

FOOD AND DRUG ADMINISTRATION
PATIENT-FOCUSED DRUG DEVELOPMENT
PUBLIC MEETING

Morning Session

Tuesday, September 22, 2015

8:57 a.m.

Food and Drug Administration
White Oak Campus
10903 New Hampshire Avenue
Silver Spring, Maryland 20903
(301) 796-9018

Reported by: Michael Farkas,
Capital Reporting Company

1 A P P E A R A N C E S

2 MEETING ROSTER:

3 SAUJANYA GIAMGONE, Office of Strategic Programs, FDA

4 DR. WILLIAM DUNN, Division of Neurology Products

5 DR. THERESA MULLIN, Office of Strategy Programs

6 DR. DAVE PODSKALNY, Division of Neurology Products

7 DR. ELLIS UNGER, Office of Drug Evaluation 1

8 DR. ERIC BASTINGS, Division of Neurology Products

9 DR. SUSANNE GOLDSTEIN, Medical Reviewer, Neurology Team

10 DR. KENNETH BERGMAN, Neurology Reviewer

11 DR. LEONARD CAPCALA, Medical Officer, Neurology Team

12 DR. PETER COMO, Division of Neurological and
Physical Medicine Devices

13 DR. LEU XU, Central Biologics

14 DR. MEGHANA CHALASANI, Office of Strategic Programs

15 GRAHAM THOMPSON, Office of Strategic Programs

16 PUJITA VAIDYA, Office of Strategic Programs

17 DR. SARA EGGERS, Office of Strategic Programs

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

2 MS. GIAMBONE: All right. Well, let's
3 go ahead and get started. Thank you all for being
4 here. Good morning to everyone. My name is
5 Soujanya Giambone. And I am with the FDA's Office
6 of Strategic Programs. And I, along with my
7 colleague, Sara Eggers, will be facilitating the
8 meeting today. And on behalf of all of my FDA
9 colleagues, I'd like to extend a very warm welcome
10 and a very big thank-you to all of you for being
11 here.

12 So what I'd like to do is go over the
13 agenda and a few housekeeping items, and we'll get
14 started. You should all have a copy of the agenda.
15 If not, we have extra copies out on the
16 registration desk.

17 So we're going to start today with some
18 presentations from my FDA colleagues. They will
19 provide some opening remarks, an overview of the
20 Patient-Focused Drug Development Initiative, and
21 background on Huntington's disease and treatment
22 approaches.

1 And then I'll come back and go over the
2 discussion format. We have two topics today, as
3 you know. Topic 1 is on symptoms and impacts of
4 Huntington's disease. And Topic 2 is on treatment
5 approaches. So for both topics, we'll have a
6 panel discussion followed by a group discussion.

7 So, we'll start with Topic 1. We'll do
8 a panel discussion and a group discussion. We'll
9 take a break, come back, do the same thing for
10 Topic 2, so a panel discussion followed by a group
11 discussion. And that will take us to the last
12 half-hour of the day, which we reserve for Open
13 Public Comment.

14 Open Public Comment is just a time that
15 we reserve for anybody in the audience, not just
16 patients or caregivers, but anybody that wants to
17 share some thoughts or additional comments which
18 are outside the scope of Topic 1 and Topic 2.

19 So if you're interested in speaking in
20 Open Public Comment, you can register for it. The
21 signup sheet is out on the registration table.
22 And we'll take registration through break time.

1 We'll see how many people signed up and how much
2 time each speaker will have.

3 And then we'll wrap up the day at 12:30
4 with closing remarks from FDA.

5 Just a few housekeeping items.
6 Bathrooms are back out in the hallway into the
7 foyer area. And if you make a right and go all
8 the way down the hallway, you'll see the restrooms
9 there. And we also have a kiosk, as you saw
10 outside in the foyer area, that sells sandwiches,
11 snacks, and drinks available for purchase. So you
12 can please feel free to, if you want to go get
13 something or if you need to take a stretch break,
14 or anything you need, please feel comfortable to
15 do so. We want you to be as comfortable as
16 possible.

17 And just one more thought. If you want
18 to preorder your lunch -- we have a pretty full
19 house today. So if you want to preorder your
20 lunch, you can go ahead and do that. Just let
21 them know what you'd like to get, and they'll have
22 it ready by the time it's lunchtime. Okay?

1 All right. So on that note, I'd like to
2 turn it over to Dr. Billy Dunn for opening
3 remarks.

4 DR. DUNN: Thanks a lot. Good morning.
5 Hey, ya'll. Glad you're here. Thank you very
6 much for coming. Welcome to this meeting on
7 Patient-Focused Drug Development for Huntington's
8 Disease. I'm Dr. Billy Dunn. I'm a neurologist.
9 I'm the Director of the Division of Neurology
10 Products here at the FDA. Our division reviews
11 drugs for a wide variety of neurological diseases,
12 including Huntington's disease.

13 We're very happy to see so many of you
14 here today. I recognize that there's many faces
15 in the audience. Many of ya'll are joining via
16 the Web, as well. And I know that here up at the
17 podium, I can't look at each one of you
18 individually, but rest assured that I want to
19 thank you personally, all of you, for coming here.
20 I can't tell you how much we value the opportunity
21 to participate in these meetings, to hear
22 firsthand the experiences of people with the

1 disease, and to incorporate that into our thinking
2 here at the agency.

3 As a testament to that, we have our
4 entire professional team here at the meeting to
5 listen carefully to what we discuss today, our
6 entire team who works on Huntington's disease.
7 These are all professionals in that area. And we
8 really look forward, as I said, to incorporating
9 what we learn today into our daily work.

10 Today's meeting is one in a series of
11 these type of Patient-Focused Drug Development
12 meetings. And I will let you know that Dr.
13 Theresa Mullin will be discussing a little bit
14 more about this initiative in just a few minutes.

15 As you know, Huntington's disease -- I
16 don't need to tell you all this -- is a fatal
17 genetic disorder that causes the progressive
18 degeneration of nerve cells in the brain,
19 resulting in many symptoms, including uncontrolled
20 movements, loss of intellectual faculties, and
21 emotional disturbance.

22 While physicians may prescribe medicines

1 in an attempt to help keep these clinical symptoms
2 under control, there is no current treatment to
3 stop or reverse the course of disease, which of
4 course is what we ultimately want to do. We want
5 to get all the way to a cure and fully prevent
6 this disease, and that's what we're after. We're
7 working assiduously on this with our colleagues in
8 industry and scientific researchers. And I assure
9 you that this is the long- term goal.

10 Dr. Dave Podskalny, our Team Leader for
11 Huntington's disease, will provide a bit more
12 background on Huntington's in just a few minutes.

13 This is a very important meeting, as I
14 said. We fully understand that Huntington's is a
15 serious condition and that there's a vast unmet
16 medical need for patients with this condition. It
17 is our responsibility here at the FDA to ensure
18 that the benefits of a drug outweigh its risks.

19 Therefore, having this kind of dialog is
20 extremely valuable for us. What we hear from you
21 today can help us understand how patients view the
22 benefits and risks of treatments for Huntington's

1 disease and, in so doing, help us with our
2 risk/benefit considerations when we encounter a
3 new drug that may be available for the disease.

4 We want to hear from you today about the
5 different ways your symptoms and your experiences
6 affect your daily life. This is what we want to
7 improve with the treatments that will be available
8 in the future, and we want to understand the best
9 way to intervene in that regard.

10 It's also important to hear what you
11 value in a treatment for Huntington's disease and
12 what you would like to see in future treatments
13 for you. It is also important to remember, as I'm
14 sure you know, that FDA is just one part of the
15 drug development process. We do not develop
16 drugs, and we do not independently conduct
17 clinical trials.

18 Drug companies, often working with
19 scientific researchers or the patient communities,
20 many of you who are here today are the ones who
21 conduct the clinical trials and actually submit
22 the applications for these new drugs to we who

1 work on them at FDA.

2 We work closely with these drug
3 companies throughout the drug development process,
4 from the point in time, scientifically, where
5 they're just discovering new molecules, perhaps
6 only exposed to animals, all the way up until
7 they're ready to submit the application to us for
8 marketing, and all the trials that happen in
9 between.

10 If we do get a drug on the market, we
11 continue to work carefully with them to conduct
12 surveillance on these drugs and ensure that we've
13 accurately described both their risks and benefits
14 as additional scientific information becomes
15 available.

16 I know there are a lot of
17 representatives from industry, academia, and
18 others in the room, and as I said, on the Web.
19 Thank you all sincerely. I personally thank each
20 and every one of you for being here and being a
21 part of this meeting. This meeting will provide
22 valuable input for you as well.

1 Again, welcome. I'd like to now turn it
2 over to Dr. Theresa Mullin, who will talk about
3 our broader efforts in patient-focused drug
4 development.

5 DR. MULLIN: Very good. Thank you,
6 Billy. And good morning, everyone, and thank you
7 so much for being here today. We're really
8 thrilled that you're here. I have to say that, as
9 part of the planning effort on this meeting, I'm
10 also really glad we didn't schedule it for
11 tomorrow or the day after that.

12 (Laughter.)

13 DR. MULLIN: Because I think it would
14 have been a lot harder for all of us to get here.
15 So that's one thing I'm really relieved about.

16 And I want to tell you a little bit more
17 about this overall patient-focused initiative that
18 we have underway. As Billy was saying, one of our
19 most important jobs in the Center for Drugs is to
20 evaluate the benefit versus the risk of a new
21 drug.

22 And in that context, the patient's

1 perspective is, obviously, most critical, because
2 the patient is the one that's going to be
3 benefiting from the drug, any benefit there is to
4 have, and experiencing any of the harms the drug
5 may present. And so, understanding their
6 perspective is especially critical.

7 We took the opportunity in the fifth
8 reauthorization, or the fifth authorization, I
9 should say, of the Prescription Drug User Fee Act,
10 and that's what PDUFA stands for, to have a
11 special initiative to try to focus on getting
12 broader input. Before that, we were really only
13 getting an individual patient representative
14 speaking in the context of a particular drug,
15 which means we had to do a lot of conflict-of-
16 interest screening. And that's a very valuable
17 perspective, but it's one.

18 And we wanted a much broader patient
19 population perspective, and so, to really help us
20 set the context for weighing benefit versus risk
21 in those decisions that we make related to new
22 drugs. This input is not only important at the

1 time of marketing preapproval decision, but really
2 throughout the drug development process.

3 So these patient-focused meetings and
4 this Huntington's disease meeting today is one of
5 the small set that we focused on in PDUFA 5 to try
6 to test out, how could we do better at trying to
7 get more comprehensive input from patients related
8 to the context of the disease and what they were
9 experiencing?

10 So it's one of the 20 that we set up.
11 Actually, we're going to get to 24 by the end of
12 the five-year period. But these meetings are
13 giving us a way to more systematically collect
14 this kind of information.

15 We began this process in September of
16 2012, so about three years ago, announcing a set
17 of diseases that our review division has
18 identified as ones which they thought would really
19 help them or where they really felt the need to
20 get more information about what patients'
21 perspectives would be.

22 We got about 4,500 comments on those

1 that we picked. We came up with a set of 16,
2 based on that input, and going back to the review
3 divisions. And in the last year, we've announced
4 another eight meetings, so that we'll have -- this
5 is our just quick showing you the diseases that
6 we're covering as part of this initiative.

7 In today's, we've got two meetings.
8 This morning we're spending on Huntington's
9 disease; this afternoon, we're going to focus on
10 Parkinson's disease. And there you can see the
11 ones we have for the remainder of the year.

12 These meetings have been extremely
13 helpful to us in terms of understanding better.
14 And each one of them is focused, first of all, on
15 two sets of questions that Soujanya mentioned
16 earlier, one about how it is to live with the
17 disease and another section devoted to what you're
18 doing to treat your disease and how well that's
19 working or not.

20 We also tailor other questions that the
21 review division may be particularly interested in
22 taking advantage of this opportunity to talk to

1 you, hear from you about other aspects of a
2 disease or trials that they may want to take
3 advantage of, this unique opportunity to ask you
4 about. And so, we have those additional questions
5 sometimes.

6 For example, when we had a meeting on
7 HIV/AIDS, we asked about patients' willingness to
8 participate in cure research, to get a better
9 understanding of that and how the risk-versus-
10 benefit tradeoffs, potential benefit tradeoffs for
11 the patients.

12 And active involvement of the patients
13 in your -- what you have to tell us today is just
14 what this is all about, and that's the value of
15 this meeting for us. And it's been tremendously
16 valuable. We try to capture in very detailed
17 notes, and using a transcript, just what you tell
18 us today in the words that you tell us so that we
19 can reflect that in a voice-of-the-patient report.
20 Takes us awhile to put that report together
21 because we collect information from our docket as
22 well, from the electronic docket. And we leave

1 that open for a little while longer.

2 Those reports are very useful for later
3 reference by the review divisions. What we've
4 learned in these meetings have also given us a
5 basis for building on, where do we go next with
6 this? How can we further build on what we hear in
7 these meetings to develop maybe more systematic
8 ways to collect information about the impact of
9 the disease and the impact of treatment in
10 clinical trials and in other ways?

11 So we think this program, which has been
12 exploratory in the last couple of years, is really
13 giving us ideas for a longer-term approach here.
14 So, thank you again so much for being here today.
15 And with that, I'm going to turn it over to Dr.
16 Podskalny.

17 DR. PODSKALNY: Again, thank you for
18 everyone who came and attended this conference
19 today in person and online.

20 I'm going to present some medical facts
21 about Huntington's disease. But I don't want
22 people to think that we've lost sight of the fact

1 that Huntington's affects people, families, and
2 over multiple generations, and that every day we
3 carry our experiences from clinic and caring for
4 Huntington's patients to work with us. And we
5 empathize with everyone who struggles to
6 understand and cope with Huntington's disease
7 every day.

8 Okay, the standard FDA disclaimer. But,
9 okay, here we go.

10 Huntington's disease is an uncommon
11 disease. And the number of people it affects
12 varies by geography, from country to country. But
13 somewhere between 2 and about 20 per 100,000.
14 It's an autosomal dominant disease, which means
15 that if one parent carries the gene, each child
16 has about a 50 percent chance of inheriting the
17 gene and the disease, in most cases.

18 DNA testing is available. And if you
19 have what's called an expansion on your fourth
20 chromosome, and it meets a certain threshold of 36
21 or more CAG repeats, you're likely to have
22 symptomatic Huntington's disease.

1 The typical onset of symptoms are
2 between age 30 and 50. When we talk about
3 Huntington's disease, we've somewhat arbitrarily
4 defined juvenile-onset Huntington's disease as
5 beginning below the age of 20, and late-onset
6 Huntington's disease beginning at age 60 or older.
7 Although chorea, the movement disorder, is the
8 most recognized feature of the disease, cognitive
9 impairment, problems with thinking, reasoning,
10 memory probably are the first symptoms of
11 Huntington's disease and probably the most common.

12 Behavioral changes can reflect other
13 changes that occur in Huntington's disease, those
14 in memory, things like decline in judgment, being
15 inflexible, and decreased awareness of self-care
16 needs. Psychiatric symptoms often involve
17 depression, anxiety, irritability, and apathy.
18 Obsessive-compulsive symptoms are present, but
19 generally are less common.

20 Swallowing difficulties can be a big
21 issue as the disease advances, and weight loss --
22 weight loss that's not just explained by the

1 movement or increased activity or decreased
2 appetite or food intake.

3 Current treatments for Huntington's
4 disease really attempt to reduce the symptoms.
5 Motor symptoms such as chorea, we have treatments
6 such as tetrabenazine. Many of you may know of
7 Xenazine. Neuroleptic drugs are used outside of
8 their intended indication, and these are
9 antipsychotic drugs, to help suppress chorea.

10 Antidepressants are frequently used,
11 nutritional support; speech therapy to modify diet
12 and to assess swallowing; occupational and
13 physical therapy to maximize physical function;
14 and psychological counseling.

15 There are family and caregiver support
16 organizations, but also professional services that
17 are available; genetic counseling. Most of you
18 who have received a diagnosis or who have
19 Huntington's disease in your family have probably
20 spoken to a genetic counselor. Many of you may
21 have sought psychological counseling. The
22 benefits and support of advocacy groups and

1 support groups, respite care and family support,
2 and good communication.

3 And that's all I have for you today.

4 Thank you very much.

5 MS. GIAMBONE: All right. Well, thank
6 you to my FDA colleagues for your presentations.

7 And I forgot to do one thing earlier
8 when we started, which is I wanted to make sure we
9 introduced ourselves. So, could my FDA colleagues
10 please introduce yourselves? I know you've
11 already met some of them.

12 DR. UNGER: Good morning, everyone. My
13 name is Ellis Unger. I'm the Director of what we
14 call Office of Drug Evaluation 1. Our office
15 oversees the Division of Neurology Products.

16 DR. DUNN: As I mentioned earlier, I'm
17 Dr. Billy Dunn. I'm the Director of the Division
18 of Neurology Products.

19 DR. BASTINGS: Good morning. I'm Eric
20 Bastings. I'm the Deputy Director of the Division
21 of Neurology Products.

22 DR. PODSKALNY: I'm Dave Podskalny. I'm

1 the Clinical Team Leader, Division of Neurology
2 Products.

3 DR. GOLDSTEIN: I'm Susanne Goldstein,
4 Medical Reviewer on the Neurology Team.

5 DR. BERGMAN: I'm Ken Bergman, Neurology
6 Reviewer.

7 DR. KAPCALA: I'm Len Kapcala. I'm
8 Medical Officer on the Neurology Team.

9 DR. MULLIN: Good morning again. I'm
10 Theresa Mullin. I direct the Office of Strategy
11 Programs in the Center for Drugs.

12 DR. COMO: Good morning, and welcome.
13 Peter Como. I'm a medical reviewer in the Center
14 for Devices and Radiologic Health in the Division
15 of Neurological and Physical Medicine Devices. We
16 review all of the neurological devices for the
17 treatment of neurological disorders.

18 DR. XU: Good morning. I'm Leu Xu. I'm
19 the Medical Officer with Central Biologics and at
20 the Office of Cell and Gene Tissue Therapy. I'm a
21 neurologist-in-training.

22 MS. GIAMBONE: Thank you so much. And

1 we have a few colleagues here.

2 DR. CHALASANI: I'm Meghana Chalasani.

3 I'm also with the Office of Strategic Programs.

4 MR. THOMPSON: Graham Thompson, same
5 office.

6 MS. VAIDYA: Pujita Vaidya, Office of
7 Strategic Programs.

8 DR. EGGERS: I'm Sara Eggers, in the
9 Office of Strategic Programs. And I'll be helping
10 with the facilitation.

11 MS. GIAMBONE: Great. Thank you.

12 So let's go ahead and give you an
13 overview of the discussion format today. Okay.
14 So as I mentioned earlier, we have two topic
15 questions that we're going to be reviewing. Topic
16 1 is on the symptoms that matter most to you. So
17 here, what we're listening for is, what are your
18 most significant symptoms? And how do they impact
19 your daily life? What are you able to do or not
20 able to do as fully as you would like, because of
21 your symptoms?

22 And also, talk to us about how your

1 symptoms have changed, how they have affected your
2 social interactions and your mood, and really how
3 you experience your symptoms on a day-to-day --
4 you know, during your day-to-day life.

5 So I know we have a lot of caregivers
6 today. We have a lot of patients here today. So
7 we're really excited about hearing all of your
8 perspectives.

9 Topic 2 is on current approaches to
10 treating Huntington's disease. And in this topic,
11 what we're listening for is, what is your
12 treatment regimen? What are you doing to treat
13 your Huntington's disease, both prescription
14 therapies and non-drug therapies? How well are
15 these treatments treating your significant
16 symptoms? And how do you know that it's working
17 for you or not working for you? What are the
18 biggest downsides to your treatments? And
19 finally, what do you look for in an ideal
20 treatment?

