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U.S. FOOD AND DRUG ADMINISTRATION
PUBLIC MEETING ON
PATIENT-FOCUSED DRUG DEVELOPMENT
FOR AUTISM
Thursday, May 4, 2017

FDA White Oak Campus
Great Room, Building 31
10903 New Hampshire Ave.
Silver Spring, Maryland

Reported by: Natalia Thomas
Capital Reporting Company

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1 P R O C E E D I N G S

2 DR. EGGERS: All right. I think we'll get
3 started. We're waiting for a few people who are making
4 their way in, but, but we'll get started so that we
5 stay on time. We have a very full agenda of things to
6 talk about today.

7 My name is Sara Eggers and I am at the Food
8 and Drug Administration Center for Drug Evaluation and
9 Research. You'll hear CDER a lot today. That's what
10 that stands for. I'm in the Office of Strategic
11 Programs and it is my great pleasure to be the
12 facilitator of today's meeting.

13 It's wonderful to see you all here today,
14 particularly the individuals with autism and the self,
15 self-advocates and family members of individuals with
16 autism. I want to welcome you to our Patient-Focused
17 Drug Development Meeting on Autism.

18 Ellis Unger will provide some opening remarks
19 in a few minutes, but first let me start by asking my
20 colleagues sitting up here in the front to state their
21 names and where you are from and the agency.

22 DR. UNGER: Good afternoon, everyone. My name

1 is Ellis Unger and I'm the director of what's called
2 Office of Drug Evaluation 1, and Office of Drug
3 Evaluation 1 oversees the Division of Psychiatry
4 Products.

5 DR. MATHIS: My name's Dr. Mitch Mathis. I'm
6 the director of the Division of Psychiatry Products.
7 So our division regulates the medications that are
8 approved to treat psychiatric illness.

9 DR. FARCHIONE: I'm Tiffany Farchione. I am
10 the Deputy Director of the Division of Psychiatry
11 Products.

12 DR. TOURE: Juliette Toure, Senior Policy
13 Advisor in the Psychiatry Products.

14 DR. DASHIELL-AJE: I'm Ebony Dashiell-Aje.
15 I'm a reviewer with the Clinical Outcome Assessment
16 Staff in the Office of New Drugs in the Center for Drug
17 Evaluation and Research.

18 DR. LEE: I'm Kerry Jo Lee and I'm a Medical
19 Officer within the Division of Gastroenterology and
20 Inborn Errors Products.

21 DR. EGGERS: Great. Thank you.

22 DR. THOMPSON: Graham Thompson from the Office

1 of Strategic Programs.

2 DR. VAIDYA: Pujita Vaidya from the Office of
3 Strategic Programs.

4 DR. EGGERS: Okay. All right. We have a very
5 full agenda today. So we're going to spend a few
6 minutes first with some presentations by my colleagues
7 at FDA to set the context, give an overview of patient-
8 focused drug development of autism, of clinical trial
9 endpoints, and why that's important to our discussion
10 today. And then I'll come back up and give an overview
11 of our discussion format so you know what to expect as
12 we have our conversation today.

13 Our two main discussion topics are the health
14 effects and the impacts of autism. And then topic two,
15 focus on your experiences and perspectives on current
16 approaches to managing autism. We have set a time
17 aside for open public comment later this afternoon.
18 While our primary discussion is focused dialogue with
19 individuals with autism and their families, the open
20 public comment gives anyone an opportunity to make a
21 comment.

22 To participate in that you'll need to sign up.

1 It's first come, first serve. Sign up at the
2 registration table. We'll close the registration at
3 the end of the break or after we reach 15 commenters.
4 The time allowed for each speaker will depend on the
5 number of participants who sign up and it'll likely be
6 around two minutes each.

7 Okay. As I mentioned, there's no kiosk today
8 with food, but we do have the vending machines and we
9 have coffee out in the front. I hear it's all, it's
10 all caffeinated coffee. And if anyone does need food,
11 please find one of our team members who can help you
12 locate food in our cafeteria.

13 The restrooms are located in the back of this
14 -- they're about as far away as you can be in the
15 building. So they're at the far hallway in the back
16 and then to the right. And you'll find those there.

17 We will take a break at about 3 o'clock, but
18 we encourage you to get up at any point, to get up for
19 any reason. Please feel free to do so.

20 We do have a quiet room that is located
21 outside the hall and behind us here. So feel free to
22 use that room at any time if you need to. And we'll

1 ask you now to silence your phones.

2 The meeting is being transcribed and there
3 will be a live webcast being recorded. So I do want to
4 take the opportunity to thank the people who are, many
5 people who are joining us through the web today. We
6 will ask for your participation as well. So both the
7 transcript and the webcast will be archived on our
8 website.

9 And with that, are there any other logistic --
10 I think, I think those are all the key things I need to
11 say now. So I will turn it over to Ellis to give some
12 welcome remarks. Thank you.

13 DR. UNGER: Good afternoon, everyone. We're
14 the Food and Drug Administration. We really should be
15 able to find food. So I don't quite understand that.
16 But if you have trouble, you talk to Sara. And if
17 you're transcribing this, so be it.

18 Okay. Again, good afternoon to everyone and
19 welcome to this patient-focused drug development
20 meeting on autism. And as I mentioned a minute ago, my
21 name is Ellis Unger. I'm Director of the Office of
22 Drug Evaluation 1 and Drug Evaluation 1 includes

1 psychiatry, which regulates the treatment - excuse me -
2 regulates drugs for the treatment of psychiatric
3 conditions, and also drugs that might assist in
4 managing autism.

5 And on behalf of my colleagues, I want to
6 extend my appreciation for the individuals with autism
7 and families who are here in the room, and also I know
8 there are a number of people who will be on the webcast
9 and I'd like to thank all of you for being a part of
10 the meeting and sharing your experiences with us.

11 And we really look forward to sharing an
12 opportunity to engage directly with you and we want to
13 learn about aspects of autism that matter most to your
14 child or to you, and the types of things that make an
15 impact in your daily lives or to your child's daily
16 life. And we want to learn about what's important to
17 you when you think about potential treatments that
18 could address some of the health effects of autism.

19 Dr. Tiffany Farchione is on my right from
20 Division of Psychiatric - excuse me - Division of
21 Psychiatry Products and she'll provide a bit more
22 background on autism in a few minutes.

1 We understand that autism is complex and it
2 affects individuals in different ways with different
3 physical, emotional, and social impacts. And many
4 individuals with autism require medical treatments to
5 help manage certain aspects of their condition, and
6 where medical treatments are concerned, it's our
7 responsibility here at FDA to help develop new drugs
8 that matter to people. That's what we do.

9 And I understand we have many people from
10 industry here, academia, and other government partners
11 joining us to listen. And some are here in the room
12 today. Some are probably on, on the web. And I have a
13 few messages I'd like to convey.

14 First, although we play a critical role in
15 drug development at the FDA, you might be surprised to
16 learn that we don't actually do clinical trials at the
17 FDA. A lot of people think we do. That's, that's a
18 misnomer. Clinical research is a lot of hard work and
19 we work with companies and researchers and patient
20 communities to help design the drug trials to establish
21 the drugs are effective and safe. We don't actually do
22 the trials here.

1 We approve drugs only when we have scientific
2 evidence that they help patients feel better or
3 function better. That's kind of the rule that we live
4 by. And then once we make that determination, then we
5 have to make a decision in terms of whether the
6 benefits outweigh the risks.

7 But what we need to know from you is what you
8 value in your daily lives. Basically what, what
9 matters to you. What would, what would, what would
10 give us a clue that you feel better or function better
11 and how one might measure that in a drug study.

12 So we want to hear what people with autism and
13 their families care about. We want to hear what
14 individuals and families think about the benefits and
15 risks of potential treatments to manage autism, and we
16 want to hear how to develop better ways to measure how
17 well a treatment addresses the aspects of autism that
18 are important to people in the room. And then we look
19 forward to incorporating what we learn through the
20 meeting in, in terms of accelerating and facilitating
21 drug development in this area.

22 So once again, we thank you for your

1 contributions to this meeting, and I think that having
2 this type of dialogue that we expect to have today is
3 extremely valuable for, for us and for others. And
4 we're grateful to each of you for being here to share
5 your personal stories. I know some of them are, could
6 be difficult. We want to hear your experiences and
7 perspectives.

8 And now I'll turn it over to Pujita Vaidya who
9 will provide some background on the patient-focused
10 drug development efforts in general. Thank you.

11 DR. VAIDYA: Thank you, Ellis. Hello,
12 everyone. I'd like to thank you all for coming today
13 to participate in our patient-focused drug development
14 meeting. We're here today to hear from you, but before
15 that I'd like to give a brief overview on the patient-
16 focused drug development initiative that we started
17 five years ago.

18 FDA recognizes that people living with a
19 condition have a direct stake in the outcome of drug
20 development, and they are experts in what it's like to
21 live with the condition. People living with the
22 condition are uniquely positioned to tell us about the

1 benefits that would be most meaningful to, to them, the
2 things that bother them the most and perspectives on
3 overall condition. And this information can then
4 inform the drug development and drug evaluation.

5 Through the patient-focused drug development
6 initiative, FDA is developing a more systematic way of
7 gathering patient perspective on their condition and
8 treatment options. This input can help inform the
9 collective understanding of the therapeutic context of
10 drug development, which is important to our role,
11 FDA's, as regulators and the role of developers and
12 others throughout the drug development process.

13 As part of the patient-focused drug
14 development drug initiative, FDA's convening 24
15 meetings in a 5 year, a 5 year period, each meeting
16 focused on a specific condition or a group of
17 conditions.

18 Here's a quick overview of the list of these
19 specific meetings we have focused on in the past few
20 years. In the five year timeframe you can see that we
21 have tried to cover a broad range of conditions which
22 include several rare diseases, conditions that are

1 chronic, that are symptomatic or have loss of
2 functioning, that might affect functioning, and affect
3 different subgroups as well.

4 One of the main outputs of these patient-
5 focused meetings is a report which is called The Voice
6 of the Patient Report that captures the patient input
7 faithfully and, and exactly in your own words, in the
8 participant's own words. We take what we hear from you
9 at these meetings, things that we hear from the webcast
10 and through the written docket, and we summarize that
11 and, hoping that we are able to capture this exactly
12 the way that you have expressed it to us today here.

13 We see this as a useful reference tool for us
14 as it can support FDA staff as they conduct benefit-
15 risk assessments for products under review, or when
16 advising drug sponsors on their drug development
17 programs.

18 We also believe these meetings can have value
19 to drug development more broadly by helping to identify
20 areas of unmet need, such as aspects of, of patients'
21 conditions that is not currently being addressed in
22 current therapies. This input may also help developers

1 as they identify or create tools used to measure the
2 benefit of potential therapies.

3 And finally we have seen the potential in
4 these patient-focused meetings to help raise awareness
5 within the community as well. So I hope this gives you
6 a brief and better understanding of our program.

7 Now I'd like to turn it over to Dr. Tiffany
8 Farchione who will give a brief overview of the
9 condition. Thank you.

10 DR. FARCHIONE: Thank you. Hello, everyone.
11 And again, as everyone is saying, thank you guys for
12 being here today. We wouldn't be able to do this
13 without all of you who are, who are here in the room
14 and the folks who are listening online.

15 So for me, I'm going to be talking just a
16 little bit about the actual diagnosis of autism itself.
17 So talking about what it is, who might be at risk for
18 autism. What the clinical manifestations are. Give
19 you a little bit of an idea of some of the
20 demographics, the current treatment options, and some
21 of the challenges in terms of drug development for
22 autism spectrum disorder.

1 So what I'm going to focus on is just the, the
2 current diagnostic criteria as I'm sure a lot of guys
3 in the room know that criteria recently changed in the
4 transition from DSM-IV to DSM-V. So I'm going to just
5 focus on the current diagnostic criteria.

6 So in order to receive a diagnosis of autism
7 spectrum disorder, an individual has to have persistent
8 deficits in social communication and social interaction
9 across multiple contexts. So this includes things like
10 deficits in social reciprocity and nonverbal
11 communication. So like trouble with eye contact or
12 trouble interpreting body language. They also have
13 trouble developing, maintaining, or understanding
14 interpersonal relationships.

15 With regards to restrictive and repetitive
16 patterns of, of behavior and interests, this would
17 include things like stereotyped behaviors, insistence
18 on sameness, restricted interests, and, and sometimes
19 you get either hyper or hypo-reactivity to sensory
20 input. So these are, I think about -- so by way of
21 background, I'm a child psychiatrist.

22 So I think back to patients that I had where

1 the parents would come in and complain that, you know,
2 my, my son can't stand to have a tag on the back of his
3 shirt and I have to cut all the tags out of his
4 clothing because if it even touches him, he can't stand
5 it. So that would be like hyperreactivity. That would
6 be an example of hyperreactivity to sensory input.

7 So other things that are on the list of
8 diagnostic criteria, you know, obviously the, the
9 symptoms have to be present in early development. Most
10 often, you know, usually this gets recognized in the
11 second year of life. Although, you know, delays in
12 diagnosis are not uncommon. The symptoms cause
13 clinically significant impairment in functioning. Now
14 this is kind of the criteria that cuts across all
15 diagnoses in the DSM. If it doesn't impair your
16 functioning, then it doesn't get counted as a disorder
17 in the book.

18 All right. And then there can't be a better
19 explanation by something else, whether it's
20 intellectual disability or some other global
21 developmental delay. You know, if there's some other
22 explanation, then you don't call it autism.

1 So what are the risk factors for, for this?
2 We don't know what causes autism, what makes one person
3 normal, and what makes another person one way. We
4 don't know why some people are more severally impacted
5 and others are not. But in the grand scheme of things,
6 it's very likely that there's multiple causes because
7 there's probably multiple types of autism spectrum
8 disorder. There could be environmental, biologic,
9 genetic factors. All of these things are likely to
10 play a role.

11 So for instance somebody who has a sibling on
12 the spectrum is at higher risk of being on the spectrum
13 themselves. So that speaks to the genetic factors.
14 There are certain genetic or chromosomal conditions
15 where autism is more common like Fragile X or tuberous
16 sclerosis. And, you know, in terms of other biological
17 factors, children born to older parents are at greater
18 risk for having ASD. So those are just a few examples
19 of things we know so far, but there is still a lot that
20 we don't know.

21 As far as, you know, if you have a person with
22 autism sitting in the room in front of you, what is

1 that -- how are you going to know? How are you going
2 to recognize that? So I've got a long laundry list,
3 two slides' worth of things that you might notice.

4 So in little kids, some of the first things
5 that you might notice are that, you know, your child is
6 not pointing to the things that he or she wants. They
7 might not look at an object when another person points
8 at it. Trouble relating to others. Trouble playing
9 with other kids. Not making eye contact. Wanting to
10 be alone. All of these things are part of the, the
11 overall clinical picture.

12 So, and then a few other things. Not being
13 interested in people or having trouble, having trouble
14 pretending. There's, and then again, like I was saying
15 earlier, some of the manifestations like repeating
16 actions over and over again, or, you know, really
17 restricted range of interests to where like, you know,
18 you can't change the conversation from one topic to
19 another because the person with autism is stuck on the
20 one, the one topic.

21 So, you know, but when you look at this and
22 you see that there's this broad range of things, it,

1 it's sort of a preview for a couple slides from now
2 when I talk about the difficulty in, in developing
3 treatments, right, 'cause what do you target?

4 So just to let you know an idea of how common
5 this is, I know that this is -- well, I mean the
6 screens are really big. So I guess it's not as small
7 as I thought it was going to be. But one of the things
8 that has been an issue is that it seems as though the
9 prevalence is increasing. You know, and there's always
10 been this argument like is the prevalence actually
11 increasing or are people recognizing it more? Are we,
12 you know, what's going on?

13 Nobody really knows, but at least in the last,
14 the last two surveillance periods it seems that things
15 have stabilized. So the, the prevalence is still, you
16 know, it's incidents, rather, is 1 in 68 children. So
17 that is a lot of people with autism. And again,
18 because it's a spectrum, you know, the, the level of
19 impairment or the level of functioning will vary
20 greatly across all of those individuals.

21 So what do we do about this? As of right now,
22 there are no FDA-approved drugs to treat the core

1 symptoms of autism. So, you know, the things, as far
2 as the social communication issues or the repetitive
3 behaviors and things like that, there's, there's
4 nothing. We don't have anything approved for, for
5 those features.

6 What we do have are drugs that are approved
7 for the treatment of irritability associated with
8 autism. And, you know, it's still a piece of the
9 picture that can be very impairing, but it's not, it's
10 not the core of, of the condition.

11 So the mainstay of treatment at this point
12 actually is, is behavioral therapy, things like applied
13 behavior analysis, the Early Start Denver Model. There
14 are a number of different approaches. We don't
15 regulate any of those. So, so I can't really speak too
16 much further to that. Again, like the behavioral
17 interventions are the main, the main treatment right
18 now.

