INTERAGENCY AUTISM COORDINATING COMMITTEE

FULL COMMITTEE MEETING

WEDNESDAY, APRIL 26, 2017

The full Interagency Autism Coordinating Committee (IACC) convened in Bethesda, Maryland, at the National Institutes of Health, (NIH), 31 Center Drive, Building 31, C Wing, 6th Floor, Conference Room 6, at 9:00 a.m., Joshua Gordon, M.D., Ph.D., Chair, presiding.

PARTICIPANTS:

JOSHUA GORDON, M.D., Ph.D., Chair, National Institute of Mental Health, (NIMH) National Institutes of Health

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

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

JAMES BALL, Ed.D., B.C.B.A.-D, President and CEO of JB Autism Consulting; Chair, Autism Society Board of Directors

JOSIE BRIGGS, M.D. (For Francis S. Collins, M.D., Ph.D.) Director, National Center for Complementary and Alternative Medicine, National Institutes of Health (NIH)

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

SAMANTHA CRANE, J.D., Legal Director and Director of Public Policy, Autistic Self Advocacy Network (ASAN)

GERALDINE DAWSON, Ph.D., Duke University

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

AMY GOODMAN, M.A., Self-Advocate, Charles Town, WV

MELISSA L. HARRIS, Acting Deputy Director, Disabled and Elderly Health Programs Group, Center for Medicare and CHIP Services, Centers for Medicare and Medicaid Services (attended by phone)

JENNIFER JOHNSON, Ed.D. (for Commissioner Aaron Bishop M.S.S.W.) Administration for Community Living

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

MEGHAN MOTT for (Walter J. Koroshetz, M.D.), Director, National Institute of Neurological Disorders and Stroke, National Institutes of Health

BRIAN PARNELL, M.S.W., C.S.W., Medicaid Autism Waiver & Community Supports Waiver Administrator, Division of Services for People with Disabilities, Utah Department of Human Services

KEVIN PELPHREY, Ph.D., George Washington University and Children's National Medical Center

EDLYN PENA, Ph.D., California Lutheran University (attended by phone)

LAURA PINCOCK, PharmD, MPH, Pharmacist Officer, Agency for Healthcare Research and Quality, (AHRQ) (attended by phone)

LOUIS REICHARDT Ph.D., Director, Simons Foundation Autism Research Initiative (SFARI)

ROBERT RING, Ph.D., Autism Speaks

JOHN ELDER ROBISON, Neurodiversity Scholar in Residence at the College of William and Mary

ROBYN SCHULHOF, M.A., for (Laura Kavanagh M.P.P.), Deputy Associate Administrator, Maternal and Child Health Bureau, Health Resources and Services Administration (HRSA)

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

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

MELISSA SPENCER, Deputy Commissioner, Office of Disability Policy, Social Security Administration (SSA)

JULIE LOUNDS TAYLOR, Ph.D., Vanderbilt University

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

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PROCEEDINGS

DR. JOSHUA GORDON: Welcome to the Meeting of the Interagency Autism Coordinating Committee. Can we just confirm that we are on webcast? That is all up and running? Since no one said no, we will go ahead. We are going to start with roll call. Susan is going to go ahead with the roll call please.

DR. SUSAN DANIELS: Let’s start with the roll call. We have Josh Gordon.

DR. GORDON: Here.

DR. DANIELS: Judith Cooper for Jim Battey.

DR. JUDITH COOPER: Here.

DR. DANIELS: Diana Bianchi. May be coming.

(No response)

DR. DANIELS: Cindy Lawler for Linda Birnbaum.

DR. CINDY LAWLER: Here.

DR. DANIELS: Josie Briggs for Francis Collins.

DR. JOSIE BRIGGS: I am here.

DR. DANIELS: Ruth Etzel.

DR, RUTH ETZEL: I am here.

DR. DANIELS: Tiffany Farchione, who may be on her way.

(No response)

DR. DANIELS: Melissa Harris is going to be on the phone. Are you there, Melissa.

((No response)

DR. DANIELS: Jennifer Johnson.

MS. JENNIFER JOHNSON: Here.

DR. DANIELS: Robyn Schulhof for Laura Kavanagh.

DR. ROBYN SCHULHOF: Here.

DR. DANIELS: Meghan Mott for Walter Koroshetz.

DR. MEGHAN MOTT: Here.

DR. DANIELS: Laura Pincock.

DR. LAURA PINCOCK: Here.

DR. DANIELS: Stuart Shapira.

DR. STUART SHAPIRO: Here.

DR. DANIELS: Melissa Spencer.

DR, MELISSA SPENCER: Here.

DR. DANIELS: Larry Wexler.

DR. LARRY WEXLER: Here.

DR. DANIELS: Nicole Williams or Stan Niu. May be on her way.

(No response)

DR. DANIELS: David Amaral.

DR. DAVID AMAREL: Here.

DR. DANIELS: Jim Ball.

DR. JIM BALL: Here.

DR. DANIELS: Thanks, Jim. Samantha Crane, may be on her way.

(No response)

DR. DANIELS: Gerry Dawson.

DR. GERRY DAWSON: Here.

DR. DANIELS: Amy Goodman.

MS. AMY GOODMAN: Here.

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

Brian Parnell.

DR. BRIAN PARNELL: Here.

DR. DANIELS: Kevin Pelphrey.

DR. KEVIN PELPHREY: Here.

DR. DANIELS: Edlyn Pena.

DR. EDLYN PENA: Here.

DR. DANIELS: Louis Reichardt.

DR. LOUIS REICHARDT: Here.

DR. DANIELS: Rob Ring, may be on his way.

(No response)

DR. DANIELS: John Elder Robinson.

DR. JOHN ELDER ROBISON: I am here.

DR. DANIELS: Alison Singer.

DR. ALISON SINGER: Here.

DR. DANIELS: Julie Taylor.

DR. JULIE TAYLOR: I am here.

DR. DANIELS: Have I missed any alternates or anyone else? All right. Finished with the roll call.

DR. GORDON: Thank you and once again welcome everybody. A couple of quick reminders before we get started. Please when you speak, make sure to press the button on your microphone. It should

light up red when you do so. When you are done speaking, can you press it again because there are only so many mikes that can be active at any given time? Of course, the reason why we want you to speak in the microphone is because this is all being webcast for the public.

It is really wonderful to be talking to you here and working together with you during Autism Awareness Month, which as you know, is the month of April. I hope many of you were able to make the event last night, which I understand went very well. I was very sorry to miss it and I will be catching up on the film. Is it live now on the web?

DR. DANIELS: We do have a link on the IACC website that will be active until August 2017 where anyone can view the movie for free. We encourage you to do that.

DR. GORDON: Other autism awareness things you should be aware about is myself and I believe Dr. Bianchi and Dr. Price, the secretary, have

written or are writing blog pieces around our efforts in autism care and research. You can check out the respective websites and our website, NIMH, and the IACC website because we link to it. Is that correct?

DR. DANIELS: Yes, the IACC has an autism awareness web page and we have all the blogs listed there and all the new ones that are still coming will be listed as soon as possible.

DR. GORDON: Thank you all for coming in the context of this busy month. I also want to welcome special guests in attendance today. First, Dr. Tom Novotny, the deputy assistant secretary of Health who is going to speak to us a little bit, actually right away early in the program. Ms. Jennifer Sheehy, the deputy assistant secretary in the Office of Disability Employment Policy. Is she here? She will be here later, speaking to us, in the US Department of Labor I should mention. And then the Honorable Mike Lake who is in the Canadian Minister of

Parliament who is also going to be addressing us later today and whom we met last night at the dinner for the event. It was really wonderful to be able to speak with him.

I also want to welcome a new committee member, Ms. Melissa Spencer. Thank you. Ms. Spencer represents a new agency at the table, one which we are very pleased to have. She is the deputy associate commissioner of the Office of Disability Policy at the Social Security Administration. Especially with the growing interest in services for adults in this group, we are pleased to welcome her and also of course for services for children.

I also want to mention that Dr. Rob Ring, who I do not think is here just yet, has changed affiliations and he is now the CEO of Vencerx Therapeutics. Maybe we could have – Ms. Spencer, if you could say a little something about your agency and what bring you to the table.

MS. SPENCER: We serve a lot of individuals with autism spectrum disorder, both evaluating adults and childhood claims for disability benefits. While we are a benefits paying organization, we are also very interested in employment opportunities and transition opportunities for teenagers and getting more into that with demonstration projects especially for the adult population of disabled individuals. I think I am scheduled to speak a little bit and I will tell you a little bit about some of the criteria we have and some of our demonstration projects.

DR. GORDON: Now, I will turn it back over to Susan for some announcements and approval of the minutes.

DR. DANIELS: I think I am going to add the announcements actually in my committee business section. I will just go ahead with the approval of the minutes. You all have a copy of the draft minutes from the last IACC meeting. I wanted to

know if there were on any comments on those minutes. I do not think I received anything by email. If not, can we have a motion to accept the minutes? A second? All in favor of accepting the minutes as written? Any opposed? Any abstaining? I did not see all the hands, but it looks like we have accepted the minutes. We are going to get those into the record and they will be on the website shortly.

DR. GORDON: Next, we are going to have an update from Dr. Novotny from the Office of the National Autism Coordinator in the Department of Health and Human Services.

DR. NOVOTNY: Good morning. It is great to be back here at the committee meeting and see many familiar faces now and people are getting more familiar to me, which is really a good sign, I think. I also want to share in the welcome of Melissa Spencer, who not only joined this committee, but also worked with us on the report that we have been talking about for some time

now, which is completed in terms of its drafting, but this is a process, as you know, within government takes some time to progress through various layers of review, makes it a lot better product at the end, but it does take some time. I was really hoping to get it out this month, but we do not have a date yet for the report release.

But what I want to tell you is that we enjoyed a very good process of interagency collaboration, not just across HHS, but with other agencies such as the Department of Defense and Department of Labor and Department of Education for sure. Larry Wexler has been a great ally in the production of the material.

We have accomplished something just by virtue of that process, getting people to communicate and to identify where the actions lie within the federal government. At the same time, we also invited many of you to participate in a listening session that we had towards the end of our production process. We are able to

incorporate not only those pieces of input, those great contributions and insights, but also those of the GAO, which as you know has also been writing a report at the request of now I understand of Representative Smith also on the transition period. I do not think there is going to be much in the way of incompatibility of those reports. In fact, not really any. IACC has been getting public comments that we were able to review and incorporate into the perspectives that we tried to put forward.

I am sorry that I cannot share it with you today. We really hoped that we were able to do that. But it is on its way. We had a briefing on the Hill on Monday at the invitation of Autism Speaks, which I want to thank – no matter what I do thank Autism Speaks for inviting me. A couple of advocates and academics to present on autism issues related especially to transition on the Hill. And Representative Smith visited and had some intense comments for HHS, but we appreciate

his interest and his support for the issues. I think that is the important thing. We look forward to working with him continually as we go forward.

I do not have a whole lot more to say except that I am glad to be seeing so much progress and the review of the strategic plan and the summary of advances and just a lot of stuff going on. I think it is worthy of the autism awareness month activities throughout. We have published a blog at the beginning of the month that Secretary Price called out. He now has a blog coming very shortly as well. We are glad that he has taken an interest in this issue as well. Thank you.

DR. DANIELS: Thanks Tom. I just wanted to make a quick comment to say that the process that we have been using for this transition report has been really helpful to us in the OARC as well as we are trying to use this opportunity to make a bridge between that transition group, the internal working group, and the IACC. I have been

sharing IACC information with them like the comments that we collected for the strategic plan. I think this report will definitely be bringing it to the IACC and hopefully it will inform us. It has also given us a few new connections, for example, with the Social Security Administration that contributed to being able to identify someone to serve from that agency. It is terrific and we really appreciate having you, Melissa. Thanks.

DR. GORDON: Thank you, Dr. Novotny. Now, it is my pleasure to introduce the Honorable Mike Lake, who is a Canadian Member of Parliament. But he is here today more in the capacity of being one of Canada's and really the world's leading autism and disability advocates. Mike is the father of a son, Jaden, who we heard a lot about last night and hear more about now on the autism spectrum. He is with us today to give us a special message in recognition of World Autism Awareness Day, which took place on April 2 as

well as Autism Awareness Month. Thanks Mike. We look forward to hearing what you have to say and show.

HON. LAKE: Thank you all for having me. It is great to come down from Canada and come into a room like this and see actually quite a few friends here, people that I have met over time and to be a part of what you are doing. Last night was an absolutely fantastic event. The film that we got a chance to see last night if you have not had a chance to see it – it is phenomenal.

As mentioned, I am a conservative member of Parliament from Canada, which is interesting, because I always say that puts me about half way between your parties here in the US or at least up until the last year I always said that. Now, I do not know where I stand compared to the politics down here. But I am a member of Parliament and have been for 11 years.

A lot of what I do relates to autism. There is a platform that you get as an elected person and I am fortunate enough to represent an area where the seat is fairly safe for me and my constituents are pretty fantastic in terms of allowing me to do this extra work that I do in autism.

Normally, the goal of my presentation when I am speaking is to educate people about autism. I do not think I have to do that too much in this room. Oftentimes the presentation I am about to show you is a presentation that I am presenting to between 400 and 1300 university students in an intro psyche class or at a teacher's convention or a meeting of doctors or nurses of some sort. That is a big part of what we are trying to do.

Also changed the way people just generally think about the people around them, all of the people around them. It is going to have six videos that are part of it. I have an hour in total presentation. It normally takes about 40

minutes. I would be glad to take some questions from you afterwards.

In some of the spots where I might explain autism, maybe I will explain a few of the other things that we are doing right now to move the ball for families living with autism.

But the first thing I am going to show you is a video that – Jaden is 21 years old now. His mom and I have been apart for several years, for three or four years now. When I hang out with my kids – I have a 17-year-old daughter as well. Oftentimes we are either driving in the car somewhere, listening to music, and those kinds of things or hanging out at my place and watching videos. In one of those moments, my daughter pulled out her iPhone and decided to take this video of Jaden and I doing something that we have done since he was a baby really. It is a song that I have sung to him since he was a baby. Just recently in the last year, he has started to in

his way sing back, which you will see in the video. This is new as of the last year or two.

Jaden has this amazing ability, we were talking about it yesterday, to connect with people. You will pick it up probably right off the bat. When we shared this video on Facebook, within a week, it had 1.4 million views of a 35-second song. The words just so you know if you cannot hear it in the video – in the context. I worked for the Edmonton Oilers before I get elected for ten years. In Jaden's whole life I have worked in either a job that had me traveling a lot or a job that had me away a lot of nights. I would sing this song to him. Think of me every day. Hold tight to what I say. And I will be close to you even from far away. Know that wherever you are it is never too far. When you think of me, I will be with you. When we sang this song, Janae captured it. This is May of last year.

(Video Show)

HON. LAKE: He agrees that it was nice. He starts when I start. He finishes when I finish. It is interesting because the first time we noticed it was with the National Anthem. But of course, the National Anthem – if you are in public and you are singing the National Anthem just like down here, people take that seriously. The first response people have is they are looking around to figure out which kid is fooling around during the National Anthem. But quickly as people realize that it is a little bit different, they will respond differently.

It is interesting. On the comments when I posted this on my Facebook page, one of the first comments I got was from someone on the spectrum. It was wow, you have a lot of remotes. We have a lot of remotes. There are eight remotes there. That gives you a little bit of a picture of Jaden. The rest of the videos go in chronological order.

I am going to jump into the next video pretty quickly. This goes back to 2010. It was World Autism Awareness Day. We do a lot of interviews to try and raise awareness of autism. We had this opportunity in April of 2010 to do a live interview. This was a little bit nerve wracking, as you can imagine because it is a little unpredictable. I said to the reporter that was going to do this interview – it is in the foyer of the House of Commons. It is this stone building. It is very echo-y. There is a lot going on. I said to the reporter, whatever happens, let's just go with it because it is the first time we have done it live. Jaden was 14 at the time that we did this interview. Sure enough, the reporter just before we went live said Mike, thanks for changing your travel plans to be here today. Jaden is obsessed with travel and obsessed with schedules or plans. This was the result of that question.

(Video Show)

HON. LAKE: One of the things that I always have to explain after that interview, remembering that that interview is seven years old, is there are some terminology that he uses in that interview that we do not use anymore. He talks about curing autism. We do not typically talk about curing autism. We also do not talk about Jaden's suffering with autism. Jaden does not suffer with autism. There are challenges certainly, absolutely, but there are also skills and abilities and strengths that he has because of that. You have to remember the context is seven years ago. If anyone wants to give Tom a hard time, Tom is trying to help us raise awareness of autism and we have to realize that that is what he is trying to do with his not having lived it all of his life and doing it in a fairly difficult circumstance in a live interview.

We had a great conversation last night with Allison and with John and Diana about the range

and the spectrum that autism is. And of course, I do not have to explain to you that when you are seeing Jaden up here, you are seeing one part of the spectrum. But I do have to explain that to other people that there are people with very different challenges and skills and abilities at what we would call the high end of the spectrum. And at the lower end of the spectrum, there are people with very profound challenges that we do not deal with with Jaden. It is important to make sure that we represent the entire spectrum when we are talking about that.

The next interview or next story that I am going to show you – this quote is very specific to that. This is fantastic advice from Margaret Thatcher for most of us. We do not always wear the look on our face that we are feeling in a moment or say exactly what is on our mind. We do not always wear our heart on our sleeve, but Jaden always wears his heart on his sleeve. If he is happy, he is smiling. If he is sad, he just

cries. If he is anxious, he is shaky and he is nervous. He has a real hard time dealing with that.

The context for the story is that every year I do an autism statement in the house. I had done an autism statement in 2012. Bob Wright saw it and Susanne Wright saw it. They wanted me to come and speak at the UN event that they put on in September of 2012. Jaden and I did the keynote address to the spouses of world leaders at this event and wound up doing some media around it. The context is when you see Jaden here, you are seeing a Jaden that is very different than you see in other videos. His eyes are watery. He is obviously off. But context is important.

We woke up at 4 o'clock that morning. We tossed Jaden in a suit in Ottawa, which he was not used to wearing very often. We hopped in a cab, went to the airport. When we got to the airport in Canada – when you are coming from that direction, you have to go through customs in

Canada. We went through the customs process. We hopped on a plan, flew to New York City, hopped in another cab, and raced to our event where we did a media interview with our national news outlet from Canada who was down there to cover it and then we did this story with CNN. It is 10 o'clock in the morning and that has been Jaden's day so far. Jaden does not do mornings very well. He does the rest of the day much better, but he is anxious in the mornings typically.

I love this video as part of the presentation because it allows me to talk about the fact that with Jaden, you have to read facial expressions. He cannot explain what he feels like. You have to read his eyes. You have to read his skin tone. You have to read his body language and things like that. You will notice that – about half way through, actually in different parts of the video the way it is edited, we are playing catch with a football. It is because at that time the football is very therapeutic. What

we really did was call a time out in the middle of the interview and grabbed the football and throw the football. Jaden loves the feel of the football. He loves the smell of the football. He loves the motion of throwing it back and forth. He loves the counting. You cannot hear it, but we are counting as we throw it. He loves that rhythm of the counting as we throw the ball back and forth.

It is funny. Motor skills – funny story. Jaden cannot mimic everything and I always find funny what he can and cannot mimic. He can throw the football back and forth. But if I ever mix him up and throw the football behind my back to him, his version of that and I think he thinks he is doing it the same way. His version of that is to go like this and then throw it forward the same way. I always find that interesting. You do not see it in the video, but this is Jaden as a 16-year-old on CNN in 2012.

(Video Show)

HON. LAKE: You can see the expression on his face. You saw how different it is than sometimes is in most of the videos. Jaden has a real tough time with the abstract. This is a key part when you are thinking about the challenges and you are thinking about all of the opportunities and skills and abilities, which is a lot of the rest of my presentation. Dealing with some of the challenges that Jaden has is critical if he is going to be able to achieve his full potential.

Jaden has no comprehension whatsoever of danger. None at all. It is way too abstract for him. He loves dogs and if he sees a German Shepherd across a field that we were in and decides that he wants to go see that German Shepherd, he will run to it, completely strange dog, squealing as loudly as he can with a huge smile on his face and if he was able to get to the dog, which thankfully he has not been yet, he would reach for the squishiest parts because he loves the squishiest parts of the dog because

from a sensory standpoint, they feel really good to him. He loves the smell of the breath and the feeling of the dog's tongue. He would immediately stick his face right in the dog's face. That would be what he would do. Pit bull, German Shepherd. He actually loves the bigger dogs best. That is something that you always have to be aware of.

Traffic is an absolute nightmare for Jaden. He has a visual memory. He knows everywhere he wants to go. I think the reason we were able to get him a full-time aide in school was because – I remember having a conversation with a principal who did not want to spend the money on a full-time aide. He actually brought up the cost. I said what would it cost – Jaden knows where the swimming pool is. At that point, it was a new school. Jaden was seven. I said he knows exactly where it is. If he decides he wants to go, he is just going to go because he does not know that he cannot, but he has no concept of traffic. How

much is that going to cost you if Jaden walks out of your school because no one is watching him? He got a full-time aide. I think everybody realized that was a challenge.

Jaden can look both ways. You can teach him to look both ways. That is routine. Number one look left. Number two look right. But number three, how do you teach the abstract idea of is it safe to cross? How fast are those cars going? How much would that car hurt if it hit you? Those are things that he does not understand. Those can be challenges.

Sometimes some of these things can be kind of funny and they create opportunities. Sometimes I say Jaden is my super-secret weapon because he introduces me to people in strange and wonderful ways. Some of them are very funny. We were at McDonald's between Christmas and New Year's one time at the mall, very busy, dozens of people in the lineup. Jaden was nine. He looks like any other nine-year-old kid at the time. He suddenly

just started laughing and I was carrying a bunch of food so I was not holding his hand, but I normally would be. He did his happy squeal and run and he ran all the way behind the counter of this McDonald's, pushing people the full length of the counter, pushing people out of his way as he went. At this point, everybody is just going like what the whatever they said. He runs the full length of the counter. He reaches into the bin where they hold the crushed smarties, which are kind of like M&Ms in Canada for McFlurries. He graves a handful of crushed smarties and just shoves them in his face. He has this ring of crushed smarties around his face and the biggest smile you have ever seen. I find someone that looks like a manager and lean over and say he has autism and just put my head down basically. Jaden kind of follows me at that point. He is happy. He has what he wanted and he comes with me.

When I worked for the Oilers, I took him to a hockey game one time and it was about the same

time. Again, nine-year-old kid. We are sitting in the seats watching the game. And the hockey is on and is fairly quiet. It is not like basketball where they play music while it is on. It is fairly quiet. We are watching the game go back and forth. And suddenly out of nowhere, no warning at all, again he kind of squeals. He is happy. He reaches over the shoulder of the five-year-old girl in front of him and grabs the ice cream off the top of her cone like you would grab a snowball and then just starts eating it right out of his hand. It is dribbling down between his fingers. Again, I turn to the dad and say I am sorry. He has autism. He had whipped around. He understood. The daughter did not understand. The five-year-old girl did not understand at all until we got her another ice cream in the intermission. That is life with him.

And sometimes it can be really helpful. When we were at the National Governors Association meetings when Jaden was 17, we had met Mary

Fallin and had dinner with her and had a great conversation. Jaden really hit it off with Mary. A little bit later in the evening I said there is Mary across – it was like a tent. It was outdoors. It was in the summer and fairly warm. I said go say hi to Mary. He would normally run to Mary and give her a hug because they had connected. But he did not run to Mary. He ran to the guy she was talking to who Jaden had never met and this guy because it was summer and it was hot he had a shirt on, but no tie. His shirt was unbuttoned down about here. Jaden loves touch and contact and smell. He apparently loved this guy's cologne. He threw his face into this guy's neck and started smelling his neck and then kissing his neck. A complete stranger. He is hugging him and he is kissing this complete stranger's neck. Jaden is 17 years old at this time. He does not look like a 17 year old because he is fairly small. He looks like he is every 14 year old. I ran over and quickly explained again.

But it turned out – I think his name was David Agnew. Is that a familiar name to anybody here? He was Obama's director of Intergovernmental Affairs or something like that. He was a director in the White House, a senior guy. When I saw Jaden is my secret weapon – he and I talked for half an hour about autism and pipelines. I am from Alberta. Pipelines are a big deal for us. We had a conversation that I never would have had if Jaden hadn't broken the ice.

I cannot tell you how many times Jaden is my ice breaker. Walking into a crowd of people, 200 or 400 people I do not know, Jaden will lead the way because he is so excited to giving everybody high fives. All I have to do is walk around and they are smiling already. I get a chance to shake their hands and say this is my son Jaden. By the way, I am your member of Parliament. It is fun to do that with him. We get to experience some pretty cool things that way.

Normally, right now, I would share my three insights and elaborate a little bit on autism that I would want a room full of intro psyche students to pick up on. I will tell you what they are, but I am not going to get into detail on them because you know it. Of the millions of things I could say about autism, I tell them I want you to know early intervention is critical, absolutely critical. Evidence-based early intervention. I want them to know that transitions are really difficult and really important. We have to carefully consider all transitions whether it is from an early intervention program to school, whether it is from school to vocation, transitions in life.

Jaden went through significant anxiety at 13 like lots of kids do. But because he could not explain it or articulate what he was feeling, it just manifested itself in tremendous sadness and shaking and things that took half an hour of holding him as tight as I could or his mom could

to help him get through. The big transition is of course when we are all gone and you wonder what life is going to look like for Jaden when we are not there to care for him anymore. That is number two that I make the point on.

The third thing is that we need to expect more of people with autism. Virtually across the spectrum we expect too little of people like Jaden. That is really where the rest of my presentation goes is talking about this need to expect more. When most of the people in this room were 12, nobody looked at you and said what is it that you like to do. Now, we are going to set you up on an endless field trip for the rest of your life doing that thing that you like to do. Yet somehow sometimes that is how we think of inclusion. Just an endless field trip doing cool stuff with other people and things like that.

Inclusion is incredibly important and has been incredibly important for Jaden as you are going to see in these next few videos. But I want

us to move beyond just inclusion. I want us to think about contribution. What does Jaden have to contribute? You will see a little bit of that as I move forward in the conversation.

This next video that I am going to play – when Jaden was in grade 10, the students in his school and one of the classes and one of the teachers, the musical theater teacher, said that they had a conversation. They said Jaden loves – he was always in a regular classroom. Jaden loves the sound of music. He loves music in general. He loves moving around. They would have him do little dances and things like that. We think that there is a minimal role that he could probably play in a play. They did that year Oliver. In that year, they just basically had Jaden in two of the scenes. They were group scenes. They dressed him up like everybody else. He milled about. What people did not know watching was that they had two students, one student posted on each

side of the stage to make sure Jaden did not leave because that was a risk for them.

And then the second year they did Bye Bye Birdie. They decided to take it up a notch in terms of his involvement. And Global TV in Edmonton came out and did this story.

(Video Shown)

HON. LAKE: The cool thing about that is that after that – that was his Grade 11 year. In his Grade 12 year, they did Joseph and the amazing technicolor dream coat. You can imagine. A lot of scenes with 12 couples dancing in that. One of the girls in her last year of musical theater actually asked if she could be Jaden's wife in the play. This girl taught him as close as possible all the moves. He could not do everything that every other boy did. But when the other boys lifted up the girls and threw them a little bit in the air, she taught Jaden to put his hands on her hips and lift up his hands and then she would jump to mimic whatever move the

rest of the girls were doing. It was awesome. Every single year they pushed him a little bit more. To see how much he was able to thrive in that was inspirational not just to us. It was inspirational to everybody in the audience. The play was better – the musical theater production was better because Jaden was in it than if he hadn't been.

But one of the things that is okay to – I am Jaden's dad and I watch that and I am amazed and we celebrated how awesome he was. It is also okay to say Jaden probably, as you watch that, is not going to have a career in musical theater. That is probably not where – when you try and take a look at the assessment of where he is going to contribute, he contributed something in that environment and sometimes how we define contribution is a little bit interesting. But in this case, it is not something that he is going to have a career in. But because they have taken this time, because his school where he has gone

to, a K to 12 school including regular classroom because he has built this community of people around him that has his interest at heart, they also notice what he is good at.

These people remember that when Jaden did his times tables from up to grade 4, he was faster than anyone else. He never made a mistake on his times tables. His spelling tests. He got 100 percent on most of his spelling tests back then. Math got a little bit more abstract later and English took on some different forms that were far more abstract and Jaden really struggled with those things. In those early stages, not only was he as good as the other kids, he was faster. You watch Jaden do a word search today, I guarantee there are few people in this room who would beat him doing a word search. He sees things differently.

When he was way too young to be able to do it – you remember those foam letters that you had when you were learning the alphabet, the frame

and the foam letters and you would put in or maybe your kids had those. He was way too young to be able to do it. A friend of ours just on a whim took away the frame because Jaden was pretty fast with the frame. He took away the frame, put the letters in a jumble and Jaden had never done the alphabet freely like that. He did the alphabet as fast as I could do the alphabet, probably faster than I could. Even within that jumble of letters, he could see where all the letters were. It was like he could see them all at one time and just knew where to grab the A and then the B and then the C, using both of his hands and just – it was amazing to watch.

But then this friend on a whim again put them in a pile and put the Z down. I would say Zed if I was in Canada, but I will say Z here. And Jaden put the alphabet in reverse order as fast as he had put it in forward order, never having even done it that way before because he

just knew. He just knew that the letters go in that order.

Jaden does not have – when we try and describe Jaden, he does not have the savant skills like you would see in Rain Man or other sort of stories of autism. He does see the world differently. There is no question. There is skill set I can identify. He is a terrible artist. He gets that from his dad. He cannot draw anything. I cannot draw anything. Music is a challenge for him. Even rhythm is a challenge for him sometimes. He does have this unbelievable ability to see the world differently.