21 So we're going to start each discussion
22 topic, hearing from our panel of patients. So in

1 just a short while, we'll hear from Panel 1. And
2 the purpose of the panel statements are to really
3 set a good foundation for our greater discussion
4 today. So each panelist will have about five
5 minutes to speak.

6 And I've had the honor and the pleasure
7 of speaking to all of our panelists over the last
8 week. And you're extraordinary, and we really
9 appreciate that you've put these thoughts down and
10 you're going to be sharing them with us.

11 So, our panel reflects a range of
12 experiences with Huntington's disease. And as I
13 mentioned, we have caregivers and patients here to
14 share experiences today.

15 And then we'll broaden the dialog to
16 include other patients and caregivers in the
17 audience. So the purpose of this is to hear from
18 more patients and caregivers in the audience, to
19 build on what you've heard from the panel. So,
20 we'll ask some questions along the way.

21 And if you're comfortable to do so, you
22 can raise your hand. We'll have some microphone

1 runners here. Or you can just let us know that
2 you're interested in sharing a comment. And we'll
3 have a microphone runner come to you so we can
4 hear from you also in the audience. And if you
5 can, please state your name before answering.

6 Throughout the meeting, we'll have some
7 polling questions. And the polling questions are
8 not a scientific survey. They are meant to just
9 aid the discussion. And it's completely
10 voluntary. My colleagues will be passing out the
11 clickers in just a little bit, and we'll test it
12 out in just a short while to get you comfortable
13 with how these work.

14 And we also, for those of you joining us
15 on the Web, you can answer these questions through
16 the Webcast. For the polling questions, we ask
17 that only patients and caregivers please respond,
18 please. And I just mentioned our Webcast
19 participants. For those of you on the Web, we
20 can't see you, but you are a very big part of our
21 meeting today. Thank you for joining us. We are
22 going to be turning to you throughout the meeting

1 to hear what you have to say.

2 We will also take some phone calls also
3 later in the meeting. So, please continue to
4 provide your thoughts through the Webcast. And
5 although we can't read through all of them or
6 summarize them all today, just know that all of
7 your comments will be incorporated into our
8 summary report that Theresa mentioned earlier.
9 And as I mentioned, we'll occasionally go to the
10 phones also.

11 The other way that you can contribute to
12 this meeting, and that we strongly encourage you
13 to contribute to this meeting, is to submit your
14 comments through the public docket. The public
15 docket will be opened for two months after the
16 meeting. So it will be open until November 22nd.
17 And it's really a way for you to continue the
18 dialog and continue sending in your thoughts and
19 comments. So please be sure to do that.

20 All of the comments that you submit to
21 the docket will be summarized and incorporated
22 into our summary report. And anybody is welcome

1 to comment, not just patients and caregivers and
2 patient representatives.

3 Also, I want to share some resources
4 that we have here at the FDA that you may have
5 already interacted with. The FDA Office of Health
6 and Constituent Affairs, and their contact
7 information is here and also on the slide deck
8 that is posted online. And the CDER, Office of
9 Center Director, has a group within it, the
10 Professional Affairs and Stakeholder Engagement
11 Group, also known as PASE, which I know some of
12 you have worked very closely with as we planned
13 for this meeting.

14 So I want to go over a few ground rules
15 for the day. And I know our panelists have heard
16 me say these a few times, so I'm so sorry to
17 repeat them again. But really, this is your day.
18 Today is the day for the patients and caregivers
19 to share your thoughts with us. So we encourage
20 you to contribute to the dialog. Also looking to
21 hear from patient representatives. But FDA is
22 here to listen, as is industry and academia and

1 other government agencies.

2 So we know that this meeting will be
3 very valuable to those of you that are here that
4 are not patients or caregivers. But we ask that
5 you stay in listening mode.

6 The discussion will stay on symptoms and
7 treatments. So again, we're going to do our best
8 to stay on topic and stay on time. Any other
9 thoughts that you want to share outside of the
10 scope of these topics should be reserved for open
11 public comment or the public docket.

12 The views expressed today are personal
13 opinions. And on that note, respect for one
14 another is paramount. And finally, at the end of
15 the day, we'll be passing out some evaluation
16 forms. So please let us know how the meeting went
17 for you today. Let us know what worked or didn't
18 work, and we read those very carefully so we can
19 improve upon these meetings.

20 Okay. And before we move on to the
21 polling question, I do want to say that this
22 meeting is being recorded and transcribed. And in

1 about a week's time or so, the meeting recording
2 will be available in addition to the transcript.
3 So a short while after the meeting is over.

4 Okay. Perfect. So, let's try out the
5 clickers and do our first polling question. All
6 right. Where do you live? Press A for within
7 Washington, D.C.

8 and metro area; or B, outside of the
9 metro area. And again, those of you on the Web,
10 please also participate.

11 (Pause.)

12 MS. GIAMBONE: Let's see here. Okay.
13 And let's see what the results are, hopefully.
14 Okay. Okay. That's okay. But I know from talking
15 to many of you that a lot of you have traveled to
16 come here. So thank you for doing that. Thank
17 you for all of you that traveled from out of state
18 to come here. But thank you also to all of the
19 locals for being here.

20 Okay. You're doing it. Okay. Oh,
21 well, look at that. Most of you came from outside
22 the metro area. That's amazing. Okay.

1 Next. Have you ever been diagnosed as
2 having Huntington's disease? Press A for yes, or
3 B for no.

4 (Pause.)

5 MS. GIAMBONE: Okay. Eighty percent of
6 you said no; twenty percent of you said yes.

7 Okay. Next. Are you male or female?

8 (Pause.)

9 MS. GIAMBONE: Okay. So we have 20
10 percent male. And it looks like the majority of
11 you that are responding to the questions are
12 female. Okay.

13 Now, there's a lot of choice here.

14 (Laughter.)

15 MS. GIAMBONE: For age, let's do A,
16 younger than 20; B, 21 to 30; C, 31 to 40; D, 41
17 to 50; E, 51 to 60; F, 61 or greater; or G, not
18 applicable.

19 (Pause.)

20 MS. GIAMBONE: I'm not sure why we have
21 a "not applicable" here. That doesn't make any
22 sense, does it?

1 (Laughter.)

2 MS. GIAMBONE: I'm sorry about that. I
3 don't know why that's there. I'm so glad to see
4 that nobody picked that one.

5 (Laughter.)

6 MS. GIAMBONE: Okay. So, it looks like
7 the majority of you that are answering either as
8 yourselves or on behalf of a loved one are in the
9 age group of 61 or greater. And we also have 41
10 to 50, and 31 to 40. So it looks like we have a
11 good mix of different age groups.

12 Okay. What is the length of time since
13 your diagnosis? A, less than five years ago; B,
14 five to ten years ago; C, ten to twenty years ago;
15 D, more than twenty years ago; or E, I'm not sure.

16 (Pause.)

17 MS. GIAMBONE: Yes, please. Yep. So
18 caregivers and patients, please respond to these
19 questions.

20 (Pause.)

21 MS. GIAMBONE: Okay. So it looks like
22 the majority of you responding are either speaking

1 on behalf of a loved one or yourselves, diagnosed
2 five to ten years ago, followed by ten to twenty
3 years ago. And then we also have a few folks that
4 have been sort of newly diagnosed, less than five
5 years ago. And it looks like we also have some
6 more than 20 years ago. Okay.

7 Do you have a family history of
8 Huntington's disease? A, yes; B, no; or C, I'm
9 not sure.

10 (Pause.)

11 MS. GIAMBONE: Okay. So it looks like
12 nearly 75 percent of you responding have a family
13 history of Huntington's disease, followed by 25
14 percent that do not. Okay.

15 All right. And can we get a summary of
16 what we heard on the Web?

17 (Pause.)

18 MR. THOMPSON: Results on the Web are
19 pretty similar to what we had in the room.

20 MS. GIAMBONE: Okay. Great. Thank you.

21 All right. So on that note, we're going
22 to begin with our panel discussion. So we have

1 our Panel 1 table right here. And may I ask that
2 each -- right here, right here. Okay. Thank you.
3 You know, I can't see the name, the card too well.
4 So for some reason, I figured Topic 1 was over
5 here. But thank you for reminding me.

6 So, we have our panels here today. And
7 again, as I mentioned earlier, they've been
8 working so hard over the last week-and-a-half to
9 put their thoughts down and to share them with us.
10 And they have been working -- you know, every day
11 I've been talking with you and getting your
12 feedback. And I know you've worked very hard on
13 this. So, thank you so much. We appreciate it
14 more than you know.

15 So, on that note, let's start with
16 Colleen. Okay? And if you could please introduce
17 yourselves and go ahead and read through your
18 comments.

19 MS. WALSH-BARNES: I'm Colleen Walsh-
20 Barnes.

21 (Pause.)

22 MS. GIAMBONE: Could you start over,

1 Colleen? We couldn't hear the beginning of it.

2 (Laughter.)

3 MS. WALSH-BARNES: Oh, well. And I'm an
4 electrical engineer; that's embarrassing.

5 (Laughter.)

6 MS. WALSH-BARNES: I was caretaker for
7 my husband and my two sons, Miles and Jason.
8 Miles was diagnosed symptomatic at age 27, and
9 Jason was 28. Miles died two years ago. He was
10 39. Jason, 40, is in a nursing home. He has lost
11 all ability to control his body, and he wants to
12 die.

13 Miles and Jay were complete opposites.
14 Even a neurologist was surprised they were
15 brothers. This is significant because HD wreaked
16 the most havoc with their respective strengths.
17 Miles as an introvert, gifted in academics and a
18 good athlete. Jason was outgoing, extraordinarily
19 athletic, and brilliant.

20 Miles's cognitive processing was the
21 most impacted, while until the end his movements
22 consisted of toe and finger twitching, facial

1 tics, and randomly touching his head. The first
2 indication that Miles had HD occurred when he was
3 17. He had easily mastered all his honors math
4 classes until he took calculus. Then he failed
5 miserably. By the time he was diagnosed, he could
6 not subtract. Early on, he could no longer plan
7 an activity, anticipate an outcome, or reason
8 logically.

9 He continued to ride his bicycle 20 or
10 more miles a day, yet he would fail to stop at red
11 lights, maintain a safe distance from cars and
12 people, or ride where it was permitted.

13 As he began the end stage, he would
14 wander. Even with keyed locks inside my doors, he
15 once took my car keys, fell 12 feet out a window,
16 and tried to drive. Because he no longer could
17 process putting his foot on the brake while
18 putting the car in gear, a tragedy was avoided.
19 In the end, he could no longer retrieve words.
20 So, any positive response became "Cool," and any
21 negative response became "Fuck you."

22 Jason's motor control and his ability to

1 interact with others were the most impacted. He
2 lost the ability to walk naturally, early on. His
3 disturbed gait resulted in a clinical DUI from a
4 New Jersey state trooper, even though four
5 breathalyzer tests indicated he had not consumed
6 alcohol. The deterioration of his motor control
7 resulted in being taken to the police departments
8 regularly.

9 Unlike Miles, he was cognizant of his
10 declining abilities, so he surrendered his
11 driver's license very early. His cigarettes would
12 randomly fly out of his hands. When a police
13 officer thought Jay had thrown a lit cigarette at
14 him, he threw him to the ground, stood on him, and
15 threatened to break his legs if he didn't stop
16 moving, which of course he couldn't do.

17 Because he retained the ability to
18 process reality, he became increasingly angry. He
19 was fully aware of how people viewed him and what
20 his future held. Given that people think HD
21 victims do not understand their surroundings, he
22 was harassed and subject to disparaging remarks.

1 This, combined with the loss of impulse control,
2 resulted in many psych ward unit stays.

3 As a result, he could not be around most
4 people. However, until very recently, when he
5 stopped speaking, being able to speak, he was
6 often asked to troubleshoot HVAC systems, which he
7 successfully did.

8 Contributing to his frustration,
9 depression, and anger was not knowing when an
10 ability would be lost. One Memorial Day, Jason
11 could swim fabulously. By Labor Day, he jumped in
12 a pool and could not even tread water.

13 Woven through the incidences that I have
14 shared are obvious examples of psychiatric
15 problems. The psychiatric problems stole their
16 lives. Both lost their wives early because of the
17 inability to contribute to or to understand the
18 relationship. Their behavior became too difficult
19 for their wives. Sadly, Miles's son was kept from
20 him for three years after his marriage ended.

21 Both began having random gay encounters,
22 which their psychiatrist attributed to HD.

1 Jason's lack of impulse control created bad
2 situations, but his psychiatric issues caused
3 violent reactions. He could not be reasoned with.

4 Miles's perseveration kept him locked on
5 one thing for days, like telling me every 15
6 minutes for 30 hours straight that he couldn't
7 have an orgasm. Miles's inability to reason caused
8 him to integrate the outside world into his
9 reality. When hospitalized with a pedophile, he
10 started calling the police to tell them he was a
11 pedophile so he would not hurt another child.

12 Jason reacted to any perceived slight
13 with violence. Most difficult for Jason was the
14 inability to work. He had five years with perfect
15 attendance and rave reviews. But after that,
16 things fell apart. His movements made him a
17 safety hazard, but his impulses resulted in
18 unacceptable behavior, like leaving inappropriate
19 messages on the CEO's voicemail.

20 The disease inhibited them from the very
21 beginning to be themselves or a functioning man.
22 Until the end, in which there are no good days, a

1 good day would be one that didn't include an
2 outburst, or one where they fell three times
3 instead of six, or they were able to eat, or were
4 not committed or arrested.

5 The disease symptoms do not come and go.
6 Abilities will vary on a day-to-day basis. But
7 once a particular ability, like walking, is gone,
8 it never comes back. A bad day would be caused by
9 not eating 5,000 calories a day, stress, or lack
10 of sleep. When the disease became obvious,
11 strangers avoided them on the street. As it
12 progressed, most friends and family stayed away.

13 (Pause.)

14 MS. WALSH-BARNES: Once in a nursing
15 home, they lost all contact with everyone other
16 than me, their sister, and her family. However,
17 to their credit, Jason's AA group continued to
18 stay connected. Thank you.

19 MS. GIAMBONE: Thank you so much,
20 Colleen.

21 We have Marie next.

22 MS. CLAY: Hello. My name is Marie

1 Clay. I'm from Rome, New York. And this is my
2 daughter, Lori.

3 (Pause.)

4 MS. CLAY: On behalf of my daughter
5 Lori, she would want you to know that her dreams
6 at the time of her diagnosis 16 years ago were to
7 be a hands-on devoted mother and to follow her
8 dream as a chemical engineer.

9 As I begin to tell you her story, I want
10 you to imagine an ice cube melting, just like my
11 daughter's precious life. I was Lori's caregiver
12 until a couple of years ago. She decided she
13 wanted the closest thing she could have to a
14 normal life. She moved in with her fiancof 19
15 years and their son. Today she can't even write a
16 grocery list, handle a monetary transaction, or
17 help her son with homework.

18 Lori was a very meticulous person. She
19 took pride in her appearance. But today she needs
20 assistance with brushing her hair, teeth, bathing,
21 dressing, having her food cut up, pouring a cup of
22 coffee, reaching for a plastic glass or a plastic

1 dish in the cupboard, and making decisions --
2 everything that we don't give a second thought to.

3 Education was extremely important to
4 Lori. Lori cannot even focus to read a newspaper
5 today. This devastating diagnosis of inheriting
6 her father's defective gene was only made worse by
7 knowing her son may inherit this deadly gene. He
8 watched his grandfather decline slowly until his
9 death in 2006. My grandson has to live with the
10 knowledge that he may end up like his grandfather
11 and mother.

12 He hasn't had a typical kid's life. No
13 trips to the park with friends, movies, or
14 spending the night with friends; no after-school
15 activities, because he has to be with his mom when
16 his father goes to work. He's hesitant to have
17 friends over because of his mother's condition.

18 I think with him being almost 18 now, he
19 handles things differently. He holds his mother's
20 hand when they go places. How many kids at this
21 age hold their mother's hand? I admire my
22 grandson. I've never seen him cry, ever.

1 Over the years, I have used Lori's birth
2 date, August 6th, as a guide to her progression.
3 Every August 6th, I can't help but look back over
4 the past year and reflect on her progression. Her
5 balance declines more and more. She has fallen
6 several times and needed staples in her head each
7 time. Lori's speech is slurred and getting worse.

8 I know the day will come when I will no
9 longer hear her sweet, delicate voice. At times
10 on the telephone, I need my grandson to interpret
11 what she is saying, and that is frustrating for
12 her and stressful. The constant chorea movement
13 wears her out to the point that it's an effort for
14 her to even speak.

15 I refrain from informing her on family
16 issues. She doesn't need the stress to compound
17 her issues, and she can't do anything about it
18 anyway. We try to keep conversations positive and
19 calm surroundings. Friends have faded away.
20 People are uncomfortable seeing her like this.
21 It's not the friend they remember.

22 There are very few outsiders in Lori's

1 life. There's more and more apathy with Lori, and
2 one day runs into another, it seems, with her.
3 Lori and I have always did mother-daughter
4 activities over the years, and they have dwindled.
5 The biggest activity we've done in the last year
6 was sitting with her to put photos in an album.
7 Lori watched as I put them in the album, trying to
8 at least laugh at the photos.

9 Spontaneity no longer exists. Either we
10 have to plan ahead or days before, depending on
11 the activity. Last-minute activities cause
12 stress. Her poor balance plays an important part
13 in what she can take part in. Crowded venues do
14 not work. She falls into people. People stare
15 and make remarks.

16 Lori has been unable to go out on her
17 own for many years. It isn't safe for her, and
18 it's depressing to lose that independence. Her
19 delay in processing thoughts, verbalizing them
20 with slow speech, is frustrating for her. When we
21 have a conversation with her, we have learned to
22 use short, precise sentences, how to give her time

1 to absorb the information, time to process and
2 verbalize her answer. A conversation that takes
3 you and I 30 seconds takes my daughter several
4 minutes.

5 Remember that ice cube? It's halfway
6 gone from melting. So is my daughter. Lori also
7 suffers from dystonia, which between the muscle
8 spasms that can last for days, poor balance makes
9 for a very rough, uncomfortable day and night for
10 her. Lori is never home alone. It's too risky.

11 The HD symptoms get her frustrated, so
12 that makes for a very bad day. When she can't
13 explain something to someone or accomplish the
14 simplest of tasks, it's another frustrating day
15 for her. Watching her favorite baseball team, the
16 Baltimore Orioles, keeps her spirits up.

17 My daughter is fortunate to have a
18 loving fiancof 19 years and their son, who is 17.
19 Lori's son has grown up to be a caregiver. She is
20 totally reliant on them. And she's reliant on
21 God. She has great faith. And so many with HD do
22 not have that support.

1 My daughter deserves the treatment and
2 medication to give her a better quality of life.
3 Lori doesn't have the option of chemo or insulin.
4 As of today, she can't even hope to make the claim
5 that she's a survivor. My daughter is that
6 melting ice cube. Thank you very much.

7 MS. GIAMBONE: Thank you so much, Marie.
8 Julie.

9 MS. ROSLING: My name's Julie Rosling.
10 I'm from Orange, California. And we did not have
11 any knowledge of previous generations having had
12 Huntington's. And so, when this all of a sudden
13 came forth, none of us knew what it was all about.

14 And I went till 2009 when I was very
15 symptomatic at that point, and I started falling
16 down in the pharmacy where I worked. And somebody
17 looked at me then and diagnosed me as having
18 Huntington's. I was told that I was certainly
19 disabled and could not work any longer as a
20 pharmacist. And it really upset me.