19 But there are a lot of challenges to, you
20 know, developing a drug to treat an aspect of autism or
21 autism writ large. One of the biggest ones is that we
22 just, you know, the pathophysiology of, of autism is

1 unknown. So this means that we don't like, we don't
2 know what, you know. So like, for instance if you, if
3 somebody says that you've had a heart attack. Like you
4 know that there was a clot that went to one of those
5 tiny vessels in your heart and it blocked it and then
6 part of the heart died. So that's the pathophysiology
7 of a, of a heart attack, right?

8 So we don't know what the mechanism is behind
9 autism. And so if you don't know what the mechanism
10 is, it's hard to figure out how you target that for
11 treatment. Or for prevention even. And we don't know.
12 You know, there's probably lots of different causes for
13 what leads to autism spectrum disorder.

14 We also don't know what the best endpoints are
15 for, for clinical trials. You know, there are a lot of
16 different diagnostic rating scales. But if you are
17 able to find a treatment that actually makes a change
18 or improves something, we don't know how sensitive
19 those diagnostic scales are for measuring change. You
20 know, we don't, we don't have, we don't have good
21 scales in order to say like, okay, we're going to look
22 at this or we're going to look at that.

1 So you end up with sort of a piecemeal
2 approach. Like, well, I'm going to look at social
3 communication and there's this rating scale for social
4 communication. There's this rating for repetitive
5 behaviors. And we're, kind of cobble it together and
6 see if we can come up with an endpoint.

7 And then on top of that, we're going to get
8 like a global assessment to say, well, you know, sort
9 of general idea are patients doing better. And a lot
10 of that is difficult to translate into a clinical
11 trial.

12 We also don't know how long it takes before
13 you see a meaningful change. So say for instance you
14 find something that works, that really helps to, for
15 instance, you know, decrease the number of repetitive
16 behaviors and a person is now able to function better
17 out in the world and have better social interaction,
18 how long does it take before that happens?

19 You know, and if you don't know how long it
20 takes before you're going to see that happen, you don't
21 know how long your clinical trial needs to be. You
22 don't know at what point you need to assess the

1 endpoint. You don't know whether, you know, maybe
2 there might be early signs that you could have an
3 earlier endpoint in the trial. So it makes it very
4 challenging.

5 And we also don't know like is there a, a
6 window where you can intervene and make a difference.
7 So if there's a, a way to treat, to affect change in a
8 child, is that going to have the same effect on an
9 adult whose, you know, brain is fully developed and all
10 of those things. We, these are things that we don't
11 know.

12 And the other big question is where along the
13 spectrum, where along the spectrum do you actually need
14 to intervene, you know, because you have one end of the
15 spectrum where folks are severely impaired and, you
16 know, have like totally nonverbal, intellectual
17 impairments, unable to live on their own, will always
18 require assistance.

19 On the other end of the spectrum you have
20 folks who are very high functioning and, you know, hold
21 down great jobs and can have a life and a family and
22 all of these things. And then you have everything in

1 between. So at what point along that line would you
2 actually say, well, maybe we ought to do something
3 about this? Like maybe we need a medication to treat
4 that.

5 And that's part of what we're going to be
6 talking about today because we're well aware that, you
7 know, there are folks who are at this end of the
8 spectrum where they're doing pretty well. They don't
9 need a drug, you know. They're doing all right. But
10 folks at this end of the spectrum are going to need
11 some help. So where along that line do we, do we
12 interfere?

13 So just broad overview, the prevalence of
14 autism spectrum disorder has been increasing in the
15 United States even though it appears to have
16 stabilized. Like I was saying, we don't have any drugs
17 approved at this point. But, you know, I think that
18 speaks to the unmet medical need that we have here.

19 And there are a lot of challenges that I've
20 just outlined and that we're hoping that, you know,
21 through some of the feedback that we get from you guys
22 today, maybe you can help answer some of those, those

1 questions for us.

2 All right. And then up next is Ebony and
3 she's going to talk a little bit more about the
4 endpoint issue that I had previously mentioned.

5 DR. DASHIELL-AJE: Good afternoon, everyone.
6 So today I'm going to take you on a brief journey down
7 the road from patient-focused drug development public
8 meetings to clinical study endpoints. Here's a general
9 disclaimer, that the views that are expressed in this
10 presentation are my own.

11 So you may be wondering how is the information
12 from these PFDD meetings used? Where do we go from
13 here and how do we take this valuable insight and
14 create clinically relevant, patient-focused endpoints
15 for clinical studies?

16 At the FDA we believe that PFDD meetings are
17 very important. They provide the opportunity for
18 individuals' and caregivers' voices to be heard. For
19 instance in the case of today's meeting, individuals
20 and caregivers can share their experiences with the
21 health affects of autism in their own words, letting us
22 know what symptoms and impacts are most important to

1 them.

2 And drug companies want to know this
3 perspective because it can give them ideas about what
4 should be measured in their clinical studies. They can
5 then select and develop questionnaires that measure
6 these important concepts and engage with the FDA as
7 they develop treatments.

8 The information from these meetings can also
9 help support the FDA's review of clinical trial
10 questionnaires to confirm that they adequately capture
11 the individuals' and caregivers' perspectives on health
12 outcomes.

13 While the PFDD meetings provide useful
14 information, we strongly recommend that drug companies
15 and researchers obtain additional input from
16 individuals and caregivers through focus groups, one-
17 on-one interviews, as well as engage experts and other
18 physicians when they develop their questionnaires. And
19 this will help confirm that the questionnaires include
20 important and relevant content and that the questions
21 and instructions are clear and understandable by those
22 who will complete them.

1 Another advantage of these meetings is that
2 they help us think about clinical study endpoints. So
3 what's an endpoint? In the case of questionnaires, the
4 study endpoint would be how the questionnaire score is
5 going to be measured and analyzed in the clinical
6 study.

7 For example, if individuals with autism or
8 their caregivers are reporting that the most important
9 treatment benefit is symptom improvement, then we would
10 use that information to encourage the drug company to
11 select or develop a symptom questionnaire that meets
12 regulatory standards. The study endpoint could
13 possibly be the change in the questionnaire score
14 during the clinical study, which would measure the
15 amount of symptom improvement.

16 I should note that many important things are
17 discussed during these PFDD meetings; however, not
18 everything will change with treatment and it would be
19 difficult to interpret results if these concepts are
20 measured within the clinical setting of drug approval.

21 So since we focus on efficacy and safety at
22 the FDA, a concept like financial wellbeing, for

1 example, may not be impacted by a treatment in a
2 clinical trial setting even though it may be important
3 to individuals and caregivers.

4 So we encourage drug companies to consider
5 focusing on important concepts that are most likely to
6 reflect the effects of treatment as their main key
7 study endpoints. If financial wellbeing is measured,
8 however, in a trial, we would suggest that it instead
9 be designated as a supportive, exploratory endpoint.

10 At the FDA we have to uphold laws and
11 regulations. And within these regulations, there are
12 regulatory standards that require us to ensure that
13 assessments like questionnaires generate responses that
14 are well-defined and reliable and are not potentially
15 false or misleading when described in labeling. To
16 ensure this, we ask that drug companies gather input
17 from individuals and caregivers through those one-on-
18 one interviews and focus groups to develop the
19 questionnaires.

20 We also ask them to perform the appropriate
21 statistical testing to support questionnaire
22 development. These methods help demonstrate that the

1 questionnaires measure the right thing, in the right
2 way, and that the score is accurate and reliable so
3 that any positive score changes can be interpreted as
4 symptom improvement due to the treatment.

5 Now we recommend that drug companies engage
6 with the FDA early and often when they're developing
7 questionnaires. So how does the FDA engage with drug
8 companies? We currently have three pathways to provide
9 advice to those interested in using questionnaires or
10 what we call clinical outcome assessments in clinical
11 studies.

12 The first pathway is within the context of an
13 individual drug development program. Through this
14 mechanism we encourage drug companies to begin
15 discussions about their questionnaires as early as the
16 pre-I&D phase to ensure that there's enough time for
17 questionnaire development before their Phase 3 clinical
18 studies.

19 The second pathway is within our drug
20 development tool or DDT qualification program outside
21 of the I&D pathway where we can work with questionnaire
22 developers to create and qualify questionnaires that

1 meet unmet public health needs and can be used
2 publically across multiple drug development programs.

3 The third and final pathway is through the
4 critical path innovation meeting process where a
5 questionnaire developer or a drug company can discuss
6 and receive general feedback from the FDA on a clinical
7 outcome assessment in the early phase of development
8 outside of the individual drug development program.

9 So I want to leave you with a few key
10 takeaways. The first takeaway is that PFDD meetings
11 are a starting point for developing patient-focused
12 outcome measures and endpoints. The second is that
13 outcomes of PFDD meetings will support and guide FDA
14 risk-benefit assessments and drug reviews.

15 And lastly, individual and caregiver input
16 ultimately helps determine what is measured to provide
17 everything of treatment benefit, how best to measure
18 concepts in a clinical study, and what a meaningful
19 improvement is in treatment benefit.

20 So that concludes my presentation and I'll
21 turn it back over to Dr. Eggers.

22 DR. EGGERS: Thank you to my colleagues for

1 the background demonstrating the complexity of the
2 condition in drug development for treatments. Now I'm
3 the only thing that's standing between us and what we
4 are really here for, which is dialogue with individuals
5 and family members today. And to do that I want to
6 give a few, a few opening, a few descriptions of what
7 our meeting looks like today.

8 So as I mentioned at the start of the meeting,
9 and I know some of you have come in after the opening,
10 so I'm going to go through this again so we're all on
11 the same page. We have two topics that we are looking
12 to cover today. One is on the health effects and the
13 daily impacts of autism, and the second is on the
14 current approaches to treatments.

15 And for the first topic that we'll cover,
16 we're really interested in looking about what are
17 health effects that are most challenging for you or
18 your child if you're the parent of a, of a child with
19 autism. How do the health effects impact you or your
20 child's daily life, and how are those experiences with
21 times changing over time?

22 When we think about the current approaches for

1 treatment, we're looking at what are you or your child
2 currently doing to, to manage your autism. What are
3 the goals for the treatment? How well are those
4 treatments meeting your goals? And what would you
5 consider to be a meaningful benefit of any treatment?

6 Understanding this allows us to understand
7 better the things that Ebony and Tiffany were saying
8 about the types of things that, that drugs and medical
9 treatment should be targeting and the things we should
10 be looking for in terms of improvement. And then what
11 are the key things you think about when deciding
12 whether to start or stop a new treatment?

13 This meeting is quite different from other
14 public meetings that you may have attended. Our intent
15 is really to foster open dialogue on personal
16 experiences and perspectives on autism. So on each of
17 these topics we're first going to kick off with a panel
18 of individuals and family members and I would like to
19 ask the, the people who are speaking on topic one, the
20 panelists, to come up and take, and take a seat at this
21 point.

22 So the purpose of the panel discussion and

1 comments is really to set a good foundation to kick off
2 our discussion by providing a brief snapshot of six
3 different experiences with autism. And some of these
4 individuals are also affiliated with support advocacy
5 or research organizations. They've all prepared
6 remarks and I thank you very much for the effort in
7 putting forth.

8 And I also want to thank the effort, those of
9 you who submitted comments and, and expressed interest
10 in participating in panel. We weren't able to, to
11 select everyone, but your comments sent to us are
12 really important because they help us prepare for this
13 meeting and they provide insight.

14 And if you submitted comments at any point to
15 our inbox, to our e-mail, we suggest, we recommend that
16 you submit those comments in their full form to our
17 public docket, which is a website. And I'll get into
18 that in a little bit.

19 Okay. So after each of the panel discussions,
20 so after you give your remarks, then we'll move out and
21 have a facilitated discussion with all of the
22 individuals and family members in the room. And the

1 purpose here is to build on what we heard from the
2 panel members to get a sense from you what is generally
3 similar and what may be different in your experiences
4 and your perspectives from what you heard.

5 So I'll ask a number of follow-up questions
6 and my colleagues from FDA will also ask any questions
7 that you like. To do so we will have our team floating
8 around with microphones to bring the microphone to you.
9 So you don't need to stand up at all. Just raise your
10 hand if you have an answer to the question that's being
11 asked.

12 We're going to ask that you state your first
13 name, and just your first name is fine, before
14 speaking. And for the sake of transparency, with also
15 request that at the time of your first comment, that
16 you disclose if you have an affiliation with an
17 organization that has an interest and issues related to
18 autism, or if your travel here today has been funded,
19 or if you have significant financial interests in any
20 autism drug development.

21 So as we move through the, this discussion,
22 we're going to navigate through various perspectives.

1 There are three main perspectives that we'll hear
2 today. We'll hear from parents who are caring for
3 children. We'll hear from parents who are caring for
4 adults. And we'll hear from self-advocates, the
5 individuals with autism.

6 Each of you will have your own perspective and
7 your own experiences. We're going to try to navigate
8 through that fluidly. They'll be times when I ask a
9 question specific to one of you, but we ask that each,
10 when you speak, just to remind us or to give us a brief
11 description of what category you're falling in, whether
12 you're a parent of a young child, or a child, parent of
13 an adult, or a self-advocate. Okay.

14 And to keep -- we ask as we, to make this
15 discussion efficient, we'll be asking questions and
16 please stay on the topic of that question that was
17 asked and keep your response to a minute. We really
18 want to make sure that we get to everyone who has
19 something to contribute today.

20 If we don't get -- if you don't get to fully
21 say what you want, that's what the docket -- and I'll
22 get to that. You'll be able to provide us additional

1 comments later. I'm going to try to, and the
2 microphone, folks with the microphone, will try to keep
3 and allow everyone to get a chance to speak.

4 A few other things. We have some polling
5 questions. So if you've been wondering what those
6 little discs are in front of you, they are our very
7 fancy clickers. We will be asking questions from time
8 to time. We're going to ask that individuals with
9 autism and a family member, or a family member who is
10 answering, thinking about a child or children with
11 autism use the polling questions.

12 These are not a scientific survey at all.
13 The, the purpose is to aid in our discussion to see
14 what kinds of, of perspectives and experiences are, are
15 shared by those in the room. So the in-person, you'll
16 use these discs, the clickers. You'll know if your
17 clicker -- you're going to see -- there's going to be a
18 question and then an answer will be A, B, C, D, E. You
19 click what's, what's most appropriate. Sometimes you
20 only click one thing and sometimes you get to click
21 more than one thing.

22 You should hear a little, or feel a little

1 buzz if you, if it has captured your click. If it
2 doesn't, raise your hand and we will come and help you.
3 And on the web, we very much value your participation
4 and these, the polling questions are a chance for you
5 also to contribute as well. So the same polling
6 questions are asked of you. And there you'll just
7 answer in the, you know, with your mouse. If you have
8 any problems, type in the comment box and someone will
9 help you.

10 And if you're on the web, you can also add
11 comments through the webcast. You can type your
12 comments. Although they might not all be read today,
13 they are captured. We will summarize them and they'll
14 be included into our summary report.

15 And we will also try to go to the phones to
16 give you another opportunity to contribute. And
17 information about the phone will be made available
18 through the webcast.

19 So I've been talking about the docket. It is
20 a fancy federal term for a way to send comments to any
21 regulatory agency through a website. So we call it the
22 public docket. This docket will be open for two months

1 following the meeting. So it will close on July 5th
2 and any time you can send multiple comments if
3 something else comes to mind. You can send in
4 comments.

5 If you know there are people who couldn't make
6 it today, whether you signed up or that didn't sign up,
7 or you know people who you think really have something
8 important to contribute, encourage them to participate
9 and send us comments through the docket. And if you
10 thought of something today, it come to your mind, send
11 it along.

12 You can visit these -- by the way, these
13 slides will be posted on our website following the
14 meeting. And so you'll be able to visit this link or
15 you can go to www.regulations.gov and search on autism
16 FDA. And there you will find it. There's a comment
17 now button you can click. If you have any problems, e-
18 mail us through the e-mail that you have received
19 communications from us.

20 Okay. There are a couple other resources at
21 FDA. Just want to point you to if your, if you become
22 or are interested in topics related to FDA and drug

1 development and drug review, if you're an individual
2 and family, I would suggest your first stop is our FDA
3 Office of Health and Constituent Affairs. They run the
4 patient network and patient representative program. So
5 you can contribute your voice that way.

6 And for advocacy and support in healthcare
7 providers, a first stop for you might be CDER. That's
8 the Drug Evaluation, Professional Affairs and
9 Stakeholder Engagement or we call the PASE. They
10 facilitate collaboration and communication between the
11 FDA experts and stakeholders on issues and drug
12 development review and safety.

13 And I also want to put a plug. On May 12th if
14 you're interested in this topic, there's a workshop
15 called Roadmap for Engaging with CDER. You can Google
16 Roadmap and CDER and you should be able to find that
17 right away. If you have any questions, again e-mail
18 us. We're not, our office isn't running that meeting.
19 It's, I believe PASE is, but we can definitely point
20 you in the right direction.