Because he was included in musical theater and because he has been included in the classroom all this time and because he is surrounded by people for whom their normal life includes Jaden and they care about how he does, they also started saying what else can he do. I am not going to give it away, but I am just going to play the video right away.

My presentation used to end with the musical theater story, which is a nice feel good story. But then I went to a reporter friend of mine who does a lot of work with Autism Speaks and MC's the Autism Speaks Walks. I said to her I need you to do a story. I need it to show a different thing that I need to end with in my presentations. She did the story and then it got picked up by the national news in Canada and here it is.

(Video Shown)

HON. LAKE: You see a different side there. A couple of thoughts on what you just saw. First of all, interestingly, when you watch his expression when he is working in the library, it looks more similar to the CNN interview than it does to the other stories. I always say to people that is his game face. That is a completely different emotion going on in his mind. He is doing something he loves to do and he is serious about it. When he is working, often times you will see the tongue

out a little bit while he is working. He gets that from me too. But he is very serious about it. He loves to put the books away.

When he is finished working, sometimes he will cry because he does not want to stop working. How many of you cry when you are done working? Not very many. But he does. Maybe you cry for different reasons when you are done working, but he does.

He is even better than what you see in there. When he is walking around the library with that pile of books -- he has them sorted. He has them ready to put away and he is putting them away. He will stop and grab a book off the shelf as he is walking by because some kid put it in the wrong spot and he just notices it. It is like he has the shelves memorized. He will just without skipping a beat put it where it belongs on his way. That is working in a school library. But you see a skill set there that is definitely

something that is going to be transferrable for him.

We have to work on some challenges, some of the life skill stuff. He needs help sometimes to know when to go to the bathroom. He can go to the bathroom himself, but he has to ask. He does not work in a work environment all the time – if your employee has to be reminded to go to the bathroom. If he sees a service dog or even looks out a window at a work place and sees a dog outside, he might take off. It would be something that would be risky.

He is so excited to put those books away that when he has a cart in the bigger library that he has worked in, he will run over a senior citizen on his way to put those books away. He might not recognize people as much because he is so excited and so on a mission to put the books away. Those are just things that we have to mitigate. We have this incredible skill set there and we have to find ways to mitigate some of the

challenges to unlock his ability to contribute and contribute meaningfully.

The last video I am going to show you – one of the great joys that I get is the opportunity to share my kids with people. It is not just Jaden. It is Janae as well. But with Jaden, I could not do what I do without Jaden. Jaden is this unbelievably connected person that connects with people in a way that I do not know very many people that connect that way. I think I know anybody that connects in the same way he does when he meets you.

But he could not do what he does in that connecting way in terms of helping to raise awareness and all the things without me because I am his voice. He cannot talk. A lot of things that even when he does work on his computer or write, it is so concrete. One-word nouns kind of thing. That is the way he thinks. He needs me to help communicate for him. We get a chance to do it together, which is in my mind the essence of

what life should be in general regardless of labels and other things.

My daughter in this clip that I am about to show – I love the fact that my daughter is in a 45-second clip at the end of this four-minute video that I am going to show you. She was 13 at the time. She gives probably what I would say is the best answer to any question – better than any answer I have ever given to any question as a 13-year-old girl at the end of this clip.

The context here is that last year we spoke to a group of 15,000 students in an arena in Saskatoon in Saskatchewan at a WE Day event. Jaden and I had a chance to go up. You will be struck by Jaden has no fear. He does not know that he is standing in front of 15,000 students. Or if he does know that he is standing in front of 15,000 students, he is energized by it. It does not scare him. It would scare some people with autism. Obviously in Jaden's case, he revels in the noises and the movement and everything

else that is going on. You will see that side of him as you watch this video clip.

(Video Shown)

HON. LAKE: When I think about Janae's answer there, she is obviously talking about herself. For her, she did not have a choice. She was both three years after Jaden. She had a brother with autism. That has been her normal. She is awesome and responded incredibly well to it. I know that some siblings have more challenge than that. There are some siblings come up in the relationship is exactly the same as Janae's.

The other take-a-way from that is I think about the other students in the school. Because Jaden has been included in a regular classroom, their normal includes Jaden. That is critical to me. I think that the idea that normal life for people includes people like Jaden, people like Jody, people like John. The more that normal life for all of us includes Jody and Jaden and John, the better the environment is going to be for

other people that come around after. Not just people with autism. It is going to change the way we think of the people around us. My normal is 47 years of what I have experienced. Jaden's normal is 21 years of what he has experienced. We all walk around and everything we have experienced is something that we have experienced personally. We have been that in that moment and experienced things that shape our lives.

The work that I do in my regular capacity is I am the critic for Global Maternal Newborn and Child Health for our party. I am opposition now. I was on the government side for ten years, but I am opposition in Canada now. In that role basically I work towards the old millennium development goals. Now, there are sustainable development goals on an international basis. But the ones focused on saving lives of kids under five and mothers in and around childbirth and a lot of work around the rights of women and girls so tons of work around those things.

The way that I would articulate my vision and my mission in life with this platform is I want every person with a developmental disability to have the same opportunities that my 21-year-old son had. I am not fighting for Jaden right now. Jaden has had a great life. The province we live in funded early intervention from the time he was two and a half. He has had a great experience in school and continues to have fantastic support right now. But I want every kid in the world to have that same support. I want every girl in the world to have the same opportunity as my 17-year-old daughter has. She could be prime minister one day in Canada if she wants to be. She does not want to be. She wants to be a music teacher. She will be excellent at that. But she can do anything that she wants.

One of the things that we are working on right on and then I will take some questions if anybody has any, but that would be relevant in this room is that we have been working towards

something that we are terming for lack of a better term a global autism partnership. Jaden and I just did a TED talk on Saturday, a TEDx talk in Toronto that is not on video yet. The argument that we make is as the world talks about whom the most vulnerable is around the sustainable development goals and reaching the hardest to reach and no one left behind. There were 17 goals that were focused on around the world. I think about hard to reach and vulnerable and how those apply to people with autism. There is debate around who those most vulnerable or hard to reach are. Someone might say it is a boy in a refugee camp in Syria, a young boy. Or someone might say it is a teenage girl in rural Africa dealing with things like early forced marriage and lack of basic education and all of the things that go with that.

I would say those are incredibly difficult circumstances, but either of those people could

have autism on top of that. What would that look like? How much more vulnerable would they be?

We ought not to get in a conversation too much about who is more vulnerable or less vulnerable. I think we have to be careful with that because even in this room, there are people that have vulnerabilities that are completely invisible to use that are absolutely life shaping for them and can be devastating for them. But it is a conversation we need to have.

If we can wire our hearts to reach a teenage girl with autism or another developmental disability in rural Africa, we are going to change the way we see all girls in Africa or all girls around the world. If we can wire our hearts to think about that boy in a refugee camp in Syria who might have autism or a developmental disability and reach him, we are going to change the way we see all boys. We are going to change the way we see all refugees and you think about some of the challenges we are facing at a global

level. We have the opportunity and an impact far beyond the autism world as we approach this.

I can tell you a little bit more about that if people want to ask questions about that. With that, I will wrap up this presentation and I will give John the first question.

DR. ROBISON: I would like to thank you for coming and presenting the videos and the story of you and your son. I think that last night we had a movie screen, which showed young people with autism in the Emirates who all had significantly more apparent communication disability than me and they had seemingly less communication disability than your son. I think that in both cases with the screening of the movie and with the advocacy that you are doing on behalf of your son and autistic people – I think that is really important work that we should support.

I would like to speak to the comment that I heard from some people after last night's film screening. I raised the question last night. If

the makers of the movie went to considerable trouble to show the autistic people in that film wrestling with communication challenges and they communicated in words. They communicated with story boards. They communicated in various ways. I said to the producers given that you showed that the autistic people could communicate, why then did they not tell their own story as opposed to having parents speak for them? They expressed a concern about their ability to tell the story.

At some point, that concern is not warranted. Clearly, I can tell my story as an autistic person. But it is equally clear that Jaden could not tell his story. One of the things that concerns me with the evolution of autism awareness around the world is that autistic people like me, verbal, articulate people have emerged in considerable numbers. We present an apparent face of autism to the public that is very different from that lived by your son or by

your daughter, Allison, or many other autistic people.

When I see things like this put up, it concerns me that sometimes critics in the autism community attack these presentations characterizing us as being made into self-narrating zoo exhibits, for example. I understand that people are concerned about that.

But I also understand that the only way we are going to build awareness of the reality of life with autism for Jody, for Jaden, for all these people who cannot speak for themselves is to present them with loving caregivers, most likely parents, who will present what is really a sweet story that the news media is going to want to show. I think that it is very important that we understand the context of that and that it is not taking advantage of a person with disability. Rather it is taking a person with an apparent disability and showing his strength and showing him finding his place in the world and it is

something I hope if the community can celebrate. I intend this really not only for you, but for the people who are listening to our webcast and reading about our transactions. It is really important.

The message for you as a member of parliament and speaking to us as a government body is how do we take a sweet story like that of your son and how do we translate that into a broader recognition in government that we absolutely need to be focusing on the kinds of quality of life issues that your daughter or that your son or that many other autistic people need. You make the point very eloquently when he stands up on stage that he is an autistic person with needs very different from me. We all need to be showing and respecting that different side of autism and we need to think how do we translate your story into actual constructive beneficial actions in America, in Emirates, and in Canada and elsewhere in the world.

HON. LAKE: Your comments are bang on. One of the things that I think is important to remember is we are a team. You and I and Allison and Jaden and Jody are a team. It is important for all of us to remember that when we are communicating as much as possible, we need to make that point about the spectrum and how broad that spectrum is. I cannot do it every time when I am telling Jaden's story. I cannot do it fully because I am telling Jaden's story. The nice thing about it is Jaden is in the middle. He can be an average representation.

How do we turn that into action? I think there is an aspect of building the broader awareness that is critically important. I think it still needs to happen. That is one of the reasons why I target intro psyche classes for the presentation. I can hit big numbers of people who are going to go out and be doctors and teachers and nurses and sort of a broad spectrum in society. But there is some real action that we

are working on as well. We want to get out and build that awareness among policy decision makers. This is what the global partnership is about. This is what the in Canada, our Canadian partnership is.

We are right at a critical point in time where we are pushing the government to fund a very minimal amount of money, $19 million over five years in Canada. That would be equivalent of about $190 million here because we are tenth the size.

Not to fund treatment. The is the provincial responsibility in Canada, but to put an expert working group together on anything that people with autism face and advise governments and their jurisdictions on what they need to do. We might have an expert working group put together by the Canadian Autism Partnership on early intervention, on housing, on transition, on education, on mental health, on a lot of different things. Any time we address or face

something within the autism community, we would work with governments and their jurisdictions to further the policy on that to give them sound advice. This organization, this partnership would not be a protest organization. There are advocacy organizations that can do that. This would be a trusted partner for governments to give them good advice on autism. That is what I envision the Global Autism Partnership to be as well.

It cannot be monopolized by one or any group of organizations. It needs to include all organizations as part of it. It needs to be an organization that includes in the US Autism Speaks and the Autism Society of America signing on, but the National Autistic Society in the UK and researchers around the world working together to form expert working groups so they can advise western governments, so they can advise governments in a place like Tanzania where I was last year on even how to identify autism because some of the senior doctors in that region do not

even know what autism is. They do not even know the word autism let alone everything else that goes along with it. Dealing with governments in the UAE and may be dealing with stigma there and things like that.

What we learned dealing with the UAE or from the video presentation that you guys last night, that is really incredible knowledge that should be shared globally. For anybody dealing with stigma, there might be an expert working group for dealing with specific cultures where there is a stigma attached and how to deal with maybe similar types of stigma and those kinds of things. This is the way I envision the Global Autism Partnership.

Right now, when I talk about this, so far we have had one video conference with 12 people sitting at the table to have a conversation about what this might look like, but these 12 people represent the WHO in Geneva, the International Pediatricians Association, UNICEF, the president

of UNICEF Canada, Vikram Patel, who many of you would know from his international work on mental health. These are people that we called March 22 to sit around a video and have a conversation about what – and Andy Shih from Autism Speaks is a big part of that conversation – what that might look like moving forward.

DR. ROBISON: May I suggest when you list organizations that you also remember to mention the Autistic Self Advocacy Network. It has impressed me greatly in the last years how they - -

HON. LAKE: I have just made a connection with them on March 31 in New York. Absolutely, they will be part of the conversation, a very important part of the conversation, but thanks for the reminder.

DR. REICHARDT: I have been to Montreal where I know they are putting together an autism research consortium. I, of course, know something of Brain Canada. I was wondering if you could

just compare what you see the balance of federal and philanthropic effort in Canada for autism science and where the major opportunities are.

HON. LAKE: One of the big challenges that I have had in Canada as we talk about a Canadian autism partnership and you will be able to relate to this is the competition aspect. Everybody has their thing that they are focused on. They are very focused on that thing, very passionate about that thing that they are working on. Building any kind of partnership is astonishingly challenging and it is understandable.

The group that we have working right now in the Canadian Autism Partnership includes the Miriam Foundation, which would be very involved in Montreal with some of the things going on with some of the other groups that are there. You cannot involve everybody. We have four researches. Steven Scherer is one of the 12 people on our expert working group. Lonnie Zwaigenbaum would be known to some in the room

here as well. Stelios Georgiades and Jonathan Weiss. That was the four researchers who were part of it.

We have really tried to capture in our working group in Canada – we have really tried to capture the – like I said, you cannot get everybody but 1 or 12 people to represent regionally and we want them to represent the broad array of organizations. They have a self advocate – sort of John's point. They have a self-advocate advisory panel of seven self advocates who have weighed in very heavily and are advocating very strongly for the Canadian Autism Partnership at the same time. It is something that sort of happened at a Canadian level.

But again, it is important as we build these partnerships that no organization that you are building a partnership that you are building is seen as yet another organization to compete with everybody else. It is so important that everyone

is a part of the partnership. That is what it is. It is a partnership. What do we agree on and how can we speak with one voice towards what it is that we agree on? Those are the questions that we had to answer in Canada. I think we have done a pretty good job of that, but it is the autism community. There is still a certain percentage that is really loud and asking for something completely different at times.

The answer for us is make sure that the coalition or the partnership is large enough that it clearly represents the 90 percent of the 95 percent to someone making a decision because I am on the decision-making side. For those of you that advocate in some way for policy changes, just understand that on the decision-making side that 5 percent is usually not seen as 5 percent. If the 5 percent looks like 50 percent because they are so loud, they are so vocal, they are so passionate then it is going to hamper any decisions we are going to make policy wise

because it is seen as too risky for a policymaker. This is the importance of partnerships.

Any time you are tempted to think that you can do it with 60 percent or 55 percent or something like that, you cannot. It has to be a bigger number. No one organization or no organization that represents just 60 percent can do it. We have to find those things that we agree on, which is a lot of things. We all agree. Early intervention has an impact. But if you are a policymaker with no background in autism and you hear one person say something different than that, it can cause chaos and cause you to make a different decision or put off that decision.

DR. GORDON: Thank you very much, Mike. I am afraid we have to move on. It is great hearing from you and you raised a lot of important issues to consider.

HON. LAKE: Thank you so much for the opportunity to be here and for everything that all of you are doing for families just like mine.

DR. GORDON: Now, it is my pleasure to invite Melissa Spencer, our newest member of the coordinating committee, to tell us about the Social Security Administration Disability Programs and their relevance for this group.

MS. SPENCER: Good morning. I really appreciate the opportunity to be a part of this committee and the presentation was fabulous. It just was really inspiring. It goes to show how important it is for our agency to not only be a benefits-paying agency, but to also begin to consider how do we transition anyone who is receiving disability benefits to be a contributor to move towards employment opportunities.

Now, I only have 15 minutes this morning. This presentation is way too long for 15 minutes, but I mainly included the information for your reference. If anybody has any questions, I will

be happy to take them today or any other occasion where we are meeting.

A quick disability one on one. For those of you who may not be familiar with exactly what benefits SSA provides for Americans, we have two disability benefit programs, Title II, which is the Social Security Disability Insurance Program. It is generally called the Workers Disability Program. You pay into it with your earnings from employment. And then we have supplemental security income, which is a means tested program, which is based on general tax revenues.

For Title II, again, you have to have work. You have to have recently worked. If somebody worked ten years ago, it was the last time, and now they are applying for disability benefits, it would be hard to say that someone can meet the disability requirements currently.

If someone is awarded benefits, they have to serve a waiting period before benefits start. One of the big things that comes with Title II

disability or workers disability is Medicare after you have been on the rolls for a couple of years, which is very helpful. My sister is on the roll. She has metastatic colon cancer and it has been a lifesaver for her in terms of helping her meet the gap for her chemotherapy treatments. It provides valuable benefits.

For Supplemental Security Income or SSI as it is known, there are benefits for adults and there are benefits for children. With Medicaid comes with SSI, another health insurance.

This is a really long-winded explanation for what the disability definition is. This is statutory. Essentially, disability means that you are not able to work for a period that is continuously going to last or has lasted for at least 12 months or is going to result in your death. The whole process that we have to assess Social Security disability eligibility is based around this statutory definition. For children, it is a comparable definition.

Very quickly, we have a five-step process. I used to adjudicate disability claims back in the '80s. This definition, this process has been burned into my brain. Essentially, if somebody is working even if they have a severe impairment whether it is an impairment on the autism spectrum or it is somebody who is a paraplegic, if they are working and earning at what the government defines as substantial gainful activity, they cannot be eligible for benefits.

The second step is we look to see whether or not the medically determinable impairment somebody has whether or not it imposes more than minimal limitations. And what we are looking at are things like standing, walking, lifting, carrying, paying attention, concentrating, and those types of activities.

Where we start to consider autism, which I am going to talk about in just a minute is at step three, which is a set of medical criteria that SSA has decided their regulation are severe

enough that by themselves are considered disabling. We do not consider somebody's ability to work. We consider the impairment at that level of severity to be enough to qualify for benefits.

If someone's medical condition is not severe enough to qualify, we then look at their function, their ability to work. We look at how much somebody can stand in a day, how much somebody can lift, carry, and again also the non-exertional limits, attention concentration, persistent, pace, get along with other people, communicate. That is generally the process that we go through.

I have defined all these here. I am not going to go over them again.

For autism in particular, in regulation, it talks about that we have to use a specific process to go through whether or not someone's impairment meets our medical requirements. We use something called psychiatric review criteria. This means that what we have to do is not only

consider the objective findings, but we have to consider what we call paragraph B criteria, which is all the functional information. These are woven in through many of our mental impairment listings, but also some of the physical criteria here. We are looking for the ability to remember, interact, concentrate, and adapt or manage yourself.

In terms of the rating scale, it is a pretty typical rating scale ranging from no limitation to being extremely limited. Essentially that means there is no meaningful function.

For autism in particular, I do not know if you are familiar with it or not, but in just early this year we published the first update to the mental listings in 30 years. It has taken us to get an update to the listings. Our mental listings cover every mental health impairment that there is. It took a long time to reach agreement on what was going to be in the listings. In particular, the biggest changes in

our listings were in intellectual disorders and some of the related impairments.

Autism spectrum disorder has been a listing by itself since 2000. But even in 2000, it was included in with other pervasive developmental disorders. Before then, it was included with intellectual disorders with what was formerly known as mental retardation. Just as was mentioned before that the terminology has changed. That is one of the big terminologies in the listings that have changed.

For autism itself, what we require is some specific deficits in verbal, nonverbal or social interaction and that there be significantly restricted repetitive patterns of behavior, interests or activities. Those are the medical documentation that we are looking for to assess any claim.

And then as I noted before, what we are looking for is either no meaningful function in at least one of those four areas or very limited

function in at least two of the areas. We assess that through getting information about function from parents, from teachers, from caregivers, from medical professionals who are familiar with the child or the adult.

I have included some information for you about just general how do you apply for benefits. You may have need for this in working with members in the community. The type of information that is required to file for benefits.

Here is some of the background about some of our demonstration projects. There are four that we pulled out where we thought there might be some interest. I am not the person who runs the demonstration projects. Bear with me if you have any questions. Probably I am going to have to get some information back to you. It is in my sister component. It is part of our research organization.

In the supported employment demonstration project, what we are looking at is if we put

different packages of services together for people who have been denied benefits and this is the first time where we are really now starting to focus on people who have not been declared severe enough to qualify for Social Security or SSI. What we are trying to find out is if we can intervene and help that person either remain in the work place or return to the work place. These are for young adults through age 50 and individuals with a mental impairment.

This is waiting. We have not got our final sites yet. Enrollment begins this fall. The months of service are going to go through 2020. I will be able to provide more information at a later time.

The second demonstration product is one you may have heard more about. It is promoting readiness of minors in SSI or as we call it and I think most of the people know it by its name of the PROMISE project. This is mainly for youth who have been on SSI and its improved coordination of

services to see if that can help an SSI child make the transition to at least some work as a teenager. This is working in several states. The states are listed. It is not a nationwide grant. Mathematica is going to be evaluating the project for us. It is going to include case management, benefits counseling, and career and work-based learning experiences and also help with parent training.

The next one is promoting opportunity demonstration. This gets into what some people say especially for the Title II or disabled workers program is sometimes there is not an incentive to work because if you work above a certain dollar amount, your benefits stop. Your Medicare stops. This begins an exploration of gradually reducing benefit amounts as your work earnings would increase.

At the point in time when your earnings would get to zero then your benefits would stop. However, your Medicare would continue for 93

months. This is randomly – again, we are recruiting and enrolling and randomly assigning beginning in October of 2017. More to come on that one.

The last one is the BOND, Benefit Offset National Demonstration. This is similar. It is a one dollar reduction for every two dollars of earnings that you have. Again, it is designed to test whether a benefit offset will encourage the return to work.

This is a large group. It involves 968,000 beneficiaries in stage one and nearly 13,000 in stage two. Again, it is providing help and support to the disabled individual to help them return to the workplace.

I have really run through these slides very fast. One thing that I would like to – this is not from the disability perspective – to encourage all of you to think about is registering from my SSA account. The more you establish your own account, the more you can be

informed about what your own retirement earnings would be, what your disability benefit would be should you become disabled. Ultimately, the plan is for every applicant to be able to file their claim online on mysocialsecurity.gov. I am not sure if Maryland yet has the ability for you to get a replacement Social Security card. I know myself with having teenagers who would routinely lose their Social Security card that you are going to be able to do much of that online without having to go into a Social Security office. That should get you to register and that you are going to be able to do that.

I am happy to take any questions. If not, thanks again for the invitation.

DR. GORDON: Any questions for Ms. Spencer?

DR. TAYLOR: I just wanted to say how exciting I think these demonstration projects and things that we see a lot are young adults or adults with autism who maybe don't qualify for

SSI, but would just take a little tiny bit of support to really make the difference for them.

And the other thing we see is people who – they may not want to work. It is not even the loss of the SSI income that they are worried about, but it is the insurance. Seeing these demonstration projects that are really tackling these issues head on I think is really exciting. Thank you.

DR. PELPHREY: Welcome to the committee. I am a parent of a 13-year-old daughter with autism. Having just finished paying off student loans, now my wife and I are working on planning for her future. We made an account and made an account for her. What we were struck by was just how complex the rules are for a family like us where we – we make a great living, but not enough money to effectively hide our money. We are right there. Just realizing the number of ways as we try to plan to establish a trust for her, to try to – we are very fortunate to be able to do that.

I am not complaining. But the number of ways we could effectively knock her out of any eligibility for the Social Security benefits that I have been paying into since I was 14, the seemingly trivial ways that she could be knocked out of benefits and my wife majored in finance and runs several companies. I do neuroscience, which qualifies me to be prevented from touching any money, but it is surprising that even with our sophistication so I cannot imagine a family with less resources and the amount of money we would spend on an attorney to help us figure this out. And then I started calculating how much attorneys must make, helping to interpret the laws.

I am not picking on you as much as just we, as a committee, thinking of ways we could possibly help to make this easier because I think there were a number of ways for a family with less means that they could knock their child out of receiving needed benefits or be so overwhelmed

that they are thinking I never want my child to work or achieve any independence because they will get nothing that they are entitled to, which is kind of throwing the baby out with the bath water so to speak. Just a comment on that and what we might do to help clarify that.

MS. SPENCER: I think that is another reason why I am glad that we are included in this committee now because I know there are actions we are taking such as the demonstration projects, trying to simplify our rules, which are incredibly complicated. I work in the program and they are incredibly complicated. I recognize that.

There are also the new ABLE accounts, which I am still learning about. But in terms of a child who is on SSI, it is the line of family resources versus the disabled adult child benefits for the worker. It is very complicated. I am looking forward to what can we do to help with public information that makes it clearer for

a family with a disabled member to apply for benefits and understand the process they are waiting through. I look forward to that discussion.

DR. GORDON: Thank you very much and welcome. By my phone, which is probably reasonably accurate, we are running only two minutes behind. We are going to take a short break to allow people to relieve whatever needs relieving or fuel whatever needs fueling. We will back here at 10:40, which is in eight minutes.

(Whereupon, the Committee members took a brief break starting at 10:30 a.m. and reconvened at 10:40 a.m.)

DR. GORDON: It is my pleasure to introduce our next speaker who is Dr. Scott Michael Robertson, a former member of our committee from 2012 to 2014, as well as Mr. Andy Arias from the US Department of Labor. They will be speaking to us about a recent report produced by the Federal Advisory Committee on disability employment. I

believe we also have the assistant secretary here as well, Secretary Sheehy – Deputy Assistant Secretary. At least it was an inadvertent promotion.

DR. ROBERTSON: Thank you for the committee for inviting us here to present on recommendations from the Advisory Committee on increasing competitive integrated employment for individuals with disabilities.

I am Scott Michael Robertson and this is Andy. We are going to be sharing the recommendations. I will emphasize multiple times throughout this presentation. The recommendations come from that Advisory Committee. One of the reasons that we are here from the Department of Labor is because that committee had a limited time period, but the final report lives on as the document that the committee disbanded and it had sent in the statute in WIOA, the Workforce Innovation and Opportunity Act. Last year is when the committee finished meeting after it has

issued its final report. That is why we are sharing the recommendations today. The recommendations were driven largely by the non-federal members of that advisory committee.

ODEP's core mission. I just want to share briefly and just give you a little bit of background on the Workforce Innovation Opportunity Act before we go into the recommendations. Just very short overview. Just to give you a little backdrop of us also as an agency is that we are the only non-regulatory federal agency that promotes policies and coordinates with employers in levels of government to increase workplace success for people with disabilities and all people with disabilities including people with significant disabilities.

ODEP's website is on here. There are also links to our campaign for disability employment. Every fall we have a new theme for the National Disability Employment Awareness month in October.

The website is there too. Next fall you will be seeing more what we call ending.

To give you a little backdrop on the space in autism and employment, I think many of you all know this, but I just wanted to go over it briefly. There are substantial barriers to employment access for autistic people across the whole life course. I can relate to that directly through my colleagues and friends and my own personal experience as an autistic adult who has experienced many substantial barriers in my own case on education and employment. It is both unemployment and under employment and are much higher among autistic people. Some of it is because of societal stigma, social-related challenges, et cetera. There are many different factors. It all converges that the unemployment and under employment are higher.

There is also less access to workplace learning and career exploration and career development for autistic youth and young adults.

There are a lot of workplace self-disclosure issues. A lot of autistic adults are very fearful at times and anxious about disclosing in the workplace because of the remaining stigma around autism that we hear around society. That has changed much I would say in the last several years, but that is still very prevalent. And a lot of folks really benefit from support – have the support to self-advocate about differences on things like body language and eye contact.

And alongside that improvements in our career pathways system and workforce development are needed for all people with disabilities, including autistic youth and young adults.

We need to be able harness gifts and talents of autistic people. There was actually a journal article that came out just last year from – I believe it was researchers at NYU that had looked qualitatively at the vocational interests of – the focused interest of autistic people and how it can relate back to employment that can help

drive the long-term career development and be centered around that. That study and some other literature I pointed to that we need to be focusing on the strengths of autistic people and other people with disabilities and increasing access to coaching, peer mentoring and other supports.

The Workforce Innovation and Opportunity Act improves employment access for everyone, including people with disabilities. This was a law that was signed into law just a few years ago, July 22, 2014, which emphasizes strongly competitive integrated employment for all people including youth and adults with disabilities. It customized employment and supported employment for people with disabilities as well as a major focus on aligning with all the other service systems, education, health care, all the other systems and all the other federal agencies and state agencies coordinating together on not only career access for people with and without

disabilities, but also employment-related supports on housing, health care, et cetera because you need to be able to have full health and wellness to be able to go to work. You need to be able to have some place to live, for instance, to be able to go to work. And an emphasis on business engagement through a development of career pathways.

Particularly WIOA promotes greater employment access for youth with disabilities. There is a major focus in there, including pre-employment transition services for youth with disabilities, pre-ETS under WIOA. This is for students with disabilities aged 14 to 21 who have eligibility under Individuals with Disabilities Education Act, special education, or the Rehabilitation Act Section 504.

It has four service areas: job exploration and counseling and work-based learning, counseling on postsecondary education and training, instruction in self-advocacy skill

development, and workplace readiness training to develop social skills and independent living skills, which relates back directly to social and emotional learning for youth and adults. They are much in line. It is very much a part of our focus at ODEP. I did serve on our youth team at ODEP. These issues are relying with a large part of our work and improving policies and practices.

Section 511 of WIOA improves access to employment for youth with disabilities by prioritizing competitive, integrated employment for all youth aged under 24. It emphasizes that as opposed to paying less than the minimum wage.

I am not going to get into on detail, but there are still allowable options for below minimum wage under the Fair Labor Standards Act. There may be in the future potential changes or shifts there depending on what happens. WIOA at least for youth was emphasizing particularly the improved employment access to competitive,

integrated employment as opposed to paying less than minimum wage.

