part of this baby sibs project [led by] Joe Piven at North Carolina. We hold conferences. We like to think we are contributing to national resources.

I think our informatics team at the Foundation has been instrumental in many of the NDAR efforts, especially in developing ways to assign every patient in the world a unique identifier so the same patient does not enroll in multiple studies so that samples truly are independent samples. This is a much harder job informatics-wise than you might think.

I will describe in a minute or two the Simons

Simplex Consortium, the SSC, which I think will contribute, and has contributed, to the NIH efforts. This is a consortium of now 12, and it will probably go to 15, universities collecting patients of a certain type. We will enter them eventually in the NIH database. There will be 2,000 families, maybe growing to 3,000, 8,000 people, and we will provide the funding for seeing these patients, drawing blood, creating cell lines, and distributing DNA. We look forward to the time when we might have joint RFAs, requests for applications, with the NIH and with other foundations.

My point of view is that there are many ways scientifically to attack autism, as shown here, from the molecular, biology, to cells and circuits, systems, cognitive neuroscience, and behavior.

Now, on the molecular level, there is no question that we will get many clues from current studies of genetics. We will get clues from studies of the brain and we will get clues from the environment. Now, the genetics, as I will tell you in a moment, are complex. This is not going to be one gene, one disorder. This is not inherited in a Mendelian fashion. There probably are somewhere between 50 and 100 genes that serve as risk factors for autism, if past experience is any indication.

If there are that many genes and they are each contributing a bit, then the difference between genetics and environment disappears because we are talking about risk factors for environment. I know at the NINDS Walter funds studies on the genetics of post traumatic epilepsy. Getting hit in the head is an environmental factor, but not everybody develops epilepsy after head trauma. There are certain genetic predispositions for that.

I think about autism in the same way, whether it is an infection, whether it is a vaccine, or whether it is a drug that precipitates the incidence. We must learn what these factors are.

The evidence for genetics in autism is overwhelming. There are gross chromosomal disruptions. Others today have mentioned these single, monogenic syndromic disorders such as Rett, Fragile X, tuberous sclerosis, and others. But the great majority of autisms we just don't understand. We call them idiopathic.

But we think even here there is a strong genetic component, most because of the concordance between siblings and, strikingly, the concordance between monozygotic twins, which is higher than any other neurologic or psychiatric disorder that I know. It is somewhere between 70 percent, if you define autism strictly, and 90 percent if you take the whole broad spectrum. There is no question genetics play a role here.

But the genetics are complicated. I think it is fair to say that no matter how good the groups, no matter how large the patient population, the linkage and association studies have so far been disappointing. They are hard to reproduce, and it is not quite clear which way they are leading.

As a result, there are over 100 candidate genes. You are not meant to read these, but there are many, many candidate genes that fall into pretty well defined categories, shown on the right-hand side of this slide.

There are various approaches to this heterogeneity. One is to look at the single-gene disorders, these syndromic autisms of Fragile X, Rett syndrome, and others, and say what is it about those diseases that may teach us something about autism. What is it about the biochemistry. Several groups are doing that, and we are funding several groups doing that.

The other is to refine the phenotype and look for one aspect of autism, either language, restrictive and repetitive motions, cognitive issues, social withdrawal, and try and focus the genetics on an endophenotype. That depends on being very, very accurate, as Stephen raised before, in defining the phenotype in the first place.

Also is increasing realization that epigenetic factors, factors that turn genes on and off, that are not related to the sequence of the DNA are very important in autism.

One thing we are betting on is that a lot of autism is due to what are called de novo mutations. That is, the parents are not obviously affected. There is an interesting debate about who is normal among us, but the best we can determine, the parents of these children are not affected, yet the child is. It is almost certainly due to a new mutation that occurred in the germ line of those parents.

We have initiated a project called the Simons Simplex Collection -- other groups are doing this as well, as Gary just described -- that is looking for families with one affected proband, apparently unaffected biological parents, and one unaffected sibling. The thought is that we have a chance here of identifying new mutations in that child which have a fairly significant effect; that is, a highly penetrant mutation.

There are now 12 academic centers involved in this. It will probably grow to 15. One advantage of doing it this way is that there is some continuity of care. People come to a specific center. We can follow them over time. I think this will supplement and complement the miraculous results that have been achieved with AGRE, where teams go out to where the patients live around the country.

We feel that one advantage of approaching things this way is that we will have some continuity and provide, in addition to research analysis, diagnostic analysis, support for the families, and some measure of therapy as they become available.

I don't know how many people are involved in this, but I bet it is over 200 around the country. Each site is funded at close to a half million dollars a site per year. They are expected to collect about 100 families a year. The important thing here, and I must say this reflects Jim Simons' attitude, is accuracy. It is to do the phenotyping as well as it can be possibly done.

We train all the individuals at the 12 sites. We test them for reliability, and we retest them. Airline pilots are tested every six months to see if they are still up to snuff. We plan to test the clinicians at least that often.

But a point that was raised earlier I want to emphasize here. It is hard to identify good clinicians who can see these patients. It is not just the physicians that were backed up, but many people have to wait two or three months to come in to see a clinical psychologist. There is a real area for cooperation here among the foundations and the NIH.

It would be very imaginative to begin a graduate program or a certificate program to intensely train people who can see, diagnose, inform, and begin treatment of children with autism. The nurse practitioners are one way, but they are not the only healthcare professionals. It is a real shortage which we find to be a limiting factor.

