U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES

INTERAGENCY AUTISM COORDINATING COMMITTEE

FULL COMMITTEE MEETING

TUESDAY, JULY 19, 2016

The full Interagency Autism Coordinating Committee (IACC) convened in Bethesda, Maryland, at the National Institutes of Health (NIH), Building 31, C Wing, 6th Floor, 31 Center Drive, Conference Room 10, at 9:04 a.m., Bruce Cuthbert, Ph.D., Chair, presiding.

PARTICIPANTS:

BRUCE CUTHBERT, Ph.D., Chair, National Institute Of Mental Health, National Institutes of Health (NIMH)

SUSAN DANIELS, Ph.D., Executive Secretary, IACC, Office of Autism Research Coordination (OARC), NIMH

DAVID AMARAL, Ph.D., University of California (UC), Davis MIND Institute

JAMES BALL, Ed.D., B.C.B.A.-D., JB Autism Consulting

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

JUDITH A. COOPER, Ph.D., (for James F. Battey, M.D., Ph.D.), National Institute on Deafness and Other Communication Disorders (NIDCD)

SAMANTHA CRANE, J.D., Autistic Self Advocacy Network

GERALDINE DAWSON, Ph.D., Duke University

RUTH ETZEL, M.D., Ph.D., Office of Children's Health Protection, U.S. Environmental Protection Agency (EPA)

AMY GOODMAN, M.A., Self-Advocate

SHANNON HAWORTH, M.A., Association of University Centers on Disabilities (AUCD)

ALICE KAU, Ph.D., (for Catherine Spong, M.D.), Eunice Kennedy Shriver National Institute of Child Health and Human Development (NICHD)

LAURA KAVANAGH, MPH, Maternal and Child Health Bureau, Health Resources and Services Administration (HRSA)

WALTER K. KOROSHETZ, M.D., National Institute of Neurological Disorders and Stroke (NINDS)

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

BRIAN PARNELL, M.S.W., C.S.W, Utah Department of Human Services

EDLYN PENA, Ph.D., California Lutheran University

LOUIS REICHARDT, Ph.D., Simons Foundation Autism Research Initiative

ROBERT RING, Ph.D., Autism Speaks

JOHN ELDER ROBISON, College of William and Mary

STUART K. SHAPIRA, M.D., Ph.D., Centers for Disease Control and Prevention (CDC)

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

CATHERINE SPONG, M.D., Eunice Kennedy Shriver National Institute of Child Health and Human Development (NICHD)

JULIE LOUNDS TAYLOR, Ph.D., Vanderbilt University

LARRY WEXLER, Ed.D., U.S. Department of Education (ED)

NICOLE WILLIAMS, Ph.D., U.S. Department of Defense (DoD)(attended by phone)

TABLE OF CONTENTS

PROCEEDINGS

DR. BRUCE CUTHBERT: Good morning, everyone. Welcome to our July 2016 meeting of the IACC, and welcome to the July weather in Washington for all of those of you who came in from out of town, as did I sleeping in 50-degree nights a few days ago, so I'm re-acclimating myself. We're happy to have you all here.

We will be joined today as well by Dr. Thomas Novotny, the HHS national autism coordinator and deputy assistant secretary for health. He is not here as yet, but he should be here shortly and we will look forward to having him join us as a guest of the committee.

We'd also like to welcome Dr. Stuart Shapira as a new member of the IACC. He is replacing Dr. Cynthia Moore, who was called away to take on additional responsibilities with respect to the Zika virus outbreak and containing that.

So, Dr. Shapira, I wonder if you would like to tell the committee about your expertise and your work as it relates to autism.

DR. STUART SHAPIRA: Sure. Thank you very much.

So, again, I'm Stuart Shapira. I'm trained as a pediatrician and as a clinical geneticist, metabolic geneticist, and molecular geneticist. I trained at Baylor -- I trained -- I'm sorry. So I trained at University of Chicago and then did further clinical training at Harvard and at Children's Hospital in Boston.

After training, I started clinical work at Baylor College of Medicine in Houston and then moved to the University of Texas Health Science Center in San Antonio and practiced clinical genetics and metabolic genetics for 14 years.

I came to the CDC 11 years ago. I was originally on the Pediatric Genetics Team at the CDC coordinating genetics components of several large case control studies, including the autism research study at CDC, SEED, the Study to Explore

Early Development. And I'm the PI on the dysmorphology part of SEED. I moved into the position of the associate director for science and chief medical officer for the National Center on Birth Defects and Developmental Disabilities at CDC three years ago and have been serving in that capacity.

And I'm very excited to be here. I look forward to meeting everyone on the committee. Thank you very much.

DR. CUTHBERT: Thank you. We will appreciate having your expertise to inform our decisions, so welcome.

Okay. Now, I'm happy to turn it over to Dr. Susan Daniels, the coordinator of our Autism Committee at NIMH, and I want to take this opportunity to thank Susan, as always, for doing virtually 100 percent of the work or leading her group who do all the work to put together the agenda, get everything all ready, and have us prepared for the meeting. So, Susan, thank you, and I'll turn it over to you to take the roll and approve the minutes of the last meeting.

DR. SUSAN DANIELS: Thank you. Welcome, everyone, and thank you to the team for all your work getting us ready for this meeting.

I'd like to take the roll first to see who's here. So Bruce Cuthbert?

DR. CUTHBERT: Here.

DR. DANIELS: Jim Battey?

DR. JAMES BATTEY: Here.

DR. DANIELS: Cindy Lawler?

DR. CINDY LAWLER: Here.

DR. DANIELS: Jennifer Johnson and Aaron Bishop are not going to be here today, and Francis Collins and Josie Briggs will not be here today.

Ruth Etzel?

DR. RUTH ETZEL: I'm here.

DR. DANIELS: Tiffany Farchione?

(No response.)

DR. DANIELS: Melissa Harris is not going to be here today. Elisabeth Kato will not be here today.

Laura Kavanagh?

DR. LAURA KAVANAGH: Here.

DR. DANIELS: Walter Koroshetz?

DR. WALTER KOROSHETZ: Here.

DR. DANIELS: Stuart Shapira?

DR. SHAPIRA: Here.

DR. DANIELS: And Linda Smith and Shantel Meek will not be here.

Cathy Spong?

DR. CATHERINE SPONG: Here.

DR. DANIELS: Larry Wexler?

DR. LARRY WEXLER: Here.

DR. DANIELS: Nicole Williams?

DR. NICOLE WILLIAMS: Here on the phone.

DR. DANIELS: Oh, thanks.

David Amaral?

DR. DAVID AMARAL: Here.

DR. DANIELS: Jim Ball?

DR. JIM BALL: Here.

DR. DANIELS: Samantha Crane I believe is on her way.

Geri Dawson?

DR. GERI DAWSON: Here.

DR. DANIELS: Amy Goodman?

MS. AMY GOODMAN: Here.

DR. DANIELS: Shannon Haworth?

MS. SHANNON HAWORTH: Here.

DR. DANIELS: David Mandell is not going to be with us today.

Brian Parnell?

MR. BRIAN PARNELL: I am here.

DR. DANIELS: Kevin Pelphrey is not going to be able to make it today.

Edlyn Pena?

DR. EDLYN PENA: Here.

DR. DANIELS: Louis Reichardt?

(No response.)

DR. DANIELS: He may be on his way.

Rob Ring?

DR. ROB RING: Here.

DR. DANIELS: John Robison?

MR. JOHN ROBISON: Yep.

DR. DANIELS: Alison Singer?

MS. ALISON SINGER: Here.

DR. DANIELS: Julie Taylor?

DR. JULIE TAYLOR: Here.

DR. DANIELS: Wonderful.

DR. CUTHBERT: Thank you.

DR. DANIELS: So perfect timing.

DR. CUTHBERT: Thank you.

DR. DANIELS: Would you like to --

DR. CUTHBERT: Yeah, let me just --

DR. DANIELS: -- say anything?

DR. CUTHBERT: -- Let me break in here to welcome Dr. Thomas Novotny, as I mentioned, the HHS national autism coordinator and deputy assistant secretary for health. Welcome, Dr. Novotny.

DR. THOMAS NOVOTNY: Thanks. Are we on here? Okay, great. Nice to see you again. Sorry for my delay but traffic coming up here from HHS building in downtown D.C. is sometimes unpredictable, so I got here a little bit late. But thanks for the opportunity to come and say hello.

I'll just give you a very, very, very brief update because this is a slow-moving process of trying to mobilize resources within HHS to accommodate the report requirements that are -- is the main sort of deliverable that I need to produce as a result of the Autism CARES Act.

We've assembled a working group of representatives from across the Department with equities in autism care and have set up our first meeting of the group to lay out our report content on August 29. And this will be then the sort of kickoff to the development of the report, which we anticipate being able to produce by the end of this calendar year. Things do get in the way sometimes, but I'm pretty confident that we can do that.

We've got a good sense of an outline on this. It's, again, devoted towards -- specifically towards the transition period, which I know there's going to be a subject matter discussion this morning, which I'm looking forward to hearing. And it will involve representatives from several of the agencies in the writing of this.

As you I think also know that we do not have any appropriations for the work of this coordination activity, but we are going to be able to do this within the confines of our existing resources, and I think we'll be able to come up a reasonable interim report. We do hope that as things move forward in the next fiscal year that we'll be able to identify additional resources that will support more sort of comprehensive work as we move forward.

But at this point I think we're pretty

confident that we've got a good representation from across many agencies, several of whom are represented here, with a working group that I think we'll be able to put forward a really, you know, robust piece of analysis about where we currently are on transitioning to these issues and what the gaps are that need to be addressed either through federal kind of support but also I think in terms of the stakeholders and non-Federal Government but also at the state level, which I think is where much of the action is actually occurring.

So I want to not take up too much time here this morning because you've got a pretty full schedule, but I do want you to know that we are working as much as -- as fast as we can within the confines of our existing resources to get this done.

So I want to thank you for your attention and hopefully more interaction as time goes on.

DR. CUTHBERT: Okay. Thank you very much.

And we will continue at NIH to try and find some resources.

DR. NOVOTNY: Please do, yes.

DR. CUTHBERT: We've been working on that. We've had a couple leads that have fizzled, but we'll -- we will keep trying and hope to give you some resources to help with that very important report. We faced similar constraints on staffing and resources but still want to help out.

DR. NOVOTNY: I know that.

DR. CUTHBERT: So thank you.

Okay. Susan, back to you for the minutes.

DR. DANIELS: Wonderful. So you'll see in your packets you have a set of draft minutes that I sent out to the committee from the last meeting that took place in April. I didn't hear by email from anyone about any comments, but does anyone have any comments or need to discuss anything about the draft minutes? Any corrections needed in the document?

(No response.)

DR. DANIELS: Not seeing anything, can we have a motion on the floor to accept the minutes?

MR. ROBISON: I'll move to accept them.

DR. DANIELS: A second?

UNIDENTIFIED SPEAKER: Second.

DR. DANIELS: Thank you.

All in favor?

(Ayes.)

DR. DANIELS: Any opposed?

(No response.)

DR. DANIELS: Any abstaining?

(No response.)

DR. DANIELS: The motion carries to accept the minutes as provided here. We'll get those up on the Web as soon as possible after the meeting. Thank you.

DR. CUTHBERT: Samantha hasn't come in yet, has she?

DR. DANIELS: No, she is running late. Yes?

MR. ROBISON: Are we going to conduct our meeting with this crew that we've got at the table now, right?

DR. DANIELS: Yes.

MR. ROBISON: Well, if I may --

FEMALE SPEAKER: Microphone, sir?

MR. ROBISON: -- let's push a couple of these chairs back so we're not all jammed together at this end of the table.

DR. DANIELS: That's fine. I think there might be one or two people who are still going to arrive, but I think we have a little extra space.

MR. ROBISON: If people could move down, I for one -- I got nowhere –

(Laughter.)

MR. ROBISON: So one…

DR. DANIELS: So we could do Margaret Miller maybe.

DR. CUTHBERT: Yes. So our first item on our agenda, as you can see, is an update on legislative and legal issues from Samantha Crane, our very own IACC member. Unfortunately, she is not here has yet.

(Coughing.)

DR. CUTHBERT: Pardon my voice. So let's move on to Margaret Miller, her presentation about the Autism Society Lifespan-Based Strategy Update.

She will be talking about the Society's new Strategic Plan and vision, and this will give us an opportunity, if we so desire, to consider all of these issues and the possible ways for collaboration.

So welcome.

MS. MARGARET MILLER: Good morning. Thank you for having me. I'm honored to be here to talk about what we're doing at the Autism Society to spend a couple minutes with you here this morning.

So for those of you not familiar, the Autism Society's mission is to improve the lives of all affected by autism. And we envision a world where individuals and families living with autism are able to maximize their quality of life, are treated with the highest level of dignity, and live in a society in which their talents and skills are appreciated and valued.

And so as we moved through our strategic planning process in 2015, which I'll go a little bit more in detail about, we pulled out three keys to achieving the mission in our vision. Those three keys: maximizing the quality of life, that people are treated with dignity, and that their talents are valued.

So in 2015 we went through a really comprehensive, highly inclusive, and transparent strategic planning process that engaged over 200 stakeholders around the country, so family members, professionals, affiliate leaders, and individuals with an autism diagnosis to really answer the question how do we not only serve individuals with autism but how do we know that we're doing it successfully? How do we transition to an outcomes-based model where we know what we're doing and know what those outcomes are, we know how we're improving people's lives.

So the goal of that strategic planning process was to define how best to assure opportunity and measurable outcome success and quality of life throughout an individual's life. And so through the strategic planning process, we identified 15 quality-of-life indicators. They're based off of QOL, quality-of-life indicators. So how do we start to identify? What are those outcomes that we should be working towards, that we should be advancing to be -- you know, to be hitting our mission of improving people's lives?

As you can see, we've categorized them under each of the three keys to our vision, and they're -- you know, they're really basic quality-of-life outcomes, things that you want for everyone, you know, on the spectrum, off the spectrum, just quality of life, independent living, health and well-being, social connections, recreation and leisure, autonomy and self-sufficiency, communication, inclusion, respect, and dignity, safety, self-identity and acceptance, financial stability, academic success, pursuit of dreams, subjective well-being, and meaningful employment with fair wages.

So the benefits that we see, of course, it allows us to start measuring outcomes, start measuring success consistently nationwide. The Autism Society has 101 affiliates around the country. The strength of our affiliate network is that we have, you know, boots on the ground, people in the community that can best serve that community's needs. But as a national organization, how do we ensure that outcomes are being met consistently around the country through all 101 affiliates and how do we start to provide a consistent experience for individuals interacting with all of our affiliates so that if they move from one city to another and move from one affiliate to another, there's -- they know they're going to be getting a consistent quality of experience and that they're going to, you know, get the same support in reaching those quality-of-life indicators.

So how we're advancing those 15 quality-of-life indicators, those 15 outcomes that we're now focusing on is through five core services. So Autism Societies nationwide, our entire affiliate network has five core services that we put programs -- you know, categorize programs through, so advocacy; national, state, and local advocacy; education, information and referral; support; and community.

So we've now rolled out our national outcomes model. We actually just rolled it out last week at our national conference. So everything that any

Autism Society affiliate is doing moving forward will fall under the five core services and advance a minimum of one of those 15 outcomes. Again, you know, the strength of our network is having boots on the ground in the community that they can take those outcomes and apply them to their local community in the way that makes the most sense and focus on the gaps in-service in their specific community.

So I'm going to assume that most people listening in and that are sitting in this room are familiar with lifespan planning, so I'm not going to spend a whole lot of time here, but I did want to touch on the five stages of life that we've identified and that we're focusing on as we move forward in implementing the outcomes model and implementing our lifespan programs and services.

So we are looking at birth to five, school-age, transition to adulthood, adulthood, and older adult. Obviously, there are unique challenges in each life stage and as you look at transition to the next stage. So now that we've rolled out this national outcomes model, we are working with that to shift the way that our network is thinking to really start thinking about outcomes. You're putting on all of these programs and providing these services. Which of those outcomes are you advancing? How are you, you know, quantitatively identifying how you're helping these people?

As we move forward, the next step for what we're looking at is now taking those 15 outcomes and identifying milestones at each stage of life. So to achieve maximum quality of life in each of those 15 indicators, they're milestones. And so how do we work back to identify different milestones, different indicators as an individual progresses through each life stage so that we know when they get to that next transition, when they get to whatever, you know, goal that they've identified through their person-centered plan, you know, how are we building those milestones all along the way?

And then once that's developed, we'll start looking at developing the programmatic supports to help individuals achieve each of those milestones. Again, I'm -- I think that this group is familiar with the life stages, so I won't go into detail there.

As we look at developing a lifespan planning initiative, what that really means, we know that there are other groups doing lifespan planning. There are other groups doing person-centered plans. We don't want to recreate the wheel. We don't want to duplicate efforts. What we really want to do is take that person-centered plan that people are creating and take it the next step. You know, how do we build those supports, those milestones and supports into the person-centered plan to really help each individual achieve their goals? So that's the next step that we're working on.

While I'm here, of course I'm going to put it out there how you can help. There's a lot of milestone and indicator work being done. We don't -- like I said, we don't want to duplicate any work, so we're absolutely looking for partnerships with organizations that are creating those milestones, creating those indicators. And then also once we -- you know, once we build out that milestone progression, also looking for partners on developing that programmatic support, whatever that, you know, programmatic structure looks like. And then, of course, funding, you know, funding to actually implement the plan.

That's kind of it in a nutshell. Any questions?

(No response.)

MS. MILLER: All right. Well, I will -- I'll be here all day. I'd love to touch base if you have questions.

Yes?

MR. ROBISON: I'd just -- I'd like to commend you for seeing the Autism Society start to take a more active role in getting involved in this. This is the first time I've seen you come here to present something like this to the committee, and I think it's great that you're here doing it so --

MS. MILLER: Well, thank you. I wish I could take credit for it. I actually just joined the national organization in March, so I'm going to kick back the kudos to our very, very recent past chair Jim Ball. But thank you. Thank you. We're -- we really are excited to have been invited to present here today. We're really excited about the direction the Autism Society is going and how we -- you know, how we're moving to develop those outcomes-based models to better serve individuals.

I do want to add just quickly so in the process, you know, we have a committee for each of our strategic initiatives, and the Lifespan

Committee has prioritized which initiatives to focus on first. And so the top three that they've prioritized are transition to adulthood, employment, and housing. So as we look at developing those milestones and programmatic supports, we'll be working on, you know, their life of priorities.

So -- yes?

DR. CUTHBERT: Thank you. That's very helpful, that last comment about the particular priorities that you have right now.

MS. MILLER: Um-hum.

DR. CUTHBERT: Does that get reflected in all of your different affiliates across the country? You mentioned, you know, a couple times the boots on the ground as an advantage, which clearly it is. Is that reflected across all of the different local affiliates across the country or is it more still up to them which of those they want to implement? I'm just trying to get a sense of how all that works, particularly with respect to potential collaborations that people hear or people that we know might, you know, want to get in touch with you about.

MS. MILLER: Sure. That's a great question. So right now, where we are is the affiliates are still very autonomous. I don't anticipate changing that because I do think that that's our strength, that we have people in each community that know that community's needs better than I would ever know sitting in my office in Bethesda.

As we move forward, the vision that we have is that from national we will be creating programmatic supports, service, structure, the framework where an affiliate will more easily be able to take that framework and implement it. I think that nationwide the feedback that we're hearing from affiliates is, you know, almost everywhere. Transition to adulthood and employment and housing are the key issues everywhere and the issues that for so long have not received the same attention as your early interventions and your early diagnosis.

I don't know if that answers your question. I would say that moving forward, we will be providing the program supports. You know, the first things that come from national will be to support those three initiatives. But the affiliates would still have the autonomy to take that and implement it in the way that makes the most sense locally.

DR. CUTHBERT: Okay. Yeah, thank you, that does answer my question.

MS. MILLER: Okay.

DR. CUTHBERT: And certainly the idea of transitions to adulthood and adult services are very much in keeping with one of our major themes of this committee throughout our discussions over the year so --

MS. MILLER: Great.

DR. CUTHBERT: -- very resonant. Thank you very much.

MS. MILLER: Thank you.

DR. CUTHBERT: Any other questions or comments?

Yes, Shannon.

MS. HAWORTH: What other nonprofits or disability organizations are you currently working with?

MS. MILLER: So we are -- we talk to a lot of organizations. We sit down regularly with -- our CEO sits down pretty regularly with Autism Speaks, with -- who else? With ASAN, with AHRC, so we have a very collaborative mindset. Where we are right now, we're really just entering what I see to be the more collaborative space or the more collaborative need in developing those milestones. Our staff is very, very knowledgeable about autism, about information and referral, and is very good at providing education.

We don't have -- you know, we don't have an outcomes research staff, and so that's where we're really looking to ramp up our collaboration and partnerships with organizations that already have done that work or, you know, specialize in a particular, you know, initiative.

DR. CUTHBERT: Okay. Thank you again. This is very --

MS. MILLER: Thank you so much.

DR. CUTHBERT: -- informative to hear and we're glad to hear about all of these programs. Thank you.

Okay. Next, we're going to just jump back now on our agenda to welcome our own Samantha Crane. Good morning, Samantha. And we're going to put you to work immediately to give us an update on some autism legislative and policy updates. So welcome.

MS. SAMANTHA CRANE: Hi everyone. I'm sorry I was running in late today. I had locked my keys in my house and had to take an Uber to the IACC meeting. So thank you for bearing with me and for being flexible in the schedule.

I'm going to take off my IACC hat and put on my ASAN hat for a second and maybe also have an IACC hat and discuss sort of policy updates. I'm the legal and public policy director of the Autistic Self-Advocacy Network. These are some policy issues that we've been focusing on and that I think the IACC would be really interested in learning about.

ASAN is the nation's largest advocacy group by and for autistic people ourselves. Its leadership is entirely autistic, so we end up having a more adult-focused policy outlook. We tend to focus on the needs of adults because we find that a lot of policy initiatives already are focused on the needs of children. We think that that is -- that the needs of adults are an area of unaddressed need.

And we tend to focus on policies that increase access to services and supports that our population really has a hard time with, including health care, access to communication for people who don't speak, and long-term services and supports to enable independent living.

We have a very diverse base both in terms of our chapter membership, our board, and the people who support us. That includes people who really need a lot of support, so that tends to be the population that we focus the most on.

There are a lot of policy-related complaints that we'll hear from autistic adults living in the community. They're particularly worried about access to health care. They're worried about access to transition and employment services. There is a growing awareness of concerns with autistic people interacting with police and emergency services, mental health system. A lot of people don't understand autistic people's particular communication style and needs.

There is a lot of need for long-term services and supports. People want to avoid therapies that they find harmful and get more access to interventions that are aimed at -- that are in the style that they prefer and that are aimed at older children and adults. And we are also seeing a lot of lack of access to communication supports.

So I just want to talk today about policies that are new or emerging or proposed that would address some of these concerns: the new guidance in home and community-based settings; state-supported decision-making legislation; better access to habilitative services under the Affordable Care Act; the Home Care Rule, which might really affect people's ability to live independently; and autism safety legislation.

So we've talked a lot about the Home and Community-Based Services Settings Rule in past meetings, but just to remind everyone, it provides quality controls for services that receive a very specific funding stream. So it does not cover all long-term services and supports for people on the autism spectrum. It just covers home and community-based services. These are often capped by enrollment, so they want to make sure that the people who are getting home and community-based services funding are really getting the services that are meant to be funded by this small capped funding stream unlike facility-based long-term services, which are generally not capped.

The goal of the Settings Rule is to require access to non-disability-specific settings to ensure maximum autonomy and choice, ensure that day services are focused on the actual interests of the person. So people have to have person-centered plans. They cannot just do mall therapy, which we've talked about a little bit in this committee where a person -- you know, a big group of people, they all go to the mall and that's considered community integration. And there needs to be more accountability.

There has -- the original Home and Community-Based Services Rule was issued in 2014, and now, two years later -- more than two years later, we're seeing the first State Transition Plans actually getting approved. States have to create plans to transition into compliance with this new rule.

The first plan that was approved by CMS was the Tennessee plan, and it's a good example to give to states as guidance for the kind of plan that will be approved in the future. Tennessee conducted extensive site assessments. They evaluated really every site where these services were being provided. They communicated consistently with a broad array of stakeholders, and that included providers, individuals, and families. They partnered with other agencies like the Department of Intellectual and Developmental Disabilities, managed care organizations, and they created pretty good accountability guidelines. And those are all things that CMS cited as positives when they approved the plan.

It's interesting to note that Tennessee took a nuanced approach to facility-based services, which is something that we've been talking about a lot in our committee in the past several months. They weren't -- I'm not focusing on residential services right now, but they talked about facility-based day services. That can be sheltered workshops. It can also be a facility where people go for their day services or day habilitation that are not recreational services.

They said that facilities were going to be limited to either time-limited training so, for example, if you're working in a workshop and you're learning a specific skill for a specific amount of time or if the person has a person-centered plan and the facility-based service is aimed at achieving a community living or employment goal. And there we see the substantive standard. We need to be aimed at achieving a community living and employment goal. We need to be person-centered. And they're going to make really sure that facilities don't just end up being a place where people go because it's an easy place to put them because it's an existing slot and they don't want to think too much about where to put someone. Why don't we just put them in a facility? It needs to be really well-justified. And I think that's a good example of what we're trying to accomplish with the Home and Community-Based Settings Rule.

There are some other interesting developments that we haven't been talking about as much at the IACC Committee meetings. One is supported decision-making legislation. Supported decision-making is an alternative to guardianship. It is meant as a supplement to guardianship. It's not replacing guardianship systems. But it adds a new option to avoid guardianship where possible for an adult with a disability. The person with a disability picks a trusted support person to help make decisions but doesn't lose legal capacity and can change their trusted support person at any time. This is a good medium support option for people who are transitioning to adulthood or who have transitioned to adulthood a while ago and just want an extra amount of support to help them make decisions. It also works well for people who are aging and need additional support that they didn't need before.

This legislation has already passed in Texas, and there's pending legislation in D.C. and Delaware. In Delaware the House has passed but the Senate is still looking at it.

In the Affordable Care Act there has been new guidance on what counts as a habilitation service. According to the Affordable Care Act, certain kinds of health insurance have to cover all essential health benefits, and one of the categories of essential health benefits is habilitation.

Habilitation is like rehabilitation but for a person who didn't have the skill in the first place, for example, a person with a developmental disability who isn't walking or talking at the expected age, something to help them get to the point where they acquire those skills that they didn't have before.

This is very important because many, many private health insurance plans do not -- did not cover habilitation services before the Affordable Care Act, so we expect many children especially to have access to these services that they didn't have before.

The Transition to Independence Act is a voluntary demonstration program that's been proposed in Congress. It would reward states for increasing competitive integrated employment and integrated day services, especially among people who are receiving home and community-based services.

The sponsors in the Senate are Grassley, Casey, and Wyden, and it was just introduced in the House as well by Van Hollen and McMorris Rodgers, and other cosponsors are Sessions, Langevin, Crenshaw, Foster, and Beyer. It's an interesting program because it would create an opt-in system for particular accountability guidelines to help people move into integrated employment, which is really great.

The Home Care Rule, this is actually a rule that came into effect a while ago like the Home and Community-Based Settings Rule but there was a legal challenge to it that just finally was rejected. The Department of Labor now requires overtime and travel pay for almost all homecare workers for people who are receiving home and community-based services.

There was a court challenge based on

integration concerns. Many people who require, let's say, 16 hours of services a day might have a really hard time achieving that level of support if their workers don't at least occasionally get approved for overtime and travel time pay. For example, if someone has one worker working eight hours and who is then relieved by another worker working eight hours, then they might need, you know, one person to end up working 16 hours if the second worker is sick or going on vacation. So they might need their existing -- you know, one of their two existing providers to work overtime for a few days or for a week or so to cover gaps in coverage.

We need to make sure that states budget for overtime and travel pay and don't simply say that they won't pay anyone working overtime. If people have gaps in coverage for their home and community-based services, they could be pushed out of the community.

And finally, an update on Avonte's Law, which you heard Stuart speak about last session, it recently passed the Senate, and there is an identical House version that is currently pending. It includes funding for not only tracking devices but also safety training programs.

But one thing that I've noticed and have expressed concern about is that there's still no real good evidence base for the most important outcome for tracking devices or really any safety training program, which is how often it prevents injury or death. The annual report that is required by Avonte's Law will track the number of missing persons found, but it won't track the number of -- the reduction in missing-persons events.

This can be particularly a problem if you have an individual who lacks road safety skills, traffic safety skills, water safety skills. That person, if they go where they're not supposed to go, into traffic or into water, they could experience a serious injury or death within minutes. So we can't just be talking about missing persons and finding missing persons. We need to be talking about saving lives.

This is an opportunity for research, and I hope that everyone will seriously consider this. And we need to do better outcomes research on that particular outcome for more safety interventions. And I'm thinking not just of tracking devices or other things to locate a missing person but things like traffic safety training, assistance with making a person aware of dangers around them, and swimming lessons for people with significant disabilities. Even a little bit of training can go a long way in these cases.

And now, I'd like to open up for questions.

MS. SINGER: Thank you, Samantha. That was a really well-organized, interesting presentation. Thank you for that.

My question is about the HCBS rules. What happens if, as part of person-centered planning, the person chooses to be in a disability-specific setting? How will that person's needs be met under the new rules?

MS. CRANE: So in the Tennessee State Plan, that was one of the things they addressed in their Facility-Based Settings Rule. If a person's person-centered plan includes a decision to be in a facility-based setting, it has to be documented in the plan, it has to be documented what community or independent living goals that setting is helping the person achieve and why. And that's really important because, as I pointed out, it's very easy to place someone in a facility-based setting, and we find that sometimes people will be steered into a facility-based setting during the person-centered planning process and then written down as their choice even if it wasn't necessarily a choice they would make if they had all of the options. So we have to have that kind of documentation requirement saying this is exactly what goals the placement is for referring.

DR. CUTHBERT: Thank you. Could you back up, I think, two slides? Because -- you're able to back that thing up. One more, yeah --

MS. CRANE: Yeah.

DR. CUTHBERT: -- this one, the Transition to Independence Act. That was very interesting. You noted that states will be rewarded for increasing the competitive integrated employment, et cetera. In what way are they to be rewarded? What's -- how's that envisioned in that sense --

MS. CRANE: They would get -- so, first of all, the states would only be rewarded if they opted in to the demonstration program. They would have to propose a demonstration project to CMS. CMS would then approve that project, and then they would be able to access these incentive payments if they increased competitive integrated employment.

There are very specific benchmarks that they need to meet. It's a results-oriented project, so it's not simply paying a state to operate a program that's designed to increase competitive integrated employment. They need to show an increase in competitive integrated employment in order to get the incentive payment, and then they'll get incentive payments from the Federal Government.

The incentive payments need, then, to be reinvested in community-based programs, so it'll create, hopefully, a virtuous cycle where states will get their incentive payment, and then that incentive payment will make additional funding available for efforts to increase access to the community for people with disabilities.

MS. HAWTHORN: I wanted to thank you, Sam, for your presentation. As a parent of a young child, I've been more focused on childhood issues, and I see that I need to kind of shift a little bit and pay more attention to adult issues and be more supportive.

I wanted to ask you, are you finding that there are the same issues for aging adults that there are -- as there are for younger adults or is it a different set of issues?

MS. CRANE: Yeah, there are going to be some similar issues for aging adults that we see for younger adults. For example, housing, aging adults are actually going to have some of the same housing concerns and some different housing concerns. They might need -- they, certainly like younger adults, will need supports in order to remain in community-based housing, and we'll see some aging adults who are looking into getting their own apartment or their own housing for the first time in their lives after living with family members for an extended period of time. Then, when their family members die or become unable to host them in their house, the aging adult will often at an advanced age themselves need to find new housing. So that's going to be really -- a particular problem.