There are three criteria that must be met for youth to actually be competitive, integrated employment. Competitive, integrated employment is assumed for youth. Receiving pre-employment transition services, applying for VR services and being deemed ineligible or have case closure without successful progress toward employment outcomes and then receiving career counseling and information and referral to other programs offering employment-related services. As you can see, there is really extensive array of emphasis on employment, supports and services across the board. It is really emphasized for all youth with disabilities including with significant disabilities.

WIOA supports equal opportunity access including for –- I have highlighted here in bold disability as well as other aspects of race, color, religion, sex, national origin, et cetera.

There is a guide that one of our technical assistants in the LEAD Center had put out on this Section 188 that is online that you all if you would like to can read afterwards that it available at LEAD Center's website.

WIOA charged the Advisory Committee on increasing competitive integrated employment for individuals with disabilities. We are just going to say the committee to shorten that here. And ODEP supported a coordination of the committee's activities. It had ten meetings between 2015 and 2016. And the final report of the committee was then released to Congress in 2016.

It has six recommendation areas. Andy is going to be sharing the recommendations.

MR. ARIAS: My name is Andy. I am so happy to be presenting with you. Scott and our boss is here, Jennifer Sheehy. I am just going to go over these recommendations really quickly. Increasing competitive integrated employment will require capacity building, capacity building for youth,

capacity building through changes in the use and oversight of 14(c) certificates, capacity building in the marketplace, capacity building in specific federal agencies, increasing competitive integrated employment for the AbilityOne Programs.

In order to have a more systemic capacity for CIE, which we always use some of the acronyms in the government. It needs to be guidance, policies, and strategies to prioritize federal funding for CIE. And then data collection and analysis requirements for recipients of federal funding based on a common definition of CIE and outcomes.

Funding and initiatives help for agencies building CIE capacity, developing national standards for professional competence, and train professionals for skilled in facilitating CIE.

A federal interagency taskforce focused on policies to expand capacity of CIE and advance economic self-sufficiency.

And then capacity building for youth. This is a huge focus for us at ODEP. We have a whole team dedicated for youth capacity building and early work experience is crucial. Family involvement and support is crucial. Professional development and training, systems integration for seamless transition, which means that all the systems have to be working together in order to meet that goal, which is the crux of WIOA of bringing and leveraging resources. Available and transferable assistive technology. That is huge too. If we do not have the technology and resources for youth to access the services then they do not get utilized successfully.

And then capacity building through changes in the use and oversight of 14(c). Scott, I thought you were going to go over this section. Is that correct?

DR. ROBERTSON: Would you rather I do the rest of the recommendations?

DR. ARIAS: You could do this part and then I can go at the very end when we talk about the committee. That is perfect.

DR. ROBERTSON: I am going to share the rest of recommendations. The capacity building through changes in the use and oversight of 14(c) certificates. I am not going to get into too much on the complexity, but this is basically what the parts of the Federal Labor Standards Act that allows for paying of wages below the federal minimum wage. The committee is amending that law to allow for multi-year, well-planned phase out of Section 14(c).

The Wage and Hour Division of the Department of Labor engage in more oversight of the current use of 14(c) and the federal government would assist states with building capacity of service system to ensure competitive, integrated employment as an alternative to 14(c). It is not just recommending the – but recommending we have

the infrastructure in place is what the committee is saying to go alongside the phase outs.

Building capacity in the marketplace. To increase competitive and integrated employment require more effective communication and outreach. The business-oriented professional development for services personnel. Work incentives to support access to employment and benefits counseling and financial coaching. This is particularly important. I believe you all had a presentation earlier on benefits and social security. A lot of autistic adults are just like other folks with disabilities are on benefits. Having that benefits counseling available so folks know when they shift to employment what that is going to look like is particularly important so they can plan that out and make sure that they think really carefully in terms of having a thought out career development plan that includes their current situation around benefits

and as well as financial coaching for financial literacy and financial management.

Capacity in the marketplace is also around increasing competitive, integrated employment for transportation access, initiatives in high-growth industries, including health care, outreach to federal contractors who are required under Section 503 of the Rehabilitation Act to have affirmative action, hiring plans, utilization goals to hire more people with disabilities as well as revisions to federal tax incentives and credits to employers to incentivize hiring people with disabilities.

And the last couple of areas, capacity building in specific federal agencies. That is going to require partnerships and actions among multiple federal agencies, including for establishing a cross-agency working group to provide policy guidance and technical assistance on integrated day and wraparound services that complement and maximize competitive integrated

employment to advance socioeconomic status and security of all people with disabilities.

Demonstrating how waiving the requirements in the Ticket to Work program could enable youth receiving Social Security to access services including SSI and SSDI to access services across systems that lead to competitive integrative employment and developing a policy reform initiative designed to increase the number of beneficiaries in Social Security to have access to competitive integrated employment and attain self-sufficiency.

And then the last area is reforming the AbilityOne program so that it can create more opportunities in competitive integrated employment on a broader scale including by amending the Javits-Wagner-O'Day Act to align that act with modern disability laws including the Americans with Disabilities Act and the Rehabilitation Act and policy goals by reforming

the criteria for contract procurement selection and program eligibility.

Researching the current use of how the program is serving people with disabilities to determine steps for improving its ability to create competitive integrated employment and evaluating the implementation and impact of AbilityOne reforms.

Andy is going to share just the last summary from the committee.

MR. ARIAS: I will give you a little back story on the committee. I was privileged enough to be asked by Jennifer Sheehy to come and present to the committee on an initiative that I was working on in California. It was new to me. I had no idea what Office of Disability Employment Policy was. I just knew that they were a great panel of advocates and professionals and federal partners were coming together and working on something really important.

Jennifer had said would you like to come work for us. It was a real privilege for me because I grew up working in the system of working with the ILs which are the independent living centers. I grew up actually in the system, growing up in foster care and then moving out of the system to competitive integrated employment. This is why I feel like the report and the committee's work is so crucial because it is real implementation. I got to see that firsthand.

The work on the committee. Its formations and recommendations were intended to increase opportunities for individuals on I/DD, which are developmentally disabled or other significant disabilities. I have CP. Essentially, I have what is considered a significant disability.

Ensuring that CIE is the first option for people with I/DD or other significant disabilities will increase their employment. It is not like an afterthought. It is not like let's get people the only job that they can have. It is

really looking at what is the most successful track that we can put – employment first, which is also an initiative that we work on at ODEP. What is the employment first track that we can put individuals on to move them forward?

And then also making sure that the usage of Section 14(c) certificates for paying subminimum wage utilized in the right way, minimized when they can be to making sure that people with disabilities have the best opportunity for success and economic advancement.

A critical pathway for an economic future and developing self-sufficiency for all youth and adults with disabilities.

Now, we are open for questions.

DR. GORDON: Before we take any questions from the committee, Ms. Sheehy, would you like to add anything to the presentation or make any comments?

MS. SHEEHY: Thank you so much for having us. We really appreciate this opportunity. I would

just say that we received over 3000 comments from the public during the process. There were a lot of important issues the committee addressed and many of them were very emotionally charged issues. The committee spent a lot of time considering the public comments and input, other presentations. We had presentations from organizations on all sides of all issues.

This document is not just hopefully a report on a shelf. While we do not, as the Department of Labor, of course represent the recommendations, I know that the committee members are still anxious to work with organizations to really increase the integrated employment opportunities to the extent that they can.

DR. GORDON: Thank you. We really appreciate the work of that committee. You have already heard this morning how important this issue is to individuals with autism. It has been a growing focus of this committee to focus on transitional

age youth and adults and supportive employment opportunities are crucial in that endeavor.

Are there comments or questions from anyone else on the committee?

DR. GORDON: Thank you very much.

Now, I would like to introduce our next speaker and the final speaker of the morning before we move on to the committee business and that is Dr. Ed Brodkin, who is an associate professor of psychiatry at the Perelman School of Medicine at the University of Pennsylvania. He is going to be talking to us about his work on services research for adults on the autism spectrum. This work has been funded by the NIMH as part of its serve ASD grant program, which funds researchers to develop innovative models to improve services for children, transitional age youth and adults on the autism spectrum. Ed, thanks for joining us today. We look forward to hearing what you have to say.

DR. BRODKIN: Thanks very much, Dr. Gordon, and thank you the members of the committee for inviting me. I really appreciate the time to tell you a little bit about the work we are doing at University of Pennsylvania.

The title of this brief talk is developing services to enhance social functioning in adults with autism spectrum disorder. And as this audience knows very well, the two main symptom domains of autism spectrum disorder is defined by DSM-5 are number one social interaction and social communication domain and number two the domain of restricted, repetitive, stereotyped patterns of behavior and interests. I am going to be focusing really on the first domain of social interaction and social communication. I am going to be focusing on this in adults and transition to adulthood.

As we have heard about this morning already and we just heard from Dr. Gordon, there is really such a need for increasing focus on the

treatment and services for adults with autism spectrum disorder. I know this committee has been really focused on that and NIMH as well.

I will just give you a sense of it. Approximately 500,000 to 600,000 adolescents with autism spectrum disorder will enter adulthood in the next decade just in the United States of America.

What are some of the challenges of transition to adulthood? Typical challenges and of course this varies. There is tremendous heterogeneity as we have heard about this morning. Some of the challenges might include completing secondary or post-secondary education, transitioning from an educational setting to a work setting, developing social and communication skills necessary for adult life, which are actually quite – there is quite a bit more social demand and subtlety involved in adult interactions, as you know. Engaging with peers and the community, developing independence and

the ability to function once one's parents become elderly or pass away, as we heard about a little bit this morning as well.

I would argue that difficulties with social functioning heighten all of these challenges of transition to adulthood and may be perhaps a key challenge of difficulties with social functioning. There is a tremendous lack of evidence-based treatment programs to improve social functioning in adults. That is what this project funded generously by NIMH is trying to address.

Just to give you a little bit more of a sense of the need here, this is from a paper from Patricia Howlin in the UK in 2013, looking at social outcomes in adults on the autism spectrum. And this I will just point out is social outcomes in mid- to later adulthood among individuals with ASD and average non-verbal IQ as children. This is not an intellectually disabled group. This is

an intellectually able group on the autism spectrum.

I know this is a lot of numbers, but if you focus on the numbers in the parentheses, that will give you the percentages. For example, of this sample, 63 percent never have had any peer relationship involving selectivity or sharing. Seventy-seven percent had never had a reciprocal relationship, a close relationship, intimate relationship.

If you look at employment outcomes in this same sample, 55 percent had never worked in any kind of setting, even a sheltered workshop or supported employment. This just really highlights the level of need and the importance of this topic.

As I was arguing, I think that social functioning is a crucial component of these different abilities of functioning in adult life. When I say social functioning, what do I mean? Just to give it a definition, I mean the ability

to navigate the social world in "real world settings" including home, school, work and the community. This is not just a laboratory measure of social cognition, but this is actually social functioning in real life.

Difficulties with social functioning have been cited as one of the main barriers to employment, independence, and overall functioning in adults.

But the thing about social functioning is it is really complex. It actually involves a tremendous repertoire of behaviors that typically developing folks take for granted.

For the purposes of this project, we broke it down into three main domains we call them of social functioning. The first domain you might call the motivational and emotional domain. Social motivation. A basic motivation to engage with other people and also anxiety. We all have some degree of social anxiety, but do we have the ability to regulate that anxiety so that

interacting with others is not really intolerably anxiety provoking? That is the motivation and anxiety domain.

A second domain is cognition and skill so social cognition so basic understanding of relationships of the social communication, the social cues that go back and forth between different people and also social skills, not simply an intellectual understanding of those communications, but the actual ability to implement communication and interact with others.

Finally, the third domain is what we call the context and community domain. Taking that understanding, that cognition and those skills and actually being able to generalize them to real-world community settings in different contexts.

All of these are really necessary we thought for true social functioning and a kind of intervention narrowly focused on one aspect of

social cognition, we were skeptical, would be sufficient to really address all of this.

Because of the heterogeneity that we are all familiar with, we know that some individuals on the spectrum may have more difficulties in some of these areas than others. Some may have really prominent social anxiety. Others may not. Others may have much more difficulty with certain aspects of social cognition and others may not. We need to develop something that might address these different domains.

As Dr. Gordon mentioned, we are lucky enough to get this R34 grant from NIMH that runs from 2014 to 2017. And the objective is to develop and pilot a new treatment program to improve social functioning in adults with ASD.

We designed this program to try to address these three main components that I just told you about of social functioning. Our strategy is to focus on what we call the fundamentals of social functioning. Rather than focusing on very applied

in a particular kind of social situation like a date, your third date. What do you say or something like that. We focus more on the fundamentals so things like tuning into our own state and the state of other people, the ability to understand and navigate emotions, the ability to understand and navigate what is going on in a conversation and generalize these skills. If this seems a little vague, I will be getting into the details in a few slides what this really involves.

I just wanted to point out though that the treatment program incorporates a variety of therapeutic tools. It is an eclectic treatment program that incorporates. It is not sort of a narrowly, only a certain kind of treatment orientation, but it includes elements of I would say cognitive therapy, behavioral or ABA type therapy as well as mindfulness-based approaches and sort of woven together in one intervention.

The outline of the flow of this study was that we went through a phase of determination of eligibility. We had pre-treatment assessments, which I will tell you more about. And then there were three main components of the intervention, which mirror those three main domains that I mentioned of social function.

Component 1 consisted of five weekly individual sessions, focused on social motivation and social anxiety. I am going to go into a little bit more detail in each of these. In terms of motivation, we addressed what the person's goals were and their motivation. We had some elements of cognitive coaching, exposure to social interaction, and mindfulness interventions.

In component 2, we focused on social cognition and social skill. We had eight weekly group sessions that involved didactics on social cognition and skill training, using video modeling of social skills.

And then in component 3, the generalization to community. We had four weekly sessions that involved participation in a volunteer work team. When this was over, which took 17 weeks, we had post-treatment assessments.

Let me go through each of those in a little bit more detail. In terms of eligibility because this was an adult study and that was what the RFA from NIMH was about, this involved adults aged 18 years or older with a diagnosis of autism spectrum disorder who can attend weekly sessions for approximately this five-month treatment period.

Exclusion criteria for this particular study and I will say more about this were intellectual disability, current severe psychotic symptoms, current severe mood symptoms, current severe substance abuse or recent suicidal or aggressive behaviors. The intellectual disability part. This particular intervention was design for more intellectually able individuals on the spectrum.

But one of our future directions is to modify this and tailor it for intellectually disabled individuals, which I will mention more at the end.

The setting for this was at the Perelman School of Medicine at the University of Pennsylvania. We also got a lot of great collaboration and help from the Center for Autism Research at Children's Hospital. Kudos to Bob Schultz back there who helped a lot.

This was a pilot study. I am going to present data on two cohorts of 20 people. This is the breakdown. You can see it is predominantly male and we are not happy with the diversity of this sample. We have plans for ways to increase the diversity, which I will tell you more about in the future larger studies.

And then in terms of the study design and timeline. This is like a diagram of what the study flow was. Here was the recruitment and eligibility determination. We had round one of

assessments, which I will tell you more about. And then we had the 17-week treatment period.

During this first 17 weeks, Cohort 1 underwent the treatment and cohort two underwent treatment as usual, meaning they did not undergo our treatment. They just had their usual – whatever their usual treatment was in the community.

Then at time two, we had a second round of assessments. And then in this next period, the two cohorts flipped. Cohort 1 went back to their usual treatment in the community and Cohort 2 underwent the study treatment. And then at the end we had a third round of assessments.

We were actually able to get some additional internal funding from the University of Pennsylvania to also run some typically developing controls in these assessments, which I am not going to really present those data for you today. Again, this was really to just develop,

optimize, and pilot the intervention for a larger study in the future.

What did our assessments consist of? This is Ashley Pallathra who coordinated the whole study. With these assessments, we also got help from some faculty members at Penn, Monica Calkins and Julia Parish-Morris at the Center for Autism Research and CHOP. And basically, I am sticking with this structure of three domains: motivation anxiety, cognition skills and generalization. These are assessment battery. I will not go through all these in great detail because I do not think we have time. But if there are questions, I am happy to answer them.

We basically picked a series of assessments that we thought would tap into each of these domains that we were interested in. Some assessments of social motivation, social anxiety, social cognition and attention, social skills. We used something called the Contextual Assessment of Social Skills. A measure of the size of the

individual's social network and their overall psychological well-being.

Many of these measures come from autism research. But what we have found was there was really one of the needs also is a need for better measures of these various domains particularly in adults with autism. Some of these measures we borrowed from other literatures like other mental health literature. I have been working with Bob Schultz and other colleagues at Penn and CHOP to optimize some of these measures. I think you may hear more about that later today from Bob.

Just to take you through the components of the intervention. Component 1, the one focusing on social motivation and social anxiety. What this consisted of was once, weekly, hour-long individual sessions for five weeks. This was with Ashley who was the coordinator who I mentioned earlier. And what we addressed in these five sessions were these major areas. One was we started out really practical. Logistics. How are

you going to get to the sessions? We are asking you to participate in the 17-weeklong intervention. Let's start with the real practicalities like do you have a calendar. What is your transportation going to be to the sessions? Things really having to do essentially with executive functioning and organizing yourself and so on. Because we knew if you did not show up, you are not going to benefit from the program.

The second part was building motivation and so social motivation. One thing I wanted to say about that is that our goal was really not to try to turn everyone into an extrovert. We certainly respect diversity and not everyone is very highly socially inclined. But what we really started with was more of a motivation interviewing approach where we asked the person like what is important to you. What do you enjoy doing? What are some of your goals? And then we started to look at when we look at what you value and what

you want for yourself, where would it help you to feel more comfortable and capable with interacting with other people? How that might help you? To try to build motivation in that way.

Our fallback if we really could not get any buy in on that, if participants really could not identify any way in which they thought social interaction might be of interest or value to them, we would say what if you just cannot avoid it. There are certain situations in life where whether you like it or not, you are around other people. Wouldn't it be nice to feel more comfortable and less anxious and less overwhelmed in those situations? In these ways, we tried to build motivation.

In terms of the social anxiety piece, we really went through a series of both cognitive approaches so thinking about thoughts, feelings, and behavior and automatic thoughts and self-monitoring of their own feelings and then some exercises to learn to regulate emotion, using

mindfulness-based approaches. This started with solo exercises where they would learn some ability to focus on their own breath and to calm themselves down. And then we started to integrate this more into social interactions. We had conversation and listening exercises during which they would simultaneously try to listen to the other person and also regulate their own emotion using some of these mindfulness techniques.

Then in Component 2 the social cognition and social skills domains as I mentioned I think earlier. This was eight weekly group sessions. There were two parts to these sessions. The first part was the didactic part that lasted about 30 minutes and the second part was a 60-minute video modeling and practicing of social skills.

The didactics was really focused on social cognition like understanding social interactions, things like where do you direct your attention to get social information. Where do you look at the person's face? How do you pick up on facial

expression cues, body language, interpersonal distance, perspective taking? How can you start to take the other person's perspective in the situation? And then as I mentioned in the social skills part, use the video modeling approach.

Video modeling is an evidence-based intervention that is proven effective in building social skills in children and adolescents with ASD. Basically, the approach to this – this is Jim Connell and Jessie Day-Watkins at Drexel who are collaborators on this. The approach to this was we had largely students from University of Pennsylvania who we trained as actors to set up certain social situations and then we saw what the person's natural response. They knew it was an artificial situation, that it was a practice situation. But we saw how we responded to that. And then if we felt the need to teach them something, we would show them a short video clip of a person doing that skill and then say try it this way and they would try it again.

To show you what those were for Component 2 – on the left hand column – on the left most column I have the session number one through eight. In the middle column here, I have the social cognition didactics. These were the themes of the social cognition didactics that we talked about. I am not going to go through them again for the sake of time.

For the video modeling of social skills, we did a baseline assessment. We looked at really fundamental skills like picking up on cues that it may not be a good time to approach a pair of people who are talking or picking up on cues that this might be a good time to approach. Like at a meeting like this, how would you know when two people are talking to each other that maybe this is not the moment to approach them or maybe this could be a good moment? And then how do you go about initiating conversations, breaking the ice, aspects of reciprocal communication, conversation, listening skills, empathic

responding and then trying to weave this all together into a natural flow from approaching, greeting, initiating conversation, maintaining a conversation.

Just a little bit of a hint of the data on this. I will show you more data later. This is just an example of some of our data with one of these skills, which was acquisition of a social approach and a greeting skill. Basically, what this shows you is on the X-axis is the probability of success. What that means is we had multiple exemplars. For each one of these sessions, we had multiple examples of an opportunity to carry out that skill. We looked at the percentage of time they got it correct on the X-axis.

The Y-axis is which week we were on of these eight weeks. The red line is where we introduced the treatment of this particular skill, in other words, the introduction of the video model. You can see before the red line, their baseline of

this group in Cohort 1, they were not doing very well. Their probability of success was somewhere from 10 to 15 percent. And then when we introduced the video model, their probability of success in carrying out this skill was much higher.

And then the last part of the intervention was what we call the context and community part of the intervention. This was generalizing the social understanding and skills that they learned in the earlier part of the intervention to a community setting.

The goals of this were to practice their newly acquired social understanding and skills in this real world setting by participating on a volunteer work team. The volunteer work was done at the Ronald McDonald House in Philadelphia. Many of you may be familiar with it, but it is a philanthropic organization that helps families who have sick children in the hospital basically.

They provide sort of like a hotel and meals for families who have sick kids in the hospitals.

Our participants were part of a volunteer work team that was both individuals on the spectrum as well as study team members and other typically developing folks who worked together to prepare meals. The way we look at this – this is just a little bit more about the Philadelphia Ronald McDonald House.

There were multiple reasons that we included this. Number one, it was an opportunity to generalize this to a community setting, not just a clinical setting.

Number two, you heard about employment earlier. It depends on the individual, but some people on the spectrum really have not had work experience before. This was an opportunity although brief and though not competitive employment, but to get a sense of what is it like to work as a group and be part of a work team.

And also another thing we worked with a professor, Femida Handy, who has done some work on the benefits of volunteer work for various individuals. There is quite a bit of evidence from other studies, not of people on the spectrum, which individuals who are socially isolated can really benefit from volunteer work. For people on the spectrum who – for adults on the spectrum who have been treated for much of their life as if they have a disability and in need of help, this sort of turns it on its head in a sense that shows that you can actually help others like families who have sick kids in the hospital and you can make a meaningful difference. Part of this included some introduction and education for them about what this organization was about and the impact of their work and that these meals were going to families who were visiting their kids in the hospital and so on.

And then as follow up, we are in the process of re-contacting participants 3, 6 and 12 months following the end of the study to see whether they decided to continue to engage in volunteer work, et cetera.

Just a little bit about the data. The data I am going to show you here in this slide is really from Time 1 and Time 2. If you are remember that diagram of the slide, there are three time points. This is really just a preliminary data analysis. At Time 1 and Time 2, remember, Time 1 was baseline for everyone. At Time 2, Cohort 1 had gone through the intervention, but Cohort 2 had treatment as usual. Really here we are comparing Cohort 1 to Cohort 2 so the cohort that had gone through the treatment and the cohort that did not.

We are looking at two measures. One is the social responsiveness scale, which I think many of you may be familiar with. It is basically a quantitative measure of autistic traits

essentially developed by John Constantino. And what we found was the higher the SRS score, the more symptomatic someone is. We found that Cohort 1 that went through the treatment – if you look at the percent change from baseline, Cohort 1 had a significant reduction in their SRS score relative to Cohort 2, which was good. That is what we were hoping.

And then we looked at the Social Network Index, which was basically a questionnaire assessing numbers of people in their social network in their day-to-day life. Again, there was a significant difference between Cohort 1 and Cohort 2 where Cohort 1 seemed to have a significant increase in their social network index.

This is a very limited sample size. It is a very preliminary analysis. We are also presenting this at IMFAR. But it just gives a taste that perhaps this is having a good effect, but we definitely need more data.

Our future directions are to complete data analysis for Cohorts 1 and 2, refine the procedures based on the experience and data from this pilot study, and then apply probably to NIMH for larger-scale clinical trials with larger number of participants to more fully test the treatment.

And the big if. If it is effective to think about disseminating this to community mental health providers. This is a way that we can make our participant pool more diverse. I have been working with David Mandell at University of Pennsylvania. We have developed partnerships with local community mental health centers. I think we can really recruit now quite a diverse set of participants for larger studies.

To develop more advanced modules for development of social understanding and skills and then to develop a program in the future that is more suitable for intellectually-disabled participants.

I have two or three minutes left for questions. But just really quickly, our team. Ashley Pallathra, I mentioned, who coordinated the whole study. And then we had a terrific set of collaborators, some of whom I mentioned, some of whom are at UNC like Gabriel Dichter. Bob Schultz I mentioned and several people at the Center for Autism Research at CHOP.

DR. GORDON: Thank you.

DR. ROBISON: With the study that you just presented, I would like to offer a quick comment first of all about something that bothers me more and more about these presentations of studies. Scientists often seize upon phrases or statistics that become boiler plate in things that we tell people. They are sometimes very misleading. At the start of your study, you had this slide that said 600,000 teenagers will become autistic adults in the next few years. And what bothers me about that is it is a fear mongering thing and frankly is meaningless because what we know is

that for every 500,000 autistic children who become adults in the next few years or 145,000 or 495,000 or whatever the number is of older autistic adults will die. The rate of increase of autistic adults is not 500,000. It is the rate of increase in the population plus whatever rate of change may be in autism in our country. It is a tiny fraction of that number. To say that is both disingenuous and it is totally disrespectful to older autistic people. It makes us appear that we do not exist.

My question then about this particular study is that you got what appeared to me to be constructive beneficial results that would in my opinion bear support to see if we can make something more of it. But when I look at what you did as far as how you structured it, it read to me as if you structured a study for late teen years or very young adults. I would not have regarded the goals and approaches as appropriate for me as a 60-year-old autistic person and

therefore I do not think you did an adult autism study. You did specifically a young adult autism study. I think that we need to distinguish that clearly.

And the reason that is important to me to keep hammering this is that almost every other issue of the mind, disease, disorder that NIH is involved with, the leadership of the agencies are older people. They are rightly concerned about things that will happen to older people. We have older people having oversight over stroke, heart disease, diabetes, cancer, what have you. In autism, we have very young self advocates speaking out and we have parents. But the fact is older people are the majority of the population. We have to keep that focus. When a guy like you wants to do a study in my opinion, NIH should be focusing more on what is the age group you are going to serve and how are you going to do it.

And the final thing that I would like to say and I know it sounds like I am really coming down

on you about this, but I do not mean this as a criticism of you. I think you presented us a good piece of work. I see over here that we have some African American folks who are here interested in issues that affect autistic people of much more modest means in cities in New Jersey. I looked at the questions that you framed there and I asked myself if I was such a person how meaningful would that be to me or have I heard the results of another study that was based on a bunch of reasonably affluent white college students. I think that is why and maybe you would say no, John, that is not true. We had a very broad demographic. But I would say that is a key slide you should be presenting. That is a lot more meaningful than the 500,000 people slide. How are we going to speak to the issues of these folks here and the folks who represent the many other diverse autism communities in our country?

I would say that you show a promising result and I comment you for that. I would vote to

support you in continuing the research. But at the same time, I want to keep us focused on the greater goal and that is truly serving adults and the group you presented was only one small segment. Let's throw away this 500,000 thing. That has no place in these things in the future in my opinion.

DR. BRODKIN: I genuinely appreciate your frank comments. I am not going to make this better unless I get people who speak up and are critical. I apologize if I made it seem as if I was discounting the older adults. In my clinical practice at the University of Pennsylvania, I see quite a number of middle-aged to even older adults on the autism spectrum. I actually am very interested in the welfare and ways to help that segment of the population.

What we did in this study – I will be perfectly frank. The eligibility was 18 and up, 18 to 99 or above. And what we found unfortunately – fortunately or unfortunately is

that the group that came to us was sort of from their early to mid-20s to their mid-40s. I think the oldest participants we had were in their mid-40s. We did not get anyone above that.

The eligibility was certainly open for them. And basically, I think what we were finding and this is one of the challenges that we may need to really think carefully about in the future study is that often times to be perfectly frank it was the parents who were bringing their young adults to us for whatever reason and maybe we were not getting our message out well enough. The older adults whose parents might not be around and still advocating for them were not bringing – they were not seeking us out even though we tried to contact local organizations for people on the autism spectrum who include older adults. That was an issue we faced. I agree that we need to think more about that.

I appreciate what you said about the 500,000. I need to think more carefully about how

to present that. I think there is a very large number of middle-aged to older adults on the spectrum who were there who are entitled to services. It is really an important question on how to access that and thinking about how to make the participant base more diverse. I think this partnership that we are going to have with community mental health centers and so on – we are really going to think carefully about that as well. I appreciate your comments.

DR. GORDON: We are out of time. But there were three hands up and I think I should allow the three hands. We will start with Dr. Dawson and Samantha Crane and then Larry Wexler. I am afraid that will be it. I am sure you can converse over lunch.

DR. DAWSON: Thank you for that presentation. I really liked the way your approach was so comprehensive. You do not really see that often. I think that makes a lot of sense.

What I wanted to ask you about is as we develop more interventions for adults with autism, how did you think about the measurement of outcome in a study like this in terms of both reflecting the personal experience of the person that is participating as well as perhaps having an outside viewer that is assessing how well this person is doing? I do not know whether that is a pharmacological study or others. I think people are really struggling with how you do that and whether people are able to report on some of their own symptoms reliably or yes they are and how do you do that. Are there good measures of that? I just wondered how you struggled with that.

DR. BRODKIN: That is a great question. I think it is a really important issue for how do we monitor treatment response. Basically, what we tried to do to answer your question is we used a combination of self-report measures, informant report measures, and performance-based measures.

Some of the measures were self-report questionnaires in which the participants could say how they felt they were doing, how they were feeling, including a scale of psychological well-being.