21 So there are a few, a few rules we'd like to
22 put out to make sure that our meeting is as effective,

1 fair, and open as possible. And, and I'll start with
2 encouraging all family members and individuals to
3 contribute to the dialogue. Whether you have name tag
4 or not, we don't know if we have name tags for
5 everyone. If you are a self-advocate or a family
6 member, we want to hear from and we encourage you to
7 contribute. Everyone else, we're asking you to stay in
8 listening mode. There is that open public comment
9 period for you to contribute if you would like to.

10 FDA is also here to listen. They'll ask some
11 follow-up questions. You may have questions on your
12 mind for FDA. We may not be able to address questions
13 as much as we would like today, but if you do have a
14 question, write it down on your evaluation form that
15 you'll find or write it down on a slip of paper and
16 send it to us. Or e-mail us and we will figure out a
17 way to answer your question.

18 The discussion will focus on the two topics I
19 mentioned, the autism health effects and the
20 treatments, and there, what we will not focus on much
21 today are the specific causes of autism or issues as
22 much with regard to the healthcare system in general.

1 We'll be focusing as much as we can on what FDA, what's
2 within our mandate and mission to think about.

3 It is imperative to understand that the views
4 expressed today are personal opinions, and not only are
5 they personal opinions, they're very personal, very
6 sensitive topics that we'll be covering today. And it
7 is a lot. We know it's a lot for you to come and speak
8 today. And we, you can know that everyone in the room
9 respects that. And if you're typing in on the web, the
10 same. We have respect for everyone and everyone's
11 perspective. We know that we have people who are
12 wearing different hats and they have different
13 experiences with autism. And so we just want to make
14 sure that respect for one another is paramount.

15 Finally, let us know how the meeting went
16 today at the end of the meeting. Evaluation forms are
17 available at the registration table. They are very
18 much important to us. Although we've conducted, I
19 think, 22 of these meetings, we learn every single
20 meeting how we can do better. And so we value your
21 input.

22 With that, we are ready to get into some

1 polling questions. So I'll ask those of you in the, in
2 the room to get your clickers. We start with, we start
3 with probably the easiest one we have, which is where
4 do you live. So if you live within the Washington, DC
5 metro area, we'll ask you to click A. And if you came
6 from outside the DC area, we'll ask you to click B.

7 Any challenges with the clickers? Just raise
8 your hand and we'll come to you. Okay. All right.
9 Your, oh, up here. This is not, this is, this is a
10 question, okay if you don't get a chance to answer. So
11 can we -- I'm getting some buzz that we might have some
12 difficulties with the polling question. So maybe it's
13 all of us that are having the problems. Okay.

14 You know what? I'm going to suggest that we
15 will figure out, we will figure out the panel, the
16 polling questions, or we won't, and we're going to move
17 on right now just to hear -- why we're really here is
18 to hear your stories. So we're going to go through.
19 Sorry about all of the screens. We'll just go through
20 and ask Nadine to start and say your comment. And then
21 we'll move through the line with your comments. And
22 then we'll, then we'll see where the polling went.

1 So when you comment, please push the red
2 button. Bring that microphone as close of you as you
3 can. The red button at the bottom. And when you're
4 done, we'll move on to the next and you can click off
5 your red comment. Yes? Nope, just press once. So
6 we'll see how Nadine --

7 MS. MORRIS: Do I come up to the podium?

8 DR. EGGERS: No, you're going to stay there
9 and give your comments.

10 MS. MORRIS: Good afternoon. My name is
11 Nadine Morris and I'm here to share information about
12 my life with autism. My daughter, Anna, was diagnosed
13 with autism spectrum disorder two-and-a-half years ago
14 when she was three.

15 Anna has a lot of classic signs of autism.
16 One of the signs is being kept on daily routines. For
17 instance, she has to have the same lunch every day.
18 Two pieces of pumpkin bread, GoGo squeeZ's brand plain
19 applesauce, and Danaable strawberry yogurt smoothie.
20 If this or any normal activities change, she will have
21 difficulties adjusting throughout the day.

22 Additionally, transitioning from one task to

1 another can be difficult for her. It is not only
2 necessary for me to give her adequate notice before we
3 can change tasks, but how I actually communicate that
4 notice to her is just as important.

5 For instance, before we leave the park, I have
6 to ask her, Anna, how many minutes until it's time to
7 go. She responds to me with a time and then I respond
8 that I'm setting an alarm for that many minutes. So
9 when the alarm goes off, she's able to stop what she's
10 doing and transition without any issues.

11 However, if I do not ask her to give me a time
12 and instead just say to her we're leaving in five
13 minutes, she's totally thrown off and I'm facing a
14 major meltdown.

15 Socializing is another challenge for Anna.
16 Although she has far exceeded the expectations for
17 developing her expressive language skills, any random
18 conversations can be similar to that of a toddler and
19 usually lacks a common interest. She also tends to be
20 socially awkward. She'll point at a person who she's
21 talking to, jump up and down, and flap her hands,
22 especially when she's overly excited.

1 The social aspect is one of my biggest fears
2 as a parent. Will she be able to function in
3 kindergarten and beyond? Will she be bullied for
4 being, quote, unquote, different? And how will that
5 affect her?

6 She also displays high levels of anxiety. She
7 becomes obsessed with objects like a toy and cannot be
8 without it. I have had to drive back home when she has
9 forgotten it because I know that without it she will
10 have a bad day.

11 She's also obsessed with events in her life
12 like taking a bath or going somewhere. She has to
13 constantly be reassured of when exactly that event is
14 going to occur.

15 Additionally, she has difficulty staying
16 asleep. She'll wake up multiple times a night, start
17 making unpleasant, methodical noises, and then proceeds
18 to rock back and forth and bang her head until I come
19 and comfort her. The sleep deprivation was causing a
20 lot of impulse, impulsive and negative comments. Or
21 I'm sorry, behaviors. I apologize. Therefore, I
22 started letting her sleep with me about a year ago.

1 The restless nights and negative behaviors have since
2 stopped.

3 The rocking and banging of her head is also
4 something she does to self-regulate her emotions. It
5 gives her the sensory stimulation that she needs, which
6 leads to another sign of autism, sensory processing
7 disorder. Sensory processing disorder is a huge
8 umbrella term for behaviors that are associated with
9 senses.

10 For Anna it means she has a lot of fears. She
11 used to be afraid of crowds, even to the point where
12 the local pharmacist would actually bring my
13 medications outside to my car because she couldn't even
14 approach the store without screaming. But over the
15 years I have worked relentlessly on this and she's
16 grown accustomed to being in public places.

17 Additionally, she is frightened by the hand
18 dryers and the flushing toilets in public restrooms.
19 That makes it very difficult for her to be out in
20 public for an extended period of time.

21 She also has a difficult time eating and
22 trying new foods because she may not like the taste or

1 the texture. But sensory processing disorder also
2 makes her a very huggable person who loves to be
3 tickled constantly.

4 Even with all the symptoms, autism has become
5 our new normal. I have had to make changes in my
6 approach with her, ensuring her a calm and patient
7 environment. I reenforce good behavior and identify
8 her triggers. But, and we have worked together over
9 the years and both have made progress in adapting to
10 both old and new situations and environments.

11 I was also fortunate enough to get her started
12 in county's early (inaudible) services when she was
13 two-and-a-half years old. These services and a group
14 of amazing teachers have also done well in molding
15 Amanda - my daughter's name is Anna - into the amazing
16 child that she is today. Thank you.

17 DR. EGGERS: Thank you so much, Nadine.
18 Before we move, Zoe, I just want to ask. The feedback
19 that we hear up in front, this is -- we're in a new
20 setup here. So we, we will be addressing that if we
21 can. Can I, do you hear feedback in the back of the
22 room? Okay. So my apologies to those of us in the

1 front of the room about feedback.

2 So, so why don't we -- we will next have Zoe.

3 And Zoe --

4 MS. GROSS: Hi. Sorry about that. I thought
5 we were taking a break to address the feedback. I
6 might as well bring my headphones up. Thank you so
7 much for having me on this panel. My name is Zoe
8 Gross. I'm autistic and I'm a director of operations
9 at Autistic Self Advocacy Network. We represent a
10 community of autistic self-advocates with a broad range
11 of disability experience. So people with and without
12 intellectual disabilities, people who speak, and people
13 who don't, people who need daily support, and people
14 who don't.

15 I want to say right off the bat that when I
16 talk about self-advocacy, that isn't limited to people
17 who work for nonprofits. A self-advocate is someone
18 who has preferences and has access to any way to make
19 those preferences known. And any discussion of the
20 needs of autistic people needs to center self-advocates
21 with all kinds of experiences.

22 I'm really glad that the FDA is interested in

1 patient perspectives, but we must be careful not to
2 treat autistic perspectives as interchangeable with the
3 perspectives of our loved ones. In order to get a good
4 range of autistic perspectives, we would need far more
5 self-advocates participating than we have here today.

6 I want to make sure that we begin with a
7 framework that prioritizes supporting autistic people
8 and improving our quality of life. So we should talk
9 about what quality of life looks like for autistic
10 people and question any assumptions that we might be
11 bringing to the table. For example, the number of
12 times I made eye contact today is not a valid
13 measurement of my quality of life, but it is a trait of
14 autism that many interventions target.

15 We need to make sure that when we talk about
16 problems we are talking about things that are problems
17 for the autistic people who are experiencing the
18 things. Not simply things that make us look different
19 or that inconvenience others. The fact that something
20 is a trait of autism doesn't mean it is a problem in
21 someone's life.

22 A lot of people have tried to develop medical

1 interventions that target repetitive behavior, for
2 example, like flapping your hands or pacing. We might
3 call this stimming. But stimming doesn't cause us
4 problems. It often helps us focus and interact with
5 the world around us.

6 So a medication or other treatment targeted at
7 reducing stimming might make us appear more normal, but
8 it wouldn't improve our lives. It might cause us new
9 problems. We strongly discourage drug development that
10 targets this type of behavior. Even if something is
11 both a trait of autism and a problem in someone's life,
12 that still doesn't necessarily mean that it is an
13 appropriate target for medical intervention.

14 For example, some autistic people struggle
15 with self-injury or aggression. These are serious
16 problems in people lives. In some cases, self-injury
17 or aggression can represent an attempt to communicate
18 that something is wrong or can be a response to
19 physical pain. If these needs are not evaluated,
20 giving someone a medication to stop them from self-
21 injuring may leave underlying needs unaddressed.

22 Autism is not an illness or a disease. It is

1 a developmental disability. Even things like self-
2 injury and aggression are often best handled with
3 supports other than medication. It's also important to
4 note that a lot of the really difficult medical or
5 difficult, or disability experiences that autistic
6 people have are not caused by autism, but by co-
7 occurring conditions.

8 Some of these can include anxiety, depression,
9 posttraumatic stress disorder, insomnia, connective
10 tissue disorders, and seizures. We need more research
11 into the interactions between autism and these
12 disabilities and more research into whether best
13 practices for treating conditions like anxiety and
14 epilepsy are working for autistic people.

15 For example, autistic people are more likely
16 to have seizures, and therefore more likely to be
17 prescribed anticonvulsants, but autistic people are
18 excluded from trials of anticonvulsants. We know that
19 in some cases autistic people may react to medications
20 differently.

21 So the lack of research and data on this is a
22 big problem, but it's important when we talk about how

1 best to improve autistic people's quality of life that
2 we remember the things like seizures and insomnia are
3 not caused by autism and would not be impacted by a
4 medical intervention that targets what we think of as
5 core autism features.

6 Thank you again for having me and I look
7 forward very much to our discussion.

8 DR. EGGERS: Thank you very much, Zoe. For
9 those of you that have been on the panel, if the
10 feedback bothers you at any point, feel free to go back
11 to the table and be part of the conversation then. And
12 now I'll move to Sharrill, please.

13 MS. HEMRY: Hello. I have three offspring all
14 diagnosed with autism, a daughter 24 years old, and two
15 sons, 22 and 19. Each presents quite differently, but
16 the greatest challenge is trying to achieve and
17 maintain a healthy immune system.

18 For almost two decades they've done bloodwork
19 about every six weeks to monitor their immune markers
20 and whenever their immune systems have improved,
21 they've likewise shown dramatic improvements in their
22 ability to speak, focus, learn, and maintain self-

1 control in public. They are much happier.

2 All three of my children have experienced
3 issues with speech and communication, environment and
4 food allergies, reduced blood flow in the brain as
5 documented through NeuroSpec scans, reduced ability to
6 fight infection due to low natural killer cells,
7 inflammation as shown through chronically elevated
8 eosinophils and ferritin levels, years of elevated
9 Group A Streptococcus bacteria as measured via ASO
10 testing, and reactivation of one or more human herpes
11 viruses (HHV) as evidenced by highly elevated IgG
12 antibodies.

13 I'm concerned about high human herpes virus,
14 IgGs because this opportunistic virus family, which is
15 in the same group of double-stranded DNA viruses as
16 small pox and adenovirus has been associated with organ
17 transplant rejection, cancers, multiple sclerosis, and
18 many other illnesses.

19 My daughter's unique immune symptoms are best
20 described by her diagnoses. As an infant she had
21 issues with bilirubin, thrush, cradle cap, latching,
22 and a large head due to fluid buildup outside her

1 skull. She could, she could speak words clearly at six
2 months, but quickly lost each new word, very likely due
3 to a seizure disorder finally diagnosed years later.

4 As a toddler she could still speak some words,
5 but her speaking voice became less and less clear and
6 she demonstrated significant auditory processing
7 issues. Both of these conditions may be connected to
8 the middle ear drainage problem that we now know
9 affects her hearing. She also began demonstrating some
10 of the obsessive-compulsive behaviors which continue to
11 plague her to varying degrees.

12 In recent years, her antinuclear antibodies
13 have often been positive, indicating autoimmune issues.
14 She's also been diagnosed with nodes on her thyroid,
15 calcifications on a pelvic cyst, endometriosis, and a
16 genetic mutation linked to susceptibility to multiple
17 cancers. Her communication remains at a basic level.

18 My older son's unique immune symptoms are best
19 described by numbers. At one-and-a-half he whined most
20 of the time, yet had no discernible speech. At age two
21 he understood everything said to him, yet lived in his
22 own world. At each three-and-a-half he became gluten-

1 free and for the first time in his life was able to
2 tolerate being held or bathed.

3 At age four he went dairy free and also began
4 an antiviral medicine, the latter because he had high
5 HHV-6 IgGs and because his alpha interferon level,
6 indicating his body was fighting a virus was 1,100, 100
7 times the normal level. The next day he slept through
8 the night for just the second time in his life. At age
9 four-and-a-half he stopped having diarrhea on a nearly
10 daily basis after starting treatment with a now defunct
11 immune modulator.

12 He spent eight years from ages 6 to 14 taking
13 an antibiotic to reduce his Group A Streptococcus
14 titers from a high of over 2,400, 12 times the normal
15 level, down to 172. Only 30 days later his strep titer
16 shot up tenfold to almost 1,800 due to his exposure to
17 a person with strep and some inconsistent antibiotic
18 administration.

19 Soon after that he became extremely violent
20 toward property, himself, and others, a situation which
21 continues when he's in poor immune health. Currently
22 after eight-and-a-half more years of antibiotic

1 treatment, his strep titers are down in the 400s, a
2 thickened heart valve resulting from strep-related
3 rheumatic fever has repaired itself, and he seems to
4 have stopped his most violent behaviors. However, he
5 remains mostly nonverbal and his ongoing immune issues
6 have left him unavailable for learning.

7 My youngest son, (inaudible), symptoms are
8 best described by his gains. After losing all speech
9 at 11 months, he regained it at age two, right after
10 going off dairy. He lost speech again a few months
11 later but regained it once again at age two-and-a-half
12 after starting an antiviral protocol to target his high
13 HHV titers.

14 As a toddler he couldn't comprehend facial
15 expressions or understand another person's mental
16 perspective. But by elementary school after his immune
17 health improved, he was able to use movies and
18 conversation to develop these skills. Diagnosed with a
19 visual tracking disorder that made reading a challenge,
20 he just received his associate's degree with a B
21 average and starts a four year college this fall.

22 Restriction on activities because of symptoms.

1 When one of two children's immune markers are bad, our
2 family's focus is forced to center around dealing with
3 that person's increase in aggression or disruptive
4 behaviors. Our best days are family vacations where
5 everyone is able to go. Our worst days are family
6 vacations when my older son's too aggressive to go and
7 gets left behind with a parent.

8 Conditioned symptoms that have changed over
9 time. My two oldest children have always had little
10 ability to communicate through speech or devices, as
11 well as issues with self-control, but these problems
12 have improved or deteriorated in near direct
13 correlation to how well their immune systems are doing.

