U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES

INTERAGENCY AUTISM COORDINATING COMMITTEE

FULL COMMITTEE MEETING

FRIDAY, APRIL 30, 2010

The Committee met in the Rotunda Room of the Ronald Reagan Building and International Trade Center, 1300 Pennsylvania Avenue, N.W., in Washington, D.C., at 10:00 a.m., Thomas Insel, Chair, presiding.

PRESENT:

KATHLEEN SEBELIUS, Secretary, U. S. Department of Health and Human Services

FRANCIS COLLINS, M.D., Ph.D., Director, National Institutes of Health

HOWARD KOH, M.D., Assistant Secretary, U. S. Department of Health and Human Services

KAREEM DALE, Special Assistant to the President for Disability Policy, The White House

MICHAEL STRAUTMANIS, Chief of Staff, Office of Intergovernmental Relations and Public Engagement, The White House

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

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

SUSAN DANIELS, Ph.D., Office of Autism Research Coordination, National Institute of Mental Health

PRESENT (continued):

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

LINDA BIRNBAUM, Ph.D., National Institute of Environmental Health Sciences

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

JOSEPHINE BRIGGS, M.D., National Center for Complementary and Alternative Medicine

HENRY CLAYPOOL, Office on Disability

GERALDINE DAWSON, Ph.D., Autism Speaks

GERALD D. FISCHBACH, M.D., Simons Foundation

LEE GROSSMAN, Autism Society

ALAN GUTTMACHER, M.D., *Eunice Kennedy Shriver* National Institute of Child Health and Human Development

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

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

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

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

CINDY LAWLER, Ph.D., National Institute of Environmental Health Sciences (For Dr. Linda Birnbaum)

PRESENT (continued):

SHARON LEWIS, Administration on Children and Families

CHRISTINE McKEE, J.D.

ARI NE’EMAN, Autistic Self-Advocacy Network

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

DENISE D. RESNIK, Southwest Autism Research & Resource Center (via telephone)

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

MARJORIE SOLOMON, Ph.D., M.B.A., University of California, Davis

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

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

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

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PROCEEDINGS

10:08 a.m.

Dr. Insel: Good morning, all. I'm assuming that our audio and video links are currently working, so we can open what is by my count the fifteenth meeting of the full committee of the IACC. This is a particularly special meeting, because we have new members, and we have some special guests with us, as well.

I want to just take a moment for all assembled to say a little bit about what the Interagency Autism Coordinating Committee is charged to do. Especially with new members, I thought it might be worth taking a minute for a bit of a review.

This is an advisory committee that brings together federal agencies, private research organizations, advocacy groups, clinicians, family members, and people on the spectrum. We are not a funding agency, and we're not a service provider.

We're not even really a national

forum for autism, but we're really set up to advise the Secretary. That's our job, and it's a special pleasure to have the Secretary with us this morning and have a chance for you to get to meet her and for her to get to meet you.

Rather than taking much of her time, because we are on very strict schedule -- she needs to be out of here by 10:45 -- I think what I'll do is simply to thank all of you for your hard work in this past month, especially during Autism Awareness Month.

This has been a period of intense activity for many of the organizations around the table, including the federal government, and HHS has really stepped up to do a number of new activities, beginning early in the month with a meeting at the White House, and we have some of the people who helped to make that happen at this end of the table, and through the month with lots of additional special activities similar to what you may hear about as we go around the table today.

I did want to take one moment to recognize one particularly sad event, which was the death of Stanley Greenspan earlier this week, someone who was very close to many of the people on the committee and a real founding member of the autism treatment community, and so this is a great loss to the community.

As I think all of you know, Dr. Greenspan had been ill for some time, but this is certainly a changing of the guard, in a sense, for particularly behavioral interventions for autism.

So, with that sad note, as one of perhaps the unique sad notes of this past month, let me just say that this has been a time of great excitement, with lots happening, and there's probably no better way to mark that than this, the final day of Autism Awareness Month, to have the IACC meeting and to include Secretary Sebelius in this meeting.

So I'd like to turn this over to the Secretary, and, Madam Secretary, thank you so much for joining us today. It's really a privilege for us to have you here at the -- at this full committee meeting.

Secretary Sebelius: Well, thank you, Tom, and I just, first of all, want to thank all of you who have been longer term members of this important committee and to welcome the new members that we have today, and what I thought might be helpful to me --

I know that Tom has been leading this effort, and just so you know, he has actually briefed me early on about the work and the strategies behind this committee and how critical it is and the fact that I think it's important to have an interagency committee and have the Department of Education very much at the table, and our White House partners, I think, are here as a clear indication of the administration's interest in this issue.

It's beyond HHS. It really is a -- it spans across government but certainly has the President's attention, but I thought we might really start with me hearing from you and maybe, if you wouldn't mind, going around the table and introducing yourselves and giving me an idea of sort of who you are and the perspective that you bring to this important topic. I don't know if we want to start at -- since you have pink on, I figure I'll call on you first.

Ms. Blackwell: Okay, I'll be first. I'm Ellen Blackwell, and I work at the Centers for Medicare and Medicaid Services in Baltimore in the areas of long-term supports and services and mental healthcare. I have a long-time interest in autism. In fact, I founded an Autism Society chapter many, many years ago.

I also happen to have a son with autism. He's 23, so I think that brings a sort of special perspective to my work on the committee. I'm particularly interested in autism issues as they relate to the adult population.

Dr. Janvier: My name is Yvette Janvier. I'm one of the public members. I am a developmental behavioral pediatrician from New Jersey.

I have had the opportunity to be one of the collaborators on the initial regressive autism study of the NIMH, and I work at Children's Specialized Hospital in New Jersey. We're one of the largest pediatric rehabilitation hospitals in the country.

We are fortunate to have funding from the New Jersey Governor's Council to enhance our clinical services, and we have been able to serve over 3,000 children in the past year on the autism spectrum.

My particular interest is early identification, and we'll be launching a new project funded by our Governor's Council to focus on identification of autism in five inner cities in underserved populations, so we're very excited about that.

Dr. Koroshetz: I am Walter Koroshetz. I'm a neurologist. I'm the Deputy Director of the National Institute of Neurological Disorders and Stroke, and NINDS, with the other neuroscience institutes at NIH, is interested in trying to learn how the brain works, what happens when it doesn't work.

And many of the disorders at our institute, many rare disorders, manifest as autism, and also, many people with autism have neurological disorders such as epilepsy, so we're very interested in trying to push this field forward.

Dr. Solomon: And I'm Dr. Marjorie Solomon. I'm an Assistant Professor at UC Davis School of Medicine, Department of Psychiatry, and the MIND Institute.

The M.I.N.D. is a multidisciplinary research institute aimed at finding causes and cures of neurodevelopmental disorders. My principal research program focuses on higher cognition in older, higher-functioning individuals on the spectrum using functional imaging.

I also founded and have been working in a socialization intervention program for the past ten years, and we serve that same population, who are now recognized to be one of the larger segments of the population. I'm one of the new members, and I'm really excited to be here to help this effort. Thank you.

Ms. Singer: I'm Alison Singer. I am the co-founder and President of the Autism Science Foundation. I have an older brother diagnosed with autism and I also have a 12-year-old daughter also diagnosed with autism.

The Autism Science Foundation is an organization that raises funds specifically to fund research, and we focus on looking at what are the causes of autism and how we might build the evidence base for new treatments and existing treatments for individuals with autism.

Dr. Battey: I'm Jim Battey. My background is in pediatrics and genetics. I spent my entire career at NIH, and I'm currently the Director of the National Institute on Deafness and Other Communication Disorders, and our interest in autism is because fundamentally it is a communication disorder, so we feel it falls squarely within the mission of our research endeavor.

Dr. Houle: Hi, I'm Gail Houle, and I'm from the Office of Special Education Programs. I represent the Assistant Secretary, Alexa Posny, and I am one of the founding members and have been very fortunate to have been able to be with this committee from its beginning and see the progress that has been made.

We at the Department of Education, of course, fund through our Large Formula Program the Individuals with Disabilities

Education Act, many services and supports for children with autism, as well as through our Part C Infant and Toddler Program, and we also have a discretionary grant program that targets professional development and research investments.

Dr. Dawson: Hello, I'm Geraldine Dawson, and I am the Chief Science Officer at Autism Speaks and also a Research Professor in the Department of Psychiatry at UNC-Chapel Hill.

I've been in the field for close to 30 years now, a Professor at the University of Washington, founding director there of the Autism Center, and have been funded by NIH over that 30-year period both as a scientist, and I've been involved as a clinician, as well.

Autism Speaks is the nation's largest science and advocacy organization focused on autism, and we have a four-fold mission, and that is to raise awareness, to advocate for people with autism, to fund family services and provide resources and tools, and then also to fund research on causes, treatment, and diagnosis.

And I want to personally thank you, Madam Secretary, for taking the time to come to this meeting, and I want to thank you on behalf of all families in our nation that you really do see the urgency of this problem and are paying attention to it. So, truly, thank you very much.

Dr. Trevathan: I'm Ed Trevathan. I am a pediatric neurologist, and I am the Director of the National Center on Birth Defects and Development Disabilities at CDC and represent CDC on the IACC. Our role as an agency has been really multifaceted but really now I think focuses on four areas.

Briefly, we are charged with estimating prevalence of autism over time and tracking those trends and are making progress with identifying children at earlier ages.

We'll hopefully start doing surveillance for prevalence in four-year-olds very soon.

We are engaged in searching for causes, along with a lot of our colleagues and partners. NIH and elsewhere have a large case control project, the SEED study, that we hope will be giving us some important clues in the next couple of years.

We partner with HRSA and many of the private partners at the table with our ***Learn the Signs. Act Early.*** campaign to try to help identify children as early as possible who have autism or risk of autism so the intervention can occur when there is brain plasticity and opportunity to really do the most good. And more and more we're becoming interested and involved in looking at the special health needs of people who are disabled by autism, including adults.

Dr. Shore: I'm Stephen Shore, and I am my own autistic adult, having been diagnosed on the spectrum at two and a half.

I spend -- I split my time between serving as an Assistant Professor of Special Education at Adelphi University, presenting and consulting about autism internationally.

My research interests include comparing approaches, not to see which one is the best approach but more for matching best practice to the needs of children on the autism spectrum.

Again, being an adult on the spectrum, another interest of mine is advocacy for the rights of people on the autism spectrum to lead fulfilling and productive lives to our greatest potential, and I'm also on the Board of the Autism Society of America, and thank you very much.

Mr. Claypool: And I'm Henry Claypool, the Director of the Office on Disability at HHS, and my interest primarily is working with the real strength that we have here on the committee to organize, coordinate, and build on a very strong services agenda that's really emerging out of the committee.

I think we have a tremendous opportunity to build and strengthen the services and supports that are available not only to individuals that are living on the autism spectrum but their families and the support they need.

Dr. Hann: Good morning. I'm Della Hann, and I serve as the Executive Secretary and designated federal official for the committee, and I have a background in developmental psychology and psychopathology. I work for this committee, and I also wear a couple of different hats at NIH.

Dr. Koh: Good morning, Dr. Howard Koh. I'm Assistant Secretary for Health for the Department of Health and Human Services, and along with Dr. Dora Hughes, Dr. Nadine Garcia, Michael McCauley, and Jennifer Buschick of our office, very happy to help coordinate autism efforts across the Department.

Dr. Collins: Good morning. I'm Francis Collins, the Director of the National Institutes of Health, and I'll have a few more words to say in a little bit.

Dr. Insel: I'm going to turn this over to Kareem.

Mr. Dale: I'm Kareem Dale, Special Assistant to the President for Disability Policy at the White House and just want to thank the Secretary and the entire team at HHS for being the leadership on healthcare for people with disabilities and autism. It makes such a huge difference.

Mr. Strautmanis: I'm Michael Strautmanis. I am Chief of Staff for the Office of Intergovernmental Relations and Public Engagement in the White House.

I wanted to stop by and just thank everybody as a representative of the White House and as a dad of a son on the autism spectrum for your leadership here on the committee. I'm here to learn a little bit, as

I always do from many of you in the past, and I expect to do so here today.

I also want to thank the Secretary. Madam Secretary, you are an extraordinary leader and an exemplary public servant, and I think we're all thrilled that you're here and that you're in the position that you're in, a position to exert such important leadership on this and so many other issues, so thank you, and thank you, everyone.

Dr. Daniels: I'm Susan Daniels. I am the Deputy Director of the Office of Autism Research Coordination, which is the office that supports this committee with policy, communications, and planning.

Dr. van Dyck: Good morning. I'm Peter Van Dyck, pediatrician and Director of Internal Child Health Bureau in HRSA, and because of the Combating Autism Act, we have money to provide grants for training, particularly for professionals to better identify and treat people on the autism spectrum. They also provide service.

We have clinical research grants, and we have state demonstration grants, as well, as part of that autism, Combating Autism Act. We are pleased that you're here this morning.

Ms. McKee: Hi, I'm Christine McKee. I'm the parent of a ten-year-old girl with autism. In my former life, I was a labor and employment defense attorney in Kansas City. After my daughter was born, I decided to stay at home full-time so that I could deal with the demands and challenges of raising and educating a child with autism.

Ms. Lewis: Good morning. I'm Sharon Lewis. I'm the new Commissioner on the Administration on Developmental Disabilities within ACF, Administration on Children and Families at HHS.

We primarily fund activities at the state level, including the State Developmental Disabilities Councils, the

University Centers on Excellence in Developmental Disabilities, the Protection and Advocacy System, and projects of national significance.

A lot of our focus and our interest in cooperating with everyone here on the committee is related to the services and supports component of ensuring that families and individuals with autism have their needs met across both Health and Human Services but also in terms of education, employment, and civil rights.

Dr. Fischbach: I'm Gerry Fischbach. I'm the -- I'm a neuroscientist and currently Director of the Simons Foundation Autism Research Initiative. We fund the studies of genetic risk factors and how such factors might affect the nervous system and behaviors and cognitive deficits characteristic of autism and other related disorders.

I am also a former Director of the

National Institute of Neurological Disorders and Stroke, and I believe that autism is a issue that touches every institute at the NIH, and I think it's so important that leadership from above recognizes that, and your presence here is a really eloquent statement, along with Dr. Collins, of that fact. Thanks.

Dr. Huang: I'm Dr. Larke Huang. I'm from the Substance Abuse and Mental Health Services Administration, SAMHSA. I work in the Office of the Administrator with Pam Hyde. At SAMHSA, we're primarily a services agency.

We don't have a dedicated program focusing on autism, but we do serve children and their families with autism in a comprehensive mental health services initiative that we fund. There are about 90,000 children we've served in that program. About three percent of them are children with autism.

The other piece that we do is develop informational materials, and we include evidence-based approaches for working with children and families in the community with autism in a compendium of best practices for children.

Mr. Grossman: Good morning. I'm Lee Grossman. I'm the President and CEO of the Autism Society, and, more importantly, I am the father of a 22-year-old son with autism.

Madam Secretary, I cannot thank you enough for being here today, as well as the other representatives from your agency and the White House. It's very encouraging to the autism community to see this type of commitment from the administration for this crisis that exists in the United States today.

The Autism Society is 45 years young this year, and we have approximately 140 chapters around the nation, and our mission is to improve the lives of all those that are affected by autism. Our particular emphasis is in services, supports, interventions, and treatments.

We come at this from the belief that although we're a very large supporter of research in the biomedical realm, we believe that there is much other types of research that have to have -- that are underserved, such as in applied research, educational community-based outcomes.

And we also believe that there is enough that we know about autism today that we can significantly improve the lives of all those that are affected by it today and that we need to greatly expand and improve the services and supports available to those individuals and their families, and that needs to become a higher priority in the administration. Thank you.

Dr. Lawler: Good morning. My name is Cindy Lawler. I'm an Extramural Program Director, and I manage the Research Portfolio in Autism Research at the National Institute of Environmental Health Sciences. I am here in place of our Director, Linda Birnbaum, who was unable to attend today and sends her apologies.

Our institute is a little unique among NIH, because we have a focus on public health and prevention research. Autism is a high priority for us, and it fits in well with a very longstanding interest we have in advancing children's environmental health and also engaging communities in multiple ways in the research endeavor.

We currently support a number of epidemiologic studies in autism looking at a whole range of environmental exposures such as heavy metals, pesticides, compounds that disrupt the endocrine system to determine whether they affect risk for autism, and we're particularly interested in how those exposures might combine with genetic susceptibility to affect autism risk. Thank you for being here with us today.

Mr. Ne’eman: Hello, Madam

Secretary. My name is Ari Ne'eman. I am the President of the Autistic Self-Advocacy Network, an advocacy organization run by and for autistic people ourselves.

I am an adult on the autism spectrum and a Board member of TASH and the Autism National Committee, and I'm very excited to be here, and our hope is that in doing so, in having added -- in your having added to the diversity of the IACC, that we can help move the conversation beyond the narrow focus on causation and cure into a broader effort to advise you on research and policy issues and services and supports and quality of life to improve the lives of children and adults on the spectrum.

Thank you for being here, and thank you very much for your leadership, Madam Secretary.

Dr. Guttmacher: I'm Alan Guttmacher. I am the Acting Director of the *Eunice Kennedy Shriver* National Institute of

Child Health and Human Development.

We are the only NIH institute that has a person's name appended to us, and it's a real acknowledgment that Mrs. Shriver first of all played a key role in convincing her brother, then President Kennedy, that there should be an institute at NIH that focused on the lives of individuals with intellectual and developmental disabilities and then her work over the years on her own -- in her own right on those issues.

While the mission of NICHD has broadened over the years to include many areas of child health, maternal health, reproductive health, rehabilitation medicine, still part of our core mission is making sure that individuals with developmental disabilities have the ability to achieve full and healthy lives, so we're obviously interested in the work of the committee.

Ms. Redwood: Hi. My name is Lyn Redwood, and I'm a public member representing the Coalition for SafeMinds. I'm also the mother of a 16-year-old son who was exposed to 125 times his EPA allowable limits for mercury. He subsequently developed autism.

The Coalition for SafeMinds is a non-profit organization that's focused on raising awareness and researching the inherent risk from exposure to mercury in pregnant women, infants, and children.

EPA recently predicted, based on NHANES data and the fact that the fetus accumulates mercury at a higher rate than the mother, that one out of every six women of childbearing age now in our country could potentially have children that would be at risk for neurological injury because of the body burdens of mercury that they have.

Over the past ten years, SafeMinds has sponsored almost a million dollars in scientific research looking at mercury and adverse neurological outcomes, including autism.

Studies in both Texas and in California have found higher rates of autism in areas where there were higher exposures to mercury. For example, in Texas, for every 1,000 pounds of environmentally released mercury, there was a 43 percent increase in special ed services and a 61 percent increase in autism.

Many of you may not be aware of this, but mercury exposure is increasing in our country. China over the last 15 years has doubled their environmental exposures of mercury. They are putting out now 1,000 tons annually of mercury, and that mercury actually reaches the West Coast of California in under ten days.

We have also found that children with autism have elevated biomarkers for heavy metals or porphyrins. They have a two to threefold higher levels of mercury in their baby teeth compared to control children, and they also have elevated body burdens of mercury after given a chelator in comparison to neurotypical children.

So we continue to advocate for more research into environmental factors in autism and for the committee to address the urgent public health needs of this growing epidemic. Thank you.

Dr. Insel: We have one other new member who is on the phone. Denise Resnik, are you with us?

Ms. Resnik: I am with you. I apologize. I can't be there in person but can only be there on the phone, but yesterday we hosted a 1,700-person event to benefit autism in our organization and announced a new alliance with a group out of Canada, the Sinneave Family Foundation.

Since we were founded in `97, we've raised more than $40 million for the cause, primarily from Arizona sources, and I'm the mother of an 18-year-old son with autism.

I also have a marketing and public

relations firm, and we're very proud of the fact that last year our organization served more than 2,600 children, teens, and young adults, 3,300 parents, families, and family members, and more than 8,000 educational and medical professionals and paraprofessionals through training, and our mission has been to support children and adults with autism and to advance discoveries toward a cure.

We are one of the most robust sites for the recruitment and enrollment of subjects in pharmaceutical trials as well as molecular and genetic studies with our partners at the Translational Genomics Research Institute, and that is squarely because of the number of services that we provide to families throughout our state.

And we have recently published a major study on the concerns of housing, teaming up with the Urban Land Institute and Arizona State University, and work closely with Autism Speaks in advancing futures for adults with autism to tackle this big issue of housing and employment and community life, and so we're very proud that Secretary -- Homeland Secretary Napolitano has been a great supporter of SARRC and very proud of our relationship with Jeff Trent at TGen, and I look forward to meeting all of you in person soon.

Dr. Insel: Thanks, Denise.

Ms. Resnik: Thank you.

Secretary Sebelius: Well, thank you all for giving me a sense of who all is here. I had a chance to look at a number of the bios and certainly discussed some of the new public members as we enlarge the public membership on this committee to eleven, and I knew that there was a --

I can guarantee you those of you who have joined the committee will be welcome new members, and there are probably several thousand people right behind you who thought they should be the members of the committee, because there is a lot of interest and a lot of effort that has gone into this.

I think you can -- I appreciate, you know, thanking me for being here, but really I want to thank you for those of you who have been members of this committee for your focus and attention and hard work.

I can tell you we have thousands of boards and commissions and committees, and I think it's safe to say you break all records in terms of numbers of meetings and substantive work that's done, and that's good news.

I mean, I think a lot of people, you know, like to have a name on a federal committee, but this is clearly a very working committee, and the work that you do informs a lot of the work that we do, which is why, you know, you have everybody from representatives of not only the Agency for Children and Families and the disability community and the Assistant Secretary on Health, the head of NIH and Centers for Disease Control.

I mean, we see this as a -- our environmental health organizations. We have a lot of assets and resources within HHS, and one of the President's focuses for members of the cabinet, and I think it's one that we all take very seriously, is the need to leverage all of our assets.

He has urged us from the beginning both outside of our agencies to work together in a collaborative fashion among agencies, so this very important work with the Department of Education is critical, but also to look at what's going on within the agencies to make sure that it's just not one entity who is looking at a problem, but clearly the autism spectrum disorder requires everything from top notch research and advancements and enhancements of what we know and what we don't know given the alarming increase in autism rates that have now been documented over the last number of years to services for families and diagnosed persons with autism and everything in between.

So it's a -- it's a very collaborative effort, one that we take very seriously. I think that there is no question that the strategic plan that was developed by this committee is a helpful roadmap in terms of where we need to go and be.

It's been a coordinated government-wide effort, and it helps us also to leverage assets at the community level. This can't be a government-only kind of lens.

We have assets to bring. We certainly are committed to doing that, but unless we engage stakeholders at the state and local levels -- and I have some experience with that as a former governor.

You know, there was a growing advocacy group in Kansas, both interfacing with our education members, and the reference that you heard earlier to Alexa Posny, Alexa is the new Assistant Secretary for Special

Education at the Department of Education.

She also is the former Kansas Commissioner of Education, so Alexa and I have a long history of working together on a variety of issues, but this is one of them that we took very seriously in our state, so that experience will help to inform me here.

I did want to also tell you that while I'm, unfortunately, not able to be present not only for all the meeting today but for all of your meetings, you need to rest assured that my representatives are informing me at every step along the way. This is a focus of attention.

This is not just a drop-in visit, and, you know, the minutes I have here will be the end of the attention on this, and then we'll move on to other areas, but it's really an indication that attention will be focused and continue to be focused, and our leadership team will be very much present at the meetings, reporting back, and we'll be, you know, considering the recommendations you make along the way.

I wanted to spend just a minute on outlining a couple of the things that I think have been advances since President Obama took office to start with that kind of frame, because there is some recommendations that were made that I think have already been followed.

In the Recovery Act investments, there was, as a result of some of the research investments, an increase in the budget of NIH for the research in this -- in this critical area. It went from $118 million to $196 million, so a fairly significant enhancement of the research going on.

The recently passed Affordable Care Act I think has some critical enhancements for a whole variety of Americans with any kind of preexisting condition but certainly will impact those in the autism spectrum, because it will be illegal for not only companies to target anyone with a preexisting condition but also to drop people from plans, which was a frequent practice once a condition is identified, illegal for companies to limit the ability of family plans to cover children with preexisting conditions and children started this year.

The rescission prohibition starts this year. By 2014, but we hope that that will kick in earlier, the more robust insurance market, which will make it illegal for any company to have any barrier for people with preexisting conditions, will go into effect.

So it's a graduated, phased-in effort to make sure that coverage is available, and I think the new framework for the insurance market will ensure that those with some kind of preexisting condition will not any longer be able to be segregated out of a robust insurance pool, because right now, as you all know, even if you can get coverage, you're often categorized in a special category, and the rates are so exorbitant that it may be accessible, but it's not affordable.

So I think the good news is that will cease to be, and new resources also in the Affordable Care Act for the Aging and Disability Resources Centers Network, which are trusted sources of information and will help us spread the word, and as we move through that act, I think there is also a lot of effort to have more affordable services available in a much more transparent fashion moving along.

So there are some steps both in the research and in the coverage area that are marked improvements over where we are today. I don't think there is any question that steps have been taken toward more appropriate screening and intervention, earlier intervention services along the way, and I think you're going to have an opportunity to discuss more of that as we go forward, but to tell you that you are being heard, not only within the Department of Health and Human Services and the Department of Education, but I would say also you have the attention of the President and the White House.

And there is an effort to make sure that attention is being paid to, I would say, not only disorder spectrum but the spectrum of issues that we need to deal with to really first get a handle on, if we can, more importantly, what is happening. What are the causes? What does the research tell us how we can enhance that?

How we can accelerate that, but also what then are the services and treatments available to both individuals with autism but also families who are dealing with autistic kids and the kind of multitude of health, educational, social services, support service is needed? And that's very much got the attention.

So thank you all. The new members

who have stepped up and are willing to join this very active committee, I think you will be doing some important work, but I want to tell you that your work will be heard and be part of what we need to inform the policy, strategic issues, budget decisions moving forward, which is why I'm here today to tell you that you have our attention, and we want to make sure that we are informed by what -- the work that you do and the recommendations that you make.