Then there were some informant report measures like the SRS and others. And then there were some performance – one might argue more objective performance-based measures like we used this battery of social cognition developed by the GRS of the University of Pennsylvania. That is a time test of emotion, identification on faces and so on. And even you might say that the video modeling in a sense was a performance-based measure. Their performance on those skills was assessed by someone. That is how we approached that.

I really feel like you are getting at an important question though. I do not feel like our assessment battery was perfect and I feel like there is a lot of need for better, more reliable

assessment measures and quantitative assessments that could see quantitative change with treatment.

You are going to hear some interesting things from Bob Schultz later today that I have had the privilege to work with him a little bit on that might be of promising interest.

DR. GORDON: Please keep the questions and answers as short as you can.

MS. CRANE: I also wanted to have a little bit of a comment on the assessment choices. I think it is going to be really interesting as you track what I would call the actual outcome assessments, social contacts and integration into the workforce. And the reason is that as an autistic individual, I am incredibly not convinced that ability to recognize emotions is measured by an assessment has any likelihood of predicting your job success unless you are a therapist or maybe an actor, something else. Most of the time if I want a job doing – the first

speaker. I cannot remember. His son's name is Jaden – doing what he is doing, which is sorting books or whatever. What he is going to need is the ability to follow instructions, the ability to follow very specific workplace norms and the ability to say – have kind of friendly interactions with people, but not necessarily deep emotional interactions with people.

I also have a workplace that is all autistic. When we are integrating a new person into our workplace who has not been in the workplace before, one of our main challenges is taking what people social skills training already was and saying that training is how you make friends. That is not what you are doing here. We have to talk about the office. I think maybe neurotypical people do not realize how completely different these skill sets are.

DR. BRODKIN: Those are great points. I know Dr. Gordon wants me to keep my answer brief. I would just say that I agree. Not every job

includes a lot of social skill or certainly not friendship types of social skills. But there are certain situations like when your boss gives you certain feedback let's say that you have to navigate some social interaction or there is stress. Just managing emotion regulation and stress I think can be important issues.

MS. CRANE: To clarify, I am not saying that it is not a social skill. I am saying that the measurement of people's ability to recognize emotions is not predictive of that skill.

DR. BRODKIN: That is a good point. I agree.

DR. WEXLER: Thank you. I will try and be brief and not frank. I was just wondering methodologically, from what you described, you are using a lot of undergraduates to do rehearsal kind of activities, some role playing kinds of things. I am wondering if you have considered as you scale up and apply for bigger bucks and larger samples the use of life size avatars. We are doing a lot of work with life size avatars.

We are finding ten minutes in front of the screen is equal to hours of actual practice. You could do repeated practice. You could do consistent practice. And the avatars are not subject to human subject review, which frankly can really be a freeing experience. You can expose people to behaviors that might not – that could be questioned if they were live action.

DR. BRODKIN: I think it is a great idea. I have been working with some people at the Center for Autism Research at CHOP on some of that work in a related project. I think it is a great idea.

DR. GORDON: Thank you very much. I appreciate the enthusiasm on the part of the committee. That is why we allowed things to go over, but it does mean we are pressed by time. I trust that Susan will find a way to make it up so we don't go too much into lunch.

Now, Susan Daniels is going to lead us in the discussion of committee business.

DR. DANIELS: Thank you. I know we have a lot of important things to discuss. If we do happen to run a little bit over, we could always bring back our lunches and eat them here if pressed. I will try to get you through it on time.

First, I want to take a moment before I get into the presentation to acknowledge the incredible team I have in the OARC that has made this meeting and last night's events and all the materials that you see regularly for IACC deliberations. All of that is made possible by this team. Puts up our website, handles the logistics for all of this, does the analysis that you see in some of the reports that I am going to talk about. I just wanted to acknowledge all of them. We have four policy analysts: Oni Celestin, Ben Feldman, Karen Mowrer, and Julianna Rava. We have Rebecca Martin who is a public health analyst in the office, Jeff Wiegand who is a web development manager and Angelice Mitrakas, as I know many of you know her because she handles all

of our logistical planning and office management. I just want to really thank them for all that they have done to make this possible.

DR. DANIELS: Moving right ahead, just to reiterate, this is Autism Awareness Month and the OARC has been active as well as many parts of our government in trying to get ready for this. Just a recap on last night, we had a film screening of As One: The Autism Project, which is a really special film made in the United Arab Emirates at the request of the Royal Family in the United Arab Emirates. This film is available on our website. When these slides go up on the website, you will be able to get to a link there, but there is a link. You can see it up until August 22, 2017 due to the generosity of Image Nation, the company that produced the film. I would encourage anyone to see it who has not.

We also have one of the people featured in the film here in the room today, Sherifa Yateem,

who was a behavioral analyst from the UAE is a special guest today listening in on our meeting.

Just to recap Autism Awareness Month activities, we have some information on our website about the UN activities, CDC's recent Autism Awareness Month Event and some of the events sponsored by other agencies.

The statement of the UN Secretary-General, the Presidential Proclamation, a couple of blogs that we mentioned here. Josh has a blog that went up a couple of weeks ago. Dr. Novotny and Robin Harwood have another blog. I understand Josh has another blog coming out. And the secretary of HHS also will have one. These are already on our website and the new ones will be added soon. You can read them there.

Next, I would like to share with you the 2016 IACC Summary of Advances. You have in front of you the printed version. This is the result of the hard work of the committee, vetting many different advances that you considered over the

last year for this volume. It includes lay-friendly summaries of the 20 most significant advances voted on by the committee in biomedical and services research. It aligns with the strategic plan's seven questions. I hope that many of you will have a chance to look over the final product. Those of you who are in our audience, you are welcome to pick up a copy of the table or people online can get it online or if you want a hard copy, you can write to our office and ask for one.

We also have another new publication. This is the final product of the 2013 IACC Portfolio Analysis. It is the final report. I know the committee has seen the data over the past year for this. We have just been working on preparing this final presentation of it with a full narrative and all the figures. This has also been provided in hard copy for you at the table. We have copies out at our booth. It is online as well. I would encourage you to look through it.

Our office is busy at work trying to get the 2014 and 2015 data analyzed. We hope that later this year we will be able to share that with you.

Next, I would like to introduce the new Autism Research Database, which is a refresh of our previous online web tool, containing data since 2008 for autism research across all federal agencies and many different private organizations who volunteer to share their data. It has some new features, some nice new graphics and interactive features. I would encourage you to check it out. I have a brief demo that we will be sharing with you from someone in my office, a policy analyst who is Julianna Rava who is going up to the podium now.

MS. RAVA: This is our new autism research database. It is replacing the old web tool. We have a savvy new design. This is the landing page you come to when you click on the link on our website. We have this expand for more. That gives

you a little more detail about it when you first come to the page.

The next thing is it is still by each fiscal year. Here is a drop down where you could pick a particular year and the seven tabs will upload to that data for that year. The seven tabs follow our strategic plan. We have the strategic plan questions, funders. We have added federal versus private funding, multi-year funding tables, objectives, sub-categories, and we also added new geography.

I will quickly go through the search tool. I will put in a wood like transition. That often comes to us, asking what projects are funded for transition. We get for 2013, 35 projects that are found. When you click on a project title, you get more information on that project: the principal investigator, the description, and so on. You get the strategic plan question. You can also get the link for that particular – but they have the external link available. You can easily put in

just an area you are interested in and that will pop up.

You can also download. Say you want to download all these search results for transition. You can download it from Excel or PDF to include all the 35 projects.

Then we can quickly go through each of the tabs. On the first tab are the strategic plan questions broken down by a number of projects, total funding, and percentage of total funding. We have a cool, interactive figure included.

When you click on Question 1's number of projects, you get the list and broken down by objective. When you click on the project title, you will get that same information that you got when you searched for projects.

Funders' page. You get the same type of thing where you have a figure at the bottom. That is interactive as well. You have the number of projects for each funder. Another cool thing is

if you click on the funder, you get their 2008 to 2013 funding broken down by ARA and non-ARA.

Federal versus private. Following the same format. You can look at all the private projects or federal and the institutes. If you click on the project title, you get the full information.

DR. DANIELS: If you could just click on each tab so people can just see what it looks like, I think that will probably be good because we will want to move on to the next portion of the meeting.

MS. RAVA: Multi-year funding tables kind of fall in the same format. You can do a dropdown to a particular question. You see the total at the end for each – that is Question 3. Objectives. This follows the same format.

Subcategories have a figure following each question. You get the projects broken down. And geographies. Pretty cool map. If you hover over, you get the total funding for that state. You click on it. It brings you down. We also have an

international map following the same format as the overall map. It is pretty cool. Check it out.

DR. DANIELS: Thank you very much. We hope that you all will find this interesting to go back after the meeting and check it out. If you are ever looking for information on what has been funded, at least through 2013 right now we have the data in there. And of course 2014 and 2015 will be added as soon as possible.

I also just wanted to say that this research database is made possible almost entirely in house by the team that we have. Our talented web developer Jeff Wiegand and a policy analyst who put the data together and just the entire team came together. I did have one outside contractor help with some of the design over the past year temporarily. He did a terrific job too.

DR. LAWLER: This is just terrific. I understand the great job people have done and the tremendous amount of work that went into it. I know you are playing catch up right now with past

years. But are you anticipating you will get to a steady state where, for instance, like 2016, today, in a couple of years would be available?

DR. DANIELS: That is what we are working toward. I am hoping that within the calendar year, we will be able to release the 2014 and 2015 and then will be almost caught up. We are going to be doing our 2016 data call soon. It also depends on just the usual as everyone in the government faces staffing levels and if you have people to do the work and all of that. As long as we do, we are going to try to catch up to being more current. Of course, we always share the data in advance with the committee before it gets published formally. You always start seeing the data many months in advance.

DR. RING: What is the process or criteria of having other organizations that are not currently represented in the database add their data? I am thinking Phelan-McDermid Syndrome Foundation or FRAXA or some of these other foundations that may

have funding data that is relevant. How do they get into that?

DR. DANIELS: Previously, a few years ago, I did ask the committee at the time about whether you wanted us to be putting in Phelan-McDermid, Fragile X, some of these other syndromes that are related to autism. At the time, the committee did not want me to mix that data set into the autism data set. I have not been requesting that information. If the committee changes its mind and decides they want to start including some other disorders in with this because you think it will be helpful then that can be a discussion for a future date and we could schedule more time to talk about that.

DR. GORDON: Let’s put that on the agenda for the next IACC meeting. I think it is worth revisiting.

DR. DANIELS: Let’s move ahead to the discussion of the strategic plan. This is just a summary of the strategic plan, which I know that

you all already know. Let's talk about what we have been doing. We had seven working groups, working to address the seven chapters of the strategic plan, the seven question areas.

Drafts have been completed for all seven chapters by the hard work of these working groups over the last few months. They include a number of different new areas, most importantly new objectives, maybe not most importantly. All of the other information is also very important. And these drafts have been shared with the committee. You all have them in your packets. They are up online for those who might be viewing this meeting online. We want to have some time to discuss any major issues that we feel might need committee discussion related to these drafts. I would like to table anything that is minor changes that you just want an example added or a reference or some mention of something that is really non-controversial. But if there are issues that we think the committee really needs to talk

about and hash out, I would like that information to be shared right at this meeting and not wait until later.

Can we go in the order of the strategic plan or do we want to – is that okay for us to start with Question 1? I put down a couple of pieces of information that came into me from committee members. For Question 1, I did not have any major issues come to my attention. Is there anyone in the committee that feels that there is an issue in C

Question 1 that we need to talk about?

DR. REICHARDT: I just wanted to say that it really isn't question specific. We had this problem in Question 2 very much in a sense that there are too many cooks in the broth. Many of these documents are written as if they were a review article. They actually are highly redundant with material that is present in other sections. They have a lot of abbreviations, which

I do not think are going to be accessible to the public and they are very different lengths.

My view is that the different section chairs should be instructed to reduce everything to ten pages.

DR. DANIELS: Let me back up a little bit to the process.

DR. REICHARDT: But I just say that many of these try because they are trying to be complete. They incorporate material that, for example, would be more properly restricted to Question 1 or some other – there are major problems with the whole thing.

DR. DANIELS: Let me back up. I was trying to save time by skipping all of that because I know I have emailed you about it. But with these chapters, this is the first draft that has come back from the working groups. The next step is I am taking IACC feedback, anything that is really important that you want to change about the way

the concepts and content are in these chapters is what I am looking for now.

After this meeting, OARC is going to begin edits. We always take a pretty hard line with edits in terms of trying to get things into a similar format. We correct all the references. We try to get everything uniform. That is really not the job of the working groups. They have already put enough time in. We are not going to worry about any of those minor issues. We really want to talk about the content. I do not know if that answers questions.

DR. GORDON: Susan, to be clear, that includes editing for redundancy and making the chapters of uniform length and the other issues that you have raised here.

DR. DANIELS: Yes. All of those and styles. Maybe some that are too technical – we will make them more lay friendly. The purpose is that we want this document to be accessible to any individual on the spectrum or family member. We

will try to get rid of anything that is overly technical. We will keep references there for those who want to go read the papers.

MS. CRANE: This is possibly something that we might just want to put a note on. There is a lot of discussion about developing better screening materials. I know that in the adults and in the lifespan topic, we talk about learning to recognize the signs of autism better and in adults who were previously undiagnosed. Someone who is reading this might start at Question 1 and think that that is not being addressed anywhere. We might just want to put a note and say we are going to put that in there.

DR. DANIELS: Yes. That is what I had in mind. I did not put it on the slide here. But there is some material about adult diagnosis, adult screening in Question 6. The part that is missing there is we do not have any scientific research information in Question 6 right now. That was something that we were just going to go

back with some working group members to try to get that information. We are planning to put it probably in Chapter 6, but we could put a reference to it in Chapter 1 depending, but we want to make sure that that is covered. That is the plan unless anyone has an objection.

MS. CRANE: I think that those things should be categorized under Question 6 because it makes it easier for us to understand how much is focused on adults. I just would want to note --

DR. DANIELS: Definitely, I think that we can do that.

DR. ROBISON: I think we had talked about including some words to address what you just said and also words to talk about the overlap between two and three and the prevention of ASD versus prevention of disabling aspects and the reasonableness, for example, of desiring to cure epilepsy even as we might say that autism itself is not probably subject to cure itself. And we talked about those things all being a component

of the introduction. And even though we talked about it, it is not mentioned here. Are we still thinking that same way?

DR. DANIELS: John, you kindly provided some beginning information for the introduction, but we felt like the middle content needs to be completed before we can really work on the introduction and conclusion. We have put that aside until we get the middle part edited.

And then Dr. Gordon wants to take a role in also looking at the information you provided and OARC will help out too. If we need help from other committee members, we will get in touch. That is a later step. We will not want to repeat everything that is in the middle in the introduction, but we will touch the highlights.

In terms of overlap between Question 2 and Question 3, I heard there were some concerns about that. Is there anything in particular that you want us to pay attention to while editing?

DR. MOTT: Actually, this relates to Questions 1, 2, and 3. We kind of struggled with Question 2 with the biomarkers as prediction for ASD. Taking a look back at Question 1 specifically with the implementation of ASD diagnostic and screening tools, we can see a little bit of overlap there.

And then I also noticed in Question 4 that they talk a little bit about the biomarkers as a predictive response treatment. Our group had a discussion about whether or not biomarkers may fit better in the context of Question 1, specifically in the diagnostic and screening tools, and whether or not we should completely remove it from the Question 2 chapter itself.

DR. DANIELS: Usually in the past with Question 1, we have focused on biomarkers when they are getting a little closer to being made into an actual screening tool or a diagnostic tool and if it is very basic research, just trying to discover biomarkers. It is often ended

up in Question 2. I will take note of that and we can take a careful look and make sure that the information is distributed properly, but not redundant. I think that there are different aspects and you would not want to skip talking about biomarkers in Question 4, for example. But I think we can look at that.

Anything else that is pressing in terms of Question 2 and 3?

This was an issue – next is Question 3. We did have discussions with the working group. I know David and Cindy are both here. In our extensive discussions with the working group, talking about how to present the idea of risk and what we are trying to prevent and talking about the shift that has gone in the community in terms of talking about whether we are talking about preventing ASD itself or preventing disabling aspects of ASD. David and Cindy might want to comment on that. We just wanted to ensure that

the direction that this has been written in reflects the view of the committee.

DR. AMARAL: It actually goes to John's comment that right now it is pretty explicitly written that the goal is to try and predict disability and eliminate disability rather than eliminate autism. It would be worthwhile reading the introduction to this section to see whether people agree with it because it has taken a pretty substantial turn from the way the last strategic update was written.

In the discussions, the sense was that we are not at a state of the science to understand a phenotype that is so debilitating that you would actually want to eliminate that phenotype like you might want to eliminate cancer or something else that is clearly a problem.

I think it is a change, but I think it is something that at least that the majority of the working group was comfortable with. I know there was some feedback from the environmental side of

this chapter. Maybe, Cindy, you could deal with that.

DR. LAWLER: I think, in general, there was a lot of agreement and awareness of this is an important issue in the field now. Questions arose when we tried to think about how do we breathe that new perspective into research that is looking at identifying environmental risks for the disorder.

To do that, there is a paragraph that I would hope everyone will look at. It is a single paragraph under the environmental piece. Prevention or amelioration of disability in ASD. That is what generated a lot of the comments.

In brief, what that paragraph tries to do was say with the shift toward preventing the disabling features of autism, if you are an epidemiologist then it will be really important that you collect deeper information. You are not just looking at autism cases and controls, for instance, but you are really dissecting that

phenotype. Then when you go on to do analyses, you are not looking at risks for ASD as a single entity. You perhaps would be able to tease out that this environmental exposure is really linked to this comorbidity or this particular feature of ASD. That was the idea that was presented in that paragraph.

There was some discussion around whether – I think this general idea of doing away with the word prevention. A general public health context with environmental risks just to some of the members just seemed sort of awkward. Many of the exposures that we are looking at and I will give – lead exposure would be an example that is not going to have an impact just specifically on autism. It affects many other aspects of development both children and adults.

DR. GORDON: Can I interrupt you? I think you have made a very important point that you have made it well. I would like to hear from members of the committee who were not on this group. I

want them to address the following question. Imagine we had a risk factor that we knew predisposed to autism that was easy to get rid of. And the result of that and reducing that risk factor would be reducing the incidence of autism writ large so reducing the incidence of the spectrum. Is that something that we want to pursue? If it is something that we want to pursue then I think it is ill advised to get rid of entirely from the document the idea of prevention of ASD.

I am trying not to guide the committee on this, but I really would like people to try to address their questions to that specific issue because it gets at the heart of this issue. I know it will be controversial, but I encourage people to speak frankly regardless.

DR. PELPHREY: Speaking frankly, it is a very important point. If we are so careful that we then eliminate a whole area of investigation that your question is suggesting, that would I think

be quite a mistake in deference to political correctness. I think we are going a little too far here.

DR. LAWSON: I agree. I think a lot of this is about rhetoric. When we talk about prevention, I think many of us have always meant prevention of debilitating symptoms. I certainly would not want to prevent my daughter's existence, but I absolutely would like to prevent the extremely challenging and debilitating symptoms that she has that prevent her from fully accessing the community and taking advantage of everything that the world has to offer to her.

My concern about this issue was that I felt like there was some rhetoric in the chapter that went too far in talking about prevention of symptoms. For example, there is one sentence in Chapter 3 that says it is fully appreciated that autism has positive and beneficial features. I do not know that that is a universal belief among families and individuals who are really

struggling with self-injurious behaviors and inability to communicate. My daughter is warm and loving, but I cannot imagine that given the choice, she would not want to be relieved of many of the symptoms that she struggles with every day.

DR. DAWSON: I wanted to also point out that the same issue comes up in the treatment chapter. We might think about them as sort of a struggle around these issues as they apply to both because there is a lot of focus right now, for example, on biological and other treatments of core symptoms of autism. I think it does beg the same kind of question about why would you want to eliminate the core symptoms of autism if you do not want to eliminate autism. We need to incorporate whatever language we decide on. We need to have it consistent on both of those chapters.

I do think that one way of resolving this is to actually reflect both points of view. In other

words, because there are individuals and people with autism as well as parents and people who are directly affected, which I think are in the best position to make these kind of ethical decisions frankly rather than say someone like myself. That because there are folks that would take the stance that they would want to eliminate an environmental factor that increase that is related to the incidence of autism that we continue to want to fund that research, recognizing that there are also other people who may have a different perspective on that and just let that be reflected in the plan.

DR. GORDON: I appreciate the courage of everyone who has spoken up with the countervailing point of view. I see Samantha's hand raised and I am going to give you a chance. But I want to urge any further comments to be new ideas that need to be introduced in the conversation in the interest of time. We will go with Samantha and then Lewis.

MS. CRANE: I just wanted to give the perspective of one of the groups that is most concerned about boards like prevention and prevention of disability. One is I am not even sure that prevention of disability is the best phrase to use. I think most autistic self-advocates believe that autism is a disability. It is the same thing. Preventing autism and preventing disability autism are going to be the same question because we all have a disability.

On the other hand, none of us want lead poisoning. If it is like a study on does lead poisoning interact with autism and cause lifelong problems, we are all fine with saying maybe we should not poison autistic people in a way that causes additional issues. I think that that interactive – focusing on the interaction between certain kinds of environmental triggers and our brains rather than saying this environmental factor causes autism, saying this environmental factor can exacerbate issues with people whose

brains are already predisposed to ASD. They might reduce our ability to live independently or do something along those lines. I cannot speak for absolutely everyone in the autistic community, but I think that is the framing that you might want to use.

DR. REICHARDT: I just want to speak very briefly and maybe the details should be offline. I thought the sexual susceptibility difference section missed major concepts in the literature from what is known about evolution and function of the X and Y chromosomes. I think that needs to be addressed.

DR. DANIELS: So then that I think you could send to us and we can try to incorporate.

DR. GORDON: If I might sum up what I am hearing about the prevention is that there is some concern that the language that is in the current draft might go too far. There is also – actually, Geraldine, I think you said it well that we need to explicitly state the idea that

the issue of prevention has I do not know if we want to use the word controversy, but there is controversy around it. There are different ideas.

In my practice with patients, I did not see autism patients, but I saw lots of patients with relatively disabling disorders that from time to time also gave them a positive side. For example, patients with bipolar disorder who felt they were very creative when they were hypomanic. We always discuss the risks and benefits of treatment in terms of curtailing what they saw as a positive aspect of their illness. We can appreciate that and nonetheless conduct research in the areas that would lead logically to prevention if that is provided as an option.

Let me suggest this. I do not want to usurp the process. Let's let the process continue. Susan will use the feedback that you have just given her to try to craft a language that would be acceptable and then bring that language back to the committee for further discussion. I think

that might need to be a separate agenda item. Do we have to resolve this before the next meeting?

DR. DANIELS: What my hope was to bring a pretty final draft to the committee to approve in July. If we bring back more language to talk about again, we are not going to be approving it until October.

DR. GORDON: Let’s try to get some language to the committee and get it out via email. Get feedback on that so that we can have what will hopefully be – if it is not, it is not, but hopefully be an acceptable draft that covers this issue by July.

DR. DANIELS: I think that we can do that with our revised language. We can of course on the entire strategic plan we will share with the committee. I guess we can take feedback at that time. We will try very hard to get this feedback incorporated. Hopefully, it is not going to be a problem.

DR. GORDON: I think this though is a very important issue to highlight.

DR. DANIELS: Absolutely. It will come up in many places in the plan. I think three is not the only one.

DR. GORDON: We are well passed. Are there any other issues that really require further discussion? I think it is wonderful that we are all willing to sit here at the table well passed the 12 o'clock for lunch, but I do want to be respectful of your time. Let's try to keep it to real issues that we need to discuss all amongst ourselves.

DR. SINGER: I sent in that Question 5. In Section 5 under the section on housing where it talks about the final role from the Centers on Medicaid Services. That ruling really stresses the importance of person-centered planning. I felt like that phrase was missing from the paragraph and it is important to be in there

because it really captures the essence of the final rule.

DR. DANIELS: We can add that. I will talk to you about the specific spot.

DR. HARRIS: Susan, this is Melissa Harris with CMS. While we are talking about Chapter 5 – first, I apologize for not being there in person today and just being on the phone. I would like to send for consideration just a couple of paragraphs about Medicaid-funded services for possible insertion into Chapter 5. I do not want Medicaid to dominate the conversation. I know it is not just a chapter on Medicaid funding. But since Medicaid is such a major funder of services for people with an autism spectrum disorder, I would like there to be just some really high-level information if nothing else about where readers can go for answers to questions on what Medicaid does and does not cover and what kinds of decisions are for the state to make in crafting its Medicaid program.

I did note with some interest the suggestion about embedding some person-centered language in there. I can also work to do that as well.

DR. DANIELS: Great. That would help. Thank you.

Any other issues that you feel are pressing in terms of the strategic plan in what you have read in terms of the content?

DR. GORDON: With that, I urge you all to read the plan carefully if you have not already and send in suggestions for edits that are of a simpler nature to the IACC staff. We will diligently get out revised versions as soon as they can so that we can have an agreeable text to go out in July.

DR. DANIELS: I have a deadline for everybody, it is May 5, to get me any feedback that you want to give us and OARC will be working on those edits.

DR. GORDON: Do you have any other business we need to attend to?

DR. DANIELS: Yes, we do. The core values in the strategic plan. There was a recommendation from Working Group 1 to add equity to the core values. We have a sense of urgency, excellence, spirit of collaboration, consumer focus, partnerships in action, and accountability that were developed by the first group of the IACC that worked on this plan, which Allison was a part of. I wanted to know if you feel that equity would be a good thing to add here. Does the committee seem like they – I see a lot of heads of nodding. Any objections to adding equity as a value? Great. That is good.

And then I just wanted to briefly tell you about budget recommendations. We have been working with David Mandell for services budget recommendations. They will not be in this version of the plan, but we have a plan to develop some data to work with. That will come to the committee at a later date.

In terms of the research budget recommendations, OARC is making great progress in gathering some data that we can use with a small group that volunteered to work on this and we will be getting in touch with you after this meeting.

We are going to get the comments in by the 5th. We will be revising drafts and submitting them to the full IACC for review and working on the final document.

Before lunch, we would like to take a photo of the whole committee. We have almost everyone here this time. I know that I heard not again. But the last one we only had half of the committee. When we use these photos for the public, it looks bad if we do not have everybody there. We have almost everyone here.

DR. GORDON: We will do it very quickly. That side of the room. Am I correct?

DR. DANIELS: And then we can go down to the cafeteria for lunch and you can grab your lunch and bring it back if you would like.

DR. GORDON: We will resume as ten after one. We will give you ten extra minutes.

(Whereupon, the Committee recessed for lunch at 12:00 p.m. and reconvened at 1:10 p.m.)

DR. GORDON: We have the public comment session, which we will start in one minute. We are going to go ahead and started with the public comment period. I note that we are starting about ten minutes late. We will take that into consideration. We will try to catch up later on, but I think it is really important that we do hear from the public members.

The public comment session is going to be divided into three sections. We have the first half hour. That is for the oral public comment. Then in the following 15 minutes, we will have a summary of the written public comments that we

received and then we will have the opportunity to discuss the public comments as a committee.

I would like to introduce the first speaker and that is Sherry Chase. Just remind me, Susan, how much time does each speaker have?

DR. DANIELS: We have three minutes for each speaker. There is a two-minute transition.

DR. GORDON: I will be timing. Sherry, if you could go ahead up to the podium. Are you here, Sherry? We will move on to the next one and we will come back to Sherry.

Mike Lowe I believe is the next public commenter.

MR. LOWE: Good afternoon. My name is Mike. I would like to thank this committee for the time and effort spent towards improving the lives of people affected by autism spectrum disorder. I appreciate the opportunity to share my thoughts regarding how we can help people affected by ASD.

My 17-year-old daughter was diagnosed with Asperger's syndrome at the age of 10. Prior to

her diagnosis, my daughter visited many doctors including pediatricians, gastroenterologists, pediatric neurologist, behavioral psychologists, child psychologists and speech therapists. All the while my daughter struggled in school, struggled to keep friends, struggled with social conventions, struggled with changes in routine and had other struggles.

The final struggle was the onset of sensory processing issues. When it was finally determined that my daughter had ASD, it was really her mother who made the diagnosis. In the seven years since my daughter was diagnosed, she has matured into an impressive young lady. She has several friends and is doing well in school, has established her own business, has been accepted by Meredith College in Raleigh, North Carolina.

While I am grateful that my daughter is dealing well, I cannot get past the fact that it took ten years to get a diagnosis and to identify and implement the needed interventions. Every day

I wonder if the diagnosis and interventions would have come sooner had my daughter been screened for ASD. The fact that my daughter was never screened for ASD is especially bothersome to me because I know that still today there are children with ASD who are not being screened for it.

In January of 2013 then director of the National Institute of Mental Health, Dr. Thomas Insel gave a TED Talk toward a new understanding of mental illness. During his talk, Dr. Insel made the very simple point that early detection and early intervention will provide the best outcomes for mental illness.

To quote Dr. Insel, the good news stories in medicine are early detection and early intervention. If we wait until the heart attack, we would be sacrificing 1.1 million lives every year in this country to heart disease. I believe that by not screening every child for ASD early in life and often during their development,

quality of life is being sacrificed for individuals and their families. Early detection is possible for many cases of ASD, but early detection will not happen by chance.

Today, I am urging, even begging this committee to make it a top quality to ensure that every child is screened for ASD per the recommendations of the American Academy of Pediatrics. The current model of recommending that pediatricians provide screening is not doing the job, but this can be fixed with some imagination and effort. An actionable and measurable plan to ensure that all children are screen for ASD is desperately needed.