14 And our biggest worry about our children's
15 condition. With their complicated health issues and
16 minimum communication skills, I dread the day my oldest
17 two children have to move to a group living
18 environment. A healthy immune system is their vector
19 to an engaged life, but I see no immune-modulating
20 treatments on the horizon.

21 DR. EGGERS: Thank you very much, Sharrill.
22 And now we have Tom.

1 MR. FRAZIER: Hi. Thanks for inviting me
2 today. That's my son, Sean (ph). He's 13 now. I want
3 to note that I am employee of Autism Speaks, but I'm
4 really here today to give three perspectives, I hope,
5 my own as a parent of Sean, and hopefully I can give
6 some of his perspective. He is nonverbal, so it's not
7 always clear what his perspective is. But hopefully I
8 can give some of that.

9 And I'd also like to give you some of the
10 responses that we received to the survey that was sent
11 out from our family advisory committee in the Autism
12 Speaks autism treatment network.

13 So my son struggles with communication all
14 day, every day from the moment he wakes up to the
15 moment he goes to bed. He's nonverbal and even
16 expressing basic wants and needs is quite a challenge
17 for him. He uses his speech-generating device and he
18 carries it with him most of the day, but he's not very
19 fluent with it, at least not yet. And he prefers to
20 use other less effective means like tapping us or
21 sometimes pushing us.

22 This causes a lot of problem in understanding

1 him, as you can imagine, and it certainly causes a lot
2 of problems in interacting with him. From his
3 perspective, I have to believe this is incredibly
4 frustrating for him. It's really hard for him to get
5 across what his wants and needs are in any kind of
6 efficient way.

7 I'm certain that at times he feels like we're
8 not trying to understand him. And that, of course, is
9 difficult for him and difficult for me, my wife, and
10 his younger sister. It has led him over the course of
11 his life to isolating himself more and engaging less in
12 social interactions, both within the family and, of
13 course, outside the family.

14 So communication is really our major struggle
15 and it's his major struggle. On the survey our family
16 advisory committee noted challenging behavior,
17 communication, sleep difficulties, and of course co-
18 occurring conditions like GI problem, seizures, etc.,
19 as being some of the biggest concerns that they face.

20 As a result of my son's autism and the
21 cognitive intellectual difficulties that he has, he's
22 not independent in most tasks, including basic daily

1 living skills. He really needs a lot of prompting to
2 engage in or complete tasks. And again, it seems to me
3 that it's frustrating for him because he becomes very
4 reliant on us and I think he would like to have more
5 independence than he can achieve at this point.

6 Just as one example, he doesn't like to get
7 helped in showering or bathing, but obviously these are
8 pretty core things that need to get done every day, or
9 almost every day. And so that can be quite a struggle
10 and a fight between us.

11 On the survey questions parents from our
12 advisory committee noted social interaction as being
13 the most frequent activity listed where their children
14 could not fully engage with their peers or with other
15 important people they wanted to interact with.

16 And I wanted to just sort of end with noting
17 that while my experience and our family's experience,
18 my son's experience, and in the experience of the
19 parents on our survey, was that the difficulties that
20 I'm describing do improve over time, that they tend to
21 remain significant, and on the worst days they cause
22 significant distress.

1 For my son this often manifests as challenging
2 behavior, sometimes kicking or pushing. He's 6' tall,
3 so when he kicks, it's not trivial. He can feel very
4 frustrated if he's not able to communicate or he's not
5 being understand, as I mentioned. And I don't think he
6 wants to be physical. I don't think he's interested in
7 hurting anyone, but this sort of pattern in our family
8 definitely leads to a loss of quality of life. It
9 certainly affects his younger sister when she gets
10 caught up in it.

11 Along with sleep difficulties and the
12 challenging behavior and the communication
13 difficulties, my son has a history of many of the
14 problems that have been described, from GI to immune-
15 related problems, and those also periodically affect
16 his functioning and certainly his wellbeing.

17 On our parent survey it was noted that, and on
18 the worst days some of the parents' children need
19 constant supervision, which was extremely difficult for
20 both them and their children with autism. And it
21 really limits the child's feeling of independence or
22 the adolescent. In some case, the adult's feeling of

1 independence.

2 I would just finish by adding that my main
3 worry as my son gets older is his ability to transition
4 to a supported living environment and also to some kind
5 of meaningful vocational placement. And on the survey
6 that we sent out, the parents noted concerns about
7 education, living, and vocation and work were really
8 the major worries for parents. Thank you.

9 DR. EGGERS: Thank you, Tom. And now we'll
10 have Sara.

11 MS. LUTERMAN: Hi. My name's Sara.
12 Disclosure, I work for the Association of University
13 Centers on Disabilities, or AUCD. While I will be
14 referencing a webinar that I helped produce with them,
15 the following comments are my own opinions and do not
16 necessarily reflect the opinions of my employer.

17 So I'm an autistic adult and I would consider
18 the most difficult issue I face with that to be a co-
19 occurring condition. I struggle with depression,
20 anxiety, and suicidal ideation. This is not uncommon
21 for autistic people. Sixty-seven percent of adults
22 with Asperger syndrome, which has now been folded into

1 autism spectrum disorder, reported suicidal thoughts.
2 And 35% reported having specific plans or attempting in
3 one study from 2016 in Lancet Psychiatry.

4 In another study, 14% of autistic children
5 under 16 talked about or attempted suicide compared to
6 0.5% of children in the general population.
7 Additionally, autistic children who reported bullying
8 where three times more likely to consider or attempt
9 suicide than autistic children who did not report
10 bullying. Sixty percent of the autistic children in
11 the study reported the bullying and that was a study
12 from the Journal Autism in 2012.

13 In the last year alone, three of my friends in
14 the autistic community have attempted suicide. I
15 myself attempted in 2014 after being fired from my
16 first full-time job after two weeks for being a bad
17 cultural fit. In retrospect, this most likely means I
18 did something socially inappropriate without even
19 realizing it.

20 I did some interviews with other autistic
21 adults for a webinar I did with the Association of
22 University Centers on Disabilities called Suicide

1 Screening and Prevention in the autism community, new
2 developments and new perspectives for autism researches
3 and professionals, and talked to them about some of the
4 barriers faced in terms of getting treatment and care.
5 You can find that archived on the -- you can find the
6 archived webinar on the AUC website if you're
7 interested.

8 I think that there needs to be more focused
9 patient-centered research on autism and its
10 relationship to anxiety and depression. Right now the
11 majority of drug treatment is centered on reducing
12 behaviors. What that means in practice is that drug
13 treatment for autism is centered on making us more
14 manageable for non-autistic caregivers.

15 This is the primary purpose of prescribing
16 things like Haldol or Risperdal and other, and other
17 heavy antipsychotics to children. It's essentially a
18 chemical straightjacket. Instead, treatment should be
19 focused on reducing our anxiety and depression and on
20 increasing our quality of life so that, life as a
21 whole.

22 This means that we would need to have better

1 access to care. Getting a psychiatrist who understands
2 both mental health and developmental disability issues
3 is a struggle. Finding someone who's competent in both
4 and treats adult is basically impossible. In the event
5 someone does treat both, they often don't take
6 insurance.

7 Anecdotally autistic people -- additionally,
8 an additional issue that anecdotally autistic people
9 seem to be more sensitive and respond atypically to
10 many medications. So the lack of specialized knowledge
11 and research is particularly damaging and unhelpful.

12 We also need a wholistic approach to improving
13 our lives with focus on employment, education access,
14 and anti-bullying efforts. While having more drug
15 research is extremely important, I want to remind
16 everyone that drugs alone won't, won't solve the
17 problem because, but drugs should be included in a way
18 that's consent-driven, research-oriented, and most of
19 all, patient-centered.

20 We are autonomous people from our parents and
21 often have different goals and needs than they do like
22 any other children and parents. And that needs to be

1 respected.

2 DR. EGGERS: Thank you very much, Sara. And
3 finally we have Kiely.

4 DR. LAW. Hello. My name is Kiely Law. I
5 like many of you in the room, I wear many hats in the
6 autism community, both professionally and personally.
7 By training I'm a physician and a researcher. I work
8 with the Interactive Autism Network and SPARK for
9 Autism. My everyday work is focused on engaging our
10 community as key decision makers in autism research.

11 The reason I'm here today is that I am the mom
12 of a young adult with autism and I wanted to share our
13 family's story. My son, Isaac, now 24, was diagnosed
14 with autism in 1996. He was three years old. I am not
15 going to say much about the early years accept that
16 they were rough.

17 I'm going to focus on how Isaac is doing as a
18 young adult. Isaac is somewhere in the middle of the
19 spectrum. He is fully verbal and at the age of 20 he
20 was able to receive his high school diploma. He
21 qualifies for residential and employment support
22 services through the Maryland Developmental

1 Disabilities Administration. He lives in agency-
2 provided housing with one housemate and part-time
3 staff.

4 To date he has not been able to find a job
5 that is a good fit for him. Isaac's biggest challenge
6 today is related to his dual diagnosis of autism and
7 bipolar disorder. He received the second diagnosis at
8 age 15. He is not alone. We know from research that
9 between 54 and 70% of people with autism also have one
10 or more other mental health conditions.

11 During adolescence Isaac developed severe
12 depression. He became withdrawn, sad, and fearful. At
13 times he was afraid of sleeping by himself. He also
14 had thoughts of wanting to hurt himself, his siblings,
15 and me and his dad.

16 Isaac has also been extremely manic. He has
17 run away from home. He has tried to flag down drivers
18 in the middle of the road to take him to the airport
19 and he has been picked up twice by the police.

20 He has been hospitalized two times in the last
21 three years for problems related to his mood disorder.
22 We have struggled to find mental health providers who

1 are familiar with adults with autism and with mood
2 disorders. We have struggled to find effective
3 treatments.

4 At one point Isaac was on five different
5 psychoactive medications at the same time. Now he is
6 fairly stable on two. We have also tried many
7 different types of supportive therapy. Ultimately art
8 therapy has been the best fit for Isaac.

9 Another problem related to Isaac's autism, and
10 now also his mood disorder, is the significant
11 difficulties he has with falling and staying asleep.
12 Sleep has always been a problem for Isaac, but I think
13 now it's even a bigger problem because the poor sleep
14 worsens his mood problems. The relationship between
15 autism, mood disorders, and sleep disorders is
16 complicated, and for our family it's an important topic
17 to figure out.

18 Other challenges that are problematic for
19 Isaac and that keep him from achieving his best include
20 slow processing speed and poor working memory. He also
21 has difficulties understanding social, social
22 situations, and he has problems with sensory

1 sensitivity. All of these challenges make employment
2 and independent living very difficult for him.

3 I wanted to end by saying a few positive
4 things. It's always hard being a mom up here and
5 saying, talking about the problems. First, despite
6 many challenges Isaac at times has been much easier to
7 parent than his three siblings who are tweens and teens
8 and who do not have autism. Isaac loves science
9 fiction and space opera. He's taught me the terms
10 multiverse and FTL, which means faster than light, in
11 case you didn't know. Isaac can replay full movies in
12 his head and he is the only person I know who has a
13 favorite theoretical physicist.

14 And finally, I want to end by sharing some of
15 Isaac's own words. I always ask his permission before
16 I talk about him. And so when I told him I was
17 speaking today, this is what he said. Mom, you know I
18 disagree with you and the doctors about autism and
19 bipolar. I do not like those labels. I am just a
20 quirky, oddball kind of guy who likes to do things his
21 own way.

22 DR. EGGERS: Thank you. Thank you so much,

1 Kiely. I would like to ask a round of applause for
2 those of you who have given comments. And I'm also
3 going to invite you to go back to the tables because
4 the feedback is less back there as you were saying.
5 Take your ten cards with you if we have questions.

6 So while they're doing that, I just want to
7 also touch upon one thing, which is the topics are
8 sensitive that we're talking about today, and one of
9 the topics that we have heard about and will talk about
10 is suicide ideation. I just want to remind you to seek
11 any help if you need it. The suicide prevention, the
12 National Suicide Prevention Lifeline is, is there. We
13 have the information. We'll put it up on the screen at
14 the break and just wanted to put that out there.

15 Thank you. So I'm going to see if I can get
16 this microphone to work. It might take me a second.
17 All right. So we hope that we've identified a range
18 of, of speakers that, that demonstrate the range of
19 perspectives that we received from the comments and we
20 hope reflect the range of experiences that, that you,
21 that the individuals with autism and family members
22 experience.

1 With a show of hands, did you hear one or more
2 things that really resonated with you and your family's
3 experience? Okay. All right. Then we've learned a
4 lot already and we want to build on that now.

5 There's a couple things we won't touch upon as
6 much in this first topic and that will be on the
7 treatment approaches. We know that some of the panel
8 speakers mentioned that, but we're going to focus on
9 health effects and impacts on daily life first.

10 And so, and I also want to remind us that as
11 we, we move through the discussion, we're going to try
12 and navigate those various perspectives that we have as
13 parents of younger children or children, parents of
14 adults, and the self-advocates in the room.

15 We didn't get to, we didn't get to ask the
16 polling question on this, but if everyone feels
17 comfortable just to raise your hands, can I ask -- I'm
18 going to ask if you, whether you fit into one of these,
19 whether you wear one of those hats. So if you don't
20 feel comfortable, don't raise your hand.

21 But if you are a parent of a child under,
22 under 21, or multiple children, can you raise your

1 hand? Okay. Okay. If you're a parent of a child or
2 children who are, say, older than 21, raise your hand.
3 That's family member. I'm sorry, family member. I
4 should -- yes, family members. And if you are a self-
5 advocate, autistic individual, raise your hand. Okay.
6 All right.

7 So we have, we have all three perspectives
8 represented in the room. I can't move? Okay, I'm
9 going to stand right here. All right. I move a lot.
10 These are new microphones. We're going to go --

11 DR. VAIDYA: Don't move your hands.

12 DR. EGGERS: Don't move my hand. Okay. All
13 right. I can do this. Anyway, as you answer, try to
14 let us know which of those hats you're wearing. Okay.
15 So we're going to start with a polling question and
16 these polling questions are never perfectly worded, but
17 what we're trying to get is a sense of where you may
18 find your experiences and perspectives. So as to
19 answer this polling -- and we'll see if it works. I
20 hope this works.

21 The polling question's trying to get at what
22 health effects of autism are most challenging for you

1 or your loved one if you're the, if you're the family
2 member of a loved one. And you can choose up to three
3 health effects. A is irritability or disruptive
4 behaviors. B is cognitive impairment. C is social
5 impairments. D, communication difficulties. E,
6 repetitive behaviors. F, sleep issues. G, depression
7 or anxiety. H, gastrointestinal symptoms. Or I, a
8 health effect that's not up here.

9 Okay. I'm not seeing any responses going up.
10 So you can just, don't worry about, don't worry about
11 answering the polling questions. I don't want to waste
12 your times or your, or your thumbs to try to do that.

13 So what we will do is start with some that
14 we've heard about and get your thoughts on them, and
15 then we'll go to other, to other effects. So let's
16 start with the first one, which would be irritability
17 or disruptive behaviors. We heard, we heard some of
18 that mentioned up above, but what we're looking now is,
19 is for you to share, if that would have been one of
20 your top concerns about autism in your life, the life
21 of your child. Let's hear a little bit about why that
22 is so.

1 DR. THOMPSON: Sara, we do have quite a number
2 of responses on the webcast, if you want to go through
3 those.

4 DR. EGGERS: Okay. Can we hear those
5 responses?

6 DR. THOMPSON: So we had 60% of people
7 responding irritability or disruptive behaviors, 40% on
8 cognitive impairment, 55% on social impairment, 66% on
9 communication difficulties, and roughly 30-35% for the
10 rest of them.

11 DR. EGGERS: Okay. Okay. So, so then
12 following up on the, on A here, irritability or
13 disruptive behaviors. And we have Jeannie. And hold -
14 - I guess we all need to hold the microphones really
15 close.

16 MS. MCGUIRE: Just focusing on irritability
17 and disruptive behaviors, is that good?

18 DR. EGGERS: Awesome.

19 MS. MCGUIRE: Just focusing on irritability,
20 disruptive behavior, let's say irritability, that's
21 really underscoring what we're, or underplaying what
22 many parents are dealing with. Our children are

1 suffering and nothing isolates them more in our society
2 than physical aggression towards others. And also it's
3 terrifying for a parent to see a child self-injurious,
4 but these, we're talking physical -- really the
5 irritability, you know, we can live with it.

6 But, you know, destructive, aggressive
7 behaviors isolate them, cost a huge amount to society.
8 We can't go out anywhere. I mean, hey, you're not
9 invited over to the neighbor's barbeque.

10 Yeah. So I, you know, I effectively treated
11 my daughter's aggression. I can talk about that later.
12 But I talk to so many of my friends with children who
13 are severely affected with autism, suffering, is how I
14 like to differentiate. They're suffering with their
15 autism and this is the biggest problem, is the
16 aggression and self-injurious behavior and destruction,
17 destruction of household items and stuff.