But aging adults also are going to have some special needs. We definitely are seeing a really hard time with aging adults accessing health care. People who are aging often have different medical needs. We need to find opportunities for aging adults to access housing that's friendly to families. So many aging adults or even just not aging but not transition age anymore -- adults might want to start a family or get married. There's not a lot of housing available for families of people with disabilities in which the head of the family is actually a person with a disability.

And we're also seeing a lot of concerns with, you know, access to supports, as someone might gradually need more support as they age. A lot of the time people are given supports and they might have a really hard time upping that when they find they need more support.

Finally, you're going to have different employment needs. A person who's transition age is much easier to get into competitive integrated employment than a person who has spent an extended period of adulthood not being employed. It's going to be much harder to get that person into a work routine, into a job that is open to them. It's much easier to get that for an 18-year-old.

Aging adults who are retirement age that's often, you know, not going to be as much of a concern, but you're going to need to find day activities for retirement-age adults on the autism spectrum, you know, other than employment obviously. So that's another concern.

DR. CUTHBERT: Okay. Thank you. We'll have time for one more question, Geri, and then we need to move on.

DR. DAWSON: I want to, Samantha, just applaud you for a very comprehensive presentation and for the work of the Autistic Self-Advocacy Network in tracking and understanding and advocating for these really important bills. It's very, very well done.

I just have one quick question, which is so you mentioned, you know, the needs of the aging adults in general may overlap in some ways with issues that, you know, people on the spectrum would face. Are there other groups that you're partnering with as you advocate, for example, in going to see, you know, people in the legislature and so forth? Are you combining with other groups in order to increase your voice as you advocate?

MS. CRANE: Yeah. There are quite a few groups. The National Health Law Program is one example of a group that's really working hard on access to home and community-based services, and they are, you know, interested in broad health advocacy.

We work with groups like the Autism Society a lot. We work sometimes with Justice in Aging, which is an aging disability advocacy organization that is very actively interested in coordinating with disability advocates and making sure that those concerns are addressed. I think Justice in Aging is also part of our workgroup on the Home and Community-Based Services Rule. So those are examples of some groups we work with.

DR. CUTHBERT: Okay. Samantha, thank you again for your deep expertise and your leadership in this area.

MS. CRANE: Okay. Thank you.

DR. CUTHBERT: It's very much appreciated. Okay. And now we move on to a presentation from Dr. Pam Feliciano from the Simons Foundation Autism Research Initiative. This is about a new initiative they have entitled SPARK. Welcome. We look forward to hearing about it.

DR. PAM FELICIANO: Okay. Good morning, everyone. Hopefully, our -- yeah, great. So my name is Pam Feliciano. It's really an honor to be here this morning to tell you about our new initiative called SPARK. I'm the scientific director of the project, and I also am a parent of an 11-year-old boy with autism. So it's really an honor to be here today.

So the goal of SPARK is to create a re-contactable research cohort of 50,000 individuals with autism plus their family members across the United States. We really want to engage these families, and we ask that they agree to be re-contacted, although they are not required to participate in future studies that we tell them about.

We want this cohort to accelerate research by making the cohort -- access to the cohort and data available to any qualified scientist in the research community, so any scientist who would like to recruit from SPARK will be able to down the road.

Okay. So one of the driving principles of SPARK is that it has to scale. So we know -- we've made great strides in autism research in the past 10 years, but we know that data from tens of thousands of individuals is required to really take autism research to the next step, so where we need it to be.

So with that in mind, we made SPARK so that it can be scalable, and we built it completely online. So any individual in the United States with a professional diagnosis of autism can come to our website and register and enroll in the study.

The informed consent process takes place completely online, so in the first consent they consent to share data and to be re-contacted. They spend about 20 minutes giving some basic medical history and information about the autism diagnosis. If they choose to -- but it is not required to participate in SPARK -- they can participate in the genetic analysis piece. So they'll sign a consent where the person will agree to give a saliva sample. So we actually mail the saliva kits to their home where they can provide the saliva sample, and that's actually mailed back to a sequencing lab that does the genetic analysis. So here we -- what we've done is made it as simple as possible. And I think so far we've been pretty successful.

We really do this as a two-way communication, a two-way street of communication. We are really wanting to connect families to researchers, and we really hope that tens of thousands of families will agree to give us their genetic and phenotypic information, and in return, SPARK is committed to giving back individual genetic and behavioral results to families. We haven't yet started doing this, but the plans are in place to do this.

In order to get to 50,000, we have to recruit from a lot of places, so we have a national network of 21 clinical sites across the country that are helping us recruit. We also are recruiting with partners such as IAN and other advocacy community-based organizations around the country. So those partnerships are really important to us. We also are recruiting from the community at large through our national media and social media campaign.

Okay. So this is a map of the different clinical sites across the country, so we think that by making this a national cohort, we will be able to, you know, build a cohort that is useful to the most researchers. This is a distribution of the web users for the past few months, so you can see they are centered around the different clinical sites across the country, although they are, you know, definitely spreading further out beyond the clinical sites, and we think that's the media campaign that's working. And also the clinical sites are reaching out not just in the metropolitan areas but also throughout their whole states. So we actually do have the participants in SPARK from every state in the country.

So far, we -- so we launched in April. We have consented 17,000 participants so far. We have a really high completion rate, so 67 percent of the people that come onto the website to start enrollment, finish. We're really pleased with so far. Of these participants, 7,000 individuals have autism spectrum disorder. Eighty percent of the cohort so far is under 18, and 20 percent of the cohort is over 18.

You can see from -- on the right the ratio of males to females in children is as we would expect. It's about four to one. And the adults the ratio is still skewed towards males but not to that extent as it is in the minors.

We also have some phenotypic information on the cohort so far, so about 17 percent of the under-18 participants, they have had an intellectual disability diagnosis. Ninety percent have had ASD-specific services, which is what you would expect. Eight-four percent have ever had an IEP. The average age of diagnosis for a community sample is what you would expect, about four years. In terms of language ability, 12 percent report as not speaking, 13 percent report as single words meaningfully, and 16 percent report as three words together into sentences, where the majority of the cohort is reported as using longer sentences.

We also have SCQ scores on under-18 participants. The average SCQ score is 23, so this is what you would expect. The score -- if you have a score over 15, that tells us that you are meeting that threshold for autism in a rough manner. And so the majority of the cohort is reaching that threshold.

Okay. So the phenotypic information that we're collecting in SPARK is obviously really important to researchers to help guide who they would want to recruit for their studies, but it's -- and also another big piece of SPARK is collecting the genetic information so that we can eventually advance precision research and precision medicine, so targeted clinical research and eventually get to targeted treatments.

We know that autism is very heterogeneous, both phenotypically and genetically, and because of that, the new treatments for autism that will come about in the next 10 to 20 years are likely to be quite diverse. And by that I mean that each treatment that comes out will not be applicable to the majority of the group. It's just going to be probably applicable to just a subset of individuals with autism. So it's really important for the community to set up the infrastructure that's required for targeted research so that researchers can recruit people according not just to their phenotypes but according to their genotypes. So participants are consenting to be re-contacted according to genotype and phenotype, and eventually, investigators will be able to recruit based on that information.

And I'll just walk you quickly through how we are approaching genetic analysis in SPARK. So once a participant agrees to participate in the genetic analysis, they get a saliva collection kit in their home, they mail it back, and the DNA extraction is done in a CLIA environment. Exome production is done elsewhere actually.

In the -- after this is done, individuals with known genetic causes of autism are identified, and that's confirmed in the CLIA lab. Then, we notify that research participant's provider. And in this way we are able to return genetic results for a subset of individuals in the SPARK cohort.

Okay. So things are going really well so far. We have a lot of things to do the rest of the year. We still have to return genetic results to individuals, and we're starting to get data back.

Also, I anticipate doing that sometime in 2016. Sequencing of thousands of autism trios is ongoing. We have hundreds on the sequencing machine to date. We will start to release data at the end of 2016 so researchers can access the data the same way they access our other SFARI resources, so data from SSC and VIP and other cohorts will be the same mechanism.

We also will open SPARK up for recruitment by different researchers, and if you would like to stay abreast of our updates, please sign up for our newsletter and also follow us on Facebook and Twitter.

And I'd just like to thank SFARI and the SPARK team. It's a really big effort on a lot of people.

And I'm happy to take any questions. Yes?

MR. ROBISON: I think that the SPARK effort is commendable, but I have to say that I'm really profoundly disappointed at the total focus on young children in all these pictures and also in your presentation of demographics. It's clear that the vast majority of sign-ups to Simons SPARK are parents enrolling on behalf of autistic children.

DR. FELICIANO: Right.

MR. ROBISON: And as aware as Simons is of the pressing concerns for adult issues --

DR. FELICIANO: Um-hum.

MR. ROBISON: -- to totally ignore that --

DR. FELICIANO: Okay.

MR. ROBISON: -- in a new initiative is bothering me.

DR. FELICIANO: Okay. I appreciate that. I don't agree that we are ignoring adults. So it's -- the demographics of the individuals who have enrolled, we've been really pleased that we've been able to get 1,500 adults to enroll in this project. We certainly have had very specific outreach efforts to adults, so we've partnered with organizations like GRASP, and through partnerships like GRASP, we've enrolled hundreds of adults. I don't think that we are purposely ignoring adults by any means. And there weren't any pictures in the presentation that I --

MR. ROBISON: Well, there were.

DR. FELICIANO: Yeah.

MR. ROBISON: There were pictures of little children, and when you showed the measures --

DR. FELICIANO: Okay. So --

MR. ROBISON: -- you cited things like IEPs, which are child-related measures.

DR. FELICIANO: Right. Right.

MR. ROBISON: But I -- no, I don't mean to say you purposely ignored adults.

DR. FELICIANO: Okay.

MR. ROBISON: I didn't mean that.

DR. FELICIANO: Okay.

MR. ROBISON: I'm sorry if I implied it.

DR. FELICIANO: Okay.

MR. ROBISON: I just think we need a greater focus.

DR. FELICIANO: Oh, I -- we absolutely agree. We have set up partnerships with organizations that have an adult focus, and we think that adults are really important. We've had some really interesting stories that have happened so far, so, for example, we have an 80-year-old elderly person who was diagnosed by Leo Kanner, who consented to be part of the study. So we really feel that by concerted efforts to get to adults, we will get there. And so, you know, this is the demographics after three months of enrollment so -- yes?

DR. RING: I have a quick question. Do you have a sense of or if -- or is it exclusionary for being involved, concurrent participation in other cohorts and studies?

DR. FELICIANO: Okay. So --

DR. RING: Do you have a sense of how many --

DR. FELICIANO: No, there's no exclusion criteria like that. We don't want to duplicate efforts, so if someone has been sequenced by AGRE, what we're doing is collecting GUID information on all the participants and we'll be able to match people who have data -- sequencing data already in NDAR. So we won't sequence those individuals if that make sense. We --

DR. CUTHBERT: Excuse me. Yeah. Does everybody know what a GUID identification is?

(No response.)

DR. FELICIANO: So a GUID is a unique identifier. It takes information that's unique to that person and generates an identity number. So if someone has been sequenced as part of the Autism Sequencing Consortium, their data is already in NDAR and we won't re-sequence those people.

Yes?

MR. PARNELL: As the community is still transitioning from DSM-IV to DSM-V diagnoses --

DR. FELICIANO: Yes.

MR. PARNELL: -- are you accepting people --

DR. FELICIANO: Yes.

MR. PARNELL: -- with the other autism diagnoses --

DR. FELICIANO: Yes.

MR. PARNELL: -- or is it just --

DR. FELICIANO: Yes, yes, yes. DSM-IV diagnoses are on there. Okay.

MR. PARNELL: Yeah. And I'm wondering, do people have to submit some sort of verification of diagnosis --

DR. FELICIANO: No.

MR. PARNELL: -- or are you using the genetic sequencing to screen out well-intentioned but not --

DR. FELICIANO: We can't -- no.

MR. PARNELL: -- genuinely autistic people?

DR. FELICIANO: No. I mean, this is a really important question and a really important decision that was made. In order to scale to 50,000, we can't manually confirmed cases so we are relying on self-report.

The good news is that other cohorts have been set up such as IAN that have previously been self-report. And when validation studies have been done, which include both bringing people back into the clinic or record review, the validation has been really high, upwards of 90 percent.

I think that there will certainly be people in SPARK who might not meet clinical criteria for autism spectrum disorder, but I think it's just a trade-off of scale, and we'll be able to know who those people are by SCQ and other basic questionnaires that individuals fill out. We also will do a validation study. Yep.

Yes?

MR. ROBISON: I think that while I don't back down one bit on my --

DR. FELICIANO: Okay.

MR. ROBISON: -- opinions about adult services --

DR. FELICIANO: Yep.

MR. ROBISON: -- I do think that I was unfairly harsh on you for this particular study, and I'd like to offer you a different request.

DR. FELICIANO: Okay.

MR. ROBISON: With you representing Simons and their funding power, I actually think that the reason that you have so few older adults is that we have a substantial problem -- those -- that population is not recognized. And maybe the way to address that would be for Simons to support a significant effort like BRUGO over in the U.K. to identify older autistic adults and interest them in participation in these studies because we see these really alarming public health statistics about mortality in older autistic people, and we do not have the identified population to study.

So I think that that could be a tremendous complement to your effort, and might Simons consider supporting such a thing?

DR. FELICIANO: I can't speak for Simons, but I can say that we are absolutely making, again, concerted efforts to reach adults and not just through partnering with community organizations but partnering with researchers who already have longitudinal cohorts. So there are people in our clinical sites who are affiliated with longitudinal cohorts that they've been following for 20 years and wanting to enroll them in SPARK.

So I think eventually we will get there. It will take some time, though, because I think the adults are just -- they're difficult to get into the studies. It just is challenging.

DR. CUTHBERT: And I think Samantha had the next question and then Shannon and then --

MS. CRANE: I have two actually very quick questions. One is I recognize that since you've been signing up for just a short period of time this probably hasn't happened yet, but do you have a plan in place for re-consenting people once they

--

DR. FELICIANO: Yeah.

MS. CRANE: -- reach adulthood?

DR. FELICIANO: Right. We don't have all the pieces in place, but we know that that's an issue. There actually have been people that have aged out in the past three months, and so those people are sort of in a frozen state right now, but we will have a plan to re-consent those.

MS. CRANE: Okay.

DR. FELICIANO: Yep.

MS. CRANE: And when the people's genes are sequenced, it looked like, based on your presentation, they're notified if they have a known genetic marker. Is there --

DR. FELICIANO: If they choose to receive it.

MS. CRANE: Yeah. Is there going to be a plan or is there any consideration of notifying people if they have genetic markers for associated conditions --

DR. FELICIANO: Sure.

MS. CRANE: -- like epilepsy or Ehlers-Danlos that we know overlap quite a lot?

DR. FELICIANO: No. So if we identify genetic cause for that person's autism, which in the case of some -- some cases that does include -- the phenotype does include epilepsy. So they're notified for the cause of autism. The affiliated phenotypes, again, would just -- would not be --

MS. CRANE: Okay.

DR. FELICIANO: -- part of the return. If you're asking about incidental findings, there is a -- people do consent to whether they want to hear them, but we absolutely --

MS. CRANE: Um-hum.

DR. FELICIANO: -- do not actively look for them.

MS. CRANE: Okay. Thank you. That's good to know.

DR. FELICIANO: Yeah.

MS. HAWORTH: You said you have 17,000 participants. I'd like to who was represented. And then is it across like socioeconomic status and across ethnicity?

DR. FELICIANO: Right.

MS. HAWORTH: And if not, what are your efforts to get these other groups involved because there's often not enough minorities --

DR. FELICIANO: Yes.

MS. HAWORTH: -- or lower-income people --

DR. FELICIANO: Yes.

MS. HAWORTH: -- represented in these studies.

DR. FELICIANO: Right. Right. Okay. So I think this is a really interesting question. We struggled again with how much data we should collect at the very beginning. And in order to get to a high completion rate, there was a lot that we sacrificed in the beginning. So we don't have actual like race, ethnicity information on participants. We do have zip code, which can kind of be used as a proxy, but we don't have that information yet.

That -- those questions are in a questionnaire that we hope that participants will fill out. And every year there is plan to check in with the participants and ask them to fill out the rest of their questionnaires with some financial incentive. So I think eventually we will know this information, but right now, we don't have it.

We certainly feel that part of SPARK is to get to underserved communities, and we are -- haven't, you know, gone through all our outreach efforts yet, but that is definitely part of the upcoming year. And we do have a -- you know, we do want to translate into Spanish at some point.

DR. CUTHBERT: Okay. Last question.

DR. SHAPIRA: I actually had the same question wanting to know how well you are reaching minority groups and underserved populations. You answered it. Thank you.

DR. FELICIANO: Okay.

DR. CUTHBERT: Okay. Thank you very much.

DR. FELICIANO: Okay. Thanks.

DR. CUTHBERT: There's clearly a tremendous amount of interest, and this is a very exciting initiative, so thanks so much for sharing it with us today.

Okay. Now, we are pleased to welcome Anne Roux from Drexel University. She will be talking about a recent report issued by the Life Course Outcomes Program on vocational rehabilitation for people in the autism spectrum, again, continuing this theme that we have been developing. So welcome.

MS. ANNE ROUX: Good morning. I'm thrilled to be back again representing the Life Course Outcomes Research Program at the A.J. Drexel Autism Institute on behalf of our director, Dr. Paul Shattuck, and our research team.

The work I'm going to talk to you about today was supported in part by a Health Care Transitions

Research Network Grant from HRSA. And we are particularly grateful to have this grant because it has allowed us to take our research findings and to translate them into a format that is usable and understandable, we hope, for people who need to use this information like advocates, policymakers, and decision-makers.

So the A.J. Drexel Autism Institute is the first autism research program in the country that uses a public health approach to studying autism. And I shared some of this information with you when I was just here in January talking about our previous report on transition outcomes. But just as a reminder, we use a three-pronged approach to studying autism research. We look at the primary, secondary, and tertiary levels of prevention.

So Dr. Craig Newschaffer runs the Modifiable Risk Factors Program, and Dr. Diana Robins runs the Early Detection and Intervention Program. And I'm here today representing the Life Course

Outcomes Research Program run by Dr. Paul Shattuck. And what we do is focus on the turning points and transitions in people's lives and where their lives intersection with community, with society, and with social institutions.

So some of our seminal work that I shared with you last time has to do with employment. And we have a finding about employment that's particularly concerning that autism in our work consistently people are having a more difficult time with finding employment than people with other types of disabilities.

And when we look further and we think about disconnection, people who do not have jobs and are also not in school after they leave high school, I shared with you last time that 4 in 10 people with autism fall in that category. And of even possibly greater concern is the 1 in 4 of those people who do not have any access to services that would help them to find employment or to continue their education.

So these statistics are what led us to focus our 2016 National Autism Indicators Report on vocational rehabilitation. And you should have in your folders today a copy of the beginning of our report. You can access the complete report online at the website that you see here. The report this year is produced just as last year's report was where it is accessible science. You should be able to understand and digest the findings, we hope, and use them in your work.

There are reports that are available about people with intellectual and developmental disabilities and their vocational rehabilitation outcomes that will be similar to what I share with you today, but to my knowledge, there's not a lot out there that has to do specifically with autism. And when I talk to people about the type of data that they need in order to advocate and make decisions, these are the types of things that they're really struggling with trying to find.

So I spent quite a long time myself trying to understand vocational rehabilitation and really to understand that across states and understand the process that's out there that people have to go to to be found eligible and qualify for services. What services are available that's consistent across states? How are outcomes tracked? It took me quite a long time. It's really difficult to find this information. So if you look through the beginning of the report that we included, we tried to produce some graphics that will help people to understand nationally what is the process for receiving services.

So I'm going to share just a little bit with you about what I learned along the way. So vocational rehabilitation is really primarily a funder of employment services. It's funded at the national level, and it's administered through the U.S. Department of Education's Rehabilitation

Services Administration. VR actually doesn't do a lot of direct service provision. That's done more at the state and the local level.

VR services are provided to people with disabilities to about one million people across the nation annually. And that includes people that are transition age, typically around age 14, and then it continues. The services are available at least through people's working-age lives.

VR serves individuals with significant physical and mental impairment, and these are all defined by VR what they mean by significant. It's people who have substantial problems with employment who require services to get, to keep, or to regain employment if they receive VR services and then lose that job and have to reinitiate services.

VR funds a variety of services, including job search assistance, counseling and guidance, job placement, and on-the-job supports, which is also known as supported employment.

The services that a person needs are determined in conjunction with that individual as a team and are written into an individualized plan for employment, an IPE. VR generally provides services until a person has maintained employment for about 90 days, or in some cases longer if that is written into the IPE.

So there are several reasons why we focused on the VR data set, and it's important to know that actually developmental disabilities is the department that provides more vocational services, far more than is provided through VR in terms of dollars. So across the nation, employment services are primarily funded through Medicaid, HCBS waivers, and state general revenue funds.

But we're focusing on VR because it is guided by federal law and because it is tracked through a large national data set. And the questions, the types of data that they're tracking are fairly consistent across states, so it allows us to do some comparisons. And that there is also a system for addressing user concerns so we can kind of get at whether people are satisfied with the services that they're receiving or not.

It's timely that we address VR quickly, and it's important to understand the context that looking at this data is occurring within. So we're really in the midst of a national experiment right now with vocational services and employment. We have several movements that are important to understand.

So Employment First is a national movement that promotes integrated employment as the primary and preferred outcome for people with developmental disabilities. And the Department of Labor is really actively promoting Employment First.

And then you've probably heard of the Workforce Innovation and Opportunity Act, which I will refer to as WIOA. WIOA was passed in 2014, and similar to what Samantha was talking about with the HCBS state plans that are just coming out, the state plans for WIOA are also just being approved as well.

And so there were several significant changes that occurred within WIOA that are important to understand as we move forward. So one of those is that 15 percent of state VR funds have to now be directed to transition-age youth. So they're trying to push funding earlier and services earlier hoping that that will improve VR outcomes.

It's -- they've also extended the length of time that you may receive services, and one significant push with WIOA is to try to improve wages that people are earning and to eliminate or reduce reliance on subminimum wages for people with disabilities.

Finally, about 50 percent of state employment funds must now be directed to youth with the most significant impairments. So you see that this transition focus is being repeated over and over, and it's really important as we go forward that we have baseline information so that we can tell whether the state plans and innovations across states are actually starting to move the needle on outcomes or not.

So we use the Rehabilitation -- whoops -- Services Administration data set, and that is called the RSA-911. Let me scooch back to that. Okay. Sorry. This is an administrative data set, and what that means is that VR counselors, when they see people, are entering information about who they see and about the cases that they're managing across time. There is no information in this data set that comes directly from people with autism, and that's different than what I talked to you about last time where we were talking about the National Longitudinal Transition Study-2 and that there were significant portions of questions that were asked to people with autism directly. So I think that's really important to keep in mind as I share this data with you.

We know that as the number of youth with autism are aging into adulthood, that the numbers of people being found eligible for services by VR are increasing. So you can see that in 2009 there were about 7,400 people with autism who were found eligible for services, and by 2014 that number had doubled to about 18,000. Now, that only represents about 3 percent of people in VR who receive services, but if you think about what we know and the data that we have about outcomes and adults with autism, that's a sizeable population for us to be able to see how they're doing.

So what do we know about VR service users with autism? We know that their average age is around 22 and that they range from age 12 to 69. And I'm talking to you specifically about the 2014 data set, which is our most recently available data.

Compared to VR service users who did not have autism, the autism group is significantly more male, white, and under the age of 21 when they begin services. Nearly 70 percent of the applicants were supported financially by friends and family, which makes sense when you consider that many of them were younger. About 25 percent were supported by public funds.

Almost half of the applicants were high school students or a little bit younger at the time of application, and about 97 percent of those were receiving some type of accommodations or special education supports. Eighty-three percent of the autism group had a high school level of education or less or they were currently in high school.

We're interested in this transition-age group because one of the things that we'd like to see is that that population of transition-age youth, the people that are getting services earlier is starting to grow across time.

So we found that about two-thirds of eligible VR applicants with autism actually received services through VR, and we wondered why that would be. Why would more people not be receiving services? And when we looked at this, we found that nearly half, at least in terms of what is recorded in the data, refused further services, and about another fifth were unable to be located.

We don't know why people refused services. There's not a second level of questions beyond that. We also don't know what happens to people who are found ineligible or what happens to people who do not get a job and are not receiving services, or perhaps they are -- found a job on their own or they're receiving services through another entity.

We looked at expenditures. VR service users with autism cost about $5,900 per person across the length of the services that they received, and that's compared to about $5,400 for people who did not have autism. And I struggled with this as I wrote this up because I think it's important to not frame people with autism as expenditures, so I'm going to offer just another thought to you, too, that there's cost and then there's investment. And in investments, we expect some sort of a return but we don't know if we have a return unless we're actually measuring outcomes. So that's an important thought, I think, to take away is what we'd like to see is that we have more information about adults with autism so that we can think about more how we're investing and the return on investments that we're receiving as a result.

So when we look at what those investments or expenditures actually bought us, about 60 percent of VR service users with autism exited with employment. Now, this does not mean that the other 40 percent could not find work. Again, we don't know what happened to those people. Perhaps they found a job through somewhere else or on their own, or perhaps they never worked following that.

For VR service users with autism, the most common reason for exiting VR services without getting employment was again that they refused further services. Others were unable to be contacted or located, a lower percentage were transferred to another agency, and still fewer were deemed to have a disability that was too significant to benefit from VR services. So that was only about 2 percent of the data set were found ineligible because they were too severe, and that's a contrast to what we hear from people in the community who often tell us that they couldn't even get their foot in the door to VR because they were found ineligible right off the bat. So that's an important question to track as we go forward.

In the VR data set, similar to our other outcomes data sets, there's not a lot of information about impairment severity of people, so we don't know their IQ or we don't know their conversational impairments. But it can be useful to look at supported employment because you have to have the most significant level of disability in order to access supported employment. And find that about one-third of the workers with autism had supported employment or on-the-job supports when they left VR.

When we look at the types of jobs that people with autism had, about three-quarters of the group fell within the top five to six jobs that were possible to have. The most common job type was office and administration support, and nearly one-quarter of the group with autism worked in those types of jobs.

So the job types were mostly similar across VR users with autism, whether they required supported employment or not. However, there were some differences. Those that were in supported employment were more likely to work in food preparation, and more had jobs in building and grounds cleaning and maintenance-type positions.

A little bit of context before I share this data. So for the year 2014 for all employees in the U.S. about 19 percent worked part-time, and $240 per week was their median weekly wage. And when we look at the autism group, we find that about 80 percent work part-time and that their median weekly income was $160. So when you calculate that out across a year, what you find is that the bulk of people that are -- with autism that are receiving VR services are becoming employed but then having jobs that place them below the federal poverty level.

So when we look specifically and we think about people that are employed with supports or without supports, those that are employed without supports, about 76 percent again are working part-time for about $170 per week, and those who are employed with supports, about 90 percent of those are working part-time for median wages of $145 per week. And again, WIOA really focuses on trying to bring up that wage level and producing sustainable wages for people.

So how do outcomes and services compare across groups and across states? I told you that about 3 percent of the people in the VR data set have autism, about 9 percent have intellectual disabilities, which is one of our comparison groups.

So when we look across groups, we find that those with autism received services at a similar rate to those with intellectual disabilities and only slightly higher rate than those with other types of disabilities.

We find that the average expenditures on total services per person with autism were nearly 20 percent higher than the group of people with intellectual disabilities. The expenditure was closer to that for people with all other types of disabilities. And we know that supported employment are the most costly types of services. Those tend to cost about two to four times more than any other services. But when we looked more closely, it wasn't that the autism group received supported employment more often than other groups. We really don't have an explanation currently for why this group would cost more.

And then also VR service users with autism exited with a rate of employment that was similar to those with intellectual disabilities and other types of disabilities. We also found that their rate of working part-time and their median wages were also similar across all the groups. So in this data set, at least for this year and at the national level, it did not appear that the autism group was faring worse, but hold that thought for just a moment.

So when we looked specifically at supported employment, people with autism received supported employment less often than those with intellectual disabilities, and of course those with all other types of disabilities.

So there was little variation compared to peers, but the story really shows up in where you live. That -- the state-level data is really where the message is. So VR outcomes vary dramatically across states, as I'm about to show you, and nearly every state has different types of policy, different legislation, and different activities that are focused on implementing Employment First systems change and will be focused on implementing WIOA. So as state plans roll out, we expect that this level of variation will probably increase across states.

So we looked at the 50 states in the District of Columbia and broke down the autism data by state. It's also important to know, though, that we did not have data for some states. There were several that either didn't report it or we're not sure why the data wasn't there. We chose to go ahead and analyze the data as it was as states reported it, but obviously, this can affect some of our findings.

So how many eligible applicants with autism received services? This number varied by about 50 percentage points across states. And then similarly, the number with autism who exited VR and went on to employment again varied by about 50 percent.

We also calculated what we call the autism wage gap. So we looked at all wage earners in the state and what their earnings were, and we compared that to people with autism who were employed without supports. And when we look at this, we find that the gap between most wage earners in the state and those with autism varied quite dramatically from almost $23 an hour in the District of Columbia to about $6 in West Virginia, but an average of about $8.

And I talked to you about some of the limitations to this data. So we covered that there are no reliable measures of impairment severity in this data set, and there likely are inconsistencies in data collection and entry across states. We have no direct reporting from service users with autism, and we don't have any information about people who do not receive VR services or who exit before they have a job.

In terms of research priorities, this type of descriptive data that we produce is really laying a foundation for where we're going to go next with all of our outcomes research, but it's particularly true with this data set and with Social Security data. So we would like to understand more about service use patterns, about people who -- churn is a term used in Medicaid research. And similarly, we think that people churn in and out of VR services where they may receive a job with VR help, be employed on their own for a while, but then possibly lose that job, have to go back into VR, and then simultaneously are probably rotating in and out of public benefits like Social Security income. So we're very interested in that.

And then the state and local level variation is another area that we would like to explore next and are seeking funding because we would like to know what are the significant factors that are modifiable across states that we could start to impact through policy and services that would help to identify model states as we go forward so that we can replicate the programs that they're using. We think this is a really important question, so we're going to be starting to track those WIOA state plans.

And that's the end of my presentation. I'm happy to take questions.

John?

MR. ROBISON: As someone who operates a high school and a post-high school training program for autistic people back in Massachusetts, one thing I observe about your comment about why people drop out of VR, in Massachusetts the VR programs are limited to six and eight weeks for most people. And I see situations where, especially people with mild or moderate intellectual disabilities and autism come into the program and they talk to the counselors and it's like, what, six weeks you're going to teach me to be X or Y or Z? And it simply isn't realistic. And people opt out because the training that's offered isn't going to work.

And so you think, well, what if they go through it anyway and try it, and I have some of those people employed in our complex, and I -- we're a part of that group that's employing people part-time and they don't make living wages, and it's because there isn't state funding to teach the people skills that would qualify them for full-time jobs. And I think that is a real tragedy.

MS. ROUX: Um-hum.

MR. ROBISON: And I wonder what could we do to address that? The idea that a six- or eight-week program is going to take many of these folks and turn them into productive lifetime workers, it's just not real.

MS. ROUX: Absolutely. And I agree that I think that's why WIOA attempts to address that at least in providing longer-term services to youth. I think it's also important that we look at outcomes from Project SEARCH-type programs and Project SEARCH adapted for autism. That is providing services for longer and more intensely in a more focused manner but also are facilitating that collaboration between VR, Department of Ed, Department of DD, and getting all the players to the table because we know collaboration works.