I am aware that some obstacles stand in the path to achieving screening for every child and I understand that there is much more that needs to be accomplished. Past screening for ASD, improve knowledge, better diagnostic tools, and effective interventions are sure to come in the future. But those affected by ASD will not fully benefit from

current interventions and future advances unless they are identified in a timely manner.

Screening is the fundamental first step that will lay a solid foundation for managing ASD in the future by providing families with knowledge that will allow them to begin solving the puzzle. Thank you.

DR. GORDON: Thank you very much. Thank you for traveling here to comment on this very important issue of screening and it is one this committee has taken up in the past and actually is on our agenda for future meetings.

We will go back to the first speaker is Sherry Chase is available now. We are going to go ahead and move to the next one. We will come back to Sherry when she has her speech.

Albert Enayati.

MR. ENAYATI: Good afternoon. This is Albert Enayati. I am a father of a 27-year-old son with autism. He is severely affected. He is severely affected. Before I start, I would like to

congratulate you for your new position. I hope under your leadership, there will be changes within IACC and also I hope under your leadership, there would be some treatment or medication for my son and almost one million children across this country.

Unfortunately, in a space of seven years, IACC has spent more than $1.7 billion. At the end of the day, they did not help my son or any of us, not even a bit, zero. As I am standing here, this agency has not helped me whatsoever.

How many researches do we have to do on the genetics? I did a very quick search. There are more than 176,000 researches on the genetics. How many more you need to do to see that this is not genetic? This is environmental. We need to look it at that way.

You cannot find what is going on in the brain by testing the saliva or the blood test. The genetic path in the brain is completely different to what you get from the saliva and

blood sample. Even though I participate in the SPARK program with Simons Foundation, my family is in there. I am so grateful to the Simons Foundation, but still I do not think that is going to have the answer.

The answer is going to be somatic mutation, which reveals the neuron history, how it started and how it ends up. I am begging you. I am asking you. If you could set up a workshop. I only found one person that is doing this study. Thanks to Dr. David Amaral, director of the MIND Institute, that he is really working so hard on the brain bank. And also, I am so grateful to the Simons Foundation for funding the brain bank. We need to look at the somatic mutation of the brain of these children.

I hope this new area of the research could be priority for the IACC to find out what has gone wrong with our children and how we can fix it. I need you to tell me that you are going to

look into this and let me know if this is possible.

I am asking other representatives in here that if they know researchers that they are doing the somatic mutation of the brain to come to this workshop if you allow to have this workshop. I hope that Dr. David Amaral would give also some information regarding how the Brain Bank is working and how this type of research could be funded.

Two other things I was going to tell you.

DR. GORDON: I am going to ask you to wrap up if you might. Three minutes has gone. You can take 30 seconds to wrap up.

DR. ENAYATI: According to the Simons Foundation, 42 percent of parents – they believe vaccines causes the children's autism. In 2009, Dr. Insel invited the National Vaccine Advisory Committee. After so many meetings, they proposed a number of research proposals have to be done to verify if the vaccines cause autism or not. Not a

single one was done. They have spent $1.7 billion. You tell me that they do not have $100,000 to develop some of these studies that they recommended to the agency. They have not done it.

So many parents coming here time after time asking, we need to study between vaccinated and unvaccinated children. There are no research articles in there. If the Center for Disease Control believes that vaccines do not cause autism, why don't they fund it? What is the big deal? Why so many years, 10 years, 15 years, we are asking Center for Disease Control, whose representative is sitting here, why don't you do it? What is the big deal? If you think vaccines are so safe and it does not cause autism, why don't you fund it?

You should not do the study because nobody trusts the Center for Disease Control. I do not trust them either. This study has to be done by independent researchers.

DR. GORDON: Thank you, Mr. Enayati. I am afraid your time is up, but I appreciate your comments.

MR. ENAYATI: Give me one more minute.

DR. GORDON: Please take your seat. We need to move on to the next person.

MR. ENAYATI: Give me two minutes.

DR. GORDON: I appreciate the comments, but I do need you to sit down now.

DR. ENAYATI: I came all the way from California. It is not fair. It is not really fair. I pay for my expenses to come here and just three minutes. You also eliminated the number of presentations you have per year. You made it one. That is not right either.

DR. GORDON: I appreciate that feedback as well. We will consider the public comment period, but I really do need to move on to the next person.

Ms. Chase, are you ready? Thank you very much.

MS. CHASE: My son, Alec, has autism. He just won an award for Reflections this past year. He was national mention. He won the State of Maryland. He actually is a child who has very limited verbalization. He came out through making his own video. Unfortunately, I did not bring the DVD. The next meeting I will. It will be him speaking with all his pictures, but that is not what my topic is about. I promised him I would bring it to show you all because he is truly a winner in my heart.

I am Sherry Chase. I am a widowed mother of a 20-year-old son name Alec Chase who has autism from being poisoned from arsenic for a lawn fertilizer at the age of 2. Alec has a life sentence and with all the early interventions, he remains short on the ability to fully converse. This emerging young man, who so eagerly who wants to learn and please, has minimal communication skills preventing him from reaching his intellectual potential. For at the magical age of

21, his educational and Autism Waiver supports will disappear.

We as a nation need interventions and details to attainable resources, but have and have not worked for others on this spectrum, to be publicized, researched, and created via an interactive website sponsored by this very wonderful group. This must include chelation and other methods to de-toxify their overburdened systems.

It is those who are already on the spectrum and leaving the public education as well as other adults that need immediate support. What is value of bringing someone to a point and then dropping them off a cliff? Individuals like my son want to contribute to society. They cry out for help via behaviors, IPads, words and family and there is no time to waste. Rather than allowing them to waste their talents, let's offer post-secondary educational training with modified curriculum and mandatory modified programs for different

learners at community colleges. IACC should come up with proven learning modules for continued education for those in the spectrum. Unfortunately, DORS and DDA fall short in this arena.

Secondly, small, independent scientists should have access to easily obtainable funding to create devices that will allow those on the spectrum to regain their control of their over and underactive neurological systems. Our young, intuitive scientists leaving the college environment will develop available electronics, grew up with those on the spectrum in integrated learning environments so they saw firsthand what is needed to function.

I ask within two months, kindly, desperately ask you, create a national website with information and interactive facts of what has worked and what has not, and details on how to implement these procedures provided by

practitioners and by families, as well as a short route for funding of device development.

We must put ourselves in the shoes of a person on the spectrum. As Alec's brother Bren says, it could have been me, mom. We must do the right thing and pull out all the stops and do what we would have wanted someone to do for each of us if we were on the spectrum. There is a young man trapped inside my son Alec Chase's body yearning and pleading to come out. Please help each of these people rise and shine. In the future, it will save time and it will save millions of taxpayer's dollars when we can see each person's spectrum rising to their own individual and fullest potential as a contributory citizen.

I thank you for listening to me. I will just take a couple more seconds that I shared. My son who is extremely intelligent, very social except with the ability to have a full conversation. Varsity cheerleader, he is the mascot for his

school, he was the last person at the bicentennial to sing the National Anthem in Baltimore for the bicentennial, but he cannot really have a conversation. Recently, and actually for the past couple of years, he would be doing a favorite activity and suddenly out of the blue start hitting his head, pulling his hair, and it would last for under 15 minutes. We thought he was having seizures. We went doctor to doctor.

DR. GORDON: I need you to finish up.

MS. CHASE: This is my last couple of seconds, I promise. I won't be rude. Please take a moment to look up a particular headache syndrome. Can I ask you for the spelling?

DR. GORDON: I believe it is SUNCT.

MS. CHASE: There you go. That is what his neurologist thinks he is suffering from. He is seeing more and more people with autism. It is a syndrome that people over 50 that are males, sometimes have. It is an excruciating and

neurological headache often affecting the trigeminal nerve. It can explain these mysterious headaches.

With that, I close. I beg you. Let's find an interactive way to share the fabulous knowledge of things that work and do not work, that will hopefully help each of our people that have autism be the best and most contributory citizen they can be. Thank you.

DR. GORDON: Next, I will ask Vashti Johnson – can you go to the podium?

MS. JOHNSON: Good afternoon. My name is Vashti Johnson. I am the founder and CEO of the Bright Minds Institute for Autism in New Jersey. I want to thank you all for allowing us to come. I have been inspired by much of the conversation that has gone on. It has been a wonderful day for me.

One of the things that is really exciting for us is most recently we had been working with the NAACP on the advocates for autism. The Bright

Minds Institute has had to bring to the attention of the organization the outstanding number of children in urban areas in minority communities that are suffering from one of the five spectrum disorders.

We have been looking for a while at little baby processes of treatment and we have not really been able to establish much more than day programs. Most of our places for our treatment are out of state or out of city. We are working on that.

But I have to tell you as I listen to so much of what goes on here today, I wonder maybe because you live in more affluent neighborhoods, you do not have any of the issues that we have to address on a daily basis. We have one school, number 22 school, which has over 250 kids that all have IEPs. The Board of Education waits until the sixth and seventh grade before they start to do testing unless the parent makes a special request. If the parent is not told to make a

special request, they do not know to do it. They observe the behaviors and they try to figure out what is wrong, and hopefully friends and neighbors come to their aid and assist them and encourage them to see their doctor and get a better diagnosis.

We need help from an organization like the Autism Coordinating Committee to address urban issues all over the United States. We just happen to be one of the higher incidences of autism in New Jersey, for the country rather, and we struggle with what to do.

While you all are designing your policies, please pay attention to the fact that so little of what you say has much to do with the urban communities. You are missing a big, huge gap in the population that needs the most help from you.

DR. GORDON: Thank you.

MR. JOHNSON: My name is Callan Johnson. I work with Bright Minds also. My issues are one of safety. I actually worked with the Jersey City

Police Department in training how to handle autistic people with care. A lot of police officers, school security, even in the prison, they are not aware of how to handle autistic people. With the police officer that has no knowledge, they can hurt someone. They can hurt a child badly. There have been plenty of incidents.

A lot of people do not know. When a police officer places an autistic person face down and they put their knee on his back, you are actually suffocating them because they have weak diaphragms. These are things police officers do not know. When identifying an autistic person, it is something they do not know.

During the training that I gave, Handle with Care, a lot of them were not aware of anything. What do you do? Police officers are trained to respond, react. A gesture that an autistic person can do can cause them to shoot. They do not understand. My thing is making police officers,

security guards in the school system, all aware of how to deal or identify autistic people.

DR. GORDON: Thank you very much for these important comments.

Next is Dr. Linda Varsou.

DR. VARSOU: Good afternoon. My name is Linda Varsou-Papadimitriou. I am allowed to be here again. My brief presentation is based on the constitutional freedom of speech and on my deep knowledge and expertise. Genes alone cannot explain the autism epidemic within one generation. We have to look at the genetics.

In the genetic studies, we do not have the possibility of the “trio” child, mother, father. That is because the chronic parental denial and usually the father, and 50 percent of families deny the problem.

Move to epigenetics. Epigenetics, so we need to see the prenatal conditions, environmental pollution, chemicals, insecticides, pesticides, drugs, herbicides, pharmaceuticals. You see up

here, this is a glyphosate, still around all over the place. You know how toxic it is. It is worse than the DDT used years ago. My question is is Monsanto more important and powerful than the NIH or the US government? Why don’t we take out from everywhere as we did for DDT?

Now, unhealthy diet, GMOs, therefore unhealthy microbiome. We know the connection between brain and GI. What do you know of that?

Animal studies. Of course, there is no comparison of the immune system of mice is totally different from one of the humans because the genome of animals is different because it is adapted to different environmental conditions and needs. And of course, all animals love and protect their babies.

Brain studies; now, you see this baby here looking at the MRI of the brain. We know that neuroimaging is very invasive technique especially when it involves a young brain, compromised with autism or other disabilities.

Because the brain is under the strong huge field of the magnetic field plus the electromagnetic radiation, both with serious effects to other agents and drugs. To make a story that if you look at the Internet, you will see comments of patients going after the MRI and what the complaints are. Amazing. You have to find them.

Also, what we are, our body. It is a cloud of energy with the frequencies of vibration of the different atoms and molecules. We are energy. Also, the electrons from the hydrogen and the MRI changes the speed and the orientation. After the MRI, not all electrons gain the first speed that it had in orientation.

DR. GORDON: Dr. Varsou, please wrap up.

DR. VARSOU: I have nothing to say more than for everyone to look at those three fantastic documented webinars. And then to tell the immune and neurological system of infants and babies is immature. We have an immune-deviation mechanism that plays at that point of early vaccination.

And the publications. The last thing is the exponential increase of autism publications does not show much positive impact on the lives of people with autism and their families.

Look please, go Google John Ioannidis. I know this person. He is professor at Stanford University. Brilliant mathematician, a doctor, and an epidemiologist. What he does on his life – he takes publications from peer reviewed journals and analyzes them, and he found that only 5 percent of publications we can count of the findings --

DR. GORDON: Thank you very much for your comments. We appreciate you bringing them to our attention.

Next, I will ask our final public commenter, Dena Gassner, please take the podium.

MS. GASSNER: Good afternoon. Thank you for the opportunity to speak her and for all your hard work.

Very briefly, I have edited my comments since you have it in writing. But for the record verbally here, I am the mother of a young man who has autism. He is currently on track to graduate from Marshall University. He started out with a diagnosis of ID and has evolved to PDD. He will graduate with honors by the way. We are very excited about that.

I am also a wife and a mother and a grandmother and a PhD candidate, a very old PhD candidate. I am also an autistic adult woman. The many years I spent advocating for my son has given me privilege in terms of being able to participate meaningfully in the national autism conversation.

In the last year, it was my opportunity and my honor to serve as a reviewer, looking at millions of dollars of grant funding. I have to tell you that after 12 hours of grant review, it was painfully clear to me that not a single penny

was going to change my future or my son's future or that of people like me.

This is in total disregard to the outcries of autistics and families who want to focus on quality of life. I would like to talk about how, like my colleague John, I do greatly respect the need for research that addresses the intensity of the suffering that involves these co-occurring conditions. I want to look at the things that we can do to support this, but I would also like us to spend a considerable more amount of money looking at what we are going to do now, not where we are going or where we have been, but where are we going in the future.

I believe and support research that minimizes these co-occurring conditions. Maybe the use of medical marijuana for seizure disorders and hyper mobility disorders, which we were not looking at nearly enough. I believe in research that is going to address policy limitations that continue to result in ongoing

poverty and ensuing homelessness, which in and of itself constitute an entirely new trauma. Health care disparities, support for the LGBTQIA intersectionality and transitioning individuals that live with autism and transgender status. Training for doctors, dentists, and other service providers to fill the void in health care access for people with autism. More accessibility to social services that we are supposed to be receiving, but actually act as gate keepers instead of facilitators.

I am grateful to have had a conversation about Social Security today. Vocational rehabilitation denies access to people who have IQs about 70 in many of our states. Food stamps. Schedule A hiring is simply inaccessible. It is simply inaccessible for our population and housing. The gender bias is destroying and maltreating and abusing women with autism who are not identified because they do not manifest

before the age of 8 in a way that untrained diagnosticians can find.

I am sad to say that none of the research that I looked at was going to address this. I had a researcher here at the IACC the last time I presented whisper to me in a meeting what is elopement. This person was talking about optimal outcomes later in the day. This reflects the siloed relationships between the research community and the autistic community. In that same pattern, I am hoping that our contribution at MFAR where John, Steven Shore, myself and Steven Cap will talk about incorporating autistic researchers in the design, the research, the recruitment by the way, I can help you find a lot of autistic participants, to do better and we can do better.

I am also wanting to express to you that we need to include autistics not just as researchers, but as collaborators. We can tell you why your sample size is small. We can tell

you why your environment is not conducive or your people are not culturally competent in how they address our population. All of this will lead to clearer, cleaner, better outcomes.

By the way, the next research study I would like to see is going to an employment environment and training an employer on how to include people with autism instead of demanding people with autism, do what everybody else does with a 60-pound pack in stiletto heels. Thank you.

DR. GORDON: Thank you very much. I would like to let Ms. Gassner and the rest of us know that elopement is actually one of the topics on our agenda for the July meeting. We are going to be hearing about that particular issue.

I thank all of the speakers for bringing up these important issues for the group to consider. Obviously, we could not accommodate all the public comment. We will get to these comments from the committee. Let's wait because we want to make sure to hear the written comments as well.

Dr. Karen Mowrer now from OARC and NIMH, is going to provide now a summary of the written public comments. And then will have a chance for the committee to consider the public comments as a whole.

DR. MOWRER: Hi everybody. Since the January meeting, the IACC received written public comments from 16 commenters. For the purposes of this summary, we have organized those under six topics. You have all on the committee been provided the comments in full, but they will be summarized briefly here.

The first set of comments was on the topic of vaccines and autism. We had six individuals comment on this topic. Dr. Linda Varsou encouraged the autism community to watch the documentary titled, Vaccines Revealed, which she mentioned in her oral comments.

Mr. Vinu Arumugham believes that there may be a link between autism and an allergy to cow's milk proteins in vaccines.

Dr. Kerry Scott Lane believes that Tylenol triggers autism by harming the body's ability to metabolize metals in vaccines. He also distributed a US patent on methods for treatment of autism.

Mr. John Best believes autism is caused my mercury in vaccines and is frustrated that this issue is not being addressed by the IACC.

Mr. Dwight Zahringer asked the IACC to investigate how glyphosate may be affecting children with ASD versus those without ASD. He also asked the IACC to request that Congress investigate the CDC whistleblower issue and provide a full debrief of the study on autism and the MMR vaccine.

Ms. Maureen Meleck urged an end to vaccinations because of her concerns about autism.

A second topic we had was autism research priorities. We had five comments under this topic. They included the following. Dr. Carlos

Gary believes applied behavior analysis and programs such as TEACH are limited in their ability to benefit autistic individuals. He believes autistic individuals have synapse activity patterns that cause them to perceive reality differently.

Dr. Eileen Nicole Simon asked the IACC to discuss her comments describing potential links between autism, disruptions in language development, and complications resulting in brain injuries such as umbilical cord clamping and asphyxia at birth.

She also expressed interest in the oral public comments presented during the January IACC meeting, and believes more research should be done on identical twins discordant for autism.

Mr. Chris Stargazer asked that genetics research on autism be deprioritized in favor of research on co-occurring conditions and basic neuroscience research to understand the human brain. He also believes that research priorities

should be set to address actual needs rather than being influenced by outside organizations.

Ms. Kelly Israel and Ms. Julia Bascom on behalf of the Autistic Self Advocacy Network, recommended that more funding go to ASD research on lifespan outcomes, co-occurring conditions, and associated medications, access to health care, effectiveness of supports and services, assistive technology, diagnostic disparities and the prevalence of autism in adults. ASAN also urged the IACC to promote the involvement of autistic adults in grant review and other aspects of the research process.

Ms. Gail Elbek urged the IACC to consider studies on the effect of soy on brain development.

The third topic is adult service needs and transition to adulthood. We had four comments under this topic. Ms. Lisa Bertone expressed concern about the lack of housing and care

options for adults with severe autism who are being cared by aging parents.

Ms. Marian Dar wanted to make the autism community aware of the Tenth Annual Hilibrand Autism Symposium, which is being held today on the topic of fostering independence for young adults with autism spectrum disorder. She helped organized access to a live stream of this symposium for her local community.

ASAN expressed concern that according to the 2012 IACC portfolio analysis data, only about 2 percent of NIH autism research funding went to research on service effectiveness. About 1 percent went to research on outcomes across the lifespan.

Ms. Carol Fedorchak shared some of the recent challenges she has faced, as the public school system has not been able to provide sufficient support to her 16-year-old son with Asperger's.

The fourth topic is autism diagnosis and interventions. We had three comments under this topic. Mr. Jesse Ryan Bayer would like to know how individuals with autism can gain access to new cutting edge treatments.

Dr. Eileen Nicole Simon believes that omission of developmental language disorder from the ASD diagnostic criteria in DSM-5 disregards that autism is evident from early childhood.

Mr. Chris Stargazer believes that education should be tailored to focus on autistic individual strengths and interests. He also believes that intervention strategies should consider the psychology of each individual with ASD and that intensive interventions often do not address the root causes of behavioral challenges.

The fifth topic was the role of the IACC. We had three comments under this topic. Mr. Dwight Zahringer feels that his comments from previous meetings were not addressed by the IACC during discussions of public comment. He also

recommended that the IACC facilitate a survey of parents of ASD children in the United States.

Dr. Eileen Nicole Simon would like her comments to be discussed by the IACC rather than only being included in a summary of written comments.

Ms. Lisa Wiederlight, on behalf of SafeMinds, expressed concerned that the IACC is not doing enough to address the personal safety of autistic individuals, which is the most significant concern of the autistic community. SafeMinds urge the IACC to prioritize solutions for addressing the documented increase in mortality among individuals with autism.

And the last comment was on the topic of the IACC's strategic plan for autism spectrum disorder. And that was that the ASAN continues to have profound concerns about the IACC's strategic plan questions. ASAN believes the new strategic plan questions should reflect the increasing scientific consensus that autism cannot and

should not be cured or prevented. In addition, they ask that lifespan issues for autistic people be included as part of all of the strategic plan questions.

That concludes the summary and we thank everyone again who supplied written public comments. Thanks.

DR. GORDON: Thank you, Dr. Mowrer.

Now, we can take committee comments and discussion about the public comments.

DR. ROBISON: I think that one thing that came through in the oral comments, I think really first with Mr. Enayati, is that we have to recognize that these men and women that come to comment and they do come across the country at their own expense, and I understand the reasons why we have to have a time limit on commentary. I am not suggesting we change that here because I know we have a time constraint, but at the same time, I feel that folks like Mr. Enayati, and all

the other commenters, deserve to be heard and they deserve an answer.

I wonder if we could create some kind of forum in which we could constructively engage with the autism community and I wonder also with respect to specific questions about what we are doing like he and others said you should be researching X or you should be researching Y, you should be researching Z. I think that we have program people and I know they have a lot of other stuff to do so maybe it is not so simple as just answer them. But I feel like we could answer people like that with what we are doing with respect to their questions.

DR. GORDON: Let's do that. We can do that right now. I can do the things that I know about. For example, Mr. Lowe mentioned an emphasis on screening. That is something that we have active programs in at the NIMH to research the effectiveness of screening. We are trying to see if it works in minority populations, which

addresses some other comments that were made. We are trying to figure out whether those screened actually responded to treatment just like those who were identified with other means.

Another comment was about – I will let others --

DR. ROBISON: What about the brain differences that he asked about, Mr. Enayati, in particular. He asked about David's brain net research and Allison's --

DR. GORDON: David or Louis, would you care to comment on the brain bank?

DR. REICHARDT: Let me let David comment on the brain bank. I just think that Dr. Enayati should realize that the only way we can do the somatic mutation studies that he wishes are in fact postmortem as opposed to cancer. In cancer, you take tissue out and you can do the very deep sequencing, which you need to detect somatic mutations.

DR. GORDON: But I would point out that the somatic mutation work that is being done is being funded by the NIMH.

DR. REICHARDT: I understand that and we are supporting it. But the main thing is that it is not something that could be used ethically to understand the brain of a living person.

DR. AMARAL: I want to thank Mr. Enayati for his endorsement of Autism BrainNet and thank the Simons Foundation for funding it, and for actually the Autism Science Foundation for doing the outreach efforts that are being done.

I would encourage people who are listening if they want to take a positive action to go to the “It Takes Brains” website and sign up for more information. We would like everybody listening to be ambassadors for us to spread the word that we do – to understand things like somatic mutations. We do need donations of postmortem brain material. And because of the heterogeneity of autism, we need large numbers.

And the only way we are going to be able to do this is with the help of the community.

DR. GORDON: And if you are not a fan of somatic mutations, there is a lot more other stuff that we need to do with these brains.

DR. PELPHREY: I will just add to that. If you are a fan of the somatic mutation work, all of the genetics work that you cited as being quite extravagant, was necessary to support going into that area as one of the people involved in Flora Vaccarino's study. That and the existence of that literature was the only thing that allowed us to do that work. It is not that you can necessarily separate out these different aspects of the science. Some necessarily depend on the existence of others.

DR. GORDON: I have two other things that I realized that we wanted to point out. Dr. Varsou commented on the need to study “trios”. That is an active area of investigation sponsored by the Simons Foundation and lots of other efforts. We

do actually recruit and study them. It had been incredibly valuable in terms of trying to understand what the genesis of autism from multiple perspectives.

Another comment was on the vaccines and autism and the need to follow through on research protocols. In fact, this group did recommend it. We did follow through. There have been enumerable studies that have compared – made the exact comparison that was requested during the public comment period, comparing those who receive vaccines versus those who did not. There is unequivocal evidence that there is no increase in risk in those who did receive vaccines compared to those who did not. That is something that we have actually followed through on over the years and have gotten really powerful scientific consensus on. There are other examples of that I think that were mentioned. Those were the two things that popped in my head.

Are there other responses that the committee would like to make with regard to any of the other public comments? I think you are right, John. I think we should engage where we can. Some of the comments we cannot engage on necessarily because we do not have the knowledge.

DR. ROBISON: Could we cite –

DR. GORDON: Do we have them now currently?

DR. DANIELS: I do not have any specific area for vaccine issues –

DR. GORDON: We will look into doing so.

DR. DAWSON: I was shifting topics to the wonderful presentation that both of you made around the issues of urban communities, disparities, and access to services and safety issues. I appreciate those being brought up because they need to stay front and center. I do feel like we have tried to weave those into the strategic plan as high priority areas. I know that they have been discussed as key objections.

DR. GORDON: But I would agree with the commenters actually that the research is under resourced in those areas. And a perfect example of that was the wonderful work that Dr. Brodkin told us about where he admitted upfront despite their desire to recruit more in minority populations, specifically in African American populations in Philadelphia, they had been so far unable to do so, which means we must redouble our efforts in that regard.

DR. DAWSON: We might consider whether we want to think about more strategies as we finalize the strategic plan to incorporate that into just the – weave it into the research endeavor.

MS. CRANE: I think participatory research design is going to be a big part of that. Regardless of what community you are trying to recruit, if you do not include them at the beginning of your research plan and you design your entire research plan, you have this idea and

then you are like where can I find some African American people who want to join this study, you are going to have a much harder time than if you are including the African American community even at the level of deciding what question you want to answer. As the public commenters pointed out, even just down to what problems are the most salient, what priorities people have, those can change based on group membership.

DR. GORDON: Thank you very much.

DR. PELPHREY: I just wanted to highlight. Two of the speakers brought up the issue of another health disparity, which is the difference in diagnosis timing for girls versus boys with autism and emerging evidence and talking about different neural mechanisms, different genetic mechanisms. If we are going to do screening, we have to have screens and biomarkers that are equally applicable and reliable for the two groups.

DR. GORDON: That is a very important comment and actually leads right into our next topic of biomarkers. Thank you very much for the comments on the public comments.

John, I appreciate you pointing us in the direction of actually responding and engaging with the comments of where we can provide information and where we can acknowledge gaps. I think that is equally important.

DR. ROBISON: Thanks for doing so. I can just see it is important to the community. I see that there is a lot of loss of confidence in our public health service. We need to build that up through our actions as best we can.

DR. GORDON: One more thing. One of the statistics. I do not know if it is reliable that one of the public commenters gave was the percentage of individuals who believe still the link between vaccines and autism. I believe that it is high. I think it was 42 percent was the number that was cited during the open comments.

Even if it is not accurate and it is some different number, it is still disturbing and important that we engage on these topics. Thank you very much.

We will move right along into our next segment, which is going to be actually a panel discussion of advances in autism biomarkers research. I think this panel is particularly timely because there have been a number of advances, several of which or at least a few of which are actually proposed to be included in next year's summary of advances. We have several of the authors of these studies and researchers here to tell us about these advances.

We have asked each of them to prepare a short talk of 15 minutes. There are four of them. That will take the first hour. And then we will have a half hour to discuss with them in an interactive way their work and its implications.

I will ask Dr. James McPartland to come to the podium. He is coming to us from the Yale

Developmental Disabilities Clinic where he is an associate professor of Child Psychiatry and Psychology and principal investigator of the Autism Biomarkers Consortium for Clinical Trials. He is going to talk to us today about the practical and scientific challenges in biomarker development for autism spectrum disorder.

DR. MCPARTLAND: Thanks. It is my pleasure to be here and have a chance to speak with you. Susan asked me to give a big picture and overview about where things stand. I want to talk specifically about some practical and scientific considerations. This is the broad array of things I want to discuss.

Really, what are we talking about when we talk about biomarkers? Why are they important and potentially useful in autism? What are some of the challenges specific to autism? Where have we come and what are some issues with progress so far? And then some areas that I think are key for moving forward, specifically thinking about

better studies, better biomarkers and thinking about practicalities as well.

This is the definition of a biomarker that actually is a byproduct of a working group put together here at NIH. Any characteristic that is objectively measured and evaluated as an indicator of a normal biological process, pathogenic process, or pharmacologic response to a therapeutic intervention. You can see from this definition, a biomarker is really defined in a broad way. When we think about a biomarker, it does not have to be something that is in a gene. It does not have to be something that is in the brain. It can be behavior. But a biomarker cannot be is something that is measuring this objective way.

I am here today – I fulfill two roles in autism. I am a clinician and I run the Yale Developmental Disabilities Clinic where I evaluate children with autism. And then I am also

a scientist. I run a lab in cognitive neuroscience research.

As a clinician, we are quantifying social behavior all the time, but that is not a biomarker. But we can use behavior in biomarker ways and Bob will actually talk about that a little bit later today.

I want to highlight where we stand with biomarker development in autism because as a neuroscientist, I have a ton of tools that I can use in my lab. In my clinic, I can really use one tool. It is the same tool that Leo Connor used in 1943, my clinical eye, and my clinical judgment. We have made tremendous progress in understanding the biology of autism. But we really yet are not out of place where we can put these kinds of discoveries into practice either in the clinic or in clinical trials.