Dr. Insel: Well, thank you very much, Madam Secretary, for being here, along with Assistant Secretary of Health, Howard Koh. It's great to have you join us.

We haven't had other visits from members of the White House staff, so it's great to have both Mike and Kareem be able to join us. Kareem, do you want to say anything before we finish this? Then we're going to move on to the next session afterwards.

Mr. Dale: You put me right on the

spot. I'll just briefly say that when I started at the White House, and the President's mission was to coordinate the administration's efforts on disability and also working on the autism issues, and it is our goal and our mission to make sure that these issues have the highest level of attention.

And working with the team at HHS and Education and Alexa, I think we've made substantial progress, and I think that the meeting that we had a couple of weeks ago that HHS helped us lead, Dr. Koh and Tom and the rest of the team, was phenomenal.

And I think the new membership that the IACC has stepped up and put onto this committee is going to bring some new perspectives, new ideas, fresh energy to an already fantastic committee, and I also -- I also believe that the strategic plan that this committee put together was phenomenal.

So we look forward to continuing

to support the efforts of this committee at the White House, and, as Secretary Sebelius said, you absolutely have the attention of the President and the White House, and we are -- we are committed strongly to this issue. Thank you.

Dr. Insel: Thank you.

Secretary Sebelius: I was remiss. Kareem was good to mention it, but I just wanted to tell you that the work that Dr. Howard Koh did on April 2 on World Autism Awareness Day, not only assembling advocates from across a wide variety of disciplines but also shining a spotlight on this critical issue I think again is an indication of the kind of level of attention that you have within our Department.

Howard is my Assistant Secretary on Health, and he has the responsibility of sort of being often the point person on critical issues, and we felt it was very important within the Department to have that kind of effort, including advocacy, medicine, academia, families, and really have an opportunity to raise the profile of this critical issue through that effort, so I wanted to personally thank Howard for that advocacy.

Dr. Insel: Well, we promised Secretary Sebelius that she would be on her 10:50 phone call, which is in about 90 seconds, so I want to make sure she has a chance to get to her next appointment and we don't delay too much.

We do greatly appreciate your being here. We look forward to having you back soon, and thank you so much for your remarks.

We're right on schedule to go for the next part of the meeting, which involves hearing from Dr. Collins, who is the Director of the National Institutes of Health and has been in that position since --

Dr. Collins: August 17.

Dr. Insel: My goodness, but we're not actually counting days anymore, right?

Dr. Collins: No, no, that got old.

Dr. Insel: We're just -- there's months. So I'm going to turn this over to you, Francis, and thanks so much for joining us.

Dr. Collins: Thank you, Tom, and good morning to all of you. I am really honored and pleased to be here and to have a chance to say a few words to this remarkable group of experts and advocates that have assembled and particularly want to welcome the new members of the IACC.

This is a critically important group for assessing what the needs are and what the opportunities are in terms of moving forward the agenda for understanding the causes and the ways to intervene in terms of preventing and treating autism spectrum disorders.

I am a parent. I'm a grandparent.

I think talking to people who have children who have been afflicted with this disorder, I get very clearly the sense of urgency that attaches to your agenda, and I resonate with that.

Earlier this year, I had the chance to meet with families and advocacy groups involving autism spectrum disorders and listen to the concerns of those around the table, and that was very helpful to me in terms of getting a sense of the wide variety of views about where we should be investing our research efforts, but I hope to continue that kind of close connection with those of you on this committee and with other groups, as well, as we try to understand what we should be doing. That is the highest priority.

Someone once said that a parent is never happier than your saddest child, and those of you who have lived in a circumstance with a child who is affected will probably resonate with that statement as something that you carry with you every day as something that both motivates you and undoubtedly causes you to feel burdened, and if we can help at the National Institutes of Health in trying to address that burden with the resources we have, then that's exactly what we want to do.

I'm grateful to Dr. Insel, my friend Tom, for his remarkable leadership of this organization given the many different opportunities and directions that research might go, and I'm very happy to see now this 2010 strategic plan that the IACC has put forward, and I can assure you that is something which NIH will be looking at with great seriousness.

And, as you know, this IACC, probably distinguished from virtually any other committee I can think of of this sort, has very high level involvement, not just from Dr. Insel as its leader but also four other institutes represented either by the Director or other very highly placed people within those institutes and myself, as well, listed as a member of this committee, and I will attempt to be here as often as I possibly can. So we take this as a matter of high, high priority.

I guess you've heard from the Secretary about her personal interest, and I'm really glad she was here, and there is no greater statement about her personal interest than her presence, and you've heard likewise from the White House, and you are aware of our President's specific interest in autism.

So this is certainly a time where the lights are shining on this condition. We just have to figure out how best we can take advantage of that.

NIH over the past decade, as many of you know, has increased its funding for autism spectrum disorder research rather dramatically. In 1999, that was $40 million. In 2009, ten years later, it was $132 million, and then, as already mentioned, with dollars from the Recovery Act, NIH funding for autism research in 2009 reached $196 million, really quite a remarkable ramp-up.

When I was the Director of the National Human Genome Research Institute, which is the position I held before coming to the Director position of NIH, autism was a condition that many of us looked at as particularly important to work on.

And I had conversations with Tom and with Gerry Fischbach about ways that we might take this revolution that is happening in the ability to understand the human genome and try to see whether there were answers that had eluded us about at least what some of the contributing factors in autism might be.

Don't get me wrong. I am not one of those who thinks that the whole story of autism can be completely written by an understanding of DNA, because clearly there are going to be environmental contributions that are also critically important.

And our charge is to try to understand both aspects of this gene-environment interaction, and we don't know nearly enough about either one at the present time, but I do think with regard to the genetic interactions or contributions that technology advances that are occurring now are getting to be quite exciting.

On the radio this morning, I listened to a report describing the complete genome sequencing of somebody who happens to be a genetics researcher, Stephen Quake, talking about what it had meant in terms of his own healthcare to have his total DNA sequence in front of him and how complicated it was to try to sort it out, but that is the kind of pathway that we're on.

And using Recovery Act dollars, it will be possible in the not terribly distant future to have that kind of information on 300 autism individuals and their parents so that we can actually see not only what can we find in the individual, but is there anything going on here that might represent a change in the DNA and being passed from parent to child that would be particularly important to recognize?

That is just one of the many things that is important right now to do in terms of understanding how best to diagnose and to treat this condition. I also -- I guess it was a pretty good morning for this conversation to happen.

I don't know how many of you read *The New York Times* this morning and saw on the front page a long story about what sounds like a very exciting advance in the treatment of Fragile X syndrome, and that's relevant to our conversation here, because, after all, Fragile X is a condition where many of the affected individuals also receive a diagnosis of autism.

Fragile X is caused by a very unusual sort of glitch in the DNA where a particular repeat of the letters CGG in the DNA sequence gets multiplied many times over, and that expanded repeat, once it reaches a certain size, actually shuts down the expression of a gene nearby.

And when Steve Warren discovered this cause about 20 years ago, I think most people thought, "Well, okay, that'll be useful for diagnosis, but how would you ever take that information and turn it into something therapeutic?"

Steve and many others working on Fragile X over the course of many years deduced that at least a significant part of the problem is a difficulty in what happens at the synapse in the brain, and particularly the Fragile X protein is normally supposed to carry out functions which when absent result in sort of a confusing crosstalk of proteins that should not be present in such quantities or in such different sorts.

And while it is very difficult, as

you can imagine, to come up with a drug therapy that actually compensates directly for the absence of a protein -- it's always pretty hard to imagine how you replace something that's not there -- they figured out an interesting pathway where a particular receptor that has a name that's not so easy to trip off your tongue, mGluR5, actually acts as sort of a yin and yang here, and if you could block partially the effect of mGluR5, you might result in a better outcome if the Fragile X protein was not working.

That showed some benefit in a mouse model, and now, just this morning in ***The New York Times***, although not yet benefitted by a peer reviewed publication, and we're all sort of anxious to see what comes forward when we can see the real data, but investigators at Novartis who have been working on this approach indicated that they do have evidence that there is benefit.

And that is really quite a

significant announcement, to be sure, because -- and I think it's highly relevant, because I think many individuals studying autism are becoming more and more convinced that the problem is at the synapse, and there may be many different ways that the synapse can be affected.

And the heterogeneity of autism at the molecular level may turn out to be quite substantial, but this is maybe a glimmer of excitement and potential hope here in terms of coming up with a strategy that at least in this bit of information that we can deduce from ***The New York Times*** seems to have real promise. So I was excited to see that and excited to have that progress after 20 years.

Now, what we would love to be able to say is how to build on that, and that would mean we'd need to understand in the broad array of things that happen in autism spectrum disorders exactly what is going on, and therefore what would the right rational strategy be to try to intervene.

At any rate, I think that is a nice example of the ways in which research, admittedly over substantial periods of time with great complexity vexing us, but is moving forward and moving forward at an accelerating pace.

All of the institute directors at NIH met all day yesterday in a retreat that we had to talk about accelerating therapeutics. How can we take the outpouring of basic science discoveries that are emerging as far as the molecular causes of diseases and speed up the process of taking those basic observations to the point of clinical benefit?

And how could NIH play an even more substantial role than perhaps has traditionally been the case in that process, because, of course, in the past many people would say that's the business of the private sector, and the private sector is very good at this.

But for disorders that are less common, where the economic attractiveness of a private sector investment is not quite so compelling, or, in fact, for situations where you've learned something about the disease, but the target that's been identified is not considered to be classically druggable, which is one of those terms that is kind of in the eye of the beholder --

But there is a certain tradition about what's druggable and what isn't, and if what you've discovered doesn't seem to be on the druggable list, it may sit there unless some further investments are made by the public sector.

Well, I think this is an area that all of us meeting yesterday felt was worth substantial consideration, and with the Healthcare Reform Bill actually including a new provision called the Cures Acceleration Network that gives us authorization to do more of this, we are embracing that and looking forward to seeing how we can empower academic investigators to play a larger role in the front end of that development of therapeutics in a partnership with the private sector.

But if we could identify projects that seem too risky right now for private sector investment, and if we could, within NIH funds, effectively de-risk those projects by investing in the early stages of development and getting something to the point where it seemed now pretty plausible, then I think we would have done a good thing, and that's clearly the kind of partnership that is emerging at this point, that seems to be well received in many different quarters, including in biotech and pharma.

So we are excited about seeing that begin to take shape, and, obviously, to the extent that we can find exciting ways to apply that for autism, we will be looking for those because of the importance of this as a disorder that is very much in need of new ideas, new approaches.

By saying all of that, I don't mean in any way to diminish the importance also of conducting studies on behavioral interventions to try to understand right now with kids that are with us what can we do that actually can show benefit as far as interventions to improve functioning, and that is also an important part of this agenda that you all have put forward, and we will certainly be looking into ways to fund research studies to accomplish that.

Another area that I just thought I would briefly mention, because it is relevant to autism, although also to many other conditions of childhood, and that's the National Children's Study. The National Children's Study, as many of you know, has been under a pilot sort of phase of investigation, having been authorized by the Congress and sometime after that appropriated to the tune of, this year, $194 million.

The idea here is to try to collect really detailed information on environmental exposures, as well as genetic risk factors, on 100,000 kids and to do this across the nation in a fashion that is representative of a wide variety of differences, geographic, ethnic, socioeconomic status, educational level, and so on.

This is a big challenge, the largest pediatric study ever considered, and the challenge is now to make sure that we have through the appropriate pilot studies identified the methods that will enable recruitment of individuals to this very substantial number of 100,000 and the ability to follow them until age 21 and see what we can learn.

That is a critical part, I think, if we are ever going to fully understand what goes on in pediatric disorders is to have this sort of prospective study, because if you wait until a disease has been diagnosed, you've kind of missed the opportunity to assess the environmental contributions.

You wanted to have that data, and it didn't get collected, because you didn't know you would need it, but if you're following 100,000 kids and collecting that data all along, well, given the frequency, the terribly concerning frequency of autism spectrum disorders, you are going to encounter many examples where that condition gets diagnosed, and you will already have data to compare and try to assess what might be going on there that we haven't previously understood.

Dr. Guttmacher, the acting Director of NICHD, is very much engaged in the oversight of the way in which this pilot effort for the Children's Study is going forward.

We are in the process now of trying out three additional methods of doing enrollment after the first method turned out to be less efficient than the models predicted, and we want to be sure before we scale up to the full study that we know exactly how this is going to play out and make sure we're planning for success.

And the full decision, then, about the main study is probably still a little more than a year away, but I think the commitment to conducting this study is very strong, and autism is one of the stronger reasons to do this because of the importance of that kind of data.

Meanwhile, there are, of course, other efforts not conducted with -- connected with the Children's Study that are aiming to do this sort of collection of environmental exposure data and genetic data, and they should go forward with all due speed, but I thought I would mention the Children's Study as one of particularly large scale and large commitment.

Well, again, I don't want to say a

lot more than this, just to sort of lay out a bit of the spectrum of what it is that we at NIH are particularly focused on. I did publish in January in ***Science*** magazine a list of the five themes that I thought were particularly appropriate to highlight right now as areas of exceptional opportunity.

If you look at those five themes, you will see that every one of them has a potential application to autism, although the themes were not themselves disease-specific, the use of high throughput technologies, the emphasis on translation of basic science into therapeutics, the focus on the science of healthcare reform, which means understanding behavioral interventions, comparative effectiveness research, which we clearly need for autism.

Even the fourth theme on global health, clearly autism is not a disorder that's limited to this country, and to the extent that we can understand those differences across the world, we might get important clues as to causation, as many of you are aware.

And the fifth of those, which I'll just finish here with, was our biomedical research community itself. We need to be sure that we're supporting the bright ideas of young investigators and more seasoned investigators.

And one of the concerns that I think many people have had is that in tight budget times, and we have been in tight budget times for medical research now for some years, and it doesn't appear that it's going to get much easier, but in those tight budget times, there can be a tendency towards conservatism on the part of the peer review process.

Let me say I think we have the best peer review process in the world. We ask people to give up huge amounts of their time to look at the grant applications of their peers, and with that kind of really rigorous and highly sophisticated analysis, I think we do a very good job of picking out what are the very best proposals.

But imagine if you are, in fact, on one of those study sections, and you have a pile of grants in front of you, and you know you're only going to be able to fund a few of them because of the tightness of the budget, and right now we only get to fund about one out of five, and it may well be in FY `11 that will drop to one out of seven.

And you have in front of you a whole group of applications from seasoned investigators who have been highly productive, published lots of papers, have a beautiful grant application with lots of preliminary data. I mean, how can you say no to that?

But then over here you have a pile of applications from earlier stage investigators who don't have such an obvious track record, who don't have quite as much preliminary data, and whose ideas in some cases may seem a little wacky.

So what are you going to do? All too often, I fear the wacky applications don't quite make the cut because of the understandable reluctance of reviewers in a tough spot to decide to take a chance on those when there's other very solid research right in front of them.

Well, we worry about that, because we at NIH believe that while we need to support that solid science, we also need some wacky stuff, and we need people who have ideas that are really out of the box, and maybe they haven't already figured out whether they're right, and they want to get the support to find out if they are, and they're going a little against the grain.

So we've started in the course of the last couple of years a number of programs that aim specifically to solicit wacky applications. We don't call them wacky. We call them high risk/high reward.

That sounds a lot better, doesn't it, things like the Pioneer awards, things like the New Innovator awards, the Transformative R01s, all of which are funded by the Common Fund. And that has been treat fun to look at and see what comes in the door, because you're not allowed to apply for those unless you have an idea that is transformative, that if it turns out to be right, it's really going to change things.

We will need to continue that attitude for autism research. There's a lot of great things that can be done now, but clearly our state of knowledge is not sufficient that we could accurately predict where the next really big insight is going to come from, and so we'll continue to try to see if there are people out there who come up with really unexpected, creative proposals and make sure that they get the attention they deserve.

So thank you. I appreciate very much the chance just to be here with you. I know this is a tough time for anybody, any family, any individual who is going through the experience of raising a child with autism spectrum disorder and that that must be something that is every day for you a struggle, and I think we all share that with you and look forward to a brighter day when we understand this condition, this set of conditions well enough to have better interventions available.

There is a quote that I am fond of from Winston Churchill, who is the source of all great quotes, which was actually something he said in the course of World War II, and it's rather simple. He said, "If you're going through hell, keep going." Think about it. The alternative, stop in place, doesn't seem like the right idea.

I know many of you must feel like you're going through hell with the difficulties, the frustrations of every day not understanding why this disease has struck and what to do about it, but let's all keep going, because I think on the other side of this battle we're going to come into a place with much better understanding and much more hope. Thank you very much.

Dr. Insel: Thank you, Francis. Before we break, I should clarify that Dr. Collins is actually a new member of the committee, but this is a situation where we don't actually expect that he will be at each of the meetings.

He has designated Dr. Josephine Briggs, Dr. Josie Briggs, who is over here, who serves as the Director of the National Center for Complementary and Alternative Medicine, who will bring, I think, a very helpful perspective to the committee, as well, and so she will be serving in his place at future meetings and perhaps even later today, as well, Josie, if you can stay around.

Thanks for being with us. We're going to take a break. We'll return, reconvene in -- I'm going to say ten minutes, because I know you're going to turn that into 15, but 11:25 we want to be right back. We have a very full schedule.

(Whereupon, the above-entitled matter went off the record at 11:13 a.m. and resumed at 11:25 a.m.)

Dr. Insel: We will be hearing from a new member of the committee, but this talk was actually scheduled when we wanted to have the Chief Science Officer of Autism Speaks tell us about the Autism Treatment Network, not knowing that she would be on the committee.

So it's a privilege and a delight, Geri, to have you join us as both a member and as a leader in the field, and this committee had talked greatly about your January publication at the last meeting, the pediatrics paper which has been one that we've been really inspired by to give us a sense of what the power may be of early intervention.

I think you've really set the bar for all of us, and in your new role, not so new, perhaps, but in your current role as the Chief Science Officer at Autism Speaks, it's going to be, I think, extremely helpful to have you on the IACC to make sure that there is the kind of coordination that this committee is supposed to be all about.

So, how fitting to have you start this off by telling us about the Autism Treatment Network, which is something that the IACC has been interested in, and we really would love to hear more about the details. Thanks for coming.

Dr. Dawson: Great. Well, let me begin by just saying how thrilled I am to be on the IACC. I've attended every meeting either in person or remotely, I think, since its inception, and I am just honored now to be part of the committee, and I look forward to meeting and working with you all.

And what better way, actually, to

start out by telling you about the Autism Treatment Network, which is a science program of Autism Speaks that is dedicated to improving the quality of medical care for children with autism spectrum disorders. So let's start by just looking at what the health experiences are like for children with autism and their families.

This was an interesting publication that came out a couple of years ago where they compared the healthcare experiences of families who have a child with autism spectrum disorder to families who have children with other special healthcare needs, and what they found is that these children are much more likely to have unmet healthcare needs, and the families are not given the appropriate support services.

They particularly have a lot of difficulty receiving coordinated care, and we know that autism does involve treatment from many different disciplines, and case coordination is one of the big challenges, and they don't receive the referrals that they need.

We heard earlier today about the tremendous financial stresses that families have, so we know that insurance doesn't cover many of the services that children need, and so on top of the stress and strain of having a child with autism, they also have tremendous financial burdens and large out-of-pocket expenses.

And then I think we even heard today from Christine about her leaving her job, that she left her job to stay home and take care of her child, often acting as the case coordinator. So, on top of the financial strains of not having insurance coverage, families then often now go from being a two wage earner to a single wage earner, and this, of course, adds additional financial stress.

So the key issues that needed to be addressed, one is the fact that individuals with autism do face tremendous barriers in accessing appropriate healthcare, and this is partly because many physicians do not receive adequate training, and they're not really aware of the many health challenges that individuals with autism face.

Particularly just the general pediatrician who is out in the community serving a wide range of children may not be aware of the particular health issues that children face, and if you look in the literature, there's tremendous variability in the documentation and understanding and in even our estimates of prevalence of the conditions that autism -- that people with autism face in terms of their healthcare concerns.

And then, finally, there really are no standardized clinical guidelines for medical care, so if a family goes to one center, they may get one kind of treatment. If they go to another center, they get another kind of treatment.

This is a very different picture than something like cystic fibrosis or cancer or a stroke, where we have standards of care, and we can turn to a center and know that we're going to be receiving a particular protocol and standard of care, so developing these clinical guidelines is also a high priority.

Now, we do know that children with autism, adults, as well, do face tremendous medical challenges, so here's a list of some of the more common medical issues.

Sleep problems. We know that seizure and epilepsies are very common, GI problems, food sensitivities, and a wide range of comorbid psychiatric conditions, particularly anxiety and depression. Now, these have immediate impact on quality of life, and these are conditions that we can intervene with now and make a difference in people's lives now by addressing these.

Many times, they go unrecognized, and this is partly because people with autism have difficulty expressing where the pain is, and even a high functioning verbal person may have trouble with determining where in their body the pain is coming from and communicating that, and often the behaviors that you'd see for a person in pain that has autism such as self-injury, aggression, tantrums, these can be interpreted as part of the autism, and people don't always think that there might be an underlying medical condition.

And then, finally, we know that these actually impact the person's ability to take advantage of educational programs, to be able to attend and that they contribute to many of the behavioral challenges that we see associated with autism.

Now, here's a publication came out just this year just showing the very high prevalence of psychiatric comorbidities that we see in autism, so actually reported that 95 percent of youth that were psychiatrically referred who have autism spectrum disorder had three or more comorbid psychiatric disorders, and 74 percent had five or more. That's just remarkable, and you can see that in the area of anxieties disorders, these are particularly high.

So the vision for the ATN was to create the nation's first network of hospital and clinicians that were dedicated to improving medical care, and the first goal was to create a common protocol that physicians and clinicians could use when a child presented with an autism spectrum disorder and to create a patient registry so that the data on the kinds of presenting problems, on the diagnoses, and also on the treatments that were being used could be catalogued, and we could learn more about quality improvement by creating this common database.

And then the goal was to develop and disseminate evidenced-based treatment guidelines that physicians and clinicians could use and then at the same time to create a platform that could be useful for conducting clinical research and particularly for comparative effectiveness research.

And this vision, by the way, as modeled on the Cystic Fibrosis Foundation's similar network and on the Children's Cancer Care Network, which has proven to be tremendously successful for improving the quality of life, as well as for creating a platform for conducting clinical research.

So the goals of the ATN were four-fold, to improve the quality of care and the quality of life through improving medical care and to provide access. In fact, the goal is eventually to have an ATN center within 100 miles of any child and eventually adult with autism in the United States. It's a very big goal.

The third is to conduct research that would actually advance the evidence base for treatment of medical issues, and then to provide leadership both in terms of clinical leadership, as well as leader -- research leadership.

So this gives you a sense of the current structure of the ATN. There are 14 academic centers across the U.S. and Canada that are participating. It's 126 physicians across six sub-specialty groups.

There are currently over 2,000 children now that have been evaluated with this common protocol and entered into the patient registry with a projected enrollment of 3,000 by 2010.

The program funding comes -- this is a public-private partnership where Autism Speaks provides $3 million annually to support the administration, the clinical infrastructure, and also the coordination of care across disciplines at the institution and also the support of the patient registry, so data entry and the data coordinating center.

And then we also have support from HRSA, the Health Resources and Services Administration -- we have Peter van Dyck here -- where they are providing $4 million a year for guideline development research, and this is called the Autism Intervention Research Network for Physical Health, which overlaps with the ATN.

I want to just mention this important funding here, the $4 million a year, is going to be sunsetting with the Combating Autism Act, which, as you may know, sunsets in 2011, so this is a very important source of funding for the ATN, and we are very hopeful that the Combating Autism Act will be reauthorized so that this funding can continue.

So here is the organizational structure. So Autism Speaks provides broad oversight of the program. We have Clinical Coordinating Center that is headed up by Jim Perrin, who is a Professor of Pediatrics at

Mass General Hospital.

We also collaborate very closely with the National Initiative for Children's Healthcare Quality, which is known for their development of evidence-based clinical guidelines, and then our Data Coordinating Center is a privately funded coordinating center, EMMES, and here is the list of the 14 medical centers that are currently part of the Autism Treatment Network.

And here you can see the geographic distribution, so fairly good geographic distribution, although, obviously, we would like to see a greater number, and there are many states that don't have a center yet.

So the clinical activities of the ATN are, first, providing care, so over 5,000 children are served by the ATN. We're also collaborating with what's called the LEND program. So this is the Leadership and Education in Neurodevelopmental Disorders

Program, which is focused on providing education and training to physicians throughout the United States.

So we work very closely with them to provide training of young people who are coming up through this program, and the ATN has also developed now three medical guidelines and are piloting these medical guidelines in the -- throughout the ATN.

So these are on the assessment and treatment of sleep disturbance, on GI conditions, and then on EEG, particularly seizures, and when -- what types of assessments are needed for assessment of seizures.

Here are the demographics of our current sample in the Autism Treatment Network patient registry. So with these over 2,000 patients you see the gender ratio that's expected, five to one. About 80 percent are white, 20 percent from ethnic minorities and average age of six, and you can see that two-thirds of the patients have a diagnosis of autism and one-third PDD-NOS or Asperger syndrome.

In terms of research activities, I mentioned the Autism Intervention Research Network for Physical Health that is supported by HRSA. I mentioned this is a $12 million grant.

Jim Perrin at Harvard is the -- at Mass General is the PI for this grant and Director of the Clinical Coordinating Center, and I should say this is part of four initiatives that were developed by the Maternal and Child Health Bureau under the Combating Autism Act that improve care for children with autism.

The six projects that are currently being funded with the HRSA funding are the assessment of nutritional deficiencies, a randomized clinical trial of interventions to improve sleep, the assessment of bone density, which now has been detected as a real problem of concern in autism, examination of creatine deficiencies and their relationships to specific genetic mutations, iron deficiencies in children with autism, and then examining the impact of sleep disturbances on behavior, both in terms of educational behavior and challenging behaviors. And I should say we are currently reviewing a second round of these pilot studies that will be funded through the HRSA program that will initiate this year.