18 DR. EGGERS: Okay.

19 MS. MCGUIRE: Thank you so much.

20 DR. EGGERS: Okay. So I saw head nods as
21 Jeannie was saying that it's not irritability that
22 we're, that's most concerning to us. It's the

1 aggression and disruptive behaviors. Does that
2 resonate with you? Okay, still head nods. So then
3 with those terms in mind, anyone else want to follow up
4 on what Jeannie has to say? Back there with Sara and
5 Kit.

6 MS. LUTERMAN: Hi. I'm Sara and I'm an
7 autistic self-advocate and I just want to say I think
8 that the separation between irritability and disruptive
9 behaviors and depression and anxiety is a little bit
10 artificial. I think the irritable, irritability or
11 disruptive behaviors are often just an expression of
12 depression or anxiety, especially in people who might
13 have more communication difficulties. It's all
14 complicated.

15 DR. EGGERS: All right. Thank you very much,
16 Sara. And Kit?

17 MS. MEAD: Hi, I'm Kit and I'm an autistic
18 self-advocate. A lot of autistic adults have written
19 about good ways to like -- like it's communication most
20 of the time that they're trying to say something is
21 wrong or there is a physical thing going on and don't
22 have, like they don't know how to like, or they -- I

1 don't know. Sorry. Words. But a lot of autistic
2 adults have written stuff about like how to work
3 through that without like, kind of like, for example,
4 there are things called self-injurious damage which
5 like don't, like -- I don't know.

6 But there are a lot of ways to like redirect
7 those instead of like going, oh, no, we must extinguish
8 all stimming. Because stimming helps us self-regulate
9 and I think that's about it. Like one of the resources
10 is like there's a website called We Are Like My (sic)
11 Child and it has an entire like page of like how to
12 work through aggression, aggression and disruptive
13 behaviors without like trying to like force the
14 autistic person to act less autistic.

15 DR. EGGERS: Okay. Okay. Thank you. You
16 know, I think we can wait 'til break and -- did you get
17 it working? It's working. Do you want to do the
18 polling question? Okay. Let's do the polling question
19 then.

20 The health effects of autism that are most
21 challenging to you or your loved one. And then we'll
22 go through that list again. And to Jeannie's point,

1 which was a good one that resonated, you would put
2 aggression in that category as well.

3 Okay. So if you didn't, if you didn't have
4 time to do all of your three, that's okay. It gives us
5 a sense that we should have started with communication
6 difficulties in our round of questioning here because
7 that is what most of you in the room have indicated.

8 And, and about very similar for several other
9 things with the exception of the repetitive behaviors.
10 That's, that's not as concerning for many of you in the
11 room here today.

12 You also have indicated a lot of other health
13 effects. We heard about the co-occurring health
14 effects mentioned. We might not get into those as much
15 today, but we'll try to save time to get into other
16 health effects.

17 So Kit made this point about the behavior
18 means something else is challenging and you mentioned
19 communication difficulties. So let's follow-up on that
20 and hear a bit more about the, the impact that the
21 communication difficulties have. And brief but
22 specific examples would be very helpful. Anyone like

1 to follow-up? Okay. We'll go with Sharrill.

2 MS. HEMRY: My older child that I spoke, my
3 older son that I spoke of before, his sole way of
4 communicating is to tap his chest once for no and twice
5 for yes. And he can't use communication devices. He
6 has them, just something won't let him. And when he
7 feels better, he does start using words, but most of
8 the time that's what we have.

9 DR. EGGERS: Okay. Thank you. Anyone else?
10 We'll go --

11 MR. SPIELMAN: Hi. I'm Stuart Spielman. I'm
12 with Autism Speaks and I'm the parent of a 22-year-old
13 with autism. My son is not verbal and he has an
14 intellectual disability. Communication is a continuing
15 challenge. My wife and I often have to guess what,
16 what Zack is trying to communicate.

17 One of the issues that comes up a lot is, is
18 the everyday issue of the bathroom. Does Zack have to
19 go to the bathroom or not? He signs when he has to go
20 to the bathroom, but sometimes he signs, he uses the
21 same sign to, to sort of go away from the situation.
22 We don't know if he really has to go to the bathroom or

1 if he's bored, if he's at a restaurant and he's
2 finished eating and my wife and I have not.

3 So obviously this is an important social
4 behavior. We have, you know, we have to be mindful.
5 We, we want to make sure that he doesn't have an
6 accident. So this is a continuing challenge.

7 DR. EGGERS: Okay. Thank you very much.
8 Anyone else? Right back there.

9 MS. PING: I hope I can convey my story the
10 way I want. Bear with me. So I have a ten-year-old
11 daughter who's on the spectrum. He's not, she's not
12 very severe; however, she's also, you know -- as you
13 know, autism for girls, the ratio is lower than boys,
14 but most girls tend to have more severe symptoms. But
15 luckily she's, I think she stays somewhere in the
16 middle of the spectrum.

17 So since she's in 5th grade now, we -- she got
18 her diagnosis when she was three-and-a-half and I
19 realized one problem years ago and I'm hoping that I
20 can do my little part to broadcasting this. So one,
21 one faith I had was I believe she can learn. She is
22 smart in some ways. She was actually, you know, placed

1 on the code called intellectual disability by the
2 public school.

3 By the way, it's a long story. We moved
4 because of her. I quit my industry job and moved to
5 Maryland to join FDA because, you know, here I believe
6 we have more resources for her. And my son, you know,
7 also moved with us to come here to attend high school.

8 I always believed that she is educable and
9 she, if she can overcome that, you know, speech-
10 language hurdle, she can be taught for many things and
11 I always believed in that. However, the assessment,
12 the numerous assessments done by the school at the end
13 of, think she is -- the best program that fits her need
14 is what they call -- what was that -- learning, LFI,
15 Learning for Independence.

16 To put in plain language, basically, you know,
17 they pulled her off the diploma track and this is a
18 certificated track. So basically, you know, they teach
19 her basics of learning skills. And I was, you know, I
20 disagreed with that.

21 So what happened was I put her in the private
22 special educational school. When she entered, I'm

1 sorry, 4th grade from 4th, 3rd going to 4th. And she
2 was eight years old at that time. So I said no time to
3 waste anymore. This child has to be placed in a small
4 setting, two-to-one. That's what we got for her.

5 DR. EGGERS: We'll be talking more management
6 approaches, but let me ask you a question. What is --
7 of her communication challenges -- and what's your,
8 what's your name?

9 MS. PING: Oh, I'm sorry. Ping.

10 DR. EGGERS: Ping?

11 MS. PING: Yeah.

12 DR. EGGERS: Okay. What is the biggest
13 difficulty with communication that you have with her on
14 a day-to-day basis, say trying to help her in her
15 daily, in her daily routines? Is there the most
16 significant communication challenge that you can say?

17 MS. PING: You know, I don't know how to
18 describe it precisely, but it evolves over years. At
19 the beginning was even the basics. But later on, you
20 know, that's how I realized, you know, if you're
21 patient -- for example, I spent six months teaching her
22 the concept of wait.

1 DR. EGGERS: Wait.

2 MS. PING: Wait for your turn. And once that,
3 once she got that, you know, everybody's life was
4 changed. Because, you know, when a person doesn't
5 understand what waiting, she needs it, she needs it
6 now. You know, you know, she's screaming and the, you
7 know, whining, but once she realizes, you know, she can
8 wait and she can get what she wants, and that way she
9 pleases everyone.

10 I think she, by now she's one of the most
11 patient person that I have ever met. She can wait for
12 me for a long time for certain things that she really
13 wants.

14 DR. EGGERS: Okay. Thank you very much. That
15 was, that was an excellent example. And as we all
16 think about the ways that we can convey to our FDA
17 colleagues specific ways that, that these effects
18 impact daily life, that wait was a, was a great
19 example.

20 Can we have, if any of the self-advocates are
21 in, feel comfortable talking about communication
22 challenges or difficulties from your perspective?

1 We'll take one comment and then we will move on to some
2 other effects.

3 KELLY: Okay. I'll take a stab at this. Keep
4 in mind this is just my perspective and not necessarily
5 the perspective of my organization. I work for the
6 Autistic Self-Advocacy Network. Okay. So I can have
7 trouble formulating exactly what I want to say. It's
8 like there's a gap between what I want to say and what
9 actually comes out of my mouth.

10 Often what I end up saying is a sort of
11 compromise between the block and, and what's actually,
12 what's actually possible. I particularly, I'm an
13 incredible writer, not so much greatest speaker, and
14 I've struggled getting my words out in speech for most
15 of my life. Most of the people who know me well know
16 me online because there I can be my full self.

17 And I don't know if there's any kind of drug
18 that could even fix this. It doesn't seem like
19 something that could be treated in the usual sense.
20 But I've often, I've often thought about it and
21 wondered if there was a cause or a source.

22 I just don't think that a lot of the research

1 into autism is going into what autistic people would
2 actually want to know about their condition.

3 DR. EGGERS: All right. Well, thank you very
4 much, Kelly. Before we move away from communication,
5 anything on the FDA panel that you'd like to ask a
6 question about? Ebony? And talk really close to the
7 microphones. We all have to do it.

8 DR. DASHIELL-AJE: Really close. So with
9 regard to the impact of communication difficulties, I
10 want to hear separately from the caregivers, as well as
11 individuals with autism. Is it the intensity or
12 severity of these communication difficulties, the
13 frequency or how often you experience these
14 difficulties, or is it the context within which you
15 experience these difficulties that has the most impact
16 on your life?

17 DR. EGGERS: Is the question clear? We'll
18 start with, we'll start with Nadine and then we'll go
19 back there.

20 MS. MORRIS: Hopefully I'm answering this
21 properly. With my daughter, she does not necessarily
22 have a problem with receptive communication, which

1 means when you talk about anything, she actually
2 understands. It's the expressive parts. And then she
3 gets overwhelmed and she doesn't know how to like
4 actually say what she's trying to say, which is when
5 she starts to try to stim and control her emotions.

6 If I'm able to actually kind of intervene and
7 say to her what do you need from me or what can I help
8 you with, and actually with my own communication, I
9 can't talk anymore than this monotype. Even if I like
10 lift my voice up a little bit, she actually feels that.

11 So I'll say, you know, what do you need. What
12 can I do for you? And that's where she can sometimes
13 barely get out in like broken, almost like broken
14 English like I can't zip my coat. And that's like how
15 she communicates.

16 But imagine at two years old or three years
17 old when she was nonverbal, that was a scream and that
18 was banging her head or biting herself. And that was
19 her actually self-injuring herself.

20 So the communication has become much better
21 because of that. But every single day we deal with
22 this 'cause she understands things coming in, but it's

1 the coming out part is where she's having the most
2 difficulties.

3 DR. EGGERS: Okay. And a lot of head nods on
4 that, yeah. Thanks, Nadine. We'll go back here.

5 DR. LEE: Hi. I'm Montessa Lee and I'm not
6 necessarily a caregiver, but I'm here on an education
7 perspective because I taught in an autism program in
8 our district and now I'm a mentor teacher. So I mentor
9 teachers in summer working with students diagnosed with
10 autism.

11 So what we see on the outside, you know, so it
12 might not necessarily be at home, but as far as
13 communication difficulties is sometimes when they can't
14 communicate what they want, it's manifested in
15 behavior. And of course in a school if you're
16 aggressive or even assault an adult at times, bite them
17 or something like that, it's because they can't
18 communicate what they want and that's, that's the
19 manifestation, the behavior.

20 And that can be problematic or seem to be
21 problematic. And until you know the student, sometimes
22 we really get to know the student, know their behaviors

1 as Nadine was saying, and we know what they're trying
2 to express. And so as she said, the frequency, it also
3 depends on where they are on the spectrum. I've had
4 kids that were verbal, but they couldn't necessarily
5 express what they wanted in words. Or before they
6 acted on a behavior, they couldn't express how they got
7 there.

8 You know, so that five point behavior rating
9 scale that we get, our emotional scale, I'm about to
10 blow my top, I'm angry. You know, so teaching them how
11 to regulate that as well to communicate, hey, I need a
12 break.

13 DR. EGGERS: Okay. Thank you very much. So
14 can we do a show of hands of -- I'll come to you, Lynn.
15 Can we do a show of hands to say -- now you can tell me
16 if this question doesn't work. But a show of hands to
17 say if you've thought about the communication
18 challenges and the communication difficulties and all
19 that comes because of it, the behavior and the
20 frustration. Is it a day-to-day constant that bothers
21 your child the most, or is it the real big, intense,
22 really striking communication challenges that happen

1 maybe once in a while or less often? Is it more a
2 constant or are there times where it comes and then
3 comes really strongly with the communication challenge
4 and a behavior that bothers you? Okay. Let's go to
5 Tom first and then we'll come to you, Lynn, for
6 whatever you want to say.

7 MR. FRAZIER: I can be quick. It's frequency,
8 intensity, and context for, for me. And I think, you
9 know, it's really all of them and I think measurement,
10 we're sort of talking about measurement and I'll put my
11 science hat on for a second, and I'm a measurement
12 person. So I think when we develop these instruments
13 we need to take all of these things into account rather
14 than having very basic severity scales.

15 DR. EGGERS: Okay. Thank you, Tom. And you
16 got lots of head nods and even a few claps on that one,
17 so. And now I'll go to Lynn, please.

18 MS. DURHAM: Yes, hi. So my name is Lynn
19 Durham. I'm the sister of a person with autism and the
20 mother of a child with autism. And I usually don't
21 disclose that, but as a child I was considered very
22 high functioning on the spectrum. I no longer fit on

1 the spectrum.

2 Actually your question about the communication
3 and irritability or disruptive behaviors kind of
4 questioned different perspectives. I just want to say
5 English isn't my primary language. From my own
6 perspective as a child, I always had the feeling that,
7 and the frustration linked to the fact that I had a
8 feeling I was communicating pretty easily, but I wasn't
9 exactly saying or passing out what I wanted to say.
10 And I always felt a little bit like it didn't fit quite
11 right. And that really echoes what I think you were
12 saying earlier.

13 And then when I look at my brother who's a 37-
14 year-old with autism, actually for my brother and my
15 son autism is a really dynamic condition, a little bit
16 like hypertension or diabetes. They really have those
17 ups and downs and good days and bad days, or rather
18 good periods and bad periods.

19 And during good periods when their
20 communication improves on measurable, in measurable
21 ways, for example, mean length utterance of speech or
22 latency in response, for example, because that's how I

1 evaluate, you know, the quality and the difference in
2 their communication between different periods. It's
3 very different in my brother and in my son.

4 My brother is, I would say in the middle
5 functioning range. He has -- I hate IQs, but he has an
6 IQ of about 85. And when he's in an up period and he
7 feels more at ease in communicating, his level of
8 depression, measured level of depression goes down.
9 So, and he's less disruptive.

10 In my son it's very strange and I do link his
11 communication difficulties with difficulties -- I do
12 link his behavior difficulties with difficulties in
13 communicating. But when his communication level of
14 function improves, he actually can get more anxious.

15 And so there's a big variance between patients
16 and I think that the key thing to consider is that of
17 course there are core impairments in autism, but, and
18 those core impairments are present in all patients, but
19 to be able to measure and that will take us probably to
20 your next subject endpoints.

21 To be able to measure endpoints you have to
22 consider patient individual endpoints with, with

1 measurable endpoints within a patient individual
2 context.

3 DR. EGGERS: Okay. Thank you. We'll go right
4 here with Tom for one, and then we'll, we'll move on.
5 We are going to stop at, at 3 o'clock for a break even
6 if we aren't quite finished with topic one. And then
7 we'll come back. Okay? So Tom?

8 TOM: Well, I think I just want to echo that.
9 It may be slightly different circumstances. So our son
10 is 30, minimally verbal, minimal expressive ability.
11 What we've got this dynamic element that we, that we
12 really struggle with.

13 If he's having a hard time and we think he's
14 trying to communicate something -- or I guess what I
15 should say, he's more apt to be communicative if he's
16 presenting as less anxious. He's more apt to be less
17 anxious if he's presenting as not stressed out by his
18 environment.

19 You know, whether it's noise or whatever the
20 case may be. And so it leaves us thinking, well, what
21 is it that we need to treat here? Is it the
22 communication issue? Is it the anxiety or is it the

1 sensory overload? And it does, it varies. It ebbs and
2 flows. So not making this any easier, I guess.

3 DR. EGGERS: Okay. All right. So you're
4 raising important challenges. Before we go on to
5 break, let's go with one that received a lower number
6 of responses in the room, repetitive behaviors. Let's
7 get some perspectives, for those of you that -- maybe,
8 can we have someone who identified repetitive behaviors
9 to describe it? Describe that impact on life? Okay.
10 We'll go here with Kiely.