I see this as a Manhattan Project. I never thought I would say that because I don't believe research is a Manhattan Project. There are too many unknowns. But this is a Manhattan Project. We know what the right tools are. We know how to go about doing it. It just means implementing it and getting it done.

I know the tools for genome scans are changing monthly, but they are getting more and more accurate. I would assume within two or three years we should have a much greater list of reproducible, clearly identified candidate genes. If we don't have that, I think we would have failed. So I believe this is a Manhattan Project of sorts.

Actually, I want to mention one more thing about the genetics. It is now becoming clear that sequence abnormalities, what you and I used to think was a classic mutation, are not the major problem in autism. It has become clear in the last three or four years that a great deal of variation in our genomes is because we have more or fewer copies of certain genes.

So that, if you went through them base by base and sequenced them, you would think that we were identical, but we are not. You may have more of one gene than I do, maybe two copies, three, four, ten, and I only have one of a certain gene. If you multiply that by 30,000 times, the combinations are enormous.

There is a great deal of interest in this copy number variation, and some of that interest was stimulated a few years ago by a paper by John Sabat and Mike Wigler where they predict -- and it is still a prediction. It is not an iron-clad fact -- that simplex families, probands in simplex families, have a higher number of copy number variables.

So there is no question that with at least two different platforms we are going to focus on copy number variance. I think this is going to be more informative than the snips and at least as informative as whole genome sequencing.

Here are some of the hurdles, and I will finish quickly. One, no matter how precisely we define it, this is a complex phenotype. I believe there is a core here, though, which is autism. Right from Canner's first paper in 1943, you know it when there is an autistic child in the room. I don't know how many variations there are on that theme, but there is a core of autism.

There is a huge time commitment here on the part of people involved. IRB issues are significant. Consent is a relative word, and to do these studies one must be really careful about privacy and other issues.

The logistics of blood collection and DNA are important. The expense is significant. We will spend $18- to $20 million on the SSC project over the next two years. As I said, there is a shortage of trained personnel.

The other thing is the genome has more and more surprises for us. While it is a Manhattan Project I believe, you have to be prepared for unknown complexity.

Now I'm going to have to skip through these other things. That is the molecular level. The cellular level; in addition to these genetics, the Simons Foundation is funding several projects at the level of cells and circuits, systems, cognition, and behavior. My calculation is as of today we will have given out $65 million in grants, and that covers a wide variety of investigators.

The last RFA, issued last December, funded 18 investigators. I'm very happy that 11 of them had never worked in the area of autism before. That is one advantage of a foundation. You can go out to the community, identify a really good scientist who would not have thought of applying but who will apply if you can point out to them the relevance of their work.

One investigator [team] that has received a tremendous amount of press lately is Josh Saines [ph] and Jeff Lickman [ph], who published a method for tracing axons, hundreds of axons simultaneously. It made the front page of Science Magazine.

I'm not going to talk about the cellular aspects.

I think, once we get past the cellular level,we have a need to build hypotheses at the neurosystems level and see how these cells work within systems. Right now attention is focused in the medial part of the frontal lobes and the anterior singulate and in the temporal lobes. We are funding research, both imaging, autopsy material, and hopefully soon physiology, in these areas. We have to know how the genes work in those areas and when they are turned on.

Now, looking ahead, I think there are lots of reasons to hope. There really have been, just in the last five years, tremendous advances in the genomics, in the imaging, in neural circuit analysis, and in cognitive neuroscience, ways people are being tested and explored. The notions that children with autism lack executive function or have a deficit in their theory of mind I think will turn out to be fairly crude concepts and we will refine those over time.

Then there is a tremendous need in the world at large and, as you can tell here, a great desire, and there is enormous talent behind these things.

Here are the challenges, I believe. I think I'm going to end with this. This is a complex disorder. Although we may know all the risk factors, that is just the beginning, the risk factor genes. Understanding how these things work in the brain will be a long time in coming. If we are lucky, we will develop therapeutics long before we understand mechanisms. That should be a major effort.

It is going to take a lot of money, much more than any of the foundations have here. It is going to take the NIH. It is going to take the government and the public understanding what is really needed.

I believe we are going through a period of time when the public doesn't understand enough about science and there is a certain lack of trust in science. I think private foundations and advocacy groups have an enormous role to play here. You don't need too many Korean fraud cases with human embryonic stem cells to make people really question whether you can do what you say you are going to do. In an era when a great fraction of our population don't believe in the theory of evolution, we have a struggle ahead of us.

As I said, the work force is not large. I believe that this country is still, in its politics, its economics, and its attitude, feeling the effects of 9/11. So I believe a triumph in this area of autism will change all of that. That is the reason I have decided to commit myself over the next period of time in my life to working in this area.

I think the best way we can proceed given the similarities you have heard is to keep talking with each other, finding out ways that we can interact, and ways that we can make the overlap between the organizations productive. Thank you.

[Applause.]

DR. INSEL: Thanks, Jerry. We are going to go on to the next presentation and then we will wrap this up with a set of questions.

Jim Gusella is coming to us from the Autism Consortium of Boston. Jim is actually the Bullard Professor of Neurogenetics at Harvard Medical School, and he is the director of the Center for Human Genetic Research at Mass General. He is certainly a world-famous scientist, often cited for his work on Huntington's gene, which he described in 1993. It has become really, in some ways, the paradigm for modern genetics research.