21 Now, I see I'm 73 years old, and I have
22 all the symptoms that are out there, yet have

1 nothing to do with chorea. This has been the
2 biggest thing is that there are so many different
3 types of symptoms that are out there that are not
4 currently being addressed. And I think this is
5 where you guys are going to help us immensely, by
6 getting the right stuff next time.

7 Now, the symptoms that I have, because I
8 don't have chorea, I still have a lot of imbalance
9 and uncoordination. I fall all the time. I can't
10 go up or down stairs. And most of the times that
11 I can, I'm hanging onto the handrails that are at
12 my house to keep from falling. I can't drive
13 anymore. I spend about 90 percent of my time
14 during the day just sitting so I can do anything
15 at all.

16 My fear of choking now has gone up
17 considerably. And I have to have water with me,
18 always water, or I'd choke, I'm sure. My mouth is
19 dry. My dental health has suffered. I often bite
20 inside of my mouth. I have little lesions where
21 I've bit them.

22 The thing that's the most important

1 thing to me is that my symptoms are affecting
2 every system in my body. We're no longer talking
3 just about CMS or brain disease or anything like
4 that. It's talking about systemic things now,
5 with GI, and GU, urgency, frequency, insomnia,
6 where we can't sleep at night due to the leg and
7 arm movements and the restlessness that go with
8 that.

9 Some of my behavior things were piano
10 lessons, oil painting, and playing with my cat,
11 Portia. Now I can't play Chopin on the piano
12 anymore. I can't walk to the corner and back.
13 And my long list of very, very favorite activities
14 is like gone, this due to this devastating
15 disease.

16 I don't have best days anymore. It's
17 really hard to say that, but it is true. I don't
18 have best days anymore. On the worst days, I have
19 days where I don't get to bed on time, wake up
20 during the night and can't go back to sleep.
21 Falling on the bed or tripping in the dark. You
22 spill food while you're sitting at the table, or

1 your plastic drink cup, I have to have a special
2 lid on it so I don't spill stuff.

3 My hearing is going, and I don't
4 remember who else has said that, but it does make
5 conversations difficult. And people do
6 misunderstand me. This -- there's nothing I can
7 do. Nothing I can do or hope for in terms of
8 medication, balance issues, or losing more memory
9 than I have already.

10 My condition and symptoms have changed
11 over time. Starting asymptotically, like I did,
12 and not having chorea, but ending up with systemic
13 issues instead, this is where we have to have some
14 new definition of the symptoms that are being --
15 that are evolving out of this disease.

16 There are no days that my symptoms stop.
17 It's been an ongoing situation. My symptoms have
18 never gotten better; they're getting worse every
19 single day.

20 Huntington's has affected my social
21 interactions because the issue seems to be due to
22 slurring of words and because I also can't hear

1 very well, too. And so, there's misunderstanding
2 all the time we're going along, when your thinking
3 no longer corresponds with my speech. As a
4 pharmacist, this is very, very distressful, to
5 know that this has been taken away from me by
6 something which I didn't know was there.

7 I am a living example of what this
8 disease is all about. No one wants to be reminded
9 of their own mortality by seeing me. Huntington's
10 has significantly affected my mood. It's
11 variable. My depression is worse, knowing that I
12 will never get better.

13 Somewhere along the line, my gene-
14 positive Huntington's situation changed my
15 demeanor and behavior. I start losing control of
16 the situations and talking loudly. Now I lose
17 patience with people who say that they're going to
18 do something for me and don't. I also get angry
19 with people that don't tell the truth, and I
20 become stubborn if I feel I'm correct about
21 something and somebody else is wrong.

22 I don't know what to say, other than all

1 of these outside stresses cause me to be more
2 depressed, distressful, upset. Why is it our
3 fault when it's the genes have made us do this?
4 Thank you.

5 MS. GIAMBONE: Thank you, Julie.

6 Next, we have Denise.

7 MS. HUDGELL: Good morning. My name is
8 Denise Hudgell. And I'm from Council Bluffs,
9 Iowa. I'd like to thank you for this opportunity
10 to share a story. A little bit about myself.
11 I've been an RN for 18 years, and most of my
12 career spent in psychiatric nursing and home
13 health. But most importantly, I'm the mother of
14 three children.

15 My son, Aden, just celebrated his 10th
16 birthday this past Saturday. He's your typical
17 10- year-old boy that loves Hot Wheels, classic
18 cars, big machinery, animals, and he loves to sing
19 everywhere to every song that he knows. I was
20 looking at pictures from his birthday party last
21 year and this year. And there are so many
22 changes. He's skinnier. He's pale. He has dark

1 circles under his eyes, and he's tired, often the
2 ravages of the awful juvenile Huntington's
3 disease.

4 Aden has been symptomatic since the age
5 of four. He started with behavior issues,
6 anxiety, walking on his toes, stiffness in his
7 arms, and changes in his handwriting, which he had
8 just begun to be able to do. After two years of
9 trying to get him seen by a doctor and countless
10 pieces of information to support the need for an
11 HD test, at the age of six, we got the devastating
12 news that Aden had a CAG repeat of 102 -- 102, a
13 number that I will remember forever, a number that
14 changed our lives.

15 There are things that Aden loves to do,
16 but can't anymore due to his symptoms, such as
17 ride his bicycle, play on a soccer league, play on
18 the playground with his classmates, slide down the
19 slide, and just ride in a car. A few-minute car
20 ride is challenging for us due to his neuropathy.
21 It causes so much pain and the pins-and-needles
22 feeling that he gets all over his body.

1 In fact, Aden expends much of his energy
2 throughout the day standing for everything he
3 does. He stands to watch TV, to eat, in the
4 classroom. And if he's not standing, he's pacing
5 the floor. His neuropathy is partially kept at
6 bay if he stands or walks.

7 Because of all the energy he uses during
8 the day, he becomes easily fatigued and has a
9 shortened day of school. He's very isolative at
10 times and doesn't like to leave the house if he
11 doesn't have to, since the car rides are too
12 difficult for him. His 44-year-old dad is in a
13 nursing home in end-stage HD. And the nursing
14 home is over an hour away. So Aden has not been
15 able to see his dad in six months due to the car
16 ride.

17 I've spoken with many other JHD
18 families, and their children have the same issue
19 with the neuropathy and the painful car rides.

20 Aden has OCD, gets frustrated easily,
21 agitated, irritability, anxiety. He perseverates
22 and tells me every day, "Mommy, I hate JHD," and

1 becomes very tearful -- very difficult as his mom
2 to hear because it makes me feel helpless.

3 You would think after all the energy he
4 uses during the day, he would be tired and would
5 crash at night into a deep sleep, but that's not
6 the case. When it's time for Aden to lay down,
7 that is when his neuropathy is at its worse. He
8 violently thrashes around on the floor, trying to
9 itch while he is trying to go to sleep.

10 He hasn't slept in a bed in over two
11 years because the bed is too soft. He said the
12 hard surface for the itching makes it better, but
13 the itching is still horrible.

14 On average, we get about three to four
15 hours of sleep at night, but there are many nights
16 we don't sleep any, and we've been up for 36 hours
17 at a time before he crashes to get some sleep.
18 Last week, we slept a total of 25 hours.

19 Once Aden falls asleep, he continues to
20 toss and turn all night, wakes up several times,
21 and gets up at his usual time in the morning. So
22 he's tired all day. After several different

1 doctors and meds, including diphenhydramine,
2 antiepileptics, melatonin, Neurontin, and
3 trazodone, none of them have worked.

4 And when we don't get sleep, I still go
5 to work the next day and Aden still has to go to
6 school. We don't receive any respite care because
7 he's been on a Medicaid waiver waiting list for
8 two-and-a-half years and we still remain number
9 605 on that waiting list, probably making it
10 another two years until we come off the list.

11 Aden has been having an increase in
12 issues with balance and gait. He falls all the
13 time. His elbows take the brunt of the injury due
14 to his dystonia and the way he holds his arms.
15 He's had to go to the ER on a few occasions to get
16 staples in his head. His right knee and ankle are
17 collapsing. His knees rub together when he walks.
18 So he has the beginning of friction ulcers. He
19 also has the beginning of a pressure ulcer on the
20 top of his foot where his opposite heel rests at
21 night.

22 His back now has some scoliosis,

1 secondary to his dystonia in a few areas, and his
2 ribs are pulling away from his sternum, so he has
3 a rather large indentation in his chest.

4 When I return home, Aden will be
5 scheduled to have a peg tube placed to assist in
6 receiving the nutrients that he is lacking due to
7 the increase in his chewing and swallowing
8 difficulties. He recently was diagnosed with a
9 dilated esophagus, and I've had to do the Heimlich
10 maneuver on him on three separate occasions. The
11 fear that I saw in my son's face was unbearable.

12 All of these symptoms, as well as
13 seizures and countless others, have been
14 progressing quickly over the last two years,
15 especially the last eight months. It is scary to
16 see the changes in your child, and you can see the
17 worry and fear on Aden's face when he talks about
18 JHD.

19 But I'm not only here for our family.
20 I'm here for all the other families that have
21 children fighting this wretched disease. I'm here
22 for McKenna, Aden's half-sister, who is

1 wheelchair-bound and fighting seizure activity all
2 day, every day. For Jacey, who has given a voice
3 to these kids for the past several years, and her
4 sister Erica; for Meg, who has been in the
5 hospital for eight weeks because her sleep and
6 itching problems. And now her mom is fighting to
7 get the help she needs to care for her when she is
8 sent home.

9 For Cameron, Ethan, Gabe, Luke, Corey,
10 Sara, Chris, and too many others to name -- our
11 children deserve to have a long, happy, pain-free
12 life. They deserve to make a lifetime of
13 memories. They deserve to go to prom, learn to
14 drive, graduate, go to college, get married, and
15 have children. They deserve to live.

16 Please help me save my son and all the
17 other children with JHD.

18 MS. GIAMBONE: Thank you so much,
19 Denise.

20 We have Katie next.

21 MS. JACKSON: My name is Katie Jackson,
22 and my husband was diagnosed with Huntington's

1 disease when he was 27 years old. I don't know
2 what has been more terrifying for me, watching
3 Huntington's disease take everything away from my
4 husband or knowing that our three children have a
5 50 percent chance of inheriting their father's
6 same fate.

7 I speak for many families, including my
8 own, when I say we fear the most depression,
9 anxiety, irritability, aggression, all of the
10 psychiatric symptoms, all of which wreak havoc on
11 our loved ones and our family members. There's
12 also apathy, loss of judgment, loss of memory.
13 The significant symptoms associated with
14 Huntington's disease, the list is long and
15 devastating.

16 Before Huntington's disease entered our
17 life, my husband was an outgoing, amazing husband,
18 a very active, loving father, and a sheriff's
19 deputy. I'll never forget the day the department
20 placed a badge on my husband's chest. He was so
21 proud to live a life of service protecting the
22 innocent.

1 Mike has always been the fun guy. We
2 had parties at our house almost every weekend.
3 Mike loved being around people, and people loved
4 being around Mike. Fast-forward to today. My
5 husband is 35 years old. My husband most days
6 barely gets off the couch. He suffers from chorea.
7 He has trouble with his gait. His speech is so
8 slurred, oftentimes you can't even understand him.
9 He chokes every time he drinks water. He has to
10 eat very slowly so he doesn't choke on his food.

11 We get stared at every time we go in
12 public. People constantly make comments at my
13 husband about how he shouldn't be drunk out in
14 public with our children. My husband hasn't had a
15 drink of alcohol in over five years.

16 One time, we took our kids on vacation.
17 We picked up our kids from the camp at the resort.
18 A security guard walked up to us in front of our
19 children and a ton of people and told my husband
20 he had had enough for one night and he needs to
21 get back to his room. It was so embarrassing for
22 my children and my husband.

1 The stares and comments and judgments
2 constantly given to us by the public is something
3 me, my children, and my husband have had to get
4 used to. As you can see, the social impact on our
5 family is great.

6 A couple of weeks ago, my husband
7 decided he would go to my daughter's soccer game.
8 Right away, my daughter scored a goal. My husband
9 was so excited, his movements intensified. I
10 looked over at the opposing side of the field to
11 see one parent mimicking my husband's movements.
12 Another parent was pointing and glaring at my
13 husband. This happened right in front of my 12-
14 year-old daughter. Talk about an exciting moment
15 taken away from a child due to ignorance and lack
16 of compassion.

17 These are just a couple of stories of
18 the hundreds that I could tell you, but I only
19 have five minutes. So let me get back to the
20 significant symptoms of Huntington's disease in my
21 mind.

22 The most significant symptoms of

1 Huntington's disease are the ones you cannot see.
2 These are also the ones that are often overlooked
3 because you physically can't see them. But
4 Huntington's disease families, we experience and
5 feel these symptoms every single day.

6 I am talking about the psychiatric
7 symptoms associated with Huntington's disease. To
8 see my husband, once so social, happy, full of
9 life, sitting on a chair staring at a TV all day
10 long is heartbreaking. To see my husband battle
11 with depression and severe anxiety is so hard on
12 our whole family. My husband, once a fun guy, now
13 often refuses to ever leave the house because it
14 sends him into a panic, the thought of it.

15 The anger and irritability and behaviors
16 is so hard on our children and our family as a
17 whole. We desperately need help with the
18 psychiatric and cognitive symptoms associated with
19 Huntington's disease. Fortunately, in my case,
20 these features have never been so bad that I fear
21 for mine or my children's safety, but I know many
22 families who live in fear daily.

1 My husband asked me before I came here,
2 "Why is there still nothing they can do for us?"
3 I told him, "The science we've been hearing about
4 has to, you know, prove safety so it doesn't hurt
5 you." He looked at me and said, "Katie, I am
6 dying, and there's nothing anyone can do for me.
7 I'm not going to be around to walk our daughters
8 down the aisle when they get married, and I'm
9 going to be lucky if I get to go to one of their
10 high school graduations.

11 "The worst part, Katie, is the kids may
12 have to go through this, too." As he told me
13 this, his eyes filled up with tears. Whenever we
14 talk about the children, he gets very upset. He
15 said, "I wish I could try all these new therapies.
16 I want to fight for my children."

17 My husband has participated in five
18 clinical trials and studies. I know he isn't only
19 participating for himself; he is participating for
20 our children.

21 Our loved ones are suffering so bad and
22 losing every bit of their quality of life. Time

1 is something we simply don't have. The suffering
2 is great, and the Huntington's disease genetic
3 fate haunts us generation after generation. I
4 cannot protect my children from the genetic fate
5 of Huntington's disease, but what I can do is
6 fight for them. I'm a mother fighting for her
7 children. And I'm sitting here in a desperate
8 plea for you all to help us.

9 I was there when my babies took their
10 first breath into this world, and I'm going to
11 fight to not be there when they take their last
12 because of Huntington's disease.

13 MS. GIAMBONE: Thank you so much, Katie.

14 So, what I'd like to do is give our
15 panel a surround of applause.

16 (Applause.)

17 MS. GIAMBONE: I think you're all so
18 courageous. And this goes to our Topic 2,
19 panelists 2, you'll be speaking in just a short
20 while. But you are incredibly courageous for
21 coming here today and sharing these thoughts with
22 us. So, thank you for doing that.

1 So, what I'd like to do now is to just
2 ask the audience here today and the other patients
3 and caregivers in the audience, what you heard in
4 the panel, does that resonate with you, too? Does
5 that sound like your experiences also? I see a
6 lot of head nods. So it sounds like there's a lot
7 of shared experiences here.

8 What we'd like to do next is another
9 polling question. So if you could get your
10 clickers out. And just a reminder that, you know,
11 we only want patients and caregivers to respond to
12 these questions. And if the patient represented -
13 - if the patient is responding to the question,
14 then the caregiver doesn't have to so we avoid
15 double-counting. However, if the patient -- or if
16 you need to help and do the clicker, please feel
17 free to, for the caregiver, you can go ahead and
18 respond on behalf of the patient.

19 So let's start with our first polling
20 question. Of all the symptoms you have
21 experienced because of Huntington's disease, which
22 do you consider to have the most significant

1 impact on your daily life?

2 And you can choose up to three: A,
3 cognitive impairment, such as difficulty
4 concentrating or difficulty with complex tasks; B,
5 chorea; C, fatigue; D, unsteady gait, difficulty
6 walking; E, depression or anxiety; F, slurred
7 speech; G, weight loss; H, difficulty swallowing;
8 or I, other symptoms not mentioned on this list.

9 (Pause.)

10 MS. GIAMBONE: Okay? Okay. So, it
11 looks like cognitive impairment, nearly two-thirds
12 of you answered that that's the most significant
13 symptom, followed by depression or anxiety.
14 Again, we also have unsteady gait or difficulty
15 walking. We have chorea and other symptoms not
16 mentioned. So we'll be sure to come back and hear
17 about that also.

18 Okay. So, what do we have on the Web?

19 MR. THOMPSON: On the Web, similar
20 numbers. We have 80 percent saying cognitive
21 impairment; 56, depression or anxiety; 43,
22 unsteady gait; 31 percent say difficulty

1 swallowing; and then everything else is 20 percent
2 or less.

3 MS. GIAMBONE: Okay. Great. Okay. So,
4 what I'd like to do now is spend some time on some
5 of these symptoms that you've highlighted and hear
6 from those of you in the audience, and also any
7 panel member that wants to participate also.

8 And can you talk to us a little bit and
9 tell us how you experience the cognitive
10 impairment? Describe that symptom for us. Is
11 there anybody that would like to -- okay.

12 (Pause.)

13 MR. NIERENBERG: Good morning, and
14 thanks for this panel. My name is Roy Neirenberg.
15 I was a software developer in Washington -- in San
16 Francisco. Before that, in the '70s, I was a
17 regulatory lawyer in Washington. So, being at a
18 regulatory agency is kind of fun.

19 I thought I had a perfect job and it
20 would last forever. But when I was diagnosed with
21 Huntington's disease, we talked to a cognitive
22 neuropsych, who said we'd better bring someone

1 else in the family to run the business because I
2 wasn't balancing checkbooks -- I was balancing
3 checks in my business. I was making bad
4 decisions. I hired someone from Yahoo who I
5 thought could take over the company, and I
6 couldn't -- when he didn't -- when he didn't
7 perform, I couldn't fire him.

8 My daughter came into the business. And
9 after awhile, when she wanted to move to smaller
10 quarters, my -- there was no desk for me there.
11 That's how I retired from my software company,
12 which I founded 30 years before.

13 MS. GIAMBONE: Thank you, Roy. Thank
14 you.

15 Yes.

16 MS. JENNINGS: Thank you for meeting
17 with us today. My name is Arlene Jennings. I'm
18 here with Charlie. Next week, we will have been
19 married 21 years. Happy anniversary, Charlie.

20 His main issue is his inability to
21 concentrate. Charlie is one of six siblings.
22 Four have had Huntington's. Two of those have

1 passed away. One took her own life because she
2 couldn't stand the idea that she might have it.
3 And the sixth person has not been tested.

4 Charlie was a land surveyor in his
5 career. And being a land surveyor, you have to be
6 very precise and clear in your thinking and your
7 writing. And Charlie is now not able to balance
8 his checkbook or count change in a timely manner.

9 There are no meds for this part, for
10 these symptoms. But Charlie does take meds for
11 anxiety. And we both are very glad that there are
12 meds for anxiety because that does make life
13 easier for us. Thank you.

14 MS. GIAMBONE: Thank you so much.

15 Is there anybody else that would like to
16 talk about how the cognitive impairment is
17 bothersome and how it's impacting your life?