11 DR. LAW: Yes. I want to say that Isaac has
12 repetitive behaviors. He paces. And for other people
13 that aren't familiar with it, I guess they could be
14 annoyed by it. But as a mom it doesn't bother me. And
15 when I ask him about it, it doesn't bother him.

16 DR. EGGERS: Okay. Okay. Any other thoughts
17 on this?

18 MS. LUTERMAN: So I, I have some repetitive
19 behaviors. Some of them are ones I've had for my whole
20 life. Some are acquired from weird psyche medication
21 side effects. I would say it's not a difficulty in my
22 life honestly. I mean it's a little weird. It gets

1 weird looks. But like just explaining it to people, if
2 they're good people, usually they'll be really
3 understanding. And if they're not, then I probably
4 don't want to spend that much time with them anyway.

5 DR. EGGERS: Okay. So show of hands. We got
6 a lot of nods in the room. Show of hands if, if this
7 perspective you think it, if that's your perspective or
8 you think that's protective of your child and you?
9 Okay. So resonating theme. So then we won't -- yes,
10 Tiffany, please.

11 DR. FARCHIONE: So I would -- okay. Okay. I
12 would just point out that that's actually something
13 that is very enlightening for me sitting on this side
14 of the table because we get a lot of folks who come in
15 and say, oh, well, you know, we're going to use this
16 endpoint and we're going to measure restrictive
17 repetitive behaviors and, you know, try to treat that.

18 But looking at all of you and I see all these
19 shaking heads saying that, you know, this isn't really
20 something that we care about. So that's, that's very,
21 'cause we don't want to, to develop treatments for
22 things that don't matter. And if it doesn't matter to

1 you, or it's really something that's more of a problem
2 for other people, maybe that's not the best thing to go
3 after.

4 DR. EGGERS: We'll see if we're getting any
5 web comments on the topic of this. And if you're on
6 the web, please chime in as well about, about
7 repetitive behavior. Before, before we go to the break
8 then, because of this is there any follow-up questions
9 you want on, on the repetitive behavior? No. Some, we
10 had one more person.

11 Well, let's let the gentleman in the green
12 shirt go first. And then we'll have Lynn and then
13 we'll go for a break.

14 MICHAEL: Okay. Quick comment. I am on the
15 autism spectrum. I don't have a lot of repetitive
16 behaviors at this point, but I have had things that
17 were -- I don't know. I felt like somewhat compulsive
18 physical motions and stuff. And I don't think that the
19 behaviors were necessarily a problem, but I would point
20 out that sometimes there were things that I've done due
21 to underlying physical discomfort and a sort of
22 physical restlessness that is actually an unpleasant

1 phenomena.

2 So I wanted to just point out that the
3 behavior may not be a problem, but sometimes what's
4 driving it may not be the greatest thing to be dealing
5 with. And it could, should be assessed as a possible
6 treatment target.

7 DR. EGGERS: Okay. So the underlying whatever
8 is leading to the, the behavior, the repetitive
9 behavior is something that is worthwhile to, to, to
10 explore further. Okay. Great. We'll go with Lynn and
11 then we'll take a break for ten minutes.

12 MR. DURHAM: I'm sorry. I didn't want to
13 speak that much, but there really was something I
14 wanted to say about repetitive behaviors. From my
15 multiple experience, it's not really the repetitive
16 behaviors that have been a problem. It's more the
17 restricted interests.

18 In the sense that in my brother, for instance,
19 he won't leave, and the rigidity. He won't leave a --
20 he won't go any further than 20 miles away from his
21 house. And my son is, his interests are so restrictive
22 that when, we can't stay at the house for, on weekends

1 for more than a half an hour because he starts getting
2 anxious because he doesn't know what to do and he
3 doesn't know how to occupy himself.

4 And so even if it's raining, snowing,
5 anything, we have to go out and take him to sports
6 activities because he doesn't -- I don't really have
7 the term to define this because it's really a feeling.
8 But he doesn't really know what to do with his own
9 skin. And so we just have to go out and, you know,
10 offer him constant activity and occupation.

11 So it's not the repetitive behavior. It's the
12 restricted interests and rigidity.

13 DR. EGGERS: Okay. Would anyone, those of you
14 that had the I, other health effects, would you have
15 put what Lynn just described, was that in your I? Show
16 of hands, please? No. So there are other things
17 besides that. Okay. Let's take a break for ten
18 minutes and we'll come back at about 3:12 and get
19 started again.

20 Again, the restrooms are back there. We'll
21 get started. We'll see if there's any follow-up on
22 here, and if we haven't fixed the feedback issues, I

1 think we'll do the topic two panel comments from the
2 tables because I think that's easier. So anyway,
3 everyone come back to your seats in ten minutes.
4 Thanks.

5 Okay. So we are going to get, we're going to
6 get started again with, with another polling question.
7 We're going to wrap up topic one. And then about,
8 about health impacts and impacts on daily life. And
9 then we'll shortly move into topic two and have our
10 panelists. This is a new setup. See, we learn new
11 things. After even 22 meetings there's always
12 something new we learn.

13 So while you're sitting here while we wait for
14 the rest of everyone to get back into the room, here's
15 the question you can think about. It, it, these are
16 the broader issues related to autism, broader than the
17 specific health effects. But what aspects of your or
18 your loved one's daily life are most negatively
19 affected by autism?

20 And again, we'll, we'll ask you to choose up
21 to three, three things. So we'll give you a few
22 minutes just to think about this question. Okay.

1 Well, let's let it go for a while. I'll give you a few
2 more minutes to think about it. And if you're just
3 joining in the, in the room, we have a question about
4 the, the aspects of, of daily life that are most
5 negatively affected.

6 As you think of this, what's most negatively
7 effected and matters the most to you or your child? So
8 it's just another polling question. Does anyone need a
9 clicker or having trouble with their clickers? Now if
10 you're on the web, welcome back. And we encourage you
11 to ask the polling question as, answer the polling
12 question as well. Okay. Another minute.

13 Okay. Let's, let's go to the results. Okay.
14 So the ability to participate or perform daily
15 activities such as work, school, sports, etc., and the
16 impact on relationships with family and friends. Are,
17 have the most attention here in the room. And followed
18 by ability to care for self or family. And then, and
19 then a range of other things. On the web?

20 DR. THOMPSON: On the web we had 65% on
21 ability to perform daily activities, 47% for ability to
22 care for self, 18% for safety of self, 47% impacts on

1 very relevant point to discuss. What I wanted to say
2 is that I thought it was very interesting that you
3 mentioned prescription medications only as CNS drugs
4 because I have the feeling that maybe that's not the
5 primary entry point to develop effective medication or
6 personalized medication for people with ASD.

7 What I mean by this is that we said that we
8 needed to develop individualized endpoints. You also
9 need to regard the development of treatments in an
10 individualized matter, meaning that for right now we're
11 phenotyping or sub-classing individuals with autism
12 based on behavior and determining, you know, adequate
13 or perspective drugs while looking at these behaviors.

14 And I think that behavioral observation does
15 not offer an optimal or a sole insight into the
16 molecular etiology of autism. And I think that to
17 develop drugs that could have an effect in
18 subpopulations of autism, you need to pay more
19 attention to clinical sets of signs and symptoms, non,
20 non-behavioral clinical sets of signs and systems
21 because that's going to offer you easier insight into
22 molecular dysregulations because dysregulations in

1 autism, like in a lot of diseases, are ubiquitous. And
2 so things that are expressed in the brain and that have
3 a genetic origin also express themselves on a general,
4 ubiquitously on a general body level.

5 And so kids who have gastrointestinal
6 disorders, while gastrointestinal disorders and
7 gastroenterology can offer insight into potential
8 targets in ASD - and I think that even though for 80%
9 of autism we don't have the gene, they're idiopathic -
10 these sets of clinical signs and symptoms can offer a
11 lot of insight into a personalized approach to
12 developing good therapies.

13 DR. EGGERS: Great. Thank you, Lynn. So
14 we've heard, we've heard about the immunomodulators
15 from someone in topic from -- yes. Sharrill on topic
16 one. The other, the other -- oh, just slipped my mind.
17 The, the broader beyond psychiatric medications and we
18 heard that in the comments that you sent in. Can we
19 have a show of hands if you, if you have a strong
20 perspective on, on the need to, to look broader than
21 psychiatric medicines?

22 Can we just -- we won't get into very much,

1 but can we have a show of hands? Okay. Okay. So, but
2 I think we want a little bit of feedback on some of the
3 psychiatric medications. Go ahead, Tiffany.

4 DR. FARCHIONE: I mean I think that what's,
5 what's important is, you know, we've, we've heard about
6 comorbid conditions and how those can influence the
7 expression of the symptoms of, of autism and how that
8 can, you know. There's like a downstream or a cascade
9 of, of effects. So, but then we've also heard that,
10 you know -- I mean in somebody who isn't able to
11 communicate something as simple as pain, can, you know,
12 also kick off that cascade.

13 So, and actually the reason why I was sort of
14 pushing for, for GI to be here, and I was really
15 surprised on the previous poll to see that the GI
16 symptoms were so low on, on the list. Because I had
17 heard a number of times from folks who would say, you
18 know, when my, my child or my loved one was, you know,
19 having meltdowns or getting aggressive or whatever, you
20 know, eventually we took him to a gastroenterologist
21 and realized that they had all of these issues with
22 constipation or, you know, some other GI thing. And I

1 would always hear stories about GI problems, GI
2 problems, GI problems and dietary interventions and
3 everything.

4 So I was like, okay, let's get GI on the, on
5 the panel. But, you know, so it's not just the
6 psychiatric medications. It's anything that might help
7 to, you know, nip that cascade in the bud.

8 DR. EGGERS: Are there any follow up, anything
9 you want to know specifically about any of the
10 psychiatric medications or anything psychiatric? Yeah,
11 sure. So we'll go here.

12 DON: What I want to say is that my son has
13 what used to be called classic Asperger's and, and I
14 know that term's not used anymore, but last year he
15 developed just severe anxiety and, and to the point
16 where my, my wife and I were panicked and did
17 everything we could think of to do.

18 You know, I was always one of these guys, my
19 son's not doing medication, right? And guess what? We
20 got him on, on Paxil and it, it made a huge difference.
21 And the doctor said, you know, this is probably not
22 going to work. We're going to have to go through a

1 whole bunch of different, different iterations and drug
2 combinations.

3 I'm telling you, it changed his entire life.
4 And I know that for a fact because he stopped doing it
5 'cause we stopped checking on him, right? And he would
6 take his pill at night and all the sudden his teacher
7 called and said he was upset at school again, crying.
8 And, and, and we asked him. We said, you know, what's,
9 what's wrong. Have you been taking your pills? Oh,
10 maybe I haven't.

11 So, so from then on we started watching him
12 pretty closely and it's made a huge difference. It
13 really has. So, Don.

14 DR. EGGERS: Thanks, Don. We got a lot of
15 hands raised. So let's keep going on this. Let's go
16 there with Kiely.

17 DR. LAW: Okay. So I will just briefly.
18 Isaac currently takes two medications, lithium, and
19 Abilify, and he hates both of them; however, he hates
20 being in the hospital more. And so that's the balance.
21 You know for the lithium he does feel like it sort of
22 takes away a little bit of his creativity and I know

1 that other people with mood disorders have, have said
2 the same thing.

3 For me as his mom, you know, I worry about the
4 fact that it has a very narrow therapeutic window and
5 when you have someone who can dip down into the
6 depression with suicidal ideations, that's, that's
7 concerning that, you know, he could take just a little
8 bit more and it would be very harmful to him. The
9 blood draw is, you know, he's willing to accept those,
10 but it's a challenge.

11 And then the Abilify, you know, he's on a very
12 small dose of that and it, it does seem to help him.
13 But at the same time, his triglycerides are now
14 horrible. So now we're getting into those chronic, you
15 know, dietary adult diseases. You know, is he going to
16 not end up with, you know, heart disease and things
17 like that related to the triglycerides.

18 DR. EGGERS: Thank you, Kylie. And I think
19 Leah, and then we'll go here to Michael.

20 MS. HELVERING: I just wanted to follow up
21 what Tiffany was touching on because I agree completely
22 with where you were heading in your thought process

1 about the core deficit of communication and also I
2 think social deficits combined lead to a very
3 heightened anxiety. And I've been trying to keep track
4 of how many times I'm hearing the word anxiety around
5 the room. I think it's a universal understanding that
6 it's a huge problem.

7 And not only does it inhibit the effectiveness
8 of like behavioral therapies and speech therapy and
9 occupational therapy, when you're anxious you can't
10 respond to those effective behaviors. But it also
11 contributes to the core deficit because it comes out in
12 a decline in speech. So when my child is not anxious
13 he will operate at a certain baseline of communication
14 disorder. By definition he'll have a certain, just
15 level of impairment. But when he's anxious it will
16 decline. When he's on an SSRI, it will improve.

17 So same thing happens in the social situation.
18 He has a certain level, a baseline of social deficit
19 that can be improved with education and different
20 things, but when he's anxious, he will decline in his
21 ability to interact socially, so.

22 DR. EGGERS: Thank you, Leah.

1 MS. HELVERING: I think the role of anxiety is
2 important.

3 DR. EGGERS: And it -- Leah, Leah. And now
4 we'll go to Michael.

5 MICHAEL: So, okay. So I'm, this is a
6 slightly challenging topic here, but when you're
7 talking about using it to treat symptoms of autism or
8 things like that, there's something really challenging
9 about it, the way this whole issue is framed for me as
10 someone, you know, coming to deal with things related
11 to potential pharmacology mostly probably here.

12 And that is is that when you're talking about
13 symptoms of autism, autism is really a set of symptoms
14 in the way it's defined. So you're talking about
15 either those symptoms or the symptoms of those
16 symptoms, but really in one way, or that's one way you
17 can think about it. But the other way is really all
18 the things that define autism are symptoms of a
19 neurodevelopmental difference.

20 And so there's a distinction between what the
21 symptom of, of a certain set of symptoms that, that
22 were one set of symptoms at the neurodevelopmental

1 difference made and the actual neurodevelopmental
2 condition underlying that, which has basically for
3 everyone I think, it's pretty well shown that one way
4 or another there's a huge amount of symptoms that any
5 given person has universally pretty much that doesn't -
6 - and they're not all the same for everyone. It
7 doesn't just fit neatly into this diagnostic criteria.

8 So one of the problems that comes as a, as a
9 consumer working with trying to treat the difficulties
10 that I have as a person on the autism spectrum, is that
11 you strip, it's like stripping layers of an onion. So
12 you've got to a point where you can find a way of
13 living with some sort of sense of cognitive difference
14 in a way that doesn't produce a symptom that's any
15 longer identified as being on the autism spectrum
16 necessarily.

17 But that doesn't mean that the cognitive
18 difference is suddenly disappeared and it doesn't mean
19 that there aren't other symptoms of it. So, you know,
20 there's, there's a sort of frustrating quality to that.
21 So recently, for example, I've used lisinopril, for
22 example, to deal with issues of high blood pressure.

1 Well, that high blood pressure probably was a symptom
2 of a symptom of being on the autism spectrum.

3 I'm not sure that the underlying
4 neurodevelopmental disorder did or didn't impact it.
5 I'm not sure exactly how the, the, the problem formed.
6 But, but as anxiety increased and, you know, other
7 things, you got this sort of byproduct. And as I take
8 a medication for that, I have to look at how it's
9 interacting with my ability to focus, function, and
10 work through everyday life. And it impacts my disorder
11 even if it's not, you know, so precisely related. So
12 that, that's a real challenge.

13 The other thing is as a different perspective,
14 I've also tried taking some medications that were
15 designed for attention deficit disorder. Now I fit
16 criteria for attention deficit disorder, but they don't
17 express exactly in the way that they usually do for
18 people with ADHD. They express as basically autism
19 spectrum symptoms that happen to lead to these sorts of
20 things appearing pretty differently.

21 So, and then if I take -- let's say I take
22 methylphenidate, in this case Concerta, and, hoping

1 that maybe I'll be able to focus better and work more
2 in everyday life. Well, it makes me more awake and it
3 will make it so that I can focus on certain things
4 better.

5 But what's noticeable about that process is
6 that I'm, I have, I can't control -- I found I can't
7 control a lot what I'm focusing on. And that's one
8 issue that I've had being on the autism spectrum. It's
9 related to the restricted interest criteria, I think.

10 So when I take that, basically that means what
11 I found is that now if I do take the methylphenidate,
12 then I can focus even better on what I'm good at
13 focusing on already. And that's not a bad thing, but
14 it's also, it's also treating one aspect of an
15 attention symptom and not another.

16 So I just want to sort of throw out the idea
17 that I think we have to get at these things in more
18 nuanced ways and see how these things are actually
19 expressing and look at it from, you know, biological,
20 to genotype, to different sort, to intermediate
21 phenotypes, to the condition, to the sort of downstream
22 consequences of it and actually start like separating

1 them out and giving us as people on the autism spectrum
2 tools to look at those things for ourselves in ways
3 that might, might be different from how outsiders would
4 look at it.