[PowerPoint presentation.]

DR. GUSELLA: Thank you. It really is a pleasure to be here. I will say that essentially my involvement in the Autism Consortium actually derives from my Huntington's work. I came into Huntington's disease in the early 1980s as a starting assistant professor who had trained in molecular biology and didn't really know much about human disease in particular but saw Huntington's disease as an area in which I could both do really exciting basic research and yet have an impact at the same time beyond the walls of the lab.

I actually set up at a hospital to do the work. I skipped doing a post-doctoral fellowship and went directly into trying to find the Huntington's disease gene. We managed to get a marker for that back in the '80s. We managed to clone the gene in the '90s. We have been working on trying to develop a treatment since then.

What it taught me over the years was, in the early days, I was dealing with clinicians. In the middle term I was dealing with geneticists. After we had the gene, I had to start dealing with neurobiologists, which was a difficult one because, at the same time, I was hearing different things from the clinicians than I had heard 10 years before, and I started talking to families and then I really started hearing different things.

In the last 10 years, I have been dealing with pharmaceutical companies and people who do drug development, and you recognize that if you are committed to solving a problem, you can do your piece but you have to be talking to all the other pieces in order to be able to do it effectively. Otherwise, you do a great job on your piece, but it isn't necessarily capitalized on as quickly as possible and not all of the things that you don't see while you are doing your piece are picked up upon.

The reason I'm doing this is because our goal in the Autism Consortium essentially is to have people talking to each other constantly at all levels. Essentially, like the other groups you heard, we have a mission, but we are actually quite a different organization. Our mission is similar, but the way we go about it is different.

Our goal is rapid advances in understanding diagnosis and treatment of autism through collaborative research to improve the care of children and families affected by autism and related disorders. To do this, the "collaborative" and the "rapid" are important.

I indicated to you, from my experience in Huntington's disease, that it takes many different groups of people. The experience of autism researchers in the Boston area, where I'm from, was one in fact of frustration.

Just like families were frustrated with where the research was going, researchers were frustrated because a lot of the stuff that was going on in the clinical enterprise was different, depending on where you were, which hospital you were in, whether you were in a neurology department, or whether you were in a developmental biology department, et cetera. The various researchers didn't always have access to families. There was just a lot of frustration.

Similarly, there were philanthropists who saw that frustration in trying to have their children treated and wanting to move autism forward with donating money but not really seeing that the system was one in which they could donate effectively.

The Autism Consortium is essentially a combination of those two sets of people. In the case of the institutions represented, there are 13 different institutions represented in Boston, where there are clinicians, clinical researchers, and basic scientists, who have all joined the Consortium and who represent all of these institutions, working together with some support from the initial philanthropists who started this but with additional support coming in.

We are not like Autism Speaks. We are not like the Simons Foundation. We are certainly not like the NIH. We are not aiming to fund all the studies of everything that we do through a single organization.

All of our people are committed to working together. They are committed to talking to each other. They are committed to designing studies and capitalizing on them, but they do seek funding from the NIH, and they seek funding from the Simons Foundation and from Autism Speaks. We have a number of studies where we are involved there.

This is not an insular organization that takes place in Boston and that is all that goes on. We are actually tentacled out both in terms of funding and in terms of collaboration worldwide.

So this group of institutions encompasses more than 60 investigators in Boston, and all of those investigators have agreed to a commitment statement. The commitment statement essentially says that the most important thing is the mission. The most important thing is not getting off on some interesting science that you happen to have picked up but moving forward in autism. You can always do the interesting science with other kinds of money or with other kinds of endeavors, but with the Consortium effort you are really trying to push forward in autism as quickly as possible.

Now, for people to work together, you have to have that spirit. You also have to have trust, and so you have to be talking and meeting and showing examples of trust along the way, which we are doing. You also have to be doing things in a way that you can compare. One of the first steps, for example, was making sure that all the clinics used the same protocols for dealing with patients and for phenotyping. So, common protocols.

You have to share the data. We are committed to open data sharing while respecting confidentiality, which means scientists have to publish to be promoted. They have to publish to make a name for themselves to get the grants from the other agencies. So you don't go stealing somebody else's data. Instead you help him to get his study done because that is going to make the whole thing go faster. It is going to get your studies going faster if you are helping him and he is helping you. Ultimately, joint publication is something that is sort of a given within the Consortium model.

Now, when we then look at how do we approach autism, the other thing that comes clear from any disease study, anybody who has worked on disease over the years, is that it really starts and ends with patients and families.

You don't learn, ultimately, what you need to know about the disease from a mouse. You may learn something from a mouse that you have studied because of something you learned from patients and families, but you always have to be relating your research to what is going on in patients and families. In effect, they need to be partners in your research.

So we envisage research and disease as a cycle that starts and ends with patients and families. We can look at that cycle in a number of different ways. We have started with genetics being a primary way of looking at it not because we believe that all autism is genetic. We certainly don't believe that. We basically agree very much with what Jerry Fischbach said, which is that there are going to be a lot of different genetic impacts, some of them subtle. But genetics is a tool that you can use that gets you into the system, that gets you into being able to look for environmental factors more effectively, being able to look at the neurobiology more effectively.

So we are not completely genetics, but you are going to hear a strong genetic bent partly because I'm a geneticist and I can explain that part better.