The ATN researchers have also been successful in applying for other kinds of funds, so they successfully received grants through the ARRA funding from NIH. Autism Speaks has funded projects for the ATN, and they have received an R40 through the MCHB.

And then, finally, last fall ATN collaborated with the American Academy of Pediatrics and also the National Association for Pediatric Gastroenterologists to hold a summit on what do we know about the pathophysiology of GI conditions in autism, and the goal of that meeting was to develop a research agenda to better understand GI conditions and their treatment.

So what I'm going to end with is just showing you some of the data that is already coming out of the patient registry, and I think with this relatively large sample we can get some sense of some of the representative presented problems that children are bringing to the attention of the physicians.

So here what we see is that the most common presenting problem is a behavioral concern, so language, attention, social behavior, hyperactivity. The second most common is GI problems.

The third is sleep disturbance, followed by neurological concerns, and, in fact, when we identified those areas as sub-specialty groups and areas to develop guidelines, it was because we were already seeing early on that these are the kinds of problems that families were bringing to our attention.

So I'm going to give you a little bit more detail on each of these areas. In terms of gastrointestinal symptoms, we find that if -- every child who comes in fills out a questionnaire about their symptoms, and we find that about 50 percent of children are reported to have some kind of GI symptom.

And we also find that when they do report a GI symptom that this is associated with higher levels of sleep disturbance with behavior problems, with lower quality of life, and also parents who have children with GI problems are more likely to be turning to complementary and alternative therapies.

This just gives you a sense of the kind of GI problems that children present with. Constipation is the most common problem, followed by diarrhea, abdominal pain, nausea, and bloating.

In terms of sleep disturbance, on a questionnaire that all parents fill out when they come in we find that 65 percent of parents are reporting some significant sleep disruption, and 14 percent of these also have seizures. This is a higher percent than the published rates of sleep problems that we find in typically developing children in the published literature.

Children who have GI problems are also more likely to have sleep problems, and sleep problems are associated with more difficulties during the daytime with challenging behaviors and poor attention and concentration and executive functioning skills.

These are some very interesting data about medication use, and what you can see here is that below three years of age that very few children are on medications but that as we enter late preschool age and then move into the elementary school age, we see more and more use of medication so that by elementary school age about 50 percent of children are on some kind of medication. And then we see that by moving into the early adolescent period that 40 percent or over 40 percent of children are using two or more medications.

And here are some data that show how medication use changes over development. This is a cross-sectional sample, of course, but looking at the different type of medications that children use.

And what you can see is that as children move into the elementary school period, you see this very high spike in the use of stimulants, probably reflecting the impact of hyperactivity and attention on school-related behavior, and then as we move into the adolescent period we see a higher rate of the use of SSRIs, perhaps reflecting the high prevalence of anxiety disorders that we start to see emerging during this period.

Here are some data on the use of complementary and alternative medications. We found that in our sample 22 percent of children are receiving some kind of complementary and alternative medication. About 18 percent are on special diets, so these are very commonly used among parents of children with autism.

Okay, I just want to end by talking about the model for growth and our vision for the future. In terms of clinical care, the goal is to expand beyond our 14 centers, and, in fact, we have recently put out an RFP to renew the Autism Treatment Network centers, and we received 34 applications for centers that are interested in becoming an ATN center, so there clearly is a much bigger demand than Autism Speaks has the ability to afford.

And then second is to continue to partner with professional organizations such as the American Academy of Pediatrics, who has been very interested in partnering with us, to develop clinical guidelines that physicians can use to treat and assess medical conditions in children with autism.

And then finally, in the area of research, we want to expand research funding for clinical research, and a piece of this that is absolutely essential is the development of a biorepository. And currently we have very excellent phenotype data on the children, but we don't have DNA, urine, other kinds of biological materials that are very important in recognizing biological sub-types.

We know that autism isn't one condition. It's many different conditions, and, in fact, the clinical trial that Dr. Collins was mentioning this morning that was discussed in *The New York Times*, one of the statements that's made in that article is that first when they conducted their clinical trial, they got very confusing results, but then they were able to identify a biomarker that identified a subtype of Fragile X that was responsive to this particular medication.

And this is, I think, the future of autism treatment -- is a personalized medicine approach where we need to have biomarkers, so: does a child have an underlying mitochondrial disorder or a specific genetic condition, or even within genetic conditions what kind of treatments might they respond to?

So having a biorepository is very high on our priority list, and I should say that we are very hopeful that we can expand in this way, and critical to that is going to be expanded funds for autism research and services in general.

And we are encouraged by the fact that during his campaign President Obama, then candidate Obama, made a pledge that by the end of his period in office that funding for autism research and treatment and services would expand to a billion dollars a year.

So we can just be hopeful that -- with the attention that we heard about this morning with Secretary Sebelius and Dr. Collins -- that this kind of resources can be brought to bear so we can begin to address the many needs that individuals with autism and their families have. So thank you, and I'm happy to entertain questions if we have time.

Dr. Insel: Thank you, Geri. Peter, would you like to say something about the HRSA role, because this is a partnership here?

Dr. van Dyck: This is a valued partnership for the Autism Treatment Network. We fund two -- with the Combating Autism Act, we fund two networks, one for behavioral health and one for physical health, and this one is for physical health.

And it's ideal, because there are 14 or so sites, and collectively they have enough clients that we can test guidelines and determine from this large sample whether they really are evidence-based or not.

The first slide in your set were the family issues that prompted what we did. If you look at that first slide in your packet, it's the article published in *Pediatrics* that we -- it came from the Bureau and outlined issues that we felt were important, and one of them was better guideline development and better treatments that were necessary, so this is our attempt to work on an issue that was highlighted for us in the survey.

The other strength of the Autism Treatment Networks, I think, and why they form an important partnership is they coincide with a lot of our LEND projects, and the LEND projects are interdisciplinary training programs to help physicians, nurses, PTs, OTs, psychologists, speech and hearing folks better serve and diagnose and treat children and families with special needs, including autism.

And because they coincide with a

lot of the sites of the Autism Treatment Network, it seemed a natural association. But this was a competitive grant, and Autism Speaks was the successful applicant, and we're really proud of the partnership and look forward to the findings that were -- from the studies that were described here.

Dr. Insel: Ari, and we'll -- we have just about three or four minutes for questions, but let's start on this side. Go ahead.

Mr. Ne’eman: Sorry. Can you hear me? I thank you very much for presenting on this. It looks like a very intriguing tool. I noticed that you provide data on both psychiatric comorbidities and the use of psychotropic medication, and I'm kind of interested if you can provide those together.

The reason is, to sort of give some context to my question, in the context of adults with developmental disabilities, it's my understanding that the percentage of individuals with dual diagnosis, mental health and DD, is lower than the percentage of individuals on psychotropic medication, which suggests very concerningly that there is some use of these medications as a form of chemical restraint, which, you know, would suggest that in some instances they're being utilized not to improve quality of life but simply to make it more difficult for an autistic child or adult to express an obstacle to quality of life, be it medical, social, environmental, or otherwise.

So I guess my question is, does the Autism Treatment Network have the ability to match the data you showed us here with the percentage of individuals on particular types of psychotropic medications and correlate that to age?

Do you have the ability to match that to the particular psychiatric comorbidities that individuals may be diagnosed with, so as to give us more data as to whether or not these medications are being used appropriately or inappropriately?

Dr. Dawson: Yes, perhaps, and I think that would be a very interesting analysis to do. I think the challenges with the use of psychotropic medicine are many.

One is that it's actually fairly complex sometimes to diagnose a comorbid difficult -- condition and autism, and, in fact, in some of the previous DSM diagnostic criteria it was indicated, for example, with ADHD that you couldn't have both, and so there are some diagnostic issues there that I think that even that kind of analysis may be difficult at this point to pull out.

But I just want to say that I hear what you're saying about the inappropriate use of psychotropic medications, and I think it's a very, very important issue and not only because of, of course, not wanting to use them as a form of restraint and inhibiting people's ability to function, but also there's tremendous side effects that are associated with many of these medications.

So it was an interesting conference I attended recently on aging and autism, and it turns out that one of the most serious issues is obesity, and obesity is a side effect of some of these medications.

So I think that the use of these medications raises a whole other set of health issues that we need to be very aware of, and the use of multiple medications, I think, is also an issue that needs better study.

So I think this kind of platform hopefully will be a way that we can address some of the issues that you're bringing up, Ari, which I think are very important.

Mr. Ne’eman: To some degree, I think, very briefly, I think this is even more important in the autism context, because for many people with impairments in communication, you know, behavior may be one of the only ways that they can communicate challenges that are being faced.

So if, you know, psychotropic medication is being used inappropriately simply to suppress behavior, that may make it more difficult to address the underlying reasons for that behavior.

Dr. Dawson: Yes, and I should say that's one of the, I think, exciting breakthroughs last year that was reported was a study where it showed that the use of both behavior management plans as well as medication is more effective than medication alone, and a good behavior management plan is a plan that allows a person to express their needs and their wants in the most appropriate way.

Dr. Insel: And requires good medication management, as well. We really don't have much time to get all of these questions in. Gerry Fischbach, and then we'll try to take --

Dr. Fischbach: Geri, a few years

ago, a paper was published from the Kennedy Krieger that stated that children with fever, low fever, seemed to improve in certain aspects of behaviors, and many parents report the same thing, and it provides very important clues about the nervous system and what may be involved. Do you see that in the ATN?

Dr. Dawson: You know, I don't believe -- I wish I had one of our ATN researchers here. I don't believe we're measuring that, per se, and, you know, it's probably not the case that we see kids presenting with fever all the time.

I think it's something you would probably see at your pediatrician, but I do think it's a very important question, and it is a question that we could try to address through the ATN. And I agree it gives very important insights into the role of the immune system in autism.

Dr. Insel: A question from over here. Marjorie?

Dr. Solomon: Geri, I was wondering if you could just say a little bit more about the sample, how they were diagnosed with autism and then anything about the composition with respect to language level, adaptive functioning, cognitive functioning

Ms. Dawson: Right. So I think one of the advantages of this sample is that it's not a sample recruited for a research project. So every child who comes into the clinic who is presenting, and then if they agree to participate in the Autism Treatment Network, would be entered, and then they -- at this point, they are getting an ADOS and a DSM-IV diagnosis.

Because these are conducted in a clinical setting, the ADI has been unwieldy. It's just you can't get reimbursement, unfortunately, for a two-and-a-half-hour interview, but we do have ADOSes and DSM-IV diagnoses on all of the children, and we'd like to be able to have a more efficient way of doing an ADI. In fact, we are working with Cathy Lord now to try to develop a more efficient ADI.

The sample is very broad in its distribution of adaptive functioning, so I think it reflects very much what you would see in the broader community, because these are children just coming in for an evaluation, so the entire spectrum. I think you saw, you know, two-thirds autism, and then Asperger's syndrome -- there were quite a few individuals that were high functioning, as well.

Dr. Insel: Well, this is extremely helpful. You know, I think we're going to circle back to this at various times, because this is obviously a resource that we need to be thinking about in the context of the strategic plan as one of the places that some of the questions in the plan could be addressed.

The concern you raised, Geri, about the future I think we also need to think about as a group a little bit. It's just a little conspicuous. The IACC sunsets on September 30, 2011, the same time the ARRA funds will give out, and so we don't want to wait until September 29 to discuss the future of this, so hopefully over the next few months we can come back to the issue of how a program like this gets supported.

I think your analogy with cystic fibrosis is right on the money, and if you look at that history, the thing that's made the difference has not been the genetic findings, which were there before the network developed, but creating the guidelines and the network so that every patient is a partner in this effort, and you can see it in now the morbidity and mortality statistics for that disease, which are just so impressive.

So this is something we really ought to take a closer look at as we go forward and think as a group, as a committee, about where the opportunities might be.

We're going to take on one other issue before lunch, which is focused on DSM-5, and we've asked Dr. Susan Swedo, who you have heard from before. She was at a previous meeting talking about the intramural NIMH efforts for autism.

We bought her -- we brought her back for a whole different topic, which has to do with the Diagnostic and Statistical Manual of the American Psychiatric Association, which is the private organization that's involved with coming up with the new nosology for autism, and there's been a little chatter about this at the meeting previously, but we thought we needed to really hear more of the details from somebody who is involved.

Sue, thanks for being here.

Dr. Swedo: Sure. Thank you for the invitation. It's truly an honor. The Neurodevelopmental Disorders Work Group is charged with those disorders defined as neurodevelopmental in nature, and that includes intellectual disabilities, learning disabilities, and some other less frequently diagnosed conditions, as well as the pervasive developmental disorders that includes, as we know, autism.

I am a pediatrician. I am not a psychiatrist, so I'm one of the anomalies among the work group chairs on the DSM, as is my committee in which we have a very broad multidisciplinary team, and the reason for that is to -- just as the IACC does -- try to draw from many different spheres, since autism and its related disorders impact on so many spheres of services delivery, but certainly of the mental health provision.

We also have a group of consultants and advisors, so, for example, the communication disorders area is just completing their work with the help of half a dozen advisors who have worked very, very hard to really word -- choose words that are the most descriptive and yet remain concise enough to move ahead.

We have been working for several years already under the auspices of the task force as a whole, and it started in 2007. At that time, we were actually supposed to be done and ready to publish next year, and it quickly became clear that the task was greater than the time that they had allotted, so there's been another delay in the publication of DSM-5. They are now pushing for 2012.

We have been charged with recommending changes that would influence accurate diagnosis, help individuals receive services that they need, but also to reflect the increased knowledge base, and part of that delay was really some very tough work that was done on how much of this can be biologically based at this point in time and how much needs to remain behaviorally based, and for autism that's been a particularly important issue for us.

It's being called DSM-5 as a

numeral, not because we're dumbing things down but because if you have DSM-V (Roman numeral), you are not able to have Version 5.1, 5.2, and that's actually what's envisioned, that there will be an online version of the DSM that can be updated almost continuously as new evidence is provided.

It was felt early on that the transparency of this process was important, particularly since this is a manual that's used very far beyond the psychiatric community. There had been criticisms of DSM-III and of DSM-IV that it was sort of a good ole boys back-room effort, and so they wanted to make sure that this one was done openly, and as part of that, all of the recommended changes were put up for public comment, which has just closed.

The autism spectrum disorder area in particular got a great deal of attention. Neurodevelopmental disorders were consistently at the top of the list of comments, I think in large part because of a previous *New York Times* article on the loss of the Asperger's diagnosis.

As you know, currently autism is defined in DSM-IV as a conglomeration of disorders under the pervasive development disorders. It includes not only autism but Asperger's, Rett syndrome, childhood disintegrative disorder, or CDD, and PDD-NOS.

One of the first discussions we had was about the category name of pervasive developmental disorders, and one of the biggest problems with that as a category is that the symptoms are not pervasive. Pervasive would include motor symptoms and other domains, not just the social communications area.

So it was determined that autism seemed to be the best and most frequently used term to sum up this category of related conditions, and one of the other concerns in this area was the fact that PDD-NOS was being used very frequently without true adherence to the guidelines, and some say it was a copy editing error. Others say it was done intentionally, but in DSM-IV it's certainly easier to make the diagnosis of PDD-NOS and to include individuals who don't meet sort of what we would consider the three main domains or the two domains.

So we're planning to recommend a new diagnostic category, autism spectrum disorder. I personally was very interested in some of the suggestions that came in through the public comments, and the committee is considering those, as well, because there are some problems with ASD.

Secondly, we proposed to move to two symptom domains and require significant symptomatology in both of those. One, as you would expect, is deficits in social communication.

This again was the conclusion of a workshop in which we invited not only our usual consultants and advisors but others, as well, to really have an in-depth discussion about whether communication deficits happened in the absence of social deficits in individuals with autism and concluded that they really do represent the same types of symptoms, same manifestations of the symptoms.

We also wanted to de-emphasize the role of language so that one of the specifiers we have will be verbal abilities, so that you could be focusing, as well, on non-verbal communication instead of just on language.

We proposed to merge the current autism spectrum disorders into a single diagnosis of ASD, and, again, in this case we not only turned to our advisors and consultants but conducted an extensive secondary data analysis of data that had been accrued through NIH-supported grants of the CPA and START centers, also from the Simons Collection in some of the work that's been going on right now.

And it very clearly showed that while you can separate autism in general from the non-affected individuals, that separation within that spectrum was very, very difficult and that there seemed to be quite large site-specific differences in the use of Asperger's and PDD-NOS.

So if you presented to a clinic in one city, your diagnosis might be Asperger's. If you present in a different city, it might be PDD-NOS, and this certainly is contributing to our inability to do cross-site research.

In the general community, it appeared that severity was used to differentiate autism, as well, so that individuals who we might describe as higher functioning or who had less impairment would be more likely to get a diagnosis of Asperger's, perhaps PDD-NOS, whereas those who had more impairment would get autism, but it wasn't used consistently across centers, number one, and, number two, there was no clear dividing line between where those individuals fell.

Now, having merged the different varieties into a single diagnosis, a lot of concerns evolved, and one of the, frankly, most surprising was among the individuals who currently have a diagnosis of Asperger's disorder -- that to lose that identity was a loss of something that had become important and was certainly part of their adaptations. I think that we will be able to deal with that very nicely in the text by really explaining it.

It's hard within the criteria themselves -- because it's only three sentences -- to reflect sort of the richness of the discussion behind this and also to ensure that those individuals with Asperger's disorder don't lose services, because that was the second and not surprising concern. We've been -- we've been working on that all along to make sure that individuals who are currently defined within the DSM-IV criterion and are receiving services wouldn't be cut out of the system.

However, in those comments one of the things that was the most interesting was the fact that as people were writing their comments back, there was almost nothing said about the actual criteria, and I think it speaks to the larger issue of we work really hard to make DSM-IV -- and now DSM-5 -- criteria that actually in standard usage are probably not even known by the majority of people.

So when they were arguing about not merging the disorders into a single spectrum, it wasn't because they didn't agree that individuals with Asperger's should have social communication deficits and excessive preoccupations or fixated interests.

Instead, it was much more related to the fact that the individuals with Asperger's have very unique strengths. So, in defining disorders, you rarely talk about strengths, but it is something that we will be mentioning again as part of talking about this disorder.

Other changes we expect and have recommended at this point in time are to have specifiers that may end up defining subgroups, and the hope here is that the heterogeneity that we always talk about might begin to be parsed out by having specifiers, so that you could go into a clinical sample and look for individuals who have either low verbal abilities, low cognitive abilities, or -- one that we struggled with -- is this issue of associated with known medical or genetic conditions such as Fragile X.

So, again, we recommended the removal of Rett syndrome. I'll get into that in a moment, but we didn't actually recommend its removal. We just don't consider it a primary diagnosis at this point, again remembering that the DSM defines disorders on the basis of behavioral manifestations and observations, and not at this point on biologic etiology.

You might imagine a lot of concerns about the fact that the few disorders in which there was known neurological cause in psychiatry were now being removed. That isn't, again, what's happening at all, and, in fact, it was an attempt to make sure that DSM-5 wasn't obsolete as soon as we published it, because if another genetic condition comes along that wasn't in there, it could get in the online version of 5.1, but it wouldn't be part of the main text.

So in an interest of not limiting ourselves to what we currently know, and whenever this is published in 2012, we move to this, and it's actually proven quite useful in some of the data analyses that we've done in order to be able to do what we said, form subgroups and begin to find homogeneous groups within the larger heterogeneous.

As mentioned, taking out Rett syndrome is a deletion of a specific category for Rett syndrome, and a large number of reasons for this, including the fact that many of the females affected by Rett syndrome never manifest symptoms of autistic behavior.

Those that do, it's often only for a very short period during development, and that containing them within what became known as the autism spectrum -- was previously known as pervasive developmental disorders categories -- we were actually limiting their ability to receive services for some of the things that they needed.

Further, those who have autism will still be able to be defined with an autism spectrum disorder, and then again it would be associated with a known genetic or medical condition, and that specifier would allow individuals to give them the further attention they need.

We proposed to delete childhood

disintegrative disorder, and it was quite interesting to -- I was one of those clinicians you talk about who didn't quite understand the differences in criteria until I was forced to read them over and over again.

And one of the things that's quite interesting is that there is just this little gap in the DSM between two years and three years or three and four, depending on your interpretation, where you don't know where to put people, and CDD also describes much more than autism.

It requires individuals to have loss of bowel and bladder control and other conditions, and so we scoured the world literature, had a call for cases not only among neurologists and pediatricians but child psychiatrists and others and found just a handful of cases.

And what it looked like was that in those who had these additional symptomatology, they might have received a different diagnosis had they gone to a neurology clinic rather than a psychiatry, and, secondly, with our increasing knowledge of what happens with regression in autism, that there really was a continuum. It wasn't the dichotomy that had been presented by leaving that age gap in the diagnostic categories. Excuse me.

So we anticipate having one of our specifiers be regression. We haven't made that recommendation yet, because it's now very clear that this is a continuum and that maybe it's easier to break people into quartiles of absolutely normal development and then a significant loss of skills at one end, and at the other end those who had very early presentation of their symptomatology, but most individuals lie somewhere between those two extremes.

So the things that are left, impairment is a huge issue for the DSM-5 task force as a whole. There is some attempt to align the DSM with ICD-10, in which impairment is a consideration for individuals rather than for diagnoses.

And so you don't set clinically significant as a threshold, and that has some appeal in the areas of autism spectrum disorders, because if an individual has the supports in place that make them appear to not have symptomatology, have they lost their disorder and therefore lose the services that are allowing them to function optimally?

The difficulty, though, is then where do you set that threshold? So we are spending some time, again, with secondary data analyses, moving cut points, using words of descriptors to go back and forth and really try to balance sensitivity and specificity.

I think we've all seen as part of the changing rates, prevalence rates being reported, some of the broadening of criteria. It was mentioned earlier that -- Geri mentioned that you can't have ADHD and autism.

So you're choosing one side or the other, and that has become a problem in the fact that the criteria for ADHD, particularly a young child with learning disabilities, may very well overlap completely with those of PDD-NOS or an autism spectrum disorder. And if you include those children on the spectrum, A), they're probably not going to get the appropriate interventions, and, B), it may be artificially affecting the rates.

However, we don't want to lose any of the folks who should be within that spectrum, and so you can't draw the line too strictly, and we absolutely don't want to be taking services away from individuals who are benefitting from them.

So, we have a lot of work to do, and I just had a call yesterday in which I was told we had less time to get that work done that I thought we did, so we will be hustling through continued teleconferences.

Field trials of the draft criteria

for autism, the field trials will probably be more narrowly administered than for the larger diagnoses as a whole. There the focus is on test/retest reliability, and we felt one of our biggest issues was actually validity of the diagnostic criteria, and so taking some gold-standard cases, both those who are clearly on the spectrum and those more at the edge, would be more useful to see how clinicians apply the criteria and what ends up coming back to us.

Then there will be another period for public comments if there are any further revisions, another set of revisions drafting the text to accompany those criteria, and then, finally, linking ASD with the other disorders.

We do know that the child committee will not be recommending that there be an exclusionary criterion under ADHD against PDD or against ASD, so I think that's one huge step forward -- that it will be possible to diagnose children appropriately so that when you see, as Ari pointed out, a figure showing that a lot of kids are getting stimulants, you would hope that they would have both a diagnosis of ASD and of ADHD.

That's all I have, so if there are questions, I'd be happy to answer them.

Dr. Insel: Very good. Thanks so much, Sue. Let's open this up for questions. I think there is a round of applause coming.

Dr. Swedo: Was that for the fact that I did it without breathing?

Dr. Insel: Lee?

Mr. Grossman: On July 9, on the third day of our annual conference, we're going to have a town hall meeting to discuss the implications that DSM-5 will have on the community, as well as public agencies.

We've invited Cathy Lord and Amy Wetherby to be part of that panel. We're going to be issuing a request for questions to be addressed there, and we're going to be --

we're attempting to broadcast this over the internet.

Where our concerns are is that when this -- when the DSM-5 is finally adopted, we're concerned that agencies, school districts, other service providers will be very confused by the new definitions and possibly use this as a means to deny service.

So the purpose of this town hall meeting is to develop a policy statement so that we can begin to move forward prior to the DSM-5 being accepted, where people will understand or agencies will understand and hopefully adopt procedures where they won't all of a sudden kick people out because perhaps there won't be an Asperger's condition or PDD-NOS is no longer.

What a child has as their previous diagnosis now doesn't exist. As you can see, this is -- can create quite a bit of problems. We have begun discussions with some state agencies, and they are very concerned about how this will impact them, not knowing -- just having this transition period of, you know, do they have to go out and re-diagnose? Do they -- what's going to happen with those that no longer PDD-NOS or Asperger's, et cetera?

So this is a concern. I'm bringing it to the attention of the entire IACC, because this certainly has service implications, and something that we will eventually have to address.

Dr. Swedo: We agree completely, and, actually, one of the other factors that was driving towards the single spectrum is the fact that there are, on the flip side, states that currently will not deliver services for PDD-NOS or for Asperger's, and so in those states individuals receive an autism diagnosis in order to get the services, and perhaps there have blurred things.

So, Lee, I think your comments are right on target, and all along we've worried how these will be used against delivery of services and tried to ensure that that won't happen, but we appreciate your help in thinking about them.

Dr. Insel: Sue, could you clarify? When you said there will be field trials, will those address this issue? Will there be a chance to look at how the new criteria would change the prevalence, for instance, in a standard set of patients that are evaluated with both DSM-IV and DSM-5?

Dr. Swedo: The closest we can do that on is actually our secondary data analyses, and that is what I had mentioned in terms of some of the, you know, sort of how are you going to describe how many of these symptoms meet?

You know, when is failure to make eye-gaze? Should it be failure? Should it be decreased eye-gaze? Those kind of key words are being taken back against some of these centers in which careful diagnosis has been done.

I don't know that it would happen in a field trial, because if we don't have the ability to sort of do what we would hope, and that is to have standardized cases in which you can then go to the state agencies and say, "Okay, is this child currently being covered or not covered, and would they still be?" But I think that that effort is possible.