MR. ROBISON: Project SEARCH has been great here like when I've seen it shown at NIH, but how do we make Project SEARCH work nationwide? Is there a model for that?

MS. ROUX: I don't believe that there is a nationwide model. There are similarities, and it is certainly administered by one person, one set of people who are trying to keep fidelity to that model across states. But I think the research that's coming out on it shows that it merits obviously further consideration.

Alison?

MS. SINGER: So in your data you showed data for people with autism and then people with intellectual disability.

MS. ROUX: Um-hum.

MS. SINGER: Where -- how are you including people with autism and intellectual disability?

MS. ROUX: We actually separate them out. So when we look at group-level comparisons, we're looking at people who have autism as their primary or secondary cause of impairment, and that means that the VR counselor said that autism was the cause of their impairment.

When we talk about group differences, though, we do not include people that have both autism and intellectual disability co-occurring. We look at those groups separately, realizing, of course, that a lot of times it does co-occur.

MS. SINGER: So what happens to those people who have both? How are they tracked?

MS. ROUX: I assume that you could look at them in the data set and look at people who have co-occurring disabilities. It's not a clean data set because even -- we talked before about clinical verification of diagnosis. There's obviously no way to verify. Not only that, but this is data that's entered by someone who made a judgment that this person does or does not have autism and that that is the primary cause of impairment as compared to intellectual disability. We simply don't know.

MS. SINGER: But they are included this program?

MS. ROUX: They are.

MS. SINGER: Okay.

MS. ROUX: Oh, absolutely they are included. Yeah. We just -- we want -- when we talk about how one group is doing versus another group, it's important to us in outcomes research that we separate out groups as cleanly as we can, knowing that they do share a lot of characteristics.

Yes, Laura?

MS. KAVANAGH: So when -- I think it was 31 percent or 30 percent of the people whose VR cases were closed were receiving supported employment --

MS. ROUX: Um-hum.

MS. KAVANAGH: -- and I just don't -- maybe I don't understand the system as well, but what happens to their supports when their case is closed?

MS. ROUX: That is an excellent question. So when you have supported employment, you needed a significant level of supports to get a job and maintain that job, and then you have that job for 90 days. At the end of the 90 days or sometimes a little bit longer than that if it's written into their plan, they discontinue receiving those services from VR. So VR does not administer those services or fund those services. However, they may be picked up by a community rehabilitation agency so they still can continue to receive services. We don't know how many people do continue or perhaps return back to VR and sort of start the process all over.

We also don't know what happens to those people after they exit VR and then are transferred to another provider because the data collection stops. And this is the problem, again, with trying to look at employment through developmental disabilities is we don't have the same rigid level of data collection like we do with the RSA data.

DR. CUTHBERT: Okay. Last question and then we need to move on.

MS. CRANE: I just wanted to add that Medicaid's Home and Community-Based Services Program also often fund supported employment, and there's some interesting demonstration programs that would sort of blend and braid those funding streams so that VR will cover the service and then it seamlessly transitions to being covered by Medicaid's home and community-based services. So those are going to be interesting, but I don't think that they would be covered by the data set unfortunately.

MS. ROUX: Fortunately, though, we can link some of these data sets, and so we're currently trying to get access to the Social Security Administration data so that we can look at the VR data, SSA data, and hopefully some Medicaid data and hopefully tell a more complete story about what's happening to people across time. And again, this is, you know, a plea for longitudinal study funding that is really important that outside of what's being asked to people and entered into these data sets administratively that we really need a means to follow people and tell their story over time outside of some of these systems.

DR. DANIELS: Anne, I have a question for you related to our Strategic Plan update. Are there any particular limitations in data sets that you notice that we should take into account when thinking about question 7 on the Strategic Plan?

MS. ROUX: I -- well, I think that the million-dollar question that people always ask us is to break down the information by severity level. There's just -- it's such a heterogeneous population, as everyone at this table knows, and it's important for us to be able to somehow get at what people need and what they're receiving relative to what their level of need is.

DR. CUTHBERT: Okay. Thank you very much.

MS. ROUX: Thank you.

DR. CUTHBERT: We can only imagine how much time went into the preparation of this talk because you cited an incredible amount of data. So thank you for breaking it down for us. It's really great to have this kind of foundational data set so that we can build forward. And this is such an important area. I'm just really happy that HRSA funded this project and you've done such a great job developing it. So thank you.

Okay. As you can see, it's time for our morning break. We're running a bit late, so let's see if we can get back in 10 minutes, by 10 to 11:00. And we will resume with a presentation again from one of our own members, Dr. Edlyn Pena. So we'll see you in 10 minutes. Thank you.

(Recess.)

DR. CUTHBERT: It's time to start up again. Obviously, a lot of work and networking gets done during the breaks, and I sometimes think we should exactly flip the ratio of presentations to breaks at these meetings and see how that goes.

But nevertheless, we do have a lot of compelling presentations today, and we are ready to move onto the next one. This one is from our own Dr. Edlyn Pena from California Lutheran University, and she will be talking about her research on transitions to college for students on the autism spectrum.

Dr. Peña, welcome.

DR. PENA: Good morning. It is a pleasure to be here today. Thank you for inviting me to present my work. My name is Dr. Edlyn Peña, and I'm an associate professor at California Lutheran University. I'm also the co-director of a brand-new Autism and Communication Center at California Lutheran University. Today, I'm going to be talking about research that I conducted with Dr. Jodie Kocur at CLU, and it is about the parents' perceptions about supporting students with autism in regards to the transition to college.

So to give you a little bit of background, we know that students with autism are accessing postsecondary institutions more than ever before, and back in 2008/2009 academic year we know that approximately 78 percent of the four-year public institutions in the United States enrolled students with autism, although we can anticipate that that number has since risen in the last six, eight years.

According to Dr. Roux and her colleagues who presented earlier, from their report, 30 percent of students with autism who complete high school attend some form of college, whether that's community college or four-year college. So we know that about one-third are transitioning to postsecondary institutions.

However, we also know that students with disabilities at times do not report their disability to their university or college. So this nondisclosure of disability can often lead to underreporting of numbers of autism -- students in college with autism. So while it's wonderful that access is increasing for students with autism and that there is transition happening, we still have a lot of work to do as universities, institutions, and high schools.

In addition to all the typical challenges and barriers that we all face when we transition into college, into our first year of college, students with autism also face additional challenges, for example, challenges with emotional regulation, stress management, socialization, intimacy, and managing academic demands. So we need more professionals and educators to really better understand how to prepare high school students with autism for the transition to college, and once they get to college, how do we support their success, retention, and graduation once they get there.

So to address some of that research and to supplement the wonderful quantitative research that has been done and is going on, we decided to do a qualitative study to really get in-depth information from parents and caregivers to understand their experiences and their perceptions in terms of supporting their students with autism in that transition college planning process.

Today, I want to highlight a few major findings from various phases of our analysis. We've presented some of this in journal articles and conference papers, and there's one under review at this moment. And I'll be happy to share those with you at the end.

So a little bit about our study, we interviewed 38 parents, 34 of which were mothers and 4 were fathers, of students with autism who are attending college, in their first couple of years of college, or were in the process of transitioning, so some of the students were juniors and seniors in high school who had undergone that transition planning process with their parents.

The way we recruited parents and caregivers for this study is that we sent out emails to key stakeholders such as university support services offices, clinicians, autism support groups, and social networking sites to see if we could get a participant pool, which turned out to be 38 participants from California.

Our data collection methods involved a brief demographic questionnaire. The primary source of data was really semi-structured one-hour interviews. Some of them lasted 90 minutes, and we asked questions about what they did in the process of supporting their students in that journey of searching for college, participating in transition planning during IEPs, and then once they got to college, what were some of the successful practices and of course challenges that they encountered.

We audio-recorded the interviews. We transcribed them. We had a five-person research team to code and analyze the transcript. And from there, we had some descriptive statistics and of course qualitative data.

I do want to acknowledge a couple of limitations from our study. So the first and foremost is that no college students with autism themselves were interviewed. It's important to add their voice to the data, and it would have enriched our conceptions about transition experiences. We actually experienced great difficulty in recruiting participants with autism in college, so we took a step back and we decided to reach out to the parents and families. And a second phase of that project in the future could be to then reach out to the students or the sons or daughters of the caretakers.

I also want to note that this is a qualitative study, so while I don't see this as a limitation -- it's more of a disclaimer -- that the findings are not meant to be representative of all families with autism in the United States. The purpose of the qualitative study was really to get rich information, really get their stories and understand their journeys in the transition process.

I want to highlight a few of the interesting findings that emerged from the descriptive statistics. And I also want to say that one of the limitations was that not all participants completed the questionnaire in terms of answering questions about race, ethnicity, income.

So for this particular question, we had 29 -- is it -- yes, 29, I believe, participants who filled out this question. And essentially, we found out the majority of participants who participated in the study, who chose to participate in the study, were white. It's interesting to note we only had three Latino students, and in the State of California, as many of you know, we're 30 to 40 percent Latino. We had two multiracial participants. There were no African-American or Asian-American self-identified participants who filled out this questionnaire.

So we know that this can lead to certain questions of -- such as who is gaining access to college? Which racial and ethnic families are actually getting access and transitioning to college? And we do have data from Dr. Roux in her report that shows that it is majority Caucasian, white families who are transitioning in.

Another interesting pattern we found within this sample is that only one of the parents reported not having gone to college at all. This means that only one of the parents had a son or daughter who was a first-generation college student. Again, we know parents are critical in this transition process, and so what we found is that about 26 of these parents have completed a bachelor's degree, and only two of them had some college but did not complete. But these parents had some of that insider knowledge to help their student research colleges, navigate the system.

And the last demographic information I want to highlight for this particular sample is that we know that 24 of those who filled out the questionnaire reported a household income of $90,000 or more. It's really interesting because if you look at the other numbers on this chart, it shows that there are very few who make under that who reported their income. And so this is interesting in that we know that $90,000 is about $30,000 more than the median income for the State of California itself. The folks who have the resources and the income to pay for therapies, advocates, attorneys, transition planning, all of that, those are the kinds of things that they reported in their stories and experiences in terms of supporting their students to make it from high school to college.

So this relates to some of the themes that emerge from the qualitative data. We found that one of the major experiences that parents discussed was related to this notion of cultural capital. Cultural capital is known as accumulated cultural knowledge that brings about social mobility, status, and power. And this is often related to parents and families who do come from high-income, white, and educated families who have the insider knowledge to navigate those college systems and educational systems.

And the way in which that happened in this study is that parents have exercised cultural capital by assisting students to research different college options, navigate policies for transition and admission, and advocate for resources to support their college success and retention. These parents were highly, highly involved in the process for their son or daughter.

Related to the notion of social capital -- or to cultural capital is social capital. Social capital involves the development of networks and relationships to others in order to gain access to resources for social mobility. These parents either had already have social capital and tapped into that, those relationships, to gain resources to help their child get into college or they generated social capital. They did this through relationships with educational advocates, disability coordinators, and academic advisors to access opportunities, information, and resources. That was a key piece of how they assisted their son or daughter in this process.

Parents often described themselves as coaches of students to navigate the college system. One parent said that -- or they described themselves as orchestrating from behind the scenes essentially. They did a lot of work behind the scenes with their son or daughter. Most of them were male in the study. The -- one of the -- or one of the mothers said, "The phone is very difficult for him," her son. "He is a very visual person, so I had to call to make an appointment to schedule an assessment or a counselor meeting. It is really hard for him. This financial aid issue is a really complicated thing."

And so you can imagine for a typical student managing those experiences, where do I go in the college, what offices do I go to, who do I go to, and what kinds of questions to ask, the parents often facilitated that process for sometimes, and with, their student.

And really what it comes down to is a lot of these parents did have difficulty figuring out and negotiating that balance of supporting their student, but also encouraging independence when their student got -- set foot on campus. One parent said, "You want to build independence and you want him to learn to take these things over, so sometimes I let him fall a little bit because that's a learning process." On the other end of that, though, is another parent who said, "I'm not interested in jeopardizing graduation over having him learn a lesson, so we tried to balance."

What's interesting about this is that we have to think about the higher education environment in terms of FERPA, the Federal Education Rights and Privacy Act. These parents had been highly involved in a K-through-12 IEP process, so that was their role. They played that role in supporting and coaching their students. But once they got to college, they had to deal with FERPA. And one mom said, "I received the message to 'back off, Mom'." So when parents reached out to faculty members or counselors on campus, many of them said I cannot talk to you because of FERPA, and they'd have to kind of navigate that system.

Another challenge that came up in the

interviews was finding supportive faculty. And it wasn't that faculty did not want to be supportive. It was -- and sometimes that was true, but for the majority of faculty, they did not know how to be supportive. So this was sort of a new population of students that were entering their classrooms, and they weren't sure how to meet their needs in terms of teaching and advising students with autism. One parent said, "Teachers at the college are not prepared to deal with his particular type of disability."

So just a few discussion points based on these findings, again, while these findings are not representative of all college students and their families, they do suggest a pattern of inequitable educational access to college for students with autism from low-income, first-generation, and underrepresented racial minority backgrounds. And these data are corroborated by Dr. Roux and colleagues' work. For example, they show that 41 percent of white students with autism attend college compared to 23 percent of black students and 29 percent of Latino students, showing an equity gap in terms of access and outcomes.

Another thing to think about is while the challenges related to FERPA are unique to the postsecondary setting, parents' difficulties with school professionals, faculty, and feeling alienated are consistent with previous research regarding barriers faced by parents and students during the transition planning process. So we know the students from the -- or parents from the research and their students have felt vulnerable and alienated during the transition planning process from the research, but we also know now that this is happening and occurring in the college environment once they get in there.

So I always like to talk about what do we do with this research. What are the implications for practice? There's a -- there are many that we can talk about that I want to highlight a few. The first is that high school and college professionals should involve parents and their students from marginalized backgrounds, meaning low income, racial minorities, first-gen students to develop cultural and social capital, so helping them develop those sorts of capital that will enable the students to access and succeed in higher education.

Colleges can also develop proactive partnerships with parents to define relationship boundaries. So I think when parents and their students' transition into college, there could be orientation, workshops, and other things to help parents establish boundaries around FERPA but also welcome them in the process in a way that works for the college and the parent.

And then of course we need more professional development for faculty members. We -- they need to know what to do in certain situations and just how to meet different needs using universal designs -- universal design for learning. So there has to be a lot more done to increase knowledge and experiences and practices to improve faculty teaching and advising.

Again, there's lots of areas for future research. One of the things that is important that I want to restate because it's very critical, for us to include the perspectives of people with autism, college students with autism. Without their voice, an incomplete body of knowledge about college opportunity access and choice is constructed.

If you'd like to look up more information, I have some of these resources on my website, articles and presentations. We have one under review as well. And we will also be coming out with a couple of articles in the press that -- one focuses on best and promising practices of faculty members who are nominated as successful and responsive teachers of students with autism. That one's coming out in 2017.

And there is another separate study. We're looking at campus climate issues for students with autism in public four-year institutions and their experiences with unwanted sexual contact and sexual harassment. So lots of really interesting research coming up in terms of postsecondary experiences for students with autism.

Thank you for your time, and it was a pleasure to be here today. Are there any questions?

John?

MR. ROBISON: I think it's important to point out something that's maybe missing there --

DR. PENA: Um-hum.

MR. ROBISON: -- for future research. You observed that low-income, minority, first-generation families are inherently disadvantaged because of this presumed lack of cultural and social capital. And you talked about the autistic students who were themselves disadvantaged navigating college because of their autistic traits of disability.

But you did not mention the idea that autistic parents likely have the same traits of disability that you cited in the student, and so, for example, a multi-generation middle-class white male like me has a tremendous disadvantage, one I could never overcome in organizing sending a kid to college or going to college because I cannot do those things, even though you would look at me and think on the face of it I would be easily able to.

DR. PENA: Um-hum.

MR. ROBISON: And I think that it's a -- makes me a little sad that the study completely overlooks the very real situation --

DR. PENA: Yes.

MR. ROBISON: -- that there are autistic parents like me who can't do those things to support our kids and send them to college. And who's going to help us? And I think that it's obvious that first-generation, minorities, other groups need help. What about the autistic adults wanting to send their kids? That's the group that we should focus on the most in supporting autistic people.

DR. PENA: That's a great suggestion. I think -- I hadn't thought of that, sadly. So I appreciate you bringing that to my attention. So for this sample we were looking at people who successfully transitioned into college, so we could be missing out on that experience that you're talking about. And I think that would be a great area for future research for us to look at the parent experience for those who are on the autism spectrum and have children who are going into college. Thank you for that suggestion.

MR. ROBISON: And we have a number of autistic students at William and Mary that would probably be very happy to give you a first-person student perspective in that research, too.

DR. PENA: Wonderful.

MR. ROBISON: And all their parents kind of have their shit together enough to get them into school, which never happened for me.

(Laughter.)

DR. PENA: That sounds fun. Thank you. I'll catch up with you on that one.

Julie?

DR. TAYLOR: Thank you for a really interesting talk. And we've seen a lot of the same things in our samples, although we haven't looked at them in a systematic way like you have, so I'm glad that you have.

But this issue of developing independence while still providing the needed support I think is something that families struggle with during this age range, whether or not you have a kid with a disability or a son or daughter with an autism spectrum disorder. But these issues are really tricky and really challenging.

The other thing that we've seen a lot -- and I'm wondering if you got at this at all in your data -- is students and families will work very hard to set up services and supports before their son or daughter goes to college, and then a lot of the time -- at least what we're seeing -- is those supports don't end up getting used or being taken advantage of for a lot of different reasons, I think some of them being that they just don't end up being very helpful, maybe the stigma associated with using some of those supports and services.

Again, we haven't looked at this in a systematic way at all, but it's just something that we've been observing. We were just asking is the student getting supports and asking about this, and the answer to those questions end up being more nuanced than what we were expecting. And I'm wondering if that's something that you asked about at all in your study and what you've been seeing in terms of students actually using the supports that have been set up and put in place.

DR. PENA: Right. No, we didn't ask about that, but that's a really good point because I have heard of other research data that shows that recently. And what I think happens is the parent is so involved in the process that it's almost like the students are let free, they're free birds at the college, and so then it becomes about initiating and following through the executive functioning piece of contacting or maintaining relationships with resources.

One of the things that the parents talked about was because they had very little role in the faculty-student relationship, right -- once they're in the classroom, the parent is pretty much locked out of that process -- but the students had a very difficult time initiating contact, going to office hours, asking for help, and that was something that was reported a lot from parents. And I can imagine that that would be translated into other support services on campus. But thank you.

DR. CUTHBERT: Okay. One more question. Samantha?

MS. CRANE: I just want to anecdotally add that one reason why you might end up seeing that phenomenon is that the parent is organizing these all -- all of these things. And the kid actually doesn't want those supports or wants something else entirely and it's just not what they really think is important to them or maybe they thought it was important before they got to college and then they realized once there at college that they need an entirely different set of supports. So you end up having like a very big disconnect.

I also wanted to ask if there was a discussion in your findings about dormitories versus living at home or somewhere else in the community because that's something that we hear a lot, especially from parents who are terrified of their autistic kid living in the dorms and, you know, any information on whether those fears were, you know, they decided that -- whether those fears were actually founded or unfounded --

DR. PENA: Right.

MS. CRANE: -- would be really interesting.

DR. PENA: That's a really excellent question. We did not ask specifically about dormitory accommodations, but what I do know is that about two-thirds of our participants had students in community college, so they were not in positions to be living on campus in a sense.

And from my recollection in analyzing the interview data, we only had three or four parents that I can recall that actually had students who did live on campus, so that number is really few and far between in terms of the sample that I had for my study. But I think that's another area that needs to be looked at in terms of campus climate and living arrangements for college students.

Thank you.

DR. CUTHBERT: Okay. Thank you again. This has been an outstanding morning, and thank you for that very good presentation. And we've seen the gamut from young adults with employment and assisted employment all the way to students going to college. So it was really a very comprehensive slate of presentations, so thanks to everyone.

Okay. We're running a little late, but I hope we have time to fit in all of our committee business this morning because, as you can see, we have three very important topics that we need to touch on, the Strategic Plan update, the working groups, and the summary of advances, all of which require a considerable amount of work and organization.

So I'll turn this over to Susan to walk us through that.

DR. DANIELS: Great. Thank you, Bruce.

So we're going to talk about some committee business items, a slow fade. Okay. So first, I wanted to talk a little bit about the IACC Strategic Plan update with you, talk about updating you on the update.

The IACC Strategic Plan working groups have been formed, and so up on our website we have the rosters for all seven of the working groups correlating with the seven questions of the Strategic Plan. Thank you to all the committee members for your suggestions of people to serve on these groups. I think that we have some nice diversity on each group and have represented a number of important points of view that will be helpful for working on each of these question areas.

So we will be convening the working groups by phone between now and October to work on the Strategic Plan update, and I will have templates for you so that we can get kind of uniform outputs from each group so that it will cut down on some of the editing, I think, if we work toward a uniform structure. And I -- at the last meeting I went over that structure with you, but you'll be receiving it in your email when I send things out to the working groups.

And all the calls will be announced in advance and open to the public for listening, as usual. And so for members of the public who are interested in this, we'll be posting it on our website and sending out call schedules through our email and Twitter so you'll be able to listen in on all those calls.

In the meantime, over the last couple of months, OARC has prepared the preliminary 2013 portfolio analysis data for use in the updating process, and so this morning I'm going to be sharing some of that with you.

And we also launched an open request for public comments to collect public input on issues that you can consider for the Strategic Plan update, and so I'm going to give you an update on that.

So, first, we're going to talk about the ASD research portfolio analysis preliminary data from 2013, and I'm going to be co-presenting this with a person from my staff, Science Policy Analyst Julianna Rava. So she's going to talk through some of the data.

But first, just to, again, give you a little bit of background, the 2013 ASD research portfolio data were collected from 19 funders, and preliminary analysis is available for use by the IACC and the IACC Strategic Plan update. So we're going to give you an overview here in this meeting, and then each of the working groups will be receiving much more detailed information that you can look at and use in your updating process.

The analysis will provide information about the portfolio across both federal agencies and private organizations and provide you with information about the research funding landscape and trends in funding. And it will help you also monitor progress on fulfilling the objectives of the current IACC Strategic Plan.

So I'm going to turn it over to Julianna to go through data.

MS. RAVA: Hi everybody. So this is the overall funding for 2013. We reached nearly $309 million funded between federal and private organizations. The number of projects was 1,291. As in previous years, we kind of followed the similar pattern of about three-quarters being federal agencies funding and a quarter for private agencies. As you can see in the text box off to the right, the total funding has increased since 2008 and so have the number of projects. And there's a slight decrease since 2012.

Here is an overall view of funding since 2008.

So you can tell there's been relatively an increase in funding from 2008 to 2013 with an extra bump in funding in 2009 and 2010 due to the Americans Recovery and Reinvestment Act.

Here's an overall look of funding by agency and organizations, including all federal and private. The big green spot is the National Institutes of Health, which had about 57 percent of funding, followed by Simons Foundation, Department of Ed, CDC, and Autism Speaks for the top-five funding. There was 19 funders for 2013. We added a new funder, which was the Patient-Centered Outcomes Research Institute. So, yes, that's everyone included in there.

This is the breakdown of funding by Strategic Plan question. Question 2 had 31 percent of funding, which has followed similar patterns in recent years. Then, it was followed by question 4 and 3. Question 6 had a smallish percentage of funding.

This is funding broken up by the alignment with the IACC Strategic Plan objectives, so 76 percent were of projects fit into our question format -- fit into objectives where 24 percent fit into our other category, so that's a good thing.

This is the breakdown of objective status based on if they were fulfilled, partially fulfilled, or inactive in 2013. Forty-four percent were fulfilled, and 51 percent were partially fulfilled, and only 5 percent were inactive, which were four projects.

When you're comparing to previous years, you can see from 2011 to 2013 there was an increase in the filled or partially fulfilled objectives. We reached 95 percent, and 5 percent overall have not been fulfilled.

DR. KOROSHETZ: Can you explain how that cut is made? What's the criteria for fulfillment on that?

MS. RAVA: Did you want to -- or --

DR. DANIELS: Just -- it's really easy for the ones that are inactive. That means there were zero projects and zero funding associated with the objectives. So we had only four objectives that had that, and in your last analysis in the 2013 Strategic Plan update, we determined that those four objectives were either poorly worded and nobody understood what they meant or they were related to things that the committee later realized were probably obsolete or not going to happen. I know that one was on -- oh, now I'm forgetting what the four were, but there was --

MS. RAVA: There was one in question 1 and three in question 7.

DR. DANIELS: Yes, three of them were in question 7. One was on promising practices. There was an objective about writing promising practices papers, which was a practice of CMS years ago and just never went anywhere, one that was about projects to -- or funding to confirm previously analyzed data or something like that, to replicate findings. That what was the wording was, to replicate findings, and that just doesn't really fit as an objective because you can't provide funding to fund grants. So there really wasn't an easy way to fulfill that.

The question 1 was "Conduct two studies to understand the impact of an early diagnosis on choice of intervention and outcomes," which probably became obsolete because by the time we were really working on that, it became much clearer that early detection was really important and helpful and that early intervention works. So that no longer was a question about whether people would be wanting to do that.

And -- okay. Oh, yes, and question 7(a), and actually, this is why I asked the question to Anne Roux, there was an objective about conducting a needs assessment to determine how to merge or link administrative or surveillance databases to allow tracking the involvement of people living in ASD -

- with ASD and health care, education, and social services. And I was curious about whether that has changed. And when we work on the question 7 in the working group, will talk about that if there is still a need for a needs assessment to link databases.

So anyway, those were the four that were never fulfilled, but there were reasons why they weren't. But all of the others had activity or significant activity or were completed.

So back to you, Julie.

MS. RAVA: Okay. So were there any other questions about the slide?

MS. CRANE: I'm still -- I'm actually -- I'm still unclear about how they made a difference between something being fulfilled and something that was partially fulfilled. So how do we decide whether something is fully fulfilled or just partially?

DR. DANIELS: So within the Strategic Plan, the

-- each of the objectives had a recommended budget that was determined by the committee. We had experts help us determine what a realistic budget might be for achieving what was written and the objective. And we also have sometimes a number of projects or specific types of projects that were supposed to be done. And so if the recommended budget on an annualized basis was met and then the whole budget for the objective was completed and the number of projects were also completed, then it was considered fulfilled. If, for example, you spent the money but you didn't complete the number of projects, it would have been partially fulfilled or vice versa. So if you both spent all the money or you achieved it in terms of the funding recommendation and the number of projects or the type of projects, then it was fulfilled. So that's how we tracked that. Does that answer your question?

MS. CRANE: Yeah, that does.

DR. DANIELS: Sure.

MS. RAVA: For the working groups, we have more detailed information than what's about to come, but we wanted to give you an overview of what type of materials you'll be expecting when you guys meet in your groups. Some of the things will be listed as a table of the objectives broken down by their funding and their status, if they're partially or fully fulfilled or inactive.

There will also be a full listing of the projects for each objective that you can use to identify the trends and gaps. And also, we broke down funding on projects according to research subcategories.

So examples of some of the materials you guys will be getting are -- this is the question 1 table of objectives broken down by its funding and status, and you'll get that for all seven questions.

This is a full listing. For example, this is

1.S.A. You'll have it for every single one of the 78 objectives, what projects went under them.

And this is the subcategory analysis breakdown by funding for each question and the subcategories within that question, as well as the project account. So you'll have that for all seven questions as well. I think that was it. Yeah, okay.

DR. DANIELS: Thank you. So does the committee have any questions or comments about this brief overview of the data? And I also wanted to ask you if there were any other kinds of breakdowns of data that you might think your working groups would like to see. And you can give some more thought to that. You can email me after the meeting if you think of something later that you would like to see.

Walter?

DR. KOROSHETZ: I think it might be useful for the groups to look at the "other" category --

DR. DANIELS: Um-hum.

DR. KOROSHETZ: -- in the sense that it -- you know, the strategic plan was put together at some point in time --

DR. DANIELS: Um-hum.

DR. KOROSHETZ: -- and the scientific community has moved into an area that wasn't in the Strategic Plan. It may be important to know that and maybe that needs to be, you know, considered as being included going forward or else some way of thinking about the others because it's --

DR. DANIELS: Yes.

DR. KOROSHETZ: -- 25 percent, so it would be nice to look at that.

DR. DANIELS: So when you receive your project listings for each of the questions, it will be divided according to all the objectives and then the "other" for that question will also be there. And so you'll be able to read through all the project titles in the -- when we do the actual portfolio analysis report, we try to give some examples of the kinds of things, but they tend to all be different so it's hard to group them. Usually, there might only be a few of each type in there. That will give you the full project listings so you'll be able to see all of that.

Geri?

DR. DAWSON: So I think this kind of analysis is really, really helpful as we think about updating the Strategic Plan. And it would be super helpful, I think, for each workgroup if we could just get a little mini-report on, you know, the progress for the area that we're reporting on.

And I would actually encourage us and be open to whether people agree with this to have a summary paragraph in the Strategic Plan for each of the domains where we comment on, you know, what is the state of the progress in addressing this area because we've done it long enough now that I think that that kind of commentary would be helpful and possibly, you know, speculation or input from the experts and so forth about what are the -- if there is slow rate of progress, what might be the barriers that need to be addressed. You know, is it bringing in people who have different kinds of expertise into the field or, you know, why is it that we're making, you know, good progress in one area and not, and is there anything we could recommend in terms of addressing whatever the barriers might be.

DR. DANIELS: Yes, and that's planned to be part of the template that we'll be using, so we -- I know that we talked about barriers in general for each of the questions.

And I believe last time we also -- as we went through the objectives, I asked for the working groups to help identify barriers, but that is really important so that we can understand what it is that we might want to try to change. So thank you.

Alison?

MS. SINGER: I think another thing that might be helpful in this process based on past experience is -- not that I want to have an extra call -- but for the chapter chair people to have a call about midway through to talk about best practices and we -- and working on their sections because the past couple of years each chapter has used a different strategy to accomplish its goals, and then the outputs -- even though we had a template, the outputs were very different. And I think some of the chapters would have benefited from having heard about some of the strategies and techniques that were used by other chapters. So again, not that I want to have an extra call, but it might be helpful to do that midway through.

DR. DANIELS: Thanks. That's a great suggestion. I think that might help us have some more uniformity, so certainly we could try to schedule an extra call for the chairs.

DR. KOROSHETZ: You don't by any chance have a running list of publications attached to grants, do you?

DR. DANIELS: No, we don't have that. So -- yeah. And we actually tried -- a few years ago we did this publications analysis, and what we were trying to do was to link grants to -- I mean, link publications to all the grants that we're tracking in the portfolio analysis, but we really ran into the barrier that a lot of publications don't even cite the grants that they're using. And I think that's improved. As far as I've heard, recently, up to 60 percent now are reporting a citation.

Sorry, what?

DR. BATTEY: I'm just saying that's a big problem.

DR. DANIELS: Yeah, so when we did it in 2010, we found 30 percent of the papers had a citation, and I've heard recently from another group that was doing some work with this that they were finding 60 percent in their field -- I think that was Alzheimer's -- that had a citation. And so maybe it's improved, but it made us so the data weren't all that great in terms of analysis. But we will have the summary of advances nominations, and the groups can do their own literature searches and submit things and we can make a list out of those.

Louis?

DR. REICHARDT: Yeah, I just wanted to ask a -- I don't know -- are you going to open it up to any comments on the composition of the individual groups that -- they differ so much in size and in terms of numbers of people that are listed, and I would just say group 3 in particular seems weak in genetics so --

DR. DANIELS: So if you have specific comments, you can email them --

DR. REICHARDT: All right.