One of the things that we noted early on was that, depending on who the patients saw, they were treated differently. So one of our initial goals was to decide whether it was possible to standardize genetic testing for autism while capitalizing on new technologies that were available, return the information to families, and thereby engage them, essentially, as partners in the research where we could recruit them to other studies while having them get better care than they were getting previously.

We also then have a workgroup that is involved in detailed autism phenotyping, with the goal of learning enough from phenotyping to optimize diagnostic procedures to then have the information necessary to correlate the phenotype with the genotype, when we have it, and also downstream, hopefully to correlate it with environmental factors and with experience.

Ultimately, we would really like to have more informative measures than the ones that we currently have, so there is research into new measures.

All of that information can be used for gene finding. There are a lot of different approaches to gene finding, so we have a group that is multifaceted. The real goal is to just discover the genetic differences that exist in autism and to combine that information with the information being collected by the other groups to say what those genetic differences means.

One of the products of this effort is a method for HIPPA-compliant data sharing, a database of information that is common across all of the institutions, a tissue repository that is shared by all of the member institutions and in fact can be shared outside this particular group, and most importantly, a cohort of subjects who become partners in the research, who understand that they are part of the research, who are willing to come back over time and be studied because they know that they are contributing to the solution.

Now, once you get into phenotyping, there are fancy, new ways to phenotype that you can't possibly apply to everybody who comes into the clinic but where you can learn a lot, particularly if you are able to study a select group who are more homogeneous, not because they show the same symptoms but perhaps because they have the same set of genes, or perhaps because they have the same aging experience. Those are imaging studies and a variety of other modalities for advanced cognitive neuroscience. We have a working group around that as well.

The combination of all these things leads to hypotheses that can be tested in model systems. Mouse models are a primary system, but cellular models and lower organism models are also being applied. Again, we have people at each of the different institutions who are working together within the group and across groups to attack the problem.

Now, I have drawn this as a cycle that ultimately leads to improved treatment. Once you understand the mechanism, you can do rational interventions, whether they be pharmaceutical or whether they be behavioral. You can understand which patients it is likely to work for. You could potentially pick up individuals who are at risk before they have suffered the abnormality in development that causes them to be picked up through behavior. Maybe you can pick them up through biochemistry before that.

In any event, the goal is to develop a rational treatment or a rational intervention. I have drawn it as a smooth cycle, but in fact, the way we picture this is all of these groups interacting and interacting all of the time. They cross-feed each other in terms of information.

I'm going to take one group and give you the example, and that of course will be genetics, since that is one of the ones I'm in, and then try to take you back to the full cycle.

You saw in the previous talks that obviously autism has many different genetic factors, from single gene disorders with autistic features to karyotypic abnormalities and deletions, with the vast majority being unknown. So when the Consortium started, it was pretty clear that the syndromic ones were cases you could work on now because you could make animal models. You could try to understand what they had to contribute to the brain developmental differences that could lead to autistic features.

We had a number of people in Boston, because it happens to be a place with probably more active scientists than anywhere else in the country within a small area in many different institutions. We had people who were already working on these model systems. They decided they were willing to join the Consortium because they saw that they could then accelerate their own research while having it be applicable beyond the monogenic disorder.

Similarly, there were people working on chromosomal abnormalities in a variety of disorders, developmental disorders and specifically in autism, and there were people who were preparing for trying to figure out how to get at this undiscovered set of genetic factors.

So the Gene Finding Working Group that got put together included a fairly large number of people who came from each of these different approaches. My lab represented, in fact, chromosomal abnormalities, because we were working on balance translocations in autism cases.

Chris Walsh's lab came from working on Middle Eastern families, assuming that the in-breeding could be used as a clue for finding the causes of autism. Mark Daley came at it from the point of view of the snips that Jerry Fischbach talked about, looking for association across the genome.

Lou Konkle [ph] and Zach Cohawney [ph] came at it from the point of view of using bioinformatics to try and tease out pathways that might be involved. Jay Oramish, Rudy Tanzi, David Paul, Susan Santangelo, these are all people who are first-rate scientists who got together as part of this Gene Finding Group to combine the approaches and cross-feed them so that we could maximize what came out of it, which I will tell you in just a second.

Now, to take that back, we have equivalent sets of people in each of these working groups, all committed to working together and all communicating across research groups.

What I have shown in yellow here is just the one-year kind of status across these groups because, in fact, we really only formed last spring, a year ago last spring. So in terms of being up and running and actively doing things, we are about a year in.

In that year, we have standardized genetic testing at five different hospital sites, five different clinics. We have introduced comparative genome hybridization as a new tool to test whether it is in fact going to be useful broadly within autism. Our goal is to do 1,000 individuals to come to a statistically significant result on that testing, and we are well on our way to completing that by next summer.

The Gene Finding Group didn't want to wait for collections, and so it turned to the AGRE sample, which had already been collected, and carried out a whole genome association scan, which we have shared with the community. The Phenotyping Group has a goal overall of collecting about 5,000 individuals, about 1,200 in the first year, and we are on our way to doing that. The Cognitive Neuroscience Group has a project based on genotype to look at 100 individuals as a starting point to optimize the protocols. We are already planning a pilot clinical trial for Rett syndrome of 30 individuals.

We established family support networks, family support individuals within each of the clinics, to help the families navigate the medical system and, at the same time to point out to the medical system what it is that is difficult about it for the families. [They] act as a real connection [by] listening to and understanding what the families' problems are, but also as support that then convinces people that perhaps we are for real and they should participate in the research. It has actually been working extremely well.