Dr. Insel: How would that happen? I mean, because it seems like --

Dr. Swedo: That's the part that's hard, because I think that one of the issues, and we're going to truly have to partner with Lee and with others who can get us that kind of information, because my little work group certainly can't get it done.

Dr. Insel: Ed?

Dr. Trevathan: Nice presentation. I have a couple of questions I would love to get your input on, specifically the issue of requiring peer impairment, as I understand it, as being present as one of those social criteria for diagnosis.

And I guess specifically in light of all of our interest in doing a better job in communities at diagnosing children as early as possible so they can receive appropriate intervention, have you all discussed what impact this essential requirement of peer impairment would have on early diagnosis, for example, in toddlers?

We have some potential concerns with that, and there is also some, at least, I think, theoretical concern that the requirement for peer impairment, especially with surveillance systems that require -- that really involve reviewing written records, that peer impairment is often very poorly documented, even if it's present, and such a requirement could have some potentially even significant impact on our prevalence estimates.

Dr. Swedo: Right. So currently peer impairment is a core requirement of DSM-

IV, as well. It's actually defined in there more specifically than what we envisioned, and I appreciate your question, because it points out how hard it is to try and sum this up in a few slides.

But one of the other new features of the DSM-5 is actually a focus on presentation at different stages of development, and we have subcommittees currently working on presentation in toddler age range, preschool, grade school, adolescence, and young adults and up, because there's two places that people tend to get missed, and one is very early, and sort of the early, you know, act-early campaigns have been very helpful in that regard.

The other place is in the older individuals who maybe have not been diagnosed appropriately at a younger age, and then start to flounder when they're in junior high and high school. The current tools that we're using such as the ADI require you to get back to at age four or five, and if you're not seeing things at that time, then they're not going to have the diagnosis.

So we are trying to deal with that, but when I mentioned specificity, the peer relationships is actually one of those things that has incredibly bad specificity and tends to mix up those groups, particularly by records review, of kids who have ADHD in which their poor peer relationships have nothing to do with a deficit of social communication but much more to do with their lack of impulse control.

Dr. Insel: Stephen?

Dr. Shore: Thank you for a very interesting presentation, and I think you -- it's gone far. You've gone far into addressing the concern of loss of specificity with the loss of Asperger's syndrome and so on.

What I was wondering is when information was going to become available, one, for reading, and then for comment, to make sure that we address the issue of specificity and hopefully getting to a point where we can match diagnosis to treatment, because as it stands now, you say autism, and it's just too big and wide to really do anything with until you get in much deeper. I like that you -- I'm encouraged by the efforts.

Dr. Swedo: Thank you. Thank you. I think that the follow-up is going to be absolutely crucial, and one of the things I've been very impressed with my work group is that they are really flexible individuals who are very willing to listen and to take input and to try and do what we can with it by testing it back and making sure that as --

Again, as a physician, I took an oath to first do no harm, and we have approached it in that way at every step, trying to make sure that we improve rather than have these accidents. Specificity, I don't know. It's going to have to come down to those specifiers and sub-groups, and I think we'll be adding them as time goes on.

Dr. Shore: Thank you.

Dr. Insel: Geri?

Dr. Dawson: Thank you, Sue. That was a great presentation. So I'm following up on the comment that Lee made, and I wondered whether it might be possible to develop some kind of a survey that could even be web-based that could go out to different states and people who oversee the educational programs and birth-to-three, and to just have questions about the impact that it would have on service utilization, on the need for training, really just to get a broad assessment, in the United States, at least, of how it might impact service delivery, because I think anticipating some of those issues is going to be really important, and I imagine that people would be willing to participate in such a survey.

Dr. Swedo: Seems like a really

help -- maybe a good reason for me to be here at the IACC, because that would certainly come under the coordination aspect.

Dr. Insel: Well, I don't think we were expecting you to do it, but --

Dr. Dawson: Or to give yourselves more work.

Dr. Insel: -- it raises the question of who will be best to do this, and it sounds like there is enough interest from at least two of the big private organizations.

We ought to put our heads together, and maybe we can do some of that over lunch, which we'll be breaking for in just a moment. Ari and then Gerry.

Dr. Fischbach: Accompanying this survey ought to be an educational statement as to why this is being suggested and why it should not impact service delivery, rather than just ask whether it will be, whether it will impact, because I think there's going to be a huge education effort needed.

Dr. Insel: Right, so this -- it may -- that's a great point. It's a chance to preempt some of the things that we're worried about. Ari, and then Lee will get the last comment, and then we'll break.

Mr. Ne’eman: First, thank you very much for presenting this and for the transparency you're showing in this process.

My question is, you know, I've noticed that you -- and I think you released a draft of this earlier in the process, so there is a proposal for a severity scale, which seems to be where the DSM-5 is going in general.

First, how do you hope to recognize the change that can occur over the lifespan as people develop new skills in such a severity scale, or people have severe challenges in one domain and mild challenges in another domain?

And then the second half of that question is, I'm wondering how you're going to avoid the use of that severity scale as a way of defining what I think you would refer to as treatment objectives.

My concern is that there are certainly autistic traits, certain autistic traits like encompassing preoccupations, which in some contexts are disabling, and in some contexts it may be strengths, as well as traits like hand-flapping or other forms of stimming which serve a definite purpose.

And if you're defining a trait -- severe as having a lot of these traits and less severe as having less of these traits -- how do you intend to avoid the risk that clinicians will take that as guidance to eliminate non-harmful autistic traits that may serve an important purpose for the individual?

Dr. Swedo: I thank you especially for your comment, Ari, because it allows me to point out that Ari and his colleagues have been very influential in this process in terms of opening our eyes to some of these questions, and it's the reason we didn't have a severity scale posted with our initial draft criteria, because of exactly what you've pointed out.

Is it the goal to get rid of things that may actually be adaptive behaviors? It shouldn't be, so without in some ways the DSM as a whole making a decision about impairment and what role it can play, it's not possible to define such a severity scale.

And we also -- we're enlightened to the use of words such as severe, mild, moderate, and just what that would do in terms of not only services delivery, but some kind of labeling that might not be useful.

So we had promised initially a severity scale. The committee is currently struggling with exactly that issue, and the probably most likely approach, if there is a severity scale -- and I think that's now the question, rather than what will it look like -

- if there is going to be one, it will most likely be by individual domain with some of the specifically impairing symptoms pointed out.

Dr. Insel: Lee, last comment.

Mr. Grossman: It's nice to follow Ari on this, because on that panel there will be a person on the spectrum, and that was one of our concerns, too, are these innate traits of a person with autism. We don't want them to be looked at as negative, and if you're changing a diagnostic criteria such as this, it can create mayhem in terms of how services are delivered.

The purpose of the town hall meeting is kind of to collect this -- the varying issues that are out there regarding this and then to compile them and then to begin to work together through a process, having what we hope will be about a year and a half to go out and educate.

We see this as a tremendous

opportunity to educate agencies and service providers and the public in general about autism and what needs to be done and then engage with agencies, most of which are around this table -- like CDC and Department of Education, CMS -- so that this new criteria, when it hits the state level, which it will, and the local level, isn't used as a criteria to deny services, which has happened in the past when DSM criteria have changed on particular diagnoses.

Anyway, we look forward to working with everybody that's around this table to make this happen, and to make it a very positive step forward.

Dr. Insel: Well, I was a little concerned when we scheduled your presentation, Sue, because we had missed the period of public comment, which ended on the 20th, but it now looks like there is another opportunity coming up after the field trials.

There will be other opportunities

to gather information from different organizations that are here, and what I'm hearing from this conversation is a need for us to pull some of the forces together to look in a kind of preemptive way at what the impacts will be of some of the suggested changes. Am I right in understanding that should we discover something that's of real concern, that could still have some --

Dr. Swedo: Absolutely.

Dr. Insel: -- influence on how this rolls out?

Dr. Swedo: Absolutely. I think that the first draft will look primitive compared to the next draft, and I fully anticipate that as we move closer and closer to refining this to deliver what we need it to, which is defining a set of individuals who require special services for a special set of symptoms, that that's our goal.

Dr. Insel: Okay. Good. Given the time, we're going to break here. I know that there are other people who have questions, but Ellen?

Ms. Blackwell: I just have one quick comment. For the new members, we do have a services subcommittee, and in hearing this discussion and especially the fact that we brought it up, I'm wondering if this isn't an issue that the services subcommittee could assist the committee with, you know, delving into how diagnosis could impact service delivery.

Dr. Insel: Could we -- let's hold that thought for about 90 minutes, and let's bring that up this afternoon, because I do want to talk about it. It's not on the agenda, but, Ellen, can I trust that you will come back to this during the time this afternoon, because we should talk about the services subcommittee and next steps, and this could be added to it, so that would be great.

We're going to break for lunch. There is a cafeteria in the food court below us. It's on the concourse level, and we'll reconvene here right at 1:30, right on time so we can begin the public comment period. Denise, I assume you're still with us.

Ms. Resnik: I am still with you.

Dr. Insel: So we'll be back online in 60 minutes.

Ms. Resnik: Okay, great. Thank you.

(Whereupon, the foregoing matter went off the record at 12:33 p.m. and resumed at 1:31 p.m.)

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

1:31 p.m.

Dr. Insel: There's generally about a 30-minute period we have an opportunity to hear from a variety of voices from the public. Generally, people who either are not represented or don't serve on the Committee.

We ask for them to spend three to five minutes to give us input about a point of view that they think is important for us to hear.

At the last IACC meeting, we discussed how we should be responding to these comments. You have them written down in your folder. So, you have all the public comment that's provided to you before the meeting.

What we'd like to do is use a session at the end of the day today for us to discuss what you've heard during the period that we have now from 1:30 to 2:00.

So, we don't generally respond at the same time when there are questions or when there are points of view brought up, but we do want to make sure that we have a chance to discuss each of these later in the day.

So, let me begin. The first person on our list is Eileen Nicole Simon. And if you can use the microphone up there, probably that's the easiest way to do this.

I think we've set this up so you have about three to five minutes. Somewhere in there.

Ms. Simon: I'll try.

Dr. Insel: I'll tell you what I'll do is when we get past five minutes, because there are other people who want to speak too -

Ms. Simon: I know.

Dr. Insel: - I'll give you a hand signal just to -

Ms. Simon: All right.

Dr. Insel: Okay.

Ms. Simon: So, I rewrote what I wanted to say, but it's outlined in the program.

The Strategic Plan needs to include something on birth injury and how trauma and anoxia affects the brain. How safe are obstetric and neonatal procedures?

Vaccinations are highly visible treatments and rightfully questioned as a cause of harm, but what about less visible interventions, or interventions we have been taught to take for granted?

It has been pointed out to me that clamping the umbilical cord at birth may be very dangerous. Effects of clamping the cord are unpredictable.

The newborn lungs cannot function until blood supply to the alveoli is established.

This blood should come from the placenta. But if transfer of blood from the placenta is blocked, blood for the lungs will be drained from other organs.

If blood is drained from the brain, a well-defined pattern of ischemic injury will occur in nuclei of the auditory pathway.

The Apgar score may be a perfect ten, but the baby left with auditory system impairment severe enough to prevent normal language development.

Developmental language disorder also needs a higher priority in the Strategic Plan. The unusual hypo and hypersensitive signs of auditory system dysfunction likewise need to be made a higher priority for research.

I have cited the evidence for auditory system vulnerability to all of autism's many causes in my written comments, and they're online at conradsimon.org, the website that I've had up there for ten years.

Do I have time to add a little more?

Also in my written comments and online, I have urged that mandatory long-term care insurance be required for all citizens from birth to cover the huge cost of life span care.

Requiring long-term care insurance would also involve actuarial scientists in research on why the prevalence of autism continues to increase.

And I have put much - I think you have eight pages, and it's all online, and I have a whole section that I responded to back in January when I couldn't come.

Dr. Insel: Thank you very much. Let me refer the Committee to the documents that are in your folders under - it says Oral Comments. And there's a considerable amount of information there, including CAT scans of the inferior colliculus and anatomy and other things. Thank you.

Ms. Simon: Okay. And I've typed these up and I'll e-mail them to Lina, who wanted these exact words.

Dr. Insel: Perfect. Thank you so much.

Ms. Simon: Thank you.

Dr. Insel: The next public comment is from Jim Moody on behalf of Lori McIlwain.

Mr. Moody: Good afternoon. These are for the National Autism Association, and congratulations also to the new members joining IACC today. You have a lot of work ahead of you.

Previous requests from the National Autism Association have primarily focused on an increase of environmentally-based research and the overwhelming need for biomedical treatment funding, the acknowledgment of underlying pathologies and the study of vaccinated versus unvaccinated populations.

Our position on these issues remains the same. Today, however, we wish to address the external causes of death among our autism population, and how the lack of research has led to an absence of preventive measures, mass awareness, resources and emergency interventions.

Yesterday Erik Lippman, a 30-year-old man with autism, was found dead after wandering from his home in Santa Cruz.

Last week Aiden Johnson, a three-year-old boy with autism, drowned in a creek near his home.

Two weeks prior, Christian Johns, a six-year-old with autism, was found dead in a pond.

Before that, James Delorey, a seven-year-old with autism, wandered from his home in the frigid temperature and was found two days later. He died shortly thereafter.

Bernard Latimore, age nine, died in a neighbor's pool. Devon Fraser, age 11, was struck and killed by a truck. These are just a few of the recent deaths related to wandering.

Last week Aiden Johnson, a three-year-old boy with autism, drowned in a creek near his home.

In 2008, Danish researchers found that the mortality rate among the autism population is twice as high as the general population.

In 2001, a California research team found that elevated death rates were due to seizures, respiratory problems and gastrointestinal bleeding. Deaths were also attributed in large part to suffocation and drowning.

The National Autism Association is working to address the external factors. In particular, most notably, suffocation due to improper restraint procedures and drownings.

Drownings, prolonged exposure and other wandering-related factors remain among the top causes of death within the autism community.

The fact that we are unable to provide data showing how many adults and children die each year due to wandering is why we are here today. We can assure you that deaths are increasing each year.

We have no research to back up our claims. Without hard data it has been difficult to gain the attention of lawmakers, government health agencies, media and law enforcement agencies.

Wandering prevention materials distributed by pediatricians to caregivers is imperative. Assigning a subclassification ICD-9 code for autism elopement could help provide insurance coverage for safety devices, raise the seriousness level of the condition and open up critical dialogue between physicians and caregivers.

Minors with autism are not yet covered under the Amber alert or Silver alert systems. Because Amber alert criteria only include abducted children, it is our goal to revise the guidelines to include any child with a life-threatening condition.

We need funding for Project Lifesaver tracking equipment, law enforcement training, access to swimming lessons and home security measures. We need awareness efforts and a better understanding of how and why these deaths are happening, how many times they've happened and how much they may be increasing.

We also need to understand that children like Aiden were in the care of their grandparents, other children were in the care of their parents, my child, this is Lori McIlwain, in particular, has gone missing from three different schools.

Our children are not wandering because of neglect or bad parenting. They are wandering because they have a medical condition. They die alone and die terrified. Many without a voice to call for help.

If we're all here to support research that increases progress, prevention services and quality of life, we must ask ourselves how much we're doing to our lives.

The National Autism Association

respectfully requests your thoughtful review of autism elopement issues and your help in seeking services and awareness that could prevent more deaths. Thank you very much.

Dr. Insel: Thank you very much.

Carolyn Rodgers.

Ms. Rodgers: Good afternoon. I know that many hours went into updating the Strategic Plan and that ending autism is a deeply-desired goal.

With that in mind, I am here to ask you to modify the Strategic Plan even further to include calling for research into the role that prenatal ultrasound may be playing in causing autism. Delaying this investigation another year could contribute to an unprecedented increase in autism.

In January when I addressed this committee, I shared what I discovered when I integrated the findings of three Centers for Disease Control reports. Those were the autism prevalence, the 2002 PRAMS surveillance report, multi-state exhibits for prenatal care, timing and adequacy, and the 2002 PRAMS surveillance report, multi-state exhibits, Medicaid coverage for prenatal care.

To recap briefly, the combined information painted a troubling picture. As more women across all ethnic groups received prenatal care, the autism rate among their children increased with greater increases among the groups that had more early prenatal care.

Since prenatal care was implicated in higher autism rates, prenatal ultrasound deserves especially close scrutiny.

Today I bring to your attention a study that could explain some of the latest autism prevalence statistics. The study, trends in prenatal ultrasound use in the United States, found that the average number of prenatal ultrasound scans nearly doubled over a ten-year period ending in 2006.

It also found that southern women

were 40 percent less likely than northeastern women to have an ultrasound scan during a prenatal visit, and that Hispanic women were 20 percent less likely to have an ultrasound scan than white women.

If prenatal ultrasound is causing autism, it is no surprise that two southern states, Florida and Alabama, had the lowest autism rates among those states monitored.

It also explains why Hispanic women consistently had the lowest autism rates in both the 2002 and 2006 CDC prevalence reports.

Not all southern states had low autism numbers, but the study limitations did not take into account keepsake ultrasounds, a thriving industry that could skew results. But combined, the fact that southern women and Hispanic women were both less likely to get ultrasounds, starts to explain an apparent statistical anomaly that was in the 2006 report. Which was while the overall autism rate in the united States was increasing 57 percent, Alabama Hispanics had a decrease of 68 percent.

Now, the low incidence of autism in Hispanics did not hold true in Florida. But in Florida, the only county monitored was Dade County, which has a very high Hispanic population, and also has a very wealthy Hispanic population. And it's possible, we don't know this, it's possible that among this population their ultrasound tendencies whether to have the keepsake ultrasounds or additional medically-indicated ultrasounds, are closer to those of other wealthy areas.

In the Committee's Summary of Advances which we received today, one key finding was that for every ten-year increase of a mother's age, her risk of having an autistic child rose 38 percent.

Could this be related to the trends in prenatal ultrasound use findings which discovered that across all periods, women over 35 along with high-risk groups, received the most ultrasounds? Women in their 40s had 50 percent greater odds of receiving an ultrasound than women in their 20s.

Was there any warning that prenatal ultrasound could cause anything like autism? Yes.

A 1982 World Health Organization report on ultrasound in its human fetal study summary concluded, quote, animal studies suggest that neurological, behavioral and developmental changes can result from exposure to ultrasound.

If prenatal ultrasound is a leading cause of autism, we might start seeing an autism rate approaching two percent by 2014, a trend that typically would not be reported until 2016 at the earliest.

Can we afford to wait six more years to start investigating prenatal ultrasound in further depth?

I am asking the Committee to

aggressively call for relevant studies starting now. You gave yourselves the authority to take such bold steps when you created the Committee's top core value which calls for a sense of urgency to respond rapidly and efficiently when challenges arise.

If there is even a chance that prenatal ultrasound is causing autism, due diligence requires that you take whatever measures are necessary to have it investigated without delay. Thank you.

Dr. Insel: Thank you very much.

Lindsey Nebeker.

Ms. Nebeker: Good afternoon. I would like to thank you all for giving me the opportunity to speak to you today.

My name is Lindsey Nebeker, and I am personally representing myself as an individual with autism. I was diagnosed at 19 months, began to speak at the age of four, and underwent several years of various speech, behavioral and other interventions.

I have one younger brother, James, and he's also diagnosed with autism. Even though we share the same diagnosis, the way that autism is manifested sets us far apart.

I am verbal while my brother does not speak. My education was generally mainstream, while my brother responded more effectively in a special education setting.

Even though I have faced many challenges in growing up, I have been fortunate enough to learn how to speak, receive a college degree and live independently without additional supports.

For James, it was more complicated. We tried speech therapy, sign language, PECS and AAC devices. And sadly, the results have been extremely limited.

From his frustrations, his aggressions and his cries, I know he wants to communicate and be understood.

I have met parents who go through similar struggles of trying to teach their nonverbal autistic sons and daughters, children and adults, to communicate and be understood.

Some do thrive on the methods that I have mentioned, but some do not. And I believe with continued research on communication, we can come up with additional ways to give nonverbal autistic individuals the greatest gift of all, an opportunity to communicate and be understood.

I am very open to new ideas and possibilities that research can do for behavioral, educational and other treatment methods which are deemed safe and ethical. I also support any genetic research which is deemed ethical.

However, because of the current need of providing effective services for families, we need to focus the majority of our funding towards assessing early intervention, transitional services and other effective intervention methods.

We need to focus on the current need, because today we, as Americans, are living in the current need.

I know very well how vast the autism spectrum is. James has given me the opportunity to see this. And after years of meeting and working with kids, adolescents and adults like him, I understand the reality of how different life can turn out for each autistic individual.

James is now 26, and for the past ten years has been enrolled in a community housing program fully funded by the federal and state government with experienced caretakers.

He occasionally participates in volunteer work, but we think he needs to be given more opportunities for community inclusion. My family knows how crucial it is for the government to step up on providing housing, transitional and employment services for people with disabilities.

Growing up in the `80s and `90s, the early intervention my brother and I was directed to was easy to locate. However, my parents were at a loss of where to direct us afterward.

The options laid in front of us were either a path towards full independence with no supports, or complete dependence with full supports. We weren't aware of the options in between.

I was fortunate enough to take that path to independence, but my brother was left with no other option than to take the path of complete dependence.

Over the past two decades, I have witnessed very gradual improvement in support groups, transitional programs and housing programs. I have begun to hear the adolescents and adults being brought up in the conversation, and I strongly encourage that we keep including adults in the conversation because they are among our greatest teachers in the autism community.

There are many autistic adults in our country who are seeking help and don't feel like they have a voice. We need to provide them with a voice.

As a female with autism, I felt even more alone during my school years. No support group, no programs tailored to girls in the spectrum. I felt alone and I felt silenced.

It wasn't until after college that I gained the confidence and courage to disclose my autism, and my hope is that no other women with autism have to grow up like that where they feel afraid to speak up because they are no longer brought up as much in the conversation on autism. Especially teen girls and adult women in the autism spectrum.

As a female with autism, I feel there's a need to increase the focus on research for females on the autism spectrum.

My signs were profound enough that I was able to receive a diagnosis at a young age. However, the majority of girls with autism are diagnosed later in life than boys because the indicators are often undetected and often mistaken as a state of extreme shyness.

When you hear that girls with autism tend to suffer in silence, it's true. Women with autism need to be included in the conversation.

In closing, regardless of where we all stand on personal views, we can all accept that autism is presently a life-long condition. These children will someday become adolescents, and these adolescents will someday become adults.

Parents and other members of the community may vary on their personal beliefs on views on autism, but they all do agree on one thing: providing the best for their children.

There are many parents I have met

who are still left in the dark as to where to direct these children after early intervention is completed. And from my personal experience, as well as my brother's experience, I must stress to you that services cannot end in early childhood. Services will be needed throughout the life span.

I can testify to you that every child, adolescent and adult with an autism spectrum disorder no matter where they are in the spectrum, deserves to receive care, live to his or her full potential and are entitled to have a voice like every other American citizen and nations elsewhere. Thank you.

Dr. Insel: Thank you. Our final comment today will be from Paula Durbin-Westby

Ms. Durbin-Westby: Thank you, Lindsey. Thank you for the opportunity to comment. I am Paula Durbin-Westby. I'm on the board of directors of the Autistic Self-Advocacy Network.

On behalf of ASAN, I would like to

welcome the new members of the Interagency Autism Coordinating Committee. The Autistic Self-Advocacy Network is the leading organization run exclusively by individuals who are on the autism spectrum.

We count among our supporters, people on the autism spectrum, parents of children, teens and adults on the spectrum, educators and practicing professionals.

For those new IACC members who are not aware of ASAN's priorities for the Interagency Autism Coordinating Committee, I'm going to list the priorities we have brought to the IACC over the past several years.

I do have one item that I'm crossing off my list for now, which is add another autistic individual to the IACC, one with the point of view emphasizing acceptance of disability and a proactive stance towards services and supports.

It is also critical to have people who have a disability be involved at all levels of policymaking. I am pleased that the IACC has realized the wisdom of adding additional autistic members. And also as a committee with multiple members on the spectrum, I urge you to adopt strategies that steer away from the language of burden, sadness and move toward a more positive stance and appropriately objective language.

ASAN's other priorities are these: focus funding toward research and practices that will have practical benefit for people on the autism spectrum, our families, friends and communities.

Focus on services for people on the spectrum throughout the life span, including adults, under-served populations such as ethnic minorities, women on the spectrum and people who do not use language-based forms of communication.

Redirect research attention toward developing functional communication systems through developing and making accessible alternative and augmentative communication systems, and individualizing communication systems so that each autistic person can have the most accessible means of communicating.

As an adjunct to this, make IACC meetings and materials accessible to people with a wide range of disabilities, both physical accommodations, communication differences, intellectual, cognitive and developmental accommodations.

Focus away from a fixation on causes and cures, especially when these research focuses on a variety of genetic or genomic differences and various biomarkers for autism have the potential to bring about a eugenics focus or the selection out of the gene pool of a certain subset of the American population. Keep eugenics out of autism research.

Ethical concerns must be kept foremost, and the ethical concerns need not stop with the concern about how to transmit notions of risk during pregnancy.

Ethical issues should also be addressed when researching medical and pharmaceutical treatments, behavioral interventions sometimes also know by the simpler term education, that without careful consideration of unintended consequences, may be physically, psychologically or emotionally harmful to the individuals receiving these treatments.

All such research and subsequent practice must be rigorously monitored so that the health and well-being of the individual person on the autism spectrum is the first priority.

In some cases as Ari pointed out during the DSM-5 discussion today, treatments and interventions will be contraindicated. In others, respectful and thoughtful strategies can be used.

Those researchers who work in

close consultation with and call on the expertise of those of us living on the autism spectrum in research areas of development, interpretation, implementation and evaluation, are the researchers who will be most likely to make advances that will directly impact the lives of autistic people in a positive way.

In closing, I'm going to quote from Ari Ne'eman's testimony at the November 30th, 2007 IACC meeting.