18 MS. SALDANA: Hi. My name is Frances
19 Saldana. I'm President of HD CARE. It's a support
20 organization under the UCI MIND. And the father
21 of my children had Huntington's. All three of my
22 children inherited juvenile onset. And what I

1 heard from the panelists is everything that my
2 late husband and my three children experienced in
3 so many different ways.

4 Whereas my youngest daughter, who passed
5 away five years ago, was just a sweetheart, she
6 suffered tremendously from the late onset -- or
7 the late stages when she was having seizures so
8 severe that when her jaws clenched, her gums would
9 bleed. Terrible infections. She could not resist
10 any kind of infection at that late stage.

11 My son, however, was -- it was totally
12 different. He's in the late stages of
13 Huntington's right now. He probably has probably
14 a year left, I would say. He's been in a care
15 home for eight years. Very combative, aggressive.
16 You just couldn't stop him. What he wanted to do
17 was what he was going to do. In fact, Dr. LaVonne
18 Goodman actually rescued him in Seattle one time
19 when he just ran away -- ran away to Paris,
20 France, at the age of 16, without me knowing about
21 it.

22 And that's not even the worst part with

1 when they get this kind of behavior. It's when I
2 have heard other stories from other family members
3 where they will actually, you know, burn the house
4 down or kill somebody else in their family.

5 So, as tragic and as horrible as
6 Huntington's is with the symptoms and everything
7 they suffer -- not being able to walk, not being
8 able to swallow -- the psychotic part of it is the
9 most traumatic to the family. This is what causes
10 divorces. And when that happens, the HD person
11 will not be able to be taken care of the way they
12 should be taken care of, because care homes don't
13 take care of them that way.

14 And that's really tragic. That's what
15 happened with my son. When he was still
16 ambulatory, no care home in Orange County would
17 take him, and he wound up in Watts for five years.
18 Fortunately, he cannot walk anymore, so he's back
19 in Orange County, where I can see him every day
20 and have a private caregiver for him in the care
21 home.

22 MS. GIAMBONE: Thank you, Frances.

1 Thank you.

2 And we'll take one -- okay, we'll take
3 two more comments here.

4 MS. SMALL: My name is Nancy Small. I'm
5 from Upper Black Eddy, Pennsylvania. And my
6 relationship to Huntington's disease is as a gene-
7 negative family member, who -- and I'm here really
8 representing my grandfather, my mother, my
9 brother, my niece, and my great-nieces, who all of
10 them except the great nieces have had Huntington's
11 disease or have it.

12 But I think of Huntington's disease as
13 like the epitome of the family disease, because it
14 will be a defining part of my life from birth to,
15 hopefully not until I pass, but potentially till
16 then. And of all the symptoms that I think have
17 had the most significant impact on my life, I
18 think they are the behavioral and psychiatric
19 symptoms, the ones that are less evident and less
20 able to be quantified. And they're the ones that
21 are most misunderstood or certainly have been in
22 my 58 years.

1 My short story is that I had a very
2 unsettling relationship with my mother during my
3 teenage years. I hadn't known my grandfather
4 because he had what was called Montgomery nerves
5 and had been closeted away from everyone,
6 including the family. I received -- my high
7 school received a call a couple of days before my
8 graduation to tell them to get me home. I arrived
9 home to find ambulances and police cars, and my
10 father passed away. He was not Huntington's
11 affected. He had committed suicide.

12 My mother was hospitalized because of
13 smoke inhalation at the time of her husband's
14 death. It was at his funeral that I learned from
15 a family member, my mother's brother, that there
16 was this thing called Montgomery nerves, also
17 known as Huntington's chorea at the time, and that
18 my brother and I were at risk.

19 Years later, after the marker, and then
20 the gene identification, I was tested because at
21 the time I was a single parent with three children
22 at risk. And my brother was beginning to show

1 some signs of the disease. He ultimately was
2 tested.

3 His reaction to being, finding out that
4 he was gene positive was absolute relief. He had
5 held 10 jobs in three years and finally was no
6 longer able to hold any job at all. He was
7 college educated, graduated from the University of
8 Richmond, a very smart man. His wife walked out
9 on him and took all the children. He was left
10 bankrupt, with nothing. She begged his family for
11 money, and they all turned against my brother.

12 So, on and on, everybody's stories are
13 the same and they're all different. But it's all
14 about the impact on the family.

15 MS. GIAMBONE: Thank you.

16 MS. SMALL: And so much of it has to do
17 with the behavioral and the psychiatric symptoms.
18 And I've just listed some of the ones as I's.

19 MS. GIAMBONE: Thank you.

20 MS. SMALL: Irrationality, irritability,
21 impulsivity, lack of initiative, inattentiveness,
22 and ultimately, impact on the family.

1 MS. GIAMBONE: Thank you. Yes. Thank
2 you very much for sharing those with us. Okay.
3 And you touched upon the chorea, and we're going
4 to go onto that in just a second.

5 Let's take one more comment back there.
6 Okay. We'll start. Okay.

7 MS. THOMASON: This is a picture of my
8 son, Randy, as I found him in May of 2013,
9 unconscious and barely breathing. Anger, physical
10 violence, depression, anxiety, apathy,
11 perseveration, compulsive spending, paranoia,
12 delusions, hallucinations, and suicide are the so-
13 called "soft symptoms" of HD, but there's nothing
14 soft about them.

15 These symptoms have ripped my family
16 apart, causing endless heartache and suffering. I
17 lost my husband and two brothers-in-law to HD.
18 But these symptoms took them away from us long
19 before they died. I'm now losing my only child, my
20 greatest love, to the ravages of HD.

21 These symptoms ended my marriage and
22 caused my son to be able to see his daddy only

1 under supervised visitation. They caused my
2 brother-in-law to put a gun in his mouth and shoot
3 and kill himself. These symptoms came close to
4 ending my son's life three years ago and again
5 two-and-a-half years ago.

6 They caused my son to be committed to a
7 state mental hospital for a year, a hospital where
8 he was beaten by a guard and put in isolation, a
9 hospital that said if my son's symptoms were
10 caused by HD, he didn't belong there because HD is
11 a medical illness, not a mental illness, a
12 hospital where the psychiatrist looked at me and
13 said, "Do you know what chorea is?"

14 My son does not have chorea, though.
15 Neither did his father, nor his uncle. People can
16 live with chorea. It doesn't rip families apart
17 or cause people to be placed in psych wards,
18 mental hospitals, and jails. It doesn't cause
19 people to attempt or complete suicide.

20 We need recognition of these soft
21 symptoms and treatments that are approved for them
22 as part of HD. We need a cure. We need clinical

1 trials to be fast- tracked.

2 I know my son is running out of time,
3 and I don't think I can bear to lose him.

4 MS. GIAMBONE: Thank you so much.

5 MS. THOMASON: As it is, I pray every
6 day I never find him again as I did that day two
7 years ago.

8 MS. GIAMBONE: Thank you for sharing
9 those thoughts with us.

10 Let me check in with the Web quickly and
11 see.

12 (Pause.)

13 MR. THOMPSON: I'm mostly hearing a lot
14 of similar points that we're hearing in the room,
15 a lot of focus on cognition issues and behavioral
16 and psych issues, especially ones that cause
17 outbursts and anger problems.

18 MS. GIAMBONE: Okay. Thank you.

19 So, let me ask you this question. Is
20 there a day when there's a -- we've heard from the
21 panel on, there's not really a good day, some of
22 you mentioned. But can you talk a little bit about

1 what it takes to recover from a severe day of one
2 of these symptoms that you've selected? If you
3 can, is there a day where maybe -- is there an
4 average day? Is there a bad day? Is there a
5 trigger that's -- always bad, I'm hearing.

6 Do we have any -- we have some hands
7 raised back there.

8 MS. RUGGIANO: Good morning. My name is
9 Jennifer Ruggiano, and I'm a caregiver. My
10 husband died January 1st this year from
11 Huntington's disease, and I lost my daughter in
12 2012 at the age of 12.

13 There is -- every day is different with
14 Huntington's disease. And any event, no matter
15 whether it's good or bad, will always, always
16 affect an HD patient in a negative way.

17 Sometimes, they get those symptoms -- those tasks
18 or whatever back, but most times they don't. So
19 each day was something different.

20 One day we would have a day where he can
21 walk fine, but his speech was way off. And then
22 there would be another day when it would be the

1 opposite. And then there would be another day
2 when you couldn't even tell anything.

3 But of course, as each event took place
4 in our lives, those tasks and his being just
5 started to deteriorate to a point where he
6 couldn't get anything back.

7 MS. GIAMBONE: Okay. So that's very --
8 okay. So, do others share that experience also,
9 that the symptom changes kind of on a day-to-day
10 basis? One day, you know, it might be one symptom
11 that's severe, and other days a different symptom
12 that's severe? Does that resonate with others?
13 Or are there different experiences?

14 (Pause.)

15 MR. NIERENBERG: This is Roy Nierenberg
16 again. My experience is a little bit different.
17 When I left, when I left work, it was a company
18 that I founded, I found a number of things to do
19 that really buoyed my life and made my life
20 wonderful. I joined a community chorus. We sing
21 like Verde's Requiem and things like that. And
22 it's the point of the week that I look forward to

1 the most.

2 I do di-ung (phonetic) Qigong, like a
3 Tai Chi sort of thing. I ride my bicycle. I
4 meditate. I sleep nine-ten hours a day. I eat.
5 I take care of myself. And I think I'm doing
6 really well, which I know is not the general
7 story. But it's my story.

8 MS. GIAMBONE: Thank you for sharing
9 that.

10 And we have a hand raised back there.

11 MS. HOLDER: So, my name is Lauren
12 Holder. I'm here representing my father, who has
13 Huntington's disease. He's 56 years old. And
14 each day, I totally agree each day is different.
15 You know, some days if he's more agitated because
16 of something, we're going to see more symptoms
17 that day. If he's more relaxed, then you're not
18 going to see nearly as many symptoms, and he
19 actually may look completely normal. My dad does
20 not have chorea.

21 He has a lot of cognitive impairment,
22 memory loss, can't remember a password that he has

1 had that's the same for 20 years. He can't
2 remember how to use the remote control some days.
3 Making bad decisions, word-finding difficulties,
4 and an overall slowing down in what he does.

5 But there are days where he will have a
6 completely clear day. And it's actually okay.
7 Other days, he's -- you know, if he's out of
8 routine, it really just depends on what he's
9 focusing on, and that will determine what symptom
10 is worse or what's better.

11 MS. GIAMBONE: Thank you.

12 Okay. So it sounds like what I'm
13 hearing is reducing stress can help sometimes
14 manage or, you know, take care of one of the
15 symptoms on that day, and it can change on a daily
16 basis. Does that resonate with others? Yeah?
17 Okay. Okay.

18 So, let's take -- let me go on to
19 another -- I'd like to ask if you'd like to share
20 some comments or experiences on some of these
21 other symptoms that you've also selected --
22 unsteady gait or difficulty walking. You've also

1 selected -- let's see here -- chorea.

2 So, would you like to share how you're
3 experiencing that or how your loved one is
4 experiencing that?

5 (Pause.)

6 MS. GIAMBONE: How you or your loved one
7 is experiencing some of these other symptoms that
8 you've selected here. Yes.

9 MS. LoCASTRO: Hello?

10 MS. GIAMBONE: Okay.

11 MS. LoCASTRO: Yes. Thank you again for
12 the opportunity to be here and share this
13 information. My name is Tara LoCastro, and I'm
14 from Rochester, New York. I'm here representing
15 my past mother and my sister, who's 44 years old
16 with Huntington's disease.

17 The other symptom beyond cognitive,
18 which I think is a priority, is the depression or
19 anxiety and the mood aspect of the disease. That
20 has really changed my sister's personality in more
21 recent years. She's had the disease actively for
22 about seven or eight. And there is a

1 transformation of the individual in the
2 personality. And it's important to recognize that
3 is a big change among the daily changes that
4 occur.

5 So, I think mood, depression, and just
6 these transformations of the person are something
7 to pay attention to. And I'd like to also just
8 emphasize the importance of cognitive and
9 psychiatric as the less- apparent to the physical,
10 but extremely important to pay attention to for
11 treatment.

12 MS. GIAMBONE: Thank you.

13 Yes, we have a comment here.

14 MS. CLARK: Hi. I would like to also
15 echo that. My mom passed away last year from HD.
16 And the hardest part for our family was probably
17 the depression and anxiety, because when I was
18 growing up, she was always extremely depressed and
19 trying to kill herself. And we didn't know that
20 she had HD. And she was untested and didn't know
21 what her father had passed away from.

22 But she -- growing up, you know, we were

1 trying to constantly be kind of parents,
2 basically, and take care of her. And it showed in
3 a variety of ways. She tried to take a lot of
4 pills to kill herself. Or she would just lay in
5 bed all day and say, "There's no point in getting
6 up and doing anything." Just stopped doing
7 everything that you need to do on a daily basis,
8 just stop eating, cleaning. Lost her job, all
9 that kind of stuff.

10 And then she became really aggressive
11 towards me and my sister, and she would not -- she
12 would fight us, you know, physically, verbally.
13 It was -- and then no one would believe us,
14 either, because she didn't have, you know, a
15 diagnosis. So no one would believe what was going
16 on, the situation.

17 So, the misunderstanding from medical
18 authorities, and it was -- it was extremely -- so
19 it was extremely hard on the family to try to cope
20 with, basically.

21 And then when we finally did put her in
22 the nursing home, she was screaming at us that she

1 wanted to die in the house and that she hated us
2 for putting her into the nursing home. And that,
3 you know, she would hate us forever.

4 I mean, this kind of stuff is like the
5 hardest to cope with, I think, because you are
6 trying really hard to help, and you want to help
7 this person that's your mother. And she's telling
8 you that she hates you and she wants to die, to
9 your face.

10 MS. GIAMBONE: Thank you so much for
11 sharing that with us.

12 We have some other -- yes.

13 MS. HAMEL: My name is Katrina Hamel.
14 I'm from the Central Coast of California. My
15 grandmother committed suicide because there was no
16 test available for her at the time, and everyone
17 kept saying, you know, it's this or that or, you
18 know, "You have depression," and, you know, trying
19 to medicate her.

20 Then my mother and my two uncles all
21 have HD. My brother has it, and my other brother
22 is symptomatic. And then I have a brother who is

1 12 and in social services somewhere on the East
2 Coast.

3 And cognitive impairment is definitely
4 one of our family's biggest struggle. But to
5 touch on some of the others, my mother would
6 basically try to eat her food, and while choking,
7 she would be having a food fight with herself
8 because of her chorea.

9 And though chorea is not something that
10 is going to, say, ravage families, it is something
11 that is significant in a way that it creates huge
12 embarrassment for the person with the HD when
13 they're trying to eat and they're literally
14 throwing food across the room.

15 And my mother and my brother both suffer
16 from the fatigue, but also the sleeplessness. So
17 my mother would go three days without sleeping.
18 And I'm being literal, three days. She would lay
19 there and toss and turn, but not close her eyes.
20 And then she would sleep for two, three, four days
21 and not eat anything.

22 And then there would be days where I

1 would come home from work, and she would have
2 fecal matter all over herself and her bedroom.
3 And she would not allow me to assist her. She
4 would not get into the shower, because quote-
5 unquote, she was fine. "Everything is fine. It's
6 going to be okay." And she obviously did not --
7 not realize, but just didn't think it was a
8 problem.

9 I had to call department of, you know,
10 elder affairs or whatever it is, like adult
11 protective services on myself, because I had no
12 support. And they weren't even able to do
13 anything. They did nothing for me. I had no
14 help, no support, no family support because the
15 family I did have has either died from
16 Huntington's or is affected by Huntington's.

17 I am gene-negative. But that brings on
18 a whole other -- a whole other lifestyle.

19 MS. GIAMBONE: Thank you for sharing
20 that.

21 And I saw a lot of heads nodding as you
22 were speaking.

1 Yes. Let's hear from --

2 MS. THOMASON: Again, I'm Sharon
3 Thomason, from Tallahassee, Florida. Anxiety is a
4 huge issue for my son. He's 30 years old. He
5 will not leave our house. He's been living with
6 me since he got out of the state mental hospital.

7 His anger and physical violence are
8 controlled by antipsychotics. His depression is
9 controlled by an antidepressant. He also takes a
10 mood stabilizer. His cognitive problems are
11 somewhat controlled by a drug that's approved for
12 Alzheimer's. We haven't found anything that helps
13 with his anxiety.

14 He cannot leave the house. And on days
15 that he has to, for example, to go to a doctor's
16 appointment, he becomes so anxiety-ridden that
17 he'll sleep all day the next day. And he
18 describes it as just feeling "fried."

19 MS. GIAMBONE: Thank you.

20 MS. THOMASON: Fried from his anxiety.

21 MS. GIAMBONE: Thank you very much.

22 And let me check in again with the Web.

1 MR. THOMPSON: So, we did have some
2 people talking about triggers. One person said a
3 bad-day trigger is when you change routine.
4 Routine needs to be maintained. Saying that
5 stress can cause an increase in symptoms,
6 especially behavioral. And one person saying that
7 symptoms can fluctuate, but they are always
8 present and never fade.

9 MS. GIAMBONE: Okay. And I know that we
10 do have some people that are dialing in, and we'll
11 be hearing from them in just a minute. But before
12 we go there, can we just take another one or two
13 comments on other symptoms that you'd like to
14 share that you experience?

15 MS. MANNICK: Hi. I'm Janine Mannick.
16 And I'm here representing Andrew Moss. We had met
17 as teenagers. And at the time, there was no
18 indication that HD was in the family. We had
19 drifted apart and found each other again on
20 Facebook in 2009. And at the time, he told me he
21 had Huntington's.

22 They found out that his dad had

1 Huntington's. He was diagnosed in 2005 at the age
2 of 68. So it was a late onset. They think his
3 grandmother had Huntington's, but in the gray
4 area. She had no real symptoms.

5 MS. GIAMBONE: Can you talk about the
6 most significant symptom?

7 MS. MANNICK: Yeah. As soon as Andrew
8 was diagnosed in 2005, he began with emotional and
9 behavioral symptoms, probably even before 2005.
10 Anxiety plagues him and has since his diagnosis in
11 2005 at the age of 37. He's now 47. Fear of his
12 ultimate fate plagues him. Fear of losing
13 complete control is the worst thing for him.

14 We were talking about changes from day
15 to day; for him, it's hour to hour. Yesterday, he
16 was staring and not responding at all. And he was
17 very, very agitated when I gave him his shower.
18 He lives in a nursing home. I'm allowed to shower
19 him. In any case, he was very agitated. And as
20 soon as I got him back to his bed, he smiled and
21 was fine. And he was fine for about an hour. So
22 it changes hour to hour.

1 And in the two-and-a-half years we've
2 been together, anxiety has been the worst. But he
3 also has paranoia, delusions, hallucinations. He
4 has voices in his head that he talks to. And it's
5 hard to bring him around.

6 MS. GIAMBONE: Thank you. Thank you for
7 sharing that.

8 So it's clear that the psychiatric
9 issues -- depression, anxiety, among all of these
10 symptoms, are significantly impacting.

11 We'll take one more comment, and then we
12 do need to go to the phone. So let's hear from
13 somebody that we haven't heard from.

14 (Pause.)

15 MS. WEXLER: Thank you. I'm Nancy
16 Wexler. And it's my pleasure and delight to be
17 here.

18 (Applause.)

19 MS. WEXLER: My, my. I think what
20 you're hearing from everybody, Huntington's knocks
21 your socks off. It's mood, movement, memory,
22 mentation, all three areas of functioning. It

1 gets you down. And we don't have really good
2 treatments in any of these areas. Occasionally,
3 some psychiatric meds, but then it's hard to get
4 ahold of them and people don't prescribe them.
5 Things for movement.