Why do I think that is important? Is my clinical eye good enough? There are things that the clinical eye cannot do that biomarkers could

probably do better. And the Holy Grail for our field has been to find diagnostic biomarkers, something that will tell us that autism is happening before we can see it in behavior.

That is actually less what I want to think about today. I want to think more about biomarkers that might help us understand what to do when we have already identified autism. We can think of these as stratification biomarkers, for example. Biomarkers that help us subgroup people with autism into groups that are more likely to benefit from a particular treatment or that let us help determine prognosis. And then we can also think about biomarkers that might let us help estimate treatment response or early efficacy biomarkers. Right now, it is the same thing. When we want to see whether a treatment is working, we rely on clinical judgment and we rely on parent questionnaires. We could probably do it more efficiently than make sound decisions about whether we should continue to invest in a

specific treatment or have a family save their energy and try something different.

We have covered this. Everybody knows this. We know how we define autism, these two areas of difficulty. It is defined behaviorally. Here are a few things about autism that really make biomarker development in this field uniquely challenging. One of them is developmental change. Autism is a developmental disorder. When we look for biomarkers for autism, we are searching for a moving target. We do not know whether we should be looking for the same set of biomarkers to advise us in 3 year olds, in 30 year olds and beyond. We need to be aware of that. It may be that we find biomarkers that work across a lifespan, but we may need different sets of biomarkers for different points in development.

Autism is not one thing. Autism has many different causes, many different etiologies. That is really important when we look for biomarkers. If autism is many things, should we expect a

biomarker to encapsulate them all? Maybe not and maybe we do not need to because we really do not make clinical decisions at the level of autism. We make clinical decisions based on our understanding about an individual person's strengths and weaknesses. And maybe that is the way we need to be thinking about biomarkers, more of an RDoC perspective that we think about biomarkers indexing processes that are relevant to understanding and treating autism rather than autism per se.

And then lastly, heterogeneity. It is a complication in autism. It is something that everyone is very aware of that we talk a lot about. I think that there is an answer there too. A lot of people will say if you have seen one person with autism, you have seen one person with autism. But I think that is a truism for all living things.

I think what is remarkable is that we can say I cannot tell you the IQ of a person with

autism. I cannot tell you what their language is like. But I can tell you that definitionally they have challenges and basic social interactions, things that most of us just pick up. In the face of that heterogeneity, it behooves us to look in that area of homogeneity for some of our answers. We should be looking for biomarkers that address social communication.

In trying to think about where we stand with biomarkers, there is really no – I could not find an objective way to narrow it down other than what I know best. There is a positive biomarker study for every symptom that we could think of for autism. What I have highlighted here is one that I am most familiar with, neuro response to faces. And Dr. Schultz wrote about this using fMRI in 2000. A lot of the work that I have done since I was a graduate student with Jerry Dawson who has been looking at this with event-related potentials, a form of electrical physiological brain recording. This is one of the most well

studied biomarkers in autism. We have made a lot of progress. We understand.

I think of certain key things that we want a biomarker for autism to do. These are some of them. These are things that have been demonstrated, for example, of the event-related potential, the N170. This is something that is sensitive to diagnostic status. We can discriminate people with autism from people who do not have autism based on this biomarker.

We see an association with symptoms and really importantly, we see a disassociation with things that are not impacted. We think about autism and intellectual disability that many people with autism experience, we do not want a biomarker that is telling us about the cognitive abilities if we do not think that our treatment is targeting those cognitive abilities. We are not going to expect the biomarker to change. We want to find biomarkers that are associated with our treatment targets, but are not just generic

markers of some other aspect of function or third variable.

These kinds of biomarkers are applicable across development. We can see a specific precursor of the N170 in a three-month-old and we can see it in adults and we can see differences in people with autism across the lifespan.

We see that one of the things we need to be aware of when we measure biomarkers depending on the kind of biomarker if I am drawing blood, it does not really matter what the child is doing when I draw that blood. But if I am looking at functional brain activity, how a child is behaving during that biomarker assay is really critical. We want to find biomarkers that are true irrespective of the behavioral context. This is true here as well.

Lastly, this is more nascent in the line of research. We want biomarkers that change as children change as they get better in treatment. We have seen work done by Jerry that some of

these face-related biomarkers change as children get better in the course of behavioral treatment. All these outstanding biomarker characteristics. Why aren't we able to use them effectively in clinics and in clinical trials yet?

There are many shortcomings, but I think the key one is reproducibility. Since those first studies that I cited, there have been for ERPs alone 25 to 30 studies looking at them. And the majority of them find differences. We actually have a meta-analysis that we will be submitting this coming week that shows that by and large it is true, people with autism have a really different N170. But it is not true in every study. We do not know why.

I think the best reason why, the best for us, practically speaking, is that it is reflecting true heterogeneity. If autism is not one thing and not everybody with autism has a face processing system that is impacted in the same way, we might not expect this biomarker to

look anomalous for everyone. That is really useful information for us.

But there are more pernicious issues too, in the research. There are many small studies that are under powered to detect differences. There is tremendous methodological variability to say that you are going to look at a brain's response to face. There is a lot of ways to do that. What kinds of faces you use, what kind of experimental paradigm you show them in What kind of recording equipment you use to capture the EEG and which electrodes on the scalp you select to analyze. There is tremendous amount of variability in what has been published. There is no way to parse out that noise from the data that exists so far.

And then lastly, when we want to do something like use a biomarker to characterize change in the course of treatment, we really want to understand how that biomarker changes in that expanse of time outside of the context of that treatment. If there is a 16-week course of

treatment and I want to see how a person's face process changes, I want to know what happens in 16 weeks of child development period. We do not have that frame of reference. We do not have those growth charts if you will.

I want to next talk about a few things that I think can solve some of these problems. It is really straightforward, ambitious, but straightforward, to build studies that address some of these weaknesses. What is noise? What is heterogeneity in a small sample that obscures biomarker information can be a really useful variance in a larger study. If we have larger samples, we can understand some of the differences, the influence of language or the influence of cognitive ability.

We can really focus carefully on controlling methods. Sometimes this could be easy. If it is a single site study, maybe what we should be doing is sharing paradigms. In some of the work that we

do now, we put our paradigms on the web right away so that other groups can use them.

For multi-site studies, it is much more challenging, but it is really important to make sure that the data is being acquired using identical equipment and identical methods.

We can build in longitudinal designs. I do not mean longitudinal years. I mean longitudinal in ways that map onto the typical course of a treatment. Either would be very helpful. And then by doing those kinds of studies in the context of a large typical groups, we can then derive the normative atlas that we need.

As many of you know, this is work that is underway. I am the PI of the Autism Biomarkers Consortium for Clinical Trials. I was here to tell you all about it in January 2016. I am happy to report that we are up and running. We have about 100 children enrolled in the study in the course of the past six months. This study is designed to do just do this. To get a big enough

sample of children with autism to examine not novel, the most well-studied biomarkers to date, using EEG and eye tracking so that we can get a sense of biomarker utility while controlling for these kinds of weaknesses. That is one thing I think that we can do.

Another thing that I think we can do is improve the sensitivity of biomarkers by thinking about their ecological validity. As a person who studies social neuroscience, I am acutely aware that the way we do it is problematic because we study how people interact with people by putting them in social isolation. We put them in dark sound proofed EEG labs or we put them in scanners. That is not necessarily the way that these brain systems function in real life. It does not resemble the kinds of contexts that tend to give people with autism difficulties.

What we can do is apply interactive social neuroscience approaches. We are embedding brain recording in real interactions or in social

simulations. This is a picture from the brain function lab run by Joy Hirsch at Yale. These machines are functioning infrared spectroscopy devices and this is a study that is ongoing now to examine brain function in autism in the context of true social interactions, true face-to-face interactions. I think that by more closely approximating social interactions, we will get better information about these biomarkers.

And then lastly and really being pragmatic, I think that we want to think about the practicality of biomarkers because how useful something could be clinically or in clinic trials. I think that a ceiling will be set by a couple of factors. One is certainly cost. If we have a biomarker that is useful but extremely expensive, the public health impact is going to be limited.

And then also accessibility. If I have a biomarker that we can only run out of a handful

of labs, it is going to be really hard to do clinical trials. It is going to be really hard to make any clinical impact. I think we need to consider those things. And the technologies are at hand. When we think about EEG, for example, this is a biomarker acquisition method, a way of acquiring brain data that costs dollars to acquire an EEG. It costs saltwater and latex gloves. It is accessible. There is an EEG system in every hospital in this country. They are already used at the population level for screening, for seizures, for hearing. I think that some of our answers are at hand with a lot of work to do as well.

I will end by just thanking collaborators around the country and elsewhere and mostly the families and kids who were involved in this study and the people in my lab who do a lot of this work. If you are wondering, yes, that is an N170 tattoo.

DR. GORDON: Thank you, Dr. McPartland. We are going to have the opportunity for questions and comments on the talks collectively at the end. We will move right along to Dr. Heather Hazlett, assistant professor of psychiatry at the Carolina Institute for Developmental Disabilities in the University of North Carolina School of Medicine. She is going to talk to us about differences in early brain development and how they predict ASD outcomes in high risk infants.

DR. HAZLETT: Thank you. Thank you for having me. Thank you for inviting me to come today. I am going to be speaking to you about a group of work. Just off the bat, I have no financial interest, but I do have a lot of funders in the audience. I would like to appreciate all of the funding we have received by NIH and Simons Foundation and Autism Speaks.

The question we have really wrestled with is why we are studying early development in autism, early brain development. This question really

started I think at the initial investigation of autism by Leo Kanner in 1943 in his observation that children had large heads. People started to look at head circumference in autism as an indirect measurement of brain.

What we know is that a lot of studies were done. A converging of evidence showed that there was an increased finding of head circumference in early years. Less is clear about later in life. But that seemed to be a gelled together finding that early head circumference was enlarged in individuals with autism.

But there are a lot of methodological differences in these studies. They were either prospective or retrospective. They were taken from medical records. The methods were different in how that data was collected. There is a lot of quality control, maybe differences between how that data was gathered.

It also made a big difference in the normative group that you compared the data to Dr.

Raznahan who had an excellent study showing that the population standard that you used really varied what you found.

Dr. Amaral's lab actually had a very nice review of imaging studies that had been done looking at brain size in autism. As you can see hopefully from this graph, there is a lot of support maybe from studies showing bigger brains in early development. It is kind of tapering off as individuals were getting older. But it really is important to say that early studies are where we wanted to focus. We did this with toddlers. We did a longitudinal study several years ago looking at toddlers following up from age 2 to age 4 to 5. We found increased brain size. But what we did not find was what we had hoped to find, which was the change. We had hoped to see something happening between two and four that the brain was increasing or in enlarging in size. But as you can see from the graph, it had already

happened. That pointed to even younger than age 2.

We had collaborators and colleagues in the field that were finding similar things. This is, again, from Dr. Amaral's lab. They found in three year olds increased surface area, not cortical thickness in young boys with autism. We felt confident that our colleagues and collaborators in the field were supporting this work. We wanted to focus on birth to three. As many of you know, children are growing rapidly in these first two years of life. A lot of brain growth is what we call activity dependent. The children are interacting with the environment. That may be shaping and sculpting how their brain is growing. We call these critical periods for development. Those very early years of life are very important.

We have a colleague at the University of North Carolina, Dr. John Gilmore. He has done quite a lot of work looking at typical brain

development. This is just to give you a picture using MRI scans the rapid differences and I think to the naked eye anyone could see from birth or two weeks on the left hand side of the screen to two years just how rapidly that brain is growing.

He is able to show this with gray matter maturation across the first year of life. You can see that in the first year of life, the gray matter is increasing over 100 percent. That is a lot of brain growth happening. It still continues in the second year of life, about 18 percent still increasing in gray matter across those first two years. I hope this is convincing you that those first early years of brain development are where a lot of change is happening. That is what we want to study in autism.

White matter is also increasing. You can see here a very colorful picture, but it is just showing you the fibers in the brain and from neonate to adulthood how rapidly and enriched those are becoming across the developmental span.

We wanted to know. Could we decipher, see brain differences to detect autism? This work is coming largely from a large ACE network. We have many collaborators and colleagues across the United States and in Canada. This network is a conglomeration of four clinical sites. We have a site in North Carolina, but we also have a site in Philadelphia at children's hospital, a site at the University of Washington in Seattle and Washington University in St. Louis. We have collaborators in Canada that help us with our data coordination and with our image processing in New York with Dr. Gerig and then we also have colleagues at the University of Minnesota in Johns Hopkins. These are helping us with some of the environmental and genetic data that we are also gathering. We have a lot of friends and colleagues helping us with this study.

The idea for this study grew out of two ideas that development was happening both in behavior and brain. Lonnie Zwaigenbaum published

a paper in 2005 from his study, showing that there was a rapid change in development between 6 to 12 months using a scale called the AOSI. Autistic behavior was emerging during this period.

We found a similar supported finding in head circumference data showing a rapid increase, but happening around the 12-month mark as well in head circumference in young children with autism. These two ideas supported the study.

The goal of the study was to follow infants longitudinally. Again, as Jamie was pointing out, the longitudinal nature for understanding child development is very important. The design was to look longitudinally. We also chose to look at infants at high risk. By this, we mean infants that were born to older siblings that had autism. They have about a 20 percent depending on the study read increased risk for autism themselves.

We followed these children from three months to age two or three. We did developmental and

behavioral assessments as well as the MRI scan. A picture of one our scanners and an infant going to sleep. This work was actually published just a couple of months ago. I am going to share with you this data.

And the sample that I am reporting on was a pretty large sample that we saw longitudinally and as you can see, predominantly males in the group that had autism by age two. Not much difference in maternal age or birth weight or gestational age as control variables that we were interested in looking at, but definitely differences in their developmental functioning as you can see from their Mullen, which is a developmental score and their Vineland, which is adaptive behavior. Those children who end up with autism look very similar at age six, but are actually functioning in a more impaired range by the age of two.

This is what we found. The red line are the children, the infants who at six started as high

risk, but at two, ended up being classified or characterized as having autism. The green line is those children who were in that same group, but they did not end up with autism. And the blue were the typically developing controls. You can see that we see an increase in brain growth happening in those first two years of life. Somewhere to the head circumference data that difference or that rate of change was even increased in the 6 to 12 months more so than the second year.

We also found a way to measure surface area, which is the outer contour of the brain if you will, as well as cortical thickness, which is the ribbon of gray matter in the brain.

Surface area had a very similar trajectory. We saw that same rapid increase in that first year of life 6 to 12 months in the children that ended up with autism, but not in cortical thickness. We do see a specific effect for

surface area that contributes to that total brain volume enlargement.

We wanted to look at where on the surface of the brain these regions showed differences. We did see some differences in the children that had autism. Middle occipital gyrus, the lingual gyrus, temporal gyrus and middle frontal gyrus were regions that were different. We are actually hoping to look more closely at some behaviors that may be associated with these regions.

We did look at the behavior that we had at the time and looked to see if we could see associations with the brain volume enlargement and the severity of autism. We did this in a couple of different ways. We looked at total brain growth and their ADOS scores. The ADOS score was used as part of their assessment. We did not see any relationship between brain volume and the ADOS score in that 6 to 12-month range, that trajectory, but we did see a significant relationship in that second year of life, 12 to

24 months. It was a positive relationship, meaning the bigger the brain, the more severe the symptoms on the social effect of the portion of the ADOS. The repetitive behavior did not have an association.

We chose a separate measure because the ADOS was part of the data that we used to help classify the children. We wanted an independent measure. We used another tool called the CSBS to see if we saw a similar thing and we did. The social deficits were related to the CSBS scores in that second year of life, 12 to 24 months.

We wanted to know and this is I think why I got invited here if surface area could be a biomarker. Could it predict? We had the help of colleagues that are computer scientists. They assisted us with applying a machine learning algorithm. I will not go into a lot of details here. But I can tell you they did it in a variety of ways to make sure that it was – were pretty confident how they did. They only included 6 to

12-month data. They only included cortical thickness surface area, total brain volume and the sex of the child. They were able to train the algorithm on a portion of the data set and then tested on the remaining portion.

And what we found was that using just these simple features, the brain volume, the surface area, the sex and the cortical thickness – we found that surface area predicted about 80 percent accuracy, those children who would end up with autism. Just to reiterate because maybe this is not a statistic that a lot of people are familiar with, but it is telling us how confident are we that that data at 6 to 12 months is telling us accurately those children who end up in that 12-month category with autism.

We were encouraged because we know that using behavioral only tools – a measure, for example, looking at 12 month olds, using a parent screener, the FYI, their same statistic was about .14. We were doing a little bit better than some

of the behavioral instruments that are available and even better than another measure that was being used a little older, 18 months, the Baby Sibs Research Consortium. That was about 50 percent.

What we are thinking is that early surface area expansion that we are seeing in this first year of life may be responsible or contributes to the brain overgrowth we see in the second year of life. Both of these things are proceeding, but contributing to the behavioral features that are emerging in that second year.

We are excited because we are able to capture we think at a time before behaviors are present of a brain difference that could be used to predict those children who go on to exhibit autism.

We also think that this information is showing a clue to the mechanism, the underlying mechanism. There is a very nice paper by Alan Packer. It was a review of all the genetic work

that has been done. It pointed very nicely to support, the idea that there are a number of autism risk genes that have a strong role in neurodevelopment. They contribute and play a role in different stages of neurodevelopment. It could be that these genes are altered neurogenesis so they are production of neurons or perhaps other mechanisms such as pruning. Neural proliferation is also a genetic feature of some of these. We are encouraged by this very nice review.

We also wondered were there other evidence from our data from this IBIS Network for early brain differences and autism outcomes. This work was done by Jason Wolff. He took the white matter information that we have from our brain data. He looked at neural circuitry at six months using DTI scans. He selected some key tracks of the white matter as you can see presented on the left and looked at just the high-risk individuals, the infants, those who developed autism and those who did not to see if there were any relationship

between their early white matter morphology and their behavior at 24 months of age. He did. He found an association between these white matter tracks at six months and the repetitive behavior, not the social behavior. We see a difference there that the brain volume is associated with some of the social behaviors. The white matter is associated with some of these repetitive behaviors and sensory behaviors.

We have a post-doc in our lab right now, Robert Emerson, who is actually taking some of this other brain information that we have. We do resting state connectivity scans. This is, again, while these infants are sleeping. He is working on this right now to see if whether this functional network data can predict those children who end up with autism.

And the goal of all of this is to provide us with a rich picture using a lot of different data. We, as I mentioned earlier, want to explore these brain and behavioral relationships to see

the influence that one may have on the other across development.

We also would like to combine the DTI data, the MRI data, the behavioral data with each other so that we can have even stronger information and our interest in looking at individual profiles. These are group-based statistics that I am showing you, but we also know that all children are individuals. We want to look at what things contribute to an individual's profile as they are developing and incorporate both their genetic and environmental risk data, which we were lucky to collect as well in this sample.

I am going to stop here and just say thank you to our very large group of collaborators. Many people are here, but not all the people. Again, acknowledge our funding support and our thanks to our families. We ask these families to do a lot for us. They travel not just once, but three or four times to our sites. They are very patient with us. We fully appreciate them. They

help us do this work. We could not do it without them. Thank you.

DR. GORDON: Thank you, Dr. Hazlett. Next up we have Dr. Mark Shen who is a postdoctoral fellow also at the Carolina Institute for Developmental Disabilities and University of North Carolina. Dr. Shen will talk to us about extra-axial cerebrospinal fluid as a potential biomarker in infants who develop ASD and insights into the role of early behavior.

DR. SHEN: Thanks for inviting me. I am going to be talking to you today about an early brain anomaly that we detected in infants, high-risk infants that go on to develop autism and then focus actually on the replication study that we just published a couple of months ago, piggy backing on Dr. McPartland's point. In order to validate potential grain anomalies in biomarkers, they need to be replicated in a larger sample. I am going to tell you about that.

I am also going to be sharing with you what we are doing now and that is really to validate the pathogenic mechanisms that we think are driving this brain anomaly and its relationship to behavior.

Back in 2013 when I was a graduate student in David Amaral's lab at the UC Davis MIND Institute, we detected a brain anomaly in infants called excessive extra-axial fluid. Here on the left just briefly, that is an MRI of a typically developing six-month-old infant. And on the right here colored in red – that is an increased amount of cerebrospinal fluid in the extra-axial space. I am going to show you some more images about that.

But essentially what we found was that high-risk infants who will later go on to develop autism had an increased amount of the cerebrospinal fluid. That cerebrospinal fluid remained elevated through 24 months of age until the age of diagnosis. It was associated with how

severe their symptoms will be two years later. It will also help predict which kids would go on to develop autism.

But what you see here is that this sample was a relatively modestly sized sample. It was actually the first study that was published in infants with this brain anomaly. But we decided that this needed to be replicated. David and I reached out to Joe Piven at UNC. We formed a collaboration with the IBIS Network. This is work that I continue now, being a postdoc at UNC.

Just to show you a little bit more of what this looks like, on the top panel, you have an infant with a "normal" MRI at 6, 12, and 24 months of age. And what you will see is that there is just a very thin layer in black. That is the cerebrospinal fluid that is surrounding the black.

Contrast that with an image on the bottom. That is an infant with excessive amount of cerebrospinal fluid in the actual space. That is

between the surface of the brain and the skull. All that in black is cerebrospinal fluid that is enlarged all the way through 24 months of age.

What we did for the IBIS Network is that when we were looking for partners for replication, but what was really important was that the IBIS study has the exact same study design as the previous study that we published in 2013. As Heather mentioned, we do MRI scans at 6, 12, and 24 months of age with a diagnosis at 24 months. The same study design as we did in 2013 at the MIND Institute.

But importantly, because there are four clinical data collection sites, we are able to see a lot more families. In this study, 343 infants were enrolled into this study, contributing a total of 804 scans.

And what we did for this study since it was a large number of families, large number of scans, we created a fully automated method to quantify the CSF. What we did which I think was

important is that performed this method with all open source freely available and fully accessible software. It is all on the NIH website that you can download.

I think that is really important because we encourage labs around the country and around the world to replicate our findings. Our hope is ultimately that this will really increase the generalizability of the results that this is a method that can be shared with any lab who is interested in doing this.

I am going to tell you now about the findings from this paper, the replication study that we just published in Biological Psychiatry. Essentially high-risk infants that were later diagnosed with autism had increased extra-axial CSF by six months of age. It remained persistently elevated compared to controls through 24 months of age. Just orient you, what you are seeing here in red, that is the group of high-risk infants that developed ASD. That is the

ASD group. At six months of age as a group, they had 18 percent more fluid compared to both high-risk kids that did not develop autism and also low-risk kids that did not develop autism. There were two control groups. Eighteen percent more CSF at six months and still 10 percent more CSF at 24 months of age.

I should mention that we also accounted for brain volume in this. This is an increase of CSF above and beyond the differences in brain size that Dr. Hazlett just talked to you about.

This was a nice replication. In fact, the magnitude of these results is almost identical to the study that we did at the MIND Institute in 2013. Because it was an entirely independent sample with a much larger sample, about seven times larger than the previous sample, we were able to look at subgroups. There were 47 babies that developed autism. We wanted to see whether or not they were subgroups based upon symptom severity. We went back to an algorithm by Kathy

Lloyd's group to break these kids up into infants that will at 24 months of age have a really high amount of autism symptoms so the most severe kids on the spectrum versus kids that still developed autism, but had more mild symptoms.

And what we found was a more pronounced increase of extra-axial CSF in the babies that will develop more severe autism symptoms. Here, you see them in the solid line here. Instead of about 15 percent more fluid at six months, the kids that would two years later develop more severe autism symptoms had 24 percent more fluid at six months and still about 15 percent more fluid at 24 hours of age.

I should also mention and I think it was Dr. McPartland that mentioned about six-specific biomarkers. There was an interesting finding here in relation to sex where the girls who developed more severe autism symptoms had actually more CSF than their male counterparts. It was a small sample of girls. Now, we are extending this out

to a larger sample to follow this up. And really the hope here is to have sex-specific thresholds of CSF. Because what we found was that it is the girls with more autism symptoms. Maybe they have a higher neurological threshold of CSF that they need to overcome in order to reach an autism diagnosis.

And we wanted to ask the question whether extra-axial CSF as a single brain measure at six months of age at a single time point, whether or not it has any predictive accuracy to classify kids that were two years later be diagnosed with autism.

What we did is we developed a machine-learning algorithm similar to what Heather described in her study. But instead of using a combination of features, we just used CSF at six months of age as a single brain measure and to predict the kids that will go on to develop autism at 24 months of age.

And what you will see here is the overall accuracy was 70 percent, sensitivity of 66 percent and a specificity of 68 percent. Not yet near what would be clinically applicable. But one thing that we did in this sample was we wanted to validate this measure in an external sample. Since we had the data found the 2013 sample at the MIND Institute, we took the exact same prediction algorithm. We applied it to this independent set of infants and convincingly or reassuringly those infants in those studies also CSF predicted about the same amount, about 70 percent of those kids went on to develop autism.

I think picking up on what Dr. McPartland, we do not think that every single child with autism on the spectrum is going to have increased CSF. I think it is a little bit reassuring that we do not have close to 100 percent predictive accuracy. We know we are picking up about 70 percent of these kids.

I think what is important about this is not necessarily that we are going to predict all kids with autism, but like Dr. McPartland said, that perhaps extra-axial CSF at six months of age is a stratification marker. Maybe it is present in the most severe kids with autism. But as far as its pragmatic use, what is reassuring is that this is an observable brain anomaly. It is a structural brain anomaly that can be detectable even with a naked eye with any structural MRI. In fact, it is how we alluded to it. Radiologists can see just with their naked eye. We think that that actually helps improve its generalizability to the field.

Like has been mentioned, replication is rare. It is rare neuroscience research. It is rare certainly in autism research in early markers. We are reassured by this finding.

One of the next steps that I will discuss is how we are combining this with other features of both brain and behavioral development to really push the needle past 70 percent into the 80 and

90 percent range that might be more clinically useful.

I am going to talk to you next about some unpublished work that we are doing now to really try to understand what are the biological mechanisms that is driving this. Is this just a phenomenon that is not related to brain development? We think that the studies that we are doing now is showing that it is directly affecting brain development.

In the last few years, there has been a renewed emphasis on CSF as the filtration system of the brain. That it is what helps the brain clean itself. There have been several studies in really high-impact journals over the last few years that have really highlighted this. Just to briefly talk about this, cerebral spinal fluid has really two functions. It is continuously being produced. In fact, our brain produces about a liter of CSF per day so about twice the size of this water bottle here. As it is being

continuously produced, it is delivering both factors to the developing brain. IGF1 and IGF2 are two growth factors that are produced by the cerebrospinal fluid aid the brain throughout the brain and help regulate brain development.

At the same time, it needs to be continuously absorbed. It is very efficient in doing this. About every six hours or four times a day you get a fresh batch of CSF. And what the old CSF is doing is it is cleaning and filtering the brain. It is removing cytokines and inflammatory proteins that would otherwise accumulate in the brain. For example, amyloid beta is a protein that is continuously being secreted by neurons and it is the function of the CSF that clears that away four times per day.

The hypothesis that we are working under is that when we see an increased amount of CSF over the surface of the brain, which is an indication that CSF is not circulating and it is not filtering and cleaning the brain as it should.

And the end result would be a neuro-inflammatory response in the brain.

How are we going about doing this? We wanted to ask several questions about these findings that now have been replicated, but now we are trying to take it to the next step. One is what is the specificity for autism. That is a question that we get very often. Is it something that is present in the monogenic forms of autism spectrum disorder or is it present in other neurodevelopmental disorders? I can tell you and this is unpublished, but that we are also following a group of infants with fragile X syndrome, an associated monogenic disorder. And they are scanned at the same time, 6, 12, and 24 months of age. Heather Hazlett is the PI of this study. Those infants at 6 months of age, the infants with fragile X, have even more fluid. They have 30 percent more extra-axial fluid so even a more pronounced increase.

What that has done now is now that we have found this in single gene disorders, it gives us entrée into looking at animal models. We are using mouse models of these monogenic forms. The fragile X has a very well-validated mouse model to perform experiments that we cannot obviously do in babies. The previous slide that I showed you about looking at CSF circulation of whether or not that actually impairs the clearance of neural inflammation. We are now testing this in animal models to see if there is a translation component to this finding.

We are also asking the question, are there genetic variance that are related to extra-axial fluid. By the generous support of Autism Speaks and the Simons Foundation, we have been able to collect DNA on all the infants in the study, their parents, and the older siblings. That is the family quad. We have partnered up with collaborators at Johns Hopkins and also at Mount Sinai New York to do whole exome sequencing and

also genome-wide SNP genotyping. And we are developing polygenic risk scores to see whether or not we can determine whether there is a genetic association to this.

And then finally and I mentioned this, is we are combining this with other aspects of brain and behavioral development. For example, if we combine the metrics that Dr. Hazlett described in her study of surface area characteristics, with cerebral spinal fluid at six months of age, we can actually move the prediction accuracy into the 85 percent range.

I also just want to mention that we are not just focused on the brain. We know that brain does not occur in a vacuum. That brain and the behavioral and language environment that parents provide to their children are really important. This is a 9-month-old. That is actually my son who turned 9 months today. What we do with the babies in the IBIS study is that we give them a little language recorder. It is called Lena

recorder. You can see it here. It is about the size of a credit card. It fits inside their little pocket. Essentially, you can think of it as a language pedometer. When the families go home, it is entirely naturalistic. It records basically all the language input that they hear and also the language output that they emit. It does it over a course of several days.

This is work by Megan Swanson, who is a fellow postdoc in our lab. And what she reported in the paper just published a few months ago was that about 20 percent of high-risk infants are hyper vocalizing. They are vocalizing at a rate that is two standard deviations above the norm. They are receiving about the same amount of input. What we are thinking that this might possibly be is an early form of early stereotyped behavior.