We encourage this committee to take the first steps towards shifting the main buzz word about autism from cure to communication, and ultimately to moving the dialogue about the autism spectrum to one of acceptance, inclusion and, above all, respect.

Thank you.

Dr. Insel: Thank you very much. That completes the public comment session. As I mentioned, we'll circle back to this later in the day so that you will have a chance to comment about the public comments and provide some responses, as well as amplify anything that's been discussed.

We're going to move on to the research updates. We have three of them. We'll start with a presentation by Jim Battey on stem cell research.

And Jim has been intimately involved with this topic and led the NIH effort on stem cells for about three years. So, he's an ideal person to take us through this.

Dr. Battey: Well, thank you, Tom. I'm delighted to do this today. What I'd like to do over the course of the next 20 minutes or so is to tell you what stem cells are, where they come from, a little bit about their biology. And then a little bit about how we get stem cell lines of various types, various sources. A little bit about the moral and ethical controversy that revolves around stem cells that are derived from human embryos. And then finish up with a brief summary of what the new federal funding policy is for research involving human embryonic stem cells.

So, let's begin with what a stem cell is. Stem cells have two fundamental properties. They are able to recapitulate themselves or replicate, and they're also able to become any one of a number of adult cell types.

Now, you can find stem cells lots of places. Many organs such as the gut, the central nervous system have stem cells in their population. And in these organs, they tend to be rare. And typically they can recapitulate the adult cell types that are characteristic of that organ, but not adult cell types characteristic of other organs.

Now, a very special kind of stem cell is called the pluripotent stem cell, and we're going to talk most of the rest of the time about pluripotent stem cells and where they come from.

When I say pluripotent stem cell, I mean not only does the stem cell have the ability to recapitulate itself indefinitely as far as we know, but it also has the property to become any one of the nearly hundreds of different cell types in the human body. And it's these unique properties that make scientists particularly interested in pluripotent stem cells and hold out hope for stem cells to teach us a lot about how the body works, and maybe offer the opportunity at some point in time for cellular therapies.

So, really the promise of stem cell research is many fold. On the left-hand side of the slide, you can see that - that's the button I'm never supposed to touch. I'm sorry.

The left-hand side that you can take pluripotent stem cells, differentiate them into a specific cell type, and use this as a human cellular model to screen for drugs. Both drugs that are efficacious or toxic.

And this is a very powerful tool for the pharmaceutical industry, and they are embracing this and developing screens of this type as we speak. And this in fact may be the first place where we'll see a good therapeutic outcome as a consequence of the development and study of pluripotent stem cells.

Of course anyone who's picked up a newspaper or looked at a television set will recognize immediately that one of the other promises of stem cell research is the capacity to ultimately generate a cell population that's been ravaged by disease such as dopamine-generating neurons in Parkinson's disease, insulin-producing beta islet cells in Type 1 diabetes, just to name a couple of examples.

And we hope someday that we'll get there, but I'm here to tell you today we are not there yet. We're at the very early stages of understanding how to coax those stem cells into becoming a specific cell type that might be used ultimately for transplantation therapy. And there are some potential issues with transplantation therapy that I think make it problematic and probably not the first place we will see stem cells coming to the clinic.

We really began studying embryonic stem cells, stem cells derived from the inner cell mass of a blastocyst, in 1981 in mouse models.

This then progressed to studies of embryonal carcinoma cells in mice and human, helped us to establish the properties needed for growing and assessing embryonic stem cells.

As I mentioned before, embryonic stem cells, stem cells derived from a five-day-old blastocyst, which is a structure that five days after fertilization consists of a hollow shell of several hundred cells - thanks, Tom - that form the trophectoderm.

That shell will ultimately go on

to become the placenta and the umbilical cord. And at one pole of that blastocyst, that five-day-old structure - there are 30 to 50 cells that comprise the inner cell mass. The inner cell mass is the part of the embryo that will go on to become the fetus and ultimately the baby.

Those cells at that stage, the five-day stage, have the capacity to become any cell type in the body. And it's by removing that inner cell mass and placing it into culture that we get embryonic stem cells and embryonic stem cell lines.

Now, immediately I think you can see the moral and ethical dilemma here. And that's that if you believe that the five-day-old blastocyst is the moral and ethical equivalent of a human being, you have destroyed a human being in the process of generating that cell line. And there are some who have that belief, and that's what's generated all the controversy surrounding embryonic stem cells.

So, just to recapitulate, all the embryonic stem cell lines we have to date were generated from embryos in in vitro fertilization clinics.

And that's what a five-day-old blastocyst looks like, just to give you sort of an image. It's much magnified. You could barely visualize it without magnification in its normal size.

So, as I mentioned before in an in vitro fertilization clinic, you'll have fertilization of the oocyte, the embryo will develop by three days to about eight cells, it will then go on in two more days to become a blastocyst. And by removing the inner cell mass from this blastocyst, you can get an embryonic stem cell line.

Now, I mentioned before that there are stem cells in a variety of organs. And this just names a few of them. But in these organs, they're relatively rare. They have a more limited capacity for self-renewal than the pluripotent embryonic stem cells, and they have a limited capacity for differentiation, which is usually limited to cell types in the organ in which they're found.

Now, three years ago we had a very exciting development in the research business. A new way to generate pluripotent stem cells was discovered that did not require the destruction of a human embryo. And this was initially done as is so often the case in the mouse animal model, by a scientist in Japan named Dr. Yamanaka.

And he built his study on earlier studies of embryonic stem cells where a number of genes were identified whose expression was crucial for maintaining pluripotency and self-renewal, the two cardinal properties of pluripotent stem cells.

And what Yamanaka did was to express these genes in a fibroblast, which is a skin cell put into culture. And when he did this, he turned back the differentiation clock and restored pluripotency in those cells. This was something that many of us thought was many, many years off.

And what's remarkable is he needed only four genes to accomplish this feat. And in fact, subsequently, it's been shown that it can be done with only three of these genes, albeit less efficiently. And the studies that worked in mice, are now working in humans.

So, we call this reprogramming the adult cell. And we call the resulting pluripotent cells induced pluripotent stem cells.

These induced pluripotent stem cells share many of the same properties with embryonic stem cells. Although, they don't appear to be completely identical, which means we still need to keep research going on both types of stem cells to learn as much as we can possibly learn.

So, this is just an image of

creation of induced pluripotent stem cells with the adult skin fibroblast. And you can do this with other types of cells as well. You add the three or four reprogramming genes and your different - your cell undergoes dedifferentiation and is returned to its pluripotent state.

One of the exciting aspects about induced pluripotent stem cells is it offers the possibility to generate patient-specific stem cells.

Imagine a child with diabetes, for example. Imagine if you could take a fibroblast in culture from that individual, which will be a perfect genetic match to that individual. You restore pluripotency, and then differentiate it into a beta islet cell which you can then put back into this child with diabetes, and that might represent a cellular cure someday for diabetes mellitus.

However, there are some problems with induced pluripotent stem cells. At least the initial protocols used to generate them. And that's that the genes were expressed in these cells, the four key genes, under the control of retroviral vectors which integrated into the genome.

One of the genes that was initially used in Yamanaka's study, was a gene called c-Myc which I studied as a postdoctoral fellow. It's a major cause of human cancer. And there is a concern that by leaving c-Myc in these cells under control of a retrovirus, that the gene may wake up at some point in time down the road. And you might end up not with a good outcome after transplantation therapy, but instead with a tumor.

Scientists are working very hard to find better ways to generate induced pluripotent stem cells that don't have these risks. And good progress is being made, but this still remains a vexing issue.

And even if you solve the problem of c-Myc, if you use a retroviral vector, you're going to get integration events at random sites throughout the genome. And these integrations may disrupt critical genes, and that could be problematic as well.

So, that's one of the reasons why we still need to continue to do research on embryonic stem cells, because they do not have these genetic disruptions that's so far characteristic of induced pluripotent stem cells.

So, safety remains a concern. But, nevertheless, these iPS cells are a very exciting and valuable research tool.

Here's some examples for how stem cells can help with human diseases. Let me preface my remarks by saying that as I mentioned earlier, we're in the very early stages of basic biomedical research using pluripotent stem cells.

Before we contemplate any transplantation therapy, we're going to have to prove that the cells will function stably after transplantation.

We're going to have to understand the key factors that underlie cellular specialization. We're just now learning the growth factors and gene regulatory factors that are critical for accomplishing this goal.

We're going to have to evaluate the interaction between the transplanted cells and the host. If there's any genetic mismatch, we run the risk of the graft that was put in for therapeutic purposes being rejected.

And we're going to have to have a key understanding of cell cycle control. Because once we transplant cells into a patient, we're going to want to be absolutely sure that those cells don't continue to divide or there isn't a small subpopulation that can continue to divide, because that could lead to a very bad outcome for the patient.

So, there's a lot of research that needs to be done before we get into the transplantation phase of cells derived from either induced pluripotent stem cells or embryonic stem cells.

This slide is here to illustrate that we have been using one stem cell therapy for decades, and that's bone marrow transplantation.

The part of the bone marrow transplant that ultimately recapitulates the patient's blood system, is the hematopoietic or blood-forming stem cell.

Just recently the very first clinical trial using cells derived from human embryonic stem cells was underway at a biotechnology firm in California called Geron. And what they're doing is using human embryonic stem-cell-derived oligodendrocyte cells to try to restore movement in individuals with spinal cord damage. And this worked pretty well in a spinal cord injury model in rats.

So, how is this relevant to

autism? I have to say, in my opinion, you're not going to see any stem-cell-derived therapies for autism any time in the near future, I believe.

And the reason for that is, as we've heard at this meeting, autism spectrum disorders affect a wide range of organs and systems.

Think about the transplantation challenge that that would pose if you're really going to treat or cure the disease. We don't know which one or ones could be replaced or repaired in order to reverse the condition.

The other thing is we don't exactly know what's broken, what's not working right in autism spectrum disorders. And they're developmental in nature, which means that there may be a limited critical period where you'd be able to use cellular transplantation to treat the disorder. So, these are major challenges.

However, as I mentioned before, if

you derive human-induced pluripotent stem cells from an individual with a specific disease, this can be used potentially to recapitulate some of the cellular properties of this disease, and scientists are working hard to make cellular models.

Scientists aren't sure, though. It could vary from disease to disease. The cause could be genetic, environmental or both. It may also be affected by the time of disease onset. And these all remain challenges for developing cellular models for human disease.

And I think I'll skip over this in the interest of time. This is just - this is in your handout. These are just some of the studies that were recently funded by NIH that are looking at the possibility of stem cells on autism spectrum disorders.

For example, Dolmetsch is using induced pluripotent stem cells to identify cellular phenotypes of autism, creating cellular models for autism, and then trying to develop ways to modulate the behavior of those cellular models. And that's just one example.

Now, the investment in human nonembryonic stem cells, that's stem cells from other organs, in 2009, at NIH, is about $397 million. The investment in the comparable period in human embryonic stem cells, about $143 million. And we continue to be supportive of all types of stem cell research in the future to whatever extent we get investigator-initiated proposals that do well in our peer review process.

You can find more information on a website that NIH maintains on stem cells at stemcells.NIH.gov. And there's information on all types of stem cells at that site. Or if you have specific questions for us, send us an e-mail at stemcells@mail.nih.gov, and we'll do the best we can to answer your question.

And now if there's any time left, I'd be happy to try to answer a few questions.

(Applause.)

Dr. Insel: If I can start off, the way that this discussion got started was a couple of meetings ago when we were trying to figure out, as we were talking about the biorepositories that we should be developing for autism, whether this should be part of it.

Can you give us some insight about that?

Should we be collecting fibroblasts and making iPS cells from people who come into a biorepository where we're already collecting DNA?

Dr. Battey: They may turn out to be very interesting cellular models for developing various forms of treatment.

Dr. Insel: Sounds like a yes. I mean, it's something we should at least have on the table.

It's in the Strategic Plan and -

Dr. Battey: Are you collecting lymphoblasts for other reasons?

Dr. Insel: Well, the lymphoblasts are being collected to immortalize cells for DNA. We have about - oh, about 8,000 at this point for autism that's already in a bank. But what we haven't done is to collect cells where you could make - well, we haven't collected fibroblasts.

Dr. Battey: Yes, lymphoblasts will work perfectly well for generating induced pluripotent stem cells. You don't need to start with a fibroblast.

Dr. Insel: Okay. That means we're 8,000 cells ahead of where we thought we were. Good.

Gerry.

Dr. Fischbach: Excuse me. Maybe you could collect them, but not go through the expense of transforming them and growing them up yet until we know a bit more about steering them down different pathways.

I didn't know the lymphoblasts were just as good as the fibroblasts. That's very interesting.

Dr. Battey: Yes, you can get cells from a whole variety of sources. And with the same key genetic factors, you can restore pluripotency.

It's really quite remarkable. And I would say you could have heard a pin drop at the first conference where Yamanaka presented his results. I mean, the community was really stunned.

Although, Jamie Thompson was only - was a few months behind him.

Dr. Insel: Alison.

Ms. Singer: What is the procedure for harvesting skin fibroblasts?

How invasive is it and what does it cost?

Dr. Battey: It's a skin biopsy, basically. You basically take a little snippet of skin, and then put a stitch in to restore the integrity of the skin. And then place that in the culture, and you get fibroblasts growing up.

Dr. Insel: Yes.

Dr. Dawson: So, I understand from a recent meeting that was put on at Keystone, that there have now been some work in schizophrenia where they have developed a model of cellular function at the synapse.

And I wondered if you know anything about that and if you could share it with the Committee.

Dr. Battey: I haven't been to Keystone lately. So, I'm sorry, I'm not familiar with that work.

Dr. Dawson: Oh, okay.

Dr. Battey: I probably ought to be, but I'm not.

Tom, do you know anything about that?

Dr. Insel: I don't know about that particular project. There's a lot of interest in the same methodology for other disorders. Particularly developmental disorders like schizophrenia.

Most of the focus as Jim said, from the examples he put up there, are going after those people who have an identified highly penetrant mutation like disk 1 or the 16 people in 1 or 21q, those individuals where we're trying to get cells in culture that will be available for study.

But that is certainly possible in autism where you have Rett and Fragile X and a number of other syndromes that cause the features of autism where one could study different families of neurons that you could grow out in culture. And hence the interest in wanting to do this in a repository.

Any other questions or comments?

Walter.

Dr. Koroshetz: Jim, the only comment I have in terms of some of these tough therapeutic challenges, is the potential that some disorders even though, like, in our field, for instance, Huntington's or ALS where there's neurons dropping out, the idea of reconstituting the neuron seems awfully difficult.

But the interesting thing is that it's been discovered that some of the support cells, the glial cells, for instance, are actually part of the problem and that replacing them may be something that's much easier and still have therapeutic effect on the function.

So at the synapse, for instance, we all concentrate on the neurons, but it's probably the glial that are actually at the bottom of some of these problems. And so they may be something that might be easier for some of these diseases.

Dr. Battey: That's a very cogent remark. And just to build on that, you know, one of the other good outcomes of studying differentiation in stem cells is, we may be able to coax an individual's endogenous stem cells into differentiating into cells that have been damaged by disease. And most protocols would not require transplantation, and there would be no risk of rejection because the cells would be recognized itself.

Dr. Insel: Gerry, last comment.

Dr. Fischbach: I think you should collect them. Because regardless of the barriers and hurdles along the way, the notion of being able to genotype these cells, as Geri was saying earlier, and tailor therapies to specific genotypes, is overwhelmingly appealing.

So, sooner or later, these problems are going to be resolved. So, the fact that you can create this diversity, genetic diversity, is really important.

And I also want to comment on Walter's point. The notion of different cell types might be involved is something always to keep in mind -- not because it's either glial or nerve cells, but it may be both.

There are many disorders now where

it's clear these are not cell autonomous. You cannot reproduce a disease with one cell type or the other. You need a pair of them. That's certainly true in something as clear as ALS affecting motor neurons. You cannot reproduce that disease by introducing the mutation only into motor neurons or only into the glial cells. You need both of them, in fact, and that should bear on studies of iPS cells.

But the potential, the Yamanaka discovery is earth-shattering, I think, and it ought to be taken advantage of.

Dr. Insel: So, it sounds like the take-home message here, Jim, if we're getting this right, is that we aren't ready to think about this for therapeutics, but may be a very important point to think about this for diagnostics or at least for understanding more about the cell biology of autism.

Dr. Battey: That's certainly the state of the art right now, yes. But it's always risky to make predictions about the future, as you know.

I don't think many of us who are involved in the initial studies generating recombinant DNA ever imagined that within 25 years the human genome would be sequenced.

Dr. Insel: Well, with that note let's move on to the next presentation which is from Helen Tager-Flusberg who's coming to us from Boston University where she is the director of the Laboratory of Developmental Cognitive Neuroscience.

Dr. Wagner: Hi. I'm not Helen.

Dr. Insel: Hi, Ann. You don't look like Helen.

Dr. Wagner: As much as I would like to take credit for her accomplishments, I'm Ann Wagner. I'm just going to give you some context for this workshop, and then Helen will give you the details.

So, this workshop on nonverbal school-aged children with ASD occurred just a couple of weeks ago. You have heard today, and those of you who were working on the Strategic Plan for autism research have been thinking out grappling with the vast heterogeneity in this spectrum of disorders. And the Strategic Plan very strongly recommends understanding different subtypes and different phenotypes, so I think that this topic fits in well there with the Strategic Plan's intent.

The original, I guess, impetus for this workshop occurred last summer when Portia Iversen, who many of you know as the founder of Cure Autism Now, and formerly on the board of Autism Speaks, and currently a member of NIH's advisory board, set up a meeting with several program staff from NIH to talk about her concern that there's a relative dearth of research that really focuses on understanding individuals with autism spectrum disorders who either don't develop verbal language, verbal communication or struggle with it a lot, and the need for more research in the area.

She had been involved or I think actually organized a couple of meetings sponsored by Autism Speaks on this topic earlier, and wanted help keeping the ball rolling.

So in parallel to that, you all were soliciting input from the community through requests for information related to the Strategic Plan, and this was a topic that came up frequently in those responses and we were looking and reading those as well.

So, Judith Cooper from NIDCD who really should be standing here, but is not available today, sort of took the ball and ran with it and organized this workshop. And she recruited two preeminent researchers: Connie Kasari from UCLA, and Helen Tager-Flusberg from Boston University, to co-chair this meeting.

This was, from our perspective, an incredibly helpful workshop where the investigators, who, you will hear more about the participants, but the participants were from a range of backgrounds and disciplines and really took to heart our request for them to tell us, sort of, what do we know, what do we need to know, what are some opportunities that really might move the field forward?

And it is fully our intent to keep meeting together for NIH to try to figure out some ways to help facilitate moving forward.

So, I'm going to turn this over to Helen, who is right here, and she'll tell you the details. Thanks.

Dr. Insel: Thank you. That's a great introduction.

Welcome, Helen.

Dr. Tager-Flusberg: Thank you so much, and thank you for the opportunity to present this workshop. It is still extremely fresh in my mind, maybe that's a good thing, but I'm really here to present on behalf of the group as a whole.

As Ann mentioned, the leadership was provided by Judith, and also Connie Kasari. And I worked together with members of the Planning Committee who were drawn from across NIH, and many of them are actually here today.

So, the goals of our workshop, we wanted to focus a day-and-a-half of serious discussion and engagement on nonverbal, by which we meant nonspeaking, okay, so some of these individuals do have means for communication, but they do not speak. School-aged children, and, by and large, we are talking about a group, a subgroup within the autism population who have gone through many different types of interventions and are continuing to, but for whom those interventions have not led to speech. And in many cases, really almost limited or nonexistent communication altogether.

So, we wanted to focus our discussion on, what do we know, what are the gaps and what are some critical opportunities that we could take hold of right now.

And we had a series of invited presentations, invited discussions and very extensive opportunities and time for discussion as a whole from the work group.

These were all the participants who were there for the day-and-a-half. And we had some additional people who attended. And these are all the individuals who presented as well as participated in the extensive group discussions. And they're drawn from many different backgrounds and disciplines and expertise within autism and outside autism research that we thought we could draw upon.

So, we focused the series of presentations and discussions on three topics: who are these individuals, how can we assess them, and what interventions are potentially effective. Okay.

So, who are these individuals? Cathy Lord presented research based on her prospective longitudinal research following individuals that she's been involved with for over 20 years.

Barry Gordon presented work on retrospective case study and literature searches on who these people are.

And Portia Iversen, as mentioned, she gave us a summary of the workshops that she had coordinated through Autism Speaks.

So, what do we know? This, in and of itself, even though it's a subgroup within the autism spectrum, is itself likely to be a very heterogeneous population. And there doesn't seem to be, as far as we can tell, a single set of defining characteristics.

But, most importantly, we don't really know much about them because it is enormously challenging to assess the skills and knowledge and abilities of these individuals.

Our current measurement tools really have extremely limited validity and almost nonexistent reliability.

We did learn from the presentations from both Cathy and Barry that it is possible to begin speaking after the age of five. Okay. It's not common, but you can do so.

Almost all of them who began after age five, did begin speaking before the age of seven.

However, Barry did present us with one case study of a young man who started therapy at about the age of 12 or 13, and who has made quite interesting gains over the last ten years, but it's been an enormous - what the presentation focused on, how many different approaches were taken with this young man and how intensive the therapy was and continues to be for him. But he does make progress, and I think that really energized the rest of the workshop.

But the other main point about this group is that there really is almost no focus at all, and they've not been included in other research studies that have been initiated.

So, why don't they speak? Well, the true answer is we don't know, but there are many possible explanations that were discussed by the presenters, by the discussants, and the group as a whole. And I've listed some of them here.

We were focusing on cognitive and neuropsychological possibilities, the lack of motivation, lack of understanding of intentional communication, symbolic or joint attention deficits, imitation, intellectual disability, severe social impairment, the presence of challenging behaviors that might interfere with communication, and then perhaps impairments in specific language mechanisms or motor or other kinds of movement disorders.

Okay. We moved on then to discuss the assessment issues. And here we focused initially on what could new technologies bring to the table of how we might assess these individuals given that our current set of tools is really very limited. And even within this, there are challenges.

We haven't put up and we didn't hear presentations about magnetic resonance imaging, and that's because even for some of these technologies there are severe constraints. And it is enormously difficult to get a nonverbal individual in a waking state, to remain motionless and to comply with the very rigorous protocol of an MRI or an FMRI assessment.

So, these still pose challenges even for the technologies that we did discuss that I've illustrated here.

So, we presented - I talked about eye movements, Nicole Gage on MEG, and April Benasich on EEG and ERPs, all of which provide what we'd call implicit measures of cognitive and/or brain function. And they're implicit in that all of them can be used to assess, and we focus primarily on language-related capacities including auditory discrimination with completely passive paradigms.

All the individual has to do is either look at the monitor in an eye-tracking technology, or wear the cap for EEG/ERP to collect the electrical signals, or stay inside the helmet for the MEG, and then you can present stimuli and you observe eye movements or brain activity to assess their processing of whatever stimulus it is that you're presenting them with.

And our work has shown that eye-tracking measures do have some capacity to assess what these individuals might understand or might not understand when presented with spoken language. They seem to be reliable and valid.

MEG has been used so far to investigate auditory processing. And EEG/ERP, this is a proof and principle study that's just underway and we don't know the results of it yet, but could be used to assess brain processing of language similar to what we could do with other methods.

Okay. Now, we know that along with the challenges for these individuals who are nonspeaking, a majority do also have sensory motor, and there's a lot of discussion in the literature about whether nonspeaking individuals have apraxia, what's called childhood apraxia of speech.

So, we had a series of presentations on this. It turns out there are no published studies in the literature on sensory impairment, sensory sensitivities in this population. And also, that there are severe limitations in the methods of assessment for the entire autism spectrum. Okay.

Motor skills are terribly interesting to investigate because they do provide a potential window into brain mechanisms, particularly brain mechanisms that might be related to speech and language. But, again, compliance with the protocols to assess motor skills are really beyond the capacity of these individuals in the sense that they're just not reliable or valid. And we may need protocols that assess both voluntary and involuntary movements that may be implicated.

So far there is no evidence that nonverbal autism spectrum disorder is associated with childhood apraxia of speech, but again we actually don't have the specific data on the kinds of language markers that are used to diagnose childhood apraxia of speech.

So, future directions? Well, I think there's a lot of promise in the kinds of implicit measures that we talked about at the meeting, but we need much more research on them. We need to extend their use from the research lab. And eventually once we've demonstrated their efficacy in assessing these individuals, move them into the clinic.

And even though they are more

expensive, perhaps, than standard behavioral assessments, there's no reason why we ought to be denying the opportunity to do the kinds of assessments that may show the greatest promise with this population.

And perhaps most interestingly we had an extended discussion of how research could incorporate, and then eventually clinical practice could incorporate, novel assessments into treatment and intervention research.

So, what interventions are effective? We had two presentations on nonaugmentative approaches. Laura Schreibman talked about standard behavioral approaches which cover a variety of methods, discrete trials, some of them newer naturalistic developmental approaches which are effective with some children, okay, particularly those who do engage with toys earlier, but they're not effective for all individuals. And we heard quite movingly from Lindsey about that earlier.

There is a new study under way. Connie Kasari, Becca Landa and Anne Kaiser are running this using what's called a SMART design, Sequential Multiple Assessment - I can't remember it all. And they're comparing two treatments; joint attention plus milieu therapy, which is a form of behavioral therapy, to joint attention with augmentative communication.

And this is being carried out with nonverbal individuals who are five to seven years old, and it will be a six-month protocol.

On the augmentative side we heard from Nancy Brady and Mary Ann Romski. Augmentative covers all nonspeech means including PECS, sign speech generation devices, which is the new term for VOCAs. These can be effective in increasing communication and decreasing challenging behaviors. And they can in some individuals, lead to speech and literacy development.

However, it's very disappointing in the research that looks at how they're employed at home and in schools, to find that there's extremely limited use of these devices even when a child actually has been introduced to them.

So, future directions? Well, we know so little about treatment with this population because even the treatment studies that have been published very rarely provide much of a description of the participants.