6 We are all really desperate because, I
7 think, everybody feels that they're sort of out on
8 a limb. And they don't understand it's genetic.
9 And the pressure on your families, I think --
10 well, you know, this gene. I'm looking at me, the
11 poor woman who had to test positive. You know,
12 what does that do to the family? You know, having
13 discovered the gene, we don't have a cure. We did
14 that in 1993, okay?

15 So -- and we'll talk about treatment
16 approaches, and we'll definitely touch upon that
17 in Topic 2. We need a lot more to go, because
18 when we had the gene in 1993, and my mom was sick
19 in 1968, we have a few better medicines than 1968,
20 but not many.

21 MS. GIAMBONE: Thank you so much.

22 So, I know that the time went by

1 quickly. Do we have any clarifying questions from
2 FDA on this topic?

3 DR. DUNN: Yeah, hey, thanks, Soujanya.
4 I'm going to jump in. Yeah, I don't have any
5 clarifying questions. What I want to do is I want
6 to thank each and every one of you for sharing
7 your stories.

8 And I also want to speak to you
9 directly. I want to make sure I reassure you that
10 if I were in your shoes, I'd be very concerned, do
11 the folks at the FDA understand what we
12 experience? Do they understand what's important
13 to us? Do they understand what we need to help
14 the drug developers incorporate into the clinical
15 trials to sort out what benefit will be provided
16 to patients with this disease?

17 I can assure you that I and others on
18 the panel who have cared for patients with
19 Huntington's disease, including pediatric
20 patients, in my experience, as well, understand
21 full well what you're saying. This is reiterating
22 our understanding of what is important.

1 We know that the chorea is a very
2 visible symptom. We understand that the other
3 issues, for a long time, have been more important.
4 This is very consistent with our understanding of
5 the disease, and it's incredibly valuable to hear
6 you reinforce that understanding. I don't want
7 anybody to think that we're not hearing that
8 message, that it's a foreign message to us. It's
9 very valuable to hear it.

10 But it's consistent. And I think -- I
11 hope that is reassuring to you to hear that we are
12 on the same page with you about what you are
13 telling us about the disease.

14 I'm particularly interested, we've been
15 discussing things -- I'm particularly interested
16 in the 26 percent of you, according to this small
17 survey, who said that something up there was not
18 captured by the categories. So as the day goes
19 on, if you have a chance to work it in -- we've
20 been doing a little bit of that already -- that's
21 the area I want to make sure that we understand
22 what things we might not be aware of.

1 So again, I just wanted to say that. I
2 hope that's a useful comment for you to recognize
3 that we share your understanding of the disease.

4 MS. GIAMBONE: Thank you, Billy.

5 Okay. So, let's hear from some of the
6 folks on the phone. I know we have a few people
7 lined up. So, operator, could we take caller
8 number one?

9 THE OPERATOR: Thank you. Our first
10 question comes from Allen.

11 MR. PFEIFFER: Hi. This is Allen
12 Pfeiffer. My daughter, my 34-year-old daughter,
13 has Huntington's disease. One of the symptoms
14 that she has that has not been discussed at all is
15 sleep disorder. She has no circadian rhythms.
16 She can sleep for two days. She can be up for a
17 day.

18 The doctor has told her that there is a
19 circadian rhythm drug for people who are blind.
20 But he didn't know for sure whether or not the
21 insurance company would approve it, because she's
22 not blind.

1 People who approve drugs need to know
2 that gel capsules are easier to swallow than
3 tablets. So format delivery systems are really
4 important.

5 My daughter has stomach problems, has to
6 take a probiotic. People with Huntington's
7 disease have different intestinal flora than other
8 people. If you do research, you will find out
9 that nicotine has a different effect on people
10 with neurodegenerative disease of the brains,
11 their brains, than normal people. So a form of
12 self-medication is actually smoking cigarettes.

13 MS. GIAMBONE: Thank you so much.

14 (Cross-talk.)

15 MR. PFEIFFER: (Inaudible) create
16 problems.

17 MS. GIAMBONE: Thank you very much for
18 sharing that. And there were quite a few head
19 nods. You talked about the sleep issues and
20 stomach problems. Do others also experience the
21 stomach -- okay. So we see a lot of head nods
22 here. Okay.

1 MR. PFEIFFER: Keep in mind that we need
2 to remove medical -- we need to have medical
3 marijuana. Marijuana needs to be removed from
4 controlled drugs and substance lists in order for
5 research to proceed.

6 MS. GIAMBONE: Thank you very much for
7 that.

8 Can we have our next caller talk about -
9 - do you have any other symptoms, for the second
10 caller, that you'd like to talk about that haven't
11 been mentioned here?

12 THE OPERATOR: Our next caller is Ms.
13 Kinser.

14 MS. CANCELMO: Yes, good morning. My
15 name is Kinser Cancelmo. I'm from Springfield,
16 Massachusetts. My daughter is 16. She has
17 juvenile Huntington's disease. She does have a
18 whole slew of issues. One that hasn't been
19 mentioned is extreme bowel and stomach issues that
20 no one can seem to get a handle on.

21 We've tried simethicone. They've given
22 her pain meds. She's currently in the hospital,

1 where she's been for eight weeks, because they
2 can't get a medication regime under control for
3 her. And I can't bring her home because I can't
4 care for her by myself. And there is no place,
5 there is no facility near me that can accommodate
6 her.

7 So she's been stuck in-patient in the
8 adolescent unit for going on eight weeks now --
9 eight weeks today, as a matter of fact.

10 Along with her sleep issues, where once
11 again she won't sleep for nights on end. Her
12 itching is uncontrolled. But her stomach, right
13 up until last night when I left her at about nine
14 o'clock, she was writhing around in pain because
15 of her stomach issues.

16 MS. GIAMBONE: Thank you for sharing
17 that.

18 MS. CANCELMO: Yes. You're welcome.
19 Thank you.

20 MS. GIAMBONE: So, stomach issues, sleep
21 issues, and itching, which I know, Denise, you had
22 also mentioned regarding Aden. Yes.

1 Okay. Let's take one more caller.

2 THE OPERATOR: Our next caller is Judy.

3 MS. ROBERTSON: Oh, hi. I'm Judy
4 Robertson, from Sacramento, California. And my
5 husband, Tim, was diagnosed with Huntington's at
6 age 39. I've got -- we were in marriage
7 counseling at the time. He had symptoms of -- he
8 was just chronically unhappy. He was unsettled.
9 He was pacing a lot. I thought he was having like
10 a midlife crisis. And I was thinking, because of
11 his impatience and cruelty towards our four
12 children, who were young, that I needed to get a
13 divorce.

14 And it was during the counseling that he
15 told me that he thought he had Huntington's. His
16 mother died of Huntington's, and his brother had
17 it. But I thought you had to have chorea or
18 movement to have Huntington's. And he didn't. He
19 had more of the rigidity.

20 Turns out I'm very active in the
21 community and have been for over 20 years. And I
22 think about 40 to 50 percent of all patients with

1 Huntington's have more of the dystonia, rigidity,
2 which is a little bit more like Parkinson's. And
3 they don't have the chorea. They seem to have more
4 -- for my husband, had more depression, psychosis.
5 Medicines help, Seroquel, Prozac. But he always
6 had erratic temperament and sleep disorder.

7 He did have stomach issues also. And
8 I'm a nurse. So I asked him to be tested for H.
9 pylori, and he tested positive.

10 MS. GIAMBONE: Thank you, Judy. Thank
11 you very much.

12 MS. ROBERTSON: We need faster approvals
13 from the FDA for clinical trials. Please help us.

14 MS. GIAMBONE: Thank you. Thank you.

15 Okay. So, technically, it is break
16 time. But let's just hear one more comment, and
17 then we'll just take a short break before we get
18 on with Topic 2.

19 So, would anybody like to share any
20 other symptoms that have not been mentioned or
21 elaborate on one of the symptoms that you've
22 chosen here? Let's try to hear from somebody --

1 we have some hands back there.

2 (Pause.)

3 MS. PAPPADIAS: My name is Mary K.
4 Pappadeas. I live in Columbia, Maryland. And I
5 have a family history of Huntington's. But it
6 hasn't been a horror story like I've heard here.
7 The symptoms in my family, nobody had to be
8 hospitalized for psychosis. My Uncle Al -- I
9 mean, my Uncle George lived next door. They
10 thought he had Parkinson's at first. And he lived
11 at home. He had chorea. I don't have any chorea.
12 My cognitive ability is doing very well.

13 I have dystonia more than anything,
14 probably. I call it "posturing," Napoleon
15 complex, where your arm goes up, and that's my
16 most bothersome. I'm involved with clinical
17 trials at Hopkins right now. The Prana drug was
18 very, ironically, helped with balance and gait,
19 which is my biggest problem. I'm in a clinical
20 trial right now with Teva. It's going very well.
21 So I'm very hopeful.

22 They referred me to a physical therapist

1 for movement disorders up at Hopkins, and I've
2 been working on retraining my brain with standing
3 postures, not just giving in to the balance and
4 the gait problems. And it has helped. And I went
5 to Barcelona and walked the city. And I found
6 walking further and longer helped my core. I used
7 to have a very strong core. I was a cross-country
8 runner in college.

9 MS. GIAMBONE: Thank you so much for
10 that. I hate to cut you off, but that's
11 definitely something that we want to hear from in
12 Topic 2, which is on treatments and what you're
13 doing to manage some of the symptoms.

14 So we're going to go to break now. But
15 I just want to thank you again so much. I know
16 that it was a short amount of time, but you really
17 gave us some great information. So, thank you
18 very much. So we'll take a five-minute break.
19 We'll be back here --

20 DR. EGGERS: Fifteen? Fifteen minutes?

21 MS. GIAMBONE: -- right around 10:55.

22 Oh, 15 minutes. Okay. We're going to take a 10-

1 minute break.

2 (Whereupon, at 10:43 a.m., a recess was
3 taken, to reconvene at 10:54 a.m.)

4 DR. EGGERS: Okay. So I think we'll get
5 started if we can.

6 (Pause.)

7 DR. EGGERS: And as you're making your
8 way to the tables, I'll just reiterate what a rich
9 discussion this morning on the experiences and the
10 burden of your disease and those of your family
11 members.

12 We're going to be moving into a
13 discussion, Topic 2, on the perspectives on
14 current treatment approaches to treating
15 Huntington's disease. I'm Sara Eggers. I'm in
16 the Office of Strategic Programs. I'm one of
17 Soujanya's colleagues. And I will be facilitating
18 the conversation in the second half.

19 We have a lot to cover in a short amount
20 of time. So, we have a very full public comment
21 interval. So we will be having to make sure that
22 we save the appropriate amount of time for that.

1 We're going to try to cover as much as we can in
2 the next 55 minutes.

3 As we talk about treatments and current
4 treatment approaches, we did hear a little bit
5 this morning, earlier in the morning, that
6 reiterated and provided some thinking of patients
7 and caretakers on treatment approaches. We're
8 going to delve a little bit further into that.

9 Because we have so much interest in this
10 meeting today, what I'll ask in Topic 2 is that we
11 really try to work on the range of experiences.
12 And I'll go to you and say, "Does the experience
13 that you heard from this person resonate with
14 you?" And that's how we'll really build upon the
15 discussion.

16 So let us know with any way you can to
17 indicate that what someone else is saying is the
18 thinking that you have as well, so that we can
19 focus the comments on really trying to get as much
20 material covered, as many treatments, as many
21 things as you care about treatments covered in the
22 next 55 minutes.

1 We have five panelists for Topic 2.
2 They're going to go through their experiences and
3 set the dialog, just like we did for Topic 1. And
4 then we'll move into the facilitated discussion.

5 With that, I think we're going to go
6 with James first. Yep. James, thank you.

7 MR. D'AMBOLA: My name is James
8 D'Ambola. And, you know, I have Huntington's
9 disease for 10 years. I'm having a bad HD day,
10 you know, so I can't talk a lot. And I'm going to
11 have my girlfriend, Jessica, talk for me.

12 JESSICA: Hi, guys. My name is
13 Jessica, and like Jim just said, he's had
14 Huntington's disease for 10 years. And today, he
15 woke up not feeling very great and doesn't feel
16 like he's going to be able to communicate. So I'm
17 going to try and read his speech to you.

18 He is currently treating his HD with
19 Namenda, venlafaxine, risperidone, tetrabenazine,
20 mirtazapine, and trazodone. He also uses over-
21 the-counter meds of CoQ, fish oil, and multi-
22 vitamins. Other things he does is pray, exercise

1 when he's able to, sleep. He does not use
2 alcohol, caffeine, drugs, or tobacco at this time.

3 The treatments address the chorea,
4 impaired mental processing, and personality
5 changes. After he tries a med, if it doesn't have
6 any side effects or make his symptoms worse, it
7 works by improving his symptoms, but never
8 completely cures him.

9 His meds have changed frequently over
10 the years, because at some point, every increase
11 or new medication becomes overpowered by the
12 disease. When he first displayed symptoms, he was
13 only put on one medication. Now he's on many.

14 He starts the med at the lowest-possible
15 dose and then increases the dose slowly over time
16 to maximize the beneficial way the medicine works
17 for as long as possible.

18 At this point, he can no longer even
19 exercise anymore.

20 His current treatment regimen makes the
21 most significant symptoms of his disease better,
22 but nowhere near a tolerable condition. Even at

1 the current state, his HD is horrible, awful, the
2 worst disease he could have ever been given by
3 God.

4 He says he just started tetrabenazine,
5 and it's improved his cognition and chorea. He's
6 now actually able to play with his son, Vincent,
7 three, who is playing on the floor here. He
8 cannot drive, cook, or interact with friends, or
9 do many other things that he used to be able to
10 do. But tetrabenazine did help him to be able to
11 play with his son, which is amazing.

12 Although the tetrabenazine is helping,
13 it's not taking enough of his symptoms away to
14 lead a quote- unquote "normal life." Before he
15 started the tetrabenazine, he felt like he might
16 die soon because he was at the point where the
17 meds were overridden by the disease. Now, after
18 taking it, his symptoms are much better. But it's
19 also not a perfect or even tolerable condition.

20 The most significant downside to his
21 current treatment and how it affects his daily
22 life is that the treatments are never enough to

1 give him that quote- unquote "normal life," and
2 the treatments don't cure him completely or
3 permanently. No matter how well the treatments
4 improve the symptoms, it never stays that way, and
5 his disease continues to progress.

6 And ideal treatment for Jim would be a
7 medication that could control the chorea that it
8 is gone completely, without having the effect of
9 the drug being overpowered by the disease.

10 Do you want to say anything else?

11 MR. D'AMBOLA: You know, (inaudible), so
12 hope to improve, you know, motor vision, to cure
13 it. You know, I'm really hopeful.

14 DR. EGGERS: Thank you. James, thank
15 you, and thank you, too. I'm sorry. I didn't
16 catch your name.

17 JESSICA: Jessica.

18 DR. EGGERS: Thank you, Jessica.

19 And the little one?

20 JESSICA: Vincent.

21 DR. EGGERS: Thank you, Vincent. A
22 round of applause for Vincent, please.

1 (Applause.)

2 DR. EGGERS: I think our youngest
3 ambassador in the room.

4 And now we will hear from -- who is?
5 Karen will go next. And we'll try to get the --
6 okay, you're going to use the microphone.

7 MS. MILEK: Hi. I'm Karen Milek, from
8 Florida. I am 54 years old. In order to try and
9 delay the symptoms and the disease from taking
10 over my body, I do a lot of things. I got gene-
11 tested 21 years ago at the age of 33. That was
12 the year my mom was pretty sick in the later
13 stages of Huntington's. I needed to know if I had
14 HD, and if I did, I wanted to do everything I
15 could to stop HD from taking any more people in my
16 life or any more people in the world.

17 I tested positive and signed up for a
18 drug study called CARE HD for CoQ10 one month
19 after I got my results. Just being part of a drug
20 study makes you feel a lot better already. I have
21 been taking CoQ10 still for the last 21 years. I
22 know they just did a lab study, and they said the

1 CoQ10 wasn't working as they wanted it to, and
2 they stopped it. But I am still on it. I am not
3 going to stop something I knew helped energize my
4 brain when I first was on it, and there have not
5 been any bad side effects on it.

6 I also have been in PREDICT-HD for 11
7 years, and I sign up for all the research they let
8 me do. I am lucky that being in studies makes me
9 feel useful and gives me hope. Some people get
10 nervous doing the studies; not me.

11 I also went to my first HDSA convention,
12 where I learned so much information about the
13 disease, met so many folks, and I helped start a
14 support group back in Florida and started
15 fundraising for Huntington's disease. I've been
16 to 19 HDSA national conventions, and they help me
17 stay very informed. They always make me feel good
18 and include me in a lot of things they're doing.

19 I also have been on the FDA Advisory
20 Committee for the new drug, for tetrabenazine,
21 when it was approved. I was the person for
22 Huntington's that got to come, so thank you, guys,

1 for letting me be a part of that.

2 I also -- I exercise all the time on my
3 own. And ever since I was a kid, I like to run.
4 And I continue to exercise, because now they have
5 so many studies that they're saying that exercise
6 is going to help our bodies and our brain fight
7 off everything. I run, bike, and swim. Even I
8 work, so I run on my lunch break every day.

9 As far as the diet, I eat a lot of
10 blueberries for the antioxidants. I also take
11 2,400 milligrams of fish oil, 6-10 milligrams of
12 creatine, 1,200 milligrams of acai, and the 600
13 milligrams of the CoQ10, and a multivitamin daily.
14 Sometimes, I forget to take them, but I try to do
15 it.

16 Since I'm a single person with no
17 children, I can take more risks with my body, like
18 signing up for spinal taps and taking the new
19 drugs and the studies. I have been taking a
20 medicine for irritability and my OCD for a very
21 long time, like 21 years, way before any of my --
22 you know, Huntington's disease symptoms would show

1 up. But that happened way, way before.

2 Right now, I take 100 milligrams of
3 Zoloft daily. And if I forget to take that, I am
4 irritable and the people around me notice. A lot.
5 (Laughing.) So I try to keep my brain cells alive
6 and working.

7 I still have a job. I used to -- I work
8 at FedEx. I used to drive, but I went off -- I
9 got off the road, and I don't drive anymore,
10 because I know driving seems to be an issue with
11 us Huntington's people. And I just chose to get
12 in the office ahead of time, before someone was
13 going to tell me it was a problem.

14 A lot of us people with Huntington's
15 keep driving even when we shouldn't, and I was
16 afraid that I might be one of them. So I just
17 decided ahead of time to get a non-driving job.

18 Anything I work on, any chores take a
19 lot longer. I kind of go from one task to the
20 next and leave a lot of things unfinished. I
21 don't like to clean my house like I used to. I
22 just watched my sister pass away at the age of 50

1 this year from Huntington's, and my other sister
2 is 56 in a nursing home with Huntington's. And
3 both of them have tried to commit suicide a number
4 of -- well, one actually put herself in the
5 facility before she did it, and the other one has
6 tried it three times. It's not good. We don't
7 like that.

8 I drink Diet Coke still. And I know
9 it's supposed to be bad for us, but since my body
10 seems to be liking what I'm doing, I'm going to
11 stay on everything I've been doing. And I'm not
12 going to change. So, all right.

13 DR. EGGERS: Any final thoughts, Karen,
14 that you'd like to share? Any important messages?

15 MS. MILEK: Okay. So, well, my
16 independence is very important. The more I can do
17 to stay independent was what I want to do.
18 Because after that, I don't think that's living
19 anymore. So I want things to make us independent.