DR. DANIELS: -- to me. If you --

DR. REICHARDT: Because I know that more people were recommended. I wondered whether people declined or --

DR. DANIELS: Some people did decline. There were people that weren't able to make it, and we tried to find substitutes and we took recommendations from all around the table and from other experts in the field. So if you do notice some particular gaps, please do point them out and let me know.

DR. REICHARDT: I'd say the other thing is the groups that differed by almost a factor of two on the number of people that were involved, and this, again, is sort of, you know, --

DR. DANIELS: Right. And I think that the most important thing is that we're covering the topics, really not the number of people per se. And so if you think that there are major gaps in the topics that would be covered in that chapter because of the people that are in the working group, please let me know and we'll consider what we can do to try to remedy that.

Any other comments? Okay --

DR. KOROSHETZ: Group 2 looks good, right? Group 2 looks good.

(Laughter.)

DR. DANIELS: So -- yes. So the working groups are up on the web and there were a few stragglers, too, who haven't quite responded yet, and so I'm still waiting for a few responses. But for the most part we got responses from everyone and a lot of enthusiasm to be a part of our process, so that was great.

So the next thing I want to update you on is the 2016 IACC Strategic Plan request for public comment that we've had on the street now since, I guess, I think it was mid-May when we opened for comment. So on behalf of the IACC, we issued a Federal Register Notice that solicited public comment on research, service, and policy priorities for the topics that are addressed in the Strategic Plan, so the seven questions that are listed here on the slide.

And comments are going to be provided to the Strategic Plan working groups by Strategic Plan question, so each working group will get information about its own question area. We will have all of the information on the web. However, because of the huge response, I can imagine every working group is not going to have time to read all of the responses for everything, although maybe some very ambitious individuals will want to try to read everything.

And so that information is going to be made publicly available on our website within 90 days of the closing date, and we've already started to roll a few of them up onto the web. And so you'll notice if you go to our website that if you look on the homepage, there's a little section that's about this request for public comment. And if you click on "responses," you can go and see some of the responses that have come in, but it's by no means complete. So if somebody out there has submitted something and you don't see it on the website yet, it's just going to be coming in the future as we continue to process them.

Within each question area, the comments have been grouped by theme, so our analysts in our office had done some analysis to try to identify the major themes in each question area. And so we've organized the comments by those means to help the working groups determine what the commentary is on each of those subject areas that are covered.

And as of yesterday, we had a total of 827 completed comments that were received, and we have another couple hundred where people have started working on their comments but they did not hit "submit" yet. And will send a reminder out to those people at the end if we don't hear from them just to make sure they have a chance to submit if they do want to participate.

So to give you a little bit of information about the responses that we have based on the first couple of weeks of data, I've given you a brief breakdown. Sorry it's a little bit small. But these are the people who have provided information about their affiliation.

We found we had a robust response from parents and family members. We also had service providers, researchers, advocates, educators, medical and therapy practitioners, family-assistance navigators, self-advocates, community educators, research trainees, government employees, international, and then of course some people that didn't choose to provide an affiliation. And so we've had, you know, some diverse respondents to this public request for public comment.

I've listed the themes here. I'm not going to read them all to you. And I did provide it to you ahead in the packets. But I wanted to give you a chance to be able to reflect on what was provided here. We've broken this down into themes, and the public also has access to this. But these are some of the things that we've been hearing about from people who've responded, you know, the need for better recognition and diagnosis of subgroups. I mean, you can read down the entire list.

But as we go through each of these questions, if any of you want to comment on themes that you've heard or that you've seen on the list, please feel free to do that. Does anyone have comments about the question 1 themes?

Larry?

DR. WEXLER: Thank you. Just out of curiosity, as a federal committee, what is our obligation to respond to comments? I mean --

DR. DANIELS: There's no obligation to respond to comments. We wrote in the Federal Register that it will not be possible for the committee to individually respond to comments. And so the comments will come in. Our committee will read and use them, but we will not be providing responses to any of the comments. Most of them are just telling us their ideas or thoughts. Most of them are not asking a question. They were citing various needs.

Any comments on question 1?

(No response.)

DR. DANIELS: Question 2, the underlying biology, we also got a number of suggestions of areas that could increase research. For the most part throughout the entire request for public comment mostly we heard about areas that we need to increase research on, although there were a few where they said we could cut down on research in certain areas. Whoops. Now it's moving forward quicker, but did anyone have any comments on question 3?

(No response.)

DR. DANIELS: That's question 4's themes. Question 5. So it's all right. I can just kind of flash through these and you can feel free to read them in more detail on your own. And we'll be providing this to the working groups, as well as access to the actual responses so you can understand what people had to say specifically.

Samantha?

MS. CRANE: I noticed like while you were going through, there was one comment on services --

DR. DANIELS: Um-hum.

MS. CRANE: -- that said that they needed to focus more on early intervention services, and I was -- I found -- and early intervention to me is something I associate with treatments, which would be question 4. Is there a sense in which people are sort of having a hard time with the definitions of the categories? Because what I would be really concerned -- not that I don't think early intervention is important, but I would be really concerned if, you know, something from one question ends up being categorized as another question, and then it would be really hard for us to tell what's actually being funded and what's not being funded.

DR. DANIELS: So this is not about funding, though. This is just about people's --

MS. CRANE: Right.

DR. DANIELS: -- comments to us. And we -- so in -- as a part of the analysis our office did, we did move things around so if we felt that certain comments came in and they were placed under one question and they really belonged elsewhere, we moved them.

And so in this case when they talk about early intervention services, they're really talking about service access and providers and things like that, whereas in question 4 it's talking more about the development of interventions and more of the science. So that's the distinction there. So those comments in that category would likely be related to service provision, maybe workforce, those kinds of issues that would go in question 5. So we tried it to do that is much as possible.

And in cases where there were comments that seemed highly relevant to more than one question, we placed an extra copy of it in another question to make sure that the working groups see it.

MS. CRANE: And we tend to draw distinction between services that are -- that we would call supports and services --

DR. DANIELS: Um-hum.

MS. CRANE: -- that we would call interventions and treatments.

DR. DANIELS: Um-hum.

MS. CRANE: And it's -- I mean, that's an important distinction for us to make because a lot of people, especially, you know, older children and adults are not going to be responsive to what we would call treatment or intervention where we really need long-term supports --

DR. DANIELS: Um-hum.

MS. CRANE: -- that aren't designed to change a person's level of disability but are intended to improve their quality of life.

DR. DANIELS: Um-hum.

MS. CRANE: And so that's just a distinction that we often use question 5 as a proxy for --

DR. DANIELS: Um-hum.

MS. CRANE: -- and that's why I raised it as a concern.

DR. DANIELS: Oh, yeah, so in question 5 over the years as it's been shaped in the committee, it's encompassed both those kinds of early intervention-type services, as well as the supports that you're talking about. And the both of them have been there traditionally, so that's why you're seeing them both there. And I think that, you know, unless the committee changes that for some reason, it probably will stay there. But it's supposed to cover all of that.

Laura, did you have a question?

(No response.)

DR. DANIELS: Oh, I thought you did. Alison?

MS. SINGER: I was just going to say this is another reason why the chapter chairs need to be in communication because there are a lot of areas of overlap, and this was another area where, based on our past experience doing this, we could save ourselves a lot of time and grief by having a little up-front communication.

DR. DANIELS: Sure. I think that's a good idea.

Walter, did you have a question?

DR. KOROSHETZ: I guess it was just the general consensus. I'm not sure where we ended up on the last discussion --

DR. DANIELS: Um-hum.

DR. KOROSHETZ: -- but maybe just start out again that this -- the initial mandate was to develop a research strategy. The question in the services side was should it be more than just research but should it look at actual access and needs.

DR. DANIELS: Um-hum.

DR. KOROSHETZ: And so going forward, what are --

DR. DANIELS: So with the new Strategic Plan -- in the Autism CARES Act, it said that the Strategic Plan needs to expand to cover service provision in more detail, and so the decision was that we were going to, in each chapter, talk about both the science aspects as well as the service provision that might be related to that area, for example, in diagnosis and screening, that we can talk about scientific advances as well as the delivery of those kinds of services. So we were going to try to do that throughout all of the Strategic Plan chapters to try to fulfill the Autism CARES Act mandate.

Geri?

DR. DAWSON: So following up on that, you know, we have the portfolio analysis and also have brought in --

DR. DANIELS: Um-hum.

DR. DAWSON: -- a lot of experts to comment on research, but I would find it, for example, in the treatment domain very difficult to comment on what is the state of access to treatment in the United States or elsewhere --

DR. DANIELS: Um-hum.

DR. DAWSON: -- for autism. I mean, that's a really big topic. Or what's the access to screening in the U.S. and so forth, right? How are we going to actually capture that and have a perspective on it and be able to comment intelligently?

DR. DANIELS: We tried to include people that could address those kinds of issues on the groups, but with interventions in particular, because a lot of intervention service is covered in 5, we're going to have more of that there, and question 4 will focus a little bit more on the research aspect. So that's -- it -- there will be a little bit of overlap, but we do have experts, I think, on both groups that will be able to address these things.

DR. DAWSON: Okay. So that's -- I guess that's another area like you're saying where we sort of have to have a top-down strategy so that we are, you know -- like I wouldn't have thought of that, for example, but that's helpful to know.

DR. DANIELS: Yeah, so it might be helpful before we have calls maybe with the chairs I could maybe share what the outline is, and if you point out anything that you think is a concern or that we need to modify, maybe we can do that to try to make sure that we cover everything adequately. And as I said, if you find that there are gaps in your groups that you would like to fill in, let me know.

Jim?

DR. BALL: Yeah, could there be in the template a theory-to-practice section so that if people want to comment on that, then you can use it towards the services end? Because that way you can look at the research that has been already out there. Is there any way to incorporate that?

DR. DANIELS: Sorry. Can you repeat that?

DR. BALL: Yeah. If there's a theory-to-practice section --

DR. DANIELS: Um-hum.

DR. BALL: -- in each of the templates --

DR. DANIELS: Um-hum.

DR. BALL: -- just so that the groups that are talking can talk about those things that have already been researched that are out there so that way you can then take that information and maybe weave it into the services section.

DR. DANIELS: That's a good suggestion. I think that kind of is similar to something that we had in mind so we can just look back at that and see that it will cover that as well.

Anything else for this?

(No response.)

DR. DANIELS: Okay. I am mindful of the time. I'm not going to spend a lot more of your time on that. But if there's anything in particular that the IACC would like to hear about from the public in addition to what's already been shared on these lists, let me know. We can always send out a Tweet and solicit emails, more comments on particular items if you have areas you feel have been missed or that you want more public opinion on.

John?

MR. ROBISON: Some time ago, in response to seeing that almost all of the public query at that meeting was about one topic, I asked you if we had data telling us what the public's concerns were about autism and what they would like from us. You had that at the time. I think that it's just worth commenting for the record that may be in our introduction --

DR. DANIELS: Um-hum.

MR. ROBISON: -- to the Strategic Plan we should have a few paragraphs citing that research and summarizing what the research shows are the biggest issues facing families and autistic people are because that is rather sharply at odds with the breakdown of comments we received to the committee.

DR. DANIELS: That would be fine. And I know that you're working on that introduction, so if you want to try to drop something along those lines or add it to the outline that you've already started --

MR. ROBISON: Yeah.

DR. DANIELS: -- that would be good, and then the committee of course --

MR. ROBISON: Yeah --

DR. DANIELS: -- can consider that.

MR. ROBISON: -- just sort of toss it out for other people to think about, too.

DR. DANIELS: So, yes, John has volunteered to work on the intro and conclusion, and others that might be interested in that can do that. I know that first having the middle of the document somewhat fleshed out helps to really crystallize the intro and conclusion, but we appreciate his volunteering to do that.

So a thought just for the public, if you have not responded to the request for public comment, it's open until July 29, which is a week from Friday. So there is still time. Please do share your thoughts with us, and everything is available on the IACC website.

Just briefly, I know that, again, we're cutting into lunch, and so I don't want to take up too much of your time to go over the summary of advances process. We're not going to talk about the actual advances yet -- that's after lunch --

but we're going to talk about the process that we're doing a monthly solicitation that's coming from the OARC to you all to collect nominated advances from the members. And so you've been receiving those emails. And we have received responses, suggestions, and nominations for articles. The advances are going to be compiled quarterly and discussed at IACC meetings, and so today, we've set aside some time for you to discuss the articles that you've nominated. And the plan is for the end of the year, after the January meeting discussion, the IACC will have a chance to vote on the top 20.

And I know at the last meeting you had suggested that you wanted time for discussion, and so we've worked that into these meetings so that we don't need to schedule any additional calls or meetings.

One thing I wanted to know is it does the IACC want to select a certain number per question area or just a top 20 overall regardless of what question areas it covers? And if you have any thoughts about that or if you want to decide later, it doesn't have to be decided right now. But that's some I wanted to throw out to you that we can consider how you want to do that and whether we would do the same type of a summary that we've done in the past where we summarize each article individually. That would be the format that we would go with, so similar to the current document, just generated a different way or if you want a totally different-looking document.

John?

MR. ROBISON: I would vote for just having 20. I don't think it would be right for us to say we're going to pick four for each question because, in fact, if we don't feel we have good results for each question, I think that's a significant point to be expressed with just 20.

DR. REICHARDT: Yeah, I would support that, what John said, strongly. Also, I would hope that maybe in the summaries there could be some leeway because -- to in fact describe related findings because I think that some -- in some fields you really -- it's almost arbitrary which one you're picking out, you know.

DR. DANIELS: Anything else?

Cindy?

DR. LAWLER: I do think we need to incorporate a way at the end of the year that we can look for balance across rather than just, you know, voting on each one individually and seeing what falls out as the top 20 because one of the issues that I think happened last year may not have -- might have gotten a better mix if all of us had seen, you know, those top 20 because there did seem to be an imbalance in the ones that rose to the top just independently voting. So is there a way we can bring that back to the committee?

DR. DANIELS: You mean vote on a top 20 --

DR. LAWLER: As a --

DR. DANIELS: -- and then reconsider what you voted for?

DR. LAWLER: Or a discussion about these or maybe the top, you know, 30 or 40 and, you know, pick and choose to make sure that we don't end up, you know, omitting some really important areas.

DR. DANIELS: Louis?

DR. REICHARDT: I actually think this is a good idea. I'll just say my perception of last year as one of the things that happened in particularly one area where there were a lot of advances, there were a lot of genetics papers, and effectively, they competed each other out so we ended up was deciding the most important papers or vaccine papers, which I thought was sort of like are you against evolution frankly. But, you know, people need to be persuaded that it was really an imbalance that reflected the fact that if you had fewer papers in an area, the votes were more concentrated.

DR. DANIELS: So is that something you'd like to do, for example, select a bigger pool, like 40 papers, and then have the committee narrow it down from that? The only issue that I see with doing that is that it will lengthen the process. We usually put out the document in April, and I don't think we'll make it if we have to do another meeting to discuss it.

Geri?

DR. DAWSON: So one idea would be to have our top 20, which really reflects the top -- literally the top advances, regardless of topic, right, that it just -- this is a major paper that really had a significant impact on moving the science forward, and then to have a separate section -- sorry, everyone -- where you basically say what were the top two papers in this area, this area, and we have our seven questions, right? Because I can't imagine there wouldn't be one or two in each area that we would be able to feel comfortable saying this is really, we believe, the best science that happened in this area. That way, you know, you get a broader representation, but you also capture what truly were the -- you know, the most impactful papers, which are two different questions really.

DR. TIFFANY FARCHIONE: Right. But I see what Louis was saying earlier, though, like with all the genetics papers last year, you know, it's hard to pick and choose like, well, you know, is this one more impactful or is that one more impactful? And so I think probably the votes got spread out among all of those papers and it diluted perhaps the influence.

So the idea that maybe if we have, again, like a whole bunch of genetics papers, maybe trying to have a discussion about those papers so we can come to a consensus as a group rather than having to individually pick which one we think may have been better than the other ones.

MS. CRANE: And conversely, on the lifespan issue, last time, both of the papers that ended up getting selected were about the cost of autism across the lifespan, which is really problematic on a number of levels, but it ended up concealing a lot of the other research that might have been more important about actually, you know, the things that adults actually need rather than the cost of our existence.

So, you know, I was pretty disappointed that the way that the voting worked we ended up with two papers on the same topic rather than anything that reflected the diversity of research on the topic.

DR. DANIELS: Cathy?

DR. SPONG: Maybe to suggest something that might be easier and less time-consuming would be to have the vote for the top 20, as you've done, and then given that we're talking about all of the articles at each meeting and they're already separated out by topic, just having a list available so that these are all the other articles that are out there that we talked about that are very, very important so that we don't have to pick which is the most important --

DR. DANIELS: Right, and --

DR. SPONG: -- genetics paper. Just list them all so that they're available by topic.

DR. DANIELS: We've been doing that, so that's what I was going to come back with is that what we usually do is we have the top 20, and those each have an individual write-up, and then all the nominations are listed in the back and they're divided by question.

And so I'm not sure -- so far, the trend is that we have fewer nominations because I think people are taking more time to choose these, although maybe in December we'll have a flood of nominations and it'll be the same, you know, 200. But if it's something that's a lot smaller and more selective, maybe that will be more of a readable list for each of the questions. And then you would have something that's really more like that but each one wouldn't get its own write-up obviously.

Geri?

DR. DAWSON: I was just going to mention that when I was at Autism Speaks, I recall that we had the same issue one year of having several -- I think it was in genetics as I recall -- several very strong papers, right, that it would be difficult to say, you know, this one was really better than the other. And we actually ended up sort of grouping them as a -- you know, a set of papers that had an impact because often they do share, you know, methodologies and things. And so that's how we got around that, that we didn't feel constrained to say, you know, it had to be this one paper. But it was really the set of papers that came out on a topic that kind of together had an impact.

DR. DANIELS: Something we could do to try to address that issue is before we have a vote if we have some people look at the papers and group them ahead of time so that when you're voting, you're voting for a group, and then the write-up reflects whatever's in that group. We could do that, so that would just take an extra layer of somebody looking at it and grouping things. All right.

DR. CUTHBERT: Ruth, I think you had a point.

DR. ETZEL: I wanted to second Cindy's opinion about broadening the pool. And I very much like the Drexel approach of primary, secondary, and tertiary prevention and wondered if we could cap -- put all of the papers under those categories and then present the findings as primary, secondary, and tertiary prevention because I find that it's a little distant from the actual patient, so it would be nice if we categorized it by prevention.

DR. DANIELS: I think that would be a little -- we -- so right now, we do it according to the categories of the Strategic Plan. I think to come up with a totally different organization might be a little confusing.

DR. ETZEL: So maybe our use for prevention and public health in the Strategic Plan as well.

DR. DANIELS: So I don't think I can wrap my head around that right now in terms of coming up with something different in terms of how to organize that. Does anyone else feel that we would want to try to think about that? If so, we might need to have more discussions.

Geri?

DR. DAWSON: So I do think public health and prevention are woven into the Strategic Plan, and so prevention is obviously part of, you know, why did this happen and there is a lot of -- you know, and there's public health that's woven into various aspects of it. So maybe it really is, as we write, you know, the new Strategic Plan, that we keep in mind --

DR. DANIELS: Um-hum.

DR. DAWSON: -- that very important focus and write about it, right, and frame some of the things from that perspective. I mean, that might be more satisfying than just, you know -- we can't really address that.

DR. DANIELS: Thank you. Other comments?

(No response.)

DR. DANIELS: All right. I think we are already 15 minutes into our lunch break, so I think that you're probably eager to be able to go. And I'm just putting up a slide quickly acknowledging my staff who put in a lot of hard work to get some of this data together for you.

Thank you.

DR. CUTHBERT: Okay. Thanks, Susan.

We have a very full schedule this afternoon, so in spite of our constrained time, I hope you can grab a quick lunch, and we will try to reconvene at one o'clock sharp to start the afternoon. Thank you.

(Whereupon, the Committee recessed for lunch at 11:50a.m. and reconvened at 1:00p.m.)

DR. CUTHBERT: We need to resume for our afternoon session. Hopefully, everybody had a good lunch.

We have a large number of public comments to start the session for which we are very glad because input from the public is a very important component of our meetings, as you all know.

Because of the large number of people, we do want to hear from everybody, and so we really need to stay to our times and allow others to be heard as well. So I hope everybody will stay strictly to the 500 words for comments, and that if you wrote any more, of course, those are all in the written summaries of the meetings and will be posted to the website.

So we are ready to begin. And our first presenter on the list is Katie Myers. Ms. Myers?

(No response.)

DR. CUTHBERT: Perhaps not back from lunch yet. So we will pick up Ms. Myers later if she's not here, Katie Myers? Okay. In that case, our next presenter, let's go to him, and we'll move -- jump back -- is Albert Enayati. Mr. Enayati, welcome.

MR. ENAYATI: Thank you, Dr. Cuthbert.

I'm going to talk about the movie of Vaxxed, so I'm going to show a segment of the movie. It's only a minute-and-a-half, and then my presentation.

(Video shown.)

MR. ENAYATI: Good afternoon. The movie Vaxxed is about fraud at Center of Disease Control, the federal agency in charge of U.S. vaccine program. Because --

(Video shown.)

MR. ENAYATI: Good afternoon. The movie Vaxxed is about fraud at Center of Disease Control, the federal agency in charge of U.S. vaccine program because a whistleblower scientist Dr. William Thompson who conducted many of the studies used to prove vaccines do not cause autism has publicly admitted data was hidden and actually showed a link between MMR vaccine and Autism in African-American children.

Nowadays, it is hard to take the defender of the vaccine program too seriously when they do not address the existence of a senior scientist at Center of Disease Control claiming that various studies they are citing as proof were done fraudulently.

Sorry, vaccine, but you also have a dark side. Like some pharmaceutical drugs, you cause brain damage in some of the kids who receive you. Don't take my words for it. Our Federal Government could not be clearer about this truth, the truth that vaccines cause brain damage in some children.

Time and again, the Department of Health and Human Services makes it clear that encephalopathy is a vaccine injury, and they go to define one form of encephalopathy from a vaccine injury table in the following way: "Chronic encephalopathy occurs when a change in the mental or neurologic status, first manifested during the applicable time period, persists for a period of at least six months from the date of vaccination."

Like many children with autism, my son is suffering from chronic encephalopathy that occurred after his vaccine appointment. I don't really have to use that many of my IQ points to think that there may be a correlation between a product that causes brain damage -- vaccines -- and my son's brain damage.

Historically, vaccines are also guilty of poisoning our precious children's brain by using a preservative thimerosal, a known neurotoxin.

Nowadays, it is hard to believe scientific studies. When it comes to the vaccine-autism science, the general game plan of obfuscation by Center of Disease Control and American Academy of Pediatrics looks like this:

One, create a study in some way related to kids and vaccines. Two, ensure the outcome will be one that exonerates vaccines. Claim it proves vaccines don't cause autism, details be damned. Rely on the fact that journalists do not read the studies

On no planet in the universe would anyone with a brain view these type of studies as in any way addressing whether or not vaccines cause autism, yet these studies remains cited on every list as proof that vaccines and autism are unrelated. It is insanity.

It is true, IACC, on your birth you gave desperate parents so much needed hope but you also failed us. In a space of six years, you have spent more than $1.6 billion and you did not help our children not even one bit, no safe and effective medication, no prevention strategy, no conclusive biomarker, no new treatment, and autism prevalence continues unabated.

You were cited by Government Accountability Office that 84 percent of the autism research projects funded had potential to be duplicative.

In 2009 the National Vaccine Advisory Committee, NVAC, recommended a number of feasible research proposals on vaccines and autism. You did not implement not a single one. Dr. Cuthbert, they have spent more than $1.6 billion. They didn't spend even one penny on vaccine and autism. And you tell me this if fair or not.

Please take note that a recent study among parents by the Simons Foundation found that 42 percent of the parents felt vaccines contributed to their child's autism. The IACC should not ignore this large segment of the community and observations by so many parents regarding their children's developmental history. IACC must and should include NVAC recommendation as a part of IACC new Strategic Plan, and IACC needs to recommend HHS that vaccine-autism safety needs to be addressed immediately.

Dr. Cuthbert, this is my fourth year I'm coming here, fourth year. I cannot keep coming here and talking about the same issue time after time after time. Dr. Insel run me around for three years. At the end of the day, he left. If I'm the only one saying that vaccines cause autism, you could ignore me. But 42 percent of the population, they believe the same way as me, you cannot ignore such a large population.

I spoke to Dr. Shapiro, who is representing the Center of Disease Control. There needs to be some kind of solution for this. Either IACC should get involved, get the parents, the leader of autism organization who believes vaccines cause autism, get Center of Disease Control official, get National Vaccine Advisory Committee, get Food and Drug Administration, the CBR division, in one workshop, two workshops in this campus and let them hear us, let them hear me, let them hear my story and let me hear their story and see how we can solve this problem. It just cannot continue like this.

DR. CUTHBERT: So I think we have heard your comments on a number of occasions, Mr. Enayati, so we thank you for that input to the committee. We are well aware of your views to be sure, so thank you for that.

MR. ENAYATI: And also, I recommend you ask that Mr. Robert DeNiro said that you should watch this movie Vaxxed. I really recommend it, especially the official at Center of Disease Control, official at Food and Drug Administration, and any other agency from Federal Government. They should watch this movie, and then you could tell what they feel, what our concern was.

And I'm going to leave some of the papers on that one also.

DR. CUTHBERT: Okay.

MR. ENAYATI: Thank you. Thank you, Doctor.

DR. CUTHBERT: Thank you.

John, we don't have much time for comment because we are already well over time now, but a brief comment.

MR. ROBISON: I'd just like to say that what we just heard from Mr. Enayati, I guess I would take that just to mean that we have a really -- a significant crisis of confidence in our public health system, and I hope that we can find a way to take that up because it's really worrisome to me. I feel like when people express opinions like his and they lose confidence in us, it makes it hard for us to implement things that could work and could help. And I think that's a much broader thing than just Mr. Enayati's issue.

DR. CUTHBERT: Okay. Thank you. It may be that we should think about a way to try once again to present a coherent account of this whole area to the public at this time given the scientific evidence of the past few years and to communicate that in a way that can engender confidence.

MR. ROBISON: Well, it's a good challenge to me and I am thinking about it.

DR. CUTHBERT: Um-hum. Okay. Thank you.

MR. ROBISON: Yes. I'm thinking hard.

DR. CUTHBERT: Okay. Thank you.

Has Katie Myers returned? She was the first --

MS. MYERS: Over here.

DR. CUTHBERT: Oh, okay. We had gone ahead to start, so we welcome your comment.

MS. MYERS: Good afternoon. My name is Katie Myers. I'm a music therapist and -- a board-certified music therapist and a member of the American Music Therapy Association. Thank you for the opportunity to discuss the importance of music therapy for today's committee meeting.

Music therapy is the clinical and evidence-based use of music interventions to accomplish individualized goals within a therapeutic relationship by a credentialed professional who has completed an approved music therapy program. There is a growing body of evidence regarding the benefits of music therapy treatment and interventions for persons with autism who have functional deficits in social, behavioral, cognitive, motor, and emotional functioning.

Rapidly emerging science on the neurobiological basis of the influence of music therapy procedures on brain functioning attests to the viability of music therapy even in those who are resistive to other treatment approaches.

When individualized music protocols are designed by a music therapist to fit functional abilities and needs, responses may be immediate and readily apparent. Music therapy provides opportunities for increased attention, decreased self-stimulation, improved cognitive functioning, increased socialization, successful and safe self-expression, improved behavior, enhanced auditory processing, decreased agitation, improved verbal skills, enhanced sensory-motor skills. All of these outcomes contribute to the well-being of persons with autism spectrum disorder, allowing them to maximize their potential and lead fulfilled lives.

Research among persons with autism spectrum disorder demonstrates that music therapy can improve communication, interpersonal skills, personal responsibility and play. It can elicit joint attention; enhance auditory processing and other sensory, perceptual, or other fine and gross motor skills. It can help identify and express emotions, modify target behavior, and teach new skills.

The U.S. Department of Education has provided written guidance that clarifies recognition of music therapy as a related service under the Individuals with Disabilities Education Act. Qualified music therapists have been providing music therapy as a related service to thousands of children with disabilities in every U.S. over the course of the 40 plus years since the passage of Public Law 94-142.

The National Center for Complementary and Integrative Health at NIH has noticed that music therapy may have a positive effect on social interaction, and communication and behavioral skills in those affected by ASDs. NCCIH recognized the evidence base from several studies and a recent Cochrane systematic review. As a growing healthcare profession, music therapists need expanded recognition of the vital role of -- the profession of music therapy plays in neurodevelopment.

I am requesting continuation of provisions related to advancing the understanding of the efficacy and effectiveness of music therapy interventions through research, education, training, and information dissemination. Currently, the National Standards Project Phase 2 identifies music therapy as an emerging intervention as opposed to an established treatment.

The potential to make important contributions to help people with ASDs is large. However, the disciplines and stakeholders often work in relative independence. Therefore, I'm asking for the recommendation to support music therapy researchers in multidisciplinary interagency collaborative work, including neuroscience research, to benefit basic, applied, and translational research, as well as applied demonstration projects.

I look forward to providing additional input through future committee activity and thank you for consideration of my suggestions.

DR. CUTHBERT: Okay. Thank you very much for bringing this very important area of treatment to our attention. We appreciate your comments.

MS. MYERS: Thank you.

DR. CUTHBERT: Thank you.

Our next commenter is Lori Frome.

MS. FROME: Hello. My name is Lori Frome, and I come today speaking out of love and compassion as a parent of a child diagnosed with ASD, as well as an early intervention provider who represents these children and families in the treatment.

I wanted to share experience of a rapid developmental improvement that has occurred in my son, as well as similar changes that seven other children I have worked with have experienced when all electronic screen media such as television, tablet, DVDs, and smartphone were removed from the young child's daily view. These children, including my son, continues therapies as previously employed, and while their parents focused on intensive and highly interactive engagement with their child in replacement of time that was previously spent with the screen.

Please listen today to what I have to share with you as I promise you have not heard this before.

I saw this method first used by a parent while working with a child with red flags for autism. This family removed screen media of their own accord as they felt their child was more interactive with them when not watching screens. This child quickly changed and began to exhibit more eye contact within a period of just one week. Within a month, they showed dramatic improvements in joint attention, exhibited an increased understanding and use of social gestures, and was able to imitate actions more readily, as well as added several functional words to his vocabulary that was almost nonexistent just a month before.

Never in my seven years as an early intervention provider had I ever seen a child make such short progress in such -- in a short time.

The attention mechanisms in this child and others with ASD that I have worked with appeared to change as they orient to people instead of objects when the screens have been turned off. What was even better was that I was able to replicate these same results with my own son with ASD at just 3-1/2 by using a similar no-screen approach while keeping all of his traditional therapies of OT, speech, and PT.

I began to constantly engage him and would have him help me with practically everything in place of the screen's absence. He took a greater part in every routine. When pouring his milk, he would help me to open the container, then open his cup. We would hand-over-hand pour and close his cup.

I took this similar approach to most other activities as he began to help me with loading the washer and dryer, making dinner, and watering plants. I did this all in the spirit of togetherness and love as I remained at a level that was close to his eye contact as much as possible and labeled everything I was doing. I provided wait time for him to repeat. These same strategies I had used often before removing screens from his view, but now more responsive he was to my bids for attention and had a greater desire to stay and be with me.

I had witnessed these same assets to attention and physical closeness in the previous child I had worked with and knew within a month of employing this method that this was also providing much of the same results in the core deficit of ASD that were displayed in my son, just as it had in the other child.