The study designs are quite limited. Mostly single cases. And there's a strong need for newer research with more flexible designs. For example, response to intervention designs, investigating longer-term outcomes, looking at predictors so that we'll get to a point of being able to match interventions to individual child characteristics.

And there's huge measurement

issues. We don't really know what is meaningful change both in language, in speech and in other areas of the child's behavior repertoire. And there's an urgent need for novel interventions for this population.

We did talk about a variety, but I think we need to go well beyond what's been tried and what we've got in our repertoire. And we've got to move well outside of that, looking to other patient populations, perhaps, for examples of ideas that might be introduced.

And it was interesting to note that many of these individuals are actually excluded from ongoing research investigations, even research studies on early intervention where often a minimal baseline of 12 or 18 months cognitive level, and we're talking now about a two or two-and-a-half-year-old in an early intervention trial, might be a minimum entrance requirement.

If a child doesn't meet that,

they're not even in our early intervention studies. And we were trying to go beyond that.

So, what are the next steps that we've concluded from this group? Well, we think there needs to be a working group put together who would develop recommended measures and benchmarks to describe the phenotypes of this population. And I emphasize the plural on phenotypes there.

And this would be used to help us establish who these research participants are when we go on to other kinds of studies, as well as being able to use these for outcome measures of treatment studies, for example.

We need to get out there a summary of what is the current knowledge in this area of autism spectrum disorder, this portion of the population and what are the gaps in our knowledge.

And we think that a paper of this sort will be very important to help to promote further research and enhance clinical and educational practices. And, of course, we need new research.

We need to advance the research on assessments. We need to start moving towards understanding what are the mechanisms that underlie the nonverbal phenotypes. And we need some comprehensive treatment and interventions research with emphasis on novel approaches.

And I've not been watching the screen. So, final words - I'm sorry to have gotten out of step there - we actually don't know at this moment in time what percentage of the population remains nonverbal after five.

We used to say in our lit reviews, and I've written quite a few of them, that it's 50 percent. And we know that that's no longer the case for a variety of reasons. This is going down.

But, nevertheless, these individuals are there, they're there as infants and toddlers, they're there as school-aged children, adolescents, as well as adults. It needs to be a priority area for future research.

And the conclusion of the group was, that unless you specifically focus on this group, they're going to land up not being involved in the studies.

I think perhaps the most surprising thing that I learned at this conference was that in existing treatment studies, even having one spoken word in your verbal repertoire was a significant predictor of further success in any kind of treatment that you might offer those children.

That's, I think, an astounding number especially after we had debated whether we should be defining this population as ten words, less than ten words, less than five words. It turns out that one is a critical distinction.

There is a great deal that we need

to learn and that we can learn from studies that begin to target this population, and that we think this is important to provide benefits to the individuals and their families.

Lindsey said being able to communicate is a gift. It's not just a gift, but as Portia reminded us at the meeting, it's also a basic human right.

So, thank you very much.

(Applause.)

Dr. Insel: Okay. We have about five minutes for questions or comments.

Chris.

Ms. McKee: In defining even one single spoken word, does it matter if it's a comment or a request, or is there any breakdown as to what that word might be? Is that a color or -

Dr. Tager-Flusberg: A word. If you could speak one word and you were then enrolled in a research study looking at a variety of different interventions, you were more likely to make gains over the course of that treatment protocol than if you had zero words.

Ms. McKee: Okay.

Dr. Tager-Flusberg: Any word at all.

Ms. McKee: And -- maybe I missed it about how you defined nonspeaking.

Are these children who have no echoic, you know, they can't make even a sound? You say "mmm," they don't say "mmm"?

Dr. Tager-Flusberg: No. We took as our minimum there, we were talking about having a spoken word used, any spoken word whether it seemed to be - of course there's always definitions about communication, so I don't want, you know, we had a lengthy discussion about the functions of echolalia, for example.

Dr. Insel: Ari.

Mr. Ne’eman: Yes. Thank you. I actually have - it's more of a comment than a question jumping off on something that you said.

You know, I think it's incredibly concerning that augmentative communication technologies and approaches aren't seeing use in the classroom or at home. And I know that, as a matter of fact, that last year this committee did hear a presentation on AAC. So, I think we have, sort of, we've been informed on the topic.

I'd like to - and you'll have to excuse me, I'm new to the Committee. So please let me know if this is not the correct point of order, but I'd like to motion that we task the Services Subcommittee with coming back to us with specific recommendations on steps that we can take.

And I know that we have in our authorizing law, the power to advise the secretary on all federal activities related to ASD, to address the lack of access to augmentative communication approaches for children and adults on the spectrum.

Dr. Insel: So, I had circled the same thing in all the comments that you made, Helen. I thought the thing that was so striking, you sort of noted this in passing, was that in the slide it says "limited real world use in the classroom, and sometimes in homes for augmentative communication."

As Ari points out, we've heard only maybe two meetings ago about the power of some of the technology that's now available.

Dr. Tager-Flusberg: Yes.

Dr. Insel: So, in reference to his point of order, did this workshop say that the technologies weren't being used because they weren't effective or because they didn't have access or because they were too complicated? What was the issue here?

Dr. Tager-Flusberg: This is based on an ongoing research study by Nancy Brady who's basically observing the use. And it's mostly with younger children in classrooms.

Okay.

And these children are all in classrooms where they do have AAC, some form of AAC, the majority is PECS, and that there's a wide range of use of it in the classroom. The teachers are the most likely to be communicating with the individual child using the AAC, whatever that was.

In the homes, it was sometimes used and sometimes not. And, basically, AAC can be quite a cumbersome means for communication. It's not -- these parents, especially of younger children, their goal is still to have their child become verbal because that's so much more direct and less - it's less problematic. Where did I put the board? Where is -- you know, how you can use those devices. And most significantly, it's almost never used for peer-to-peer communication.

Dr. Insel: Right. So, we've heard that in this committee before. But, I guess, in reference to Ari's question, is it a problem of access or is the problem that the technology just isn't serving a need there?

Dr. Tager-Flusberg: My sense is some of the technology is - I don't think the technology is where it could be given what we know we're able to do now in terms of speaking devices.

That's at least for the SGDs, but what's most widely used is PECS with this population. That's picture exchanges, and that's a little bit what you're seeing on the board there, you know, using pictures to communicate.

And that's a very cumbersome method, but it is one that there is a well-established training program for teachers and for families to be able to use. So, that's why it's more widely used.

Mr. Ne’eman: So if I'm understanding you correctly, you're saying that there are challenges both in the method of service provision, as well as attitudinal barriers that are coming up, which seem not to make that much -- I would assume not to be based on fact, because as you point out, the use of augmentative methods can lead to speech, as well as potentially some policy barriers.

Would that be correct?

Dr. Tager-Flusberg: It can, but I think we can't oversell AAC either, because it isn't effective for many individuals either. It's just one option that some individuals can take advantage of.

Mr. Ne'eman: Certainly.

Dr. Insel: Yvette.

Dr. Janvier: Just a comment from my clinical experience with this as a developmental pediatrician.

What I'm finding in New Jersey if you use PECS, for example, the communication carryover to home could be nonexistent.

So, the parent might not even

understand which of the pictures the child is able to recognize and utilize functionally to request or communicate. So, that's one piece.

The augmentative devices; one, someone needs to refer you for that; two, you need to be able to access it.

The access is limited. I could tell you the expertise with specialists in that area working with kids on the spectrum is not a hundred percent, you know.

Many of those professionals were used to working with children with cerebral palsy, for example, and it's a very different population.

The other piece is the expense of the devices. So, if you get referred and you get an assessment and a device is recommended something, for example a DynaVox, that's an $8,000 device.

Sometimes the school will pay for the assessment. Sometimes they'll pay for the device. Sometimes your medical insurance will pay for the device. And then you have a child with autism. How do they use these devices?

It's not what you would necessarily expect. I recently had a mom who is a physician who pushed for her child for years to get a device. Had to go to multiple providers for an appropriate assessment. And, you know, just asking oh, well, can he show me how to use the device?

The way I would ask him a question, he couldn't use that device at all. But recently mom says, you know, he's learning how to spell despite the fact that he doesn't seem to have a lot of skills. So, he was able to actually spell words of shapes and colors and things. And his mother couldn't even believe it.

So, there are very many barriers in the community. And I think one is access to professionals and, you know, cost truly. But at least in New Jersey, every town has their own school district. They're not necessarily willing to send you for an evaluation to pay for a therapist to implement a recommended device, bring it home, carry it over. There are many, many challenges.

Dr. Insel: Gail and then Lee.

Dr. Houle: We have some experience with this and some information on augmentative communication devices used in schools. And this is where the support in the term "services and support" comes in. Because in order to make these devices successful in their use, there's a lot of personnel training that has to be done. There's turnover of personnel. You may have new teachers coming in. They have to learn the system. You've got to have some consistent kind of almost a case management that follows through and ensures that people are trained, that the devices are working, that the devices are maintained, that they're the correct devices.

So, it takes - ideally the support would be in the form of some oversight to see that those services of this device and communicative services were actually being used and were actually beneficial to the child.

In addition, the family has to be trained as well on anything that is to be used at home.

One kind of bright spot in this is that we also have ARRA funds. And the funds that were not - we weren't able to put out discretionary priorities for them, but they did go to the formula grant programs. And they are to be used for special education and related services, and they are not to supplement the salaries of personnel who are there.

So, many states are choosing to use those because that is an accepted use, is to provide training, oversight in the actual augmentative communication devices for use. So, some of the ARRA money is going for that, and that's one of the things we're going to be tracking is how states use their special education formula ARRA money over the next two years.

That was something that had the potential of - they saw it as having less potential of falling off the cliff at the end of the ARRA funding. And hopefully it won't - that won't happen, but I would be able to try to track that. And at some point in time, bring it back to the Committee and see how those funds have increased the use of augmentative communication devices and systems.

Dr. Insel: Yes, I'm hearing a movement here that may involve the Services Subcommittee to try to pull some of the data together.

Lee, last comment, and then we'll have to move on.

Mr. Grossman: Yes, this is very interesting. So, I did want to present it in the light of the Services Subcommittee because

I think that this is just one aspect of autism that we're looking at right now. And in that, you can see the tremendous complexity and diversity of the issue.

Yvette presented a whole list of very realistic obstacles that exist. The fact is, is that these programs do work. I've seen AAC work, and work very well, very effectively.

I was - last August I was in a - at a school from kindergarten to 12, a grade school in a township in Cape Town, South Africa. They had AAC of every level available at that school, and it was remarkable to see what was going on.

And there was buy-in from the parents, from the teachers, from the therapists. And the kids were communicating with PECS, with sign boards, with iPhones in a township, poor neighborhood, 200 kids there with autism in Cape Town, South Africa.

I'm just using that as maybe the

extreme example, because we see this being done in classrooms throughout the U.S. So, this can be done. It's more of a capacity issue. More of a service-related issue in terms of can these kids benefit having the right supports, having the right services and training of personnel and family members to make this work.

So, I think that Ari's point about this becoming part and parcel of a whole service array should be part of the Services Subcommittee. Something to look at.

Dr. Insel: So, since you and Ellen are leading that effort, could you help us to get some of the data that we would need, I mean, to actually get a sense of where the problems are?

It sounds from this workshop that was done as if there are some significant gaps.

Helen, I hear your concerns about the technology. But even for the technology that seems to be most promising, there seem to be problems with being able to get at least to where we need it.

Dr. Tager-Flusberg: Well, I think some of the things we discussed, for example, is that for some of these children, they need to even be taught the skills to be able to even approach a device like this.

For example, they almost all require pointing or pressing on the button. Okay. That can be a huge challenge. And I think probably except in certain very dedicated environments, probably people just give up because immediately, you know, on the first couple of days the child is not responding by pointing even for a very simple association.

So, there's huge challenges because this is a very complicated and very multifaceted group.

We are moving ahead to write up the summary. That was one of our next steps to do a summary of what do we know and what are the gaps. And this is a very interesting discussion, and I'll be sure that a lot of the - we'll expand the citations particularly in this area so that when that paper is complete, it will be of use to your committee.

Dr. Insel: So, I hear three things. One is that you'll provide some written documents that the subcommittee can use especially. Then the Services Subcommittee will dig into this a little more deeply.

And then the third would be we've made a commitment to this area and the Strategic Plan. And I think part of what we're looking for as IACC, is to give the field a sense of where the needs are within this - at least for research, where we need to put the push.

So, that report will also be helpful for the IACC as we begin to look at how the plan is being implemented. If we need to update the plan in the coming year, you may give us some of the specifics that we'll need.

It was very clear in the 2010 update that the needs of nonverbal people was of new priority that we wanted to point to, but I'm not sure that we had the granularity in anything that we said that we now need. So, this will be helpful as we go forward.

Dr. Tager-Flusberg: I do want to just say though that we didn't - our workshop was focused much more on the knowledge needs as opposed to the service needs.

So, it may be that your Services Subcommittee could build on what we worked on to address those issues which are very real.

Dr. Insel: Exactly. So, we could use this maybe as the foundation for the next step as well.

Dr. Tager-Flusberg: Yes.

Dr. Insel: Thanks very much for joining us and giving us this summary in very real time after - because this was just two weeks ago that the workshop was held.

I want to move on because we are behind schedule, and introduce Dr. Rosaly Correa-de-Araujo who's known to most of us because she's been at previous meetings and has served from the Office of Disability with Henry. She's the deputy director of that office in the Office of the Secretary at HHS.

Welcome.

Dr. Correa-de-Araujo: Thank you very much, and thank you for the opportunity to share with this group the Office on Disability's initiative on comparative effectiveness research.

Comparative effectiveness research is designed to inform healthcare decisions by providing evidence on the effectiveness, the benefits and harms of different treatment options.

This evidence is generated from research studies that compare drugs, medical device, tests, surgeries or ways to deliver healthcare. The latter is what our initiative is actually about.

As you know, the 2009 American Recovery and Reinvestment Act has a provision for CER that calls for research in many different areas including prevention, diagnosis and treatment of disease or disorders and other health conditions.

It also encourages the development and use of clinical registry, clinical data networks and other forms of electronic health data that can be used to generate and obtain outcomes data.

The more than one billion allocated to CER has raised concerns that the results of such research must be used to ration care, thus controlling costs.

The intent of the Administration, however, is that CER results will be used to inform quality and efficiency improvement efforts. Therefore, ensuring that individuals get the most effective care because people with disabilities are generally excluded from clinical trials used to compile evidence for comparative effectiveness research in studies, and health service data also have limited information about this population.

So, with studies using biomedical research or even using health service data have still limited information. So, one may continue to question the value of a CER for people with disabilities.

However, as a biomedical and a health service researcher, I can tell you that the scientific evidence is good and it's growing in particular areas like rehabilitation and behavioral and psychosocial interventions. And, therefore, any studies that we conduct involving the CER approach will certainly bring numerous benefits for the population of people with a disability.

And I wanted to share with you how our initiative to establish a center of excellence in research on disability service, care coordination and integration, we just do that.

First, let me share with you the numerous shortcomings and the challenges with existing data that preclude researchers and policymakers from reliably assessing the health, well-being and type and quality of care and outcomes of care for people with disabilities.

Existing databases like claims data from large national insurers, as well as electronic health records and patient registry data, they are potential sources of data for comparative effectiveness research.

These data sets, they can be used to study prognosis, risks and harms, etiology of disease to analyze trends over time and capture long-term outcomes, to examine the causes of geographic variation, to analyze racial and ethnic disparities in both access and outcomes of care, to study low prevalence conditions, to assess clinical effectiveness in populations and subpopulations such as minority groups like women and other types of minorities, people with co-morbidities, and to generate hypothesis for experimental research.

The challenge to using claims data are that - include the ability to link data at the patient level from multiple source because we don't use the standard definitions and identifiers. So, if we all use the same ones, then it would be easier to link the data.

Also, protecting the privacy and the security of patient data is an issue. Obtaining access to this data through the agencies that manage them is also problematic. It takes some time. Ensuring the accuracy and reliability of the data once the data are merged is a problem.

However, I think the most critical issue for us is that there are limitations with claims data because they - very rarely they reflect functional status. And so if this information is not well captured, then it's not good for evaluating people - issues related to people with disabilities.

And despite the usefulness in large-scale analysis of cost and service utilization, the administrative data actually does not give any information about patient experience of care.

And when the basis for effectiveness includes elements of coordination of care and quality of life, having information on patient experience data becomes very, very much important. So, those are some of the difficulties that we have.

Administrative data generally have little or no information about the physical, sensory, cognitive or emotional functioning. It also has little information or sometimes no information about physical and social environments.

For autism, some of the specific challenges include the broad array of potential ICD-9 codes that can be utilized to reflect diagnosis related to autism and the fact that autism is rarely captured as a diagnosis in adults.

As I already stated under our CER initiative, we will be awarding funds toward the establishment of a center of excellence in research on disability service, care coordination, integration.

Our goal then is to build the infrastructure necessary to carry out research on the effectiveness and comparative effectiveness of service and supports and community-based models of care for individuals with disabilities.

There are specific charges that the organization that is being awarded these funds will have to accomplish. The first one is working with the Chronic Conditions Warehouse to document the public data available from the Centers for Medicare and Medicaid Service, identify and interpret data gaps in support of HHS agencies in making necessary data improvements to better reflect information on health and support service for people with disabilities.

The second charge is that they will be linking additional data sets that they will identify that are relevant to disability. Therefore, they are going to increase the ability to use the CCW, the Chronic Conditions Warehouse, for research on people with disability, including CER of health and support service for chronic care.

This organization will also conduct a thorough review of HHS activities, and also outside efforts in research and evaluation of the effectiveness and comparative effectiveness of health and support service for people with disabilities.

This must be a systematic review of published and unpublished studies, but the unique feature of this work is going to be that for the first time we will be bringing to the table the opinions of consumers. So, we will have consumer input so they can tell us what is working best for them.

In addition, this organization will assess Medicaid data reported by selected states on both their state plan and waiver of service to identify the types of benefits offered, the information reported and the data available.

You know that Medicaid at state level, they vary considerably across the country, they have different benefits. Therefore, their reporting is different.

So, what we are trying to do is if we wanted to conduct any comparative study, we need to select a group of states, at least. We need to try to standardize what they are providing and how they are reporting so we can then establish a pilot project that will allow us to compare the data that they are reporting and the service that they are providing.

So, there is a lot to be done. There are other activities that I am not going to take some time to discuss, but those are critical issues that the organization that is being awarded will have to deal to face in the next two years of this award of ARRA funds.

Well, it's very important to link data. And why is that? Because merging data with other data sets can greatly enhance analytical utility, including that for disability-related research.

In addition to that, linked data files have been used extensively to study patterns of a service used particularly for older adults with functional deficits.

So, there are many, many reasons for us to try to bring together numerous data sets so we can obtain a better exposure to data and better understand what is going on in terms of access, quality and outcomes of service that are received and well-being of this population.

Here are some reasons or examples of why it is important or the outcomes of merging some data. I'm going to focus basically in two of them, and I would like to mention this one and this one.

Those are interesting. And the issue of merging data, this has been going on for a long time. So, some of those examples are old studies that were conducted, but they are very important because they provided us with the information that was very critical.

Particularly this one here, it's a prominent example of merging Medicare claims with the National Cancer Institute's Surveillance Epidemiology and End Results Program data, the SEER data.

The SEER program captures information from population-based cancer registries and other supplemental registries that cover millions of cancer cases.

These merged files, they have been used to examine many cancer-related questions. And in one of these studies, it was found that young women with disabilities, they are diagnosed with breast cancer at later stage than women without disabilities of similar age.

So, although this data do not indicate functional status, they do provide important information on cancer stage and treatment.

The other example that I have here is one that relates to the merging of two Medicare sources. The Medicare Current Beneficiary Survey, the MCBS, and the Medicare National Claims History File, which created a valuable database to study people with disabilities.

And the MCBS is a longitudinal survey of Medicare beneficiaries with an over-sampling of persons under age 65 and those over 85. Two types of MCBS surveys based on residents in communities or institutions solicit detailed information about the physical, the sensory functioning, health conditions, satisfaction with the care and with access to care, service that are reimbursed and other types of information for people with disabilities.

So, merging these two Medicare data facilitate the analysis of people with disabilities, access and quality of screening and preventive service, and also out-of-pocket expenditure according to their ability to perform routine daily activities. So, it's very important that we are able to bring data together.

But why partnering with CMS particularly using the CCW, the Chronic Conditions Warehouse? Well, Section 723 of the Medicare Prescription Drug Improvement and Modernization Act of 2003, instructed CMS to develop a separate research data warehouse to support the study of chronic illness.

Initially, the CCW was only populated with a five percent national Medicare sample for the years of 1999 and 2004. CMS then modified the CCW to contain a hundred percent of Medicare claims and eligibility data from 2005 to the present, and a hundred percent of prescription drug data.

The CCW also contains patient assessments and health status information for nursing home, for home health and inpatient rehabilitation care.

All of the data are linked at the individual level to facilitate tracking of total Medicare utilization and spending for a unique individual over time.

In addition, the CCW has flagged the Medicare population for 21 predetermined chronic conditions. Consequently, it's possible to identify cohorts of beneficiaries by predetermined chronic conditions or by researcher's definition of diagnostic and procedure codes.

Another important feature is that this database is housed in a relational database that can easily be customized to meet individual data requests. So, the database can easily encrypt sensitive data elements so we can use social security information or we can use the Medicaid or Medicare number.

And these are critical issues because we wanted to protect the confidentiality of the data, but also we wanted to allow a researcher to track an individual over time and associate multiple-provider claims to a unique individual. So, those are unique features that we have now.

The ability to match records in the CCW enables it to be linked to other federal data sets very easily. So as you can see, all of those characteristics make the CCW a critical database to be associated with to track and to study our population.

Another piece of very good information is that the CCW is currently being enhanced through a separate scope of work under recovery funds. So, it's separate of ours, but we are working together then with our initiative and what they are doing.

So, these additions and enhancements of the CCW is what I am listing here in this slide. So, it's important. So, you can see that we are adding actually additional information here on Medicare, on Medicaid data that is very important for us, and other things that are being added that will really increase our ability to have a better understanding of what is going on with our population.

In addition to CCW, of course there are many other types of data within CMS. And I am listing here some of them, but they are going to be included in the merge of data that we are talking about.

So, I am not going to spend time talking about those programs, but they are relevant to our population.

I would like instead to show you what other federal agencies have to offer. And of course those are options that I'm bringing to the table.

We still need our guarantee to assess all those data that are out there and start the feasibility of really having the data linked. And we need to be perhaps selective as we cannot do all at one time, but I just wanted to show you the wealth of information that is available out there.

I would like to highlight from the agency for Healthcare Research and Quality, the Healthcare Cost and Utilization Project, the HCUP data that enables research on a broad range of policy issues including cost, quality of health service, medical practice patterns, access to care, treatment outcomes.

And this is at national and state and local market levels. So, it's a very important database that we hope we'll be able to use.

The other one is the Consumer Assessment of Healthcare Providers and Systems. It's the CAHPS database. It's a public/private initiative to develop standardized surveys of patients' experiences with ambulatory and facility-level care.

The good thing about CAHPS is that it is essentially a data set that has a patient-centered approach.

HRSA also has an important database for us. It's the National Survey of Children With Special Healthcare Needs that provides information on the health status and systems issues for children and youth with special healthcare needs at the state and national level.

CDC has a series of databases that are very relevant for us. And of course what I am listing here, it's just a sample. We have many others that I didn't bring here to this slide, but we hope that we will be able to do a lot of work with the CDC.

We are particularly interested in the behavioral risk factor surveillance system, the BRFSS, which contains demographics, health and health behavior information. We are also interested in the National Health Interview Survey, which has specific disability-related questions, but it has not been updated for a long time.

Also, the Legacy for Children Multi-Site Randomized Controlled Trials, it's a longitudinal data on demographics, assessments related to child's cognitive language, emotional and behavioral development, maternal and child interaction, self-efficacy, emotional well-being, parental commitment and positive parenting practice.

Finally, we have to think about the CDC's Autism and Developmental Disabilities Monitoring Network surveillance that brings us with good and current information on autism cases.

And certainly NIH, the National Database for Autism Research, sometime further down the road maybe this will be an option to be linked to the work that we are doing.

The Administration for Children

and Family, they have a series of data collection that are longitudinal data that illustrate important surveys, delivery trends in community living, public and private residential institutions, family support, supported employment, supported living, Medicaid waivers and demographics.

Basically, the bottom line is that those - this type of information show exactly the impact over time of a federal and state partnership.

SAMHSA also is an important contributor with the National Survey on Drug Use and Health. Includes information on households and noninstitutional group homes and shelters, substance abuse, health status, risks and behaviors, healthcare and economics.

I wanted to highlight here the World Health Organization International Classification of Functioning Disability in Health, the ICF. Unfortunately, the ICF was promulgated in 2001, but has not been used in the United States.

The data coding involved is functional abilities in a social and environment context. So, it would be very important for us, for our population.

The coding scheme is not used routinely here for data collection in our country, but it would be extremely helpful to have it linked as part of our initiative. And I will be seeking this type of opportunity with the ICF.

This slide is basically just to show you what you know better than I do. It's a display of informational service and supports used by people with autism. The point that I'm trying to make here is that these service and supports, they are captured in at least some of the data sets that I highlighted here.

But what is missing is that we need to work towards finding a way of identifying and retrieving such information for proper analysis. The information is there. It's just hidden. It's not held in a way that we can easily separate particularly when we talk about service, health service and support service.

So, I think we have a great opportunity ahead of us with our CER initiative to build the structure, the infrastructure, the foundation for us to continue to do research in the field.

There are plenty of opportunities to increase data availability, to support health service research effectiveness and comparative effectiveness research studies that will benefit people with disabilities.

With our CER initiative, we have the potential to identify relevant data sets that will help us better understand access to care, quality and effectiveness of care provided to people with disabilities, including those with autism.

We will be able to conduct

research that will tell us what treatments, interventions and models of care work best for these populations, but it's important to recognize here that this is not a short-term effort.