We have carried out the genome scan. We made the data publicly available already, although the final analysis of the association isn't done. The copy number variant work is done and in fact, as a nice success of the approach, not only discovered a deletion that occurs recurrently in autism but we have already shown that it is useful for clinical practice because we are already working with the genetic testing labs and therefore we already know that what we found in the AGRE scan has been replicated in the clinical testing labs.

So the rapidity of being able to move from lab to diagnostics was only possible because we were all talking to each other all the time.

We do have this clinical trial in development for Rett syndrome based on some of the findings coming out of the Mechanisms and Models Group and the mouse work that has been done. We are finding that a significant proportion of people agree to the genetic testing study, but of those who agree, an even higher proportion, upwards of 70 percent, agree to go on to the next phase of detailed phenotyping. As I say, we view them as becoming longer-term partners in the research.

Really importantly in Boston, the clinicians at all the different competing hospitals are actually working together on common protocols and standards of practice, and in doing so, they have found that it is cost effective for them. Their clinics actually lose less money as a result of the streamlined procedures than they did previously.

Our short-term goals, quickly, are to find the genes responsible for the different autism spectrum disorders. We clearly don't expect to do this completely on our own. Our genome scan; I said the analysis is being finalized. One of the reasons it is being finalized is we are collaborating with the Autism Genome Project to generate more data to make sure that what we find is replicated in another sample.

The same will be true. We expect to find the genes responsible for autism spectrum disorders as part of the overall research that goes on in autism, with us hopefully trying to act as a model for the kind of collaboration and free exchange that will really move things forward.

The genetic testing study will continue with follow-up. Particularly, we will be studying how we introduce the findings from the gene finding effort into the clinic. The genome scan follow-up is being done, and we expect a paper this winter on the result. Deep resequencing for genes is ongoing. We want to understand traits and behaviors, so those are our 5,000 individuals, and we want to do the rest of the work.

Just very quickly, the funding strategy here is we don't have a group that is funding all of these studies. We have a group that is funding where the money can accelerate the work that enables the investigators to then also get funding from other agencies in a more traditional mode.

So it escapes from the traditional waiting period and the traditional kinds of constraints that exist but is complementary to those because it then allows you to be sustained by those kinds of organizations rather than having sustaining funding from here. Ultimately, it is all mission-driven.

I won't bother to go through that. That is just the organization. Basically, this just says the role for the private foundation in our case is to innovate and hit the sweet spot while allowing for the infrastructure over time and the long-term positive results to come from funding that we gather by virtue of our investigators being able to compete for it with the other organizations. Thank you.

[Applause.]

DR. INSEL: Let's take a few minutes for questions for any of our three speakers. Comments, issues?

[No response.]

DR. INSEL: If I can summarize, since there aren't any questions, it does sound like there is an opportunity here for all three organizations to be meeting with people around the table because there is so much overlap. Someone said this earlier today. It is kind of difficult to know, when a single investigator is funded by three different organizations, when a family comes in, how those samples get assigned or if they are being paid for by all three sites. It is not clear. But one wonders whether this is the most efficient way to do it, or if we are still in our silos.

One hope will be that as we think about the strategic plan and we lay out an agenda that there is a way to imagine this as synergistic and that each of us is putting in funding for some part of whatever the goal is. We ought to think about how to do that and eventually make sure we are all around the same table and getting really clear about those commitments.

We have one more item on our agenda. There was time for a break that we zapped through. Let's do a two-minute stretch. Don't leave the room. Then we will come back for open session for public comment.

[Break.]

DR. INSEL: The final part of the program involves public comments. Several people have sent in comments that they would like to share with us. I'm going to suggest we use this chair up here so that those who want to make a comment don't have to stand up. They could sit down to do that and join us at the table.

We will just do this alphabetically. Erin Lopes Bak is the first name we have up here. Do you want to come up here? You can sit at the same time that you talk to the Committee.

A couple of ground rules. Because it is late and because there are a lot of people who want to speak, we hope to keep these to under five minutes at the very max. The other is, as part of all of our deliberations, I just want to encourage people to be respectful of each other and of the whole Committee.

So, help yourself.

MS. BAK: Thank you for this opportunity to speak. I'm terribly nervous, so I'm going to try to get past that.

My name is Erin Lopes Bak, and I am a mother. I have an eight-year-old son who is diagnosed with epilepsy, autism, and he is hearing impaired. I guess I came here really to give you all a message from the front lines of autism. I was involved in public health. I had a career in public health before my son was born, and I left it in order to become a full-time mother and advocate for him.

After the diagnosis I got to work in autism, and I guess what qualifies me to say I'm from the front lines is that I joined a local support group and I'm a parent leader. I listen to a lot of families and work with a lot of families of children with autism. I joined research efforts. I'm a parent advisor on CADDRE and the EARLI Network.

I think what qualifies me the most to say I'm from the front lines is that every summer I run a summer camp for children with autism. If you have ever run a summer camp for children with autism, that, more than anything else, qualifies you. It is a challenge.

In 2006, I went to the MFAR conference and I heard your keynote address, which was wonderful. One of the things that you said that resonated with me entirely was that research needed to work to alleviate the burden of disease. I took that message home to our support group and shared it with the mothers in our group, and they heard that message. They all took a deep breath, and they are still holding it. We really do need treatments that are effective, we need treatments that are safe, and we need them soon.