All seven children I speak of had high exposure of three or more hours of screen media in infancy and early childhood for various reasons, including my own son. Many studies show that there are no benefits to watching television or screens before the age of two and that there is a negative association between screen time and attachment, attention, play, social and emotional interaction, language, behavior, and self-regulation before age two or three.

These areas described also coincide as areas cited as deficits for young children diagnosed with ASD. Many children in this early age group are developmentally functioning under the ages of two and three, and screen exposure may be impeding their development, just as if they were under the chronological age of two or three.

Lead author Zwaigenbaum in 2005 found that children with a predisposition to ASD have a more difficult time disengaging from a visual stimulus on a screen. Due to this finding, these children at higher risk may be more fragile to the developmental harm from early screen exposure.

I implore you today that further research be done regarding screen removal and young children with ASD as a therapeutic protocol that may lead to quicker achievement of development outcomes and diminishment of the core deficits of ASD. My own son showed a complete recovery from the core deficits of ASD in just nine months' time and was discharged of all seven therapies less than 18 months after diagnosis.

From my personal experiences and those of the other families I represent, I do believe that this method of screen removal, paired with a high amount of social interaction, can be beneficial to all young children with ASD, not to mention it is completely free to all families. A call for more research to be done can confirm this finding and lead to greater benefit and awareness for other children and families affected by ASD.

Thank you.

DR. CUTHBERT: Okay. Thank you for your comment and about this interesting new development. We appreciate it.

Our next comment is by Carolyn Gammicchia. Ms. Gammicchia? Are you ready?

MS. GAMMICCHIA: Yes.

(Video shown.)

MS. GAMMICCHIA: Dear Chair and members of the Interagency Autism Coordinating Committee, I'd love to spend this three minutes allotted to discuss all that we are concerned about as parents of a now 25-year-old young man living with autism. However, that would be virtually impossible.

Each time members of our family have come before this committee, we've presented concerns we've felt have fallen on deaf ears. Yet I still appear before you today, traveling from Michigan, with the hope that you will listen because our family's story is not rare.

I am playing this video for you to see as I speak because there are parents standing up all across the country who have stories just like ours and could not be here today.

In 1991, our son was born a healthy child. In 1992, our son developed ahead of his milestones, started crawling early. He climbed stairs at six months, he started walking at nine months, and he began saying two-word phrases at a year old. His brother, 15 months older, was his role model and they were inseparable.

In 1993, I took our two sons to the health department for their vaccinations. We are not anti-vaccine. We vaccinated our sons. At that point our oldest was vaccinated with -- on that day with one vaccine without any problems. The attending nurse advised me that I should catch up my youngest son. It would be more convenient for next -- in later visits, and I asked the nurse at that time if I this was safe and what that would entail. She stated to me he will be given four vaccines and this is perfectly safe, we do this all the time, there is no need to worry. I trusted that nurse at our public health department, and I allowed her to inject our son with four vaccines.

That day still is fresh in the mind -- in my mind, I'm sorry -- and when it occurred, our son sat in my lap and the nurse injected the first vaccine into his thigh. I want you to know that these parents standing up at each of these vac screenings across the country are being asked if they have a child that sustained vaccine injured -- injury and now have autism. All across this country the film Vaxxed is being screened. It's now being listed in 500 theaters across this country, and we have an engagement in Michigan and it ran for three weeks and it was almost to sellout crowds.

I'm not going to describe the rest of the encounter with the nurse at the health department because I only have three minutes. What I do know on that day when our son was caught up he was actually given six vaccines in one sitting because one of the vaccines was the MMR. I was not told at that time that these vaccines our son was given were not tested for safety, especially when given in -- all in one sitting due to the ingredients they contained. I was not told that giving him the suggested Tylenol to ease his pain and fever, which he had before we even left the office, and the swollen thighs where the injection sites were, I was not told that Tylenol contains acetaminophen, which would fuel the fire to what transpired for him that day.

You can turn that off if you want. Sorry.

I was not told that we would lose our son that day, that he would no longer speak, that he would no longer be able to sustain being held, that he would no longer be able to play with his brother, that he would no longer make eye contact, that he would no longer be the healthy, happy, loving child that we had known for almost two years.

Within the next six months, our son was diagnosed with PDD-NOS, and we were told to concentrate on our other son because we were told that he would have to be institutionalized that day by the time he was 10.

Within the following year, our son was diagnosed with autism. We were told there was nothing we could do to alleviate his condition, nothing we could do to stop him from self-injury and head banging, nothing we could do to stop him from not sleeping more than two to three hours in a night, nothing we could do to stop him from lashing out and screaming at his older brother, nothing we could do to get our healthy, happy, loving son back.

Our child did not have these challenges when he was born. These challenges were not present prior to his vaccine injury. They were not missed by us, nor was the diagnosis of autism, because our son was not born with autism.

Twenty-four years later we now that vaccines are not safe when given in combination. I've included that handout for you, and it's a recent study stating combining childhood vaccines in one visit is not safe. This just came out this year.

We now know that researcher Dr. William Thompson of the CDC has come forward and indicated that vaccine research associated with the causation of autism he participated in was flawed and has gone without investigation. I've included the attachment from Congressman Bill Posey giving five minutes of testimony asking for Dr. William Thompson to be subpoenaed before Congress to address CDC fraud and the studies that he worked on as a scientist.

We now have scientific experts in some field of autism coming forward and indicating that autism is being caused by environmental factors. That's the third attachment that I've given you, Project TENDR, Targeting Environmental Neurodevelopmental Risks. The TENDR concession statement actually indicates that widespread exposures to toxic chemicals in our air, water, food, soil, and consumer products -- I guess vaccines could be considered a consumer product -- when -- can actually increase the risk of cognitive, behavioral, or social impairment, as well as specific neurodevelopmental disorders such as autism.

We ask as a family that you now revisit the fact that vaccines and environmental issues have been and will continue to cause cases of autism in the United States. As Dr. Coleen Boyle testified before Congress in the past, we have yet to have one single study done of children in the United States that have been vaccinated and have autism versus those who have been unvaccinated and has autism. Until that study is done and at least replicated once, no one, no one in this room can say vaccines do not cause autism.

We will not go away. Our son will continue to seek remediation of his vaccine injury while an adult living with autism. He has testified before you twice, twice. He has come here and testified, and he has actually participated in an NIH study on adults with autism and brain inflammation. He has participated as a person vaccine injured.

We will not go away. We will continue to ask these questions and have you represent us for our concerns.

This last year alone our son has been newly diagnosed with seizures. He has never had seizures prior to this year. He just turned 25. And just this week was given the clinical diagnosis of PANDAS by his neurologist after a sudden onset of regression. This was our son who presented before you, has been on a sailing team, who is ready to get his driver's license, who has obtained his associate's degree from his local community college. He currently will be facing infusions of intravenous immunoglobulin, IVIG, due to being -- due to having been diagnosed recently with an immune deficiency. Vaccine injury is the gift that keeps on giving for our son.

He no longer bangs his head. He no longer is not able to speak. He's come before you and asked for you to understand what is transpiring for not only him but for every one of those families where those parents stood up in those screenings.

Then, I think to myself all the children who could have been spared vaccine injuries and co-occurring medical conditions and an autism diagnosis in this country. And I look at the next two women who will be speaking before you and one of my very good friends right here who have children under the age of 15 who when we first brought this to you in -- since -- in -- I'm sorry, 1999, 2000, 2002, the Federal Government and vaccine injuries, their children would not be damaged today if something was done.

So I do ask and thank you, Mr. Robison, for asking for this to be reconsidered for vaccine injury, for vaccines and causation with autism to be reconsidered because we will not go away. And more and more parents will be asking the Federal Government to bring Dr. Thompson before Congress to testify regarding the vaccine studies that he participated in and the fraud that had occurred.

Thank you very much for your time.

DR. CUTHBERT: Thank you for your comment. And as you mentioned, I think Mr. Robison's comment about presenting -- being a summary of the current scientific evidence in this area that the public can relate to is a similar response in this case.

Our next commenter is Heidi Scheer, and I really please do ask you to mind the three-minute limit. We are already way over time for the session, and out of courtesy to others, we want to hear from everyone and have time for everyone to present their views in this and many other areas with respect to autism.

Ms. Scheer?

MS. SCHEER: Good afternoon, committee members. My name is Heidi Scheer, and I am the mother to a son -- my son, whose name is Gannon, and he was diagnosed with autism at age four.

I am here to discuss the critical importance of research for biomedical treatments for children with autism. I have been an international autism advocate for 10 years and have traveled throughout the world meeting parents and caregivers of children on the autism spectrum.

The need for research of biomedical interventions for children with autism is critical as we face the astronomical numbers of cases of autism, as well as the debilitating financial affect this is having on our country. I meet families every day who are unable to help their children due to lack of funding and resources available to heal their medically ill children.

I speak from experience when I say that biomedical interventions have changed my son's life. After 10 years of treatments, he is recovering and no longer needs the tremendous amount of special services that were once required to help him function. When he was first diagnosed, he couldn't speak a sentence or interact with other children in a safe way. He would bite, scream, and run away from us as he had no comprehension of fear, danger, or safety.

He was in three schools during the first two months of kindergarten where we tirelessly pursued many, many plans to educate him. We tried a one-on-one aid and later found a self-contained classroom for him where he would remain for the next five-and-a-half. As you know, these self-contained classrooms cost tax payers millions of dollars each year, as they need one teacher and two para educators to run safely and smoothly.

Of course biomedical treatments do not work for all children on the autism spectrum, just like drugs and ABA don't work for all children with ASD. But I have personally met hundreds of families with children with autism who have improved and recovered utilizing these biomedical interventions. And unfortunately, I know many that haven't had the means for biomedical treatments, and their sons and daughters have continued to be very, very sick, sick with pain, pain that emerges as self-injurious behaviors, intense gastrointestinal distress, and the inability to communicate and function in our world. The children of this nation need us to be responsible and tend to their needs.

My son, who was not supposed to be able to speak a sentence, was the first student ever to graduate from a self-contained classroom at his elementary school with an ASD diagnosis. In middle school this past year, he had a lead in his school play and he also competed for his school's forensics team in the field of public speaking.

As a result of numerous sacrifices my family made in covering all of the horrendous expenses to pay for my -- for biomedical treatments for my son, he no longer needs to be a tax burden on the citizens of this country throughout his life. We were fortunate to have the means, as well as the help and support of family to accomplish this goal. There are so many families out there that are not as fortunate, and so their children continue to suffer greatly and the taxpayers' burden grows exponentially.

As members of the Interagency Autism Coordinating Committee appointed by the HHS, I am asking you on behalf of myself, as well as autism families around the country, to please, please include research for biomedical treatments for individuals with autism in the IACC's recommendations for the Autism CARES Act. Each and every one of you have the power to change lives.

Thank you.

DR. CUTHBERT: Thank you very much for your comment, and I'm sure that's an area that we are all trying to work on is the need for improved treatments, and that's a major reason that brings us together.

Our next commenter is Sheryl Melling.

Ms. Melling?

MS. MELLING: Good afternoon. My name is Sheryl Melling, and I am also of course a parent of a 13-year-old boy who has -- was diagnosed with ASD. I was on the board of understanding that there was something very wrong with my son. He did have a vaccine reaction. He did have -- you tell me. It says right on the insert as a side effect grand mal seizures. He did. He had three grand mal seizures within four days starting a week after his DPT. He never got as far as the MMR. And I will tell you honestly he lost all of his social skills and eye contact and imitation skills the day I brought him home from his hospital admission after his grand mal seizure. If you don't think that is vaccine-related, please tell me what you think it is.

But that's not what I'm going to talk about today. Besides being a parent, I am a schoolteacher. I teach kindergarten. I've been teaching since the year 2000. And I can tell you that when this happened and my son was a young baby or a child and I believed he had autism when I researched parent testimonials adverse reactions to vaccines, I wanted to know have other parents gone through this? Maybe it's something that they -- maybe it's a temporary side effect. Maybe they'll come out of it. How long is my son -- how long is it going to take for him to come back? And that's when I read my story over and over and over again.

And then I thought, well, I'm a schoolteacher.

What is autism again? Oh, lack of eye contact. Yeah, he lost that. Lack of imitation skills. Yep, he's no longer doing that. And honestly, I just -- part of me died that day when I read that, and I thought here I am a schoolteacher and I don't really -- I never really had a child or a student with autism back then. Now, I teach kindergarten so there's three kindergarten teachers. Almost always one of us has a student with autism.

And reflecting with my coworkers and seeing what they know about autism, even know it's still very, very little. And I think as far as, yes, there's a big lack of money everywhere but especially in the education world with helping these children. And I'm trying to say where is the training in education not just with special needs -- or, I'm sorry, special education teachers. You have to bring the training to general education teachers so that somebody like myself can have those children mainstreamed in a classroom setting and -- that we will be trained and know what to do.

I'm sorry, yes, these kids do have behavior issues but it's rooted from challenges within autism, from anxiety, from stress. How can we deal with that stress and that anxiety before those behaviors come out?

I can tell you that I've learned a lot in the last decade, and I feel that just the things that I've learned have really helped those kids in my classroom. And then they go to first grade, it all falls apart and they get moved to where? Emotionally impaired. Do these kids have emotional issues? Yeah, but what is the definition of emotional impairment? The root cause of EI is very different than the emotional reasons for ASD kids. It is different. So to say, you know, they -- let's -- oh, we can't deal with it. Let's now move them and transfer them to EI. That's not appropriate.

And I just want -- I know that I have three minutes but I just want to quickly tell you what happened with my son. He did okay in elementary school. They worked really, really well with him. I was pretty pleased. I thought this is great. And then came time for him to go to middle school, and I had the IEP meeting with his elementary school where the middle school team came in and, okay, we're talking about what his needs are, how are we going to address his needs. I said, well, what about this? I got the same answer every time. He'll get what he needs. What about this? He'll get what he needs, Mrs. Melling. And it was an absolute nightmare when he went into middle school.

It's just heartbreaking what our family had to go through. He was rejected. My son has said, Mom -- honest to God, my son said, Mom, the government gives everyone a free and appropriate education except me.

He went there and they came with a punitive behavior plan where he was granted six tickets a day and he would lose two tickets at a time. This is our education system, people. You get six tickets a day. You come in, here's your six tickets. Any little boo-boo, you get two -- take away two at a time. So really it's three tickets because you're taking away two at a time. You get that.

When you lose all six tickets or really three, what do they do? They sent him home. And why are -- why was he getting tickets taken away? Oh, you said hell, oh, we didn't like how you had that little meltdown, we didn't like tone of voice. Your tone of voice could lose you two tickets. This is our education system. Where's the training?

So my son was rejected. And this punitive behavior plan was a nightmare for him. It made him much, much worse. Now, he's got that defense mechanism. You talk about a kid that's got great anxiety and then you put this punitive system on him. They wanted to move him to EI. We had to eventually remove him from school and pay $24,000 a year for private school that was an hour-and-a-half away.

Please, please fund the education system and train teachers as well as aides. Don't throw an aide in there that has no idea what autism is.

Thank you.

DR. CUTHBERT: Okay. Thank you for your comment.

Our next commenter is Dr. Eileen Simon.

Dr. Simon?

DR. SIMON: An article in the October 1969 issue of the *Scientific American* reported damage of the inferior colliculus caused by asphyxia at birth. The inferior colliculus is a component of the brainstem auditory pathway. For me this provided a plausible explanation of why my first two sons were not learning to speak.

Language is the defining characteristic of the human species. Developmental language disorder is a disaster. Aphasia following brain injury in an adult is likewise a disaster. Understanding the brain circuits between the temporal lobes and frontal cortex has been an important focus of research since the discoveries of Broca in 1861 and Wernicke in 1874. Why these circuits fail to develop in autistic children should be a primary goal of research.

The Combating Autism Act and the IACC were intended to promote scientific investigation of what causes early childhood autism and why the prevalence began to increase in the early 1990s. I have proposed that, one, injury to the inferior colliculus during prenatal life or early infancy could disrupt auditory signal processing and also maturation of the language areas in the cerebral cortex

Two, damage of the basal ganglia appears to underlie the repetitive movement disorder of autistic children. The basal ganglia are also damaged by asphyxia at birth.

Diminished environmental awareness is most likely, in neurological terms, part of a diminished level of consciousness. In my written comments, I discussed research on how this might also result from injury of the inferior colliculus.

"Social disorder" was a euphemism adopted to promote a sense of hope. I could be wrong, but autism diagnosed later should be considered a distinct and different affliction.

Thank you.

DR. CUTHBERT: Thank you very much for your comment about this aspect of ASD.

Our next commenter is Brooke Potthast. I'm not sure if I'm pronouncing that right, Potthast? Brooke Potthast, is she here? No, I guess not.

Okay.

Let's move on then. Perhaps she will come in a minute and we will go back if we can.

Our next commenter then is Chaira King. Ms. King?

MS. KING: I am here to discuss the study publicized by Johns Hopkins earlier this year, which showed increased risk of having a child with autism in women with excessive quantities of folate and vitamin B12 in their bloodstreams after birth.

Women with excessive folate had two times greater risk, women with excessive B12 had three times greater risk, and women with excessive levels of both folate and B12 had over 17 times greater risk of having an autistic child.

The media's downplay of these results is shocking. Genetic mutations impairing folate and B12 metabolism in the methylation cycle are extremely common. Despite this, current obstetric practice in this country is to recommend folic acid supplementation throughout the entire pregnancy, well after the danger of neural tube defect has passed, without any regard whatsoever to maternal methylation impairment. This is important because women with these mutations cannot efficiently metabolize folic acid, which is of course a synthetic substance. This may allow folic acid to accumulate in pregnant women's bodies to an unprecedented extent.

Folic acid has been known since the 1950s to promote estrogen-sensitive growth. Estrogen impacts a number of cognitive functions that are commonly affected in autism like motor coordination, movement disorders, epilepsy vulnerability, attentiveness, regulation of pain pathways and the serotonin system, memory, and spatial ability.

Testosterone converts to an estrogen in the brain during fetal development, and then acts upon neuronal estrogen receptors, so simply being a male fetus may be a natural risk factor for excessive estrogen-sensitive brain development.

There are many other drugs and chemicals that interact with estrogen receptors that might add to the cumulative effect. SSRI antidepressants and pyrethroid insecticides, for example, have recently been linked to autism. SSRIs are used to complement estrogen therapy, and pyrethroids are known to interact with estrogen receptors. Thus, infantile autism may be the result of excessive estrogen-sensitive brain growth during a specific period of fetal development.

Children born of methylation-impaired women would be expected to possess some of their mothers' metabolic mutations. Autism is indeed associated with various combinations of methylation mutations. Methylation cycle impairments have also been associated with developmental regression, as well as increased incidence of adverse vaccine reactions.

I am here today to ask you what possible benefit there could be to 90 percent of American women taking folic acid for an entire nine months when the neural tube closes by the 28th day after conception, and is this practice worth the risk?

Thank you.

DR. CUTHBERT: Thank you very much for your comment.

Our next commenter is Lisa Wiederlight.

MS. WIEDERLIGHT: My son's drawing.

Good afternoon. My name is Lisa Wiederlight. I'm the parent of a 15-year-old young child with autism and now epilepsy. I am also the executive director of SafeMinds.

Years ago, when I worked for the Office of National Drug Control Policy, I had the honor to help produce the National Drug Control Strategy. We had to accomplish two things. The first was to answer the "so what" question and second was to be accountable to Congress for making a difference with real outcome measures each year.

At every IACC meeting, I'm reminded of these principles. Stakeholders are providing the "so what." The question is are the IACC's federal agencies listening and being accountable to make a measurable difference?

Each meeting, passionate parents convey the struggles they face in addressing severe autism. The committee hears letter after letter about the dangers from wandering; the toll of seizures and gastrointestinal disease; the harm of uncontrollable aggression and self-injury, the diminished quality of life from unremitting anxiety, depression, and suicidal behaviors; the lack of respite from 24/7 care for those with diminished cognition. For three minutes or so, committee members discuss how important these so-what's are, but little is proposed that would make a measurable difference.

Over a million children have been diagnosed with autism since 2000. With rising prevalence, unmet demands on services, and grim reports from parents, it's obvious that the government response is inadequate.

What is being done to improve the epidemiology so that we have an accurate count of the number of affected individuals? Is the prevalence 1 in 68 and flat, as just reported by the CDC or is it 1 in 41 and still rising, as reported in New Jersey? There's a big difference in projected costs and needs between 41 and 68.

What proportion are severely impacted by co-occurring conditions? What are the trends? The CDC's methodology cannot give the answers. Should federal coordinating agencies allow this sloppy research to remain the foundation for autism policy?

Has severe autism always been around at the present rate, or have we witnessed a true epidemic due to modifiable environmental factors which are addressing an increasing risk? How can federal agencies charged with autism not demand a rigorous answer so that strategy aligns with reality?

The Senate Appropriations Committee, in report language for FY 2017, urged -- it's okay -- urged the NIH to include research on environmental factors related to autism, especially regressive autism, in the upcoming revision to the Strategic Plan for Autism Research, and then ask the IACC to consider research on environmental factors related to autism, including onset patterns, in the upcoming revision to the IACC Strategic Plan for Autism Research, assure that research on environmental factors continues to be supported, and study the relationship between GI diseases and autism spectrum disorders. How will the IACC be accountable to Congress for these directives?

The President proposed $1.9 billion to Congress to address Zika virus. As of July 6, according to the CDC, 1,133 cases of Zika virus in the United States were reported. In contrast over 1.5 million Americans are diagnosed with autism, which increases mortality and significant disability and costs this country $268 billion a year. How much have your individual agencies asked Congress for autism this year?

The committee's work is to inform and promote effective public policy. Please take a moment now, on record, to tell Congress and those facing autism across the country when and how you will do this.

Thank you.

DR. CUTHBERT: Thank you very much for your comment, Ms. Wiederlight.

We have one more comment from Adrienne McBride.

Ms. McBride?

MS. MCBRIDE: Good afternoon. I'm delivering comments on behalf of Madison House Autism

Foundation and the president, JaLynn Prince, who can't be here today due to a family emergency.

This is not the first time Madison House has presented comments to IACC and it will probably not be the last. Our goal is to stand up for adults with -- on the autism spectrum so their needs will be known and perhaps their lives' trajectories will be changed for the better. It's not looking good the way things -- if things don't change and if they don't change dramatically.

Through Madison House Autism Foundation, now 10 years old, and Madison Fields, our farm and housing project, we are addressing the many issues that adults on the autism spectrum face after they turn 21 and no longer receive federally mandated services. A large part -- portion of our society has never even given thought that adults -- that children with autism grow up to be adults with autism.

The outcomes are dismal. The funding on state and federal levels is most scarce for those who are most vulnerable among us. The services that do exist are inadequate. Job prospects are virtually nonexistent with researchers projecting 80 percent underemployment or unemployment. Many autistic adults live with their parents for decades. What is going to happen when these parents can no longer care for their adult children?

Let me share some background. Madison House Autism Foundation is a 501(c)(3) organization headquartered in Rockville, Maryland. Madison House addresses quality-of-life issues for adults with autism and their families. Madison Fields is a local project which provides a location for respite, recreation, writing and agricultural-based employment, and job training for adults with autism, veterans groups, seniors, neurotypical volunteers, and all those who can benefit from our services.

Some of our other recent initiatives include a re-launch of our Autism Housing Network to great acclaim. This national initiative is sparking ideas to create innovative residential opportunities. It's an online resource; a new and exciting arts employment initiative, a replicable program for those on the autism spectrum who may be considering a career in the arts.

We've declared autism -- April 21st has Autism after 21 Day, and we're asking our colleagues, other organizations, and you to observe this day accordingly.

We've been championing universities to develop training for careers in the field of autism and for greater accommodations for those on the autism spectrum who are candidates for education to have a higher level of success.

And finally, we're working with the medical community to look closely at the uniqueness of autism when providing medical care. However, more than awareness, we need evidence-based studies and creative action on the federal level. Not all adults with autism will grow up to be self-advocates, much like most neurotypical individuals will not grow up to be politicians. In fact, self-advocates may have very different support needs than those -- than many others on the spectrum.

Finally, as you know, support needs are costly, even supports delivered in a community-based setting, a family home. Supports can bankrupt families both emotionally and financially. We are living in times that are rapidly changing, and the way we deliver services must change as well. Our politics and our leaderships reflect this complexity.

These are frightening times for families. However, we're looking to change these outcomes and we need people like you. And Mrs. Prince is very honored to be part of the working group to change the future of adults with autism.

Thank you.

DR. CUTHBERT: Thank you for your comment. Your comments are certainly very consistent with the theme of all of our morning's deliberations.

That's the end of our oral public comment session. We are well over our time, so I think we are going to have to forgo the summary of written public comments that was to be presented by Dr. Karen Mowrer, a policy analyst from our autism office staff.

I would remind you, however, that all of the written comments -- excuse me -- are presented in the full on our website for those of you who wish to read them.

I do think that we have time -- well, it would be important to have maybe 10 minutes of the time that we had set aside for the committee member discussion of the public comments. So let me throw the floor open at this time for a discussion and -- of any of the comments that you have heard.

John?

MR. ROBISON: I'm still wrestling with this introduction and conclusion thing, but one thing that I think is a good idea and maybe some of the committee members would speak to this would be if you would send me all of the comments written and spoken for '14 and '15. And in the introduction we know that we have our questions that the committee has chosen. But those comments provide the questions that the public has brought us. So let's summarize what the seven or -- seven, eight key issues that the public has brought us are, and then we can comment briefly in the introduction on how those questions relate to the actions that fall out of our strategic plan and how we have addressed those. I think that would be a fair thing to do.

DR. DANIELS: So you're asking for an analysis of all the public comments that have been coming in for '14 and '15?

MR. ROBISON: I think it would be unfair --

DR. DANIELS: That's pretty --

MR. ROBISON: -- for me to just lay it off on you. If you send them to me --

DR. DANIELS: That's --

MR. ROBISON: -- I'll do it.

DR. DANIELS: I -- we have them. They're all on the web. It's a --

MR. ROBISON: But do you have -- do we have -- do you have statistics of them? I'll have to make those, right?

DR. DANIELS: I don't have them analyzed. It would take time to analyze them. I'm not sure how that's really different from the request for public comment. That's kind of the purpose of us doing a request is to bring in public comment. I don't think the nature of these oral comments and written comments are significantly different although -- well, I guess they're more focused on the Strategic Plan itself.

MR. ROBISON: Well, what they speak to is how they've evolved over the last two years. If we can say what people said to us in '14 and did we do anything about it in '15, that would be meaningful.

DR. DANIELS: So you're asking about what the committee did in -- that's another entire analysis so we'd have to think about that. We -- given limited time and resources to do various analyses, we already have been working on the analysis of the comments that we've brought in specifically for the strategic plan.

We have all the comments. They're available on the website for everyone to read, but I think I'd hesitate to promise that we could do an entire analysis of all of them in a timely manner to use for the Strategic Plan update.

MR. ROBISON: Um-hum.

DR. DANIELS: So we'll think about that and see what we can do.

DR. CUTHBERT: Certainly in a statistical sense the number of comments that have been received in response to the RFI is much greater, I think, than what we would see even from the written comments to the committee over the past couple years.

MR. ROBISON: Yeah, the 800 are a lot --

DR. DANIELS: Right. I mean, overall, I mean, I wouldn't say that I can think of too many themes that have been brought up in regular public comment that we're not seeing in the RFI. So I think those themes are all still going to be there, but we'll give that some more thought.

David?

DR. AMARAL: So I'm actually -- I've been thinking about John's comment that it may be a failure of communication of what is known scientifically about some of the issues that we've heard about. So I don't think anybody would dismiss the passion of the parents and certainly parents who have an affected child that have some deep feeling about what causes the injury, but I think there's two issues. One is it would be interesting to know how representative some of these comments are because, you know, it takes a lot of guts to make these comments in a public forum, yet how representative are they of the sort of national feeling of parents who have children with autism. I mean, I don't know if we have any data on that, but it would be interesting to know.

But I do think that there's enormous amount of data, for example, that suggests that vaccines, you know, if they're a culprit at all, are affecting a very, very small number of children. Yet somehow we haven't been able to get those data across to convince the general public that -- you know, that this is not a major cause of autism.

So I think the idea of somehow mobilizing an effort to synthesize the data and present it in an easily comprehensible form is something that this committee may want to consider. You know, maybe -- you know, we're deliberating about these things, and I think we all have our own senses about, you know, what's going on scientifically, but I think part of our mission, if I understand it, is that we translate that to the general public. And maybe that's where there's -- you know, we've not been as successful as we could be. So I would just like to hear more discussion in the future about how we could do better at synthesizing and translating to the general public.

DR. DANIELS: In the Strategic Plan update, the working groups do have an opportunity to review the literature and if there are new findings that you think are relevant to that topic or any other topic related to risk factors. And I know that you're one of the chairs of that working group. You can make sure that that literature is reflected in the chapter that you're working on. That would be one way, aside from, you know, a bigger project.

DR. CUTHBERT: I'm just trying to think. Do you think it would be useful if the IACC as a body were to try to write such a paper that could be published in a relatively visible place? And I don't know if our website would be the place. I can imagine that the clearance process for such a document emanating from a government committee would be impressively onerous, but still, perhaps that is part of our responsibility to try to undertake that.

DR. DANIELS: That is actually -- if the committee wanted to do some sort of a statement or a white paper or something like that, the committee, because it's not a federal agency and the work of the committee doesn't have to be approved by any agency, it's possible to get it done but you have to have pretty much unanimity among the committee on what's in the document.

DR. AMARAL: Just if I can comment on that, I would just like to say that, as an editor of an autism journal, I think we would welcome something like that, and then actually we can promulgate it through channels to have that at least accessible to a lay audience as well. So I think that that -- you know, it's work, but I think it's a terrific idea if we want to consider that.

DR. WEXLER: No problem. I would caution us as federal representatives on this group. We were faced with something like this before. My recollection is when the committee wanted to respond to the GAO potential duplication of research report that the federal members had to -- well, they didn't have to; they were crazy not to frankly -- recuse themselves from participating because as a federal employee we can't take a public position like that unless it's actually cleared. And I think onerous clearance would be one of the great understatements of the century. So I think we need to really think about whether the -- if the -- I think what happened was a subset of the committee made a recommendation relative to the GAO report without federal representative participation.

DR. DANIELS: Right. The recommendations or the response letter to the GAO was kind of a different scenario. I mean, we've had a statement on the Sandy Hook situation that we did as a group. We've had recommendations around DSM-V that we put out as a group, so those kinds of things can be done. And so this isn't really -- something like this would not be in response to a particular government body. But again, any kind of project on any topic like that you do need to have a significant portion of the committee that is in agreement.

Alison? Oh, sorry, Geri?

DR. DAWSON: No --

MS. SINGER: I would also add that I think we may be trying to solve the wrong problem here. I think -- I don't necessarily agree that it's been a problem of communication. I think there has been document after document after document, a mountain of scientific studies, and yet there is still a segment of parents who have children with autism who are unconvinced. I don't really believe that a document from this body would serve to convince them.

I'll ask you, would you be convinced if the IACC put out a statement summarizing the scientific literature with regard to autism and then would that put an end to it? So --

MS. GAMMICCHIA: I wonder if you would if it happened to your child.

MS. SINGER: What?

MS. GAMMICCHIA: I said if it happened to your child, I wonder if it would.

MS. SINGER: I do have a daughter with autism. I also have a brother with autism. So I have lived your experience.

MS. GAMMICCHIA: I didn't say with autism. I said if you experienced what we experienced --

MS. SINGER: I have experienced what you have experienced, believe me. So -- but the question we're talking about right now is whether it's a worthwhile endeavor for this committee to write an additional statement, and my feeling is that I don't think it will achieve the purpose that we would want it to achieve.