Instead, it should be based on long-term partnerships among federal, state and the private sector to share data relevant to people with disabilities.

We are aware of the challenge ahead associated with identifying and merging data. These are not only technical difficulties or challenges, but we are ready to move forward to find ways to resolve the problem.

The partnership that we established under our CER initiative with CMS is very promising and it's just the beginning. In the future, we hope that this center of excellence will be able to expand its research focus to build on CER, on rehabilitation, behavioral and psychosocial intervention and other disability-related areas that at this time have already some more robust scientific evidence.

We look forward then to continue this dialog with this group and other groups to help us succeed with these efforts. The intention today was just to let you know what we will be doing in the very near future.

And this is for us, I think it's a tremendous opportunity in the hope that we will be able to have lots of data to help us better understand where we are with autism and other types of conditions, other types of disabilities. And what we can do to improve quality of life, quality of care, access to care, and develop interventions that will allow people to live better lives in their communities.

Thank you very much.

Dr. Insel: Thank you.

(Applause.)

Dr. Insel: Rosaly, before you go,

we want to take just a few minutes to see if there are questions or comments. I had one.

I may have missed it, but on the rather mundane question of money, what is the commitment to this program?

Dr. Correa-de-Araujo: Yes, the commitment is about $7 million.

Dr. Insel: And those are ARRA funds?

Dr. Correa-de-Araujo: Those are ARRA funds.

Dr. Insel: So, don't those need to be spent out by -

Dr. Correa-de-Araujo: That is correct.

Dr. Insel: - next September?

Dr. Correa-de-Araujo: As I mentioned, we will have two years to do all this work. And in the meantime, Henry and I will be working towards bringing additional partnership so we can bring sustainability to this center of excellence.

Dr. Insel: Questions or comments from the Committee?

Yes, Stephen.

Dr. Shore: I find this very encouraging. Especially the idea of taking data that already exists and putting it together in new and very useful ways. And I also like the person-centered planning aspect and just checking in with those of us who are most affected by this and will most benefit.

That's great. Thank you.

Dr. Correa-de-Araujo: Thank you very much. And I think you are absolutely right.

Sometimes we have the information available. It's just not in the right format. So, we need to explore more what is out there, so we are able to use things and produce faster some results. That's what we are trying to do.

Dr. Insel: Lee.

Mr. Grossman: Yes, we're part of a

coalition of many, many groups that have been pushing for CER funding and I can't express how happy we are that the Administration has committed the $1.1 billion to this.

And thank you, Henry, for your leadership on this because you're definitely keeping this moving forward, keeping this in front of everybody.

Because we believe as part of - as a result of the heterogeneity of autism that unless we really begin to understand everything that these families and these individuals are going through in terms of behavioral, educational, medical support so we can compile that information, that's the type of research, that's the type of data that will drive us towards finding better solutions for these individuals.

So, I encourage you to keep this up. I think it really should be an emphasis of this committee because this is the type of data that we really need.

And there's a wealth of information out there in what people are currently doing. We just have to find a way to compile it. And you can count on us for continued support.

Dr. Correa-de-Araujo: Thank you very much. And one of the ideas is really that not only we will be compiling or merging this data, but trying to use at the end of the contract or the award to ask the organization, the ROD, to really select a few areas or questions that were never being able to be answered before so we can demonstrate how useful the merging of this data has been or the evaluation of a few states in terms of benefits or service that they are providing and reporting.

So, we hope that we will be able to work on a dissemination strategy or knowledge transfer because not only we need to do this work, but it's important that we get the word out there that this is being done and what are the results that we are getting.

This is the way that we find to bring together additional people in partnerships and expending, exchanging knowledge and acquiring also experience from others and it's in the plan.

The plan is really that we have also a dissemination strategy that we be able to reach out not only to providers, but also to policymakers and to consumers at the same time.

Dr. Insel: Other comments or questions?

Geri?

Dr. Dawson: Well, I was just going to mention that we're in the process now in the United States of state-by-state passing major insurance coverage reform for access to behavioral health. And it does seem like it's an opportunity, a natural experiment, so to speak, about what is the impact of passing this kind of legislation.

Is it true that when you pass legislation that provides greater access in terms of insurance coverage, you know, does this in fact translate into benefits?

So, for example, would fewer children be having psychiatric hospitalizations or accessing lower levels of care both medically and educationally?

So it is, I think, just a unique time to be able to look at an impact of discrete events related to insurance coverage on the autism community.

Dr. Correa-de-Araujo: Absolutely.

Dr. Insel: Henry.

Mr. Claypool: Just to underscore one aspect of Rosaly's presentation aside from the clear implications that research has for access to healthcare, there are the very routine service and support issues that I know are important to a number of the Committee members. And the challenge we face there is really working with state Medicaid programs since they are the primary mechanism for funding these services and supports. And their data are - they vary greatly from state to state.

And so we have a rather daunting process of bringing states in and trying to share information and building towards a goal of perhaps coming up with some common reporting requirements that might one day lead to a more uniform set of Medicaid data in this arena of home and community-based services so that we can really bring the knowledge level up to the point of where we could conduct some truly comparative effectiveness research on how these services are working for different populations.

Dr. Insel: Yes, I think these are really great points. If I could just share, and we've been at this for a little while within NIMH and have made a number of mistakes, if any of this is helpful to you, I think the three things that I would consider, and some of this is already coming out from the conversation, is that in compiling data you put a lot of attention into quality besides just quantity.

One of the places where I think we've had the greatest struggle in using administrative data was the recognition that much of what we were getting didn't have the rigor that would allow you to really feel confident about any conclusions. And you've got a sense of that even from hearing Sue Swedo talk about the variety in the way that diagnostic terms are being used.

So, this is really even in the most basic sense, a problem of what you call disability what you'd call ASD, any of these issues.

We just launched a big effort using ARRA dollars to work with the National Survey of Children With Special Health Needs that was run through CDC to join with them to provide a lot more granularity to their survey. It's a several million dollar commitment, but we thought that that was one place where we could have a database that would have the kind of information you're talking about that we could really build on the quality and longitudinal approaches as well.

The second issue which is what Henry was just suggesting is I think so important, if the point of comparative effectiveness research is ultimately to change policy and to change particularly provider practices and payer practices, I think one lesson that we've learned the hard way is you want to start with them rather than going to them after you're finished.

So, to find out what is the evidence that a state would need or that a particular provider/insurance company would need to be able to extend benefits is really important. And then to go after that in a very focused way even as we're doing now with some studies bringing them in as partners to make sure that they have bought into this, and sometimes even literally bought into this, they're actually paying to get the data.

Because at the end of the day, they're the ones who are going to have to be responsible for providing the supports. And this gets very complicated in the state arena, but it's so important to do up front, not later on, because you may find you don't have the very specific thing that they will say that they need.

And then the final point which is what Geri brought up, is this is such an interesting time to be doing this. We are in the middle of an extraordinary change with a combination of mental health parity which will affect the needs of particularly children on the spectrum, as we heard earlier today, and with healthcare reform. And you heard that a bit from the secretary and all that that will mean.

So, it's just so exciting to be putting this in place now and then to be able to track over the next five years what this will mean. There are so many concerns about cost and about the sort of unintended consequences of healthcare reform.

And it will be absolutely critical to have the data to make the arguments when this is all said and done because there are going to be people pushing back at every stage of this. And so you'll need longitudinal data before and after to actually demonstrate how this is going to play out.

And there's probably no better way to do it than what you're talking about here. So, I think you'll get lots of support from everyone on the Committee to make sure that this is successful.

Dr. Correa-de-Araujo: Well, this is good news. The one thing that I didn't share, but I think it's important, there are, as you saw, there are so many different tasks under this initiative. And for each of those tasks, one of the things that the ROD will have to do is to create expert - technical expert panels.

And those panels will have representation from consumers, from people at state level, state Medicaid experts doing research, providers. So, this will allow us to bring the input that we need to the table at every single task so we can capture exactly what is needed and deal with the reality.

Sometimes we do those studies and then they do not fit well on what is the real practice, what is really out there.

Dr. Insel: Well, this is great. The other thing it allows us to do is if you go back to the Strategic Plan, it says to be able to use some comparative effectiveness research efforts in the plan.

So -

Dr. Correa-de-Araujo: Absolutely.

Dr. Insel: - looks like we may be

able to at least announce progress on one of the 64 objectives on that sense. So, thank you very much, Rosaly.

Dr. Correa-de-Araujo: Thank you.

Dr. Insel: We have one more piece of business before we get to our break. I'm going to move around the agenda a little bit because we're so far behind.

But I wanted to get your approval or at least your perusal of the January 19th IACC Committee minutes. This is the full Committee meeting that we had in January. Those minutes are in your package.

If there's anything that needs to be changed, let us know. We'll give you a minute to comment.

Lyn.

Ms. Redwood: Tom, I had e-mailed Della about just changing a couple of words on Page 11, and I didn't see it reflected in the -

Dr. Hann: Right. The minutes that

you have were done before we got your comment, but we are - we're making the change that you had suggested, yes.

Dr. Insel: Okay. Anything else from the minutes?

Hearing no recommendations, can I get a motion for approval?

Mr. Ne’eman: So moved.

Dr. Insel: Second?

Dr. Trevathan: Second.

Dr. Insel: In favor?

(Chorus of ayes.)

Dr. Insel: Anyone opposed?

I think we have minutes that are accepted, and you've - what we'll do is we have now a set of Committee business issues that are really important to involve all of you on some decisions around both the Planning Subcommittee, we want to have a very brief conversation about Services Subcommittee, and then some issues from the Office of Autism Research Coordination as well.

And then we'll get to the - a chance to talk about public comments. So, with all of that happening, I think rather than moving to the updates, why don't we take a break now for ten minutes and come back to the table, and we'll move quickly into this next session. Okay.

So, it's 3:47 by my watch. We want to get started no later than 3:55.

(Whereupon, the meeting went off the record at 3:49 p.m. and resumed at 3:58 p.m.)

Dr. Insel: Okay. In the last part of the meeting we have a number of Committee business issues to deal with. Some of them are updates, and some involve decisions from you.

We'll start with this issue around the Planning Subcommittee. And I want to take just a moment to also talk about the Services Subcommittee. Though that's not really on the agenda, but we'll use these next few minutes to talk about both subcommittees.

Both of these are subcommittees of the IACC for new members. We'll let you know that much of the work of the Committee actually gets done in these subcommittees.

And by definition according to the law, the subcommittees can only have members of the Committee and they can't be larger than half plus one. That is they can't have a quorum of the Committee, otherwise they'd end up representing a quorum of the full Committee, which they aren't supposed to do.

So, the Planning Subcommittee was put together when we were working originally on the Strategic Plan and we realized that we couldn't do this with what was then 18 members around the table. And there were a number of people who were willing and able to meet outside of the full committee meeting to talk about how the plan should be updated, mostly around the process for doing that.

And that's really what the

subcommittee deals with is what's the best process for bringing new ideas into the plan and for creating a plan in a very efficient way.

So, it's a group that met several times last year leading up to the January 2010 update. Again, the Combating Autism Act is very specific that there are five things we need to do. And the fifth thing that we need to do is to have a Strategic Plan for research that's annually updated.

And that annual update means that it's due next January 2011. So, the Planning Subcommittee met in - I guess it was earlier in April, I think it was April 19th, to talk about how we should do the next update.

And that was a broad conversation about what worked, what didn't work last time, and to think about how we might do things differently going into 2011.

So, what we've tried to do here is to summarize their recommendations from this

April 19th meeting.

First of all, they felt that they did not want to see the plan rewritten by January of 2011. There was a sense that the original 2009 plan had been extensively reworked for the update in 2010, and now may be a time to spend most of our effort on measuring progress rather than on moving the goal posts once again, that we needed more time to actually implement what we said we wanted to do in 2009, and 2010. So, they weren't endorsing a full rewrite, but measuring progress.

They felt that any new objectives, that new objectives could be added. But any new objectives that were going to be added should be based on some very significant new scientific events, you know, a major new discovery which could be a new technology that comes online which would be transformative for cancer or Type I diabetes that someone says, hey, we need to now try this in autism, or perhaps something that had been recognized in autism that's a game changer, something that was not in the plan before that we want to be able to put in. That's the idea of having an update. That could be in the form of progress on a current research objective.

And then finally on this slide, they wanted to use the portfolio analysis to be able to gauge progress.

Now, remember, we do this extensive portfolio analysis each year that includes not only the federal part of the IACC, but all of the major private funders as well.

So, we have that from 2008 before the 2009 or the 2010 plan was out there. And we thought it would be very useful, at least the subcommittee thought it would be very useful, to find out what that portfolio analysis looks like now with the Strategic Plan already out there.

They did think it would be useful

to use the Summary of Advances that we're also required by law to do to update the What Do We Know sections of the plan. Remember we had the What Do We Know, What Do We Need, and then the objectives?

So, they felt that this was probably the most appropriate way since we were already collecting that information, but they wanted to do this in a somewhat different timescale. Because if we do it the way we've been doing it, we won't get the Summary of Advances until too late.

So, they suggested that we have a summer/fall, this time, collection of advances so that we can get this done in time to be able to use that to update the plan for 2011.

And we talked a lot about, well, should we have town hall meetings, RFIs, are there, you know, other ways of gathering information?

And the subcommittee felt that rather than having a series of meetings, that they felt it would be useful to have an RFI to cover the whole plan. And that would be one way of sort of addressing the What Do We Need sections of the plan to get the public information about that.

On the question about meetings, they thought that it could be useful to conduct a scientific workshop. And people felt that the workshops that we've had in the past have been very helpful for shaping some of the objectives of the plan, but they weren't sure exactly how to choose what that workshop might be about if we were going to do one.

Certainly if we do one, it has to be probably no later than October if it's going to inform the plan for January.

So, they decided to go back to all of you to the full Committee to see whether you felt that there was a need for a scientific workshop in one particular area that could be helpful in this updating process.

And the last thing I think on here was they expressed a willingness to develop the revisions within the subcommittee and bring them to you rather than trying to write this as a committee of the whole, because they realized especially now that the Committee's even larger, that trying to do this with 25 people would become a fairly complicated process. It's already hard enough with just the subcommittee itself.

So, I think that is a pretty good - oh, there's one more piece here. This has to do with the RFI itself. So, let me put that off for a moment and just see if there are any questions about this set of recommendations.

And, please, members of the subcommittee who may have a much better memory than what I've put up here, add anything or revise anything.

Alison.

Ms. Singer: I wanted to add that I thought towards the end of the Committee meeting Lee had raised the point of using the scientific workshop to build on our knowledge of services research which was an area that was greatly expanded in the 2010 plan and I thought that we had agreed to propose that as well.

So, I just wanted to add that.

Dr. Insel: Lee, you looked surprised when you heard that.

Mr. Grossman: Thank you, Alison.

Dr. Insel: Okay.

Mr. Grossman: I was going to bring it up.

Ms. Blackwell: Actually, I was going to bring up the same point, Alison. I thought in our discussion, we actually had some ideas about three workshops that we talked about. Perhaps one on services and supports, I know there was discussion of one on drugs. And I can't remember what the third one was, Tom, but I know you will.

Ms. Redwood: Environmental factors.

Ms. Blackwell: Was it, Lyn? Okay.

Dr. Insel: So, those are all options for the Committee. And I think, again, for the benefit of new members, I think many of us have felt that the workshops we've done in the past have been really helpful for digging deep in a way that we try to use these meetings for you to hear about new opportunities.

So, if you just think about it like the Fragile X story, we had Marc Beyer come about a year-and-a-half ago to give you an extensive overview of what was coming. And it was good to see that all confirmed today in the New York Times.

At the last meeting we heard about epigenetics in great detail from Andy Feinberg, and today a bit about stem cells. But the great thing about a workshop is we can actually hear from more than one person and go much deeper into a topic like environmental issues or services or medications.

On that one, I think there's already some conversation about another meeting that Geri has been organizing.

Do you want to say a word about that?

Dr. Dawson: So, actually we're organizing two meetings this year. And we're co-organizing this, actually. Tom is on one of the planning committees, but also with the academic community, PhRMA, several pharmaceutical companies, and also we'll be brining in the FDA.

But one meeting is on measuring outcomes, which is an area of challenge in work on translational research. And then the second is more on the neuroscience, so it's drug targets and development of animal models and kind of where we stand in terms of barriers to drug discovery.

And one idea would be rather than use up one of our workshops, we could have people from each of those workshops, key people come and report on those workshops.

Dr. Insel: Yes, I think that would be great the way we did today for the nonverbal. So, if we could use this as a forum to hear about those kinds of efforts, that would be terrific.

Cindy.

Dr. Lawler: So, Tom, the NIEHS is also in the initial planning phases of a very small workshop of really more of a brainstorming session in late August or early September around the role of the environment.

And as was just suggested with these workshops that Geri mentioned, we'd be happy to sort of feed any recommendations that were relevant, back to this committee.

Dr. Insel: Well, one question that members might have is whether they're invited to these meetings.

Is that an option?

Could the IACC sit in like on the environmental meeting that NIEHS is - Cindy, just to be clear, is that about autism or -

Dr. Lawler: Yes, autism and the environment.

Dr. Insel: Okay.

Dr. Lawler: Trying to think about whether some of the advances in other areas of autism research provides some new clues for going after the environmental contributors, looking at some recent advances in environmental health sciences and seeing whether those provide new opportunity.

So really just, you know, looking back over the last three years where are we, you know, what do we know now that we didn't know then, how can we speed up progress?

Dr. Insel: Yes, this is exactly the kind of thing that we would have planned to do, so we don't need to be redundant.

Dr. Lawler: Right. That's why I

mentioned it, because it will definitely move forward and we'll be glad to -

Dr. Insel: So, it sounds to me like two of our three ideas have already been - they're so good that other people have gotten to them already.

Is anyone doing a services workshop that we need to know about?

Henry, is there anything like that?

Mr. Claypool: I think that's ours.

Dr. Insel: Okay. I think we've got a workshop; is that fair to say?

Alison.

Ms. Singer: I just also want to point out that actually one of the new objectives that we included in the new Strategic Plan calls for us to convene a workshop to advance understanding of clinical subtypes and treatment personalization.

So, is that going to be covered by your workshop that you were describing, or is that something that we need to - and it says, too, by 2011.

Dr. Insel: Yes.

Ms. Singer: Is that the same?

Dr. Insel: I think there will be some pieces on biomarkers that will emerge, which I think is the same issue, you know. It's mostly around medication development.

But as you could even see today on the Fragile X story, where much of that is going is around figuring out which medications might be best for which individuals and trying to come up with biomarkers to predict that.

But, Geri, you're really the organizer. Do you think that's going to cover this or what's your sense?

Dr. Dawson: Well, I think from a biomarker as predictor of response to treatment, it certainly will be a topic. Probably it could be a topic unto itself, of course. So, I think it will definitely intersect.

And whether it completely addresses, you know, everything that could be talked about in that topic, it probably doesn't, but -

Dr. Insel: Well, why don't we do this: Why don't we plan to try to work this into the agenda?

We're still working on the agenda for these meetings. And if we don't cover it in sufficient detail - it says by 2011 - we can come back around and do this in the spring so that we can get this done in real time.

But it sounds like we have already a focus on one area that the IACC could take on as a topic.

Ari and then Lee.

Mr. Ne’eman: I just wanted to sort of jump off from one of the other points that you mentioned from the April 19th meeting.

The idea that we should be limiting the new research objectives to scientific advances and progress in current research objectives generally does make sense with the exception of those that relate to services, I think, primarily because we are proposing a more in-depth look in services and we're likely to see a more active Services Subcommittee.

I think it's likely that we're going to be putting thought and developing new priorities for research in the services research area that we perhaps haven't in the past.

So, I'd encourage us to keep an open mind to putting in new services research-related objectives in future Strategic Plans.

Dr. Insel: And the only reason to do a workshop, I think, is so that you can let these ideas incubate enough to decide where there's an opportunity to really have some impact.

Lee.

Mr. Grossman: It's a little bit premature, but we are - we're struggling to see how it fits into this personalized aspect of ASD, but in October we're planning to do a consensus type of workshop around more personalized - well, it's around risk and resiliency, identifying risk and then finding out how we can better treat so that people can live a higher quality of life with autism.

And it's going to be based very similarly to what we did at the GI conference. And we think that it will cover some of the aspects of the personalized intervention that we're looking at which we think is what was spelled out in the Strategic Plan.

So, we might be covering that and those plans are in process and we'll have them finalized by the end of May.

Dr. Insel: Gerry.

Dr. Fischbach: The Simons Foundation has many conferences through the year, and we would like to share that information. And I can say that we don't have all that much room, but we would make them open.

You asked the question to members of the Committee. I think members of the Committee are involved in so many different organizations, it would be great to have a calendar circulated that we could all contribute to. I think it would be overwhelming, actually. And then people might be able to pick and choose what they might want to go to.

But ours are - a lot of them are on the fundamental science, but we have had one on experimental therapeutics. And we're interested in education, but it's mostly on neurocircuits and on synaptic biology.

And I wonder not only could we attend, but if there's enough room if a surrogate or a member of our organization might attend.

Dr. Insel: Yes, what a great idea. Actually, there isn't, as far as I know, there's no central calendar for all the things happening in autism across all the organizations. And maybe that's something that we can help with if you can all provide information to us where we can at least let the Committee know what's happening.

And maybe that even if the meetings aren't open, if they're relevant to the Strategic Plan or to our task which is to advise the secretary not only on research, but on services and on public participation, that we can then ask someone from the meeting like we did today with the nonverbal, to come and report out what the major findings were.

That sounds like that's one great way to use the IACC.

Dr. Fischbach: I mean, some of those meetings may be inspired by what goes on here, actually, and you really ought to know about them.

Dr. Insel: Right. Okay. So, what I'm hearing from this conversation is that there's an interest in at least sponsoring a single workshop around services research, so the research agenda for services in ASD. We would do that in the fall.

We will come back to - and this may be a place to bring some of the Services Subcommittee together with a Research Planning Subcommittee so that we can have a small group to help advise how to make this happen.

The other issue that we talked about was having an RFI. And the RFI was meant to look - this is a request for information. This is a way we get much broader public input than we would have at any given meeting.

The idea was to do something similar to what we did in the past. Have it organized by chapters, but we wanted to include the introduction this time, which we didn't last time.

You can read this yourselves. It's two questions for each chapter. And we do constrain the number of responses slightly to - it's 500 characters per area. But when you put that together with the 17 boxes that are allowed for response, it's actually quite a lengthy response that we can get from each individual who sends information in.

As it says on the slide, we got close to 300 responses last year. I know that members of the Committee got all of them, and you all will get them again in 2010.

We will have to do this fairly soon to be able to get information, because we want to provide enough time for people to respond. So, we want to be able to do this well ahead of when the Committee begins to talk about any revisions or updates.

So, this is likely to happen probably summer, early fall, something like that. Probably summer. Okay.

Ms. Redwood: Tom?

Dr. Insel: Yes.

Ms. Redwood: I received some complaints regarding the 500 characters per box, and that is really limiting if you want to put in more than maybe a paragraph.

So, I wish there would be some mechanism where we could - because not everybody is going to respond to every single one of those questions. But if there's one area that they're interested in, it's an area of their research, they really need more than just 500 characters to respond.

So, if we could come up with some mechanism for either additional responses at the end or additional comments, I think it would be really helpful because it was very limiting last time to only have 500 characters to respond to a question.

Dr. Insel: Yes. Go ahead, Susan.

Dr. Daniels: I was just going to say there was an "other comments" at the end, and that's planned this time too.

Dr. Insel: Right. So, the concept here is it's better than Twitter, but maybe not as extensive as a blog. But what we're trying to do is to give people a sort of format to follow.

If in the rare case where someone has a very important message that requires much more text, there is the opportunity to do that, but we thought it would be just to make this manageable, in a sense, because we're talking about 300 responses and we want the Committee to look at all of them. That if we could constrain this, it would make it more likely that people will get a sense of the whole input.

But this is really, you know, it's a committee decision. So, you can decide. It's really up to you how much you want to read, I think, because the - you've had this in years past. This is the format that we followed last year, and we wanted to be clear. And we can do this in the format itself that if someone has a longer and really critical message, there is an opportunity to provide that. But as a standard, we wanted to keep it more constrained.

Ellen.

Ms. Blackwell: And, Tom, do people have opportunities to send us, you know, just like today we received written comment at any time in addition to in the RFI format?

Dr. Insel: Yes, there is the opportunity to send both written and then oral comments. And you've seen both of them today.

But to be realistic, you know, a lot of people don't do that and yet have something to share with the Committee. So, this is a way of sending a broader net out to get more input than we might get from our regular unsolicited comments.

Geri.

Dr. Dawson: Well, as a person who's actually used it as a consumer, I think the challenge is that there's the nine categories, but you probably only have something to say about two of those categories or maybe three.

And so essentially you're trying to fit in everything right that you want to say into a short space, right? So, I don't know if there were any way to say you've got three pages total, right, and it just cuts off or something because I don't think most people want to respond to every single category. They have one issue they want to bring up or two issues they want to bring up.

So, that was the struggle that I had and it was hard.

Dr. Insel: Okay. Anybody else have experience using this?

What are the constraints on our side from being able to open this up and have let's say a maximum of three pages single spaced per respondent but allow someone to write 2,000 characters on one particular box?

Dr. Hann: I've been sitting here trying to think about it from a technological point of view, and I don't have an answer right now.

The reason it's set up this way is so that the responses can be codified to the original - to that area. So, that's why - right. So, that's why the limitation for the boxes.

So, I think - I'm not sure technologically if we can have it so that it would be sort of like this accordion, but then cut off if you try to go someplace else. I don't know whether we're actually able to do that.

Dr. Insel: Why don't we look at that and see if we can have a little more flexibility than - the accordion is the right metaphor here, and see what we can do. We'll have a little bit of time before this goes out. So, we'll see if we can't provide a little broader range of options for how people respond.

Anything else from the subcommittee, people who were at the meeting, Lyn, Alison, anybody have other comments that you want to convey to the full Committee?