Indeed, these kids actually are having lower scores on their social babbling. This is kind of a cliff hanger because these kids have not yet

reached diagnosis, but we think that these 20 percent of kids are going to be similar to the kids that will go on for an autism diagnosis.

And then I will just wrap up here, which is a summary slide of both work that is done in IBIS with Dr. Hazlett, and with our collaborators with Dr. Amaral, and others around the country. We are really moving forward a multi-dimensional approach to early markers of autism. With the work that Heather described of surface area, increased CSF, possibly a Lena recorder, which is much more scalable, certainly than an MRI, and now we have molecular genetics. We are looking towards two goals. One, can we improve prediction in infancy? Two, can we really develop better treatments and move towards more personalized medicine? We know that all kids with autism are not going to show all of these different attributes, but we are hoping that in combination, we could really move towards better

treatment that would be more personalized and move towards a more prediction medicine approach.

With that, I just wanted to thank the many collaborators that we have around the country, in particular, Joe Piven and David Amaral who led these studies. Thanks.

DR. GORDON: Thank you, Dr. Shen. Then finally for the final talk of the panel, we have Dr. Robert Schultz, the RAC professor of psychology in the Departments of Pediatrics and Psychiatry and the director of the Center for Autism Research at the University of Pennsylvania who is going to talk to us about digital clinical assessment for diagnosis and treatment outcome measurement.

And then I will just remind you. Once Dr. Schultz is done with his talk, if all the panelists could come and sit up at the front then we can engage in a discussion between the committee and the panelists.

DR. SCHULTZ: Thank you. It is my great pleasure to be here today and to follow up on all the other great work. We are going to talk about something different. We are going to talk about the use of new technology, the digitized behavior and to use it as a characterization tool, a diagnosis tool, a prediction and I will argue a biomarker.

Behaviors if you really think about them – they are exquisitely organized representations of neurocircuitry activity. Behaviors are the sensor of what the brain is doing. In many regards, behaviors are no different than what we do with neuroimaging. We use EEG. We put sensors on the surface of the head and we are sensing the activities. We put people inside MRI machines and we are trying to infer brain activity from blood flow. With behaviors, they are direct representations of organized neurocircuitry. They have many desirable properties, first and foremost, the behaviors that we are looking at or

the behaviors that bring individuals with autism to the clinic in the first place. They are direct representation of the phenomenon we want to study of the symptoms and patterns of difficulties that we may want to treat.

This is only true and I think it hasn't been as true in the past if we can quantify them well. I think with the advent of new especially computer vision technology, linguistic language processing that we can now measure behavior with the kind of precision that attracted all of us to – attracted to me to other fields. I had been a brain imager my whole life. But now that we have the precision to really measure behavior, I think this field is ripe for exploring.

I want to remind us. I think it is obvious, but autism is a behaviorally defined condition. What I would like to say my colleagues when I am explaining my work is that everything that an expert clinician or an expert person in autism can perceive when they are trying to

understanding someone with autism, they are making a diagnosis, they are assessing treatment change, everything that they can perceive with technology, we can now digitize. There is nothing that I cannot record with cameras or with microphones or with sensors that looks at arousal that you cannot perceive.

But there are some advantages that technology has. One is that computers do not forget. I know I forget from week to week if I am following someone longitudinally and they do not have lapses of attention. There is some really advantages to it.

All of these could be digitally captured with high accuracy. Repetitive behaviors, imitation, which is a skill, which is often difficult for people with autism. These are gross motor behaviors, facial expressions, eye contact, and gesture. These are all non-verbal behaviors. Acoustic properties of the speech, including rate, volume and porosity. Language. The words

you use really reflect your inner lives. We can capture that. That would require transcription. And then autonomic nervous system activity.

Because my time is brief, I am going to focus – we are doing all these things in our lab. Because my time is brief, I am going to focus on facial expression and non-verbal communication mostly. But I will tell you a little bit about gross motor behavior as well. If I have time, I have one slide on language. If we can measure things in a granular, quantified, and reliable way and even in the real world, which is another point for this, we can make predictions. We can make predictions about diagnosis. We can characterize people. We can use that characterization for intervention planning. We can use that characterization for measuring the effects of an intervention, positive or negative, including side effects. We can use it to understand the natural history of a disorder. We can use it to understand genetic variance. We can

use it to understand brain imaging. Right now, we use behavior, but we code it as simply as zero or one and that is the way most of our biological studies are doing. If we explain the behavior in much more detail, we would have a lot more power to understand the biology at the same time.

Let me give you some examples. This is a measure in gross motor behavior. This young boy is named Ollie. He is about two and a half years. He is a typically developing child. His mother was a postdoc until recently in my lab. You can see here sitting here. Ollie just walked into one of our assessment rooms. This is our gross motor lab. He is not wearing anything. He is not wearing any sensors – using advances in computer vision, estimate where all of his bones and joints are in his body and we can map them as he moves across space.

Up here, you see some cameras. These are little cameras that are on the wall up high. We stitch all the images of him together using

computer vision software and to make a whole body representation of him. The magic here enabling us to do this is not the hardware. Those cameras that are capturing it literally cost $7 a piece. It is not in the hardware. It is in the advances in how to analyze this.

With this, we can begin to do things like measure motor coordination, balance and posture stability, repetitive behaviors, stereotype these. The IBIS Network, which I am part of, may not have mentioned it today, but one of the earliest things that we found in the phenotypic domain of kids who go on to get autism is immaturity and gross motor behavior starting at six months of age. We find differences between those who go on to have autism and those who do not. There may be something very fundamental to motor behavior in understanding autism.

Using the same approach, we can actually track people's behavior across time. This comes for free. We can understand exploration, social

proximity seeking, and social approach. We can understand motor learning. Karen Adolph at NYU has done very nice studies about motor learning, learning to walk. She has a paper entitled thousands of steps and dozens of falls per day. The way she had to do this was laborious. She had a grid on her floor where she had RAs code behavior and what quadrant were people in in order to trace this out. It literally took her months to do this. This is data that we get essentially for free.

We are also interested in estimating imitation skills. Imitation skills are when you ask someone to do what I do or to pretend to be doing something or skills which have long known to be difficult for kids with autism or individuals with autism.

I have spent a lot of my career looking at the perceptual size of things like recognizing faces, recognizing facial expressions. And we now have a lot of data. There are definitely

difficulties in this area. But the average effect size in that field is about .5 or .6 standard deviations. The average effect size in imitation tends to be between 1 and 3 standard deviations. If you are interested in prediction especially diagnosis, you want to be able to start measuring things that have big effect sizes, that will be important features in your prediction.

What you see here is the camera showing – this is Emily in my lab and this is a research participant. This is looping. They are not doing it over and over themselves. And you can see the precise arm path. What we are doing here is we are calibrating the work of the cameras with the wearable and you can see it on their wrists. We would like to be able to know that the wearables are as good as the camera and they are used interchangeably and then move them into the natural world.

What I also want to point out here is what we call our tree camera when we do face-to-face

analysis of dyadic synchrony, which I will show you in a couple of slides. This is the little camera we use. Up here, these are other kinds of cameras. These are connects from the Xbox that are used to also help us with gross motor behavior measurement.

This is a simple demonstration of how you might measure the quality of imitation. We have a confederate on the left doing a simple arm movement and a participant. I am not sure if it is a person with autism or a control in the study. You can see that across time that you can measure the fluidity of the individual who is modeling the behavior and then you can do a time series analyses to understand precisely how well did the person imitate it. We begin to quantify the imitation skill.

Another pilot project in my lab is being led by Allison here who is an undergraduate at the University of Pennsylvania. This is part of her senior thesis. We want to know about motor

learning. She happens to be a dancer. She is taking a small group of healthy late teens or young adults and she has been training them how to dance across six sessions.

What they do is they look at a video of her, which is this and this is a participant trying to follow her dance steps. And then to do the quantitative analysis, we quantitate her movements, quantitated the participant's movement and we can do a direct comparison of how well are they learning to synchronize their behavior in the form of dance. We can look at change across time from the first session to the sixth session. We might not only find difficulties with motor imitation, but we might find difficulties with motor learning.

I have a colleague at the University of Pennsylvania, Danny Bassett, who studies motor learning with functional connectivity within the brain. There is about 12 or 13 different sub-networks in the architecture of the brain with

fMRI. She finds differences in the relationships between sub-networks in the brain. Another aspiration here would be also to pair this to imaging.

We do this portable. It is not as portable as the phone. But you can see a set up here, which is two connects, a milk crate with some materials and a laptop. We do take this out to YMCAs and school programs. Last summer we took it out to camps. One of the benefits of this approach is that it is scalable. We want to get lots of data on lots of kids.

Moving on to measuring non-verbal facial communication. This is Keith, who is a computer scientist in our lab. He is sitting in front of his laptop using a little web cam and making facial expressions. This is the representation of his facial expressions. By being able to represent it, we can measure it. That is the measurement itself. You can see with exquisite

detail how good we can begin to capture these things.

This is now measuring eye gaze. He is going to move his eyeballs a lot here. You can see how well we can capture it, again, driven by software.

I have been involved in a lot of screen-based eye tracking in my career. This now promises to allow us to do eye tracking in real environments to understand really what people are paying attention and not.

When we measure dyadic interactions, we put this little tree cam in the middle. This is something we use 3D printers to print and create. It is our third generation of our camera. In the base, there is a battery that can run for six hours. There is a little hard disk that can store 40 hours of high definition video data. It is very portable.

This is now Keith in the real world. I do not want volume because we are not analyzing

speech in this data. But you can see Keith and his stepdaughter talking. That is the beach. That is the ocean. That is the Outer Banks. From this particular software pipeline, we have 70 different readouts. One of them is just eye gaze direction. You can see at one point Keith averted his eyes and Brianna followed it. You can see the exact phase lag that becomes a quantitative feature. You can see the duration of how long that Keith looked away. All those things are measurable and we were able to use them in algorithms to make predictions.

Ted Brodkin this morning spoke about his intervention study. One of his main outcome measures is called the contextual assessment of social skills. It is a six-minute conversation. The first three minutes – there is a confederate who is asked to just talk to the person. Get to know you. We analyze the facial expressions and movements of 17 individuals in this study who had autism and 27 typically developing kids who were

matched on age and IQ. Again, we used the tree camera.

Less than half of the dyads had someone with autism. I always like to ask people to look at this now and decide whether there is anyone in this dyad that might have autism because that is the computer's test. The computer's test is to – I want to label who has autism and who does not. It does not have the benefits of language or sound. I am not going to tell you the answer yet.

I will stop that. That is a three-minute conversation so I cut it short on you. This shows that we are using landmarks on different features of the face. This is translation, which is just a head position in space. This is the head pose in X, Y, Z. Eye movements, blink, brow, corners of the mouth, mouth opened, body movement. These are all features that we are tracking in real time. This red bar is this young man's median for his activity across this experiment. You can see the dynamic movement of it. This is a confederate and

you can see her scores on each of these. We could have chosen a lot more different features. These are just the ones we happen to put into this analysis. I should back up. This is really the first sets of analyses we have done on this data.

And our question is can we get a measure of dyadic synchrony. Can we predict this person's behavior based on this behavior? We do it in a fully crossed way. Any movement here. Does it list it in a time lagged way any movement over here? We think of it as a kind of mutual information. If I can understand what is going in you for me then there is some sort of structure to that conversation, which measures the synchrony or the residents of the conversation. That is going to be our key dependent variable in our prediction equations.

This is the lady you saw earlier. Again, we had 17 individuals with autism, 27 typically developing individuals. We used a machine-learning classification approach. We did what is

called a 44-fold cross validation where you leave one out. You basically train the model 143 and then test one and then you put that one back and you train the model again.

What we were able to find – these are preliminary results. They are published, but we have run them by many good computer scientists and we think they are accurate for the sample. We found an overall unbalanced accuracy of 90 percent prediction as to had autism and who did not. We were slightly better at predicting who did not autism and who did. And the kappa, the diagnostic agreement based on the base rate of the diagnosis in this group was .81. And just for reference, the kappa in the DSM field trials was .69. We are doing better than that. It may be our sample. I do not know.

The overall severity of these individuals in terms of their calibrated severity score in the ADOS was about moderate. It was about 7.3. As you

can tell, they are not what we might say as frank individuals with autism.

One of the features. There were three features that were consistently present. The top feature was present in every fold, which gives us some confidence that it is accurate. It was this rocking behavior that this young lady is exhibiting. That was an important feature diagnostically.

I am going to speed through this because I may have taken too much time. I really want to tell you – down here, since we do have language in all these people, we can improve our predictive power by adding other features to the model. We have the entire language domain that we have not included in the model yet. We have a lot of findings in the language domain already like increased use of disfluency, longer pause rate between terms, different fundamental frequency and pitch. All these are things that we know in a

T test sense predict autism. They should be helpful in this.

What does all this mean? I think what I am calling perceptual computing, other people use different names, has a lot of potential and a lot of promises. I think it can help with clinical care. If it is done in school-aged kids or younger kids, it can help reduce wait lists by doing remote screening, assessment and triage in very young kids if we can get paradigms to work down there. It can be done for earlier more accurate diagnoses, earlier interventions, and better long-term treatments.

As an outcome measure, it provides something that is very granular that can be repeated in real worlds because you just observe people. You do not interfere with people. And you can measure change without the problems of practice effects. Often times our change measures actually change across time because we ask families to do so many things.

I also think it can help with the problem of scientific reproducibility. The two main culprits I think for the field of autism is heterogeneity. If we can characterize the heterogeneity, we can control it and it is scalable so we can get big samples.

Lastly, as I have already said, I think it can really help accelerate biological discovery whether it be genetics or brain imaging because we can enrich our modeling. It is not going to be genetic information or brain information against a one or a zero. It is going to be a much richer model of the behavior that we are trying to predict. When it comes to risk genes, it is going to be able to help isolate what those genes are doing within the behaviors of kids with autism.

I will stop there. Thank you.

DR. GORDON: Again, if we could have all the panelists come up and sit at the table. I am sure that there are lots of questions from the committee. You can address your questions to

individual panelists or to the group. Samantha, I see your hand up in the air already. Why don't you start us off?

MS. CRANE: I really like movement-based studies on autism. I just want to say. I have two questions though on that study that we just saw. One is I wonder if you are going to have an easier time doing movement-based diagnosis of younger autistic people because by the time we are adults, we have often gone through intensive deliberate interventions to change how we move. We are not all going to look – some of us are going to be very stiff and are not going to rock because they are thinking at the back of their heads don't rock even if that is not explicitly something that they think that it is something that has been trained into them. You might have an easier time with younger kids.

And the other is I just wanted to also ask about the gender and racial diversity because I think that there are embodied cultural

differences across cultures in America. That might actually notice mannerisms that are culturally mediated.

DR. SCHULTZ: I thank you for that question. I think you make a really good point about how it may be easier or more difficult at different ages to make these predictions and to do these characterizations because life happens and interventions happen as well. One of the challenges will be, which we want to explore next is that we can take our predictors, our set of features which predict, and we can begin looking across different ages and do they still predict. We do not know the answer to that.

This is actually all unfunded work at this point. We have just piggy backed on Dr. Brodkin's study and he was doing this assessment. We said great. Let's measure it. We did not have the liberty. We did not make the choice any other way other than it was an easy thing to do.

And for the same reasons – I appreciate your second question and comment. Differences in cultural backgrounds and ethnicities could really affect not only the movement, but the language. The languages were drawn from ADOS. I did not say a whole lot about it, but we have hundreds and hundreds of ADOS. We are just transcribing them and looking at the acoustic properties. And those did come from funded studies where we have a much more graded concerted effort to get all cultural diversity. And there we matched both participants with autism and controls on background, on IQ, on ethnicity. That was not an interacting variable in those studies so far, but they are still rather small. That one study I showed you briefly had 100 individuals in it. We can get bigger data and we will.

DR. GORDON: I am wondering if the two folks from North Carolina on the imagine studies could speak about whether you were able to look at minority populations or other ethnic or cultural

populations and how that affects the differentiation.

DR. HAZLETT: I will say that we did not use that as a characteristic that we examined specifically, but we did I think benefit from the fact that we had a fairly diverse geographic ascertainment plan. We were funded and able to fly families. They did not have to use their own resources to fly or drive to our centers. We tried to be mindful. Our data core was very helpful in helping us track and catalog families that enrolled and make sure that we were trying to be representative as much as possible to the US population statistics. But again, we also supported families who may not have had the resources to participate in a research study because the study provided those expenses.

DR. SHEN: I will just piggy back and just say that we did conclude that groups, the groups that kids went on to develop ASD did not differ on material education, social/economic status or

ethnic diversity. We also tested to whether or not to see if – were we covariate in other words for those factors to make sure that it is not driven by those differences and it was not.

DR. GORDON: I guess the question though, which was not explicitly answered was whether your prediction algorithms would work in minority populations. I am gathering that would require more study.

DR. SINGER: My question is for Mark. First of all, that is a beautiful piece of work and very exciting to see.

I am curious though what you saw in the scans of the low-risk kids who did go on to be diagnosed with ASD. Wouldn't you need that for predictive values? What did those look like? They were not on the graph.

DR. SHEN: That is a good question. Only three kids in the low-risk group went on to develop autism. Theirs was no different than the low-risk kids who did not develop autism. But I

think it is just a small – we are talking about literally three kids. But I think that your overarching question if I am understanding it correctly is whether or not this brain anomaly is present just in high-risk infants or whether it is present in low risk or in other words a community – ascertain a sample.

And actually David and I were working on a sample of kids from the MIND Institute of toddlers that were ascertained in Sacramento from the community. Again, that is unpublished, but those kids also have increased CSF. That is a "low-risk sample".

DR. BIANCHI: I am Diana Bianchi, the director of NICHD. I want to first congratulate Heather on her excellent study and we are very proud of the work. It was published in Nature. I would like to congratulate all of you on your very interesting data.

However some of you presented your results as sensitivity and some of you presented it as

positive and negative predictive values. I would like to hear from all of you about whether you think it is better to present the data as sensitivity or in the context of positive and negative predictive values. Can we be consistent and decide on one approach?

DR. HAZLETT: I think that is one thing that is true if you look across a variety of studies. There is reporting of PPV, positive predictive value, or the sensitivity or even correlations. Sometimes correlation is being presented in the literature as a predictor. It is really just an association of two things.

We have thought a long time about how we want to best characterize the data. We wanted to use the sensitivity rating. We had a lot of input from Lonnie Zwaigenbaum. He had done this work using a different sample from his Canadian study. We wanted to know I guess going into it how accurate. I think the sensitivity was helping us to determine were we missing kids, how many were

we missing and when we got it right, how good were we.

DR. DAWSON: I also want to commend all of you on just an amazing set of work. I absolutely love these presentations. I know it is also very hard work.

It seems to me that the next step is to think about looking at some of these same measures in populations that may have other kinds of clinical conditions, but do not have autism. For example, the extra-axial CSF. I was so excited about that and still am. I think it is a really important, early marker. I work with a number of pediatric neurologists now at Duke. I ran in with this. They said that is really interesting. But you know, that is a pretty nonspecific finding. We see this actually in a lot of our kids that we deal with that have different kinds of brain injuries or other kind of metabolic conditions. Or even if you think about face processing, which is one of my areas,

we know that they can show up and people with schizophrenia and things like that.

I think that we need to really think when we do these – whether it is positive predictive value or specificity and sensitivity that we have to put it in the context of if you are trying to use this in a general population and to say now what is the sensitivity and specificity, which is very different than when you have people with autism versus typical people. That is a completely different statistical analysis. I do think we have to force ourselves now as a field to take that broader perspective.

I do think that the solution will be that what uniquely predicts autism is going to be this multi-dimensional prediction approach. There is a specific profile that may point in this direction.

And then the other way to think about it is more from an RDoC perspective. This is a good marker of a neural inflammatory process or this

is a good marker of something that has to do with social approach behavior. I do think we have to be careful when we think of these as diagnostic markers when we have not done those other kinds of studies.

DR. SCHULTZ: I appreciate your comment. As you know, it is going to be harder to do it in imaging than it is in other kinds of biomarkers – toot our own horn. We are putting all of our cameras in – there we 10,183 kids – half of them came through specialty clinics. We built a new building recently. We have wired two high-speed Internet connections to every clinical room for the 5000. If we can get families to agree, we are going to start measuring it for all the kids they see. There are a lot of ifs in there. But it is an opportunity to really do the kind of study you are asking for.

DR. SHEN: I just want to say that we agree completely. The issue of specificity I think is a major issue when we are trying to develop

biomarkers for autism and comparing just low-risk kids or typically developing kids, is not really a fair comparison when we are trying to roll this out to the community.

In order to do that, it takes collaboration. We are collaborating with folks around the world now to look at kids with other genetic syndromes, kids with other developmental disabilities, ADHD, for example, kids that are at risk for other aspects of psychiatric illness, babies that are at risk for schizophrenia because they have a mother that has been diagnosed. Really to answer that question of is this specific to autism, I think that is a question that needs to be considered for all our biomarker research.

DR. REICHARDT: I had two questions. One is, I was wondering if there were reasons why psychophysics, rivalry(?), sensory hypersensitivity, habituation, were not included in your FNIH study.

DR. MCPARTLAND: A lot of these things were stipulated by the RFA. I think the idea was really to specifically to hone in on social communication. One of the nice things about doing electrophysiology is that you can design experiments to look at social communication. You can pull a lot of things out of it. We can look at low-level visual perception and sensation in that way. But really the battery is focused specifically on social communication.

DR. REICHARDT: I had a question on the cerebral spinal fluid. When I see fluid outside the brain, I think it is indicative of pressure basically, because you have to create space between the skull and the brain. Have you looked at that? Have you looked at, for example, lymphatics, which are now thought to perhaps be a major drainage?

DR. SHEN: Really good question. In regards to intracranial pressure, it has been shown that kids with increased CSF in that space do not have

increased cranial pressure, which is strange except for when you think about the sutures of the skull have not yet fused at that early age so the skull is kind of expanding with that. These kids have bigger brains and they have more CSF. But their intracranial pressure is normal because the skull is allowing that to grow with age.

As far as the lymphatics, that is absolutely the question that we want to answer here. That is kind of the cartoon that I was showing there – collaborate with Jonathan Kipnis' groups and folks that are looking at the basic mechanisms of lymphatic tissue and its role of CSF and how to clean the brain. That is the mechanism that we are testing in the mouse models.

DR. GORDON: One of the things that I believe may be, if am mistaken, but most of the studies that you were describing were comparing high-risk individuals who go on to get it versus those who do not or to typically developing. I am wondering if you can speak to whether you think some of

these predictors are going to work in a more general population, obviously maybe not as well, but do you think that they are the same phenomenon that are happening in non-high-risk individuals, but who later go on to develop autism.

DR. HAZLETT: I have two comments I guess to say to that. We have, as Mark mentioned, another study. We are fortunate to be funded. Actually, it is an NICHD study as well to look at fragile X in a different syndrome so we can test the specificity a little bit between an autism and an fragile X modality to see whether or not we are seeing a strong effect, the same effect. The fragile X infants that we have included were able to distinguish if they have autism or not although some may argue that there is the confound of trying to tease apart some of those symptoms.

But certainly I would anticipate that if you just roll this out into a general population that

the – it would not be as strong as a predictor because it is muddier waters. We very tightly control for things like prematurity and birth weight specifically to age at the time of the scan. We were able to have a really clean sample and did not get confused by other variables and were able to look at the brain effect that we wanted to look for. I anticipate in a general population that it would be more difficult.

DR. GORDON: Let me ask the panel. As a follow up to that, we can do a fairly good job of screening using clinical instruments and parental instruments at the age of 18 months to 24 months. That is where the recommendations come from the American Academy of Pediatrics.

But what is the hope or possibility of doing that kind of general population screening at an earlier age? One thing we do know is that even with that screening when it does happen, there are still delays to getting into treatment and we know treatment should start as soon as possible.

DR. SHEN: Maybe I will just kick it off and then I will hand it to my colleagues who are more experts with this. The way I see it is that the work that Dr. McPartland is doing and work that Dr. Schultz is doing could possibly be a first tier screening. In almost every biomedical condition, you have different tiers. You first take a blood pressure before you give any medications. What they are talking about is something that is tractable. It is easy, implementable and it is not as expensive. I am sure that they are hoping to downward extend it to really young babies. Maybe that is a tier that puts a certain amount of specificity and then maybe an MRI is for those kids that are at ultra-high risk in order to really confirm that those kids are suitable candidates for treatment.

DR. MCPARTLAND: I think the most interesting and challenging part of your question relates to the service delivery system. Even if we got it all working then what. The first question is what

do you do. If you find that a one year old is going to autism, what do you do? We have ideas about that. Now we have premier data about that. This is I think one of the reasons why we want to have biomarkers. A rate-limiting factor for everything we do is the availability of experts. We are collaborating with Vikram Patel to try to figure out ways to use tablets to detect autism in India, for example, because there are not autism experts around.

I think that one of the ideas is going to be – and people are working on this. I am not. But to continue to translate treatments into ways that could be delivered by people who are not the clinical experts, by parents, by teachers, by local health care providers. You are right. Implicit in your question is there is a tremendous amount of infrastructure that has to be created to really run with some of these findings. I agree.

DR. SCHULTZ: I will just add one more thing. One of the things that we have done in our lab with the cameras in the language reporting is every paradigm we have is five minutes or less. We envision one day whatever aspects that the paradigms are meant elicit behaviors you care about and there is no cookbook on how to do that other than things – but we envision nurses in primary care administering these things for everyone who comes through if we can whittle it down to a conversation.

DR. GORDON: I have to follow up on that with just one quick very selfish question, which those who know me know why I am asking. Couldn't you do them through a computer with a video instead of a person interface some of the things at least that you are talking about doing and roll it out over the web?

DR. SCHULTZ: We could. We have actually talked to cable TV providers and we are asking them. Could they create an autism channel where

the paradigms would be the commercials and the content would be things that the kids might stem to?

DR. DAWSON: In thinking about your question, I think a very reasonable approach would be the so-called risk calculator approach that is being used in cancer and now in some mental health conditions where if you think about a pediatrician knowing a variety of risk factors, prematurity, advanced parental age, certain genetic markers, increased head size, et cetera. Perhaps some of these other markers would be put into that. And the actionable step then would be increase surveillance.

I think the key is that when you have a high-risk infant to be able to identify them so you have increased surveillance. Because indeed we are developing infant interventions that are pretty low intensity where you can provide stimulation and mitigate some of the consequences

of what we see now as a vulnerable brain because of this risk calculation.

DR. PELPHREY: Coming back to a point Jaime was making and relating back to one of the first points he made about predictors and somewhat stratification biomarkers. If we set as one of our goals, finding biomarkers that can be used as levers for the enhancement of treatment. One of the advantages of brain imaging is that you are fairly directly measuring the system that is producing behavior. If you find an activation pattern predicts a treatment response and in those kids who do not have it, they do not respond to the evidence-based treatment, a strong prediction is that if you generate that activation pattern prior to the onset of the treatment, you will bring about a responder.

You can leverage the strengths of those tools and think creatively about using brain stimulation or a pharmacological agent or something like that. That is something that I

think is only now becoming possible in work around, for example, neural feedback showing that the mirror instantiation of the state of controlling obsessive, compulsive thoughts brings about subsequent change. It does not really matter how you get there, which is fascinating.

DR. GORDON: Thanks. I think with that remark we can close. Larry has a burning comment.

DR. WEXLER: Bear with me for just a moment. The question I have is is there an advantage to characterizing this as predictive of autism or as predictive of kind of a constellation of behaviors that we interpret as autism. Again, I do this from a policy perspective. Our early intervention program under IDeA, which is birth through two, is almost predicated on not identification a disability at that age, not that they cannot, but there is a real bias towards not identifying the disability.

I would hope that somehow you would interface with that behavior on the part of the

thousands and thousands of practitioners and diagnosticians out there who are coding a kid in order to get services because the bias is really on just developmental delay or kind of a generic diagnostic category.

DR. GORDON: I have no idea what you are arguing for, Larry.

DR. WEXLER: I am not arguing for anything. I am putting out there as there is a reality that calling it autism at that age as opposed to calling it this child is going to develop a group of behaviors that needs intervention because you are doing it within the context of a system that is biased – in your universities and in all your clinical hospital settings and medical settings, you do diagnoses. But within the world of early intervention, which is where these children are going to be functioning, at that age, a diagnostic category is not necessarily an advantage especially because parents drive a lot of that and they do not want a diagnosis at 12

months of age. They want to know there is a possible problem and how to deal with it, but not necessarily saying the kid is intellectually disabled, the kid is autistic.

DR. GORDON: Now I got it.

DR. HAZLETT: I think the thing that maybe excites me about the work that we are doing looking at these early trajectories and the brain differences that we are seeing with the knowledge that all this growth is happening in those early years that you could alter that trajectory. But if you could do something at 12 months to veer that trajectory to a different course that maybe we are not talking about diagnosis so much as what is happening that you have changed. That to me is what is exciting and inspiring.

DR. WEXLER: That was my exact point. It is not that you are declaring it autism. It is that you are declaring there is a trajectory of behaviors that you could possibly influence in a positive way.

DR. GORDON: On that positive note, we are going to take a break. We are going to return at 3:40, which is six minutes from now. Please do try to get back because I do want to stay on time.

(Whereupon, the Committee members took a brief break starting at 3:30 p.m. and reconvened at 3:42 p.m.)

DR. GORDON: While you are getting to your seats, I will introduce our next presentation, which is from a fellow member of the IACC, Dr. Stuart Shapira, who is going to give us the latest updates on the Learn the Signs, Act Early program at CDC. Dr. Shapiro is the chief medical officer and associate director for science at the National Center on Birth Defects and Developmental Disabilities and the Centers for Disease Control and Prevention.