MS. GAMMICCHIA: But, Ms. Singer, we're not asking for that. There's been -- not one study has not been done on that. That's what we're asking for. And, Ms. Singer --

MS. SINGER: The vaccinated, non-vaccinated?

MS. GAMMICCHIA: (inaudible)

MS. SINGER: Can you use a microphone so we can hear you.

MS. GAMMICCHIA: So it's a conflict of interest --

DR. CUTHBERT: Excuse me. Can you just --

MS. SINGER: Can you use a microphone? I can't hear what you're saying.

MS. GAMMICCHIA: A conflict of interest --

DR. CUTHBERT: Excuse me. Can you use a microphone? We want to hear you not to not hear you.

MS. GAMMICCHIA: You know what, I'm really trying to not be frustrated. I'm trying. I'm really trying. But, Ms. Singer, you have a conflict of interest because on your board you have Paul Offit, who is a vaccine -- has a vaccine copyright. You have -- your organization in itself and your participation on this committee has tried to mainline this topic. And I -- you saw the people standing up. We will not go away. The deliberate indifference on this, though, is your liability.

I presented on that the last strategic planning meeting. I know what your limitations are on this committee. We'll -- if you come up with a statement regarding the current research, no, we won't accept that because we don't have the study.

Colleen Boyle admitted it. Dr. Thompson has admitted fraud within the research that you used to parlay vaccines causing autism.

So -- and my major concern now is he hid research that indicated African-American boys are three times more likely to be damaged by the MMR and end up with autism than their Caucasian counterparts. Where is the -- where's the outcry about that? Why has Dr. William Thompson not been subpoenaed by Congress?

We have Dr. William -- or we have William Posey, a Congressman, speaking about this topic for five minutes. I ask you to watch that presentation. He's not some crazy mom from Michigan who says her son was vaccine-injured. Our son wasn't born with autism.

MS. SINGER: So given that response, I would say the committee need not summarize the scientific literature at this point.

MS. GAMMICCHIA: Well, it's not --

DR. CUTHBERT: So --

MS. GAMMICCHIA: But it's not about that.

MS. SINGER: But that is the question --

MS. GAMMICCHIA: It's not about that.

MS. SINGER: -- on the table.

MS. GAMMICCHIA: You can summarize it.

MS. SINGER: That was the question on the table.

MS. GAMMICCHIA: Well, you've already summarized it actually. You already have.

DR. CUTHBERT: So I think Dr. Dawson has a comment.

DR. DAWSON: I mean, I agree that I don't think that that would be a fruitful exercise. And also, we -- there were two meta-analyses published last year. I do think that that's not the issue that's going on here, right, is the summary of the literature.

I do think, however, that in the context of the new Strategic Plan that we should always be looking at the range of issues that are on the table, including the public input that we get, which we tremendously value. And in that context I think probably in question 2 you'll need to grapple with how you want to, you know, think about whether that would impact or not impact any objectives. But I think that's the context and the charge that we have for handling this.

DR. CUTHBERT: So thank you. I think that's a very good place to leave this discussion and an appropriate way to think about it. We are clearly not going to resolve this issue today, nor any time soon. And do have many other important elements on our agenda today that we do need to get to.

So I think just so we can plan and sort of altering our agenda as we go along, we do have an important segment coming on next about a discussion of the nominated 2016 science advances. So I am going to turn it over to Susan to lead that discussion, which will involve presentations by some of you at the table. And obviously, given the time, that will need to bleed into our break, but we do have a very important panel coming in at 2:45. So we'll have this segment go until about 2:40, take a very quick five-minute bio break, and then resume at 2:45. So thank you to everyone for your comments on all sides of all of these issues, and let's move on to Susan and the science advances.

Susan?

DR. DANIELS: Okay. So this is just an opportunity for everyone who submitted nominations for the 2016 summary of advances to discuss the advances you submitted. I didn't have you prepare any kind of formal presentations, but in your packets, you'll see the articles listed, as well as the justifications that we provided. As you'll recall, at the last meeting it was requested that for each nomination there's a three- to five-sentence justification for why this advance is important and should be considered.

And so we've prepared them here on the slides, and you're -- any of you are welcome to share something about your advances. I don't know if you would like to go in any particular order or if you would just like to just have the floor open to share any comments you have about the articles that you nominated.

(Pause.)

Did you find the information in the -- in your packets?

DR. KOROSHETZ: Can you go back one?

DR. DANIELS: Sure. Here?

DR. KOROSHETZ: Yeah. So I submitted the top one. I think it's -- it kind of uncovers something that no one expected, and that was actually looking at multiple genetic either causes or genetic influences for autism, including Rett syndrome, fragile X, what the -- these investigators are experts in understanding sensory systems, and what they found was that in the mouse models that there were disturbances in real primary sensory detection, and so it raises the question of -- which I think, you know, has been out here at the -- even from the public comments that people with autism may be receiving real altered sensory stimulation as part of the problem, whether it's auditory but this one tactile.

So, again, it's somewhat of a surprise. I guess the other -- from my medical point of view when you want to try and develop a therapy, you'd like to have, you know, some kind of convergence of all the mechanisms on one area, and here, interestingly, multiple different genes associated with autism all caused the same kind of problem, some kind of points, maybe some convergence.

And the other thing is that if you try and develop a treatment, you'd like to have some way of measuring it and it's easier to measure things kind of like sensation than it would be, you know, other things that are inside the head. So I just thought that it was kind of an interesting, unsuspected, and potentially useful finding.

DR. DANIELS: Thank you.

DR. CUTHBERT: Yeah, thank you, Walter. These are the kinds of animal models that can readily translate to humans much more than other things, as you say, that are inside the head but much more difficult to gauge in animal models.

DR. DANIELS: David, do you want me to flip to a particular slide?

DR. AMARAL: Could you go back to the Nordahl one. I just --

DR. DANIELS: Oh, there it is.

DR. AMARAL: Yeah, so the one on the bottom --

DR. DANIELS: Um-hum.

DR. AMARAL: -- that I was very happy that Dr. Spong suggested. But I just wanted to make a comment about it since she's not here. And that is that we often hear that it's difficult to carry out research with individuals on the autism spectrum that are very severely affected or have intellectual disability.

And what -- this is a paper from our group, but what we were able to do is we've been following kids from two years of age. Now, they're 11 years of age. These are kids that often have IQs in the 40-50 range, nonverbal, and we were able or Christine Nordahl and the team were able to come up with a way of using a BCBA to take each child as an individual case study and get them through the process of doing structural imaging.

And so we are now doing routinely structural imaging with all levels of the autism spectrum. And these kids go through 30 minutes of imaging and we're getting, you know, fantastic scans. And, knock on wood, we're at -- we've done -- we've had 43 children go through this study, and we are at

100 percent success. So I think, to me, it epitomizes the fact that if you put enough effort, enough patience into it, you really can do research and involve people at all levels of the spectrum. So that's why I was happy to see somebody else select this for the nominations. Thanks.

DR. DANIELS: Larry?

DR. WEXLER: There are four of those from the Department of Ed, and I'm not going to go through each one of them but just to say that we have a saying in our shop that regardless of the state of the research, the school bus comes up -- picks up the kid every day and delivers them. So what we tried to do was to identify some studies that were either randomized controlled trials or had some rigorous research behind it or were meta-analyses. And they're mostly practically, not change the world, things like using theater for communication. They're not bio-behavioral or biomedical or genetic, but we thought they ought to be included because they're practical and useful within an actual educational context.

And I will credit one of our doctoral interns Kristi Morin from Texas A&M who helped us pull this together. I don't know if our next round will have quite so many. They may not be here. But thank you.

DR. DANIELS: Thank you. Other comments or anything else you want to talk about?

Julie?

DR. TAYLOR: So I nominated the Wehman study for kind of the same reason. So this was a randomized controlled trial of Project SEARCH, so one of the very, very few RTCs that have be done among adults with autism and employment. And it certainly has some limitations, but I think what it shows is that -- oh, the other thing that I liked about this study was that it's focused on people with ASD who have an intellectual disability or some -- and working on employment within that group, which we don't see very much of in terms of employment intervention.

So I think what this shows is that with a really intensive long-term internship-type program, these people had remarkably high rates of employment that they were able to maintain over time. And so I thought that it was a nice addition.

DR. DANIELS: Thank you.

Louis?

DR. REICHARDT: Can I just ask if people, when they're summarizing, would say which page the written is on. That would just help us. That's all. Yeah.

DR. DANIELS: Alison?

MS. SINGER: So at the bottom of page 3 --

(Laughter.)

DR. WEXLER: Good response.

MS. SINGER: -- I nominated "Risk of

Psychiatric and Neurodevelopmental Disorders among Siblings of Probands with Autism." I thought this was an important paper for two reasons. One, I think it's instructive for the scientific and research community because it showed that a lot of the risk factors that we're identifying for autism are also risk factors for other psychiatric conditions, so we need to be looking at that -- aware of that when we are talking about risk factors.

Also, it sort of serves as a warning to us about using siblings as controls in some of the studies. But even more importantly, I think is a really important paper for families because it really speaks to the fact that we have to be vigilant about looking for early warning signs of anxiety, depression, OCD, bipolar disorder, among our other children. So for those reasons, I nominated this article.

DR. DANIELS: Great. Thank you.

David?

DR. AMARAL: So I nominated the one just above that one. It's page 3, middle, "Effect of Co-Twin Gender on Neurodevelopmental Symptoms: A Twin Register Study." I just thought that this was a cool study that -- it's a naturalistic study where they ask the question does fetal exposure to testosterone increase the risk of having a child with autism. And it's -- there's so few really -- real hypothesis in autism that the extreme male brain that Simon Baron-Cohen has postulated for years and testosterone exposure.

And so the bottom line is they looked at a huge number of dizygotic twins, over 8,000, and it turned out that there was a greater risk to the sibling if your sibling was a female rather than a male. So it was the exact opposite of what we predicted from the extreme male brain. So, again, as a natural experiment, it's sort of providing evidence one way or the other against prevailing hypotheses. I thought it was an interesting study.

DR. DANIELS: Thank you.

Anyone else? Walter?

DR. KOROSHETZ: I don't know if you'll agree with this, but I also picked out this paper -- I don't have the sheets. It's the SHANK3, so it's another mutation --

MS. SINGER: Top of page 3.

DR. KOROSHETZ: -- that's been associated very closely with ASD and also in the Phelan-McDermid syndrome where the deletion of these gene SHANK3. And so this paper, they actually found that the -- in human neurons, IPS cells with this mutation there's actual channel defect. Channels are, you know, openings in the cell membrane that current flows through, and that's how neurons work. And they can be manipulated. So it brings up the idea that you could potentially normalize an abnormality in an IPS cell so it's a human cell. It's not an animal model but potentially get at the mechanism. The question is how does that explain the phenotype in people. That's -- that would be the next step to go to. So anyway, that's why it was interesting.

The other point to make is that it's from the lab of Tom Sudhof, who's a Nobel Prize-winner, and so I think the thing -- the other thing I think which is interesting -- I don't know what it was like, but I think, you know, 20 years ago the research in autism was at one level. It's now at a completely different level. So you have Nobel Prize-winners who want to try and solve this problem, which is great for us, I think. So we keep giving them money and keep our fingers crossed. Thanks.

DR. DANIELS: Thanks. Further comments?

(No response.)

DR. DANIELS: I think we've had a pretty good discussion. Thank you for everyone for submitting these responses. I'll be continuing to have folks from our office send out monthly solicitations of articles, and then at our October meeting, we can discuss what comes in. So if you didn't get any in this time, next quarter is your chance.

DR. CUTHBERT: Okay. Thank you very much for all your thoughtful selections and the comments about these. It's very useful to hear from all of you directly about what you liked about these studies and why you thought they were interesting.

So we'll have a little bit closer to our normal break time than we'd expected, but please do be back promptly at 2:45 because, you know, this is -- as it suggests, the panel on challenging behaviors in autism. This is something that speaks directly to the concerns that we have heard from many of the public commenters about the difficulties in living with and managing children but also adults on the spectrum. And so I think this will be a very important panel for us to listen to so -- yeah, Susan has one comment before we break.

DR. DANIELS: Yes, before we break, just a question to you all regarding how we're doing public comments. So this time around we had more oral commenters register than what we had room for, and so I did have to turn a few people away. As you can see, things went over time anyway even though we did try to have -- you know, we provided guidance on the length of comments, et cetera. But we were not able to do the summary of written comments or have the full amount of time for group discussion.

So what is your preference? Would you like in the future for us to be a little bit stricter about having fewer oral comments to fit within the time period to allow for more and not do the written comment summary or dispense with some of the discussion or -- so right now, we have an hour set aside for public comment. Are you happy with that? Would you like it to be more than that?

DR. REICHARDT: I think it would be -- personally, I think it would be very disrespectful to not hear as many as possible oral comments. I mean, I think we can all read the written comments and summaries can be useful when John does them, of course, but the -- but, you know, in fact I don't think they're essential, that I think it's really important you hear what the people want, you know.

DR. DANIELS: Samantha?

MS. CRANE: I would just agree in that, you know, a lot of people who do write written comments can't be here. There are a lot of people who, for example, if you're on the autism spectrum, this is not an accessible location or format for a meeting for a lot of people on the autism spectrum who might be writing comments. And the only way that they can be heard is through written comments.

I like the summaries in that they can kind of give people an opportunity to be heard through written comments in the same way that oral comments are heard, and I don't want to disadvantage people who can't travel or can't be here.

DR. DANIELS: Tiffany?

DR. FARCHIONE: Yeah, I think that it would also be really helpful -- I mean, I know that we've been reminding people, giving them guidance and everything about their time limits but, you know, letting people know in advance that you have three minutes and we will cut you off because part of the problem is -- and I know that people are very passionate and they have a lot to say, but there are a lot of people who are very passionate and have a lot to say. And so we -- if we're going to fit them all in, if we've said you have three minutes, it has to be three minutes.

DR. DANIELS: So we do provide all of that guidance.

DR. FARCHIONE: I know but we don't --

DR. DANIELS: It's --

DR. FARCHIONE: -- cut people off.

DR. DANIELS: And we have a timer up there as well. I mean --

DR. FARCHIONE: But nobody pays attention to it. It's --

DR. DANIELS: So --

DR. FARCHIONE: You need to just start --

DR. DANIELS: We need to start --

DR. FARCHIONE: I mean, and I hate to say --

DR. DANIELS: -- just saying like --

DR. FARCHIONE: -- interrupt --

DR. DANIELS: -- time, yeah.

DR. FARCHIONE: Sorry, I didn't realize I shut it off. But even if -- you don't -- I know we don't want to interrupt because, you know, it's very sensitive and people are getting emotional and everything, but with all of the advanced warning and all of the guidance and everything, we just have to say, look, I'm sorry, but your time is up.

MS. SINGER: I also think that one of the reasons people come to make public comment is because they want us to discuss them. And if people make 10 minutes of public comments, it eats into the time that we have to discuss them.

DR. DANIELS: So I don't think I'm hearing a really strong message about -- so should we just accept fewer and try to allow the ones that are there to -- I mean even when we give them the guidance, it's taking up the time or -- like this time we put in with hope that people would really be able to fit it all in, it really didn't and it went over.

MS. SINGER: If people were told they only had three minutes, we still wouldn't be able to hear all of the public comments and discuss them because people today went on for much longer than three minutes.

DR. CUTHBERT: Yeah, and we -- it's -- as Susan said, we did limit it. I mean, we turned some people away and said, sorry, we just don't have time for anymore, so sort of a first come, first served, I think, but even then, we couldn't accommodate everyone.

And, you know, as chair obviously it's a bit of dilemma for me. These -- as we've said, these people have really heartfelt comments to make, and one is reluctant to have them feel that we are cutting them off when they are expressing their stories.

On the other hand, obviously we have to pay attention to the time and we would hope that people could attend to that. I mean, my experience in the few sessions I've led is that however much time you tell people, they'll go two to three minutes long. You know, we said three, they took five and six. When we said five when we started, they took seven and eight. So, you know, when it was tough to have a buffer for however long you tell people because they're going to go over unless you really just like turn off the microphone or something.

DR. FARCHIONE: So --

DR. CUTHBERT: Tiffany has a comment.

DR. FARCHIONE: Yeah, I mean, I think we keep telling people -- it keeps shutting off. I had it on.

We keep telling people the amount of time and -- you know, and there are some people who routinely go over each time. If we warn them in advance and say you will be cut off, you only have three minutes and that's it, I would feel less bad about cutting people off as long as they knew that that was going to happen.

MS. SINGER: I agree. I think from my perspective the goal would be to maximize the number of people who can give public comment and maximize the time that the committee has to discuss the public comments that people travel here to make. And if we implement the three-minute rule fairly and cut everyone off at three minutes, I think that would be worth trying.

DR. COOPER: I'm subbing for Jim Battey, NIDCD.

I'm taken with what Samantha said about the folks who do the written comments, and I'm even wondering whether the oral comment opportunity is an unfair practice. It's for folks who can afford and are able to come. And so we're already struggling with, well, we're going to cut you back to three minutes, and yet those who have -- who are unable because of financial or other constraints are not able and we don't even have a discussion of the written comments.

So I think the whole process is worrisome to me from the level playing field that we like to talk about here at NIH.

DR. DANIELS: We are required to have oral public comments at our meetings.

DR. CUTHBERT: By law, so it's --

DR. COOPER: Okay. Never mind.

DR. DANIELS: So we have to have some. We don't have to have every person who registers. We could say that we're only going to take the first five that register and -- or we could do other processes. It's -- we've done different things over the -- over time, but lately, it has been not fitting in the time limit.

David, have one and then Geri.

DR. AMARAL: So I agree with everybody who said we should have the three-minute limit, and I think we should adhere to that and set that as a culture. And I know it's really, really difficult, you know, to -- so -- but, you know, we have to really establish a culture.

I'm just wondering, it just occurred to me, what if we tried to set it up so that we could do video presentations instead of written versus oral, just -- I mean, the technology is easy now, right. You do a three-minute video. We just have a series of videos from people. Then anybody could present it that way and then we could have -- you know, we could make sure that -- adhere that -- because it's going to be prerecorded. You make sure it's three minutes.

DR. FARCHIONE: We get a lot of that actually at FDA in terms of our advisory committees. We'll --

DR. AMARAL: Yeah.

DR. FARCHIONE: -- because, again, people can't travel --

DR. AMARAL: Everybody can do it with their iPhone so --

DR. FARCHIONE: -- and people just submit their three-minute video.

DR. AMARAL: Yeah. Yeah. That would be good, particularly if it's anybody younger than 30, right? It'd be a snap.

MS. CRANE: I would say that some people in our community would definitely take advantage of a three-minute video and others would still not be able to take advantage of a three-minute video, for example, a person who has really significant communication challenges will only be able to utter a certain number of words per minute and will do a lot better if they're able to either directly write or have their thoughts transcribed by another person and submitted as a written comment.

I'm not saying that -- I think that a video would actually be a really good idea as a supplement, but I don't know if they could replace written comments.

DR. FARCHIONE: No, I don't think --

DR. AMARAL: Sam, I --

DR. FARCHIONE: -- we're talking about replacing. I think it's just in terms of adding structure to our -- and making sure that people adhere to the three minutes because you can't submit more than a three-minute video.

DR. DANIELS: But you're then talking about replacing the in-person oral comments with videos, right?

DR. FARCHIONE: I guess it would be -- yes.

DR. DANIELS: Not both because if we add yet another section of more things --

DR. CUTHBERT: No, I think --

DR. DANIELS: -- I think that's be --

DR. CUTHBERT: No, we would consider --

DR. FARCHIONE: No, it would be in lieu of.

DR. CUTHBERT: -- it public oral comment. I mean, it would still be an oral comment, just videotape it.

Just to be clear, I think -- that doesn't mean we would not still allow written comment. And I think what we've expressed that we are missing is in fact a summary of the written comments that we find useful. And you make a compelling point that we need to accommodate people who want to send in written comment.

DR. DANIELS: So if we were to, for example, have videos sent in, if we got 25 videos, would we be able to show all 25 videos? Because if they're all three minutes long, we would go over our time limit once again or we would only show the first five and the rest of them are online or -- you know, that gets difficult as well. So that would be --

DR. FARCHIONE: I mean, I guess --

DR. DANIELS: -- another challenge.

DR. FARCHIONE: -- we'd have to use the same process that you use to pare it down now.

DR. AMARAL: But if you could put them online, I mean, then that's again representative, right? I mean, it may be a lottery. I mean, if you get 25, you could just do a random drawing or something like that.

DR. DANIELS: Right. And the logistics of managing all the video and all of that, we don't have NBC or ABC here in the OR office to manage all of that, but it's something we can definitely consider as a possibility.

John?

MR. ROBISON: I think that's -- it's an excellent idea. I think that, logistically, if we were to set up a record-your-video comment provision on the IACC website, that would take away the stress of you as the chair having to manage the time limit for the comments. You have a three-minute window and you record into it. And you -- I'm happy with the result. And then, as you suggested, if we have too many, we just have a lottery system. We -- the computer randomly picks however many minutes we're going to allocate, and all the rest are put online to see.

I think that's a really good solution because it's maximally empowering. Nobody has to travel here. If they want to travel here, they could, but you can do it without travel. If you want to address Sam's concern, somebody who can speak for you can read your comments into the video and it's still a comment that we sit and watch on the screen. I think that would be a great idea, and the three minutes would be managed right in our system them.

DR. DANIELS: Laura?

MS. KAVANAGH: I like the idea of a video but I'm wondering are there technical issues like redacting personal information? Like how would that happen on a video?

DR. DANIELS: Right. We -- you can redact things on a video. It's labor-intensive.

MS. KAVANAGH: Do we have the -- yeah. Okay.

DR. DANIELS: We would have NIH VideoCast edit every video, which is expensive and challenging.

DR. FARCHIONE: Well, we don't redact during the live presentations so --

DR. DANIELS: We don't.

MR. ROBISON: Why should we have to redact? If somebody voluntarily says it, just like they say it here.

DR. DANIELS: Only if it was something super-sensitive like -- there have been a couple of instances where we had to -- for the oral comments we normally don't, but in the written statements, we redact out some personally identifying information. We haven't had that issue too much, though.

DR. CUTHBERT: So we will investigate this thoroughly and hope to implement something like this at the next meeting.

So do people want to take a very fast bio break and -- okay. Bio break is needed. Please come back here as soon as possible. We will start at 2:50. Thank you.

(Recess.)

DR. CUTHBERT: So let us get started. We've had a good long bio break. And now, I want to again introduce this panel on challenging behaviors in autism. Again, this a topic in which several IACC members have expressed interest. And our panelists will include Denis Sukhodolsky from the Yale Child Studies Center, James Bodfish from the Vanderbilt University School of Medicine, and Frank Symons from my old stomping grounds, the University of Minnesota.

So we will lead off with Dr. Sukhodolsky talking about behavioral interventions for anxiety and irritability in children and adolescents with autism spectrum disorder. Denis?

DR. SUKHODOLSKY: Thank you for inviting me. It's an honor to be here. I'm a clinical psychologist by background, and at the Yale Child Studies Center my lab conducts research on behavioral interventions for children with autism.

We're very grateful for support from NIMH and NICHD, and one of our treatment approaches has been published as a treatment manual by the Guildford Press. I will skip the slide but I put it in the presentation because sometimes I find it hard to switch my own routine off. And I like to think about autism as having core symptoms and also associated difficulties so that my research has been concerned anxiety and irritability as problems that often co-occur with the core symptoms of autism.

And about 40 percent of children with autism have co-occurring anxiety. And it took a while to get at this number, and I think it's fairly accurate. Assessment of anxiety and autism is very difficult because excessive fearfulness is part of the presentation of autism. Changes in routines and social situations can trigger anxiety. But honest to God, anxiety can also be a co-occurring disorder so that children with autism can have social anxiety disorder. They also can have generalized anxiety disorder that comes on top of the core features. And then they exacerbate function and make children miserable.

What is the treatment for anxiety and autism? The broad umbrella category is cognitive behavioral therapy, but then within cognitive behavioral therapy there's a very specific approach called exposure and response prevention where individuals are taught to face their fears.

So, for example, on this picture there is an illustration of a person who is afraid of germs. Germaphobia is a very common condition so that a person is asked to expose themselves to their fears where for the first five minutes the person is miserable and she is frowning. For the next five minutes the level of distress has diminished, and then for the last five minutes, the person is smiling, right? So anxiety goes away and they're the mechanism of exposure and response prevention.

Those interventions have been studied in children and adults with anxiety disorder without autism for a good 30 or 40 years and are considered to be the first line of treatment for anxiety.

And the good news for children and adolescents with autism is that this treatment is also very effective in autism. In fact, a couple of years ago we reviewed available literature. There were eight randomized studies at that time, and the effect sides of this were quite large. In fact, 1.2 for parent ratings and for clinician ratings, but what's even more exciting, about .68 for child self-report. So children with autism consider those treatments to be helpful.

Now, what's the bad news? The bad news is that there's a good number of children who do not respond so that we don't really know what to do for those kids. And we also know very little about the mechanisms of treatment. The treatment that would be considered effective, we don't know how they work so that we could be conducting research trying to understand whether or not treatment that reduced behavior can also engage neural targets that are presumed to be associated with behavioral problems.

And today, I will tell you about some of the pilot studies and some of the plans that we have for the future. We looked at fMRI, functional magnetic resonance imaging, before and after treatment in an open pilot study where we enrolled 10 children with anxiety, three girls and seven boys in the age range from 10 to 13 years, IQ ranging from 79 to 122, who all were in the upper quartile on a measure of anxiety that was validated in a previous study. So they had pretty high level of anxiety and they all met criteria for co-occurring anxiety disorder.

And they received treatment with 12 to 15 sessions of CBT and were also rated their reduction in anxiety using pediatric anxiety rating scale and where the children complete two tasks during functional magnetic resonance imaging, during one task they viewed pictures of unpleasant images. And their job was to either passively view those images or to pretend that the images are fake so that -- we assume that this task would require that children will down-regulate their emotional reaction to unpleasant images.

And in a second task children were asked to look at faces and compare faces to shapes. And we picked this task based on the assumption that amygdala response is involved in the experience of anxiety in general.

Now, an example from one of the participants who had social fears and he thought that being rejected or offended in front of children is a very likely thing to happen and that in every social situation he will feel somehow embarrassed. And what did it mean to this boy on a daily basis? He was miserable in school, didn't want to go to school but went to school, was a straight-A student, did really well, but suffered every day when he went to school.

And we came up with an exposure hierarchy: arrive to school five minutes before the first class, say hi to one kid in the morning, sit next to seventh grade children in the morning meeting, participate in a group project at school, spend at least 10 minutes in the lunch room. So every week, he would work on one of those behaviors.

Now, at the end of the study across 10 children were observed meaningful reduction in anxiety, 55 percent reduction on the Pediatric Anxiety Rating Scale, and were also pleased to see reduction of amygdala activation to fearful faces and increase in prefrontal activity to unpleasant images when children were asked to pretend that the images were fake.

So we figured that some of the brain regions that are involved in the experience of anxiety were also affected by the treatment or least it was different from before to after treatment. That was an open pilot study and that was supported by a grant from NICHD. We'll conduct a randomized control trial to see whether or not similar changes in anxiety and brain activity can be observed in a randomized study.

Now, to switch gears I will talk about disruptive behaviors. And about 25 percent of children have both anxiety and irritability, but it just so happened that I am interested in those two areas of work. And we have been conducting those studies independently with a long-term plan to aggregate the data and compare children with anxiety, with irritability, and other forms of emotional dysregulation.

When we talk about irritability, when we're doing research, we really mean anger outbursts, temper tantrums, aggression, and self-injury. They call this irritability because the irritability subscale of the aberrant behavior checklist happen to emerge at a gold standard in measuring clinical outcomes in trials.

Now, a lot of those behaviors happen when parents tell their children what to do, right? Stop watching TV, go do your homework, brush your teeth. So a lot of irritability occurs in the context of children's noncompliance with parental requests so that we usually track irritability and noncompliance as two main outcome measures.

Now, when I look at disruptive behaviors, they appear in their own right, tremendous burden on families, pose risk of injury and property damage and interfere with education. Probably 25 to maybe 30 percent of children in our studies for irritability have major problems with school, being expelled or they cannot find a school that will take them in. And it's just a constant struggle for children and their families to have access to appropriate educational services if they have both autism and disruptive behaviors.

Now, how are children with autism and

irritability different from children without autism and irritability? So there's a number of areas that we're particularly sensitive to. Being frustrated by minor changes in routines, failure to recognize social context, unusual triggers of frustration and difficulties with communication, deficits in social domains, they can contribute to expression of irritability.

So I put a picture of stuffed animals, which are really cute. The first patient that I worked with would bring a huge duffel bag with stuffed animals and Beanie Babies, and she wouldn't leave her house without those toys. And why was that a problem? It will take her hours to get the toys that she considered were the right toys to take for a particular occasion.

As a result of the treatment, we were able to discuss with her -- I negotiated with her that she will settle on taking three toys. And then it took us a long time to get to this point, but the family felt it made a tremendous difference in their lives. And the girl was able to leave the house quickly and go to places without hauling a huge bag of items with her.

I sometimes have a different picture here of a thumb with a big bite like with a big injury from tooth marks. And I took down this picture because it's from a real patient. And probably halfway into the treatment they showed this to me said, well, that's also like a little bit of self-injury that has been going on. It turns out that the boy will bite on his thumb in the middle of the dinnertime. And the dinnertime was time for everybody to get around the table just like this one and have a nice dinner, pleasant conversation. It was hard for this boy to participate in social interaction during this time so that he was biting on his thumb, right, so -- and this a connection that took a long time to make, right? So for the family and for me in treatment and when we got to the bottom of that so -- we were able to provide him with alternative behaviors and also some feedback to the family about how to make it easier for this kid to participate in dinnertime conversation.

Now, what are the treatments that exist already? There is applied behavioral analysis, there's psychopharmacology, and parent management training. So there are treatment options. And they're terrific.

Now, how about teenagers with autism? So disruptive behavior is likely to persist in adolescence, on many occasion has side effects. So few families want to keep their children on antipsychotic medication for years, and parent training and applied behavioral analysis don't make use of cognitive and communication skills of adolescents with high-functioning autism.

So for a period of time where we're trying to adapt a type of treatment that is used for disruptive behavior in children without autism for adolescents with high-functioning autism. So we started with an approach that we have been developing for a while at the Child Studies Center and published. And many describes step-by-step instruction on conducting cognitive behavioral therapy for anger and aggression in children regardless of their diagnosis.

The treatment consists of 12 weekly sessions, has parenting components, school consultation. And the goals are very narrow: to reduce the number and intensity of anger outbursts and aggression, right? So it doesn't presume to change other areas, just the number and intensity of anger and aggression by increasing children's skills for managing their own frustration, right? So this is self-management intervention in a sense and by improving social problem skills.

Just to give you some examples, there's a lot of handouts. There's a lot of activities and material that can make it easier for kids to get through the training, so children are educated that every time they get angry, things happen, and it starts with a trigger. Then you might feel certain emotions such as anger. Then you might do something. And your actions can lead to certain problems for you and for others. So if you can think differently and if you can recognize social context of the situation, you might avert those negative consequences for yourself and for others.

And we would add the child to make a list of things that make them angry. And I remember one of the kids took a second and he wrote down school, homework, parents, sister, right? And that's a great list, right? So I think that's terrific. And then we just started to discuss what specifically is making you angry about each of those things. We have a lot of interest in sibling aggression. So I probed. So how about your sister? What makes you angry about your sister? The boy said her essence, her essence, right?

(Laughter.)