5 DR. EGGERS: Okay. Thank you very much,
6 Michael. We'll take a few more comments, and on the
7 web if you want to type in any comments on this thought
8 and the thread that we've been talking about. But
9 we'll go back here with, with Kit.

10 MS. MEAD: So hi. I assume, assuming I didn't
11 get lost somewhere in like all the people talking.
12 We're still on the psychiatric medications, right?
13 Okay. Good. I'm on several and what I want to say is
14 that like I think it's, the side effects are like
15 extremely serious for like -- hold on.

16 Like Abilify gave me akathisias, which is like
17 an uncontrollable, like it makes me want to like move
18 all the time, but it's not like wanting to stim. It's
19 like very different. It feels like, it's kind of like
20 restless leg syndrome, but like everywhere and dialed
21 up to 11. And some of my friends even ended up in like
22 the ER after being on it because they ended up like,

1 they needed to move so much that they moved, like they
2 ran themselves into exhaustion and they're not, they're
3 not autistic. But they were on it for other reasons
4 and it did that to them.

5 But I feel like people aren't told about all
6 the stuff that comes with drugs a lot because people
7 want something that will solve all the problems. And
8 if it has side effects like, that might deter people
9 from using the thing. I'm not sure if I'm making a
10 whole lot of sense.

11 DR. EGGERS: Oh, you absolutely are making
12 sense. And Kit, you're, you're bringing up something
13 that we're going to be moving into about how you think
14 about benefits versus the risks of, of the drugs.

15 MS. MEAD: And I think that medication like
16 all other treatment should be a choice. If a person
17 has any -- like all people have some form of
18 communication and you should like, and everyone one has
19 a right to have support to make their own decisions.

20 DR. EGGERS: Thank you, Kit. We'll take one
21 more back here.

22 HELENE: Hello. Thank you first of all for

1 having this public meeting. Otherwise, I wouldn't be
2 here. I have a nephew. He's about 20 -- he's 26 right
3 now and he's very nonverbal. Every once in a while we
4 might be able to get a sentence or so out of him, you
5 know, out of the day somewhere to somebody who, very
6 close to him.

7 But my concern right now in hearing what the
8 self-advocates are saying, especially has been really
9 important in terms of being able to have medication
10 that deals with the nuances of the things, like the
11 attention deficit and what the young lady was saying in
12 terms of the side effects.

13 My nephew actually is in the process of going
14 through major physical therapy and occupational therapy
15 right now because of a very adverse side effect to a
16 psychiatric medication. And he basically went through
17 the state of paralysis. And in addition to the
18 paralysis, severe pain was occurring. But because of
19 his nonverbal ability, wasn't quite articulating it the
20 best, pretty much at all because the pain made him even
21 more nonverbal and he just sort of went within. And it
22 wasn't until the paralysis actually occurred that we

1 were aware of what this adverse reaction was.

2 So is, I want to just support the young lady
3 who was just speaking about, the knowledge about the
4 side effects are really, really crucial because even
5 the slightest side effect, adverse side effect can
6 affect not just that person's ability to deal with his
7 or her autism, but also how that person is safe. How
8 the family is adjusting to his wellbeing and his care
9 and how he's able to self-care as well.

10 So I just want to, like I said, advocate more
11 knowledge and focus being --

12 DR. EGGERS: And what was your name? What's
13 your name?

14 HELENE: Oh, I'm sorry. My name is Helene
15 Fischer (ph).

16 DR. EGGERS: Helene, thank you, Helene. Are
17 we getting anything on the web?

18 DR. THOMPSON: Not as much about psychiatric
19 medication.

20 DR. EGGERS: Or any summary?

21 DR. THOMPSON: Regarding sort of behavioral
22 challenges such as anxiety and aggression, several

1 commenters have linked them to lack of sleep and
2 sensory overestimation. And for lack of sleep a
3 variety of sort of treatment options people have tried
4 including prescription medication, but also things like
5 medication or relaxation or music therapy or things
6 like that.

7 Similarly for senior overstimulation, trying
8 to get systems at either school or in public places
9 where they have, you know, headphones or other sorts of
10 methods to control noise and lights and things like
11 that.

12 DR. EGGERS: Okay. Thank, Graham. All right.
13 So we need to move on, but I have a few show-of-hands
14 questions if you feel comfortable raising your hands.
15 We don't get to probe into the non-drug therapies. We
16 did hear about various things throughout the
17 discussion.

18 But a couple questions. How many feel here in
19 the room today - and on the web please comment on this
20 as well - feel that you as a self-advocate or your
21 child, if you're a, if you're a family member, is
22 managing their health as best as you can expect today?

1 So they're managing, managing autism and life as, as
2 good as you could hope or expect, or as you would want.

3 Okay. So, let's try -- what? Yes. That you,
4 that it's, that it's optimal -- whatever you're doing,
5 however you're managing your symptoms, that it's
6 optimal for you today. If not optimal, as much as you
7 could hope for, as much as you can expect. Show of
8 hands? Okay. Great. Okay. Give us one second, Kit,
9 and we'll come to you with the microphone.

10 MS. MEAD: Sorry. I thought I had -- I got
11 mixed up and thought I was talking. Sorry.

12 DR. EGGERS: That's okay. So can I ask the
13 flip question? Then how many of you feel that your
14 autism or your child's autism is not well-managed or
15 getting progressively worse? Okay. So there's a
16 middle. Okay. Yep. So, okay. Okay. You want to
17 explain the thinking?

18 DON: So as I was saying earlier, some of the
19 things that, that treatments that my son has had have
20 been very positive. There's a lot more I wish I could
21 do. And so in the middle.

22 DR. EGGERS: Okay. How many of you -- was it

1 -- Don. How many of you share Don's perspective, said
2 much better than my two questions? Okay. All right.
3 Then another -- bear with me for one more show-of-hands
4 question. How many of you feel that in your situation
5 or your child's situation, that medical treatments for
6 some aspect of, of autism are, are necessary? So
7 medical, medical treatments. Any kind of medical
8 treatments, yeah.

9 Okay. I'm going to ask the flip side. How
10 many of you feel that in your situation or in your
11 child's situation that medical treatments are currently
12 not, not necessary? That you can you manage, manage
13 autism without needing medical treatments. Okay.
14 Okay.

15 We did get some comments in indicating that
16 some, that some of you thought that you didn't need
17 medicines at this point, that you're doing, that what,
18 how you are living and managing and other therapies
19 you're taking meant that you didn't need any kind of
20 medications? Okay. So a few people in the room feel
21 that way.

22 But most of you raised your hand to say that

1 medication, some sort of medication is, is necessary
2 for you or your child in the current situation. Okay.
3 Go ahead.

4 MS. LUTERMAN: I find that question really
5 confusing because I do take medication, but it's for
6 anxiety and depression and suicidal ideation, and
7 that's not the same thing as autism.

8 DR. EGGERS: Okay.

9 MS. LUTERMAN: Like, so I, I mean when it
10 comes to the question about what's optimal, I discussed
11 during, when I was speaking on the panel, difficulty
12 finding a psychiatrist who's competent in multiple, in,
13 in DD and in psyche stuff. But, yeah. I just, I just
14 don't, -- the question doesn't make sense to me because
15 I don't feel like my autism gets better or worse. It's
16 just a fact. But my anxiety does get better or worse.

17 DR. EGGERS: And that is an excellent point.
18 Okay. We'll take one comment there to follow up on
19 this.

20 MS. GROSS: I was just going to say I agree
21 with Sara. I think that a lot of us are having that
22 reaction, that we don't know how to answer this

1 question, 'cause like for me, I take medications and I
2 need them, but they're, I don't, I wouldn't describe
3 them as medications that I take for autism or
4 treatments of autism.

5 DR. EGGERS: Okay. One more. Kit? Yeah.
6 Wait. We'll let Tiffany ask a question.

7 DR. FARCHIONE: Yeah, just, just a quick
8 follow-up. So even though you take medications for
9 things other than the autism, if, if those things are
10 not under good control, do your symptoms of autism
11 flare up? So, I mean, I guess I'm wondering like do
12 you see them -- even though it's not a direct treatment
13 of autism, do you see it as being related?

14 MS. MEAD: I would say that like I wouldn't
15 directly correlate them mostly because like the
16 question was kind of confusing, but I'm trying to
17 answer it anyway. So like basically if I feel better
18 mental health wise, then like that means I just feel
19 better generally. It doesn't mean that like my
20 autistic traits are suddenly like better or worse.

21 And sometimes my autistic traits can like do -
22 - like when I hand flap, that makes me really happy and

1 it also helps with like a bunch of other stuff. I
2 don't know if I'm making sense. I don't know how to
3 correlate it.

4 DR. EGGERS: Okay. Well, I think we, I think
5 we have heard a very clear point made, that it is
6 difficult to talk about medical therapies in, in the
7 same way that we might for other conditions. And so do
8 you have -- okay. And so Kit and, and Sara and Zoe and
9 the parents here in the room have all made this same
10 point, that it's not going to, it's not cut and dry. I
11 think that's what we'll, that's what we'll take from
12 here.

13 So to move on, we, we -- let's try -- can we
14 try another polling question and see how you react to
15 this one? And first of all, raise your hand if you
16 want to answer this polling question 'cause we have
17 other we could go to. This might be -- we don't have
18 to take a polling question on this if there's, or talk
19 a lot about it if, if you think that this would be a
20 hard question to answer. Do you think you can answer
21 this question? Okay. We're getting head nods. So
22 let's do it.

1 When, when considering treatment options,
2 which of the following benefits would you or your loved
3 one consider to be the most important? What you're
4 looking for in a treatment would address the following,
5 the following aspects: A, reduced irritability or
6 disruptive behaviors. And let's put in, Jeannie, I
7 think, made the point earlier about aggression in that
8 category. B, reduced cognitive impairment. C, reduced
9 social impairment. D, reduced communication
10 difficulties. E, reduced repetitive behaviors. F,
11 reduced sleep issues. G, reduced depression or
12 anxiety. And H, reduced gastrointestinal symptoms. Or
13 some other would be I.

14 I can tell you while you're doing this, we
15 learn so much from just asking the questions to see how
16 you respond to the questions. It is, it is so helpful
17 even if it's not getting exactly the answers that we
18 thought we might get when we first started. So, so
19 this is a, this is a good thing. Okay. Okay.

20 So we have a mix with bringing back, tying
21 back to our discussion on the health effects that were
22 the most challenging. The, you know, if you could

1 reduce communication difficulties, reduce depression
2 and anxiety, that goes with what we've been hearing
3 about. Reduce social impairments. Reduced
4 irritability with much less on reduce repetitive
5 behaviors.

6 So I think we have -- I think it's, it's
7 reenforcing the input that you've already provided.
8 I'll see is -- are there any questions that you have
9 about, about this? Okay. Okay. Let's get a few, just
10 a few comments. Just very brief. In a few words, what
11 were some of the other things that you'd want benefits
12 out of a treatment? So a few things. Well go, we'll
13 go to Kit and then Michael, and then if there's anyone.

14 MS. MEAD: So I want a treatment that works
15 with me and like not against my autistic traits, but
16 rather with them and I would benefit. What I would
17 want that I would -- sorry. Hold on. This question
18 isn't like as ideal as it could be for me because a lot
19 of my problems come from the fact that like society is
20 not like -- society is discriminatory against autistic
21 people.

22 And some of my other problems come from like

1 not having, like supports that I need instead of like,
2 like -- I don't want something that like is going to
3 say, oh, well, we must fix the autism because that is
4 clearly the only problem ever. Like I'm not going to
5 like -- I don't want that. So I've put other.

6 DR. EGGERS: Thank you, Kit. Before we go to
7 Michael, if, if we could take one or two callers on the
8 phone very briefly. If you want to call in about --
9 we'll ask if you've been following on the web and you
10 want to call in about something about looking for what
11 you want to get out of medical treatment that hasn't
12 been mentioned yet. So if you have a unique
13 perspective on that, we could tee up the phone for
14 that. Okay. Michael, yes.

15 MICHAEL: So, so for me, I mean I first of
16 all, I echo Kit's perspective to some extent, but I
17 also have a different feeling. And that is what I
18 would want to treat really would depend on the totality
19 of the effect of the treatment. So I, I have
20 neurodevelopmental differences and some of them have
21 given me things in life that I'm very, very happy
22 about. And some of them have given me some very

1 challenging things too.

2 And so I don't necessarily know in all cases
3 where the biology will separate between the two and
4 what kind of tradeoffs. If, if something simply gives
5 me the flexibility to, to interact in the world as if I
6 was a person who didn't have the neurodevelopmental
7 difference, but also gave me the flexibility to
8 interact in the world in the, and think and process
9 things in the way that I do now, or have all the
10 positive features, I, I would probably sign up for that
11 very quickly.

12 But, but there's this, there's this sort of
13 dialogue that goes with the fact that some of the
14 reasons that I probably have some of the positive
15 features I do as a person may well exist because of the
16 differences in how my brain's configured over time and
17 stuff.

18 So I, I just, just sort of throwing out the
19 fact that I'm not averse to treating autism in terms of
20 the diagnostic features of it. I might be averse to
21 becoming typical.

22 DR. EGGERS: Okay. Okay. Apologies. (Music

1 playing.) Again, have I said before we're in a very
2 new room configuration? So, so our apologies. So with
3 that, let's just all take a moment. We have, we have
4 five more minutes left, okay? So we're not going to do
5 anymore scenario questions.

6 I just want to see the FDA panel, you've been
7 listening. Do you have any other burning questions
8 that you want to, to ask? And it's okay if you don't.
9 We have taken in a lot. Can I -- we'll go to Sharrill
10 and then I want, if you haven't spoken yet and there's
11 something really key on your mind and you'd like to,
12 raise your hand, raise your hand high and we will come
13 to you for any final thoughts on, on ideal treatments,
14 what you want out of a treatment, a medical treatment.
15 But we'll go to Sharrill first.

16 MS. HEMRY: A medical textbook changing -- a
17 medical textbook changing study at the University of
18 Virginia recently identified that the brain is directly
19 connected to the peripheral immune system by previously
20 unknown lymphatic vessels and that these vessels may
21 play a major role in every neurological condition that
22 turns out to have an immune component.

1 Additionally, multiple studies starting with
2 the 2005 Johns Hopkins brain autopsy study have
3 provided evidence that there's a chronic neuro-
4 inflammatory process in regions of the autistic brain
5 caused by perpetually activated astrocytes and
6 microglia which police the brain for pathogens, as well
7 as proinflammatory cytokine profiles in the brain and
8 cerebral spinal fluid.

9 With such evidence of inflammation and immune
10 issues associated with autistic brains, we need to be
11 more focused on developing drugs to help the immune
12 system starting with immune modulators to stabilize and
13 balance the immune system. Having an autism diagnosis
14 should not be an excuse for a serious disease process
15 to go untreated, ultimately compromising quality of
16 life for many.

17 DR. EGGERS: Thank you, Sharrill. Is there
18 anyone on the phone? Okay. So we have one person on
19 the phone and I, I have to say it's good to follow
20 protocol. Operator, can we have the next caller?

21 OPERATOR: Yes. Her name is Brenda Cosi (ph).
22 Brenda, your line is open.

1 DR. EGGERS: Hi, Brenda. Brenda, are you
2 there?

3 OPERATOR: Brenda, is your line muted?

4 MS. COSI: Yes. Thank you. I would like
5 medical treatment for what I've termed the foggy brain
6 for my son who's 12 in July, diagnosed at the age of 3.

7 DR. EGGERS: Okay.

8 MS. COSI: He's had an MRI and they say
9 there's nothing worrisome about that. I don't know the
10 medical term for it, but he definitely has what we call
11 foggy brain and it takes him to maybe 11 o'clock to
12 come out of it. And that is impacting his school days.
13 Thank you.

14 DR. EGGERS: Thank you very much, Brenda.
15 Okay. So we have -- then let's go here for -- we have
16 a few final comments. Thank you. And I forgot your --
17 you pronounced it for me, but I, I forgot.

18 MR. SURIO: Hi. My name is Suraksha Attila
19 Surio and I was recently diagnosed with autism spectrum
20 disorder. So I have --- I was late diagnosed. And my
21 concern is like for people who, you know, are late
22 diagnosed or if there's like some kind of

1 complications, many people usually have to wait four
2 months to a year to get help and that can be kind of
3 challenging for someone who's like, you know, waiting
4 and waiting and waiting to get help. And it can be
5 stressful and it can cause anxiety.

6 Another issue of mine is that, what is being
7 done for people who have autism spectrum disorder that,
8 you know, I'm high functioning, but, you know. Another
9 issue is what is being done for people who are in the
10 workforce and stuff like that. Because not many
11 employers understand and then sometimes like they could
12 be terminated or something wrongfully. And that, that
13 is my concern.