I wanted to convey that message to you, but also to say that I applaud your efforts to take on the research into treatment without fully understanding the biology of the disease. I would like to see that continue.

I'm also thrilled to see the diversity of the research questions that are coming out of the NIH. I think that is important. It is important for all of you to think outside the box with autism because just when you think you know it, something comes along that changes your opinion and your view.

I'm humbled by the challenge before you because there are many different phenotypes of autism, it is very clear. That means there are going to be a lot of different treatments. Some may work, some may not, and even within one child there may be one profile that is different from everybody else.

From the front lines I would also like to say that there is a new frontier that is ahead of you and I would like this panel to look ahead to the future. I think it concerns public education for these children. I see that as a topic that is going to come up more and more for you. My son is in the public education system. It is an enormous challenge.

Public education was never designed, I think, to educate children with autism, and public school systems are really struggling under the impact of the increase in numbers. Special education costs are skyrocketing, yet school budgets are staying the same. I see that as impacting children not only on a psychosocial level but their families as well, and it becomes more and more of a mental health issue not just for me but for a lot of people that I know. I would like you to consider that as you move on in the future.

Finally, what I would really like to ask from all of you is your continued collaboration. From my experience in public health, having worked on diseases like HIV and West Nile virus, divisions and strife only give diseases opportunity. I would like you all to consider that and continue with your collaboration because your cooperation will have a positive impact on our children. Thank you.

DR. INSEL: Thank you. Dr. Kristina Chew.

DR. CHEW: Good afternoon, and thank you very much. I feel very honored to be able to be here to speak on behalf of my son and my family.

My name is Kristina Chew, and I am an assistant professor of classics at St. Peter's College in Jersey City, New Jersey. I am the mother of Charlie Fisher, who is 10 and a half years old and who has autism. I write a weblog about autism, Autism Vox, V-O-X, Latin for "voice," that attracts some 4,000 visitors a day from around the world, from autistic adults and parents of autistic children to doctors, teachers, journalists, and many more members of the public.

According to some autism organizations, parent advocates, and the media, it is most important to find the causes of autism and to find treatments for autism, but finding out whether or not there is something in vaccines or in the environment that is causing autism is only one among many concerns in the autism community. Families with autistic children and autistic persons have other issues than what we hear about on Oprah and Larry King and from Jenny McCarthy.

Families also want to know about education, about schools, about day care and after-school care for autistic children. They want to know about how to integrate autistic children not only into classrooms but into all aspects of everyday life in a community. They want to teach their children to be as independent as possible so that their children can learn to get jobs, to take care of themselves, and leave fulfilling lives.

We need research to find out what are the best educational methods to teach autistic children to communicate, to interact with others, and simply to learn. I think we also need research to see what works over the life span over the course of a child's education, from when they are a preschooler to when they are an adult.

We need to figure out what are the best types of school environments that autistic children can learn in and how best to train teachers and therapists, and also how to maintain autism programs over time.

I know that it is possible to create a high-quality education for autistic children in the public schools, though it is very hard. My son attends a public school program in New Jersey that some autism experts say is as good as the best autism schools in the country.

Further, we need research to find out how to prepare autistic children to get and to keep jobs and to live as independently as possible, and how to best integrate autistic persons into our communities.

Films such as "Autism is a World," which featured an autistic woman named Sue Rubin, and a film called "The Key of G," which is about a severely disabled young man -- he doesn't have autism, but he lives in a community in a house in San Francisco with other adults -- show how autistic adults even with severe disabilities can live as full-fledged members of a community. Books, such as "Unstrange Minds: Remapping the World of Autism" by Roy Richard Grinker and "Reasonable People: A Memoir of Autism and Adoption" by Ralph Savarese, also provide perspectives about autism other than what you will hear about in the mass media.

Autistic adults tell me that they want to have their voices heard and their experience about life with autism understood. Other perspectives about autism can be found in the works of autistic adults like Ari Ne'eman, president of the Autistic Self-Advocacy Network, who will be speaking here in a few minutes, and a college student studying politics and economics, and also Kassiane Alexandra Sibley, who can be heard speaking at a conference on autism advocacy that was held at Fordham University in New York City in October of 2006. I have a website. If you would like to find out about it, I can give it to you.

In closing, though, rather than focusing so much on preventing and curing autism, I ask the Committee also to turn attention to how to make the world a better place for autistic persons through education, jobs, and understanding, by listening to the full range of voices and perspectives of life with autism. Thank you very much.

DR. INSEL: Thank you for those comments. Nancy McPartlin.

MS. McPARTLIN GARDELLA: My name is a little longer than that, it is Nancy McPartlin Gardella. I just want to say to you, thank you. Thank you so much for being part of this Committee. I know you are coming from so many different places and have so many different opinions on what needs to be done, but at least we all agree something needs to be done. Research, in my opinion, is the best way to go.

I happen to be a hospital administrator. I'm also the founder of a biomedical research group of parents that is a hospital-based group. We have been very instrumental in trying to move the medicine ahead.

I happen to have a child that has recovered from autism. There are thousands of us out there. Excuse me for saying this, but we are treated like we are having backstreet abortions because the doctors are not respected that we use.

Granted there are some wonderful people out there and there are some people that are looking to steal people's money, but there are some fine doctors out there, like Dr. David Perlmetter. There is Dr. Philip Defina, a clinical psychologist. There is Ken Bach. There is Patricia Kane. There is Josephina Finegold. There are many, many fine physicians out there that are helping to recover our children.