DR. SUKHODOLSKY: Good word. And then, right, we're behaviorists so we're trying to look for the behavior. So after a lengthy discussion, it turns out that she sits in his seat during his favorite TV show, right? So it's a simple conclusion but it took a while to get to it. And the parents, very thoughtful, very educated family, they couldn’t get to the bottom of this issue, right? So it took a discussion and then we got a family to agree to have the kids watch their shows on different TVs and so on and so forth so that we actually didn't try to convince the boy that it's okay for him to tolerate the fact that his sister is sitting in his chair. We actually found a way for the family to come up with a different seating arrangement.

Now -- but there are also strategies that children are learning, and this is another one of my favorite examples. One child in the program reported that a kid in his music class was throwing paperclips at him when the teacher was not looking. And he made a list of thoughts that went through his mind. I'm going to punch him in the face, human nature is driving me crazy, it's not worth getting all worked up about, he's an idiot, I don't need to stoop to his level. Right? That's a great list. But what's great about this example that the child actually reflected on the thoughts that went through his mind as he was experiencing interpersonal frustration.

Now, we also spent a lot of time with parents, and I hope I'm not going to get in trouble. This is a cartoon from *The New Yorker*. I loved it so much that I included it into this presentation. It says, "Listen up and listen good because I'm only going to say it a million times."

(Laughter.)

DR. SUKHODOLSKY: So that as part of parent training, we help parents give more effective commands, understand antecedents and consequences of behavior, and praise children for engaging in appropriate behaviors.

So it's hard to find rewards for kids on the spectrum. Oftentimes, parents say that, well, they only like one thing. One of the kids in our study really, really liked dinosaurs. And it turns out that he also liked playing with his sibling but the sibling wouldn't play with him because the kid on the spectrum had a lot of difficulty selecting activities and staying -- you know, following the rules and so on. So we spent a lot of time helping those two kids play with each other as part of them being -- as part of the kid on the spectrum being in the program.

Now, the pilot that we did included nine adolescents, and they were also selected for high level of irritability measured by the aberrant behavior checklist. Seven out of nine were on medication, and they received 12 to 15 sessions of

CBT. And that was a pilot study that we conducted. We observed about 65 percent reduction of irritability and also an increase in a prefrontal region of the brain that is involved in emotional regulation.

So we're so excited about these pilot findings that we submitted a grant that we were fortunate to receive funding for under the RDoC Initiative where we are inviting children across diagnostic categories, if they have significant levels of aggression. We randomly assign them to CBT or supportive psychotherapy and we collect fMRI and EEG before and after treatment so that we can confirm that the change in the brain circuitry is indeed associated with reduction in behavioral problems and that the change is caused by treatment, right, as opposed to passage of time.

So what did we see so far? We saw that 50 children with aggressive behavior relative to 25 matched community controls did not engage prefrontal regions of the brain which we believe are involved in anger control and frustration regulation. Ventromedial prefrontal cortex was -- activity in ventromedial prefrontal cortex during frustration was negatively correlated with parent-rated aggression.

And here is a result of one child, a 15-year-old girl with autism and frequent anger outbursts. She happened to be randomized to supportive psychotherapy condition, and we collected her fMRI before and after supportive psychotherapy, and then she received cognitive behavioral therapy for aggression and we collected her fMRI one more time so that disruptive behaviors stayed at the same level after supportive therapy. Then, there was a reduction. And we also saw no change in the brain activity after supportive therapy, and we saw increased inactivity in the ventromedial prefrontal cortex.

So this is of course just a case report. I hope that one day we'll have statistical instruments to analyze single-subject design with fMRI, but we're excited about that and we're almost done with the study.

So thank you.

(Applause.)

DR. CUTHBERT: So thank you very much. Just a mention that that kind of trial reflects the new NIMH approach to experimental medicine, and if we try to have investigators demonstrate mediating mechanisms and not simply doing an intervention and looking at outcome but making sure they can actually identify the mediating mechanism both for those who succeed and those who fail and make that case, so the cause and effect. So thank you.

One or two clarifying questions, we have time for a general discussion afterwards, but are there just one or two quick questions about this study before we -- yes.

MS. SINGER: Are there any modifications for

CBT or alternatives to CBT for kids who have intellectual disability and anxiety?

DR. SUKHODOLSKY: We use that in kids --

DR. CUTHBERT: Use the microphone.

DR. SUKHODOLSKY: I'm sorry. We use those in kids with IQ from 60 to 160, and I think kids with cognitive difficulties, they can relate to this approach. And in fact, we are starting a new project that we call principles-based CBT so that we're looking at the core elements that we can deliver in a various step-by-step gradual fashion so that as long as kids can sit down with a therapist like myself for 15 minutes, I think we can deliver the core elements of this approach.

DR. CUTHBERT: Okay. Thank you very much.

So now we'll move in -- move on to Dr. James Bodfish from Vanderbilt University School of Medicine, and he will be talking about repetitive inflexible behaviors: measurement, mechanism, and intervention.

Dr. Bodfish?

DR. BODFISH: Right. Yes, just -- I'm a Mac guy. Excuse me. There we go. Thank you.

Okay. Thank you very much. It's an honor to be here, fascinating to watch the process and to -- just to think of the scope of the work that the committee is doing and the passion that I also heard from the parents.

What I want to do today is talk about the role of a core feature of autism -- repetitive and flexible behaviors -- and how that potentially could be driving challenging behaviors in some segment of this population. And as we study that, I also would like to try to address a little bit of our work that we're doing today to think about does this give us new insights into novel mechanisms about autism? And then can we use this to help us think about developing novel treatments in autism as well.

So a little bit of background that Denis covered very well, very interested in the fact that the committee is focusing on challenging behaviors. As everyone here knows, challenging behaviors in autism take many forms and can be very common, can persist throughout the lifespan and can be very stressful for personal -- for persons with autism and their family members, so certainly a very significant aspect of the spectrum that's largely understudied in our research. These are individuals who it's difficult to get into our research protocols. So we don't have enough information and it's exciting to see a focus on that.

Just very quickly, we might think of two general models that we could use to think about to understand challenging behaviors in autism. One that Denis covered is sort of an autism-plus. It's the idea that there's a comorbid condition like a psychiatric impairment that it -- that it's not the autism. It's that autism is -- increases the risk for a comorbid condition that then could be driving the challenging behaviors so that the challenging behaviors might be coming from something like ADHD or OCD or anxiety, okay?

And there's a lot of evidence to support these kind of comorbidities in autism. There are some problems, and that is that the instruments that we use to establish the comorbidity are not developed for people with autism by and large. And so often you have symptoms of autism that are counting for both the primary disorder and the comorbid condition. So you can think of something like hand-flapping that we've seen instances where this can be counted in the clinic or in the studies as sort of an overactivity, as a compulsive behavior, or as a symptom of anxiety. And it's hard to sort that out at the level of psychometrics. We need more objective sort of biological measures to sort of move forward with that.

Another potential limitation is a lot of this has led to pharmacologic interventions where we have had some successes, but by and large, importing those pharmacologic treatments into autism has not been effective, especially in terms of the core features of autism and really at this point we're not thinking would be an effective way to think about moving that down to early intervention. What could we be doing to present -- to prevent the development of these kind of challenging behaviors as the child ages, okay?

So an alternative model that we've used to guide our work is thinking -- and this was actually Leo Kanner's original idea about the challenging behaviors in autism. And this is a simpler model and it's the idea that potentially the core features of autism that you've already identified as the primary disorder, that these could be more directly driving the manifestations of challenging behavior. So just some potential examples here, could the social deficits lead to social isolation that itself is leading to a form of anxiety or depression that's relatively specific to autism, okay? Could the communication limitations be leading to frustration that might be leading to aggression, okay?

And then in terms of repetitive behaviors, could something like lack of predictability in a massively unpredictable world be leading to stress and self-injurious behavior, et cetera, okay?

So this is a little simpler model. It has some face validity. Any of the parents or people that have worked directly with autism can think about these specific scenarios directly. But it also has some possibility, we believe, in terms of thinking of novel forms of intervention for these challenging behaviors in autism, okay?

So just a little bit of data, we've tested this directly. This is sort of a 30,000 foot view of testing this, just looking at sort of statistical associations. And in fact, we find an increased association of these repetitive behaviors to the challenging behaviors that is significant and far less so in terms of the social communication impairments potentially driving these kinds of problem behaviors. And this is in a fairly large sample going from kids to at least young adults.

One of the things that we've been able to do in focusing on the repetitive inflexible behaviors is also look at individuals with autism and very significant cognitive impairments, too. So this is a diverse sample that we're looking at here.

So based on that kind of support then this is the approach that we've taken. This is in one grant that's currently funded by -- and that's funded by NIMH to study repetitive behaviors in autism to get -- together with Gabriel Dichter. And we're focusing in on what aspects of repetitive behavior might be driving these challenging behaviors in autism. We're interested in looking, as I said, across the spectrum of autism, both individuals with autism with and without significant cognitive impairments.

And then a little bit of a change from a lot of the research is we're also include not just a comparison to typically developing peers but finding age-match individuals who have other psychiatric disorders to see what's unique about these impairments in autism and what's shared between autism and other disorders like anxiety or depression and OCD, okay?

Another thing that I just wanted to point out is we've been successful in attracting new investigators to this field to study this area, and so we've been very thankful to get support from NIMH for K awards for this -- is Dr. Kate Gotham, who's looking at adults and focusing on the question of depression, also the Wellstone pre-doctoral fellowship from Autism Speaks to extend our work as well, okay?

So these are our research questions, and let me just kind of go through those and just kind of looking at this schematically. We're interested -- can we measure this targeted phenotype within autism that might be driving challenging behaviors? If so, can we use that sort of focused phenotype to think about mechanism differently? Can we develop a preclinical model of this? So instead of modeling autism in general in a mouse, can we model this specific feature of that? And could this support further studies in terms of the neurobiology or things like drug screening?

And then in addition, one arm of our work has been focused on thinking about this in terms of an intervention that families could do very early on in their homes. So I'll just touch base on some of that research.

One of our early findings here and one of the interesting things about autism is that it is so diverse, all of the symptoms of autism, and it's no different even within this targeted domain of repetitive behaviors. There's many, many types of repetitive behaviors, okay? So this is the ADI, a standard instrument that measures those repetitive behaviors, and when we look at this statistically, we see evidence for three distinct subtypes of repetitive behaviors on autism. And then when we compare those to our psychiatric control groups, we can ask questions like which of these repetitive behaviors is relatively unique in autism, is contributing more of the variability towards things like challenging behaviors than other kinds of repetitive behaviors, okay?

And sort of surprising to us is that we found evidence that one specific type of repetitive behavior, these preoccupations or attachments or circumscribed interest is relatively unique to the autism spectrum disorder cases. We don't see much of it in OCD, as an example. It's not associated with IQ or the co-occurring social impairment.

It's also familial. Part of our sample included a subsample of siblings with autism and so we can look at the correlation of each of these types of repetitive behaviors within families. And it was relatively common. So there hadn't been much research on this, and we were very interested in sort of understanding these interests and preoccupations and attachments further.

So one thing that we did is develop a way to measure these and to measure not only the type, the examples. This shows in a sample of 57 adolescents with autism spectrum disorder the types of interest that they have, the content of those interests. And so you see things like -- that we would expect like trains or Legos, okay, but also very unusual ones like interest in birds of prey, Confederate wars, the number 22, all things that, if you spent some time around autism, it's not just a hobby, it's something much different, okay?

Another thing I'll point out is that you'll also see examples of this in individuals with cognitive impairment, too, so one sort of historic idea is that this domain of autism is really about savant autism, is really about "higher functioning" individuals. But we also see examples of this or things like staring at things that are in motion, fascinating -- fascination with running water or washing machines, et cetera, okay?

And these -- of course, everyone has hobbies and everyone has things that they're interested in, so what differentiates an interest in someone without autism from an interest in somebody with autism. So we tried to get at that as well. Is there any functional impairment associated with the symptom domain? And two of the things that we found is that, unlike individuals without autism, individuals that -- with autism that have these interests are much more interested in doing them alone, also not surprising. But right away then you get worried about how these interests could be limiting their social experience and their opportunities for further social development, okay?

And then also the link to challenging behaviors, parents told us, you know, time and time again and we could see this clinically that interrupting these interests is very likely to lead to the whole list of challenging behaviors that I mentioned in a subset of cases, okay? So parents are -- become experts at this and there are workarounds, ways that you can make sure that that doesn't happen. But the point is that that is part of the morbidity in autism is that we often -- in the subset of cases you have to go to heroic efforts to manage these sorts of unusual and intense interests, okay?

So just very quickly, I can show you a couple examples. This is in a toddler and I don't have sound on all of these, but we've asked Mom just to try and interrupt -- he's interested -- his focused interest is these foam pieces that he likes to hold onto and line up, and we've asked Mom about every 15 or 30 seconds just to try another toy. These are also toys that we identified that he likes. But what you'll see here is how he responds to her efforts to interrupt that, okay?

(Video shown.)

DR. BODFISH: Okay. He said no thank you, okay? And of course the kids with autism are experts at this sort of end-around I'll put that here and while you go for that, I'll go get more of these things that I can get here, too, okay? But this points that -- to -- that's -- this points out some of the social isolation aspects of this and how we could become concerned that these -- there's such an intense focus and interest on these activities that they could be interfering with other opportunities for social learning, okay?

This is an example in an older child, the school-age child. I'll just show a little bit of this.

(Video shown.)

DR. BODFISH: This young man is very interested in puzzles, and a couple of days before this had thrown a chair through a plate-glass window to get to a puzzle that he hadn't had a chance to complete a couple days before. And as horrific as that is, these are common scenarios for this subset of individuals with autism.

So what we're doing here is the teacher's assistant is going to interrupt his puzzle -- this is part of the baseline of one of our behavioral treatment studies -- and have him do an academic task that he can do as long as he's doing it outside of puzzles.

All right. So this is tough to watch, but you can see this -- how the -- interrupting this ritual, interrupting this interest, there are occasions of kind of challenging behaviors that we would be interested in. Okay. Okay. Yeah, it's -- yeah, it's less about the -- sorry. It's less about the audio.

So really the main points here are she's asking him to do a math task that he can do independently, and he has a lot of errors doing this task, okay, because he just wants to get back to the puzzle, okay? And so this goes on and on and eventually in some of these probes -- and you'll see this going from distress to self-injury to aggression, et cetera, okay?

Now, again, we can all think of workarounds. Just let him have the puzzle or make the puzzles available, but the point here is that that has to happen, that that adds to the difficulty here within autism, okay?

And so there's the last interruption there. Stop it there.

And I just wanted to include this. We also see this in adults. This is a young man who lives in a group home and is very interested in arranging the things within his home. And also -- there's no sound on this -- this attachment to the small basketball and some very interesting rules like the legs of the chair have to be outside the legs of the table, and all this seems innocuous, but he's living with his peers and he arranges these things, and then someone comes behind him and undoes that. And that leads to -- that can occasion significant aggression and self-injury in other people, okay?

So you see the other folks that he lives with and just very quickly, some of the other parts of this, certain light switches have to be on, certain light switches have to be off, certain pictures have to be up, certain pictures have to be down, and just the life becomes consumed with that, okay, so just to give an example of that.

Sally Ozonoff and Mikle South and others have published on this. From a parent's perspective -- and it's important to point out -- that this is really beyond hobbies and beyond interests, that parents report that these kinds of preoccupations are among the most difficult things to deal with on a day-to-day basis, okay? There's other greater needs like language and social connection and friends and work. Those are huge needs, but as far as a day-to-day basis, this can lead to a lot of difficulties in terms of managing family routines, et cetera, in the subset of individuals that has that.

So moving to other kinds of studies, this is work that was directed by Gabriel Dichter. We're able to use fMRI to ask questions about mechanism. And so the intense interest that individuals with autism show in these activities made us wonder about rewards. Is it possible that this is like an addiction-like phenomenon that these nonsocial objects, these nonsocial events activate reward circuitry differentially in individuals with autism than in their typically developing peers?

So this was actually a study of adults, not selected for individuals who had very, very high rates of this. This is just individuals on the autism spectrum because this nonsocial bias, we think, can be quite common within autism.

And just to make a long story short, what we've seen is about a 200 percent increase in activation of a critical node within the reward circuit to these nonsocial images that you don't see in typically developing peers and that you don't see in individuals with autism when they're looking at social images or when they're trying to earn money, okay? So there's the possibility here that this behavior could be related to this increased reward response that we're seeing, okay?

So this just sort of states that. We might think this is a -- kind of a new way to think about repetitive and flexible behaviors in autism and how they could relate to challenging behaviors. We might think about these like addictions. Remember that addictions, outside of autism, are not just to substances but they can also be to activities, okay? Addicted in surfing the internet, addicting in shopping, okay, et cetera. It just goes on and on, okay?

So what we know now from affective neuroscience is that these are activities that can "co-opt" the adaptive, the usual reward circuitry in the brain, okay? And the successive or enhanced experience of reward can lead to ever-growing anticipation -- I want, want, want -- that can't be satisfied by actually engaging in the interest, okay?

And so that's the working model that we're after, and applying that to autism might be something like this: We know that these nonsocial interests occur very early, within the age span.

We know that there's the possibility that they could crowd out other experiences, including social experiences, as I mentioned.

We can borrow the concept from addiction and affective neuroscience of what we call motivational toxicity. This is the idea that when one reward is excessive, other things lose their efficacy as a reward, including potentially social rewards in autism, okay?

And then the possibility, as we've seen here, that mood and behavior, these challenging problems -- challenging behaviors can evolve as reactions to interrupting these intense wants, these intense sort of desires, okay?

Imaging is not really a viable biomarker for this because we're not able to do this very young in infants and we're not able to take this -- individuals with significant cognitive impairments. So just very quickly, we were interested in finding another potential biomarker, another way to objectively measure this. And we came up with an exploration task. This is just individuals are looking at a monitor that has an eye tracker embedded within it and seamlessly is measuring where they're looking on the monitor and the eye tracker contains -- the images -- the arrays contain both social and nonsocial images, okay? And so they're just shown for 10 seconds. There's no instructions so you don't have to worry about sort of the cognitive, the intellectual level of the participants as long as they can watch a video, as long as they can watch a picture, then we're able to assess them, okay?

We're very excited because we actually have been able to test adults with very significant language delays and cognitive delays on this task, okay? So I'll just show you a couple examples of that. This is -- this task from an individual without autism, and what you're seeing is the 10 -- over the 10 seconds what the individual is looking at, okay? The line is showing you the trajectory of what they're looking at, and the size of the dot is showing you how long they perseverate on that, how long that they're looking at that. So that individual does what many folks would do. You explore the environment. You look at many different things both social and nonsocial.

Here's an example trial of an individual with autism on the same array, okay? And it's -- what you can see is the sort of driven attention towards these nonsocial images. And also you have to ask what's missing? They're missing the opportunities to experience those social images as well, okay? So we can readily come up with objective metrics for this in terms of time spent looking at social or nonsocial in terms of a bias, and this allows us to sort of quantify this phenomenon at a greater detail.

So there's the example I showed you, and what we've seen is individuals with autism explore less because they're perseverating on these nonsocial images more, okay? And what's interesting to us -- we've only looked cross-sectionally at this point. We've actually gone down to about 12 months of age. We're able to do this in infants that young. And you see less of a separation of the groups. This interest in nonsocial things is, of course, present in typically developing infants, too, but it seems to really grow over age in autism. So this suggests an opportunity for early intervention here.

Just the last two things I'll mention, the other reason we do this task is that exploration or foraging is conserved across species, and so we can use this to create a behavioral assay of social and nonsocial exploration in mice. We're able to do this with infrared technology so we can do this in a high throughput fashion.

Experiments that we can do on the clinical side that take years we can do in weeks with animal models because we can quantify this phenotype. This allows us to screen a large number of mouse models that have been associated with autism features, look for the strain that shows this reverse pattern of nonsocial, greater-than-social exploration through genotype analysis, focus in on the region of the genome in the mouse that might be harboring this unusual phenotype. We've also crossed that with the mouse homologues of the hundreds of autism risk genes to find which of those autism risk genes are in this region, okay? And then this is also the kind of phenotype that we can use to look at screening new compounds, okay?

So at this point we're just at proof of principle. We're able to do this and now we're beginning to think of these genetic findings in terms of screening new compounds, okay?

The last thing is, because that work is a long way away and because what we found in terms of early intervention -- this is work directed by Brian Boyd in collaboration with our group -- we're working on developing an intervention that families can implement, can learn to implement in the clinic that maps onto existing reimbursement models for how long they have coverage to come into the clinic where the parents can learn to start with the child's interest and gradually expand it, broaden that interest, bring in more social aspects to that, okay? So we've been through sort of the case studies, the feasibility studies, and in initial trials showing efficacy, that parents can do this and find this acceptable. Again, this isn't toddlers so we have the opportunity to sort of move forward from there.

Okay. I'll stop there. Thank you very much.

(Applause.)

DR. CUTHBERT: Okay. Just one quick question and then we need to move on. John?

MR. ROBISON: Just -- I'd just like to say that

I appreciated some of the ideas in your presentation, but much of it was spoiled for me by the fact that I don't think you gave much thought to how autistic people would feel listening to this stuff. And I think that if I take a particular example, your illustration of the two eye tracking patterns --

DR. BODFISH: Right.

MR. ROBISON: -- and you described the autistic people who looked at the computer monitors exclusively in terms of being broken and not doing the normal thing. And I would wager that my ability to engage those machines is superior perhaps to yours and certainly to most people in the general population. And that's taken me very far in life.

And to characterize that kind of behavior as exclusively broken, we inevitably pass that characterization on to the parents, to the children who participate in these studies, and that kind of thing is really, really unhealthy. And I wish that you would keep that in mind because what we hear here, it's -- parents hear it, kids hear it, adults hear it, and it's not good because the fact is there are some of us who have mixtures of disability and gift. And even in autistic people who are primarily disabled in that area, we would do better to train them to do the thing they naturally do anyway than we would to suppress it.

DR. BODFISH: No, that's a great point. I apologize profusely. That was not my intent. Our intent with those videos with the eye tracking task is just to measure what individuals are doing, where they're at, what they're interested in so that we can quantify that. A lot of the work that this would be based on we don't have good measures of it.

And then secondly, I would add that I think your point is very well taken, and that's the point of our family-based intervention is we start with what an individual is interested in, right, and see that as a strength and a gift and use that as a way potentially to build on things.

So I apologize profusely if it came across that way. That certainly was not my intent.

MR. ROBISON: Disability is real, but we have gifts, too.

DR. BODFISH: Yes, I agree. Thank you.

DR. AMARAL: Could I --

DR. CUTHBERT: Just a quick point, David. We need to be moving on but --

DR. AMARAL: Yeah, I just wanted to make a quick point to John. So your point is very well taken. I think it's something that, you know, is not only in Jim's talk but is endemic in science of looking at disorders or diseases. And I've been struggling with this myself. And where we used to phrase change in the brain as abnormal, we may say altered or different, and I think it's just going to take some time for the language to sort of adapt to your point of view and I think -- which is the right point of view.

But it's not intended as malicious in any way. It's just, you know, the way we were educated, I think, which was wrong but it's changing.

MR. ROBISON: I don't think he meant to be malicious either, and I -- sometimes I feel bad, you know, jumping on people like that, but I think I got to speak up, you know, because for every one of me that speaks up there's 1,000 autistic people who don't and it hurts them.

DR. BODFISH: Well taken. Well taken.

MS. CRANE: I would say that I'm on board with John's comment on that, too, that, you know, there are a lot of ways -- and I -- and there's also a sense in which kids can develop higher distress tolerance to being told that they can't do the thing they're interested in now. If there is that acknowledgement and respect of like, you know, I know that this is important to you. You're going to have a chance to do this later. We're not taking it away from you. We're not trying to take away the thing that you love the most. And that's a really important nuance that, you know, when we talk about things as an addiction model, what I hear is if it's an addiction model, then, you know, you're going to be asking this person to quit something cold turkey and never engage in their interest again. That might not actually be how people always respond to addiction but that's a way that a lot of people will think when they think addiction, that if you're an alcoholic, you can't drink ever. And that's not an appropriate way to deal with a person who's got an intense interest.

DR. CUTHBERT: Yeah, just one comment about this even though we need to move on. As Dr. Bodfish said, a lot of this is trying to develop better ways to measure the phenomenon which we are interested. We talk about autism as a spectrum a lot, but we don't really address that in our research. You know, the standard research design continues to be a group of children with -- or children or adults with autism versus controls as though it's a disease, you know, a disease model. You have Zika virus versus not or something like that. That's the implicit model there. And we're trying to get away from that to say it is a dimension.

Some people will, as you're suggesting, John, be differentially abled but that's, you know, not necessarily a bad thing, but some people are very disabled. And how do we understand that dimension that goes from different capabilities into being something that anyone would say this is a clear disability. We lack measures that contract that dimensionality and relate it to genetics, to brain function, to behaviors, to interactions.

And so a lot of what Dr. Bodfish and others are doing is to say what kinds of measures can we have? And right now, we sort of validate the measure by saying, okay, just to get started we looked at a group of children with autism in this case versus controls. But eventually, what you want to do is to say that's a quantified measure and we can use that to help look at a dimensionality that helps us understand individuals better and figure out differential abilities versus disability and understand what goes into those more fine-grain distinctions, just as we try to understand gradations of blood pressure or something like that.

So that's where this is going and it's in an early stage. But that's -- you know, I think where it's -- it has a very positive intent in that sense, and it's unfortunate, as Dr. Amaral says, that we still have this vestige of some implication that there's something wrong there, and that's really not the intent at all.

MR. ROBISON: Well, I believe the intent is positive, Bruce, and I know that it's a really hard problem and I know that it's fundamentally different from most problems in medicine where we just seek a straight-out cure. And I'm -- every day I'm aware of the autistic people who say there's nothing good about my condition and how lucky I am that I can speak out about it. I know very much there's a spectrum and we've got to just do our best with this.

DR. CUTHBERT: Thank you.

Okay. So moving on, we're pleased to have now Frank Symons from the University of Minnesota, twin cities, who'll be talking about severe self-injury and developmental disorders, sensory and immune findings from the periphery.

Dr. Symons?

DR. SYMONS: Thank you. It's a pleasure and an honor to be here. Just a couple of observations and comments. I was a little bit ignorant on the

IACC and didn't do my homework so I wasn't sure what to expect in terms of what kind of group I was going to be in front of so I've tried to put a few things together. Then over the course of today thinking about issues like stimulus over-selectivity and anxiety, this little light system here has me really worried, particularly after the three-minute conversations and the blinking red.

And then following Denis and Jim, I've been watching the green, the yellow, the blinking red. And then I'm noticing -- I know -- I think you guys got a five o'clock hard deadline. We could make this easy. I could just take questions now and we could -- I could give you the haiku on self-injury and call it a day.

So I will try to be mindful of time and move this along. I have -- I organized this in three batches, just some slides that relate to context to give you a sense of how I think a little bit about self-injury, slides that relate to an approach we're taking, and then some data slides.

A couple things on disclosures, none in the traditional sense, but I want to kind of underscore I don't consider myself an ASD expert and so you could think that's a bad way to end a talk at an Autism Interagency Coordinating Committee and maybe I should have been coached, but my focus has been fairly exclusive on self-injury, regardless of diagnostic category, primarily among individuals, child or adult, with severe developmental disorders. Almost all of our study samples are nonverbal and there's going to be a fraction in any one of our studies that meet diagnostic criteria for autism, but it doesn't follow that I think of our work necessarily with respect to specific issues in autism. So I just wanted to clarify that.

This is an email I received I think -- today's Tuesday -- on Friday, but it -- we've heard this already over the course of the day, particularly during the open comment period. "Good evening" -- this is an email I received out of the blue from a parent. "My name is -- I am typing on a phone so excuse obvious typing issues. I'm a mom to a nine-year-old with autism. His repetitive behaviors in toddler years grew into highly intense head-punching a few years ago." Et cetera, et cetera. I'm not going to read this entirely. I get these routinely, and probably a number of you in this room do. And so the need is obvious.

There are families with children across the lifespan living with intractable self-injury. And we've been at this for -- scientifically for a good three decades, and we've got some workarounds, as Jim might say, but I still think we've got some fundamental knowledge gaps to fill with respect to underlying path of physiology to think about what this phenomenon is.

So from a parent perspective, it's pretty straightforward. Why and help, please.

Scientifically and clinically, it -- there's a puzzle here with a lot of different pieces, and there's a paradox of why would someone engage in actions that should normally be regulated by their outcome but become out of control in chronic or intractable self-injury.

So just a quick overview and I've boiled some of this in reading and rereading some of Jim's work and trying to put it into an ASD context. The prevalence estimates vary. You can't get much wider. And it may be useful to think within the ASD spectrum of subgroups that relate to high and low functioning. I made a point already of saying I don't think we understand well the path of physiology.

In terms of interventions, both Denis and Jim alluded to a variety of approaches. There are certainly applied behavioral interventions. Issues there are things that have plagued applied behavioral interventions for decades that relate to generalization and maintenance. And in particular, when you get into very severe self-injury cases, the ability to maintain any treatment gains from an applied behavioral analysis perspective at times can be quite limiting.

Biomedical -- and by that I mean really pharmacological -- there's no real consistent evidence in terms of the efficacy. I don't think there's really a "self-injury drug." And so there tends to be an evidence vacuum again with respect to severe self-injury, severe developmental disorders, and a lot of sad and bad things happen in terms of people spending time in -- their waking hours in restraint, they're heavily sedated, aversives are used, et cetera.

It's no surprise to this group the cost and burden of care is significant. NIH sometime ago had convened a consensus committee meeting around destructive behavior, and the estimate then was upwards of $3 billion. As far as I can tell, there's no change in the incidence of cases. So from a public health perspective, I don't think the burden has changed. It's probably gotten worse for the families likely far exceeds the impact of the diagnosis alone. Again, living with severe challenging behavior in general, self-injury in particular is a part of the repertoire. And for the individual, for the reasons I listed earlier, this has a significant impact on quality of life.

So Jim has alluded to this and so did Denis on some general conceptual models. There are developmental and behavioral models in particular. I'm an applied behavioral special ed guy by training, and so when I see a behavior problem in general or self-injury in particular, if I can count it, I want to relate it to antecedents and consequences and look for patterns. It could be that for some individuals over a period of developmental time self-injury acquires communicative properties, it's learned in other words, and then it gives me an opportunity to plan and target an intervention.

There's certainly psychological and psychiatric-related models -- Denis and Jim went over that -- but there's another perspective that hasn't really been brought to bear in my opinion to think about self-injury. And I put it broadly under neurological and particularly thinking about the sensory components, there's sensory features, and pain in particular is no exception.

And in the face or presence of severe self-injury, there's an -- if not explicit, there's often an implicit assumption that the individual is insensitive to pain, else why would they self-injure? So there's a lore, a clinical lore built around that notion of these folks don't feel pain, and that is -- I don't know what that is. That's evidence that they have increased pain thresholds, tolerance, et cetera. And so our work is designed in part to kind of -- to be informed by this neurological model broadly and then focusing on science of sensory mechanisms and pain in particular.

So if you do that, just quickly, this is just a summary slide from a lot of -- none of our work -- a lot of work out there. When you get into -- and usually at this point I remind people -- I'll do it again later on. I'm a special ed guy so much of what I have to say about biology, take with a grain of salt because when I talk about molecules, I truly have a metaphorical understanding.

But when you look at clinical areas of research in chronic pain in general and neuropathic pain in particular, it's striking to me in the preparations they might use. So they might have a preclinical model where they're going in and crushing the particular nerve, and the behavioral evidence that they used to infer that the organism, the animal's pain would be self-injury.

Now, that's not the term they use. They use different terms. But once you start cracking the language across disciplines, you realize, well, phenomenologically, maybe we are, maybe we aren't talking about the same thing, but at the surface level, at that model -- in that model they're damaging their skin, I'd like to know about it.