DR. SHAPIRA: Thank you very much for this invitation. Let me briefly say what the genesis of this presentation is. A few weeks ago, I gave

an overview presentation for Learn the Signs, Act Early at another NIH meeting. Susan heard that presentation. She said why don't you update the committee on Learn the Signs, Act Early. That is the reason for providing this presentation.

For those who are not aware, Learn the Sign, Act Early – the basis of it is to improve early identification of children with autism spectrum disorder and with other developmental disabilities so that children and families can get the services and the support that they need as early as possible.

The program equips health care providers as well as early care providers, education providers and families with free tools and resources to monitor a child's developmental milestones and to know how to act early if there are any sort of developmental concerns.

The goal is to increase early identification of young children with autism spectrum disorder and other developmental disabilities by helping

families learn the signs of typical development and to act early if there are any concerns.

Now the Learn the Sign, Act Early tools and materials are high quality. They are all research based and parent friendly. They help parents monitor or track their child's development and progress in an ongoing way through the age of five years. Parents are also provided with practical guidance on what to do if they have a developmental concern.

Some of the Learn the Signs, Act Early materials and resources are pictured here. They are all available on the website that is listed on the slide.

Learn the Signs, Act Early developmental milestones are adapted from the American Academy of Pediatrics' Caring for Your Baby and Young Child: Birth to Age 5 and from Bright Futures: Guidelines for Health Supervision for Infants, Children, and Adolescents.

And the milestones have been adapted for plain language and tested with parents for readability and for their ease of use.

The materials are reproducible and they do not have any copyrights. They are in Spanish and other languages. They support and complement developmental screening. We have heard some earlier today about developmental screening.

Some of the materials shown on this slide are a milestone checklist from two months to five years, which include warning signs and red flag and messages about what to do if care givers have concern. Additionally, there are children's books, which are interactive children stories that also educate parents about developmental milestones.

One other resource to point out that is shown on this slide is free continuing education trainings, which include the Autism Case Training for health care professionals and the Watch Me,

celebrating milestones and sharing concerns training specifically for early educators.

Getting the materials for Learn the Signs, Act early is pretty easy. They can be printed right off the website or a disk can be ordered that has all the materials to print or printed copies can be ordered from the CDC in limited quantities.

Here are some of the newest resources from Learn the Signs, Act Early. The newest children's book is called Where is Bear. It is an engaging story for two year olds that utilizes age-appropriate developmentally milestones. And then last summer, Learn the Signs, Act Early finished what is called the Milestones in Action, which is a milestone's photo and video library. This resource presents each developmental milestone from age 2 months to 5 years and photos or videos so that parents can appreciate what it means for their child to reach a particular milestone.

And then the other item shown here is – we are pretty excited about. A Milestone Track, which is a Smart Phone app for parents to monitor and track the developmental milestones. It alerts parents if there are any delays in their child's development and advises them on how to take action. It will be available in May of 2017.

And now I will share with you some more information about the app and its features. It will be released on the app store soon for iPhone or other IOS devices and an android version will follow sometime this fall. Spanish versions are coming next year. CDC Milestone Tracker app provides a fun and simple way for parents to track their child's early developmental milestones.

The app includes a number of different functions and features. First, there will be developmental milestone checklists from two months through five years of age that include the

photos and videos for all milestones from the Milestones in Action photo and video library.

Along with the ability to email a child's checklist results, there is a When to Act Early section with warning signs lists and information on when to act early and talk to a doctor about developmental delay.

There are also parenting tips and activities to promote development as well as health care appointment features and reminders about age-appropriate developmental screening.

The main menu is shown here in this slide in the image on the left. And an image from the milestone checklist feature is shown on the right.

Now, here on the left is a screenshot of the milestone quick view section where there are lists of milestones in each domain. And on the right is a screenshot from the milestone summary page, which summarizes responses to the milestone checklists and warning signs list. From this

page, parents can email their child's personalized summary to a health care professional or a specialist.

Once the app is available in the app store, it will be promoted to parents, to early care, and education providers, to health care providers, and other important family service providers.

Now continuing with the update of Learn the Signs, Act Early, the program also supports 45 Act Early ambassadors who in US states and territories to improve early identification of children with developmental delay and disabilities on a grassroots level. They work within state and local systems.

And partnerships are also very key to Learn the Signs, Act Early. The program works closely with US federal agencies and national organizations to make sure that the materials are responsive to the needs of different programs. The materials, resources and messages are

embedded in health care systems, in child care, in home visiting, in child welfare, and in other programs.

I want to thank you for your attention and for more information, this is the website for Learn the Signs, Act Early.

DR. GORDON: Thank you very much. Are there questions or comments for Dr. Shapiro? I have a question. In contemplating similar efforts for public outreach, there is always the question about how to update as new information becomes available. I am wondering if you have a process to continually update this program with new scientific information or new interventions that come along, new recommendations, et cetera or whether it is still in the planning process for that.

DR. SHAPIRA: All of the information is evidence based and updates have occurred to Learn the Signs, Act Early materials as new information has become available. I do not know if there is a

specific – I am not aware that there is a specific updating process that the program uses. I do have colleagues on the phone from Learn the Signs, Act Early that may be able to address. I do not know if we can hear them.

DR. GORDON: Anyone out there capable of speaking to us?

DR. SHAPIRA: Katie, do you have information on updates to Learn the Signs, Act Early as new evidence comes forward or scientific information?

PARTICIPANT: Yes, certainly. Our whole team is constantly evaluating our website and all of our educational materials to make sure that they reflect the latest information that we have and the best information that we have. Specifically in terms of the app, I do not know if you were directing that question related to the app in particular, but we do have a contract in place that will continually work to improve the app over time. We all know how many different versions of apps we always get. We are committed

to making it the best app it possibly can be at any point in time and have some resources dedicated to doing so.

DR. DANIELS: Can you tell us about how Learn the Signs, Act Early interacts with Birth to 5: Watch Me Thrive?

DR. SHAPIRA: Birth to 5: Watch Me Thrive is a coordinated federal effort to promote universal community-based developmental and behavioral screening referral and support. Learn the Signs, Act Early has been a key member of Birth to 5: Watch Me Thrive initiative since its inception. It addresses one of the critical components of the broader effort. The parent education and engagement around early child development component before and after developmental screening.

And Learn the Signs, Act Early educational resources for families and care providers promote and enhance the developmental monitoring that are a complement to, but they are not a replacement

for the developmental screening. And the resources of Learn the Signs, Act Early are promoted as part of the Birth to 5: Watch Me Thrive initiative.

DR. BIANCHI: Maybe I missed this, but is the intent for a parent to use this as a vehicle to bring to their pediatrician or to keep a personal record or will CDC or other people use the information for further research?

DR. SHAPIRA: I do not believe that CDC collects data from or would collect data from the app. Katie can correct me if I am wrong. I think this is designed for parents to follow their child's development to get essentially good reports if their child is meeting expected milestones and then getting alerts if their child does not seem to be meeting expected milestones and information on what to do in those circumstances. And the app provides the opportunity to email the summary reports to their health care provider and to bring to their health

care provider their concerns so that formal developmental screening can occur. Because this is developmental monitoring. It is not developmental screening.

It will also give alerts when developmental screening should occur during the pediatric timeframe as has been recommended by the American Academy of Pediatrics.

Is that right, Katie, which CDC does not plan to pull data from the app and collect it?

PARTICIPANT: That is correct. We will see information in the aggregate form in terms of usage of the app, but that is about it.

DR. GORDON: Thank you. Other comments or questions? We will move to the next phase. Thank you very much, Dr. Shapira.

We are now turning to the summary of advances discussion that Susan is going to lead.

DR. DANIELS: I am starting off and then I will of course turn it back over to you, Josh. We wanted to talk a little bit about the revised

process that was used to develop the 2016 IACC Summary of Advances, which you have in front of you on the desk.

We revised the process in the past year to issue requests for nominations through the year instead once a year. We send you monthly requests asking for nominations. This was just to avoid having to do it all at the end of the year so people could get reminders throughout the year.

Requiring submission of a justification with each nomination. Having the nominations discussed at each meeting. And then using each meeting to help eliminate and narrow down the items to be included on the final ballot in January.

OARC did a survey together, feedback from the committee, about how you felt about the process that we used last year and if we needed to make any improvements. I am going to turn it over to Karen Mowrer, a science policy analyst in my office, who can tell us a little bit about the survey.

DR. MOWRER: I am just going to do a brief review of the results of the survey that we sent out to collect feedback from you all. Up there on the screen you see just as a reminder, it was a brief survey. Those were the six questions that were included to gauge your feedback on how the process went. As you can see, we had 11 committee members respond. There were positive responses that were in favor of the process. You can see that the response was overwhelming positive. We had one responder who was not satisfied with the process and seemed to be predominantly concerned with feeling that the articles were scientifically significant enough and that they were not in favor in continuing the process again in the same way for 2017. But everyone else seemed to be in favor of how we did it with maybe some minor tweaks.

To review the process that we are thinking of going forward with for 2017 and also to highlight a couple of points we might want to

discuss here. As a reminder, you all receive a monthly solicitation from Summary of Advances' email account that asks you all to send in any nominated advances for the previous month. That comes out the first of every month and is asking for advances from the previous month.

We found that we do not typically in any given monthly reminder get a whole lot of responses. One thing we could discuss is the frequency of that email and if you feel that that is an effective way to serve as a reminder.

We also, as was mentioned, ask for a few sentences of justification for your nominations. We do not often receive those at least initially with the nomination. We can discuss whether that is something you feel is useful to continue. Although I know a couple of you indicated that you thought it was helpful during the voting process to have that written justification as a reminder.

We compile the advances that are nominated quarterly and have a time set aside during the meeting for discussion. One thing that has been brought up is the possibility of doing a more thorough vetting during each meeting similar to what we did at the end of the process for last year at the January meeting. The plan is to try and do that at the meeting today.

Then similarly to last year, we would send out the final nomination list in January for voting by email ballot. We count the votes, do a tie breaker if necessary, and then once the 20 articles are selected, start preparing the lay-friendly summaries and circulate that to you all before final approval and publication for release in April.

DR. DANIELS: Thanks Karen. Are there any comments on any of this? Do people have suggestions?

DR. REICHARDT: I guess I would have some concern about a survey that clearly got only a

minority response. I suspect I was one of the silent ones and probably would have been at –

DR. DANIELS: I believe we sent it more than once. Was it three times that we solicited?

DR. REICHARDT: It does bother me when you do not have a majority of response.

The second thing in terms of – I would actually encourage probably sending an email asking for nominations much more frequently because people read papers. They catch their attention. That is the time they are likely to nominate them. Even a month later, it has faded into their long-term memory in many cases. As a practical suggestion, I just think you might get more nominations if these emails came more often.

DR. DANIELS: We do it monthly now. Would you want it weekly, every other week? At what point would people start just completely ignoring the emails because they look so generic and boring and filling up your inbox?

DR. REICHARDT: I understand. There may be a risk.

DR. WEXLER: I am wondering if using your resources in your office, Susan – you could not send an email out where you have done a search and have a list of things that have come out that month or however often that have autism as a topic or a focus just a suggestion. I do not know how difficult it would be to do a search of journals. And then people have something in front of them. I know what happens in my office. I have someone that I tend to say can you look for something. And maybe if the universe was initially defined and then people clearly can go beyond it, it might get more responses. I do not know.

DR. DANIELS: I think the only concern I would have is that we may not be aware of all of the different fields that you all are experts in. You might receive a list from us that is biased toward what we know about. I do not know if

people would feel like you could still nominate other things, but if you would feel that this is biasing you or we would have concerns about not a fair representation of everything. There is PubMed, which is obviously very comprehensive for biomedical research and there are other data bases for other kinds of research.

DR. GORDON: If you do a PubMed search on autism, you get 2000 publications already in 2017. It would require a lot of curation actually.

DR. DAWSON: I do not think it is a perfect process. I do not know how we can improve on it. I think we all have to force ourselves to be good citizens and if we are excited about a paper, try to remember to send it in.

The only other thing I can think of would be we might want to highlight very high profile journals. If something got into JAMA or – or Nature, New England Journal of Medicine and other journals that we really know set a high bar in

terms of the quality, it might be good to at least capture those. I do not think there is unfortunately as many of those.

DR. DANILES: You mean in terms of our office doing surveillance of particular journals.

DR. DAWSON: Or just as a group. I do not want to put more work on you guys because I know you are so busy. That would be one way to think about if your office wanted to look for things, which is where I would start.

DR. DANIELS: How do you feel about OARC having a bigger role in trying to tell you what kinds of things you might want to nominate? I think the way we develop the process was really for it to come from the committee. I just want to be sure that that is really what you would like to do.

DR. PARNELL: Another approach to that might be for OARC if you are willing to accept nominations on an ad hoc basis – reading a paper that we think is particularly noteworthy then at

that moment we can send you an email and say this is really good.

DR. DANIELS: I did mention that in the last meeting. Everyone I think mostly knows my email address. If you reading a journal article and you like it, you can just send it to me. I know Josh has done that. Some other people here have done that before. I would just forward it over to the email inbox where we keep the stuff and we would just record it. You do not have to wait for the monthly email. You can just let us know.

DR. REICHARDT: Every couple of weeks I get a list from the Spectrum web team of papers they are covering. We can certainly share – you can ignore them or not. In fact, they do go through the 2000 papers.

DR. DANIELS: We had talked about that too of nominating things on blocks. A lot of organizations are tracking things, but if we bring everything that every organization is tracking for various purposes, I do not know if

that makes it easier. Part of our goal is to narrow down to the top quality based on the criteria of the IACC. If somebody sends us a block of 20 papers that just gets added onto the list of narrow down. I do not know if that helps us. If you see things that are on those lists that you really like, maybe it would be better just to tell us about those ones.

I guess based on this discussion, it sounds like we may be should just continue the frequency of the current emails just letting everyone know you can always just email as you are reading a paper. It does not take too much time just to forward – if you get an article in your inbox and you like it, just forward it to me and say summary of advances. That is enough to get it in.

It sounded like nobody had any objection to us doing the narrowing all the way through the year so we do not have to do everything in January.

I think with that unless there is anything else to discuss, we can just proceed with looking at the nominations we received. The justifications. With the justifications, do you want to continue with that? That puts more pressure on sending things. You cannot just forward the article without writing anything if you needed justification. Do you want to keep doing that or do you not want to continue with it? I know sometimes people feel like they have the time to send the article, but they do not really have time to do the justification.

DR. SINGER: I think the justifications are very helpful especially given that there is a wide range of expertise in areas that are outside your particular knowledge. It is useful to have those explanations.

DR. GORDON: I think last time or two times ago, there was quite a discussion we had about the importance of ensuring that these papers have rigor and import to them even at the nomination

process as opposed to the voting process in January. Without that justification, it has been hard.

I would like also just in looking over the justifications here that especially for the clinical trials, but actually I take that back. For everything, put in the ends so that we know how to judge the size, because more and more we are learning that our studies are under powered. I took it back about clinical, because it is absolutely true of preclinical studies as well. For us to start getting an appreciation for how big the studies are will help us judge their impact.

With that, we have received nominations. You all have it in your folder. I have some concerns based on some of those issues for some of these nominations. I am happy to describe them. And then I will open it for others as well.

Dr. Koroshetz, who is not hear to defend himself, suggested the Mahik et al. paper on

Maternal immunnoreactivity activity for HSV-2. The statistics on there are abominable. There is no justification for the claims made in that paper. I would suggest we not include that nomination. If there are objections to that, please speak up. I do not mean to just because I am chair, have my opinion go fiat.

Schaafsma et al., Sex-specific gene-environment interactions underlying ASD-like behaviors. I have problems with that because it is an animal study. I am not sure how well we can really – I would say the ASD-like behaviors in animal studies are very difficult to translate. Without a neurobiology, I am not that enthusiastic about it, not that I am saying that the results are not valid, but just I do not see it as a major advancement. That was also by Walter, unable to defend himself.

There was a paper, Geraldine, that you proposed on repairing on transcranial magnetic stimulation and that is really a protocol

proposal as opposed to actual data as far as I can tell.

And then another Koroshetz, the ketogenic diets. Similar reasons. It is an animal study and I do not really know how to – I worry that putting it forward as an advancement from this committee might inspire people to put their children on ketogenic diets. I do not know that we have the data for it.

DR. REICHARDT: You skipped one. The Stessman paper has clearly been challenged for its statistics. It is Walter's. It is immediately below –

DR. GORDON: Stessman paper. Targeted sequencing identifies 91 –

DR. REICHARDT: It is clear that the statistics were flawed. They have acknowledged that actually, and have redone it. I question just whether we should be featuring something --

DR. GORDON: We need to give Walter a statistics lesson. Is there any dissent to that? We will remove that as well.

Any other articles that came to anyone's attention that we might consider? Remember that we are not saying these are the advances we are going to endorse. These are just the nominations, which we review at each meeting and then in January or the meeting around then we vote on them to pick the ones that are most impactful.

DR. DAWSON: I think I did four, but one of them was from a study that Sarah Webb and Emily Jones and I, and others did. The treatment sample is relatively small, although we did have a comparative normative sample of 150 infants. But it was very novel in its approach. I would be totally comfortable with people saying it is just too small. I put it in just because it was something new that hadn't been – I am just saying don't feel awkward about saying that the sample is too small. It was 33 high-risk infants that

were randomized. There were 19 treated in pre-symptomatically and looked at brain measures and a comparison group.

DR. SINGER: Can someone explain the Vitamin D study, because there is no description or summary?

DR. GORDON: What page is it on?

DR. SINGER: It is at the top of page 5, Vinkhuyzen AA.

DR. GORDON: Gestational vitamin D deficiency and autism-related traits, Generation R Study.

DR. SINGER: I think Ruth left.

DR. GORDON: I think Ruth's comment – additional studies are needed to evaluate this interesting association might speak for itself. Again, Ruth is not here to defend herself. Although she was one of the voices for increased rigor. I think she would not mind if we put a nix on it. I am nixing that one off. Ruth can of course re-nominate or contest it. We will make sure to contact her about that.

Anything else? We will put the rest of them and give this to you.

There is question about the injury paper. Injury mortality in individuals with autism. There are concerns about the comparison group as well. Apparently I raised and did not even remember. Should we say brief report comparison group. We should nix it. And that one I am nixing my own nomination. Is there any dissent about that one?

We will move forward. Is there anything else about Summary of Advances? Look at that, behind by 10 minutes and now ahead by 15, which is good for very selfish reasons. I have to leave to take a flight at 4:45. Hopefully, we will get done with the round robin and I won't miss out on anyone else's advances. But I will take chair's prerogative and since chair is leaving to start with NIMH. For the newbies, we will go around the table and each person can bring any developments or events or exciting things to the table for the

public to know about and for the rest of the committee to know about.

DR. GORDON: Just briefly, I have three things that I think are relevant – that NIMH is working on that are relevant to the priorities of the IACC. First an update on our services research for ASD across the lifespan, the ASD project. We awarded 12 grants under this program for fiscal year 14. This is the one that supports research on service delivery and strategies to improve functional outcomes across the lifespan.

We reissued funding announcements to try to target more of the transition age youth and adult populations. We have a number of applications in that with the expected award date to come soon this year. That project is humming along. I think we did get more of the adult transition age youth applications this time around, which was good to see.

In terms of the autism sequencing consortium, which is a partnership with the

National Human Genome Research Institute, we have agreed to continue our collaborative agreement for another five-year grant period. We are really trying to sequence now 50,000 autism subjects. I think that is probably in collaboration with Simons if not in competition. All data from that effort are publicly available as soon as we can make them so through our national database as well as the dbGaP.

And then finally of interest I think to this group is that we have – actually, in deference to some of the comments that were made in the public comment period, we are beginning to approach a post-genomics era in the sense of we are identifying genes for autism or at least that increase risk for autism is a much more accurate way of putting it. And the question is what to do from a priorities perspective of the NIMH. We have convened a work group of our National Advisory Council to help us decide questions that were asked legitimately during the public comment

period. How many genes are enough? When do we stop searching for genes or at least slowdown in those efforts and put the resources towards exploiting those genes to understand neurobiology and behavior and develop novel treatments? We are actively putting our heads together to try to answer some of those questions.

With that, I will turn it over to my colleague.

DR. BIANCHI: I will be brief. Let's not throw genetics out yet because we had a very interesting two-day workshop yesterday and the day before celebrating the 50th anniversary of the intellectual and developmentally disabilities research centers, which there is alignment with some of the investigators in this room.

We heard that current state of the art is that 40 percent of children with developmental delay actually have a genetic mechanism for their developmental issues. Genetic testing is important and can direct therapy.

It was a very exciting workshop. It was multidisciplinary. Basically, I just want to let you know there will be a white paper coming out from it. There were some specific questions directed at the group and stay tuned. I think it might be something that you want to hear about at the next meeting.

DR. DAWSON: I wanted to make a few comments in my role as president of the International Society for Autism Research and most importantly we have a meeting coming up May 10 through 13 in San Francisco. I invite you all to come to IMFAR if you haven't already registered. The scientific program was organized by Susan Bookheimer and Matt State and we have keynotes by Pat Levitt, Connie Kasari, Ami Klin, and Warren Jones and a lot of symposia on topics ranging from how to promote partnerships between families and researchers to use of technology for screening and treatment. I hope you will all come.

I also wanted to mention that we a couple of years ago started to having these regional meetings, which are in places around the world where INSAR does not typically have a meeting. Our next one is going to be in South Africa September 7 through 9 in case you want to come to that. This is going to be led by Professor Petrus de Vries and will include speakers from all over the world with a strong focus on understanding cultural influences on our understanding of autism and on issues related to implementation and dissemination science.

And then finally, I wanted to mention that INSAR now has a new mechanism that is called an INSAR policy brief. I think this reflects the maturity of the organization moving from just gathering information, scientific information to thinking about how to translate that information into practice and policy. We have funded our first policy brief, which means we bring together people as thought leaders to create a document

that can be used for a variety of purposes. It is going to be tapping the talent and improving employment outcomes for people with autism that is headed up by Alycia Halladay from the Autism Science Foundation, Sven Bolte from Sweden and Sonya Girdler from Australia so very much looking at employment for adults across the world.

DR. LAWLER: I will follow up on a joint activity of NIEHS and Autism Speaks. I believe this will be the eighth year. We will sponsor – it is around a three-hour meeting, one of the evenings of IMFAR. It is the Environmental Epidemiology of Autism Risk Network or EEARN. This brings together – I think last year we had about 60 individuals that are interested and actively studying risk factors writ large for autism. A major focus of the network over the years has been promoting the career development of young, early stage investigators, trainees. We provide a forum for them to interact in a meaningful way with more senior established

epidemiologists. Last year we had I think some testimonials for some young investigators that started as graduate students attending those meetings and talked about how helpful it had been. We usually incorporate a brief postrecession. This year we are having a speed dating exercise and some lightening talks. And then there is normally an educational piece where we bring in a speaker.

This year we are having internal discussions around – it address this idea of heterogeneity and specificity of risk factors. We are also I believe – considering how to expand into more of an international forum especially given that next year's meeting is international. It has been incredibly successful.

NIEHS provides limited travel scholarships to young, early stage investigators as well. This year I think we will make 11 travel awards.

DR. COOPER: I will say that given the institutes that I am associated with, obviously

the research that we support is focused on communication disorders, communication abilities and deficits and challenges in individuals with autism.

We do not have any special initiatives related to that, but I think the encouraging thing is that we are seeing applications coming in at all levels of an individual's career path from pre-docs and postdocs to early stage investigators all the way up to senior investigators who are now turning their attention to looking at language and communication, both identification, intervention, and the challenges that some of these individuals particularly individuals who are minimally verbal.

We also support a conference real similar to what Cindy was talking about that is the major conference in child language disorders. I have seen over the last three, four, or five years that the focus has shifted from children with what we call specific language disorders,

specific language impairment to children with autism and the challenges that they present.

I guess what I want to convey is that we have a lot of attention and support for trying to unravel these challenges.

DR. REICHARDT: The Simons Foundation. I should say first in this collaboration I guess with NIMH – we released last year 500 whole genome sequences. The SSC will shortly release another roughly 500. We expect the whole Simons Simplex Collection to have whole genome sequencing done by the end of the year. We do not expect to make a larger commitment to whole genome sequencing. I should say in honesty we think the hits have been rather modest. We would rather go for numbers than whole genome.

I think big news I should say is that the Simons, actually above my pay grade, decided to make a five-year, 20 million pound commitment to the University of Edinburgh Center that will be directed by Peter Kind and Adrian Bird who I

think should be well known to all of us. We are collaborating with them.

We have committed to making a number of rat models. We are collaborating with them to decide what other ones. We expect to run all our mice and rats through their behavior and also through the Bangalore facility that they collaborated with SPARK, which is our 50,000 goal autism family project. I should say at this point we have roughly 18,000 individuals with autism, about 3000 of which are adults, 4600 trios. I think it is pretty clear on the individual level that we are well on track to get the 50,000. The dads are a bit of a challenge I should say.

We have sequenced exome sequence 460 of these through our pilot, but we will be committed to 30,000 more individual sequences with a priority on trios during the coming year.

Our RFA for this year were reviews largely. We will make decisions in May. We have started a

new collaborative group of the number of faculty at MIT on the thalamic(?) nucleus.

PARTICIPANT: I do not have any updates.

DR. FARCHIONE: I mentioned this at the last IACC meeting, but I just want to remind people that next week is the FDA's Patient-Focused Drug Development meeting focused on autism. It is on Thursday the 6th in the afternoon on the FDA campus. All you have to do is just Google PFDD and you can find the Patient-Focused Drug Development website. You can click through there to register.

At this point in terms of the folks who have registered for the meeting, it is looking like it will be a very pediatric-focused meeting. I am hoping that we can get more adults who on the spectrum to attend the meeting and participate so that we can hear more lived experience from individuals who are able to express for themselves rather than have their parents represent them. Again, the registration is still

open all the way through the third. If folks are interested, just Google PFDD and then you can find it from there.

DR. MOTT: No updates from NINDS.

DR. WILLIAMS: About two months ago, the Autism Research Program met to go over our funding recommendations or to create funding recommendations for FY16 submissions. The panel decided upon nine different projects, three or more focused on our clinical trial award mechanism and then the other six were high impact, high innovative research mechanism. More to come on that since negotiations are now under way. Those awards have not been made yet, but hopefully by the next round or the next meeting I will have more details on those projects.

MS. CRANE: I do not have any updates right now.

DR. GOODMAN: Since I am a self-advocate and I am not working – it has been a year and a half and I still have not found a job. I know we talk

a lot about services for adults on the autism spectrum. I just wanted to know if anyone knows that there is a program for individuals on the spectrum for how to keep them home and a mortgage even if you cannot keep a job long enough to pay the mortgage. I do not want to lose my house. I just do not know where to start. I just thought if anybody had any ideas where to start looking. Does anybody know about any refinance programs for people with disabilities?

DR. GORDON: The question is about refinance programs for individuals with disabilities specifically. I do not know of any.

Susan Daniels suggestion was that Jennifer Johnson may know of such things. She had to leave early. Perhaps follow up with her. Sorry about that. It is a worthy question. I am sure it is not just you who has it to ask.

DR. PINCOCK: The Agency for Healthcare Research and Quality has two reports that we are hoping to get out pretty shortly. They are

updated systematic reviews of evidence in children aged 2 to 12. The first one is entitled Interventions Targeting Sensory Challenges in Children with Autism Spectrum Disorder. And the second report is entitled Medical Therapies for Children with Autism Spectrum Disorder. We are hoping those will definitely be out before the next meeting.

DR. WEXLER: The Department of Education has been running competitions and publishing new grand priorities. However, we have no budget. We are not going to be making any announcements until we are able to write the check. We have no idea what the outcome of that is going to be for 2017. That is where we are at.

DR. SINGER: For the Autism Science Foundation, next Monday, we will be posting all of the videos from our annual Autism TED talks. Those will all be available for free. They include videos from Wendy Chung from the Simons Foundation, David Mandell, Craig Newschaffer,

Celine Saulnier, Amy Lutz, Jamie McPartland, Bob Schultz, and Donna Werling.

This Friday we will be announcing the recipients of the latest round of pre- and post-doctoral fellowships. We will be announcing nine new awards. Two weeks ago, we announced six undergraduate fellowships for research to be conducted this summer in laboratories across the country.

Finally, we are currently in review of one round of our accelerator grants. We are also accepting new applications for accelerator grants. Those are designed to leverage novel findings or make a rapid response. We in turn try to have a rapid response to those applications.

DR. SHAPIRA: Briefly, regarding CDC's Study to Explore Early Development or SEED, which is a case control study evaluating genetic and environmental risk factors for autism spectrum disorder. All of the approvals for the third

phase, IRB, OMB, and so on have been completed so that enrollment will start this summer.

And then tentatively we have on the schedule for October an update and report on SEED at the IACC meeting this fall because a lot of very fascinating reports and studies have been written up and are being submitted to journals for publication. We would like to share with the group what has been going on with the research and the priority areas for SEED.

DR. SPENCER: As the newbie, I do not have anything today. Thank you.

DR. DANIELS: Thanks. It was a terrific meeting today. Wonderful presentations and a lot of hard work by the committee and our working groups on the strategic plan.

Following this meeting, we will be working in OARC to start updating the rest of the chapters of the strategic plan. By May 5 if you can get us any further comments you have, we will work on that and then we will be in touch with

you by email about further actions with the goal of getting you a fairly final draft in July hopefully, to approve. We will be back with people on the budget issues as well.

DR. GORDON: I want to thank you all for coming. I especially want to thank Susan for organizing the meeting. To the extent that you found the presentations and discussions helpful and illuminating, it is Susan's fault. To the extent that you did not like any of it, blame it my interference. Thank you very much, Susan. I look forward to seeing you. And Susan's staff of course.

(Whereupon, at 4:35 p.m., the Committee adjourned.)