20 And I want to say, for the drugs, in
21 treatment, I would like something that can slow
22 down the progression so that we can start showing

1 symptoms a lot later in our lives, not at 30, 40,
2 or 50, but like at 70 years old would be okay with
3 me. Death is a part of life. I just like it to
4 be a lot later on.

5 DR. EGGERS: Thank you so much, Karen.
6 Thank you.

7 Now, Stacey? Okay. We'll have Stacey
8 go.

9 MS. SARGENT: Hello. My name is Stacey
10 Sargent. I'm from Douglasville, Georgia. And
11 this is a picture of my son, Corey, who's now 21.
12 I was very young when I decided to get married and
13 have children, and family history was not
14 important to me. I thought I was young and in
15 love.

16 When Corey was born, due to an abusive
17 relationship, he was born three months premature,
18 weighing only two pounds. No one thought he was
19 going to make it in his little incubator, attached
20 to a ventilator, feeding tube, and numerous other
21 machines. But he was trying to push himself over.
22 So I knew early on I had a fighter on my hands.

1 I knew due to his premature birth that
2 he would always be developmentally delayed. When
3 he started school, Corey had some learning
4 difficulties and a slight speech impairment.

5 First grade, a student intern in the special-ed
6 program tried to diagnose Corey as autistic, due
7 to echolalia.

8 We went to a neurologist, who decided
9 Corey had ADHD, and at that time the drug of
10 choice was Ritalin. Luckily, knowing what I know
11 now, I refused and did diet modification.

12 A few years later, we started noticing
13 that Corey had a facial chorea, took him in to his
14 neurologist for an MRI, and was given the
15 diagnosis encephalopathy. But in order to get
16 insurance to cover therapies and to put a label on
17 him that everyone would understand, he was given
18 the diagnosis of spastic cerebral palsy.

19 By age 10, he started walking on his
20 toes. By age 12, he had another decline affecting
21 his posture, ability to walk, speech, eat, and
22 swallow. It was time to find a new doctor,

1 because this one wasn't listening. I knew
2 something was wrong with my child.

3 Numerous neurologists looked at me like
4 I was crazy. Finally, one showed concern and ran
5 tests, ruling out metabolic disorders. Finally,
6 Corey started having itching, kicking, kicking
7 like a horse, unable to sleep at night, often
8 lasting for days at a time. The doctor decided to
9 try Sinemet at that time. It was our miracle
10 drug. He still had the itching, but it was
11 controlling his sleep and he was able to -- it was
12 controlling the kicking and he was able to sleep.

13 That medication was started in 2009, one
14 tab at bedtime. Here now, at 2015, we are on two
15 tabs three times a day, and one as needed.

16 Often, when he gets agitated, it
17 increases his chorea and dystonia. Sometimes,
18 even the Sinemet doesn't help, and we have to give
19 him pain meds in order to help him sleep and give
20 him rest.

21 It was discovered when Corey was in the
22 hospital getting diagnosed in 2009 that he had

1 many ulcers of his esophagus and stomach. I was
2 devastated in 2009 when I got his diagnosis, a CAG
3 of 85, because there's nothing I knew I could do
4 to help my baby boy.

5 I cried, I screamed, and then I cried
6 some more. As a mother, I'm supposed to kiss my
7 child's hurts away, but because of Huntington's,
8 those hurts are so much more profound than I ever,
9 ever imagined. At the age of 15, instead of
10 getting a learner's permit, he was learning how to
11 use a wheelchair.

12 The disease progressed so quickly that,
13 by the age of 17, he was unable to speak, unable
14 to attend school, bedbound and completely
15 dependent on us for his every need. He is on meds
16 for chorea, dystonia, reflux, muscle relaxers,
17 seizures, sleep, itching, pain, and agitation --
18 all only providing minimal relief.

19 At the age of 18 when he is supposed to
20 be choosing a college to go to, we are choosing
21 which hospice agency to use. He did manage to
22 graduate at 19, something that four years before

1 we had been told we probably wouldn't see.

2 He is now 21, less alert of his
3 surroundings, never had a girlfriend, never had
4 his first kiss, never got to go to prom.

5 Corey never met a stranger, having a hug
6 and kiss for everyone who ever crossed his path.
7 I know that not being able to control his facial
8 expressions, to smile at someone he has just met,
9 to hug and kiss us every night when we tell him
10 good-night, I know it has to hurt him emotionally,
11 even though in his eyes I can see him smiling.

12 I do know that this bothers him, because
13 recently my sister gave birth to a little girl, a
14 little girl that I took Corey to see when she was
15 11 days old. He was so excited, the dystonia was
16 just so bad I couldn't let him hold her, because I
17 was scared he would hurt her. Telling him no
18 triggered a seizure.

19 He has to have Botox injections every
20 three months into his cheeks into chin, into his
21 saliva glands, to keep his saliva down, because he
22 produces so much he chokes. He can't even control

1 his head to keep from -- to try to spit it out. I
2 do this to keep him safe, to keep him safe from
3 aspirating.

4 He receives therapies on homebound
5 education, originally to preserve independence.
6 Now they are for comfort and to give me some
7 relief. But those are services that, once he
8 turns 22 in February, I'm going to lose because,
9 see, with him on hospice, we won't qualify for
10 community-based programs.

11 I believe JHD research and trials are
12 important because these kids don't have time to
13 wait. These kids deserve a better quality of life.
14 We need to preserve their ability to think and to
15 communicate so that they can tell us what's wrong
16 and how to help them.

17 We realize that there are risks, but our
18 children are dying. We will do anything to save
19 them. Some of us are even doing things that are
20 illegal, like using medical marijuana in states
21 where it's not permitted. We believe that if they
22 are allowed to participate in research and trials,

1 that at least their death won't be in vain.

2 Our family made a promise to Corey six
3 years ago that we're going to fight this as long
4 as there are breaths in not just our bodies. And
5 we're not going to fight it just for him, but for
6 all the children affected by Huntington's disease.

7 DR. EGGERS: Thank you so much, Stacey.

8 (Applause.)

9 DR. EGGERS: Everyone deserves a round
10 of applause, I think.

11 (Applause.)

12 DR. EGGERS: So, is it Cheryl next?

13 Cheryl, thank you.

14 MS. SULLIVAN STAVELEY: Hi, everyone.
15 My name is Cheryl Sullivan Staveley. I'm from
16 Massachusetts, and I'm a patient representative
17 for my husband, John, who was diagnosed at the age
18 of 37, and for my daughter, Meghan, who was
19 diagnosed with JHD at the age of 19. John passed
20 away seven years ago at the age of 56, and Meghan,
21 last May at the age of 26.

22 John was a 12-time Boston Marathoner,

1 who ran six miles each day for about eight years
2 in the beginning to early mid-stage of his HD, to
3 keep physically active. He kept himself
4 intellectually stimulated by reading textbooks
5 related to his law enforcement career, daily
6 newspapers, and watching the news. He took
7 vitamin supplements, niacin, riboflavin, and
8 coenzyme Q10. After about 10 years, he took
9 Zyprexa to help with his anxiety and depression.

10 In 1996, he underwent a fetal pig tissue
11 transplant to see if the fetal pig tissue could be
12 a substitute for his own brain tissue that was
13 being destroyed. After four years of close
14 observation and taking cyclosporine for possible
15 tissue rejection, the medical researchers felt
16 that the surgery had neither helped nor harmed
17 him. However, emotionally, I believe that it
18 helped him maintain more of a positive attitude.

19 Meghan went to the gym three times a
20 week, doing cardio and stretching during the early
21 to mid- stages of her JHD. After receiving her
22 associate's degree, she continued to audit a

1 couple of classes each semester for about two
2 years to try to keep her mind cognitively active.

3 She took 30 grams of creatine and 2,400
4 milligrams of coenzyme Q10 for about five years.

5 She was prescribed a wide variety of
6 antidepressants, anti-anxiety, and antipsychotics
7 during her 10-year battle with JHD. At one time
8 or another, she was on Zyprexa, Zoloft, Celexa,
9 Abilify, Ativan, Klonopin, and Remeron.

10 Both John and Meghan strived to eat
11 6,000 calories a day by eating a combination of
12 fruits, vegetables, healthy protein, and carbs, as
13 well as the not-so-healthy high-caloric junk food
14 like ice cream, donuts, cookies, and candy.

15 All of the abovementioned treatments
16 were designed to maintain physical strength,
17 balance, agility, emotional stability, and to
18 remain as cognitively intact and to keep their own
19 personality for as long as possible.

20 As their HD progressed, their level of
21 physical activity declined due to increased chorea
22 for Meghan, and rigidity for John. They both,

1 obviously, experienced decreased strength and
2 balance.

3 Meghan tried Xenazine in 2009, but it
4 did not decrease her chorea. It made her very
5 depressed, agitated, and caused difficulty
6 sleeping for the three months she was on it. John
7 died before the Xenazine became available.
8 However, although this was not its intended use,
9 for Meghan, Abilify decreased Meghan's chorea for
10 almost two years in the early stages of her
11 JHD.

12 Cognitively, their ability to focus and
13 read declined, although they both enjoyed being
14 read to. Carrying on conversations ultimately
15 became very difficult, due to the delayed thought
16 processes and slurred speech. However, they
17 always seemed to understand what was being said to
18 them, and they could answer yes-or-no questions.
19 They basically continued to enjoy the
20 entertainment that they liked.

21 John and Meghan's treatment regimen
22 ultimately did not help with their chorea or

1 prevent their cognitive or personality decline.

2 Emotionally, their meds did a good job in

3 controlling the anxiety, depression, and

4 perseveration, which did improve their emotional

5 overall wellbeing.

6 Significant downsides for both John, and

7 especially Meghan, from the emotional medications

8 were that sometimes it made them apathetic,

9 irritable, restless, and lethargic. When this

10 happened, neither one wanted to participate in

11 varying activities, or interacting with their

12 family or friends.

13 It also often caused them to sleep all

14 day, be up all night, which was very disruptive

15 for them both when they were at home, and each in

16 their respective nursing homes.

17 For Meg, her personality could change,

18 making her more aggressive or negative at times.

19 For my family and I, an ideal treatment would be

20 one that could slow down the progression of all

21 three aspects of HD in general, but for my family

22 in particular, especially the cognitive aspects.

1 I see this -- I say this because I know there is
2 some treatment for the emotional as well as the
3 motor aspects.

4 To me and for my family, if each stage
5 of HD could be longer and the symptoms slower to
6 evolve, ultimately that would mean a better, more
7 productive quality of life for a longer period of
8 time. We would consider this a victory should a
9 cure not be able to be fully realized. Thank you.

10 DR. EGGERS: Thank you so much, Cheryl.

11 (Applause.)

12 DR. EGGERS: And finally, we have Karen
13 Douglas.

14 MS. DOUGLAS: Good morning. My name is
15 Karen Douglas. I'm here with my husband, Matt,
16 who has Huntington's disease in his family. I'm
17 fairly new to the Huntington's world. We've been
18 married for 20 years. But I didn't know what
19 Huntington's disease was before we were married.

20 Currently, we are doing some treatments
21 that, we've done treatments in the past that we're
22 not doing now, and I'm sure we'll have other

1 treatments that we're doing in the future.

2 But currently, right now, we have been
3 doing exercise with an exercise DVD that he has.
4 He loves the Wii, with the hand-eye coordination,
5 and the Wii Fit for balance. He has ankle weights
6 that he'll wear to wear at his muscles and to keep
7 his feet from flying up when he loses balance
8 throughout the day.

9 We were able to obtain a service dog.
10 Some of you have seen Jerry around today. He's
11 down here. And that's been a huge blessing in so
12 many ways. It helps Matt with balance, so as he's
13 maintaining his walk, he can hold onto the handle.
14 He also helps with picking him up when he falls.
15 I'm still working part of the day, most of the
16 day. And when Matt falls, I know that he's able
17 to get up and continue on.

18 He opens the doors for him, and he picks
19 up things for him. And besides that, he's a great
20 companion and a great joy and responsibility for
21 Matt to take care of.

22 Every other week, we go to OMT, which is

1 Osteopathic Manipulative Services. It helps to
2 relax his muscles and the spasms for about a day.
3 So going every other week really is not enough.
4 But it does help in some aspects. He has
5 nutritional drink supplements, like Boost, to try
6 to take care of the 5,000 calories each day that
7 we've been seeing.

8 And he also uses technology tools.
9 Praise the Lord for the technology that we have
10 today, with different apps and so many ways that
11 you can use them. He does Luminosity, with the
12 brain games, to try to keep that memory going and
13 sharp. The hand-eye coordination, he loves these
14 racing games.

15 And weight management, we've been using
16 a Fitbit, which has been really a lot of help to
17 me. As he wears the Fitbit, I can tell how many
18 calories he is burning that day, and then how many
19 calories he needs to eat in order to even maintain
20 his weight. So he's been averaging 28,000 to
21 30,000 steps a day and burns about 5,000 calories
22 a day.

1 There's another app for oral management,
2 which is Oral-B. It sets reminders to remind him
3 to do his teeth and to be able to remember to
4 floss and rinse and all that type of thing. And
5 then I don't feel like a nag. And then he also
6 uses the social interaction with Facebook and that
7 type of thing. Since he's not able to drive and
8 go out, he's able to still socialize with people
9 that he's had previously in his life, and he
10 enjoys that.

11 The prescription medicines -- trazodone
12 for sleep, mood, and anxiety. It has worked, but
13 not to the degree that it helps anymore. So we
14 try to increase and add Haldol onto that. I'm
15 going to talk about that a little bit more later.

16 For movements, he was on Xenazine,
17 tetrabenazine. He's been on that for 12 years.
18 Thank you to the FDA for approving that. Chorea
19 has been our most prominent symptom to have to
20 deal with, and it has been not cosmetic. I've
21 heard that before, but it's very dangerous. And
22 we've had some situations that he could very well

1 have harmed himself with. So we're very thankful
2 that he's been able to prolong independence for a
3 little bit longer with the Xenazine,
4 tetrabenazine.

5 He's got Galantamine Hydrobromide for
6 memory, Zoloft for mood, Flomax for bladder
7 control, and Ativan for anxiety. As you can well
8 imagine, with all of these different drugs,
9 prescription medicines that he is taking, there's
10 always side effects to each one of them. And so,
11 it is challenging. Sometimes, you have to take
12 another medicine in order to make up for the
13 medicine that you're on. So it's a constant
14 journey of trying to balance things out.

15 How does your treatment regimen change
16 over time? It has changed by us having to
17 increase the strength. As new treatments are
18 added and as the decline continues, we just
19 continue increasing strength. Obviously, it
20 doesn't get to the point that everything is taken
21 away. You just manage.

22 DR. EGGERS: Any final thought? You

1 were going to talk about one more product.

2 MS. DOUGLAS: Sure.

3 DR. EGGERS: And then, what really Matt
4 would like to see out of treatments.

5 MS. DOUGLAS: Absolutely. Thanks.

6 DR. EGGERS: Um-hm.

7 MS. DOUGLAS: One of the ways that we
8 would really like to see an ideal treatment,
9 obviously, we would love for a cure, and you've
10 heard that a lot today. But I did call some
11 friends and family. It is a family disease. It
12 doesn't just affect one person.

13 And I found that, as you've heard from
14 many stories today, so some of the friends and
15 family have said communication options would be
16 really helpful. Speech becomes very difficult to
17 understand, as you've seen, and then it's
18 nonexistent. And so I did see in his mother that
19 passed away that she communicated with her eyes.
20 And that was just really interesting to be able to
21 still see her trying to communicate that way.

22 Speaking and swallowing process, the

1 fear of frequent choking -- got to get that weight
2 management taken care of, and therefore you need
3 to eat.

4 And then the movement, as I mentioned,
5 and mood -- if there's some type of effective low-
6 side- effect antidepressant to cope with
7 depression and mental anguish, that was another
8 thing that somebody mentioned.

9 But in summary, my request would be to
10 continue to approve new treatments coming down the
11 pipeline as quickly as possible. Matt had that
12 request, that sometimes it does take a long time.
13 And so, we need it sooner than later, as you've
14 seen and heard from many people here.

15 With it being hereditary and a family
16 disease, our families need the help of the FDA.
17 People ask me where Matt and I find our hope. And
18 we really find it in our faith, our family, and
19 our friends. We appreciate all that you guys have
20 done to take a moment to hear from the families
21 here today. It really does make a huge
22 difference, and we've seen your sincerity. And it

1 just really has moved us.

2 So I appreciate your time, and hope that
3 echo from everyone else. Thank you.

4 (Applause.)

5 DR. EGGERS: Thank you. Thank you,
6 Matt. Thank you, Matt, and thank you, Karen.

7 And thank you again to all of the
8 panelists for so eloquently showing the complexity
9 of the management of your condition, ranging from
10 the pharmaceutical treatments, but you can't --
11 there's so much else to cover and so much else
12 that you require. And that came out very clearly
13 in your comments today.

14 So I think that this demonstrates the
15 range of perspectives, and I'll ask for an
16 indication from the audience. Did that reflect
17 the range? You might not have -- not everything
18 would have resonated with you, but something did?
19 Something did? Okay. Great. Thank you.

20 Please, one more round of applause for
21 the panelists.

22 (Applause.)

1 DR. EGGERS: We are going to now move in
2 and try to delve in a little bit more into aspects
3 of treatment that you've experienced or your loved
4 ones have experienced and that matter to you.
5 Again, we're not going to be able to cover every
6 possible treatment or every experience. But I
7 think we'll be able to cover both pharmaceutical
8 treatments first, and then the range of other
9 therapies, but more, other life management that
10 require.

11 So I'm going to put up a polling
12 question first. And this is first focused on the
13 pharmaceutical treatments. And I have to stand
14 over here. I'm not going to -- or I can go
15 through this list. It's not an extremely long
16 list, so let me walk through it.

17 So again, if you've got your clickers
18 out, have you ever used any of the following drug
19 therapies to help reduce your symptoms of
20 Huntington's disease? And you can check all that
21 apply. Tetrabenazine, A; antipsychotic drugs, B;
22 antidepressants, C; other drug therapies. And

1 those focus on the drug therapies not mentioned.

2 And E, not sure.

3 (Pause.)

4 DR. EGGERS: Okay. I think we can --
5 okay. A wide range, with the most focus on the
6 antidepressants, but there is experience reflected
7 all throughout in person, including the
8 tetrabenazine.

9 On the Web, can I ask what we have?

10 (Pause.)

11 DR. EGGERS: We will come back. We will
12 come back to that. Graham --

13 MR. THOMPSON: Never mind. All right.
14 We're back now. Bad local mic's.

15 Everybody on the Web who answered this
16 said that they're taking antidepressants. Sixty-
17 five percent said they take antipsychotic drugs.
18 Thirty- five percent say tetrabenazine. And then
19 50 percent say other drug therapies not mentioned.

20 DR. EGGERS: Okay. All right. Thank
21 you.

22 One thing I want to reiterate, if we

1 don't get to cover all the topics here, we had a
2 hard time identifying the panelists who would
3 represent and kick off the discussion, because you
4 sent in, collectively, a tremendous response. You
5 sent in your comments to us.

6 We will use those comments, and they
7 will be reflected in our report as well. So we
8 have all the comments that you might have sent us.
9 We also have the public docket. So if you're
10 hearing something and you want to build upon it
11 and we don't get to discuss it today, that docket,
12 where you can electronically submit your comments,
13 is extremely important. It doesn't matter if you
14 already said it here today. You can expand upon
15 it in the docket.