So if you start looking at that body of work, both the preclinical and clinical neuropathic pain model, I think there's some information in there that might be relevant to transport or import into thinking about self-injury in severe developmental disorders.

And two constructs that are relevant for the work we're doing or one of the areas we're working in is hyperalgesia, and this is an idea of increased sensitivity to a painful stimulus; and allodynia, a non-noxious stimuli received as painful. And a way to think about that just colloquially is if you've ever had a sunburn. So that's part of your biology of your body and the skin in telling you that things aren't right, and so that warm shower feels really, really hot, and things that would normally be innocuous become noxious. That's the notion behind those two constructs. And underlying those, there are a host of neural and immune-relevant mechanisms, crosstalk going on supporting that in these preclinical and clinical models of neuropathic pain.

So that's what I've -- that's a lens that I'm trying to look through at this long-standing, very old problem, puzzle of self-injury and severe developmental disorders, and we're doing it in two ways. Behaviorally, we're trying to import how do folks in a clinical world assess neuropathic pain, and we're modifying quantitative sensory-testing protocols. And what I want -- just -- I'll just review today is our more biomarker approach of thinking about sensory sensitivity and altered immune activity using the skin as a sensory model and then trying to get -- trying to sample that.

So just quickly, you know, I'm more of an ambassador than anything else these days. There's a lot of moving parts behind us in terms of managing the biomarker part. We have three S's -- saliva, skin, and sensory mechanisms. I mentioned the sensory mechanisms. We're interested in saliva. It's noninvasive. There's a lot of molecules in saliva that show up in blood and CSF2 and so we've got a program of research where we are trying to look across three compartments.

But I want to focus on the skin today. And I -- we've got a turn of a phrase in our group that skin is where behavior meets biology at least with respect to some forms of chronic self-injury. So bear with me and forgive me, a quick tutorial on the nervous system and the skin from a non-dermatologist, non-neurologist special educator.

But, you know, the question -- and this is -- the flavor at Minnesota, particularly the child development, which is across the street from my building -- is how does experience get under the skin? And there are direct routes. We are in -- we're more than in. We are well into the era of -- not on the edge but in the era of direct access through neuromod, right? But there's other ways that experience can get to the brain, and it gets under the skin in my opinion through the skin.

So we tend to forget that to get to brain for touch, tactile, pain nociception, you have to go through the skin. There's just no other way around it. And just to remind you, the skin is our largest -- our body's largest sensory organ, and it's comprised by -- in part by an array of very different and very highly specialized nerve endings that are very important obviously for transmission of touch, tactile, and pain nociception.

So here's my rendering of what I want to just draw your attention to. This is the skin, and they are -- what's of interest is -- we forget this, but from skin and these free nerve endings that -- I'll give us better pictures in a moment -- I mean, you're -- this is -- it's primary sensory afferents going dorsal horn and then a secondary -- second-order afferent will go up to brain. You're one synapse away from skin to brain. It's just one synapse for touch, tactile, and nociception from skin to brain.

So -- well, what's carrying that information? What we're interested in are -- we're interested in all the fiber types, but in particular in this talk focus on A deltas and particularly C fibers. And C fibers are friends that live out in the skin in cartoons that most people think about -- whether they're thinking about it or not in terms of the names of the fiber types -- free nerve endings.

So in the epidermis live C fibers and referred to more generically as epidermal nerve fibers. For many, many years, just as parenthetically -- their existence in the epidermis wasn't fully appreciated certainly in the dermis, not necessarily in the epidermis, really difficult to stain. But once the staining got figured out -- here's a micrograph cross-section -- the dark blue band which becomes important to orient you to the images that are coming up, that's the epidermis. There's a dermis-epidermis junction, then the deeper dermis. Red will almost always be capillaries for us, and green, to draw your eyes to it, think 1970s shag carpet. Green are individual sensory afferents. Those are primary sensory afferents, epidermal nerve fibers in the epidermis, the majority of which will be polymodal. Also they respond to a variety of modalities, polymodal C fibers, okay?

So that's what I'm interested in. So here's the project, thinking about severe self-injury and severe developmental disorders is trying to put together that behavioral phenomena with underlying sensory mechanism and nociceptive fibers.

So remember, we're dealing with C fibers. These guys really slow acute injury model and so if we know that tissue injury leads to a cascade of events that start neural and quickly become a very microenvironment local neural immune, and that's injury, well, what about self-injury, right?

So I mentioned we're modifying quantitative sensory testing. Our tool for getting at the skin biology is an epidermal punch biopsy. We are accruing a number of cases. Our dependent measures are to count, quantify the epidermal nerve fibers, characterize their distribution. We look at a variety of peptide content count in the nerves and immune activity in the form of mast cell granulation status.

Mast cells, many of you know them, think about allergies and histamine, but there's a lot in a mast cell besides histamine. They're really in the periphery a sentinel cell for the immune system for surveillance.

I've showed this before. So here's when we first looked under the hood. This is an adult case in working with Jim many years ago in North Carolina. On the left is what a normal cross-section would look like. On the right is a self-injury case.

A couple points to make, we sample skin from individuals with long-standing chronic self-injury from non-self-injurious sites. The initial idea I had was when I learned about this group studying this at the -- we -- there's a peripheral nerve lab at the University of Minnesota, and they work -- their bread and butter is in advanced chronic diabetes and some of these sensory issues that go along with that, but they also do rare diseases and study chronic insensitivity to pain. And there's a variety of subtypes of that.

And what they were interested in is quantifying these nerves. And so we met and I introduced him to the fact that in many of their participants' section descriptions, the individuals have very severe intellectual impairments and often self-injury is described, but the group studying these individuals weren't interested in the self-injury; they're interested in the underlying genetic disorder.

So long story short is the agreement was if I could figure out a way ethically -- and I'm glossing this over. We spent a lot of time with families talking about collecting small samples of skin with no treatment benefit -- but if I could figure out a way to do that and pay for it, can we work together? And that was about 14 years ago.

So what do you see here? This is what you should see, and what you see here along the blue is a distinct absence of the peripheral enervation. So this is to first look at, hmm, maybe there's something going on out in the periphery. I know everybody wants to get the brain, but I'm interested in how that information gets there and the integrity of that pathway.

So -- excuse me. So, again, the idea was initially, well, could we get some skin that's at a self-injury site, and we backed away from that idea to let's go ahead on individuals with, without chronic self-injury matched on gender, age, developmental level, any drug status and sample to the degree that it was possible from normative sites that the lab we work with has built up over the years.

So that's the first look at it, and we quantify that across a few more cases looking at the distributional differences through a coefficient of variation and just seeing these really, really -- you know, I'll use some qualitative terms -- odd, very different spacing, irregular patterns.

Substance P content, substance P is a very important peptide for -- in the pain transmission pathway, elevated counts three, four, fivefold in some instances. And then mast cell degranulation in the periphery again where the shift is -- red is -- or individual SIB cases, this is a rating of degranulation from fully intact to fully degranulated. And individuals with chronic SIB from non-injurious sites where we see time and time again mast cell degranulation. And we're taking that as a proxy for degree of immune activity.

So now I've hit the yellow and I see there's a little clock going there. Okay.

(Laughter.)

DR. SYMONS: So let me do this. So what? So what? So we also are running our quantitative sensor -- modified quantitative sensory testing protocol on the same individuals, and I say modified. For those of you familiar with quantitative sensory-testing protocols, they're designed to establish tactile and nociceptive thresholds. We aren't doing that. It relies on self-report.

So what we're doing is a stimulus response. At least we can calibrate with the known intensity, the stimulus, and then we have a variety of ways to measure reactivity.

So when we do that, it's the individuals with severe SIB who -- remember I said the dominant model is don't feel pain. In fact, they tend to be more responsive, not less, as measured in this case by facial action unit change in response to a variety of calibrated sensory stimuli that we use light touch, deep pressure, warm, cool, and pinprick. And that tends to go along with the individuals for whom there are differences in the epidermal nerve fiber pattern, as well as the mast cell degranulation presence.

So I'm -- there -- that was my so what. So in the interest of time, I'm going to end there. I just want to make one point, and I'll show an image. That one slide is very striking that, hey, so there's no epidermal enervation, wrong message to take away from Frank's talk. There are cases where we see the exact opposite. We see tremendous -- and I'll just paraphrase my peripheral nerve lab colleagues like we have never seen anything this dense.

So there are cases where there is high density per millimeter of tissue enervation. So we see things on both -- I don't know if they're tails or not because I doubt whether nature is normally distributed the epidermal enervation of the skin, but just for the sake of it, we see SIB showing up in both cases where there's very few or great density of the epidermal nerve fibers.

So with that, I'll pause or stop and thank you very much for your attention.

(Applause.)

DR. CUTHBERT: That went over by a minute. Can I jump in with a question? You -- I really like being the RDoC person. The approach that you take to looking at self-injurious behavior independent of any particular diagnosis. That said, are you mostly looking at kids that one would generally consider somewhere in the neighborhood of the autism spectrum? The reason I ask is that, as you probably know and may well have studied, people with borderline personality disorder, which is also a horribly heterogeneous syndrome, also are renowned for this. And in fact, our psychiatric colleagues tell us that many adolescents with early serious mental illness, including what we would think of as the schizophrenia prodrome, also showed those self-injurious behaviors. And interestingly, the borderline advocates tell us that they see distributions of borderline like that, that some people have extraordinarily high pain sensitivity. They'll max out a laser or pain stimulus --

DR. SYMONS: Yep.

DR. CUTHBERT: -- in the back of their hand, and others are extremely sensitive to things. So I just wonder if you have any experience with, say, the adolescent groups as opposed to early childhood groups.

DR. SYMONS: Well, so those are good points and great questions, and you probably are familiar with this. There is a group that -- more than one group, but there is a group at the U studying borderline personality disorder and self-injury and so, you know, I've gotten to the point in my career where it would become dangerous not so much because I believe what I'm saying but I show up and I'm the guy with -- you know, if only tool we have is hammer, everything looks like a nail. So I get talking to them like, hey, you ever thought out the periphery? And we could do a punch biopsy and take a look at under the hood that way.

And you're right in that you can subtype self-mutilation or non-suicidal self-injury, NSSI, by whether or not pain's on board with -- and with those patient groups, you can establish threshold in a way -- a lot more precise than we can.

But to the first part of the question, the group -- what -- we live right now in preschool global developmental delay, birth through five, severe developmental delay. We have a pending competitive renewal. Hopefully it can move along. There, we're finally moving from starting adult with Jim and cross-sectional to pediatric cross-sectional to prospective in which we will be able to model whether -- what the diagnosis adds to understanding the early development of whether this underlying sensory stuff, biology can predict who's going to have a problem -- a real problem of self-injury and who isn't and look at that in relation to diagnostic labels like autism or not as well. So that's in the plan.

Just historically, with relatively small samples, I have not pulled them apart by their current diagnosis partly because we work around on a piggyback model in rehab hospitals where when kids are in for sedated procedures when we do work like this -- and it goes over years in relying on different sources of information for the diagnoses that kids carry, I've just -- I haven't abandoned it, but it just -- I'm just always worried that I'm not sure if we're really comparing apples/apples, apples/oranges, fruit or whatever. So we're -- we'll -- we're refining diagnoses in addition to trying to move to perspective with this in preschool with global developmental delay.

DR. CUTHBERT: Yeah, thank you.

DR. SYMONS: Thanks.

DR. CUTHBERT: Yeah, my take on that would be that you're probably closer to an accurate diagnosis with this than what we would think of as a traditional diagnosis because it gives you a more homogenous independent variable you look at. So thank you.

Other questions? We have just a couple minutes for all of our presenters. We've had three really interesting talks, so I think we might open it up now for questions or comments within or across any of our three presentations. Yes?

DR. WEXLER: Jim, what -- in terms of actually being more sensitive rather than less sensitive, have you looked at all into the fact that it might be enjoyable? I'm sure you have. I mean, we all engage in self-injurious behavior that is enjoyable, and I'm sure that if we looked around this room, we'd see people who are biting their nails, people who are twirling their hair to the point of trichotillomania and people who smoke cigarettes, amongst other things, that are highly enjoyable but very self-injurious, and just out of curiosity.

DR. SYMONS: Yeah, Denis and Jim could jump in on this, too. I mean, there's a few things there to impact that. There's certainly -- within the big three of biological models in self-injury in developmental disorders is dopamine, serotonin, the opioids. And there's certainly a story with regard to opioids, and Jim alluded to this of thinking about -- there's the pain side of self-injury and what I talked about, but there's also a reward-addiction model. So there's -- that's certainly in the mix for some people's thinking conceptually.

Clinically, what that can lead to, either one of that -- the pain or the opioid addiction model can lead to treatment with naltrexone just as an editorial comment. I mean, naltrexone came and it went, but amongst the dopamine antagonists, the serotonergic agents and naltrexone in terms of the quality of the scientific evidence, there's certainly -- it's certainly clear that there's a subgroup that respond to naltrexone, which suggests that opioid -- there's endogenous opioid activity.

On the issue of is it pleasurable, two thoughts. One -- and I don't -- I'm not being facetious. I don't know for our individuals we study because they can't tell us. Two, what I thought you might be alluding to, and there's probably people sitting here on the table that know this better than I -- and it's not irrelevant for that cell article -- there's certainly work so I -- these fiber types I'm talking about, epidermal nerve fibers, there's a lot of flavors to them. They're almost all C fibers, so it just means unmyelinated. But there's -- they respond to a variety of different modalities.

And there's an emergent set of work and comments on this notion that for -- there's a C -- someone help me out -- CT -- there's a pleasure in

-- that -- you know, why it feels good to have somebody massage or rub you is in part mediated by a sensory -- by those -- a subgroup of those C fibers. So maybe there's something that starts out pleasurable but eventually becomes injurious. Whether there's pain or pleasure associated with that is back to the starting point for me of I'd like to know -- and I'd like to know whether or not because it might matter to get to different ways of treating.

MS. CRANE: One of the things that I think is really interesting is that, as much as people often ignore this fact and will argue that self-injury is some sort of like specifically low-functioning problem, I don't know any autistic people at all who I know very well who haven't engaged in self-injurious behaviors. And that's like the entire spectrum. And I'm counting things like skin picking or pulling out hair, scratching, biting.

And I was actually thinking when you were doing this talk, it's an amazing talk and I think it gives scientific backing to what a lot of people who self-injure and speak will say is that it's a response to distress. And many people who self-injure, they'll say no, it's not that I don't feel pain. I know that this hurts, but it's -- you know, for one reason or another I need to do it.

A lot of people who aren't autistic will self-injure in response to pain, right? If you have a headache, you might like bite your finger and the pain in your finger can distract from your headache and no one's going to be saying, you know, how can we stop this guy from biting his finger? People will think, well, gosh, his headache is so bad that he's biting himself. Maybe we should really pay attention to this headache.

And I -- that's -- it's a really interesting theme that I've seen in this whole panel that we're recognizing behavior problems as responses to distress. And you can either approach this through CBT by saying, you know, you're going to experience some distress but we need to talk to you about how to respond to it or you can say, look, this person is experiencing distress and we need to reduce the amount of distress they experience so that we -- they don't engage in this behavior.

I think that's just very interesting and thank you so much.

DR. CUTHBERT: I just want to relate again to some people who are diagnosed with borderline personality disorder, you know, engage in the cutting and other self-injurious behavior, the self-report that accompanies that is often that I felt this increasing nervous tension to the point it became unbearable and I'm relieved by doing the cutting or other self-injurious behaviors so --

MS. CRANE: They'll definitely still feel pain.

DR. CUTHBERT: Oh, no, no, they feel pain but they seem to find it, for some reason, soothing or it breaks the nervous tension is the report, which who knows what that means but that's the frequent report.

So thank you again to our panelists for a fascinating afternoon discussion.

(Applause.)

DR. CUTHBERT: So now --

DR. DANIELS: Geri will go first because she has to leave.

DR. CUTHBERT: Oh, okay. We are ready for our round robin comments, and Geri Dawson needs to leave shortly, so we're going to jump her up from fourth to first to give us a 10-minute update --

DR. DAWSON: I'll be okay at fourth. I'm leaving at 5:00.

DR. CUTHBERT: Go ahead. Go ahead.

DR. DAWSON: Okay.

DR. CUTHBERT: Having said that --

DR. DAWSON: So do I -- should I go up there --

DR. DANIELS: Either way.

DR. CUTHBERT: However you'd like.

DR. DANIELS: Whatever you'd like.

DR. DAWSON: Is that right? That's forward.

UNIDENTIFIED SPEAKER: Do you have slides here?

DR. DAWSON: Yeah.

UNIDENTIFIED SPEAKER: You have slides. Okay.

DR. DAWSON: Oh, there we go. Okay. We're good. Okay. So Susan just asked me to give a brief overview of the most recent International Meeting for Autism Research, which was held in Baltimore, Maryland, May 11 through 14. So this is the annual meeting of the International Society for Autism Research, which is the largest society that is devoted specifically to autism research.

So just to show you how many people attended, so there were over 2,000 people that came to IMFAR, and we are an international organization. And you can see that 49 countries were represented. Most of them were from the U.S. We do every five years have a meeting in another region and so you see more participation from other areas such as Europe when we go out of the U.S. And we also now are sponsoring a regional meeting, which I'll tell you a little bit about in a minute.

There were close to 1,400 presentations made. These included oral presentations, panels that were around specific themes, and I'm going to show you what those panels were this year so you can get a sense of some of the topics that people are interested in and researching. And then we also have just a large number of posters, which is actually a wonderful opportunity for networking, which is one of the key purposes of having IMFAR.

So this year, we published for the first time our -- an annual report, and we're sort of proud now to have that. And I encourage you to go on the website, the INSAR website, and you can download this and look at it. But it will tell you about all the activities of 2015. It includes that we this year updated the strategic plan for INSAR. It hadn't been updated for a number of years.

We also described our first regional IMFAR meeting so what we're trying to do here is to hold meetings in areas where we often don't attract people from that area because it's just too far to be able to travel. So our first regional meeting was in Shanghai, China. It was extremely successful. I could give another presentation on that, but we were very pleased with attendance and the quality of the research that was presented.

It also talks about our summer institute, and this is part of our initiative to try to reach the autism community, researchers and families worldwide, and so, again, a lot of people don't have the resources to be able to come to the United States so we now have a summer institute where leaders in the field provide lectures on important topics, and this can be accessed on the web by anyone. We actually have a summer institute ongoing right at this moment. So that's just a -- it's a great way to get information about what's going on in autism research.

Also, you'll get an update about the awards that were given. You may or may not know that autism research, which is -- a very, you know, prestigious autism scientific journal is sponsored by INSAR and the editor is our own David Amaral here, one of the members of this committee. You can also look at a financial report for the organization.

Okay. So I mentioned that we updated the strategic plan, so very briefly, these are our strategic initiatives. Actually, the first five are really initiatives that have been in place for a number of years, although we modified them and updated them somewhat. But we also added two new initiatives, and this really reflects a maturing of the organization from an organization that was mostly about gathering information about science to one that is mature enough now and the science is mature enough now that we're wanting to actually have an impact on policy and practice.

And so you can see that we have added this -- that we have as an initiative to disseminate science-based knowledge in order to inform policy and practice, and we also added an initiative to foster communication between autism researchers and individuals affected by autism, really recognizing the key importance of that partnership in informing the science and doing the science.

But in addition, there's -- increasing the quality of the research, cultivating interdisciplinary research and translational research, representing a diverse and global community, fostering the next generation of autism researchers. We have a lot of activities that are focused on the young people and really promoting their career development and then promoting INSAR as the premier society for autism researchers.

So going back to the IMFAR 2016 meeting, our keynote presentations, one was Irva Hertz-Picciotto. She talked on environment and autism. Dr. Feng talked on synaptic and circuitry mechanisms of autism, and Paul Shattuck spoke about life course research in autism.

I'm going to briefly just tell you some of the themes of the panel so you can get a sense of what autism researchers are focusing on and interested in, so environmental influences; there was a panel on transcranial magnetic stimulation, TMS; a panel on improving access to screening and specialized services in underserved communities; creating better outcome measures for early intervention studies; and a panel on behavioral interventions for adults with autism; recent advances in genetics and neurobiology; I think an important panel on growing older with autism and looking at quality of life for aging individuals; what's different about females, that's a very, very strong theme and a lot of work going on in that area now; perspectives on pain, which included some of the presentations that we just heard; and then how do you take the good science that's done in the lab and actually get it out into the community so that it has impact, so evidence-based practices in the community; life course and ecological perspectives; using big data and machine-learning approaches to analyzing eye-tracking data; recent advances in statistical methods; understanding cultural differences in diagnostic and treatment services, again, drawing upon the international flavor of the community that is there; and then understanding anxiety in autism.

So every year we also have -- we sponsor a number of what are called special interest groups, and these are people that want to spend time together talking about topics that are usually kind of in development and often become panels for future meetings. Our special interest groups this year were on community-based early intervention, on new ways of thinking about the autism diagnosis, on older adults with autism and aging, on suicidality, anxiety, incorporating the autistic intellect into the research design and evaluation, and genetic and environmental risk factors.

We give many awards and I'm not going to go through all of them because of the time, but two of our most prestigious awards are -- one is a lifetime achievement award, which went to Professor Christopher Gillberg, who's done really foundational work on really understating the -- both the etiology and the nature and diagnosis of autism, and then to our own Tom Insel, who received the advocate award, which I think is a wonderful thing for us all to reflect on since of course Tom was our leader of the IACC for so many years.

And I'll end by just reminding people that IMFAR 2017 is going to be held in San Francisco, so I hope you all will come.

DR. CUTHBERT: Okay. Thank you very much, Geri.

Are there any others who need to go early who would like to present next in order to catch a plane or other departing vehicle?

(No response.)

DR. CUTHBERT: Okay. Seeing none, we'll resume our regular order of slides, so if we can back the slides up to the first one for this session, please. I'm not sure if anyone else has slides, but we do.

There it is. Thank you.

So this is an update that I am giving on behalf of NIMH, and I would like to talk about the ASD Pediatric Early Detection, Engagement, and Services network, which abbreviates to, as you can see there, ASD-PEDS network. This is, as you can see there, a network of five large-scale studies in early identification of ASD and its linkages to treatment and services.

The studies address questions about the implementation and effectiveness of combined strategies for universal screening, expedited diagnosis, and engagement in treatment for children between the ages of 12 and 36 months, including a focus on eliminating documented disparities among racial and ethnic groups.

The network has just completed the second year of activities in the following studies, and there are the studies that are listed there.

Data collection has begun, and the studies continue monthly conference calls to maintain coordination, refine common data elements, and develop new studies to be built off this research infrastructure.

On June 15, the network had its second annual in-person meeting, which included discussion of how the studies might address the questions raised by the U.S. Preventive Services Task Force report and screening, which, as we all know, has been a controversial topic of discussion.

David Mandell also met with a group to discuss implementation strategies and ASD services research.

Also along this line, NIMH also reissued two ASD lifespan announcements, pilot research on services for transition-age youth, and pilot studies of services strategies for adults with ASD. Both of these were funding set-asides or RFAs. In total, 29 responsive applications were reviewed on June 17th. Based on the scores from the review committees, we anticipate that several of the proposed studies will be funded, but we haven't been able to determine the exact number as of yet. We're still going through the review comments. Applicants who are not funded through the RFAs, however, will have the opportunity to revise and resubmit under the standing NIMH announcement for pilot studies. So that's an announcement from us, and we are, as with other agencies here, trying to move ahead in research on the both child and adult services areas.

Okay. So our next update is from Alice Kau from NICHD, and she will share an update on the Autism Centers of Excellence. Doctor, welcome.

DR. KAU: Thank you. I'm sitting in for Dr. Spong, so it was convenient just to give you an update on the Autism Centers of Excellence program. And I would like to inform the committee that NIH has just released the RFAs for the Autism Centers for Excellence with an expiration date on November 17, 2016. And again, this is a funding initiative with set-asides.

The funding for this program came from five ICs of NIH and of -- five directors are members of the IACC. And these five institutes are NICHD, NIMH, NIDCD, NINDS, and NIEHS. So this is a trans-NIH collaborative funding. And the funding of this program started in 2007.

So to build on the research progress and momentum of the past decades, with this initiative we intend to fund innovative interventions and services research for individuals with ASD across the lifespan and also to fund cutting-edge research on a neurobiological basis and phenotypic characterizations of ASDs.

So we're very excited about this initiative. If you have -- so the -- both RFAs will be listed at IACC's website, so for people who need more information can definitely direct them to the website. And all the program directors are ready to answer questions and help along with that.

(Laughter.)

DR. CUTHBERT: Thank you. Any comments or questions about this initiative?

(No response.)

DR. CUTHBERT: Okay. Thanks very much, Alice.

And our next comment is from Stuart Shapira with an update on the SEED program. Stuart?

DR. SHAPIRA: So thank you, Bruce. And I promise not to take any more than three minutes.

(Laughter.)

DR. SHAPIRA: So the Study to Explore Early Development or SEED is a multi-site case control research study funded by CDC to examine genetic and environmental risk factors for ASD. And the participants are three- to five-year-old children who fall into one of three groups. They have ASD as determined by ADOS and ADI-R performed by study staff or they have a developmental disability but do not have ASD, or they come from the general population but they don't have ASD.

So two phases of enrollment in SEED known as SEED 1 and SEED 2, have been completed with over 5,000 children enrolled to date. Data analyses on SEED 1 participants are ongoing and some key papers already published, and a number of studies are anticipated to be completed before the end of the year. And SEED 2 data will be organized by early 2017 and merged with SEED 1 data for analysis.

Now, the CDC just funded SEED 3, which will enroll more three- to five-year-old children so that in-depth analysis of research questions that require large numbers of participants will be able to be conducted.

And the awardees for SEED 3 are the University of Colorado at Denver, Johns Hopkins University, the University of North Carolina at Chapel Hill, Washington University at St. Louis, and the University of Wisconsin system. Now, Johns Hopkins will also provide central laboratory services, and Michigan State University will serve as the data coordinating center.

Now, what is exciting about SEED 3 is that, in addition to continuing the case control study format of the prior phases of SEED, SEED 3 will conduct a follow-up study of children with ASD who were enrolled in SEED 1. So the purpose of this follow-up is to better understand the long-term health and development of children identified with ASD at younger ages. And these children who were originally three to five years of age at the time of SEED 1 will be early teenagers at the time of follow-up. And this follow-up study is important toward providing us with information to support children with ASD as they grow into adolescents and adulthood.

DR. CUTHBERT: Alison?

MS. SINGER: So one of the best aspects of SEED 1 was the collection of the genetic data, but it's my understanding that that genetic data was consented in a way that it can't be contributed to any of the existing larger databases. As part of SEED 3, when you re-contact the SEED 1 families, can you re-consent them for the genetics?

DR. SHAPIRA: Yes, that's part of what's going to happen with the SEED 3 follow-up is to contact and re-consent for the genetic analyses.

DR. CUTHBERT: Any other questions or comments?

(No response.)

DR. CUTHBERT: Okay. Thank you.

And next up we have Larry Wexler, who will give us some updates on the Department of Education programs. Larry?

DR. WEXLER: I feel like I'm between Miller time and the end of the day here.

So we've developed -- we've supported a development eventually of 27 modules for persons who work with children with ASD. These are all evidence-based practices. I think that the woman who spoke in -- during public comment who was the kindergarten teacher was a perfect example that these can be used for general educators as well as special educators. They're designed for children really birth to 22, but that's only because it's IDEA money, which only goes to 22. But all of these modules are free, downloadable. They have supporting materials. Again, all are free and downloadable and really applicable to the full age span.

They include case examples that demonstrate the behavior or practice in use. They're multimedia. They have interactive assessments. Each module they -- the user has the option to select either a certificate track or a non-certificate track so CEUs can be gained, which is really critical in schools especially.

Just the 14 that are done include antecedent-based intervention, discrete trial training, exercise, functional behavior assessment modeling, peer-mediated instruction and intervention, picture exchange communication systems, prompting reinforcements, social narratives, social skills training, task analysis, time delay, and visual prompt. There'll be 13 more of those. University of North Carolina at Chapel Hill, Frank Porter Graham is -- who is developing these. Sam Odom is involved in this, as well as a number of other folks. They are really nifty. They're easy to use, and they're very in depth. And Susan will send out -- you can send out the website. I think you -- or I'll give it to you right now. So thank you.

DR. DANIELS: That's great.

DR. CUTHBERT: Okay. Any comments, questions?

(No response.)

DR. CUTHBERT: That is great, yeah, thank you.

DR. WEXLER: The school bus does pull up.

(Laughter.)

DR. CUTHBERT: Yeah, yeah, yeah, thank you.

Okay. Next, Susan will give us an update on behalf of AHRC agency on health care research and quality.

DR. DANIELS: Yes. So Laura Pincock, who is going to be sitting in for Elizabeth Kato asked me to give this brief update. So AHRQ has ongoing systematic review updates on medical and sensory-related therapies for children with autism spectrum disorder, and these topics have been split into two reports. One is going to be on medical therapies and one on sensory-related therapies. They expect the report's drafts to be posted for public comment sometime in August, and so our office will be advised as soon as they're open for public comment and we'll put a notice on our website and send out some information in case members of the public would like to be able to provide comment.

DR. CUTHBERT: Thank you, Susan.

Are there other updates or comments from anyone else around the table?

Yes, Tiffany?

DR. FARCHIONE: I just wanted to mention really quickly that FDA has these patient-focused drug development meetings, and one of them that has been on the schedule for quite some time as upcoming is PFDD on autism. We actually have a tentative date now. Nothing is officially official until it's in the Federal Register, but it should be in May of 2017. So as I get more details, I can hopefully announce those at a future IACC meeting.

DR. CUTHBERT: Okay. Thank you very much. Can you give us just a brief idea of what that kind of meeting will entail?

DR. FARCHIONE: Sure. So the main point of the meeting is to try to get the patient's perspective more involved in drug development. So the end result is a document that various, you know, pharmaceutical companies or other research organizations can refer to to say these are things that are important to people with this condition, and these are things that they want to have some kind of treatment for. And then that can help to hopefully drive development in that direction into something that's more meaningful to patients.

DR. CUTHBERT: Very good. Thank you.

Other comments and questions?

(No response.)

DR. CUTHBERT: Okay. We'll of course have several meetings before May 2017, so we'll look forward to -- you know, I'm sure there are many people who have since left this meeting who will want to hear about that, so we'll look forward to hearing the definite date from you, you know, when it's available in another meeting or two. So thank you.

Okay. It looks like we have come to the close of the agenda. Susan, before we close, do you have anything to add?

DR. DANIELS: I just want to encourage anyone who has ideas for speakers or topics for future meetings to email me about that and let me know. And also, if you do notice any gaps in the rosters that I handed out for the working groups, let me know. We did put them together pretty quickly, and as you can see, there were a lot of different people on them and so it's possible that someone inadvertently got missed. And so we will correct that if we find any issues.

DR. CUTHBERT: Okay. So I'd like to thank all of our presenters today, both those on this committee and those who came in to present specially for a really diverse, interesting, and engaging set of presentations and to all of you for the good discussion about these topics.

And we've also, as always, heard from the public about their concerns, and I hope we can move ahead in thinking how those can best be addressed.

So thank you very much. And we already have a date, as I hope you noted, for the next meeting. We are confirmed for October 26. I'm not sure yet whether that will be here on main campus or up at the neuroscience center.

DR. DANIELS: We'll try to get a room here on campus, but we'll let you know the room as soon as we can.

DR. CUTHBERT: So we'll be in touch.

Okay. So that said, thank you very much, everyone. Safe travels back home. And we will see you next time. Bye-bye.

(Whereupon, at 4:42 p.m., the meeting was adjourned.)