I really would like to say that, as a stakeholder, I would be more than happy to assist you in finding stakeholders that are like myself that have recovered children that we can learn from.

What we are concerned about at this particular junction is not what to do. We are concerned about how to fund it. We need IV glutathione and phospholipids and choline. We need injections of all the B vitamins. We need to get IVIg. We need IGg allergy tests, not IGe. There is a multitude of tests that we need.

Each child is unique. There isn't going to be one profile. We have to think of this like cancer. There already are six different brain prototypes that we know exist. It is not going to be one specific gene. It is going to be several different genes. We have to think of it like cancer.

I personally feel that I would be more than willing to help you as a member of the public to move this medicine along. We have many answers out there. There are pockets throughout the community, throughout the United States, and throughout the world that the children are getting better. Please listen to us and listen to the providers. They have something to add. It is an opportunity that we can really move the medicine forward.

Thank you for listening to me. I wish you godspeed in getting this mission accomplished.

DR. INSEL: Thank you. Katy Beh Neas, I think the name is. "Neece"? Excuse me if I corrupted your name.

MS. NEAS: Thank you for the opportunity to be here. My name is Katy Neas, and I'm vice president of government relations for Easter Seals.

Easter Seals is the leading nonprofit provider of services to people with autism, developmental disabilities, physical and mental disabilities, and other special needs. In addition to providing direct services, Easter Seals is engaged in research efforts across the country, partnering with universities and medical centers to help find effective interventions and to hasten the gap between research and practice.

We are also part of an effort sponsored by NIMH to explore the efficacy of an intervention that hopefully can augment the limited choices of evidence-based interventions that are currently available to individuals with autism.

We strongly encourage the IACC to promote research on direct services for children and adults with autism, as many of the previous speakers have also asked.

People living with autism today and the individuals who teach them, provide their health care, assist them to work and live with independence in the community need evidence-based interventions. This is especially critical in communities of color.

Research also has to be applicable to the large volume of individuals that exist and are coming. We have to be able to apply these interventions broadly so that we can meet the demand.

Finally, we encourage the Committee to prioritize research that will build the scientific evidence for some of the new models of interventions that have been noted to be promising. Families need more choices to fit the varying needs of their individual family members and we can't focus exclusively on children but rather we must address supports that adults with autism need and look for ways to allow them to work, live, and play in their communities.

Thank you for the work you do, and thanks for letting me speak.

DR. INSEL: Thank you. That is the list of names I have. Joyce, I understand there are a couple of other people who asked to speak. Yes, Ari Ne'eman.

MR. NE'EMAN: The written copies of my testimony are not in your folders, but I can get a copy here if you would like.

Members of the Committee, thank you for this opportunity to give comment on the IACC's important work. My name is Ari Ne'eman, and I am here today in my capacity as the president of the Autistic Self-Advocacy Network, a volunteer, nonprofit organization run by and for adults and youth on the autism spectrum.

ASAN works to promote the autistic culture movement, offer opportunities for individuals on the spectrum to interact with each other, and to improve the representation of the autistic community in public policy deliberations about autism and disability affairs.

As an individual on the autism spectrum myself -- I am an Asperger's autistic -- I am heartened to see the interest and resources being directed towards the spectrum as of late. Unfortunately, as positive as the strong awareness campaign about the autism spectrum could be, it is counterproductive without an equally strong commitment to autism acceptance.

Upon the passage of legislation authorizing this Committee, the Combatting Autism Act, a prominent parent lobbyist announced "a federal declaration of war on the epidemic of autism." A war on autism approach is not in the interest of people on the spectrum. It offends and alienates the autistic community, the community of verbal and non-verbal individuals on the autism spectrum.

While the rhetoric surrounding autism has focused on the idea of cure, many people on the autism spectrum are not interested in pursuing as a goal making autistic individuals normal. Instead, we agree with the opening language of the proposed Expanding Promise for Individuals with Autism Act, which states, "Autism is a natural part of the human experience."

This is not denying in any way the very real and pressing hardships placed on families and people on the autism spectrum. Instead, it is to encourage the promotion of research that will truly do something about these hardships for individuals and families.

We encourage the IACC to refocus its research exclusively on how to improve quality of life for America's many autistic citizens. Promising research leads are already present and are not being followed up upon due to a misguided focus on cure.

ASAN encourages the IACC to make the focus of the research agenda augmentative and assistive of communication, AACC, technology; positive behavioral supports; restraint reduction methods; adult supports; educational inclusion; employment; deinstitutionalization; independent living services; and other possibilities that provide tangible improvements in our lives.

For example, if one-tenth of the attention of funding now focused on finding a cure was put towards the promising possibilities of assistive communication technology, many people on the spectrum today viewed as low-functioning would be communicating successfully today.

I applaud the IACC for beginning to fulfill its moral obligation to have autistic representation on the Committee. The inclusion of Stephen Shore, a respected self-advocate with a long history of contributions to the autistic community, is a great step. At the same time, I note there is a distinct underrepresentation of autistic representatives, and I hope to see the inclusion of self-advocate organizations like Autism Network International and the Autistic Self-Advocacy Network.