16 So, please remember to go home, to think
17 through, and to submit a comment on what you're
18 hearing today.

19 So with that, let's go into a few
20 comments on tetrabenazine. And when we talk about
21 any of these therapies, what we're looking for is,
22 how does it work for you, or how did it not work

1 for you? And how did you know? And how long did
2 you give it? How long did it take before you were
3 able to come to some sort of determination?

4 Immediately, or some time, or you tried it for
5 long enough, and then you decided -- it was
6 determined that that wasn't the right treatment
7 for you? Any comments on tetrabenazine?

8 So we'll go here first, and then we'll
9 go into the back, over there.

10 MS. ROSLING: Tetrabenazine is a great
11 drug.

12 DR. EGGERS: So, this is Julie.

13 MS. ROSLING: It is the only drug we
14 have -- I'm sorry. But tetrabenazine, as we know,
15 is only good for chorea. They put me on chorea-
16 type drugs, tetrabenazine, just because there's
17 nothing else around. I felt so sick on that drug
18 that it was not worthwhile for me to take.

19 DR. EGGERS: Okay.

20 MS. ROSLING: And again, we have to work
21 on things that are available for other types of
22 symptoms than for that.

1 DR. EGGERS: Thank you for that point,
2 which is a point that is, I think, going to be
3 reiterated and is resonating.

4 Back there?

5 MS. RANDALL: Hi. My name is Laura
6 Randall.

7 DR. EGGERS: Hi, Laura.

8 MS. RANDALL: My son is 26 and has
9 Huntington's. I'm just -- we don't -- he doesn't
10 take any of those drugs up there. So, he has
11 really bad tremors that affect everything that
12 we've heard today. He can't eat, he can't really
13 do anything himself. So he's taking Depakote,
14 which is a seizure medicine. He takes Sinemet,
15 that we've heard of, and he takes amantadine for
16 the rigidity.

17 But what I've noticed is it seems to --
18 it's all trial and error, right? And you don't
19 know if something's working until you don't take
20 it. So, you know --

21 DR. EGGERS: So what do you look for?
22 How do you know it's working for your son?

1 MS. RANDALL: He -- it's horrible. He
2 misses a pill, I know right away. He can't walk,
3 he can't do anything himself. You know, he has a
4 really bad day. And most of the time, I find a
5 pill in the pillbox or I find something on the
6 floor. So I've tried to take him off some
7 medicines because I don't think they're working
8 and, you know, as soon as we go off them it's like
9 the symptoms are ridiculous.

10 So I feel like there should be a better
11 way -- you know, and we've heard today that
12 everybody has different symptoms and it's
13 affecting everybody differently. But it's just
14 such a hunt-and-peck at this point. You know,
15 what works and what doesn't? It's very maddening.

16 And I want to ask the dumb question of
17 the day. Since we've known of the gene since
18 1993, why aren't we working on that? That's what
19 we should be working on.

20 (Applause.)

21 DR. EGGERS: Your question has -- is an
22 important one and is resonating with others.

1 So, let's go on to another comment,
2 another experience shared. Right here. Oh, and
3 then -- I'm sorry. Then we'll go back. Is there
4 someone back there? Um-hm.

5 MS. LoCASTRO: Again, my name is Tara
6 LoCastro. I think that I want to emphasize the
7 comments made by the panel about prevention and
8 somehow making sure that we're not discussing
9 treatment during the symptoms as much as we might
10 be able to before they occur. Whether it's over-
11 the-counter, mixtures of fish oils and things of
12 that nature that have some efficacy, but also
13 things that can be given to whether you're at-
14 risk or you are gene-positive very, very early,
15 well before onset.

16 DR. EGGERS: Thank you very much.

17 Ashley, was there someone back there?
18 Okay. Then we'll come -- then we'll stay.

19 MS. HUDGELL: I just want to make a
20 comment. Aden hasn't been on tetrabenazine, since
21 it's for chorea, but he's been on antipsychotic
22 medication and Depakote and several anti-

1 epileptics, not only for his seizures, but for
2 mood stabilization.

3 But I think one thing that I want to
4 point out is that when we talk about the way that
5 HD patients metabolize medication, we can be on a
6 medication for a very brief amount of time and we
7 have to increase it.

8 So, of course, we all want a cure. But
9 when we're talking about meds and when we're
10 talking about how our kids and our husbands and
11 wives and whatever loved one we're talking about,
12 sometimes the meds just aren't it. We need to
13 find a cure.

14 DR. EGGERS: Okay. We'll go here, and
15 then we'll go with Colleen. Okay.

16 MS. THOMASON: Another thing I'd like to
17 mention is that, except for tetrabenazine, none of
18 these others are approved for Huntington's
19 disease. And that can be a problem.

20 For example, my son had been taking
21 memantine, or Namenda. And it was helping him a
22 lot. But then, the insurance company said they

1 wouldn't pay for it anymore because it wasn't
2 approved for Huntington's disease. And so, we had
3 to jump through some hoops and do appeals that
4 failed. And then I had to take him to a
5 neurologist and have a neuropsychiatric battery of
6 tests done and prove that he had dementia. And
7 then they would approve it.

8 So, we need these other drugs, the
9 antipsychotics, the antidepressants, the mood
10 stabilizers, the drugs for cognition. We need
11 those to be approved for Huntington's.

12 DR. EGGERS: Thank you for that point.

13 Okay. We'll go with Colleen.

14 Feel free to clap. It's a good way to
15 show that a comment really resonates for you. So
16 feel free to clap when something resonates.

17 MS. WALSH-BARNES: As I mentioned
18 before, my sons were complete opposites, my sun
19 and my moon. The only drug that helped Miles with
20 his severe cognitive processing and integrating
21 the outside world into his reality was Depakote.
22 The only drug that helped Jason with his violence

1 was Depakote.

2 And I actually had to fight for Jason to
3 go on Depakote because no one thought it was help
4 his violence. But it did. He was being sent to
5 the psych ward regularly from the nursing home.
6 Once he went on the Depakote, that completely
7 ended. He became very calm.

8 The other two non-drug things --
9 clinical trials. My sons were in the best place
10 during clinical trials, especially clinical trials
11 that they saw -- you know, they went into the
12 hospital frequently. You know, not the ones where
13 you go like maybe once every two months.

14 That, of course, alleviated some of
15 their depression. It made them feel in control of
16 things. And it also gave them hope. The only hope
17 they ever had was clinical trials. So, you know,
18 the expansion of that would be great. I started
19 with clinical trials with my children and myself
20 and my husband in 1979. And it's one of the best
21 things for the treatment of Huntington's disease.

22 The other thing is not really related,

1 but my grandson was born using genetic testing, in
2 vitro fertilization. And my son, knowing that he
3 wasn't going to pass the disease on was huge,
4 huge. Because I know what it did to me to know
5 that my children were at risk, and he didn't have
6 to suffer that.

7 So those were the three things that I
8 think had the best impact on my son.

9 (Applause.)

10 DR. EGGERS: Thank you, Colleen. Thank
11 you.

12 Are there any questions on any
13 particular drug therapy that you'd like to ask?

14 (No audible response.)

15 DR. EGGERS: Time is tight, so we're
16 going to move on.

17 Okay. Let's go in and see -- let's move
18 on into the non -- the other types of therapies.

19 I'm sorry. Time is -- we've only got a few
20 minutes left. So, okay, we'll take one comment
21 here from -- what was your name again?

22 MR. NIERENBERG: Roy Nierenberg. I'm

1 taking a couple of things off-label.

2 DR. EGGERS: Um-hm. Okay.

3 MR. NIERENBERG: I'm taking Verapamil,
4 which is a calcium channel blocker. And it's --
5 when I took it, it restored my creative thinking
6 abilities and it countered my apathy. I'm also
7 taking Namenda, but I have to take -- you know, I
8 have to pay extra for it. And I'm also taking
9 melatonin.

10 The Namenda and melatonin were
11 recommended by a neurologist who's not an HD
12 neurologist. And the Verapamil was -- I heard
13 about through the Stanford HOPES site, but I'm
14 taking it -- my internist, he prescribed it.

15 DR. EGGERS: Um-hm. Thank you, Roy. I
16 saw a lot of people nodding with what you were
17 saying.

18 Okay. We will really go with one more,
19 and then we are going to move on to the nondrug
20 therapies. Please, go ahead.

21 MS. CLARK: Okay. I just wanted to add
22 really quickly that tetrabenazine worked really

1 well for my mom. And that was a really important
2 drug that really helped control her chorea. But
3 near the end, it got really bad and even that
4 couldn't control it.

5 And the worst part about the drugs and
6 trying to treat the symptoms with my mom was, she
7 would keep on changing. Like one symptom would
8 get really bad, and then you would fix that. And
9 then something else would get really bad. So,
10 like the motor symptoms or the cognitive.

11 So it was just constantly juggling. And
12 every single day was a new puzzle to be solved.
13 And as soon as you fixed that, then it would just
14 all start all over again. And she was obviously
15 deteriorating throughout. And so, I mean, it's
16 really, really tricky to try -- there's like
17 definitely not like one answer here.

18 And I wanted to also say that I tested
19 positive. And I have 45 CAG count. And I am 31,
20 and I don't really know what I should be doing to
21 try to be as healthy as possible, other than eat a
22 good diet and work out and, you know -- I see my

1 therapist, and I have Prozac, 40 milligrams a day
2 for my depression, which seems to help some. But
3 I don't really know what to do.

4 I was on CoQ -- CoQ10 and creatine until
5 I saw that those really weren't working. So,
6 yeah. So, I don't really -- for a person that is
7 gene-positive that is trying to stave off HD, it's
8 really -- it's really hard to have that cloud,
9 that shadow hanging over my head, especially after
10 seeing what it did to my mom and taking care of
11 her. So.

12 DR. EGGERS: Thank you. Thank you.

13 For the others whose symptoms have --

14 (Applause.)

15 DR. EGGERS: Okay. You've answered my
16 question then, that this is an experience and
17 perspective that's shared by others who maybe have
18 not reached the point of progression of symptoms
19 yet.

20 We were going to ask a question about
21 other therapies. But I don't think -- I think in
22 the interest of time, the few wrap-up questions we

1 want to get at, and we want to get at a Web
2 summary. But I think we heard -- so let me just
3 show. If you can indicate somehow the importance
4 -- the importance as was shared of others of the
5 nondrug therapies currently to your overall
6 management or the management of your family
7 member.

8 Okay. We have one comment back there.
9 So we will take that.

10 MR. SERBIN: Yeah. My name is Kenneth
11 Serbin. I'm known in the HD community as Gene
12 Veritas. My mother died of Huntington's disease
13 in 2006. She had 40 CAG repeats. We tested our
14 daughter during the pregnancy in '99, 2000, before
15 pre-implantation was available. She tested
16 negative. It was the happiest day of our lives.
17 Today she's a healthy 15-year-old in high school.

18 When I saw my mother get symptoms and
19 die, and when I see someone with HD, I say it's
20 like looking into the genetic mirror because of
21 looking at my own future. Like Karen, an
22 asymptomatic gene carrier, and I really would like

1 to see a medication that prevents me from ever
2 getting any kind of symptoms.

3 I'm very lucky at this point, at age 55,
4 well past the point when my mother had onset of
5 all types of the symptoms. She began with the
6 mood symptoms. Then it developed into chorea, and
7 cognitive loss, memory loss, so on and so forth,
8 swallowing difficulties.

9 A really important point I want to make
10 to the FDA is that I think that there's got to be
11 a really open dialog with the scientists working
12 on the new areas such as gene silencing. I don't
13 really know why, but the first gene silencing
14 clinical trial we have is happening in Europe and
15 Canada. And I couldn't really find out from the
16 company, Isis Pharmaceuticals, why they didn't
17 want to do it in the U.S., but they're not.

18 I was disappointed at that; so were a
19 lot of us in the HD community. Hopefully, in
20 phase two and three, if it gets to that, we can
21 include people in the United States.

22 I've also heard from drug company

1 executives who want to use MRI, cerebral, spinal
2 fluid, and other kinds of new technologies or ways
3 of looking at these parts of the body, the brain,
4 the CSF, the blood, where the new types of
5 biomarkers are being found, that there's been, as
6 it were, a kind of lack of flexibility on the part
7 of the FDA. And I'd really like to urge that
8 these new kinds of technologies that can get us to
9 looking at drugs that will help gene-positive pre-
10 symptomatic people like me avoid the disease.

11 DR. EGGERS: I think you're raising a
12 really good point that I'm going to ask for in the
13 docket. Because the asymptomatic gene carriers,
14 you have a different -- everyone has a different
15 perspective, but your perspective is very
16 different from people who are more, in the more
17 advanced stages.

18 So make sure that the asymptomatic gene
19 carriers, you're telling us, sharing with us what
20 you want to see in the future before you ever have
21 symptoms, what's going to matter most to you, to
22 either identify or delay or address it right away.

1 The same goes -- we're going to have to
2 move on. The same -- so I'm going to put your
3 homework assignment for the docket. At all stages --

4 (Applause.)

5 DR. EGGERS: Well, you didn't hear your
6 homework assignment yet.

7 At all stages, you know, what is it that
8 you wish you could stop, or you wish you could
9 slow down, or you wish you could regain if that
10 was at all possible? Tell us what those specific
11 aspects -- think of them as things that could be
12 addressed, perhaps, by a pharmaceutical therapy --
13 the cognitive, the behavioral -- and write that in
14 to us. We aren't able to address all your
15 comments, but we will read all of them as they
16 come in. So there's your homework assignment.

17 We have one person on the phone. And
18 before that -- we'll go to that in a second --
19 Graham, could we get just a brief summary of what
20 we're hearing on the Web? We have a very large
21 Web presence, and we so much appreciate it. I'm
22 looking where a camera would be. So that we

1 appreciate your contributions as well. So keep
2 those webcast comments coming in, because that's
3 what the camera is looking at.

4 We had the camera today pointing so that
5 people on the Web could see you all. You are the
6 most important people to be viewing today. Yes,
7 so wave hi to everyone on the Web.

8 Graham, please.

9 MR. THOMPSON: So we have several people
10 were talking about tetrabenazine, various
11 responses. People said that it helped gain weight
12 and reduce movement. But several people mentioning
13 issues with perception and depression.

14 And then we had several people who asked
15 some questions about the current state of gene
16 therapy and the progress of gene therapy in the
17 future.

18 DR. EGGERS: And you can ask -- we might
19 not be able to answer questions. But you can ask
20 your questions. What are those most important
21 questions that you have? What are the things you
22 want FDA to know that you're concerned about and

1 that you have questions about? And that is just
2 important feedback on what your perspectives are
3 in terms of treating this condition.

4 We have one person on the phone. And
5 so, I'm going to ask, who's on the phone? Oh,
6 yes, that's right. Operator, can we have a
7 caller, please?

8 THE OPERATOR: Yvonne (phonetic), your
9 line is open.

10 DR. EGGERS: Is it Yvonne?

11 MS. SWEETON: Good morning, everybody.
12 My name is Ivonne Sweeton (phonetic). I live in
13 Henderson, Nevada. I am an HD ambassador, which
14 means I'm very involved in the HD cure. I do have
15 a diagnosis, just got it. I have a 41 CAG. It
16 ran in my father's family. He had it. His father
17 had it. We've lost most of his side of the family
18 to HD. It's like a Holocaust, but a different
19 kind.

20 I agree with everybody. I echo all of
21 you. And I applaud you for going there. What I
22 agree with mostly is, first thing, you need a

1 diagnosis. Thank goodness we had one early in our
2 family, so we all had choices on whether or not to
3 have children, whether or not to pursue a certain
4 career, whether or not to get married. So we
5 didn't allow it to define our life, but it
6 definitely helped us make decisions.

7 The second thing is the connection, the
8 support. I feel connected to all of you because I
9 have a defective HD gene from my father and the
10 normal HD gene from my mother. So therefore,
11 we're all connected either by whether or not you
12 have the disease or were part of a family.

13 The third thing is the cure. What I
14 learned at convention this summer -- and thank you
15 to HDSA for a great convention. I learned that
16 the scientists are so excited about a cure. They
17 are going to find a cure, and it will be in our
18 lifetime. Thank you.

19 DR. EGGERS: Thank you. Thank you,
20 Yvonne. There were a lot of heads nodding. You're
21 getting a round of applause from the folks in the
22 audience.

1 (Applause.)

2 DR. EGGERS: Any final things from the
3 panelists? No.

4 So, I want to thank you all for such a
5 rich discussion. It was so rich that we have gone
6 a little bit over our time. So we will ask the --
7 there's going to be a public comment next. And
8 we're going to ask you really to keep your
9 comments brief. If the comment that you have to
10 make has really resonated with something someone
11 else said, you could just agree with that person,
12 and that way we won't be rushed as we go through
13 our public comments. Okay? Thank you very much.

14 MS. VAIDYA: Hello, everyone. I'd like
15 to thank you all for coming today. So we're now
16 moving into the Open Public Comment session. And
17 for those of you who are not aware, the purpose of
18 this session is to allow an opportunity for those
19 who have not had a chance to speak on issues that
20 are not related to our two main discussion topics
21 today to present your thoughts.

22 Please keep in mind that we will not be

1 responding to your comments, but they will be
2 transcribed and be part of the public record.

3 Since we would like to make this a
4 transparent process, we do encourage you to note
5 any financial interests that you may have related
6 to your comment. If you do not have such
7 interests, you may state for the record. And if
8 you prefer not to provide this information, you
9 can still go ahead and provide your comments.

10 So we have collected signup before the
11 meeting and during the break. We have 12 people
12 who have signed up, and roughly 30 -- 25 minutes,
13 let's say, for this session. So please be
14 respectful for other colleagues here and other
15 patients, and try to stick to the two-minute limit
16 that we have for each comment.

17 I'll be keeping track of time here. And
18 as you approach the two-minute mark, I will have
19 to slowly nudge you to wrap up.

20 So I will run through the order of
21 speakers, and I apologize in advance if I
22 mispronounce your name. So, we have first Cheryl

1 Sullivan, then we will have Jonathan Monkemeyer,
2 Loretta, Melanie Rehm, Jennifer Mann, Karen Clark,
3 Louise Vetter, Brian Win -- Brian, Sharon
4 Thomason, Katrina Hamel, Lauren Holder, and
5 Kenneth Serbin.

6 So, could I please have the mic to
7 Cheryl, please? Cheryl Sullivan.

8 MS. SULLIVAN STAVELEY: I just find I
9 don't think there's anything additional that I
10 wanted to say that has not been said.

11 MS. VAIDYA: Okay. Great. Okay.

12 So, can we move on to Jonathan
13 Monkemeyer?

14 MR. MONKEMEYER: Hi. I'm Jonathan
15 Monkemeyer. Just wanted to emphasize that our
16 relationship with the FDA is, we really want to
17 bring therapeutics through absolutely as fast as
18 possible. You could see it's a horrendous
19 disease, from JHD on to HD. It's just a whole
20 spectrum of suffering.

21 And we're willing to take a lot of risk
22 and are not so concerned about the safety of what

1 we want to try. And we're really looking forward
2 to some of these high-tech gene therapies that are
3 curative solutions.

4 A lot of the treatments are really just
5 palliative that are even in the pipeline right
6 now. And it's when everyone starts to make a
7 significant difference in their suffering, and we
8 really appreciate being able to speak with you and
9 have this dialog to emphasize how fast we need to
10 go. Thank you.

11 MS. VAIDYA: Thank you so much,
12 Jonathan.

13 (Applause.)

14 MS. VAIDYA: Next, we have Loretta
15 Morris. Loretta, are you in the audience? Oh,
16 right there.

17 MS. MORRIS: Hello. I'm Loretta Morris.
18 I have no financial connection here, just
19 supportive of my friend whose husband is suffering
20 from it.