Okay. So, we'll go forth with the idea that there will be a single workshop in the fall, and an RFI with the accordion built in somehow that will look something like this. And then the plan, and maybe this is the most fundamental thing, is that the subcommittee itself will take on the responsibility of trying to come up with what that update might look like and bringing it to you in some real-time.

We want to have this done again by end of January 2011. So, that's the final date for delivering next year's report to Congress.

Della.

Dr. Hann: So, just for my clarification for the workshop on services research, will the individuals who are going to help organize that come from the Planning Committee or from the Services Subcommittee?

Dr. Insel: Would it be okay with

the Planning Committee if we took both, I mean, if we borrowed some people from both subcommittees to put a small group together?

Is that all right?

Okay. And we'll help to organize that.

Ms. Blackwell: Would that, Tom, would that exclude folks who aren't on the Services Subcommittee or on the Strategic Planning Committee?

Dr. Insel: So, you've raised the question that I was going to bring up now which has to do with membership. Okay.

The membership of the subcommittees up until this point, is based on those people who were part of the full Committee starting in November of 2007. We have five new members of the full Committee, and we want to make sure that they have an opportunity to serve on these subcommittees as well.

Now, our constraint is that the

subcommittees can't have more than 12 people on them. And the Planning Subcommittee, the one that we were just talking about, the one that plans for the update of the Strategic Plan, the research plan has nine. The Services Subcommittee currently has 12.

I'm on that subcommittee and will volunteer to step down so there will be 11. That will open up one space. But I'm asking for anyone else who's on either subcommittee currently, who may want to step down so we can make space for new members of the Committee who would like to serve.

Any volunteers from either one?

Dr. Hann: So, the rosters for each committee are in your packets just in case folks may have forgotten.

Just for everyone's benefit, the Services Subcommittee currently is co-chaired by Ellen Blackwell and Lee Grossman. The members include Henry Claypool, Gail Houle, Larke Huang, Jennifer Johnson.

Then Tom has a slot, but it is filled currently by Denise Juliano-Bult who's his proxy. Christine McKee for Ed Trevathan. Cathy Rice is sitting in. Stephen Shore, Alison. And then for Dr. van Dyck, Bonnie Strickland has been on the panel.

Dr. Insel: So, that would open up one slot, but it may be - and it may be that the new members don't want to serve on the subcommittee, but I suspect at least one person would like to.

So, let me first get a sense from the new members if there's interest in serving on either of these subcommittees. If we start with the Services, because that's the most - the tightest squeeze, Ari is interested.

Is anybody else interested in serving on the subcommittee?

Okay. We may be all set. We don't have a problem.

And what about on the Strategic Planning Subcommittee where we have three slots open; is that right?

Is anybody interested in serving there?

We have Marjorie, Geri. And then Denise, are you still with us? We may have lost Denise. So, we may have to check with her at a later point. And Ari is interested in serving on the Planning Subcommittee.

Gerry is out of the room. And Denise is off the phone. So, we can poll both of them later, but I think at this point since we've got - we may have a match, but I want to make sure that we've got - we've checked with Geri and Denise, Ari, before we give you the second slot. Okay.

Mr. Ne’eman: I understand entirely.

Dr. Insel: At least we've got Geri and Marjorie signed up for the Planning - you really don't know what you're getting yourselves into.

Dr. Insel: But I take it as a good

sign that no one on the subcommittee has volunteered to step down, because this was a huge amount of work.

Denise.

Ms. Resnik: Tom, I'm back on the line. I've been volunteering here, but no one could hear me.

I volunteered for everything, actually. So, use me where you think I best fit, but I'm obviously most interested in the services because of the amount of services that we do provide through SARRC and the clinical side of our programs, as well as how we blend that with the research and recruitment.

And then of course I've been interested in the plan for some time.

Dr. Insel: Sure. Well, let me - we were going to do a little bit of work here on the current members to see if we can encourage anyone to volunteer to open up a space on the Service Subcommittee so that you would be able to serve on that.

If that would work out I think given your experience with employment and housing, it would be really helpful to have your insights.

Ms. Resnik: I do want to boast that of our 110 clients in our adult services program, 40 are gainfully employed. So, we have beat the national average.

Dr. Insel: Oh, terrific. I think you've earned your seat.

Ms. Resnik: Okay.

Dr. Insel: Alison.

Ms. Singer: I'll step down from the Services Subcommittee to make room for Denise, who I think would be a tremendously valuable addition to that subcommittee.

Dr. Insel: Okay.

Ms. Resnik: Thank you.

Mr. Claypool: Just one point, Tom. Serving on the Services Committee, I would prefer to be kind of adjunct to it in some way because health reform implementation has perhaps overwhelmed my small office, might be one way of describing it.

And I think I can be very helpful with the services agenda, but I don't need to occupy an entire spot. I can be there periodically, episodically.

But if there is an interest in others joining it, I think my ability to attend every meeting may be something I can't fulfill.

Dr. Insel: Well, we want you on that so badly, Henry.

Mr. Claypool: I understand.

Dr. Insel: I think we really do need either you or Rosaly to -

Mr. Claypool: Right. We understand.

Dr. Insel: Because for the department, you're fundamental for that area.

Mr. Claypool: I understand and we are there. I'm just trying to signal some openness to -

Dr. Insel: Okay. Well, thanks for being flexible.

Mr. Claypool: - co-hosting that one slot. Because realistically -

Dr. Insel: Great.

Mr. Claypool: - there will be limitations on my time for that.

Dr. Insel: Okay. But I think right now we may have a pretty good fit. And the only question will be on whether we need to encourage anybody else to come off the planning - the other subcommittee, but I think we're okay if I've got the numbers right.

Okay. I think we're ready to move on with the agenda as far as I can tell. So, we've done the piece on the update of the Strategic Planning Subcommittee, the Services Subcommittee membership.

Lyn.

Ms. Redwood: Just real quick before we move on, could I get some clarification just about the other two workshops that were mentioned?

Gerry, I think you mentioned one in terms of drug development, and then the other one that Cindy mentioned.

How is that going to feed back into the plan, and are those meetings open?

Dr. Dawson: So, I don't want to speak for the Planning Committee about opening that up to a very, very large number of people just because it's - we're trying to design it to be small and interactive. But I would say that it seems to me we should at least, at the very least, if not wide open for everyone to come, to have representation of the IACC there.

And certainly, I think, having people from there come back and do a review for the IACC, I think, is essential.

Dr. Insel: Yes, so at the very least I thought what we agreed to is that we have someone report out the way we did today.

And most of these meetings will also have some written report, written summary which we can also have distributed, hopefully.

But it would be great if meetings can be open. It is going to depend on the venue and the organizer.

I don't think we can force that issue. But any of you who are organizing meetings, please know that there's lots of interest from your colleagues around the table in being able to attend.

Dr. Lawler: Well, just on the part of NIEHS just echoing Gerry's comments for the meeting that we're planning on organizing, it's still in the very early stages. It's meant to be a pretty small, intimate type of brainstorming session, but certainly there will be room for some additional individuals.

And certainly members of the IACC we would welcome them attending, but it's not intended to be open as in very large numbers of people for this particular meeting.

Dr. Insel: Okay. The OARC update. We're behind schedule, so we want to move quickly through this.

Dr. Hann: This will not take long.

So, this is - I just wanted to - this is a reminder for the members who have been with us for a while, and then for the newer members, the office that helps to support the committee is the Office of Autism Research Coordination.

And that's what we do. We help support this committee in terms of its roles for coordinating activities across the department and across various federal and private agencies.

We do this through a variety of means. We have a website that hopefully all of you have seen. If not, please check it out.

As a FACA Committee, we are required to have a great deal of documentation and proceedings available to the public, which we do through the minutes, as well as all of our meetings, our standing full committee meetings are videocast. And then that's in an archive that people can go to as well.

On the website, too, one can gather the materials that have been presented at meetings and find out information about the Strategic Plan and other activities of the committee.

These are the members of the staff. You can see we're small, but we're mighty. I serve as the acting director of the unit. And Dr. Susan Daniels, our deputy director who really carries a great deal of the water for the committee.

Erin Bryant who is our science writer who's over there diligently listening today to do the minutes. David Cabrera has been with us an NIH management intern.

And Nicole Jones is our web developer. You probably have not seen her because she's usually at the web putting out information when we meet.

Also Dr. Monica Mallampalli is with us as a science policy analyst. And then Lina Perez who I think most of you have interacted with in terms of your paperwork, as well as other arrangements for the meeting.

There's one person who's not a member of our staff that I want to recognize. She works with us a great deal. She works with all of you a great deal, and that's Kate Whelan. She's already left. She was here this morning.

She did yeoman's work to get our five members up and ready to go so that they could actually be here today. And she works with all of you throughout the year in terms of the required documentation as FACA members, and I wanted to acknowledge her at this meeting.

You've already seen some of the benefits and proceeds that I just wanted to make sure. You've received copies of the 2010 plan. It's available on the web. It has been for a while.

You also have received a bound copy of the 2009 Summary of Advances which we were delighted we were able to produce as early as we did this year. In the past, this wasn't available until July. So, we're way ahead of schedule.

There is a second piece to the Summary of Advances which will be coming out later on. There will be a bibliographic index that goes beyond the articles listed here and will be available on the web for essentially what happened in 2009 in the areas of autism research.

You also received, and it's in your packets, and it's now available on the web, we took the analysis of the Research Portfolio that we did based off of 2008, which we literally just did last year, and wrote it up as a very short summary report in terms of the descriptive statistics.

And that will help potentially

those people who are on the Planning Committee and others to sort of see how we might potentially be using that information in the future for updating the plan and talking about progress. But it's available now on the web for everybody out there to have.

The last thing I just wanted to mention was the IMFAR update. Let's see. I'm going to just skip. Here we go.

IMFAR is coming up May 20th through the 22nd in Philadelphia. This year OARC is going to have a booth at the meeting, essentially, and the booth - the function of the booth is for the IACC as an outlet of information that you all have produced, as well as potentially listening and hearing ideas that other individuals have.

We've very, very grateful that four members of the committee have agreed to help us out at the booth at various times to sort of be ambassadors for the committee. And we thank you very much for doing that.

If anyone else is there, wants to stop by, we'd love to see you. This is a first for us. We've never done this before. So, it will be very interesting to sort of see how it works, but we're excited and happy to do it on the benefit of the committee.

That's it.

Dr. Insel: Thanks, Della.

Questions? Lyn.

Ms. Redwood: I just had a question about the updates. If you look through the last minutes, I think it was Ms. McKee who said that the larger pool of articles that have been provided last year was a valuable resource to the community and asked that the list be made available again this year.

And I noticed on the website when I went to look at the updates, it was just the ten selected and I was wanting to know if the larger list of updates was going to also be included.

Dr. Hann: Right. I'm sorry if I

wasn't clear. That's what I had just said. That has been delayed, but we are going to be putting that up on the web along with this.

This is already on the web. This piece is already on the web. So, it would be adding the full bibliographies of all of the research articles.

Mr. Ne’eman: So, do you perform this portfolio analysis on an - you said you do that on an annual basis.

When can we expect the 2009 version?

Dr. Hann: We are now in the process of gathering the data. It takes a while to - we are very much at the gratitude of the various funders to provide us the information. Okay.

So, we have started the data call for that and we hope that we will have that information by July, right, in final form? By fall. Okay. Susan is correcting me.

It is a fairly large endeavor,

but, I think, very worthwhile and incredibly interesting.

Dr. Insel: If you haven't - well, you can take a look through to see how this plays out. It's been one of the most useful things in doing the Strategic Plan, is to recognize what the portfolio really looks like. This is the way we could identify where the gaps were.

Alison.

Ms. Singer: I just wanted to say thank you to the whole team from OARC. Particularly for the process through which we did the Summary of Advances this year.

I know in 2008 we put it together, we spent a lot of time talking about the process, trying to make improvements to the process, and those were very well implemented such that I think we have a much more concise, readable, useful document in half the amount of time.

So, I just wanted to say thank you

to everyone on the team who worked so hard to get this together.

Dr. Lawler: I would like to add my thanks. I know there's a tremendous amount of work that goes behind these kinds of committees that are very active. And I know whenever I get an e-mail from Della, it has many attachments.

But the instructions are always very clear and your team is very responsive. And any question I have ever had is answered really promptly whether it be evenings or weekends, and very cheerfully as well.

So, thank you for all your efforts.

Dr. Insel: And the terms evening and weekends, we don't use those. They don't know what that means in the - in this particular office they don't exist, really.

Other comments or questions?

Okay. The final piece of our meeting on our agenda is to circle back to the public comments that we had and to see whether there was anything that you wanted to discuss from what you heard that you wanted to either share with the committee or share with the public or ideas that you think need further explication here before - Lyn, go ahead.

Ms. Redwood: Tom, I wanted to ask a few more questions about the comments from the National Autism Association.

Is there any agency, a federal agency, that does collect information on the number of children or adults that die with autism? Because that's a critical piece of information and we need to do more than we're doing now to be able to address that issue.

Dr. Insel: Thank you. I was going to go right there.

Ed.

Dr. Trevathan: Yes, thanks. I was going to bring that up as well. I guess before getting into that, just to make the observation I thought the public comments today both in content and preparation and presentation, they were really very well done and I'd like to thank all of you who put an enormous amount of time and effort into doing that. I think we don't often enough thank you for your efforts.

And I think an example of just how sometimes these are very, very helpful is the comments that Jim Moody read. Jim and I have already talked about it. They got quite a bit of attention already from some of us at CDC who we - I think as clinicians we recognize that, yes, we have seen those sorts of problems ourselves that Jim described.

And we do believe, perhaps, I don't want to promise, that we think that we can address some of these questions Jim's raised with some of the data sets that we have. And we've already started to put in motion some activities.

I think we'll see what we can get from the data we have to address some of the data needs that Jim mentioned.

So, yes, I think we can at least do the best we can with some of the data we have. And I think perhaps what might be valuable here is for us to as we look and see what we can do with our data, to identify some gaps where perhaps we need to do better in terms of data collection.

So, I think it's an example of a very valuable comment from the public.

Dr. Insel: Yes, having morbidity and mortality data right now are just critical. And the absence of that is one of the things that, you know, when I sit down with our colleagues at NIAID or NCI, that's actually one of the most difficult places where we sit as we don't have those kinds of numbers.

Lyn, did you want to follow up?

Ms. Redwood: Yes. And the other thing as tragic as that is, and I know I've dealt with the families before that are really looking for answers as to why their child developed autism and why this happened, and they want to donate brain tissue, but they're just not aware of how to do it.

So, if there's another way where we could somehow promote, because this happens and oftentimes it stays afterwards when the parents think, gosh, I wish I could have been able to donate tissue to help get answers about this devastating disorder.

So, if there's another way that we could also promote our brain and tissue banks along the way too very sensitively to parents, I think that that's an important issue to address as well.

Dr. Insel: I'm going to ask Geri Dawson to speak to this. We've been talking about this a lot. And this, again, is in the Strategic Plan that we develop by a repository in real-time. We've got lots of conversations about how to do this.

And the interesting piece is that

the same time that we provide that service, we can also provide services that have to do with bereavement and for families to adjust to this enormous loss.

So, Geri has been the one probably thinking the most about this.

Dr. Dawson: So, Tom is right. We've been having several conversations between the - or I should say among the NIH and Simons Foundation and Autism Speaks of how we can really collaborate to put together a much more aggressive and effective autism tissue program.

And I do think Autism Speaks is in a very good position to do what you're talking about which is to increase our national campaign for awareness around brain tissue, and to increase our outreach to families and just all of those educational efforts.

And we've been kind of waiting to see how this collaboration takes shape before we move to a more aggressive program, but I'm happy to say that I think our conversations are developing very, very well.

We had a meeting this morning about it and I think we'll see hopefully in the next several months, some real increased attention on developing a national resource and also a much more active recruitment campaign because I agree that this is - it's just we haven't done as well as we should.

Dr. Insel: One place where everybody seems to understand, everybody agrees, is that the status quo isn't acceptable. We need to find a way to have a much better resource.

Ms. Redwood: Geri, is Autism Speaks also looking at issues with wandering and how to protect children from injury?

Is that another initiative that you're working on?

Dr. Insel: This is Peter Bell from Autism Speaks.

Mr. Bell: So, we have a project

called the Autism Safety Project which really is designed for first responders. And it's an educational tool resource for really anyone. It's available free on our website and it provides - and we've really - it's a conglomeration of what's been available out there in the community from a variety of people from Dennis Debbaudt to a number of other folks.

And it references a lot of the tools that are available throughout. And this is an issue - and actually I know Stuart Strelan, one of my colleagues, and Lisa Goring in Family Services, have recently reached out and had some conversations with NAA as well, and we see that this is an area that we need some more effort and focus.

And Jim did a beautiful job of talking about a very hard subject and that is a lot of news in the last - just really it seems like in the last several weeks and months of children, as well as adolescents and adults, who have unfortunately gotten into some very difficult circumstances, but this is an area that we believe needs some significant attention.

Dr. Insel: Ari.

Mr. Ne’eman: Well, I think you're absolutely right. Essentially what we need to keep in mind here is we can't just stop at documenting this problem. We can't assume that - I think it's unconscionable to assume that these kinds of tragic deaths are inevitable results of being autistic.

And I think particularly when we look at some of the areas in which this is coming up, elopement, interactions with law enforcement and particularly restraint issues in which there's, I think, a growing body of research and interest at the policy level in doing more to address that.

I think we have the ability to be engaging in discussion on formulating policy recommendations and formulating research objectives.

I'm wondering again if we can't make this area of safety concerns and avoiding - I think the phrase the NAA used was external causes of death, a priority in regards to the Services Subcommittee so that we can see it reflected in the Strategic Plan and hopefully in any policy recommendations we might be able to advise the secretary on.

Dr. Insel: Lee.

Mr. Grossman: This is an amazingly critical problem, and there is such a misunderstanding in the public about what's going on.

I was interviewed live on Good Morning America a couple weeks ago. They had a lead story about this young woman in Florida who was found after four days. And they did a report of four other individuals over the last year who had autism that disappeared for four days and they were found. And they were saying their premise was does autism give these people an inherent ability to survive under those circumstances?

And I was on there and I had to obviously refute that because not a week goes by when we hear about a tragic death of somebody that's eloped, that's gotten out.

I've been to numerous funerals of family members who have lost their child because of a drowning accident or being hit by a car.

But the key to this is that this is part, again, it can't be isolated. There's nothing in autism that can be isolated. And this one particularly because as tragic as those things are with elopement, for example, and these accidental deaths, bullying, the abuse in care homes is of equal, if not more tragic, because that can be controlled and it's not happening.

And we have an initiative that's five years old now called Safe and Sound. And at our conference we have our president Ann

Stevens on this committee too. We do a day-long workshop that incorporates all the aspects of the criminal justice system, the courts, first responders, ambulance drivers, the fire department, as well as families on how they can best protect and keep their families safe and sound.

It is a huge problem and it's one that again with greater awareness, education, we can protect these individuals to a much greater degree.

Eileen Richmond who is the secretary of - I believe it's Health Services for the State of Pennsylvania, has stated that 50 percent of the individuals in the prison system in Pennsylvania are on the spectrum.

So, and obviously they're in there probably under false pretenses. They're being victimized, they're being - just being a victim of circumstance.

Dr. Insel: So, Ari was asking about having the Services Subcommittee take on this issue in some deeper way.

Ellen, Lee, as the people who are responsible for that agenda -

Ms. Blackwell: Actually, I was waiting for the right time to make a comment about the Services Subcommittee because I've heard a lot about services today and I've been making a little list over here.

And Lee and I exchanged an e-mail, a couple e-mails a few weeks ago. And one of the things we wanted to talk about with the committee was perhaps having a services item on the agenda at every meeting.

And it sounds after listening today like that might be something that the committee is open to.

Lee, do you have anything to add there?

Dr. Insel: So, prepare for July 16th.

Ms. Blackwell: Okay.

Mr. Grossman: And this is a

suggestion I guess I'd like some clarity on if you don't mind. I hate to take the time.

On the Services Research Workshop that is scheduled for the fall, and you said the Planning Committee will take over that, would you like to maybe in July start with the process of planning that and we could have -

Dr. Insel: No, before then.

Mr. Grossman: Okay.

Dr. Insel: You'll be part of a phone call, you and Ellen and others. We'll bring both subcommittees together to think about the best way to plan that.

Ms. Blackwell: And I have one more item I just wanted to draw to the committee's attention.

CMS recently issued an environmental scan report and it sort of tails under Rosaly's discussion earlier about comparative effectiveness research.

So, I'm going to ask that OARC distribute it to all the members. And it's really a condensation of the evidence behind different services and supports for children, youth and adults with autism. And I think the public could also really benefit from this information.

So, unfortunately our weblink is not active yet. But as soon as it is, we'll make sure that it will be up on the Promising Practices website on CMS. And this is specific to services for people with autism spectrum disorder.

So, I just wanted to draw that to the committee's attention as well.

Dr. Insel: Geri, Stephen and then Ari. And then we go to Denise for the last word.

Dr. Dawson: Very quickly I just wanted to say as you begin to think about planning for that workshop, that one of the people you might want to call on is - Lisa Gilotty and Joe Piven organized a conference this year on autism and aging.

And on the second day, they brought in some phenomenal people to talk about services and the kind of research that's been done in other health concern areas about how to address large-scale service issues particularly at such an early stage, and it was very, very informative.

So, I just think getting the information that was gained from that conference would be really helpful, and also maybe using some of the same speakers. They were really good.

Dr. Insel: This is why we need this calendar. It would have been good to have known that.

Stephen.

Dr. Shore: Yes, I just wanted to reiterate what Ed mentioned a little bit earlier about the quality of the public responses commentary. And especially the poignant commentary by Lindsey, as well as Paula.

This is very important stuff that we need to reckon with. And even better, I see that we are beginning to do that. So, thank you.

Dr. Insel: Ari.

Mr. Ne’eman: Well, it sounds like the Service Subcommittee will be meeting more than once in the time between now and the coming meetings.

I just wanted to take a moment before we close to also bring up two of the other issues that were brought up during public comment.

The one being I think Lindsey raised what I think is a very important issue, the topic of women on the spectrum and the under-identification and lack of access to diagnostic services that many women on the spectrum face.

And I wonder if that's something that we might be able to arrange presentation for the committee on at one of the subsequent

IACC meetings.

It seems to definitely be an area that should carry a high priority just as racial and ethnic disparities and diagnosis carry a priority.

The other area I just wanted to highlight was something that Paula raised around ethical issues in autism research. And I know Paula has actually already delivered an invited presentation to the IACC I think last year on that topic.

And there was I think to some extent, a limited amount of deliberations to the type of follow-up that we could undertake from that.

So, I wonder if - and it probably - I don't know whether or not we would have the time at the July meeting. But certainly by the October meeting we might be able to put on the agenda some time to specifically discuss the issue of what types of ethical safeguards we can put in place to ensure that autism research is pursued with all due consideration for the ethical pitfalls that sometimes come up.

Dr. Insel: Duly noted. Okay.

Other comments?

Lyn.

Ms. Redwood: I just wanted to comment too regarding Eileen Nicole Smith's presentation. And I know in the past in looking at the Strategic Plan, we sort of bounce back and forth whether or not we're specific about what environmental factors we want to look at.

So, when we are in the process of updating the plan, I think we need to consider things like she brings out with early ultrasound or cord clamping.

I think the issue about brain stem injury is something important that we need to look at as well.

I know there was comments during the nonverbal presentation in terms of why children aren't talking, and I think that's one of the areas we need to look at as well as some of the brain pathology that might lead to an inability to be able to talk.

So, I would really like to make sure that those things are considered when we are in the process of updating the plan this next time.

Dr. Insel: Along those lines, the comments from Carolyn Rodgers about ultrasound reminded me that there has been a body of work through, I think it was Kaiser of Northern California, that was presented in IMFAR, but I believe has never been published, or has it been published?

Ms. Redwood: It was published earlier this year.

Dr. Dawson: It was published, this is Lisa Croen. And we actually had a discussion about this during the break. And I think you were saying the woman who - I'm sorry I've forgotten your name, that brought up this issue that there were some methodological issues.

And I really suggested that some of these longitudinal studies, whether it's the National Children's Study or the IBIS-EARLI ACE Networks, I think, are going to be a mechanism for looking at some of these early prenatal factors that I think we still are very, very interested in.

Dr. Insel: Absolutely, but we just have to remember to collect those data. So, it has to go in on the front end.

Denise, you've been very patient. You've stayed with us through the whole day. We're going to give you the last word.

Ms. Resnik: Well, I appreciate that. And I appreciate everything that's been discussed today and the hard work by this committee that I followed for years and I thank all of you.

I am particularly of course interested in the service model and what we're doing every day for families. And at the same time, how we can do a better job of knitting that together with our scientific requirements understanding that the biggest roadblock we have is those subjects whether it's the brain banks or whether it's the genomic studies, that what kind of strategies can we deploy that will more closely align families and subjects, individuals with autism who are involved in these services and programs that could be tied more directly to scientific research.

And so that would be a goal that I would like to see from the subcommittee and learn more about the subcommittee and its focus. And, again, it's something that we, I believe, have been very effective here demonstrating. And families just need to be asked and we know there needs to be an infrastructure to support enrolling them in that research.

Dr. Insel: Well, thanks very much.

And thanks to all. This has been a really great meeting. And I think that expanding the committee has just made it richer and more interesting and allows us to often bring in new issues, new perspectives that we might have been missing before or only hearing about intermittently.

I also want to provide my thanks as well to those who made public comments. I agree as Stephen and Ed and others have said, this was really a very rich discussion and you brought up some great issues for us, every one of you. So, that's very, very helpful for the IACC.

Thanks to all for your being so engaged in this. We will meet again on July 16th. We're going to work hard to see if we can get the secretary to yet another meeting sometime this year.

I don't know whether we'll do that or not, but it was great to have her here today and to get both her comments and the comments from White House staff about their commitment to the work we do.

Thanks everybody. We're adjourned.

(Whereupon, the meeting was adjourned at 5:03 p.m.)