Regretfully, we must also express concern over one of the public members appointed, Alison Tepper Singer of Autism Speaks. Ms. Singer's comments in the fundraising video "Autism Every Day" where she discusses refraining from driving her daughter off the George Washington Bridge "only because of the fact I have another child" sparked outrage throughout both the autistic self-advocate and the parent community.

It should be noted that four days after the release of said film, a mother did in fact kill her autistic daughter, Katie McCarron, and that there remains a notable increase in such murders in recent years. Many self-advocates and parents believe Autism Speaks to be morally complicit in these murders through these and other examples of continued dehumanized advertising, encouraging a lesser value for autistic life.

In conclusion, we live in a society where the lives and opinions of individuals with disabilities are often viewed as less valuable and less deserving of basic human respect than those of other citizens. The IACC should break with that mind-set, and we encourage the Committee to pursue a new direction in autism research: to maximize quality of life and opportunity for every person on the autism spectrum, not by insisting that we attempt to become what we are not but by recognizing that with the right services, education, and supportive environment we can succeed as we are. Thank you.

DR. INSEL: It is a matter of policy that we don't usually comment after public comments, but I think in this case there is some need to say something. I really think that your comment about one of our members was disrespectful, and in many ways completely misread the intent and what I think many people experienced as the meaning of Alison's public comment.

I would hope that as we go forward there will be a little more sensitivity to both the people on the Committee and to others involved in this process. I think if we are going to work together successfully we have to find a way, even when we disagree, to be understanding of each other's feelings and to recognize that we have to be able to respect differences.

MR. NE'EMAN: I certainly respect that sentiment, and I wouldn't want to give the impression that we have anything less than all due respect for each member of the Committee.

At the same time, I hope the members of the Committee do realize that these are the feelings of large segments of the self-advocate community. If we who are the purported aim of these efforts feel this way, then there is probably a significant problem with the direction of current funding.

DR. INSEL: We will go on to hear the final public comment from John Erb.

MR. ERB: Good afternoon, ladies and gentlemen. Thirty years ago, autism, one in 10,000; today, one in 140. At this rate, 30 years from now, one in two. Global warming? We have more to worry about than just global warming. Autism is much, much bigger than anyone suspected.

I have been working with autistic individuals front-line for 20 years, over 200 of them, and one thing I have noticed is that in many cases they were smarter than me. This perplexed me. How could they be smarter than me? Yet I knew some with multiple languages, abilities beyond in skills of math and music.

I came up with a theory and published it four years ago when I was researching something called monosodium glutamate, an excitotoxin that overexcites neurons of the brain. Glutamate is an amino acid which is one of the predominant building blocks of the human brain. I theorized [about] MSG in diet. If we are getting too much, what if our brain is growing because of it.

I did notice that recently they have discovered that autistic individuals have larger brains more densely packed with neurons. So I did more research, and I found out that over 12 vaccines have monosodium glutamate or glutamate as an additive. This was quite alarming to me, and I published a 24-page report which is now before the World Health Organization in the hands of the director of food safety, Dr. Yorgin Schlent [ph.] It also has been passed by the director of food safety at the FDA, Dr. Laura Tarentino, to the Food Safety Committee, where it is sitting right now.

What is interesting to note is that glutamate is in many things: Doritos, all your Campbell's soup, Top Ramen, Hamburger Helper, your processed foods, and it is not just labeled as MSG, it is labeled as autolyzed yeast extract and hydrolyzed vegetable protein.

In the 1970s they were all concerned about [what they called] the Chinese Food Syndrome. They were blaming the Chinese food for having the MSG. Well, what was happening was Kentucky Fried Chicken and other corporations were using massive amounts of MSG but they had a lobby group called the Glutamate Association. The Chinese restaurants were family-owned and had no lobby group, so the large corporations pointed the finger.

Before 1950, 13 cases of autism. After 1950 with the introduction of MSG by Colonel Sanders, we have an exploding amount.

This is my concern. I have presented this to the FDA. I'm not waiting for further research. What I'm going to be doing is I'm taking the Capitol. I'm going to demand that and pressure the FDA to remove MSG from the food supply. Hopefully, in a few years I will come back and say, "Got MSG out of it. Maybe we will see a drop in autism." But I'm certainly going to try because prevention is what we are all about. If MSG could be the cause of autism, then it is one less thing our children should be eating. Thank you.

DR. INSEL: Thank you. We are now at the end of the agenda. I want to just take a minute to wrap up and see if there are any additional comments from the Committee, or questions? Lee.

MR. GROSSMAN: I hope my negative vote doesn't mean that I move to the end of the table again.

[Laughter.]

DR. INSEL: It won't happen, I promise. I'm still trying to understand, actually, the logic of the seating arrangement. We will figure that out before next time.

We will also have to figure out whether we will meet here or meet back on campus as we did in the past.

I suspect that people would prefer to meet here. It is a little more accessible. So if that is possible, we will try to do that.

I want to thank all of you for your participation. This is going to be a huge amount of work, especially over the next six months, but we think it couldn't be for a better cause. I'm delighted to have this crew here. I think this is the group that can really make a difference.

As I said at the very beginning, this is a new chapter. I'm looking forward to reading it with all of you, and writing it with all of you. I think we will do something important here.

Good luck. We will be in touch in terms of what we talked about with the strategic plan, and if we don't meet other than electronically before the holidays, I wish all of you the very best. We will be back together in vivo probably in February or March.

[Whereupon, at 3:54 p.m., the meeting was adjourned.]