21 My question is, having no affiliation
22 with the FDA, what kind of reports -- I understand

1 you send reports to the pharmaceutical
2 manufacturers. Besides, is there a communication
3 back and forth as they're making progress with
4 their research and development? As an outsider, I
5 would like to know an answer eventually, I guess,
6 about that. Thank you.

7 DR. DUNN: We don't have time for
8 specific responses, but I'm just going to quickly
9 reassure you that we're intensely engaged in
10 ongoing dialog throughout the spectrum of drug
11 development for any given drug. So there's active
12 and ongoing dynamic dialog. I know you'd probably
13 like a longer answer, but we have to move on. But
14 I wanted at least to address your specific
15 question.

16 MS. VAIDYA: Next, we have Melanie Rehm.
17 Melanie, are you in the audience? Oh, yes.

18 MS. REHM: I don't really need a mic.
19 I'm very loud. The heartwarming stories that were
20 told today, and I cannot, you know, follow up with
21 anything like that. So thank you for everybody
22 sharing, and thank you for everybody attending

1 today.

2 (Applause.)

3 MS. VAIDYA: Thank you, Melanie.

4 Next, we have Jennifer Mann.

5 (Pause.)

6 MS. VAIDYA: Okay, great. Thank you,
7 Jennifer.

8 Karen Clark. Do we have Karen in the
9 audience? Ashley, could you get the mic over to
10 Karen?

11 (Pause.)

12 MS. CLARK: Thanks. Since we only have
13 two minutes and I have a lot of really like hefty
14 subjects, I don't really want to delve into them
15 too much. I just wanted to mention that we should
16 also be thinking about issues like genetic
17 discrimination and getting access to -- changing
18 the benefits.

19 And I'm sure someone will follow me and
20 talk more about HD Parity Act and talk about how
21 we need to get that passed so that people don't
22 fall into the gap or they don't get any benefits.

1 Because I know when I first put my mom into the
2 nursing home, she wasn't able to get access to an
3 HD specialist for two years. And she wasn't able
4 to get specific HD treatment for two years.

5 And that was just really horrible at the
6 beginning stages of her disease -- well, not the
7 beginning, but the early to mid-stages in which
8 some of the cognitive and psychiatric symptoms
9 could have been managed a lot better.

10 So, in terms of quality of life and all
11 of that, and -- I'll just write the rest of my
12 comments in the docket.

13 MS. VAIDYA: Okay. Thank you, Karen.

14 Next, we have Louise Vetter.

15 MS. VETTER: Good afternoon, everyone,
16 and thank you to the FDA for hosting this hearing,
17 and to everyone in the room for contributing your
18 powerful stories. My name is Louise Vetter, and
19 I'm the CEO of the Huntington's Disease Society of
20 America.

21 I wanted to just raise awareness to
22 everyone in the room, and especially all of the

1 members of FDA who may not have seen the results
2 of surveys that HDSA ran last year to compile the
3 feedback from the HD community, so many of whom
4 could not be here today. We have 250 or so
5 participants in the room and online, but there are
6 hundreds of thousands of families affected by
7 Huntington's who could not be here.

8 HDSA ran two surveys focused on the
9 symptoms and the treatments for Huntington's
10 disease. And we had more than 3,600 respondents
11 that provided powerful information related to the
12 symptoms that are most impactful, and also the
13 treatments they are most hopeful for. We've
14 provided top-line summaries to the FDA in advance
15 of this meeting. All of that data is available to
16 you as you mine this area and bring treatments
17 forward.

18 I also want to pick up on just one other
19 thing that Ken Serbin and several others in the
20 room have mentioned. And that is the need to
21 really consider the needs of pre-symptomatic
22 individuals affected by Huntington's disease.

1 As we talk about treatments for those
2 who are symptomatic, it is also very powerful to
3 include the feedback of those who are watching the
4 future play out in front of them, the families
5 that they're caring for, and the needs and visions
6 they have. So I would encourage you to listen
7 carefully to their feedback, and I would encourage
8 everyone in the room who may be thinking about
9 this to make sure that your feedback is included
10 in the docket, loudly. Thank you.

11 MS. VAIDYA: Thank you, Louise.

12 (Applause.)

13 MS. VAIDYA: Next, we have Brian Wisnet
14 (phonetic). Did I say that correctly? Brian, are
15 you in the room?

16 (No audible response.)

17 MS. VAIDYA: Okay. We will move on to
18 Sharon Thomason. Sharon Thomason?

19 MS. THOMASON: First of all, thank you
20 so much to the FDA for giving us the opportunity
21 to make our voices heard.

22 (Applause.)

1 MS. THOMASON: Those of us who are here
2 are speaking for thousands of others who couldn't
3 be here.

4 I have two things that I would like to
5 add. First of all, with the treatment of the
6 psychiatric symptoms, we're all familiar with
7 genetic testing, but there is now also genetic
8 testing for psychiatric meds. And I don't know
9 that many people are aware of that yet.

10 The psychiatrist who treats my son has
11 used it with a number of patients who are very
12 difficult to medicate, and it helps to pinpoint
13 which particular psych meds will help, rather
14 than, you know, trying something for a month and
15 then something else for another month until you
16 hit on the right thing.

17 The other thing that I wanted to talk
18 about is, we need to change the diagnostic
19 criteria for Huntington's. We need to be able to
20 get a diagnosis on the basis of the so-called
21 "soft symptoms," the psychiatric and cognitive
22 symptoms, and not depend on chorea for a

1 diagnosis.

2 (Applause.)

3 MS. VAIDYA: Thank you, Sharon.

4 Next, we have Katrina Hamel.

5 MS. HAMEL: Thank you. I spoke a little
6 bit earlier about my family's situation. And
7 there was just something that I had left out that
8 I thought was, you know, not mentioned. And that
9 had to do with my mother becoming homeless due to
10 her situation.

11 So, I'll just read a little bit of what
12 I wrote, quickly. That my mother died three years
13 ago at the age of 50 from complications of HD.
14 She suffered for half of her life. Half of those
15 years she was suffering. She left her family of
16 three kids, her husband, and she left Connecticut
17 with a man that she didn't really know. Of
18 course, that was HD-related. And she just went on
19 a whim. She just thought it would be a good idea.

20 So, when she came back, I was 20 years
21 old, and she was 40, and both of us were pregnant.
22 And my, my -- I'm sorry. But my son is two weeks

1 older than his uncle. She left again, and this
2 time, you know -- and these relationships created
3 her to be homeless. And at that point, you know,
4 she lost her son to social services due to safety
5 issues. And we didn't know what was going on
6 because (inaudible).

7 When I found her in Connecticut, I
8 picked her up. You know, I got somebody to bring
9 her to LA from Connecticut. And when I found her,
10 when I finally got her, she was full of urine and
11 her hair was one big red blob. She was homeless,
12 had no one and nothing to her name.

13 She was beaten. She was swollen from
14 taken advantage of, and that's something that a
15 lot of us aren't here to talk about, because if
16 that were the case, if we loved them so much, they
17 wouldn't be out there and homeless. But sometimes
18 situations create that. And for me, our family
19 loved her, supported her. But because she left us,
20 we were unable to know where she was. And she
21 ended up that way because she was no longer able
22 to care for herself and her basic needs.

1 (Applause.)

2 MS. VAIDYA: Thank you so much, Katrina.

3 (Applause.)

4 MS. VAIDYA: Next, we have Lauren

5 Holder. Lauren, are you in the room? Lauren,

6 could you just raise your hand if you're here?

7 (No audible response.)

8 MS. VAIDYA: Okay. And then finally, we

9 have Kenneth Serbin.

10 MR. SERBIN: Thank you to the FDA for

11 this opportunity. And I just wanted to -- my day

12 job is as a historian. So I do a lot of

13 historical work and reading in social sciences.

14 And I've observed some interesting things.

15 Panel 1, no men. Panel 2, practically

16 all women representing men. Interesting bias in

17 the data, don't know what caused it, but as a

18 person who reads in social science, I thought it

19 was interesting, especially in this day of gender

20 equality.

21 And the very sample of the meeting

22 itself is probably skewed because a lot of, as

1 Louise pointed out, Louise Vetter pointed out,
2 it's a whole big community out there. A lot of
3 those people can't come to a meeting. People like
4 my mom could never have participated in something
5 like this because she couldn't walk or talk,
6 although she lived many years with HD.

7 And even the people at home looking at
8 that list of questions would have a hard time
9 filling out that questionnaire. So I think we're
10 getting -- and I'm not necessarily saying this is
11 bad. But we're getting a bit of a caregiver bias
12 on what's going on in the disease. And there's
13 nothing wrong with that, but we have to keep in
14 mind that the patients' data needs to be there,
15 too. And that's why the docket will be, I think,
16 extremely important, and tapping into the data
17 that Louise referred to is important, too.

18 Early on, it was said that HD is not a
19 very common disease. It's my understanding that
20 among the rare diseases, it's one of the most
21 common. In fact, hundreds if not thousands of --
22 I mean, in the past two decades there have been

1 thousands and thousands of papers published on
2 Huntington's disease. So it's a very well-known
3 disease.

4 And Michael Hayden's work, and others,
5 have shown that there may be many more HD people
6 out there. In the community, we constantly talk
7 about the fact that there are probably more than
8 30,000 affected individuals out there.

9 (Applause.)

10 MR. SERBIN: Regarding pre-symptomatic
11 people such as myself, most of us don't get tested
12 because of the immense fear of the disease and the
13 fact that there are no treatments. I see this in
14 my own personal experience. And there's also,
15 associated with genetic testing and getting your
16 results, a lot of suicidal tendencies.

17 And I myself, when I first saw what was
18 happening to my mother, before I got tested, I
19 thought to myself, "There's no way I'm going to go
20 on in life with this, if I have to live like my
21 mother." And I did think a lot. I never actually
22 had, I guess, a real suicidal thought. But I had

1 a lot of fantasies, you know. "I'll get my family
2 together, my friends together, and I'll just, you
3 know, drink some hemlock like Socrates and say
4 good-bye to the world." I used to think that way.

5 But once my daughter was born and once I
6 got more involved in this movement, I saw that I
7 couldn't possibly take my life. But I know that's
8 a thought that occurs to a lot of us having to
9 face this situation.

10 So, I guess I just want to close by
11 saying that that pre-symptomatic community out
12 there needs to really be a part of the
13 conversation. And thank you to the FDA for this
14 opportunity.

15 MS. VAIDYA: Okay. Thank you, Kenneth.

16 (Applause.)

17 MS. VAIDYA: So, Billy, would you like
18 to say something?

19 DR. DUNN: Yeah, I just wanted to make a
20 brief comment. Thank you for all the comments. I
21 think that concludes the comment session.

22 MS. VAIDYA: We actually have one person

1 on the phone.

2 DR. EGGERS: No, no, no. One more
3 person.

4 MS. VAIDYA: Oh, one person here. Okay.

5 But, Billy, did you want to address
6 something?

7 DR. DUNN: Sure. This is as good a time
8 as any. A number of ya'll said "thank you" to the
9 FDA, and I just want to make a brief comment. We
10 appreciate your thanks. But we signed up for
11 this. Ya'll didn't. You know, this is our job.

12 (Applause.)

13 DR. DUNN: I want to say thank you, and
14 I want to encourage all of my colleagues from the
15 Agency here to say thank you for you to your
16 courage to come here to share your stories with
17 us. Thank you very much.

18 (Applause.)

19 DR. EGGERS: So, there's -- so I think
20 we have one more person who wanted to -- who had
21 signed up, didn't get signed up on time. But I do
22 also, I had meant to say and put up on a resource,

1 so before we go to that last speaker, that you
2 have talked, and the last commenter talked more
3 about the personal struggles of the condition.

4 And we just wanted to remind you that
5 there are resources available. And the
6 Huntington's Disease Society of America reminded
7 us of their hotline. So, please seek resources if
8 you need them.

9 MS. VAIDYA: Okay. So, finally, we have
10 LaVonne.

11 MS. GOODMAN: Ken Serbin will be a very
12 hard act to follow. And my comments are really
13 much shorter. I'm LaVonne Goodman. My first
14 husband died of Huntington's disease. I'm a
15 physician who takes care of Huntington's disease
16 families, and I'm a patient advocate. So I wear
17 many hats. I also facilitate a support group and
18 help monitor other support groups in the
19 Northwest, near Seattle.

20 We conducted a survey there similar to
21 the one that HDSA did, but we added a couple of
22 questions. And that was about slowing down

1 progression. And the questions had to do with how
2 much disease slowing would be acceptable before
3 you would want to take a drug that was given
4 orally or a drug that was given intravenously or a
5 drug that was given intra-cerebrally?

6 And those results were interesting from
7 a number of perspectives. One, they weren't so
8 sure they wanted to take something if it were 10
9 percent. It needed to be closer to 25 percent.
10 That was their perception. I queried only people
11 who had the gene or had symptoms already. This
12 was not a care provider -- excuse me, a care
13 partner or caretaker answer.

14 And it was interesting to me that, and I
15 think interesting for everyone, that the
16 discomfort with taking something via spinal fluid,
17 by an LP, was as frightening as was an intra-
18 cerebral delivery.

19 The other thing that I think the FDA
20 needs to think about, and perhaps our research
21 community needs to think about, too, is that there
22 was a question in there about, if there were gene-

1 lowering therapy, what risks would you take and
2 how much benefit would you want before you would
3 take that risk?

4 And another question that had to do with
5 slowing down the disease progression by the same
6 amount if it were -- and it wasn't gene-lowering.
7 People were more interested in taking the gene-
8 lowering therapy, although something that were
9 equally neuroprotective was not as acceptable.

10 And I think the FDA and our community
11 needs to educate people that neuroprotection is
12 neuroprotection, whether it's gene therapy
13 protection or not. And I think our community
14 isn't aware of that, and perhaps that's because
15 the FDA won't let people taking -- or drug
16 companies taking things into clinical trial that
17 may have some neuroprotective benefit from
18 mentioning that.

19 MS. VAIDYA: Thank you, Lavonne.

20 MS. GOODMAN: Thank you very much.

21 MS. VAIDYA: And if you have any
22 additional comments, please submit it to the

1 docket.

2 (Applause.)

3 MS. VAIDYA: So that ends our Open
4 Public Comment period. Before we move on to the
5 last agenda item, I would like to let you know
6 that folks will be going around and picking up
7 clickers. And also, we have evaluation forms at
8 your tables. We really want to hear from you to
9 get your feedback on how this meeting went today.
10 So, please fill it out. Thank you.

11 And finally, I'd like to call upon Dr.
12 Eric Bastings to the stand for our closing.

13 DR. EGGERS: As Eric is coming up, we
14 have one earring that we found. So if it's your
15 earring, come find us

16 DR. BASTINGS: Hi. I am Dr. Eric
17 Bastings. I'm the Deputy Director of the Division
18 of Neurology Products. I want to thank all of you
19 today for participating in this meeting. I think
20 what we heard from you today is incredibly
21 valuable. And I want to assure you that we will
22 use that information as we review new drugs for

1 the treatment of Huntington's.

2 There was a lot of information discussed
3 this morning. And I would like to use the next
4 few minutes to summarize some of the key points of
5 what we heard.

6 So, first, we heard loud and clear that
7 the behavioral and cognitive aspects of the
8 disease have a very deep impact on patients and on
9 their families. In particular, we heard about the
10 memory problems, the difficulties with mental
11 processing, difficulties with initiation, and
12 difficulties with speech.

13 We also heard of problems with
14 swallowing and the deep impact that that can have
15 on patients, and sometimes the embarrassment that
16 that can give when people have to interact with
17 others and be outside of their homes. And we
18 heard the deep impact on all of these symptoms
19 sometime making friends stay away, other family
20 members, other families stay away, leading to
21 isolation of patients. So, all of these cognitive
22 symptoms are very important.

1 Another important aspects are the
2 behavior aspects of the disease. We heard of
3 sleep being a big problem, in part because of
4 movements that people, patients can have during
5 the night, and issues with circadian rhythm. So,
6 sleep is a big problem.

7 Depression is identified very often as a
8 big impact as well. Anxiety, irritability, and
9 apathy are also aspects of the disease that need
10 to have a lot of attention.

11 The motor symptoms are, of course, still
12 present. They're not presented by most people as
13 the most problematic, but they also deserve
14 treatment, as you know. We have a drug available
15 to treat chorea. And a number of people reported
16 some good success with the drug, but it's not an
17 absolute treatment. And there is still a major
18 and medical need in that area, as well.

19 Gait is often reported as a problem in
20 the disease. And we need to have some treatments
21 that would address the issue of gait and movement.
22 And again, speech and swallowing are reported by

1 many as being a problem.

2 In terms of treatment available, we all
3 know that there is a major, unmet medical need.
4 We at the FDA fully recognize the devastating
5 nature of Huntington's and the need to have more
6 treatments, not only to treat the motor symptoms,
7 but especially to treat the behavior aspects and
8 the psychiatric aspects of the disease and the
9 cognitive symptoms.

10 We heard of people using a variety of
11 treatment. They can be non-drug therapies,
12 exercise, nutritional supplements, and they can be
13 a variety of drugs such as antidepressant,
14 antipsychotic medications, and tetrabenazine.
15 Anti-epileptic medications are also used.

16 I think this is a good point to assure
17 you that safety is really not what is keeping your
18 drugs from coming to the market. Again, we really
19 recognize the severity of the condition, and we
20 take that fully into consideration as we balance
21 the risks and the benefits of the treatment. And
22 for a disease like Huntington's, we really would

1 tolerate some significant safety issues before
2 considering not putting a drug on the market.

3 And again, we want to exercise
4 flexibility for conditions like this. And we are
5 fully aware of, you know, the major unmet needs.

6 Finally, I want again to thank you for
7 coming today. I want to assure you that we share
8 the same goal, which is to find a cure for this
9 devastating condition, and on the way to that, to
10 find any way to slow down the disease. If there
11 are treatments that can be given before patients
12 become symptomatic -- I heard some comments about
13 that before -- that certainly it would be a very
14 good area for targeting treatments.

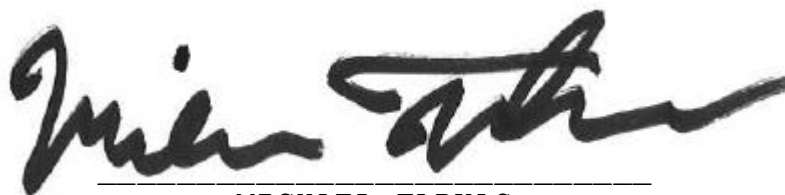
15 And I want to assure you that the team
16 present here will be extremely responsive and
17 supportive for the development of your drugs for
18 Huntington's. So, thank you very much for coming
19 today.

20 (Applause.)

21 (Whereupon, at 12:21 p.m., a luncheon
22 recess was taken, to reconvene at 1:27 p.m.)

1 CERTIFICATE OF NOTARY PUBLIC

2 I, MICHAEL FARKAS, the officer before whom the
3 foregoing proceeding was taken, do hereby certify
4 that the proceedings were recorded by me and
5 thereafter reduced to typewriting under my
6 direction; that said proceedings are a true and
7 accurate record to the best of my knowledge,
8 skills, and ability; that I am neither counsel
9 for, related to, nor employed by any of the
10 parties to the action in which this was taken;
11 and, further, that I am not a relative or employee
12 of any counsel or attorney employed by the parties
13 hereto, nor financially or otherwise interested in
14 the outcome of this action.

15 

16
17 MICHAEL FARKAS
18 Notary Public in and for the
19 State of Maryland
20

21 My commission expires: 6/27/2018

22 Notary Registration No.: 256324

Capital Reporting Company
 FDA Patient-Focused Drug Development Public Meeting (Morning Session) 09-22-2015
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