14 DR. EGGERS: Thank you so much for raising two
15 important points that we didn't actually get into much
16 today. So I thank you for that. So with that, I think
17 we will close -- no, no, we're not closing the -- no,
18 no, not wrap up yet. No, no, no. According to the
19 agenda, we're going to move into the open public
20 comment session. And so, but the facilitated portion
21 of the meeting has come to an end and on behalf of my
22 team, I want to give you a sincere thanks from the,

1 from the position with the hat of the facilitator.

2 This has been a truly insightful meeting and we'll let,
3 we'll let Mitch sum up. But it really has been.

4 And the fact, even just how you reacted to
5 questions is extremely insightful. It helps us
6 communicate and have dialogue better with you. So a
7 round of applause for, for all of you in the room. And
8 we thank you for contributing on the web as well. And
9 with that, Meghana will do the open public comment.
10 Thank you.

11 MS. CHALASANI: Thank you, Sara. Okay. Let's
12 see if -- can you guys hear me? Oh, there we go.
13 Okay. So we're now moving on to the open public
14 comment session and for those of you that are not
15 aware, the purpose of this session is to allow an
16 opportunity for those who have not had a chance to
17 speak on issues that are not necessarily related to our
18 two main discussion topics. This is also an
19 opportunity for participants who are not individuals
20 with autism or family members to comment as well.

21 Please keep in mind that we will not be
22 responding to your comments, but they will be

1 transcribed and be part of the public record. Since we
2 would like this to be a transparent process, we highly
3 encourage you to note any financial interest that you
4 that are related to your comment. If you do not have
5 such interest, you may state that for the record as
6 well. If you prefer not to provide this information,
7 you may still provide your comments.

8 We have collected sign-up before the meeting
9 and during the break. We have eight participants
10 signed up and about 12 minutes for this session. So
11 please be respectful and stick to the two minute time
12 limit. I will be keeping track of time. So if you
13 approach that two minutes, I will be asking you to wrap
14 up.

15 So I'm going to quickly run through the order
16 of the speakers and I really apologize if I
17 mispronounce your name. We have Jeannie McGuire,
18 Sharrill Hemry, Fatima Dufois (ph), Suraksha Attila
19 Surio, Joan Fallon, Sharon Walter, Leah Helvering, and
20 Stuart Spielman.

21 So first could we please get a mic to Jeannie
22 McGuire, please?

1 MS. MCGUIRE: Thank you for this opportunity
2 to meet with you and to express our concerns. We
3 sincerely hope we will be heard.

4 DR. EGGERS: Pick the mic up real close.

5 MS. MCGUIRE: Can you guys, can you guys hear
6 me? I think I've said enough before about my daughter
7 and her severe problems. But what I want to address
8 here is that -- is that close enough? Okay. Okay.
9 Is, you know, what, what is the FDA, your limitations
10 in the sense of we can talk about, you know,
11 medications and treatments, but the end of the day it's
12 the funding.

13 And what I've confronted in the situation with
14 this dietary supplement for my daughter is that
15 pharmaceutical companies don't want to fund things that
16 they can't get a nice, tight patent for that will last
17 a long time. So if the remedy that's safe and
18 effective just happens to be a simple, naturally-
19 occurring phytochemical, or maybe methyl B12 or
20 something like that, well, there's no money out there
21 to do the clinical studies to get to the I&D and the
22 and NDA.

1 We got a problem and I don't know if you guys
2 can answer that, but we've got a problem. I know you
3 have the best interests, you know, at heart, but we all
4 have to work on this together to help, you know, our
5 kids or ourselves to find safe, effective treatments
6 because what we've got right now in this nation is not
7 acceptable.

8 And I want to say we put a man on the moon.
9 We could do better than Risperdal and Abilify. Thank
10 you.

11 MS. CHALASANI: Thank you, Jeannie. Now we'll
12 have Sharrill.

13 MS. HEMRY: I'm just a parent. I'm Sharrill
14 Hemry. I've spoken a few times today of my three
15 children and their constant battle to achieve and
16 maintain neuroimmune health. In the past many well-
17 meaning medical practitioners often couldn't see past
18 my child's autism diagnosis to test for possible
19 underlying diseases and issues with seizures, strep,
20 viruses, food allergies, and middle ear drainage, went
21 undiagnosed for years.

22 Eventually we found a doctor in the state of

1 California who ordered the right tests and we've seen
2 improvements, but the available drug choices remain too
3 limited.

4 I mentioned before that we desperately need
5 multiple immune-modulators to be made available, but
6 each needs to have extensive pre-and post-trial testing
7 of every participant to identify which blood and other
8 markers are shared by those on whom the drug was a
9 success.

10 We need antiviral drugs able to target
11 antibodies for the entire human herpes virus family.
12 These trials should be designed to guide physicians
13 through every possible side effect and what to do in
14 response, hopefully minimizing the number of patients
15 taken off the drug because a side effect was mistaken
16 for a reaction.

17 An antiviral drug I'd hoped would now be
18 available failed its trial for this reason. And we
19 need every drug to be made available in a form which
20 not only contains none of the eight allergens, but also
21 contains no dyes, no flavorings, no grains in any form
22 such as rice starch, and no dairy in any form such as

1 lactose, allowing people with autism or their
2 caregivers to be certain that any reaction is to the
3 drug, not an additive.

4 Many people with immune issues, not just those
5 who also have autism, would benefit from the above
6 recommendations. And I'm happy to further discuss this
7 with anybody at the end of the meeting. Thank you.

8 MS. CHALASANI: Thank you, Sharrill. Next we
9 have Fatima. She still here? Fatima Dufois? No.
10 Okay. Next we have Suraksha Attila Surio.

11 MR. SURIO: Hi again. This is Suraksha Attila
12 Surio and my comments and concerns are towards people
13 who, you know, like I said earlier, about like
14 employment and stuff like that. From what I've, from
15 what I've experienced recently is that it can be
16 challenging when you're trying to communicate to your
17 employer about what's going on and stuff like that
18 'cause sometimes they're, they're not going to
19 understand or anything like that. And then there's
20 going to be more challenges.

21 Because for me the issue was trying to find
22 someone, you know, trying to communicate with someone

1 that would understand my needs. And then half the time
2 I would be nervous and half the time would be like
3 apprehensive thinking that they're going to like go out
4 to get me or something like that.

5 And another issue is just being on a waiting
6 list or waiting for care for people who have autism
7 spectrum disorder, and it's important that they don't
8 have to wait, you know, four months to a year and get
9 the care that they need immediately.

10 And like for me, I've been waiting since
11 January or February, and, you know, like, you know,
12 next week I'll be able to see someone. But it
13 shouldn't take that long for someone to get care that
14 they need because, you know, in that timeframe they
15 could like, you know, something bad could happen or,
16 you know, they could, you know, they could end up, you
17 know, in the hospital or something, God forbid.

18 But on a personal standpoint, it's important
19 for people to understand and I think there needs to be
20 more advocacy and that other people who don't know so
21 that education about this, and there's like goes to the
22 general public and there isn't a stigma towards this.

1 Same thing with the depression because I've had
2 personal people that I've known tell me that depression
3 is a choice or something like that. It's not, you
4 know.

5 It's like a mental disorder with autism
6 spectrum disorder and it's important to understand that
7 everybody has their needs and it's important to find
8 those needs are met. Thank you. And if anyone asks me
9 more questions more about it, feel free to.

10 MS. CHALASANI: Thank you. Thank you. Next
11 we have Joan Fallon.

12 MS. FALLON: Thank you. I'm the CEO of a
13 biotech company called Curemark and we've been working
14 on an enzyme drug for autism since 2005. Our drug has
15 been granted fast-track status by the Agency and we
16 currently have a rolling NDA. And I just want to
17 publically thank the Agency and Dr. Mathis in
18 psychiatry and all his team, and the GI division for
19 all your guidance throughout this process. It's been
20 very helpful to us.

21 And I'm also very grateful to have the
22 opportunity to be here with all of you and to hear from

1 caregivers and parents and advocates, and self-
2 advocates, about your journeys and your needs and your
3 perspectives. And thank you to the Agency for allowing
4 me to be here today. Thank you.

5 MS. CHALASANI: Thank you, Joan. Next we have
6 Sharon Walter.

7 MS. WALTER: Thank you so much for hosting
8 this fantastic event.

9 DR. EGGERS: Louder, please. Even closer to
10 you.

11 MS. WALTER: Thank you for hosting this
12 fantastic event today. I am the mother of an eight-
13 year-old girl with nonverbal, very low functioning,
14 what I call medical autism. She has a lot of medical
15 issues including seizures, a lot of GI pain
16 undiagnosed, a lot of sleep issues.

17 I also work in industry. I work conducting
18 clinical research for a pharmaceutical company in the
19 setting of oncology. And what strikes me in that role,
20 and it's not related to autism, but it strikes me that
21 we have a number of agents in our pipeline, in our
22 portfolio that I think would be really effective

1 potentially in treating children like my own who
2 actually has been tested and found to have a lot of
3 autoimmune markers and immune dysfunction.

4 And so I don't know if there's anything that
5 you all can do, but I want to put it in your heads to
6 think about ways to potentially encourage my colleagues
7 in pharma to really develop those drugs for children
8 and adults with autism that have the sort of medical
9 forms of, of this disorder. So thank you.

10 MS. CHALASANI: Thank you, Sharon. Next we
11 have Leah.

12 MS. HELVERING: Hi. My name is Leah
13 Helvering. I'm here as a parent of a child who's 20,
14 largely nonverbal. He was one of those regressive kids
15 that developed normally and then lost all his language.
16 I do work in the pharmaceutical industry as well, not
17 in the field of autism and neuropsychiatric diseases at
18 all. But for full disclosure, I don't benefit from
19 anything here today.

20 But I want to thank you for diving in the deep
21 end of the pool with us to imagine that FDA would
22 choose an autism spectrum disorder as 1 of the 24 of

1 the many disease you could have selected. Thank you.
2 This was a huge blessing to me as a parent. Thank you.
3 I'm very grateful that FDA is investing their time and
4 their energy to help develop new drugs.

5 I appreciate very much the complexity of drug
6 development and the absolute necessity for sensitive
7 clinical endpoints to find that are modulatable to
8 treat autism and the core symptoms, or the associated
9 symptoms such as anxiety. So I applaud you for what
10 you're doing and I'm looking forward to how we will see
11 fruition come over time. It will take time.

12 There were just a couple of things that I
13 wanted to respond to that you teed up at the beginning,
14 and one is where in the spectrum do you treat. When do
15 you intervene in the spectrum? And I think that's a
16 difficult -- I found it is difficult just to say my
17 child is low, mid, or high because it depends which
18 core symptom you're talking about.

19 Is he a low in the communication or high in
20 communication? You've seen some examples of brilliant
21 communicators here today that, patients that are here
22 that are able to speak for themselves. My child, very

1 poor communicator. So seeing baseline move for each
2 child is going to be so critical with endpoints.

3 So I think I want, it would be wonderful to
4 see whatever endpoints we come up with that you think
5 of those in terms of change from baseline for that
6 patient. And patient segmentation is going to be
7 absolutely crucial too for some of these endpoints.

8 I already spoke to the fact that anxiety can
9 increase symptoms, the core symptoms, and can impair
10 the ability of other treatments to hit the core
11 symptoms. While you may be high on the communication
12 spectrum, if your anxiety declines, you might not see
13 that change. But for my child it's dramatic. If his
14 anxiety is low, he's able to communicate. So those
15 would be good endpoints as well.

16 Sensory issues would be novel endpoints, but I
17 think you've heard too that there's a lot of different
18 -- hypo, hyper, you brought it up yourself at the
19 beginning of symptomatology. These endpoints would be
20 very valuable to monitor and be novel.

21 MS. CHALASANI: Thank you, Leah. I'm just
22 going to have to ask you to wrap up. I don't know if

1 you have any closing -- oh, okay. Perfect timing.

2 Last we have Stuart. Right up here.

3 MR. SPIELMAN: I'll be brief. Thank you for
4 doing this. This has been very valuable to me as a
5 parent and I'm speaking now from, from that role and
6 I'm, I'm sure that other people in the room would share
7 my sentiment.

8 There are many of us in the room. There are
9 many of us who are participating in this group through
10 the web. And then there are others who are not
11 participating. People like my son. The challenge you
12 have, and I think the challenge all of us have in the
13 autism community, is to be mindful of all these
14 differences and come up with solutions, strategies,
15 product that help, help everyone.

16 And I'm always mindful of the split I have as
17 a professional, someone who works for Autism Speaks,
18 and as a parent. I'm always mindful that when I come
19 home at night, when I take that Metro train home, I'm
20 coming home to a nonverbal young man with an
21 intellectual disability and needs my help in the most
22 basic, basic ways.

1 I respect your, your engagement with, with us
2 on these issues and, you know, and I'm aware that these
3 are enormous challenges. But, but you are responding
4 not just to a medical issue, but you're responding to
5 our lives and for that I thank you very much.

6 MS. CHALASANI: Thank you, Stuart. And so
7 with that, I'd like to call Dr. Mitch Mathis for
8 closing remarks.

9 DR. MATHIS: Thank you. Here's someone's
10 watch. So thank you. This won't, won't take very
11 long. I actually had some prepared remarks and decided
12 that I wouldn't use those today.

13 This is very different than what we usually do
14 in the division of psychiatry products at FDA. It's -
15 can you hear it? It's -- sorry, it's kind of short.
16 It's, it's very personal and -- am I here? Yeah. It's
17 very personal and that's not what we usually do. What
18 we do is very clinical and very, I think, by design not
19 personal, to find, to find the answer scientifically is
20 something safe and is it effective.

21 And I think a big part of what safe and
22 effective is, is, is what matters to people who have

1 the disorder, people who are going to take the
2 medication. And so I learned a few things. I saw
3 Tiffany was taking just scads of notes, but I have, I
4 have a few things here I'd like to just mention.

5 First of all, stimming, stimming, which is,
6 which is what a lot of sponsors would like to measure
7 as an endpoint because it's so obvious and so easy to
8 count, and you can show that it's getting better by
9 decreasing. May not be making things better at all.
10 It might be taking away one of the coping mechanisms
11 that people use to make themselves better. So that's
12 not likely a good part of an endpoint.

13 So, and people with autism are people, so they
14 of course get all kinds of other medical and
15 psychiatric problems like all people do. And then if
16 anxiety or depression is there, that's got to be sorted
17 out and treated as part of making this better.

18 So we'll pay attention to that. We, we knew
19 that, of course, but now, now we'll never forget that.
20 So, so thank you for that.

21 Communication was a big deal just from the
22 surveys, and endpoints that look at communication with

1 regard to autism should be considered. They're
2 obviously a big deal to the community.

3 Problems with sleep in autism look like
4 they're a big deal and big enough that we should look
5 at those together.

6 And I have -- here's one. Irritability was
7 perhaps not the best term for the approval of the few
8 drugs we have to treat symptoms of autism. It sounds
9 bigger than irritability and even in the label we
10 called it irritability, but we said it was destruction
11 of property and, and harming self, etc. It's bigger
12 than irritability and it's almost insulting, I think,
13 to call it irritability. It's, it's bigger than that.
14 So we'll call it what it is next time we get a chance
15 with a medication.

16 I think, and what matters most are the, the
17 social and occupational function of people with autism.
18 That's what got the highest score, at least. People
19 want to be able to be normal. They want to function
20 normally socially and occupationally.

21 And second biggest thing was with
22 relationships, to have normal relationships.

1 So thank you. I won't take any longer, but I
2 do appreciate you being here. I know you have other
3 things to do. Thanks for taking the time to spend with
4 us. It's been a very valuable experience for me and I
5 know for my crew as well. And we'll take what you gave
6 us today and we'll be better regulators because of it.
7 And I think better stewards of the public health and at
8 least for myself, a better physician.

9 So I appreciate it. Thanks very much. And
10 good night.

11 DR. EGGERS: So I'll just follow up. It's
12 Sara over here. Evaluation forms, please fill them
13 out. Leave the clickers on the table and, and safe
14 travels home and around the Beltway.

15 (Meeting concluded at 5:01 p.m.)

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CERTIFICATE OF NOTARY PUBLIC

I, Natalia Thomas, the officer before whom the foregoing proceeding was taken, do hereby certify that the proceedings were recorded by me and thereafter reduced to typewriting under my direction; that said proceedings are a true and accurate record to the best of my knowledge, skills, and ability; that I am neither counsel for, related to, nor employed by any of the parties to the action in which this was taken; and, further, that I am not a relative or employee of any counsel or attorney employed by the parties hereto, nor financially or otherwise interested in the outcome of this action.

Natalia Thomas

Notary Public in and for the

State of Maryland

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I, Penny Knight, do hereby certify that this transcript was prepared from audio to the best of my ability.

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5/13/17

DATE

Penny Knight

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